

By Senator Fasano

11-677-06

See HB 311

1                                   A bill to be entitled  
2           An act relating to vaccine production  
3           facilities; providing incentives for vaccine  
4           production facilities to produce certain  
5           vaccines; exempting certain business entities  
6           from liability under certain circumstances;  
7           establishing a loan and loan guarantee program;  
8           requiring the Department of Health to purchase  
9           a portion of vaccines produced in the state for  
10          a specified period of time; providing an  
11          effective date.

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13           WHEREAS, the adequacy of our country's supply of  
14          vaccines has been called into question because of the growing  
15          demand for the influenza vaccine and other vaccines in  
16          response to the exhortations of public health officials, and

17           WHEREAS, this growing demand for vaccines has increased  
18          the pressure on the nation's domestic suppliers and created  
19          the potential for a major public health crisis, and

20           WHEREAS, the issue of the inadequacy of vaccine  
21          supplies to meet the needs of our citizens, and particularly  
22          to protect the public against influenza, which kills some  
23          36,000 Americans each year, has now advanced to the forefront  
24          of the public health agenda, and

25           WHEREAS, urgent action is needed to augment the limited  
26          domestic vaccine supply, especially the supply of influenza  
27          vaccine, in order to protect the health of the American  
28          public, not only those individuals who are most at risk from  
29          vaccine-preventable diseases but also the rest of the  
30          population as well, and

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1           WHEREAS, given the impediment to the increased  
2 production of vaccines created by the regulatory requirements  
3 imposed by the United States Food and Drug Administration, the  
4 state should offer financial incentives to pharmaceutical  
5 manufacturers to increase the production of vaccines and  
6 thereby ensure their availability in quantities that are  
7 adequate to protect the most vulnerable individuals in the  
8 state and to permit the rest of the citizens of the state who  
9 wish to be vaccinated to receive this protection as well, NOW,  
10 THEREFORE,

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12 Be It Enacted by the Legislature of the State of Florida:

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14           Section 1. Vaccine production facilities; incentives  
15 for vaccine production; liability; loan program.--

16           (1) The Department of Health shall conduct an outreach  
17 campaign to encourage pharmaceutical companies located in this  
18 state to produce vaccines for the prevention of communicable  
19 diseases and to encourage pharmaceutical companies located  
20 outside of this state to establish facilities in this state to  
21 produce vaccines for the prevention of communicable diseases.

22           (2) A business, corporation, sole proprietorship,  
23 partnership, subchapter S corporation, limited liability  
24 corporation, nonprofit corporation, consortium, or other  
25 business entity located in this state that in good faith  
26 develops or produces vaccines for the prevention of  
27 communicable diseases shall not be held liable for civil  
28 damages for any act or omission, except for knowing and  
29 willful acts or omissions, in the development or production of  
30 vaccines for the prevention of communicable diseases which are  
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1 approved for market distribution by the United States Food and  
2 Drug Administration.

3 (3) The Department of Health shall establish a loan  
4 and loan guarantee program to increase the financing available  
5 to fund the costs incurred by new or expanded production  
6 facilities in the state which produce vaccines for the  
7 prevention of communicable diseases, including, but not  
8 limited to, the influenza virus. Loans or loan guarantees  
9 shall be made available to pharmaceutical companies,  
10 partnerships of such companies, and consortia of such  
11 companies, provided that the production facility meets the  
12 requirements of the United States Food and Drug Administration  
13 to ensure the safety, efficacy, purity, and potency of the  
14 vaccines produced at the facility.

15 (4) The Department of Health shall enter into an  
16 agreement with each production facility that commences  
17 production of vaccines for the prevention of communicable  
18 diseases to purchase a portion of all vaccines produced at the  
19 facility which are approved by the United States Food and Drug  
20 Administration to ensure the safety, efficacy, purity, and  
21 potency of the vaccine. Such an agreement may be for no more  
22 than 1 year. The department shall take all actions that are  
23 necessary to encourage physicians, nurses, health care  
24 facilities, pharmacies, and other entities that dispense  
25 vaccines in the state to obtain a portion of their vaccine  
26 supply from vaccine production facilities currently located in  
27 the state or facilities that commence production of vaccines  
28 in the state after July 1, 2006.

29 Section 2. This act shall take effect July 1, 2006.  
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