

# 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.)

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Prepared By: Health and Human Services Appropriations Committee

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BILL: CS/CS/CS/SB 1826

INTRODUCER: Government Efficiency Appropriations Committee, Education Committee, Health Care Committee and Senators Saunders, Fasano and others

SUBJECT: Biomedical Research

DATE: April 6, 2006

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Bedford</u>	<u>Wilson</u>	<u>HE</u>	<u>Fav/CS</u>
2.	<u>Harkey</u>	<u>Matthews</u>	<u>ED</u>	<u>Fav/CS</u>
3.	<u>Gilreath</u>	<u>Johansen</u>	<u>GE</u>	<u>Fav/CS</u>
4.	<u>Fabricant</u>	<u>Peters</u>	<u>HA</u>	<u>Favorable</u>
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

## I. Summary:

This bill increases state funding for biomedical research and revises statutes that govern state-funded biomedical research to:

- Require state-funded biomedical research grants to be awarded on a competitive basis after peer review of the proposals and with adherence to ethical standards and avoidance of conflicts of interest.
- Continue annual distribution of alcoholic beverage tax collections from the State Treasury for the following programs:
  - \$6 million for the James and Esther King Biomedical Research Program, with up to \$250,000 of that amount designated for operation of the Center for Universal Research to Eradicate Disease (CURED), and
  - \$15 million for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, requiring 80 percent of those funds to be distributed as grants to researchers.
- Maintain the power of the Governor and the Legislature to appoint members to the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, the Biomedical Research Advisory Council, and the advisory council for the CURED center.
- Establish the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program in the Department of Health (DOH) to advance progress towards cures for cancer through grants awarded by the Biomedical Research Advisory Council.
- Appropriate \$9 million General Revenue for the 2006-07 fiscal year to the Biomedical Research Trust Fund for The William G. "Bill" Bankhead and David Coley Cancer Research Program to provide grants to researchers seeking cures for cancer.
- Require the following new reports:
  - An annual report from the DOH on the Bankhead-Coley program to the Governor and legislative leaders.

- An annual operating budget for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute to be submitted to the Governor and Cabinet, President of the Senate, Speaker of the House of Representatives, and the Chair of the State Board of Education.
- Revise requirements for the annual report of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute to require more detailed information about the center's expenditure of funds and research.

The bill provides for repeal of the James and Esther King Biomedical Research Program, the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, and the Bankhead and Coley Cancer Research Program on January 1, 2011, and requires the Legislature to review the programs in the 2010 Regular Session. Based upon its review of the performance, the outcomes, and the financial management of the programs/center, the Legislature will determine the most appropriate funding source and means of funding the programs/center.

The bill revises the duties of the Florida Public Health Foundation to allow the foundation to provide services and personnel to the Department of Health. The provision of the personnel and services would be exempt from chs. 110, 112, 253, 255, and 287, F.S.

This bill amends ss. 20.435, 215.5602, 381.855, 381.921, 381.98, 561.121, and 1004.445, Florida Statutes.

The bill creates s. 381.922, F.S., and 5 unnumbered sections 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 the loss of language skills. 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. In 2002, 58,866 Americans died of Alzheimer's disease.<sup>1</sup> According to the National Institutes on Aging, up to 4.5 million Americans suffer from Alzheimer's disease. Approximately five percent of individuals between the ages of 65-74 have the disease. Scientists estimate that nearly half of those 85 and older may have Alzheimer's disease.<sup>2</sup>

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

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<sup>1</sup> National Center for Health Statistics. Health, United States, 2005, With Chartbook on Trends in the Health of Americans. Hyattsville, Maryland. 2005. <http://www.cdc.gov/nchs/data/hus/hus05.pdf> (last visited on March 10, 2006).

