HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 311 Vaccine Production Facilities
SPONSOR(S): Cretul and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 706

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee		Halperin	Brown-Barrios
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

Across the nation, concerns over vaccine shortages and production have increased due to threats of both bioterrorism and pandemic influenza virus. Efforts to bolster vaccine production and accessibility are now a focus of government policy to better address general health issues and the threat to domestic security.

HB 311 addresses the issue of vaccine shortage in Florida by providing incentives for the production of vaccines in Florida. The bill:

- Provides incentives for vaccine production facilities established in or relocated in Florida to produce vaccines for the prevention of communicable disease.
- Exempts vaccine manufactures located in Florida from liability
- Establishes a loan and loan guarantee program within the Department of Health (DOH) to increase the financing available to fund the costs incurred by new or expanded production facilities in the state that produce vaccines.
- Requires the Department of Health to purchase a portion of vaccines produced in the state by vaccine manufactures for a specified period of time.

If enacted, the bill takes effect upon becoming law.

This bill has a fiscal impact.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Maintain Public Security: The bill may increase the physical security of Floridians were it to result in an increase in the quantity and accessibility of vaccines.

Provide Limited Government: The bill may increase the work for governmental organizations by creating a loan guarantee program and industry outreach program to be administered by the Department of Health.

B. EFFECT OF PROPOSED CHANGES:

Effect

This bill addresses the issue of vaccine shortage specifically for Florida. The bill provides incentives for vaccine production facilities established in Florida or relocated to Florida to produce certain vaccines. It exempt vaccine manufactures from liability; establish a loan and loan guarantee program within the Department of Health for the construction or relocation of such facilities; and require the Department of Health to purchase a portion of vaccines produced in the state by these facilities for a specified period of time.

Background

Social Benefits of Vaccines

In the United States, vaccines exist for preventing 11 once common childhood diseases and for preventing diseases responsible for high rates of sickness and death among adults. Vaccines provide a wide range of social benefits, including reducing the medical costs of diseases that are prevented, and enhancing the length, quality, and productivity of life.[1]

The Costs and Challenges of Vaccine Production

Vaccine production is "painfully slow compared with other sectors of drug and medical technology markets."[2] A 1985 Institute of Medicine (IOM) report on vaccine development describes the "technical problems, high research and development costs, the expense and logistics of clinical testing and surveillance of reactions, the risk of litigation" in the vaccine market.[3] A modern manufacturing vaccine production facility can cost $300 million to $500 million and take three to five years to build.[4] In 2002, the Tufts University Center for the Study of Drug Development estimated that it took an investment of $802 million to develop a new vaccine. An expert panel convened by the Department of Defense (DoD) estimated development costs at $300-$400 million per vaccine.[5]

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[1] Institute of Medicine, August 2003. "Financing Vaccines in the 21st Century: Assuring Access and Availability." National Academies Press. Full text available at http://www.nap.edu.

[2] Gottlieb, S., and Calfee J.E.. 11/1/2004. "Putting Markets to Work in Vaccine Manufacturing." *American Enterprise Institute for Public Policy Research.* http://www.aei.org/publications/pubID.21659/pub_detail.asp.

[3] Institute of Medicine, Division of Health Promotion and Disease Prevention, *Vaccine Supply and Innovation* (Washington, D.C.: National Academy Press, 1985).

[4] Agres, Ted. "Vaccine Supplies Remain Sickly." Column by *Washington Times deputy managing editor.* Published in Drug Discovery & Development. http://www.dddmag.com/ShowPR.aspx?PUBCODE=016&ACCT=1600000100&ISSUE=0505&RELTYPE=PR&ORIGRELTYPE=PNP&PRODCODE=00000000&PRODLETT=AG

[5] Rettig, R.A. and Brower, J.B. 2003. "The Acquisition of Drugs and Biologics for Chemical and Biological Warfare Defense: Department of Defense Interactions with the Food and Drug Administration." Prepared for the Office of the Secretary of Defense by the National Defense Research Institute and RAND Health. Available online at http://www.rand.org/pubs/monograph_reports/2005/RAND_MR1659.sum.pdf.

The U.S. has a very expensive process for regulating the manufacture of biologics, and especially the flu vaccine because companies must gain approval for a new product every year from the FDA. In addition, techniques and equipment for manufacturing other biologics[6] have advanced dramatically. The processes for producing vaccines must adhere to strict regulation of development and manufacturing.[7] While advances in these technologies help ensure the public safety, they also add costs to the manufacturing process.

Decline of Manufacturing Capacity

The number of producers of recommended vaccines for the US market has declined from more than 25 companies 30 years ago to only 5 today.[8] The factors for the reduction of manufactures of vaccines include:

- Narrow profit margins associated with the cost of producing vaccines and uncertain demand.
- Fear of litigation.
- A number of mergers and acquisitions of vaccine manufacturers into larger companies.
- Globalization of the market.

