THE SENATE TWENTY-FIFTH LEGISLATURE, 2009 STATE OF HAWAII

S.B. NO. 805

JAN 2 3 2009

### A BILL FOR AN ACT

RELATING TO HEALTH.

#### BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. The legislature finds that thimerosal is a 2 preservative that has been used in some vaccines since the 3 Thimerosal consists of 49.6 per cent mercury by weight 1930s. 4 and is metabolized or degraded into ethylmercury and 5 thiosalicylate. Mercury is a heavy metal and, like lead, is a 6 neurotoxin. While the use of mercury-containing preservatives 7 has declined in recent years, thimerosal is still used in 8 certain vaccines recommended for adults, pregnant women, and 9 children.

10 The Food and Drug Administration of the United States 11 Department of Health and Human Services acknowledges that 12 depending on the vaccine formulations used and the weight of the 13 infant, some infants may be exposed during their first six 14 months of life to cumulative levels of mercury that exceed 15 Environmental Protection Agency guidelines for safe intake of 16 methylmercury. As a precautionary measure, the Public Health Service, which includes the Food and Drug Administration, 17 18 National Institutes of Health, Centers for Disease Control and SB LRB 09-0192.doc

Prevention, and Health Resources and Services Administration,
and the American Academy of Pediatrics issued two joint
statements urging vaccine manufacturers to reduce or eliminate
thimerosal in vaccines as soon as possible.

5 The legislature finds that because the public has the right 6 to know about potential health risks, individuals who receive a 7 mercury-containing vaccine should be provided written 8 information on risks associate with the vaccine.

9 The purpose of this Act is to ensure informed consent prior 10 to the administration of a vaccine containing any amount of 11 mercury by requiring that written information about the possible 12 effects of the use of the vaccine be provided to patients.

13 "§671−3 **Informed consent**. (a) The Hawaii medical board 14 may establish standards for health care providers to follow in 15 giving information to a patient, or to a patient's guardian or 16 legal surrogate if the patient lacks the capacity to give an 17 informed consent, to ensure that the patient's consent to 18 treatment is an informed consent. The standards shall be 19 consistent with subsection (b) and may include:

The substantive content of the information to be

20 21

(1)



given;

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| 1  | (2)       | The manner in which the information is to be given by  |
|----|-----------|--|
| 2  |           | the health care provider; and                          |
| 3  | (3)       | The manner in which consent is to be given by the      |
| 4  |           | patient or the patient's guardian or legal surrogate.  |
| 5  | (b)       | The following information shall be supplied to the     |
| 6  | patient o | r the patient's guardian or legal surrogate prior to   |
| 7  | obtaining | consent to a proposed medical or surgical treatment or |
| 8  | a diagnos | tic or therapeutic procedure:                          |
| 9  | (1)       | The condition to be treated;                           |
| 10 | (2)       | A description of the proposed treatment or procedure;  |
| 11 | (3)       | The intended and anticipated results of the proposed   |
| 12 |           | treatment or procedure;                                |
| 13 | (4)       | The recognized alternative treatments or procedures,   |
| 14 |           | including the option of not providing these treatments |
| 15 |           | or procedures;   |
| 16 | (5)       | The recognized material risks of serious complications |
| 17 |           | or mortality associated with:                          |
| 18 |           | (A) The proposed treatment or procedure;               |
| 19 |           | (B) The recognized alternative treatments or           |
| 20 |           | procedures; and  |
| 21 |           | (C) Not undergoing any treatment or procedure; and     |



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| 1  | (6)        | The recognized benefits of the recognized alternative                      |
|----|------------|--|
| 2  |            | treatments or procedures.  |
| 3  | (C)        | [ <del>On or before January 1, 1984, the</del> ] <u>The</u> Hawaii medical |
| 4  | board sha  | ll establish standards for health care providers to                        |
| 5  | follow in  | giving information to a patient or a patient's                             |
| 6  | guardian,  | to ensure that the patient's consent to the                                |
| 7  | performan  | ce of a mastectomy is an informed consent. The                             |
| 8  | standards  | shall include [the]:   |
| 9  | (1)        | The substantive content of the information to be                           |
| 10 |            | given[ <del>, the</del> ] <u>;</u>   |
| 11 | (2)        | $\underline{\text{The}}$ manner in which the information is to be given by |
| 12 |            | the health care provider; and [the]  |
| 13 | (3)        | $\underline{\text{The}}$ manner in which consent is to be given by the     |
| 14 |            | patient or the patient's guardian.   |
| 15 | The substa | antive content of the information to be given shall                        |
| 16 | include in | nformation on the recognized alternative forms of                          |
| 17 | treatment  |  |
| 18 | (d)        | Before January 1, 2010, the Hawaii medical board shall                     |
| 19 | establish  | standards for health care providers to follow in                           |
| 20 | providing  | written information to a patient or a patient's                            |
| 21 | guardian,  | to ensure that the patient's consent to the                                |
| 22 | administe  | ring of any vaccine containing more than a trace amount                    |
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| 1  | of mercur  | y is an informed consent. The information provided     |  |
|----|--|--|--|
| 2  | shall include:   |  |  |
| 3  | (1)  | The condition to be treated;                           |  |
| 4  | (2)  | A description of the proposed treatment or procedure;  |  |
| 5  | (3)  | Current information from the Centers for Disease       |  |
| 6  |  | Control and Prevention of the Department of Health and |  |
| 7  | ·  | Human Services regarding claims of a correlation       |  |
| 8  |  | between the administration of vaccines containing      |  |
| 9  |  | mercury and the incidence of neurological              |  |
| 10 |  | developmental disorders;                               |  |
| 11 | (4)  | Any potential side effects of the proposed treatment   |  |
| 12 |  | or procedure;  |  |
| 13 | (5)  | The recognized alternative treatments or procedures,   |  |
| 14 |  | including the option of not providing these treatments |  |
| 15 |  | or procedures; and                                     |  |
| 16 | (6)  | The recognized benefits of the alternative treatments  |  |
| 17 |  | or procedures.   |  |
| 18 | As used in this subsection, "trace amount" means 1.25                        |  |  |
| 19 | microgram  | s per administered dose amount.                        |  |
| 20 | [ <del>(d)</del> ] <u>(e)</u> Nothing in this section shall require informed |  |  |
| 21 | consent f  | rom a patient or a patient's guardian or legal         |  |
| 22 | surrogate  | when emergency treatment or an emergency procedure is  |  |
|    |  |  |  |

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rendered by a health care provider and the obtaining of consent 1 2 is not reasonably feasible under the circumstances without 3 adversely affecting the condition of the patient's health. 4 [<del>(e)</del>] (f) For purposes of this section, "legal surrogate" 5 means an agent designated in a power of attorney for health care 6 or surrogate designated or selected in accordance with chapter 7 327E." 8 SECTION 3. Statutory material to be repealed is bracketed 9 and stricken. New statutory material is underscored. 10 SECTION 4. This Act shall take effect upon its approval. 11

INTRODUCED BY:



### Report Title:

Mercury-Containing Vaccines; Disclosure; Informed Consent

### Description:

Requires the Hawaii medical board to establish standards for health providers relating to required disclosure of information to patients prior to administering a vaccine with more than a trace amount of mercury.