<sup>2</sup> Alzheimer's Disease Education and Referral Center. National Institute on Aging. <http://www.nia.nih.gov/Alzheimers/AlzheimersInformation/GeneralInfo/#howmany> (last visited on March 10, 2006)

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. The institute reports that, in January 2004, it awarded 16 doctors, representing research and educational institutions from around the state, more than \$1.8 million in grants to further ongoing research on Alzheimer's disease. The grants were awarded to each recipient based on a criteria system developed by the National Institute of Health.<sup>3</sup>

### **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 21<sup>st</sup> 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. The Florida Dialogue on Cancer 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; and
- Enhance and promote Florida's capacity to conduct cancer research, clinical trials, and treatment programs.

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

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

The 1999 Legislature established the Lawton Chiles Endowment Fund to receive monies from the state's interest in settlements with the tobacco industry. Monies from the fund are to be used to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human services initiatives, and biomedical research. Funds are transferred from the endowment fund to support the James and Esther King Biomedical Research Program, established in s. 215.5602, F.S., which provides competitive grants for research

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<sup>3</sup> <http://www.byrdinstitute.org/>.

relating to the prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke, and pulmonary disease. The amount of this transfer for FY 2004-05 was \$3.5 million, and for FY 2005-06 and FY 2006-07 the projected amount of the transfer is \$3.4 million and \$3.5 million, respectively.<sup>4</sup> Under s. 561.121, F.S., the program also receives \$6 million annually from beverage tax collections. In 2005, the program awarded \$8 million in funding for 16 new projects rated as highly significant by a panel of national experts.<sup>5</sup> The program funds three types of grants: New Investigator Research Grants, Small Business Technology Transfer Grants, and Team Science Project Grants.

### **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 the 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 also:

- 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;
- Encourage the discovery and production in Florida of vaccines that prevent disease; and
- 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

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<sup>4</sup> The Florida Legislature. Office of Economic and Demographic Research.  
<http://edr.state.fl.us/conferences/tobacco/toboutl.pdf>

<sup>5</sup> The James and Esther King Biomedical Research Program. 2005 Annual Report.

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.

- Be funded through private, state, and federal sources.
- 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.
- 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 is to 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 2005 Annual Report acknowledged that CURED has not existed long enough to make major policy recommendations. The report made two recommendations:

*Generally, CURED recommends that the Governor and the Legislature support further significant investments in biomedical research and research capacity building, using competitive, peer-reviewed processes. Evidence that the Florida Legislature supports continuing disease-related research at institutions in the state will strengthen Florida's position as a location for biomedical and biotechnology businesses and as a place for innovative and groundbreaking biomedical research.*

*Funding for the Scripps organization in Southeast Florida has generated major interest in Florida among funders and outside research organizations. Florida law requires a reinvestment of \$150 to \$200 million of funds earned by the Scripps organization to support biomedical research in the state. See section 288.955(13), F.S. When that reinvestment materializes, CURED recommends that those monies be placed in a selfperpetuating trust fund similar to the biomedical research fund set aside in the Lawton Chiles Endowment Fund. Earnings on this fund would be used for a grants program, similar to the James and Esther King Biomedical Research Program, to fund research in support of CURED's goals.<sup>6</sup>*

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;

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<sup>6</sup> 2005 Annual Report of the Advisory Council of the Florida Center for Universal Research to Eradicate Disease. January 2006.

- The Florida Tri-Agency Coalition on Smoking OR 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 must serve without compensation and each organization represented must cover all expenses of its representative. According to the DOH, two of the entities that must have representatives on the council no longer exist—the Emerging Technology Commission and the Florida Tri-Agency Coalition on Smoking OR Health.

### **The Florida Cancer Council**

The 2004 Legislature created the Florida Cancer Council within the DOH to make 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 may 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 DOH, 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 CURED, 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 CURED 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.

## **The Institutional Review Board in the Department of Health**

Under s. 381.86, F.S., an institutional review board (IRB)<sup>7</sup> is created within the DOH in order to satisfy federal requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an institutional review board review all biomedical and behavioral research on human subjects which is funded or supported in any manner by the department. The jurisdiction of the IRB covers research funded by the DOH, involving DOH clients, involving DOH researchers, or involving DOH facilities.