Liability

Liability has discouraged manufacturers from investing in vaccine development. Vaccines are given to millions of healthy people, and because they are grown from living organisms instead of synthesized chemicals, they are prone to uncertainties in the manufacturing process. This makes vaccines targets for tort litigation on behalf of anyone who suffers any sort of illness after vaccination. Congress implemented the National Vaccine Injury Compensation Program (VICP) on October 1, 1988 as an effort to make sure that children injured as a result of a routinely recommended vaccine could be quickly compensated. This no-fault compensation system restricted the scope for liability and helped stem the exodus of manufacturers from the childhood vaccine industry. However after 20 years, the VICP is perhaps insufficient to cover recent trends in litigation against vaccine manufacturers, and the viability of the VICP is threatened.[9]

Federal law provisions enacted through the Department of Defense Appropriations Act, 2006 (See Comment Section), provides additional protection from liability for vaccine and pharmaceutical manufacturers under certain conditions.[10] Federal law further details that because the FDA is responsible for testing the safety of vaccines and pharmaceuticals, lawsuits against manufacturers of FDA-approved products are to be held in federal and not state court.

Federal Role in Vaccine Administration

The FDA is legally responsible for regulating the pharmaceutical industry and ensuring that drugs and vaccines released to the public are safe and effective.

The National Immunization Program of the Centers for Disease Control and Prevention (CDC) administers the vaccine purchase program for the federal government. Each state government has its own immunization program, which estimates the level of vaccines needed to assure access to immunization among underserved groups of children and adults. The CDC negotiates a federal contract for each vaccine product, using large volume purchase as leverage to obtain discounts on the

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[6] Biologics (biological products) include a wide range of products such as vaccines, blood and blood components, gene therapy, allergenics, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics tend to be heat sensitive and susceptible to microbial contamination.

[7] Gottlieb, S., and Calfee J.E.. 11/1/2004. "Putting Markets to Work in Vaccine Manufacturing." *American Enterprise Institute for Public Policy Research.* http://www.aei.org/publications/pubID.21659/pub_detail.asp.

[8] Institute of Medicine, August 2003. "Financing Vaccines in the 21st Century: Assuring Access and Availability." National Academies Press. Full text available at http://www.nap.edu.

[9] Offit, Dr. Paul. "Vaccine History Shows Need to Update VICP." November 15, 2005. *The Hill.* http://www.hillnews.com/thehill/export/TheHill/News/Frontpage/111505/offit.html

[10] H.R. 2863, Department of Defense Appropriations Act, 2006.

manufacturer's list price. The states also rely upon the federal discount price for vaccines purchased with state revenues. Although the discount has declined significantly in recent years, the discount pricing process also has the effect of deflating payments to pharmaceutical which tends to discourage future investments in vaccine development.

Florida's Role in Vaccine Administration

States have an important role in setting immunization policy and establishing an immunization infrastructure. Policies for immunization requirements, including minimum school and day care entry requirements, are made almost exclusively at the state level, although cities occasionally impose additional requirements. Each state also establishes an immunization infrastructure to monitor infectious disease outbreaks, administer federal immunization grants, manage centralized supplies of vaccine, direct professional and public education efforts, and otherwise promote immunization policies. The DOH plays a key role in this aspect. The DOH Bureau of Statewide Pharmaceutical Services has been responsible for administering and managing annual statewide contracts for pharmaceuticals, including vaccines since 1993. The DOH Bureau of Immunization promotes, monitors and provides technical assistance to facilitate the completion of childhood immunizations and adult immunization.

Recently, Florida joined the Minnesota Multi-state Contracting Alliance for Pharmacy (MMCAP), a free and voluntary group purchasing organization for pharmaceuticals. Drugs purchased through MMCAP are for the benefit of all state agencies and political subdivisions that utilize pharmaceuticals for their clients. Previous to joining MMCAP, Florida did its own drug bids. Existing Florida contracts for pharmaceuticals were cancelled effective September 14, 2003. At this time, Florida only accesses the pharmaceuticals and vaccines offered by MMCAP.[11]

Section 288.108

288.108, F.S., delineates a framework to attract, retain, and provide favorable conditions for the growth of certain high-impact facilities provides widespread economic benefits to Florida citizens. This section allows the Office or Tourism Trade and Economic Development (office) to engage in activities to attract high impact[12] business to Florida. The office may, in consultation with Enterprise Florida, Inc., negotiate qualified high-impact business performance grant awards for any single qualified high-impact business. In negotiating grant awards, the office is required to consider the following guidelines in conjunction with other relevant applicant impact and cost information and analysis.

