

# MAINE STATE LEGISLATURE

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# 123rd MAINE LEGISLATURE

## FIRST REGULAR SESSION-2007

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Legislative Document

No. 1523

S.P. 546

March 20, 2007

### **An Act Requiring Heavy Metal-free Immunizing Agents**

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

A handwritten signature in cursive script that reads "Joy J. O'Brien".

JOY J. O'BRIEN  
Secretary of the Senate

Presented by Senator COURTNEY 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 heavy metals**

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 if the immunizing agent contains more than a trace  
13 amount of a heavy metal, including 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 a heavy  
19 metal, including mercury or thimerosal, or is free of heavy metals. An immunizing  
20 agent that contains a heavy metal, including mercury or thimerosal, even if only a  
21 trace amount, must be clearly labeled with the words "contains a heavy metal,"  
22 "contains mercury" or "contains thimerosal."

23 B. An immunizing agent with more than a trace amount of a heavy metal, including  
24 mercury or thimerosal, must be labeled as unsuitable for a person in this State.

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 a person from receiving the needed immunizing  
33 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 heavy metals, including mercury and thimerosal, including trace amounts of a  
4 heavy metal, including mercury or thimerosal, as defined in the Maine Revised Statutes,  
5 Title 22, section 1066, subsection 1, paragraph B. In designing the plan, the department  
6 shall consider methods to eliminate all heavy metals, including mercury and thimerosal,  
7 from immunizing agents, including, but not limited to, requiring the use of single-dose  
8 immunizing agents.

9

## SUMMARY

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