The DOH IRB has entered into an agreement called a "Federal Wide Assurance"<sup>8</sup> with the federal Office of Human Research Protections (OHRP), whereby the department provides an assurance or commitment to review all research under its purview (regardless of source of funding) using the Food and Drug Administration and OHRP regulations. The review of research must address the following criteria.<sup>9</sup>

- Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by s. 45 C.F.R. 46.116.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by s. 45 C.F.R. 46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

## **Excise Taxes on Alcoholic Beverages**

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<sup>7</sup> <http://www.doh.state.fl.us/execstaff/irb/index.html>.

<sup>8</sup> [http://www.hhs.gov/ohrp/assurances/assurances\\_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html).

<sup>9</sup> 45 CFR 46.111.



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 the DOH for use by the James and Esther King Biomedical Research Program; and \$9 million is distributed annually to the Florida State University for the School of Chiropractic Medicine.

### **The Biomedical Research Trust Fund**

Section 20.435(1)(h), F.S., creates the Biomedical Research Trust Fund within the DOH. Funds from the Lawton Chiles Endowment are deposited into the fund to be used for the James and Esther King Biomedical Research Program. Notwithstanding the provisions of s. 216.301, F.S., which requires that, at the end of a fiscal year, any balance of any appropriation, except for capital outlay purposes, must revert to the fund from which it was appropriated, any balance in the Biomedical Research Trust Fund at the end of any fiscal year must remain in the trust fund and will be available for carrying out the purposes of the trust fund. The Governor may certify any balance of any appropriation from the Biomedical Research Trust Fund which is not disbursed but which is obligated pursuant to contract or committed to be expended for up to three years following the effective date of the original appropriation.

### **The School of Chiropractic Medicine 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.

### **The Florida Public Health Foundation, Inc.**

In 2002, the Florida Public Health Foundation, Inc., was incorporated as a Florida non-profit corporation operating within the exemption established by 26 U.S.C.A., Internal Revenue Code, Section 501(c)(3), to engage in charitable programs dedicated to improving the health of Florida citizens and to conduct educational programs for those working and interested in public health. The 2004 Legislature established the foundation in s. 381.98, F.S., with a reconstituted mission and an expanded board of directors. The foundation's mission includes disseminating biomedical research breakthrough findings and promoting health awareness in Florida. The foundation's duties include procuring funds necessary for accomplishing its purpose and mission. The foundation may receive, hold, invest, and administer property and any moneys acquired from private, local, state, and federal sources, as well as technical and professional income generated, or derived, from the its mission-related activities. The foundation must complement, supplement, and enhance the missions of the various organizations, entities, and departments represented on its board by serving as the lead overall public health awareness corporation in the state.

### III. Effect of Proposed Changes:

The bill increases accountability requirements in the awarding of biomedical research grants by requiring peer review of proposals, adherence to ethical standards and avoidance of conflicts of interest. The bill maintains the power of the Governor and the Legislature to appoint members to the boards that oversee the James and Esther King Biomedical Research Program, the Florida Center for Universal Research to Eradicate Disease, and the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

The bill provides legislative intent to:

- Provide funding to support grants for biomedical research in Florida with particular emphasis on cancer research and Alzheimer's disease research;
- Reduce the effect of the state's "inordinately high cancer burden";
- "Address the debilitating and deadly effects of Alzheimer's disease"; and
- Stimulate dramatic economic development, particularly in the biotechnology industry.

#### **The Biomedical Research Trust Fund (s. 20.435, F.S.)**

The bill authorizes use of funds in the Biomedical Research Trust Fund for purposes of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program and the James and Esther King Biomedical Research Program. The funds awarded in grants from those programs could be expended over a period of up to three years.

