

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.)

Prepared By: Health and Human Services Appropriations Committee

BILL: CS/CS/SB's 1872 & 2378

SPONSOR: Health and Human Services Appropriations Committee, Health Care Committee and Senators Saunders, Fasano, King, Smith, Rich, Dockery, and Wise

SUBJECT: Biomedical Research

DATE: April 12, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Harkey</u>	<u>Wilson</u>	<u>HE</u>	<u>Fav/CS</u>
2.	<u>Fabricant</u>	<u>Peters</u>	<u>HA</u>	<u>Fav/CS</u>
3.	_____	_____	<u>WM</u>	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill states the intent of the Florida Legislature to provide increased funding to support biomedical research in the state, with particular emphasis on cancer research and Alzheimer's disease research. The bill redistributes funds that are deposited in the Alcoholic Beverage and Tobacco Trust Fund. The bill deletes the requirement for a \$15 million annual distribution to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and instead requires an annual distribution of \$15 million to the Biomedical Research Trust Fund within the Department of Health (DOH) to be used by the Florida Center for Universal Research to Eradicate Disease to provide grants to researchers seeking cures for Alzheimer's disease. The bill deletes the requirement for a \$9 million annual distribution to the Florida State University School of Chiropractic Medicine and instead requires an annual distribution of \$9 million to the Biomedical Research Trust Fund within DOH to be used by the Florida Center for Universal Research to Eradicate Disease to provide grants to researchers seeking cures for cancer.

The bill revises the purpose and duties of the Florida Center for Universal Research to Eradicate Disease to include the provision of grants for cancer research and Alzheimer's disease research. The bill revises the composition of the advisory council within the center to provide for an 18-member board instead of the current 54-member board by requiring one member from the University Research Consortium rather than all 37 members of the consortium board of directors.

The bill renames the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute as the Ronald Reagan Alzheimer's Center and Research Institute.

This bill amends ss. 20.435, 561.121, 381.855, 381.921, and 1004.445, F.S., and creates one unnumbered section of law.

II. Present Situation:

Alzheimer's Disease

Alzheimer's disease is a progressive, irreversible brain disorder with no known cause or cure. Symptoms of the disease include memory loss, confusion, impaired judgment, personality changes, disorientation, and loss of language skills. Always fatal, Alzheimer's disease is the most common form of irreversible dementia. How rapidly it advances varies from person to person, but it eventually causes confusion, personality and behavior changes and impaired judgment. Communication becomes difficult as the affected person struggles to find words, finish thoughts or follow directions. Most people with Alzheimer's disease become unable to care for themselves.

There is no known treatment that will cure Alzheimer's disease. For those who are currently suffering with the disease, medications can only help control symptoms and/or slow the progression of the disease. Approximately 100,000 victims die and 360,000 new cases of Alzheimer's disease are diagnosed each year in the United States. It is estimated that by 2050, 14 million Americans will have this disease. In every nation where life expectancy has increased, so has the incidence of Alzheimer's disease. It is estimated that by 2020, 30 million people will be affected by this disorder worldwide and by 2050 the number could increase to 45 million.

The Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute

The 2004 Legislature amended s. 1004.445, F.S., to rename the Florida Alzheimer's Center and Research Institute at the University of South Florida as the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, in honor of the late father of Johnnie Byrd, Jr. who was the Speaker of the Florida House of Representatives from 2002-2004. The center is established as a not-for-profit corporation for Alzheimer's research and receives \$15 million annually in state funding.

Cancer Research

According to the Florida Dialogue on Cancer, of \$10 billion spent nationally on cancer research funding in 2002, the National Cancer Institute provided \$4.2 billion; industry and pharmaceutical companies provided \$5 billion; the U. S. Centers for Disease Control and Prevention provided \$269 million; the American Cancer Society provided \$125 million; and other non-profit groups provided \$375 million. In 2003, Florida, ranked 21st among the states in the amount of money (\$38.4 million) the National Cancer Institute provided for cancer research in this state. Florida ranked second among states in the incidence of cancer (97,290 diagnoses) and mortality (40,090 deaths) from cancer in 2004.

The Florida Dialogue on Cancer

The Florida Dialogue on Cancer (FDOC) is a collaboration of Florida leaders of hospitals, research centers, universities, professional medical groups, community-based organizations, and private business groups, as well as government officials. FDOC is an initiative designed to expand the state's capacity to reduce the incidence and mortality rates of cancer. The goals of FDOC are to:

- Create a coalition that speaks with one voice on major statewide cancer issues for Florida;
- Enhance and promote Florida's capacity to conduct cancer research, professional education, clinical trials and treatment programs; and
- Identify and promote the replication of best practices in providing access to cancer prevention, education, and screening, diagnosis, and treatment programs for all Floridians and to reduce the disparities that exist.

The Florida Division of the American Cancer Society sponsors FDOC, which is based on the work of the National Dialogue on Cancer.

