**The Florida Senate**

# PROFESSIONAL STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Prepared By: Health Policy Committee

| | |
|---|---|
| BILL: | SB 284 |
| INTRODUCER: | Senator Fasano |
| SUBJECT: | Biomedical Research |
| DATE: | March 19, 2007 |
| REVISED: | |

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|---|---|---|---|---|
| 1. | Bedford | Wilson | HP | **Favorable** |
| 2. | | | CM | |
| 3. | | | HA | |
| 4. | | | | |
| 5. | | | | |
| 6. | | | | |

## I. Summary:

This bill provides legislative intent to support the development of botanical drugs from a patented complex derived from pinecones that enhances the effects of vaccines, helps suppress cancerous tumors, and improves the functioning of the human immune system. The bill explains that the research and clinical trials will take at least one fiscal year. There is an appropriation of $15 million for the 2007-08 fiscal year from the General Revenue Fund to an independent biomedical organization within this state as described in this act.

This bill creates one undesignated section of law.

## II. Present Situation:

### Florida Biomedical Research Program

There are two grant-funding programs within the Florida Biomedical Research Program administered by the Florida Department of Health, Office of Public Health Research. These programs are the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program. An 11-member Biomedical Research Advisory Council (s. 215.5602(3), F.S.) advises the Secretary of Health on the direction and scope of the James & Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program.

In addition to these grant programs, the Office of Public Health Research provides support to the Institutional Review Boards, which protect the health and safety of research participants. Also contained in this office are the Florida Center for Universal Research to Eradicate Disease, which coordinates, improves, expands, and monitors all biomedical research programs within the

state, facilitates funding opportunities, and fosters improved technology transfer of research findings into clinical trials and widespread public use, and the Florida Cancer Council, which improves cancer research and treatment to make the state a center of excellence for cancer research.

**The James and Esther King Biomedical Research Program**

The James and Esther King Biomedical Research Program is created in s. 215.5602, F.S., within the Department of Health. The purpose of the program is to provide an annual and perpetual source of funding in order to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease. The long-term goals of the program are to:

- Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease;
- Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of disease related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease;.
- Improve the quality of the state' academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers;
- Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional funding from outside the state; and
- Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

The sum of $6 million is appropriated annually from recurring funds in the General Revenue Fund for the James and Esther King Biomedical Research Program. These funds must be used exclusively for the award of grants and fellowships for research relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

**The Bankhead-Coley Cancer Research Program**

On June 13, 2006, Governor Bush signed into law legislation authorizing the investment of $120 million in biomedical research in Florida over a four-year period. The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (also known as the Bankhead-Coley Cancer Research Program) is an important component of this investment. Beginning in fiscal year 2006-07, the sum of $9 million is appropriated annually from recurring funds in the General Revenue Fund in response to compelling evidence that more cancer research and improved cancer treatment are necessary in the state.

Codified in s. 381.922, F.S., the program was created effective July 1, 2006, within the Department of Health, and is supported by the advice and counsel of the Florida Biomedical Research Advisory Council. Section 1 of the enabling legislation for the Bankhead-Coley Cancer Research Program describes three important elements of the legislative intent in creating the program:

- To provide funding to support grants for biomedical research in this state with the anticipation that sustained funding for biomedical research over a period of years will lead to an alleviation of human suffering from diseases such as cancer;
- To dramatically reduce this state's inordinately high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in this state, making this state a world class leader in cancer research and treatment; and
- To stimulate dramatic economic development, particularly in the biotechnology industry, through investment in this state's biomedical research.

Goals for the program include the following:

- Significantly expand cancer research capacity in the state by:
    - Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state;
    - Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
    - Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
    - Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;
    - Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
    - Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research.

- Improve both research and treatment through greater participation in clinical trials networks by:
    - Identifying ways to increase adult enrollment in cancer clinical trials;
    - Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
    - Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and
    - Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks.

- Reduce the impact of cancer on disparate groups by:
    - Identifying those cancers that disproportionately impact certain demographic groups; and
    - Building collaborations designed to reduce health disparities as they relate to cancer.

Any university or research institute in Florida may apply for grant funding to support these goals, and all qualified investigators in the state, regardless of institution, have equal opportunity to compete for funding. All awards are made based on scientific merit, as determined by open competitive peer review.

**Florida Research to Develop Botanical Drugs from Polyphenylpropenoid Polysaccharide Complex**

The polyphenylpropenoid polysaccharide complex (PPC), an extract from pinecones, was developed through research efforts of the Tampa Bay Research Institute. It was initially sold as a dietary supplement to the general public by a third party, however the Tampa Bay Research Institute is currently researching drug applications of the PPC relating to its ability to stimulate the immune system. Founded in 1981, the Tampa Bay Research Institute is an independent 501(c)(3) biomedical research organization.[1]

## III. Effect of Proposed Changes:

**Section 1.** Creates one undesignated section of law declaring the Legislature's intent to support the combating of disease through biomedical research conducted by an independent biomedical organization. During the 2007-08 fiscal year the Legislature will fund the development of FDA-recognized botanical drugs from a PPC, a complex produced from pinecones, which has been developed and patented by an independent biomedical organization. Research has shown to date that this complex enhances the immune system making other therapies more effective. The procedures needed to develop the botanical drugs include research and clinical trials that will last at least one fiscal year and will cover several areas of study including cancer research, autoimmune diseases, anti-aging research, and infectious diseases.

**Section 2.** Provides an appropriation of $15 million from the General Revenue Fund to an independent biomedical organization in this state as described in this act.

**Section 3.** Provides an effective date of July 1, 2007.

## IV. Constitutional Issues:

### A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

### B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

[1] Tampa Bay Research Institute website at www.tampabayresearch.org/About.htm (last visited on March 17, 2007).

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

## V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Many lives could benefit from enhanced effects of treatments and therapies and improved immune systems. The independent biomedical organization will benefit from the funds to continue their research and development of PPC and botanical drugs.

C. Government Sector Impact:

The Department of Health stated there was no impact on the department.

## VI. Technical Deficiencies:

Page 1, line 23, and on page 2, line 9, the word “polyphenylypropenoid” should be “polyphenylpropenoid.”

## VII. Related Issues:

The bill appropriates $15 million to an independent biomedical organization in Florida to develop botanical drugs from a PPC. The bill does not contain any standards for the expenditure of those funds or require the funds to be disbursed pursuant to a contract with a state agency.

# VIII. Summary of Amendments:

None.