SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: SB 2142

SPONSOR: Senator Webster, Senator Klein, and Senator Fasano

SUBJECT: Biomedical Research

DATE: March 30, 2003 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Favorable
2.	Matthews	O'Farrell	ED	Favorable
3.				
4.				
5.				
6.				

I. Summary:

The bill establishes the Center for Universal Research to Eradicate Disease (CURED). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings. The center must encourage clinical trials in Florida on research that holds promise of curing a disease or condition. The center must facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, cord blood, and other tissues needed for biomedical research.

The center must also encourage the discovery and production in Florida of vaccines that prevent disease. The center must monitor the supply and demand for types of human tissue relating to research, including stem cell research, and other needs of researchers.

The center will be funded through private, state, and federal sources. The center will serve as a registry of all known biomedical grant opportunities and may assist any public or private biomedical research program in this state in preparing grant requests. The center must maintain a website with links to peer-reviewed biomedical research. The website must contain a list of all known biomedical research being conducted in Florida and must facilitate communication among researchers and other interested parties.

The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida. The duties of the center may be outsourced to a private entity or state university.

The bill requires that the long-term goals of the Florida Biomedical Research Program include the expansion of biomedical knowledge relating to cures, in addition to prevention, diagnosis and treatment, of diseases related to tobacco use. The bill requires that priority in grants awarded by the program be given to research aimed at preventing or finding cures for disease.

This bill amends s. 215.5602, F.S., and creates s. 215.5605, F.S.

II. Present Situation:

Coordination of Biomedical Research

Biomedical research contributes ultimately to the health of a population, and biomedical discoveries and the resultant products or treatments contribute to the economy of the area where they are produced. For both health and economic reasons, governments have an interest in furthering the work of biomedical researchers and in helping researchers collaborate and share resources. A number of states have initiatives to coordinate cancer research. Some state governments as well as private foundations, and companies are addressing the need of researchers who are conducting stem cell research.

Stem Cell Research

Stem cells are cells that have the ability to divide for infinite periods in culture. They give rise to specialized cells. Research involving stem cells shows the possibility of treating diseases and conditions such as Alzheimer's and Parkinson's diseases, spinal cord injury, stroke, burns, heart disease, and arthritis. The possibility that an organ could be grown from stem cells has implications for tremendous changes in organ transplants.

A significant debate about stem cells involves the source of the cells. Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). Human embryos are the source for pluripotent stem cells—cells that are capable of giving rise to most tissues of the human organism. The development of embryos for the sole purpose of harvesting the stem cells is considered immoral by many because the embryo is killed. In August 2001, President Bush announced that he would allow federal funding of research using the 60 existing stem cell lines. Thus federal funds will not pay for stem cell research that involves the destruction of human embryos.

In November 2001, President George W. Bush created The President's council on Bioethics "to advise the president on issues that may emerge as a consequence of advances in biomedical science and technology" (Executive Order 13237). In particular, the council was authorized to study ethical issues connected with specific technological activities such as embryo and stem cell

research. After studying the issue of human cloning, the majority, ten members of the council, voted to ban cloning for the production of children and to place a 4-year moratorium on cloning for biomedical research. The minority, seven members, voted to ban cloning for the production of children and to regulate the use of cloned embryos for research.

The Florida Biomedical Research Program and the Florida Biomedical Research Advisory Council

The 1999 Legislature established the Lawton Chiles Endowment Fund (ch. 99-167, L.O.F.), through which the state will use funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, F.S., establishes the Florida Biomedical Research Program funded from earnings of the endowment fund and provides that funds appropriated to the program are devoted to competitive grants and fellowships in research relating to diagnosis and treatment of tobacco-related illnesses including cancer, cardiovascular disease, stroke and pulmonary disease. The Biomedical Research Advisory Council in the Department of Health assists the Secretary in establishing criteria and guidelines for the competitive grant programs. Grants and fellowships are awarded on the basis of scientific merit, as determined by an open, objective peer-review process. The council is required to submit a progress report to the Governor, Secretary of the Department of Health, President of the Senate, and Speaker of the House of Representatives by February 1 of each year.

The Emerging Technology Commission

Under s. 1004.225, F.S., the "Florida Technology Development Act," the Emerging Technology Commission is a commission created within the Governor's Office for the purpose of guiding the establishment of centers of excellence within, and in collaboration with Florida's universities.

ITFlorida and The Florida Research Consortium

ITFlorida is a private umbrella organization comprised of both public and private technology leaders for high-tech in Florida. ITFlorida's stated mission is to make Florida a leader in high tech advancement, providing guidance to the state on technology issues and initiatives, guiding the Governor, the Legislature and Enterprise Florida on the strategic technology direction and initiatives of the state and working to ensure the successful integration of technology infrastructure statewide.

