HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 311 CS 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	7 Y, 4 N, w/CS	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 CS addresses the issue of vaccine shortage in Florida by providing incentives for the production of vaccines in Florida. The bill:

- Requires Enterprise Florida, Inc., to conduct outreach activities to encourage pharmaceutical companies located in the state to produce vaccines, and to encourage pharmaceutical companies located outside of the state to establish vaccine facilities in Florida.
- Exempts vaccine manufactures located in Florida from civil liability associated with the development or production of vaccines under specified conditions.

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.

B. EFFECT OF PROPOSED CHANGES:

Effect

This bill addresses the issue of vaccine shortage specifically for Florida. The bill requires Enterprise Florida, Inc. to conduct outreach activities to encourage pharmaceutical companies located in the state to produce vaccines, and to encourage pharmaceutical companies located outside of the state to establish vaccine facilities in Florida.

The bill exempts vaccine manufactures located in Florida from civil liability associated with the development or production of vaccines under specified conditions. A company will not be held liable for civil damagers or any act of omission associated with the development or production of a vaccine so long as:

- the act or omission is not knowing and willful;
- the company is a business, corporation, sole proprietorship, partnership, subchapter S corporation, limited liability corporation, nonprofit corporation, consortium, or other business entity located in this state;
- the company in good faith develops or produces vaccines for the prevention of communicable diseases;
- the vaccine is approved for market distribution by the United States Federal Drug Administration (FDA).

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

[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

$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]

The U.S. has a very costly 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 been identified as a factor that 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.

The Vaccine Injury Compensation Trust Fund[9] was established to ensure that a constant source of funding would be available for the payment of compensation for vaccine-related injuries and deaths, as well as for attorney fees and costs incurred by families in presenting their case to the Special Masters who adjudicate petitions. The Trust Fund is financed by excise taxes of 75 cents per dose imposed on each vaccine covered under the Program.

According to OMB documents, in 2005 the Trust Fund currently had a balance of about $2.1 billion and over the past three years has grown at an average rate of 7%. In 2003, about 224 million VICP-covered vaccines were administered. As of April 12, 2005, 11,302 (4,689 autism/thimerosal and 6,613 non-

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[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.

[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] 2005 Vaccine Injury Compensation Program Assessment, Office of Management and Budget (OMB) http://www.whitehouse.gov/omb/expectmore/detail.10003807.2005.html

autism/thimerosal) claims have been filed and compensation totaling over $1.5 billion has been awarded to 1,910 families.

Public Readiness and Emergency Preparedness Act

Federal law provisions provide additional protection from liability for vaccine and pharmaceutical manufacturers under certain conditions.[10] 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.

Access to Courts[11]

The bill's provision regarding liability protections for vaccine manufacturers could possibly conflict with of Article I, s. 21, Fla. Stat. that provides the following:

> SECTION 21. Access to courts.--The courts shall be open to every person for redress of any injury, and justice shall be administered without sale, denial or delay.

The right to go to court to resolve disputes is a fundamental right.[12] In order to make a claim of denial of access to courts, an aggrieved party must demonstrate that the legislature has abolished a common-law right previously enjoyed by the people of Florida.[13] A person's guaranteed access to the courts should not be unduly or unreasonably burdened or restricted.[14] If the legislature asserts a valid public purpose, it can restrict access to the courts as long as it provides a reasonable alternative to litigation.

[10] H.R. 2863, Department of Defense Appropriations Act, 2006.
[11] HCG staff consulted with staff of the Civil Justice Committee on the Access to Courts issue.
[12] DR Lakes Inc. v. Brandsmart U.S.A. of West Palm Beach, 819 So. 2d 971 (Fla. Dist. Ct. App. 4th Dist. 2002).
[13] Yachting Promotions, Inc. v. Broward Yachts, Inc., 792 So. 2d 660 (Fla. Dist. Ct. App. 4th Dist. 2001); Strohm v. Hertz Corporation/Hertz Claim Management, 685 So. 2d 37 (Fla. Dist. Ct. App. 1st Dist. 1996).
[14] Preferred Medical Plan, Inc. v. Ramos, 742 So. 2d 322 (Fla. Dist. Ct. App. 3d Dist. 1999); Swain v. Curry, 595 So. 2d 168 (Fla. Dist. Ct. App. 1st Dist. 1992).

Currently, a person can bring a negligence cause of action to seek damages, even if the defendant did not act knowingly or willfully.[15] This bill removes a previously available cause of action, as provided for in common law and in Florida statutes, to any person who is injured by the negligent development or production of vaccines for communicable diseases.

The Florida Supreme Court, in the case Kluger v. White, 281 So.2d 1 (Fla. 1973), held that where a right of access to the courts for redress for an injury has been provided by statutory or common law of the State, the Legislature does not have power to abolish such a right without providing a reasonable alternative to protect the rights of the people to redress for injuries. The only time the Legislature may restrict access to courts is when it can show an overpowering public necessity for the abolishment of such right, and no alternative method of meeting such public necessity can be shown.

In order for the immunity provision in the bill to address potential constitutional concerns, the bill would need to provide that it serves a valid public purpose and that there is an overpowering public necessity for the abolishment of such right, and that no alternative method of meeting such public necessity can be shown. HB 311 CS contains a series of "WHEREAS" clauses that endeavor to establish public purpose and necessity.

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 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

[15] The only time a plaintiff seeking damages based on negligence has to show that the conduct was willful is when they are seeking punitive damages.

pharmaceuticals were cancelled effective September 14, 2003. At this time, Florida only accesses the pharmaceuticals and vaccines offered by MMCAP.[16]

Section 288.9015
288.9015, F.S., provides that Enterprise Florida, Inc., is the principal economic development organization for the state. It is the responsibility of Enterprise Florida, Inc., to provide leadership for business development in the state by assisting in the retention and expansion of existing businesses and the creation of new businesses. Enterprise Florida, Inc., may develop and implement specific programs or strategies that address the creation, expansion, and retention of Florida business; the development of import and export trade; and the recruitment of worldwide business.

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

C. SECTION DIRECTORY:

Section 1.

Subsection (1). Requires Enterprise Florida, Inc., to conduct outreach activities to encourage pharmaceutical companies located in the state to produce vaccines, and to encourage pharmaceutical companies located outside of the state to establish vaccine facilities in Florida.

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.

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

[16] 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

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.

The bill requires Enterprise Florida, Inc., to conduct outreach activities to encourage increased vaccine development and production in Florida.

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:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On February 22, 2006, the Health Care General Committee adopted one amendment to the bill. The amendment:

- Requires Enterprise Florida, Inc., to conduct outreach activities to encourage pharmaceutical companies located in the state to produce vaccines, and to encourage pharmaceutical companies located outside of the state to establish vaccine facilities in Florida.
- Clarifies conditions in which vaccine manufactures located in Florida are protected from civil liability associated with the development or production of vaccines.
- Removes references and requirements for: the Department of Health; vaccine purchasing mandates; and the establishment of loan guarantee programs.

As amended, the bill was reported favorably as a committee substitute.

This analysis reflects the bill as amended.