- A qualified high-impact business making a cumulative investment of $100 million and creating 100 jobs may be eligible for a total qualified high-impact business performance grant of $1 million to $2 million.
- A qualified high-impact business making a cumulative investment of $800 million and creating 800 jobs may be eligible for a qualified high-impact business performance grant of $10 million to $12 million.
- A qualified high-impact business, engaged in research and development, making a cumulative investment of $75 million and creating 75 jobs may be eligible for a total qualified high-impact business performance grant of $2 million to $3 million.
- A qualified high-impact business, engaged in research and development, making a cumulative investment of $150 million and creating 150 jobs may be eligible for a qualified high-impact business performance grant of $3.5 million to $4.5 million.

Section 381.003

Section 381.003, F.S., requires DOH to conduct:

- Communicable disease prevention and control program as part of fulfilling its public health mission.
- Programs for the prevention, control, and reporting of diseases of public health significance.

[11] More information on MMPAC contract is available online at: http://dms.myflorida.com/dms/purchasing/state_contracts_agreements_and_price_lists/state_term_contracts/pharmaceutical_purchasing_program_mmcap/complete_contract_contract_notice

[12] Defined as a business that makes invest a minimum of a $75 million and creates a minimum of 75 jobs.

- Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children.

C. SECTION DIRECTORY:

Section 1.

Subsection (1). Requires DOH to conduct an outreach campaign to encourage pharmaceutical companies located in the state to produce vaccines for the prevention of communicable diseases. The bill further requires DOH to encourage such companies located outside the state to establish vaccine manufacturing companies within the state.

Subsection (2). Limits the civil liabilities of any business located in the state that manufactures vaccines approved by the United States Food and Drug Administration (FDA) to prevent communicable diseases.

Subsection (3). Requires DOH to establish a loan guarantee program for manufacturers who locate to the State of Florida for the purposes or producing vaccines for the prevention of communicable diseases.

Subsection (4). Requires DOH to enter into an agreement with vaccine manufacturers located in Florida to purchase a portion of vaccines from these companies for a specified period of time. The purchase of such vaccines from pharmaceutical companies referenced in the bill would not be subject to the competitive procurement process currently used by the department.

Section 2. Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments

2. Expenditures:

   See Fiscal Comments

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill could encourage vaccine manufactures to construct facilities in Florida or relocate, as a result there would be an increase in economic activity in specific locations in the form of construction, job creation and related services and commerce.

D. FISCAL COMMENTS:

Increased economic activity as a result of vaccine manufactures to construct facilities in Florida or relocate to Florida would generate tax revenue for the state.

According to DOH, the bill would have a fiscal impact on the DOH. However, no specific estimates where provided. The following provisions of the bill would require a specific appropriation to DOH.

- The bill requires DOH to establish a loan guarantee program for manufacturers who locate to the State of Florida for the purposes or producing vaccines for the prevention of communicable diseases.

- The bill requires DOH to enter into an agreement with vaccine manufacturers located in Florida to purchase a portion of vaccines from these companies for a specified period of time. According to DOH analysis this could force the state to purchase vaccines it does not want at prices that are not competitive; and could leave Florida dependent on single manufacturers.

- If the bill becomes law and the DOH is required to purchase vaccines from specified companies, it could jeopardize the Florida's membership in the MMCAP buying group for both vaccines and for other pharmaceutical products. This could result in substantial changes in the price and purchasing of pharmaceuticals.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. The bill does not reduce the percentage of a state tax shared with counties or municipalities. The bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

On December 30, 2005, President Bush signed into law the "Public Readiness and Emergency Preparedness Act" (PREP Act) as part of the 2006 Defense Appropriations Act (H.R. 2863). The PREP Act offers targeted liability protections to those involved in the development, manufacturing, and deployment of pandemic and epidemic products and security countermeasures. The Act creates a shield of immunity for claims arising out of, related to, or resulting from the administration or the use of a covered countermeasure (i.e., vaccines, countermeasures, devices and certain other products). This immunity covers a wide range of uses, including design, development, testing, manufacturing, distribution, administration, use, and other activities so that the protections can be applied as broadly as possible.

The immunity created by the Act can be overcome, but only upon a showing of willful misconduct that proximately caused a serious injury or death. The Act creates a single new Federal cause of action related to claims arising out of the use of pandemic and epidemic products and security countermeasures. To meet the "willful misconduct" exception, a plaintiff must show that acts or omissions were undertaken to "intentionally achieve a wrongful purpose." Most significantly, prior to any claim of willful misconduct, the Food and Drug Administration or Department of Justice must take and complete a specific enforcement action establishing the willful misconduct. Plaintiffs must specifically detail their claims, and there are mandatory penalties for counsel which file frivolous or baseless suits.

If claims can proceed, there are other restrictions, such as a limit on damages and reductions for collateral benefits received by a plaintiff.

The liability protections under the PREP Act are triggered when the Secretary of Health and Human Services makes a declaration that a disease or other threat constitutes a public health emergency, or that there is a credible risk of such a threat. This flexibility allows the Secretary to be proactive and prepare the nation's infrastructure for threats that are real, but may not be occurring in the immediate future.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES