

MAINE STATE LEGISLATURE

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L.D. 1947

DATE: 3/22/06

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HEALTH AND HUMAN SERVICES

minority

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STATE OF MAINE
HOUSE OF REPRESENTATIVES
122ND LEGISLATURE
SECOND REGULAR SESSION

COMMITTEE AMENDMENT "A" to H.P. 1366, L.D. 1947, Bill, "An Act To Protect Children from the Onset of Autism"

Amend the bill by striking out the title and substituting the following:

'An Act To Protect Children from Mercury Toxicity'

Further amend the bill by striking out everything after the enacting clause and before the summary and inserting in its place the following:

'Sec. 1. 22 MRSA §1065 is enacted to read:

§1065. Immunizing agents containing mercury

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Label" means written information on outside packaging or bulk packaging; descriptive information, instructions on separate pages or brochures provided with a product; and written information that appears on individual vials or dispensing units.

B. "Trace amount" means one microgram or less per dose.

2. Prohibition. Except as provided in subsection 4, beginning January 1, 2007, a person may not sell, market, offer or otherwise provide an immunizing agent for use by health care

2 practitioners in this State on children under 8 years of age and
3 pregnant women if the immunizing agent contains more than a trace
4 amount of mercury.

5 3. Labeling. Except as provided in subsection 4, beginning
6 January 1, 2007, a person may not sell, market, offer or
7 otherwise provide an immunizing agent to any health care
8 practitioner in this State unless the immunizing agent is clearly
9 labeled in accordance with this subsection.

10 A. All labels must clearly indicate whether the immunizing
11 agent contains mercury or is mercury free. An immunizing
12 agent that contains mercury, even if only a trace amount,
13 must be clearly labeled with the words "contains mercury."

14 B. An immunizing agent with more than a trace amount of
15 mercury must be labeled as unsuitable for children under 8
16 years of age and for pregnant women.

17 C. A sticker, such as that commonly used to identify
18 special information on a prescription medication, with text
19 in a font size no smaller 10 points affixed to an existing
20 label is acceptable labeling.

21 4. Exemption. The commissioner may allow the use of an
22 immunizing agent otherwise prohibited under this section if the
23 commissioner finds that an exemption is necessary to protect the
24 public health in response to an actual or potential bioterrorist
25 incident or other public health emergency, including an epidemic
26 or shortage of supply of an immunizing agent that would prevent
27 children under 8 years of age and pregnant women from receiving
28 the needed immunizing agent.

29 A. An exemption under this subsection is limited to 12
30 months, renewable once per incident or emergency.

31 B. Upon issuing an exemption or a renewal of an exemption
32 under this subsection, the commissioner shall provide notice
33 of the findings justifying the exemption or renewal within
34 48 hours to the Legislature and within 7 days to parties who
35 have filed with the commissioner's office a request for
36 notification.

37 **Sec. 2. Development of plan.** The Department of Health and
38 Human Services shall develop a plan to ensure that all immunizing
39 agents administered in the State are free of mercury, including
40 trace amounts of mercury, as defined in the Maine Revised
41 Statutes, Title 22, section 1065, subsection 1, paragraph B. In
42 designing the plan, the department shall consider methods to

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eliminate all mercury from immunizing agents, including, but not limited to, requiring the use of single-dose immunizing agents.'

SUMMARY

Beginning January 1, 2007, this amendment prohibits the use of more than trace amounts of mercury in any immunizing agent for administration to children under 8 years of age and to pregnant women. It imposes requirements for labeling and written information packaged with the immunizing agent. It provides for an exemption if the Commissioner of Health and Human Services determines that an immunizing agent containing more than a trace amount is necessary due to an actual or potential bioterrorist incident or public health emergency. The amendment also directs the department to develop a plan to ensure that all immunizing agents are mercury free, including considering the requirement of the use of single-dose immunizing agents. The amendment removes the requirement that the Department of Health and Human Services, Bureau of Health prepare an advisory poster regarding eating certain fish that may contain mercury and requiring that poster to be displayed in supermarkets.

FISCAL NOTE REQUIRED
(See attached)



122nd MAINE LEGISLATURE

LD 1947

LR 2832(02)

An Act To Protect Children from the Onset of Autism

Fiscal Note for Bill as Amended by Committee Amendment "A"

Committee: Health and Human Services

Fiscal Note Required: Yes

Fiscal Note

Minor cost increase - General Fund

Fiscal Detail and Notes

Any additional costs to the Department of Health and Human Services resulting from this bill can be absorbed by the department utilizing existing budgeted resources.