

MAINE STATE LEGISLATURE

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123rd MAINE LEGISLATURE

FIRST REGULAR SESSION-2007

Legislative Document

No. 1446

H.P. 1015

House of Representatives, March 15, 2007

**An Act To Protect Children from Mercury and Thimerosal Toxicity
in Immunizing Agents**

Reference to the Committee on Health and Human Services suggested and ordered printed.

Millicent M. MacFarland
MILLICENT M. MacFARLAND
Clerk

Presented by Representative BURNS of Berwick.
Cosponsored by Senator NUTTING of Androscoggin and
Representatives: CANAVAN of Waterville, CARTER of Bethel, FARRINGTON of Gorham,
HARLOW of Portland, HAYES of Buckfield, VALENTINO of Saco, WALCOTT of
Lewiston, WEAVER of York.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 22 MRSA §1066** is enacted to read:

3 **§1066. Immunizing agents containing mercury or thimerosal**

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

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

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

10 **2. Prohibition.** Except as provided in subsection 4, beginning January 1, 2008, a
11 person may not sell, market, offer or otherwise provide an immunizing agent for use by
12 health care practitioners in this State on children under 8 years of age or pregnant women
13 if the immunizing agent contains more than a trace amount of mercury or thimerosal.

14 **3. Labeling.** Except as provided in subsection 4, beginning January 1, 2008, a
15 person may not sell, market, offer or otherwise provide an immunizing agent to any
16 health care practitioner in this State unless the immunizing agent is clearly labeled in
17 accordance with this subsection.

18 A. All labels must clearly indicate whether the immunizing agent contains mercury
19 or thimerosal or is mercury-free or thimerosal-free. An immunizing agent that
20 contains mercury or thimerosal, even if only a trace amount, must be clearly labeled
21 with the words "contains mercury" or "contains thimerosal."

22 B. An immunizing agent with more than a trace amount of mercury or thimerosal
23 must be labeled as unsuitable for children under 8 years of age and for pregnant
24 women.

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

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

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

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

1 **Sec. 2. Development of plan.** The Department of Health and Human Services
2 shall develop a plan to ensure that all immunizing agents administered in the State are
3 free of mercury and thimerosal, including trace amounts of mercury or thimerosal, as
4 defined in the Maine Revised Statutes, Title 22, section 1066, subsection 1, paragraph B.
5 In designing the plan, the department shall consider methods to eliminate all mercury and
6 thimerosal from immunizing agents, including, but not limited to, requiring the use of
7 single-dose immunizing agents.

8

SUMMARY

9 Beginning January 1, 2008, this bill prohibits the use of more than trace amounts of
10 mercury or thimerosal in any immunizing agent for administration to children under 8
11 years of age and to pregnant women. It imposes requirements for labeling and written
12 information packaged with the immunizing agent. It provides for an exemption if the
13 Commissioner of Health and Human Services determines that an immunizing agent
14 containing more than a trace amount is necessary due to an actual or potential bioterrorist
15 incident or public health emergency. The bill also directs the department to develop a
16 plan to ensure that all immunizing agents are mercury-free and thimerosal-free, including
17 considering the requirement of the use of single-dose immunizing agents.