The Florida Research Consortium, an affiliated entity of ITFlorida, is governed by a board of high-tech industry leaders and university heads whose mission is to advise the Legislature and Office of the Governor on strategic policy initiatives for expanding and strengthening Florida's high-tech industries. The consortium aims to identify specific disciplines in science and technology where Florida has the greatest potential to achieve economic and academic successes –and to promote collaboration between academic and industrial researchers, scientists and engineers.

Enterprise Florida, Inc.

Enterprise Florida, Inc., created under part VII of ch. 288, F.S., is a partnership between Florida's business and government leaders and is the principal economic development organization for the State of Florida. The organization's mission is to increase economic opportunities for all Floridians by supporting the creation of quality jobs, a well-trained workforce and globally competitive businesses. It pursues its mission in cooperation with its statewide network of economic development partners.

BioFlorida

BioFlorida's mission is to promote biotechnology and related science in Florida by creating a favorable business and legislative environment; to provide the platform for business, academia and government to work jointly to support and encourage development of existing companies in the state and to attract new business and organizations to Florida.

The Florida Medical Foundation

The Florida Medical Foundation is the Florida Medical Association's philanthropic organization for medical education, research, community service, and physician support programs. The foundation emphasizes support for physicians at all stages of their professional careers. The foundation has a current project relating to doctor patient communications as a way of addressing the problem of low health literacy among patients.

Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that improve the health and longevity of patients. The industry invested more than $30 billion in 2001 in discovering and developing new medicines. PhRMA companies are involved in the search for new cures.

III. Effect of Proposed Changes:

The bill creates s. 215.5605, F.S., to establish the Center for Universal Research to Eradicate Disease (CURED). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for diseases such as cancer, heart disease, lung disease, diabetes, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures for diseases. Summit attendees will be required to cover the costs of their attendance or obtain sponsorship for such attendance.

The center must: encourage clinical trials in Florida on research that holds promise of curing a disease or condition; facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, cord blood, and other tissues needed for biomedical research; and encourage the discovery and production in Florida of vaccines that prevent disease.

The center must monitor the supply and demand for types of human tissue relating to research, including stem cell research, and other needs of researchers. If the center determines that there is a need for increased donation of human tissue, it must notify hospitals licensed under ch. 395, F.S., that have entered into partnership agreements with research institutes conducting stem cell research located in the same geographic region as the researchers demanding the stem cells or other tissues. The hospitals must then implement programs that encourage voluntary donations of cord blood or other needed tissues.

The center will be funded through private, state, and federal sources. The center will serve as a registry of all known biomedical grant opportunities and may assist any public or private biomedical research program in this state in preparing grant requests. The center must maintain a website with links to peer-reviewed biomedical research. The website must contain a list of all known biomedical research being conducted in Florida and must facilitate communication among researchers and other interested parties.

The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida. The duties of the center may be outsourced to a private entity or state university.

An advisory council, established within the center, must meet at least annually. The council will consist of the members of the board of directors of the Florida Research Consortium and at least one representative from:

- The Emerging Technology Commission.
- Enterprise Florida, Inc.
- BioFlorida.
- The Florida Biomedical Research Advisory Council.
- The Florida Medical Foundation.
- Pharmaceutical Research and Manufacturers of America.

Members of the council will serve without compensation and each organization represented must cover all expenses of its representative.

The bill amends s. 215.5602, F.S., which creates the Florida Biomedical Research Program, to require that the long-term goals of the program include the expansion of biomedical knowledge relating to cures, in addition to diagnosis and treatment, of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease. The bill requires that priority be given to research to prevent or cure disease.

The effective date of the bill is July 1, 2003.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Private entities involved in biomedical research or furnishing supplies to biomedical researchers could benefit from the coordination that would be provided by the CURED.

C. Government Sector Impact:

The proposed Senate budget for FY 2003-2004 contains the following biomedical research appropriations from the Lawton Chiles Endowment:

Salaries	$ 55,723
OPS	$ 26,193
Expenses	$ 17,934
Grants for Biomedical Research	$ 6,001,746

VI. Technical Deficiencies:

None.

VII. Related Issues:

Currently grants under the Florida Biomedical Research Program are based on the scientific merit of research proposals. The bill requires that priority for the grants be given to proposals designed to prevent or cure disease. Scientists conducting biomedical research investigate aspects of biological processes and diseases without knowing whether a particular project might eventually lead to better prevention, earlier diagnosis, more effective treatment, or a cure.

Ultimately all biomedical research leads to prevention and cure. Restricting grants to proposals that are aimed at prevention or a cure could have the effect of withholding support from important lines of inquiry. According to the Department of Health, "The concept 'research designed to …cure disease' is not easily defined in scientific terms, thus leading to potential grant award challenges." The department recommends striking from the bill the sentence on page 5, lines 22 and 23, which says, "Priority shall be granted to research designed to prevent or cure disease."

VIII. Amendments:

None.