The Florida Center for Universal Research to Eradicate Disease

Section 381.855, F.S., creates the Florida Center for Universal Research to Eradicate Disease within DOH. 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, autoimmune disorders, 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, or obtain sponsorship for, the costs of their 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, placentas and cord blood;
- Facilitate the formation of partnerships between Florida researchers and institutions in other states and countries where research with rare plants or animals could lead to cures;
- Encourage Florida's agricultural colleges and agricultural businesses to be active in the search for cures and the provision of public information about disease prevention;

- Facilitate partnerships among researchers working to cure all types of diseases, including those that are prevalent in developed countries and those that occur in developing countries; 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 in need of 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 by DOH to a private entity or state university.

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

- The Emerging Technology Commission;
- Enterprise Florida, Inc;
- BioFlorida;
- The Biomedical Research Advisory Council;
- The Florida Medical Foundation;
- Pharmaceutical Research and Manufacturers of America;
- The Florida Tri-Agency Coalition on Smoking and Health;
- The Florida Cancer Research Council;
- The American Cancer Society, Florida Division, Inc;
- The American Heart Association;
- The American Lung Association of Florida;
- The American Diabetes Association, South Coastal Region;
- The Alzheimer's Association;
- The Epilepsy Foundation;
- The National Parkinson's Foundation;
- The Florida Public Health Foundation, Inc; and

- Scripps Florida, or the entity formed by the Scripps Research Institute in Florida.

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

The Florida Cancer Council

The 2004 Legislature created the Florida Cancer Council within DOH for the purpose of making Florida a center of excellence for cancer research. Under s. 381.92, F.S., the council may create not-for-profit corporate subsidiaries to fulfill its mission, and those subsidiaries could receive, hold, invest, and administer property and any monies acquired from private, local, state, and federal sources as well as technical and professional income from the mission-related activities of the council.

The council consists of:

- The Chairman of the Florida Dialogue on Cancer, who shall serve as the chairman of the council;
- The Secretary of the Department of Health, or his or her designee;
- The Chief Executive Officer of the H. Lee Moffitt Cancer Center, or his or her designee;
- The President of the University of Florida Shands Cancer Center, or his or her designee;
- The Chief Executive Officer of the University of Miami Sylvester Comprehensive Cancer Center, or his or her designee;
- The Chief Executive Officer of the Mayo Clinic, Jacksonville, or his or her designee;
- The Chief Executive Officer of the American Cancer Society, Florida Division, or his or her designee;
- The President of the American Cancer Society, Florida Division Board of Directors, or his or her designee;
- The President of the Florida Society of Clinical Oncology, or his or her designee;
- The President of the American College of Surgeons, Florida Chapter, or his or her designee;
- The Chief Executive Officer of Enterprise Florida, Inc., or his or her designee;
- Five representatives from cancer programs approved by the American College of Surgeons, three of whom are appointed by the Governor, one by the Speaker of the House of Representatives, and one by the President of the Senate;
- One member of the House of Representatives, to be appointed by the Speaker of the House of Representatives; and
- One member of the Senate, to be appointed by the President of the Senate.

Appointments made by the Speaker of the House of Representatives and the President of the Senate are for 2-year terms concurrent with the terms of the presiding officers who make the appointments. Appointments made by the Governor will be for 2-year terms, and the Governor may reappoint directors. Members of the council or any subsidiaries serve without compensation and each organization represented must cover the expenses of its representatives.

The council must issue an annual report to the Florida Center for Universal Research to Eradicate Disease, the Governor, the Speaker of the House of Representatives, and the President

of the Senate by December 15 of each year. The report must contain policy and funding recommendations regarding cancer research capacity in Florida and related issues.

The mission and duties of the council are established in s. 381.921, F.S. The council must work in concert with the Florida Center for Universal Research to Eradicate Disease to ensure that the goals of the center are advanced and must endeavor to dramatically improve cancer research and treatment in Florida through the following efforts:

- Efforts to significantly expand cancer research capacity in Florida by:
 - Identifying ways to attract new research talent and attendant national grant producing researchers to Florida-based cancer research facilities;
 - Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in Florida;
 - 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.
- Efforts to 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.
- Efforts to 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.

Excise Taxes on Alcoholic Beverages

Section 561.121, F.S., requires that all state funds collected pursuant to s. 563.05, F.S., related to the excise taxes on malt beverages, s. 564.06, F.S., related to excise taxes on wine and beverages, and s. 565.12, F.S., related to the excise tax on liquors and beverages are to be paid into the State Treasury and disbursed according to certain criteria. Under s. 561.121(1), F.S., \$15 million is distributed annually to the Department of Elderly Affairs to support a contract with the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; \$6 million is distributed annually to the Biomedical Research Trust Fund in DOH for use by the James and Esther King Biomedical

Program; and \$9 million is distributed annually to the Florida State University for the School of Chiropractic Medicine.

The Chiropractic Medicine School at Florida State University

The 2004 Legislature created s. 1004.383, F.S., to authorize a chiropractic medicine degree program at Florida State University. Subsequently, the Board of Governors of the State University System voted against authorizing a chiropractic medicine degree program at Florida State University.