#### **The James and Esther King Biomedical Research Program (s. 215.5602, F.S.)**

The bill:

- Reduces the Governor's appointments to the Biomedical Research Advisory Council from six to four and requires two appointments by the President of the Senate and two by the Speaker of the House of Representatives. The Governor will appoint two members with expertise in biomedical research, one member from a research university in Florida, and one member representing the general population of the state. The President of the Senate will appoint one member with expertise in the field of behavioral or social research and one representative from a cancer program approved by the American College of Surgeons. The Speaker of the House of Representatives will appoint one representative from a professional medical organization and one representative from a cancer program approved by the American College of Surgeons.
- Requires the expiration on June 30, 2006, of all appointments to the Biomedical Research Advisory Council that were not made in accordance with the provisions of the bill.
- Requires the council to award cancer research grants under the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.
- Continues the automatic annual distribution of \$6 million of alcoholic beverage tax collections from the State Treasury to the program under s. 561.121, F.S., and authorizes up to \$250,000 of that amount to be used for operation of the CURED program.
- Provides for a January 1, 2011 repeal of the James and Esther King Biomedical Research Program and requires the Legislature to review the program in the 2010 Regular Session. Based upon its review of the performance, the outcomes, and the financial management of

the program, the Legislature will determine the most appropriate funding source and means of funding the program.

**The Florida Center for Universal Research to Eradicate Disease (CURED) (s. 381.855, F.S.)**

The bill:

- Revises the composition of the center's advisory council to provide for a 16-member board instead of the current 60-member board by requiring one member from the University Research Consortium rather than all 43 members of the consortium board of directors and by deleting two members representing entities that no longer exist.
- Requires the expiration on June 30, 2006, of all appointments to the advisory council for CURED that were not made in accordance with the provisions of the bill.
- Establishes 4-year terms for advisory board members and requirements for the election of a chair and for periodic meetings of the board.
- Continues annual distribution of up to \$250,000 of alcoholic beverage tax collections from the \$6 million distributed to the James and Esther King Biomedical Research Program under s. 561.121, F.S., for operating costs of the CURED center

**The Florida Cancer Council (s. 381.921, F.S.)**

The bill provides 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.

**The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (created in s. 381.922, F.S.)**

The bill:

- Creates the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program in the DOH to advance progress towards cures for cancer through grants awarded by the Biomedical Research Advisory Council.
- Establishes application procedures for the research grants awarded under the program. Grant proposals must be evaluated fairly on the basis of scientific merit by a peer-review panel appointed by the Secretary of Health. The peer-review panel must follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest.
- Appropriates \$9 million in General Revenue to the Biomedical Research Trust Fund for the program for FY 2006-07 to provide grants to researchers seeking cures for cancer.
- Requires DOH to report to the Governor and legislative leaders concerning the program by December 15 each year.
- Provides for a January 1, 2011 repeal of the Bankhead and Coley Cancer Research Program and requires the Legislature to review the program in the 2010 Regular Session. Based upon its review of the performance, the outcomes, and the financial management of the program, the Legislature will determine the most appropriate funding source and means of funding the program.

**The School of Chiropractic Medicine at Florida State University**

The bill deletes the \$9 million dollar annual appropriation to the Florida State University for the School of Chiropractic Medicine.

### **The Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute (s. 1004.445, F.S.)**

The bill:

- Maintains the authority of the Governor and legislative leaders to appoint the members of the Board of Directors of the center.
- Requires the expiration on June 30, 2006, of all appointments to the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute that were not made in accordance with the provisions of the bill.
- Requires the center's annual report to describe the expenditures of all funds, information concerning research conducted or funded by the center, and the expected or actual result of such research.
- Requires the chief executive officer of the center to develop and submit an annual operating budget to the Governor and Cabinet, President of the Senate, Speaker of the House of Representatives, and the Chair of the State Board of Education.
- Establishes procedures the center must follow when awarding peer-reviewed, competitive grants for Alzheimer's disease research. Grant proposals must be evaluated fairly on the basis of scientific merit by a peer-review panel appointed by the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and must adhere to a strict policy with regard to conflict of interest.
- Continues annual distribution of \$15 million of alcoholic beverage tax collections from the State Treasury for the center under s. 561.121, F.S., and requires that eighty percent of the funds must be distributed as research grants.
- Provides for a January 1, 2011 repeal of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and requires the Legislature to review the center in the 2010 Regular Session. Based upon its review of the performance, the outcomes, and the financial management of the center, the Legislature will determine the most appropriate funding source and means of funding the center.

