SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 2468

SPONSOR: Fiscal Resource Committee and Senator Kirkpatrick

SUBJECT: Health Technology Industry

DATE: April 19, 1999 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Fournier	Wood	FR	Favorable/CS
2.			CM	
3.				
4.				
5.				

I. Summary:

This committee substitute expresses the intent of the Legislature to encourage and facilitate the location and expansion of the state's health technology industry.

- It exempts medical device manufacturers from fees and registration requirements of the Florida Drug and Cosmetic Act.
- It directs the State University System [SUS] and the University of Miami to perform certain evaluations relating to health technology business incubators and health technology companies and it directs the State University System to submit a report of its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives.
- The bill encourages the State Board of Community Colleges to continue its effort to develop health technology curricula to support the industry's work force needs.
- It encourages Enterprise Florida, Inc., and the Department of Banking and Finance continue their efforts to enhance small-capital formation in Florida and to evaluate ch. 517, F.S., to determine its impact on the ability of health technology firms to raise capital.

This bill substantially amends, creates, or repeals the following section of the Florida Statutes: 499.015.

II. Present Situation:

The Health Technology Industry in Florida

There are presently 60 biotechnology firms located in the state of Florida that employ 2,200 workers earning annual wages of $45,000, and generating approximately $2.9 million state sales taxes.

According to a 1998 study prepared by Enterprise Florida, Inc., Florida's Health Technology Industry leaders indicate that the state is making steps to improve the health technology infrastructure needed for the industry to grow, flourish and remain competitive. However, the industry leaders report that in order to be fully recognized as a "serious player" and global leader in the health technology arena, improvements are needed in the following areas: workforce, availability and skills; adequate financing programs; and a share of federal and private research and development funds.

Enterprise Florida Inc., states that presently Florida receives only approximately two percent of the total federal research funds available at the nation's universities. Currently, there are not any federally funded research and development centers in Florida. Florida is well positioned to take advantage to this sub-sector's growth, as the state is already the third location of choice for medical device manufactures, following California and Texas.

Sales Tax Exemptions for High Technology Firms

Paragraph (j) of subsection (5) of Section 212.08, F.S., provides a sales tax exemption for machinery and equipment used in silicon technology production and research and development. This exemption was granted in 1998 in Ch. 98-205, and is available to businesses certified by the Office of Tourism, Trade, and Economic Development as authorized to qualify for the exemption.

Regulation of Manufacturers of Medical Devices

Chapter 499, Florida Statutes, provides for the regulation of drugs, cosmetics and household products by the Department of Health. Part I, ch. 499, F.S., (ss. 499.001-499.081, F.S.) sets forth the Florida Drug and Cosmetic Act. The purpose of this Act is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. The part provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under, the federal Food, Drug, and Cosmetic Act and the applicable portions of the Federal Trade Commission Act which prohibits the false advertising of drugs, devices, and cosmetics. The part specifies prohibited acts and requirements for the distribution and manufacture of legend drugs and legend devices by pharmacies, manufacturers, and other entities. Florida duplicates the federal requirements for the registration of medical devices.

Part I, ch. 499, F.S., defines manufacturer to mean any person who prepares, derives, manufactures, or produces a drug, device, or cosmetic. Section 499.015, F.S., requires any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in Florida to register the drug, device, or cosmetic every 2 years and pursuant to s. 499.041, F.S., to pay an annual product fee no less than $5 or greater than $15 for each separate and distinct product in package form. The Department of Health has adopted an administrative rule that provides for a two-year registration fee of $20 for each separate and distinct product (64F-12.018(4), Florida Administrative Code). Medical device manufacturers applying for an initial product registration must submit a product label or copy for every product registered, list each separate and distinct product, provide documentation that shows that the product is legal in interstate commerce (such as evidence of a premarket approval or pre-market notification letter (510K) from the FDA), and submit the appropriate fee (64F-12.016, Florida Administrative Code). The Department of Health

may issue a certificate of Free Sale on any product that is required to be registered under ch. 499, F.S., to any applicant who requests the certificate and pays a fee of $25. A certificate of Free Sale, a document required by many foreign countries before a product may enter their country, attests to the marketable status of the product in Florida.

Section 499.013, F.S., requires any person who engages in the assembly or manufacture of medical devices for human use to obtain a permit, to annually pay a fee not less than $500 or greater than $600, and to comply with all appropriate state and federal manufacturing practices. Medical device manufacturers must pay a $150 initial application fee for each new permit which requires an onsite inspection.

As part of its review to improve access to investment capital, the Health Technology Industry Advisory Council to Enterprise Florida, Inc., recommended a reduction or elimination of Florida's medical device registration and fee for any device manufactured or assembled in Florida that has been approved by the FDA.

III. Effect of Proposed Changes:

Section 1. Provides legislative intent to encourage and facilitate the expansion of the state's health technology industry.

Section 2. Amends section 499.015, F.S., to provide exemptions from fees and registration requirements for certain medical device manufactures under the requirements of the Florida Drug and Cosmetic Act. Requires the manufacturers to submit evidence of registration, listing, and approval by the federal government of such devices.

Section 3. Charges the State University System [SUS] and the University of Miami with evaluating the feasibility of expanding health technology business incubators to other universities in the SUS. The State University System and the University of Miami shall consult with the Health Technology Advisory Council of Enterprise Florida, Inc., and Bio+Florida as part of these evaluations and recommendations. Results of the evaluation shall be reported to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, 1999.

Section 4. Encourages the State Board of Community Colleges to continue its efforts to develop health technology curricula to support the industry's workforce needs.

Section 5. Encourages Enterprise Florida, Inc., and the Department of Banking and Finance continue their efforts to enhance small-capital formation in Florida and to evaluate ch. 517, F.S., to determine its impact on the ability of health technology firms to raise capital.

Section 6. Provides an effective date of July 1, 1999.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

A. Tax/Fee Issues:

This committee substitute is estimated to cause a reduction of $27,500 in the Drugs, Devices, and Cosmetics Trust fund in the Department of Health.

B. Private Sector Impact:

The purpose of this bill is to encourage development of the health technology industry in Florida.

C. Government Sector Impact:

The State University System has certain responsibilities under this bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.