Ronald Wilson Reagan

Ronald Reagan, the 40th President of the United States, served two terms as president from 1981 to 1989. He obtained legislation to stimulate economic growth, overhaul the income tax code, and strengthen national defense. His presidency oversaw the ending of the Cold War. He was a beloved president with a personable conversational style. In his later years he suffered from Alzheimer's disease, and the disease caused his death in June, 2004.

III. Effect of Proposed Changes:

Section 1. States that it is the intent of the Legislature to provide increased funding to support biomedical research in Florida with the anticipation that sustained funding for biomedical research over a period of years will lead to an alleviation of human suffering from disease such as cancer and Alzheimer's disease. It is the intent of the Legislature to dramatically reduce Florida's inordinately high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in Florida, making the state a world-class leader in cancer research and treatment. It is also the intent of the Legislature to support Alzheimer's disease research statewide through the awarding of research grants on a competitive basis. Additionally, it is the intent of the Legislature to spawn dramatic economic development, particularly in the biotech industry, through investment in the state's biomedical research.

Section 2. Amends s. 20.435, F.S., to increase the purpose of the Biomedical Research Trust Fund to include the Florida Center for Universal Research to Eradicate Disease.

Section 3. Amends s. 561.121, F.S., to redistribute funds that are deposited in the Alcoholic Beverage and Tobacco Trust Fund. The bill deletes the requirement for a \$15 million annual distribution to the Johnnie B. Byrd, Sr., Alzheimer's Center, and Research Institute and instead requires an annual distribution of \$15 million to the Biomedical Research Trust Fund within DOH to be used by the Florida Center for Universal Research to Eradicate Disease to provide grants to researches seeking cures for Alzheimer's disease. The bill authorizes the Florida Center for Universal Research to Eradicate Disease to use up to \$200,000 of these funds to administer the grant program and up to \$250,000 may be used for the operating costs of the Florida Center for Universal Research to Eradicate Disease.

The bill deletes the requirement for a \$9 million annual distribution to the Florida State University School of Chiropractic Medicine and instead requires an annual distribution of \$9 million to the Biomedical Research Trust Fund within DOH to be used by the Florida Center for Universal Research to Eradicate Disease to provide grants to researchers seeking cures for cancer. In providing grants for cancer research, the center must give emphasis to the goals of the Florida Cancer Council enumerated in s. 381.921, F.S. The center may use up to \$200,000 of these funds to administer the grant program.

The bill deletes the availability of up to \$250,000 for operation of the Florida Center for Universal Research to Eradicate Disease that is currently designated in the \$6 million distribution to the Biomedical Research Trust Fund for use by the James and Esther King Biomedical Research Trust Fund. As described above, the bill authorizes the center to use up to \$250,000 from the \$15 million appropriated for Alzheimer's disease research for the operating costs of the center.

Section 4. Amends s. 381.855, F.S., to expand the purpose of the Florida Center for Universal Research to Eradicate Disease to include the provision of grants for cancer research and Alzheimer's disease research. The bill requires the center to provide grants for cancer research and Alzheimer's disease research to further the search for cures for those diseases. The bill revises the composition of the center's advisory council to require only one member from the board of directors of the Florida Research Consortium rather than all of the members of the board. With this change in membership, the advisory council will consist of 18 members.

The bill establishes application procedures for the investigator-initiated research grants and institutional research grants that will be awarded by the center for cancer research and Alzheimer's disease research. The Secretary of Health must appoint peer-review panels of independent, scientifically qualified individuals to review the scientific content of the cancer research proposals and the Alzheimer's disease research proposals and establish a scientific priority score for each proposal. The priority score must be forwarded to the advisory council and must be considered in determining which proposals will be recommended for funding. Meetings of the council and the peer review panels are subject to the public records and meetings requirements of ch. 119, F.S., s. 286.011, and s. 24, Art. I of the State Constitution.

Section 5. Amends s. 381.921, F.S., which governs the Florida Cancer Council's mission and duties, to provide that the council will identify ways to attract new research talent and national grant-producing researchers to cancer research facilities "in this state" rather than "Florida-based" facilities.

Section 6. Amends s. 1004.445, F.S., to rename the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute as the Ronald Reagan Alzheimer's Center and Research Institute.

Section 7. Provides an effective date of July 1, 2005.

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 Art. I, s. 24(a) and (b) of the Florida Constitution.

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:

Private institutions could apply to the Florida Center for Universal Research to Eradicate Disease for funding for cancer research and Alzheimer's disease research.

C. Government Sector Impact:

There is no cost to state government because the bill redistributes funds that are deposited in the Alcoholic Beverage and Tobacco Trust Fund.

The bill deletes the requirement for a \$15 million annual distribution to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and instead requires an annual distribution of \$15 million to the Biomedical Research Trust Fund within DOH to be used by the Florida Center for Universal Research to Eradicate Disease to provide grants to researchers seeking cures for Alzheimer's disease.

The bill deletes the requirement for a \$9 million annual distribution to the Florida State University School of Chiropractic Medicine and instead requires an annual distribution of \$9 million to the Biomedical Research Trust Fund within DOH to be used by the Florida Center for Universal Research to Eradicate Disease to provide grants to researchers seeking cures for cancer.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
