

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

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

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

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

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

29 WHEREAS, given the impediment to the increased production  
 30 of vaccines created by the regulatory requirements imposed by  
 31 the United States Food and Drug Administration, the state should  
 32 offer financial incentives to pharmaceutical manufacturers to  
 33 increase the production of vaccines and thereby ensure their  
 34 availability in quantities that are adequate to protect the most  
 35 vulnerable individuals in the state and to permit the rest of  
 36 the citizens of the state who wish to be vaccinated to receive  
 37 this protection as well, NOW, THEREFORE,

38

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

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41 Section 1. Vaccine production facilities; incentives for  
 42 vaccine production; liability; loan program.--

43 (1) The Department of Health shall conduct an outreach  
 44 campaign to encourage pharmaceutical companies located in this  
 45 state to produce vaccines for the prevention of communicable  
 46 diseases and to encourage pharmaceutical companies located  
 47 outside of this state to establish facilities in this state to  
 48 produce vaccines for the prevention of communicable diseases.

49 (2) A business, corporation, sole proprietorship,  
 50 partnership, subchapter S corporation, limited liability  
 51 corporation, nonprofit corporation, consortium, or other  
 52 business entity located in this state that in good faith  
 53 develops or produces vaccines for the prevention of communicable  
 54 diseases shall not be held liable for civil damages for any act  
 55 or omission, except for knowing and willful acts or omissions,  
 56 in the development or production of vaccines for the prevention

57 of communicable diseases that are approved for market  
58 distribution by the United States Food and Drug Administration.

59 (3) The Department of Health shall establish a loan and  
60 loan guarantee program to increase the financing available to  
61 fund the costs incurred by new or expanded production facilities  
62 in the state that produce vaccines for the prevention of  
63 communicable diseases, including, but not be limited to, the  
64 influenza virus. Loans or loan guarantees shall be made  
65 available to pharmaceutical companies, partnerships of such  
66 companies, and consortia of such companies, provided that the  
67 production facility meets the requirements of the United States  
68 Food and Drug Administration to ensure the safety, efficacy,  
69 purity, and potency of the vaccines produced at the facility.

70 (4) The Department of Health shall enter into an agreement  
71 with each production facility that commences production of  
72 vaccines for the prevention of communicable diseases to purchase  
73 a portion of all vaccines produced at the facility that are  
74 approved by the United States Food and Drug Administration to  
75 ensure the safety, efficacy, purity, and potency of the vaccine.  
76 Such an agreement may be for no more than 1 year. The department  
77 shall take all actions that are necessary to encourage  
78 physicians, nurses, health care facilities, pharmacies, and  
79 other entities that dispense vaccines in the state to obtain a  
80 portion of their vaccine supply from vaccine production  
81 facilities currently located in the state or facilities that  
82 commence production of vaccines in the state after July 1, 2006.

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