### **The Florida Public Health Foundation**

The bill revises the duties of the Florida Public Health Foundation to allow the foundation to provide services and personnel to the Department of Health. The personnel would not be state employees. They would be employed under contract and not be entitled to receive benefits under chs. 110 and 112, F.S. The corporation is authorized to purchase goods, services, and property and will not be subject to laws governing state lands (ch. 253, F.S.), public property and publicly owned buildings (ch. 255, F.S.) and procurement of personal property and services (ch. 287, F.S.).

### **Effective Dates**

Except as otherwise provided in the bill, the bill will take effect July 1, 2006. Three sections of the bill take effect upon the bill becoming a law; those sections require the expiration on June 30,

2006, of all appointments to the Biomedical Research Advisory Council, the advisory Council for CURED, and the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute that were not made in accordance with the provisions of the bill.

#### **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 institutions and researchers at such institutions may apply to the William G. "Bill" Bankhead and David Coley Cancer Research Program for funding for cancer research; to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute for funding for Alzheimer's disease research; and to the James and Esther King Biomedical Research Program for funding for biomedical research involving tobacco-related diseases.

C. Government Sector Impact:

The bill continues the requirement for a \$15 million annual distribution from the State Treasury to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and requires that no less than 80 percent of that amount be distributed in research grants.

The bill continues the requirement for a \$6 million annual distribution from the State Treasury to the Biomedical Research Trust Fund for the James and Esther King Biomedical Research Program and continues the requirement for an annual distribution of up to \$250,000 from that \$6 million for operating costs of the CURED program.

The bill repeals the requirement for a \$9 million annual distribution from the State Treasury to the Florida State University School of Chiropractic Medicine.

For FY 2006-07, the bill appropriates \$9 million in General Revenue to the Biomedical Research Trust Fund for the William G. "Bill" Bankhead and David Coley Cancer

Research Program. The Department of Health may expend up to 10% of the appropriation for administrative expenditures.

The Department of Health estimates the following expenditures to administer the newly created William G. “Bill” Bankhead and David Coley Cancer Research Program:

<b>Estimated Expenditures</b>	<b>1<sup>st</sup> Year</b>	<b>2<sup>nd</sup> Year</b> (Annualized/Recur.)
<b>Salaries</b>		
1.0 Program Administrator @ \$57,000	77,805	80,139
1.0 (0.5) Administrative Coordinator @ \$32,000	21,840	22,495
1.0 (0.5) Administrative Assistant @ \$28,000	19,110	19,683
0.20 Senior Attorney @ \$55,000	15,015	15,465
0.15 Administrative Assistant @ \$27,000	7,371	7,592
<b>Expense</b>		
1 Standard professional w/ maximum travel	19,100	15,757
1 (1/2) Standard professional w/ limited travel	6,867	5,195
1 (1/2) Standard support staff	3,993	2,598
Other general office expenses	4,296	4,296
Staff development	5,000	5,000
Council travel	2,400	2,400
Honorarium individual applications @ \$500 each	75,000	75,000
Honorarium team applications @ \$2,100 each	52,500	52,500
Honorarium interim/annual progress reports	9,600	9,600
Grant Manager contract (see note 4)	420,000	370,000
<b>Operating Capital Outlay</b>		
Computers	2,100	0
<b>Total Estimated Expenditures</b>	<b>741,997</b>	<b>687,721</b>
<b>Expenditures as Percent of \$9 million</b>	<b>8.2%</b>	<b>7.6%</b>

**Notes:**

1. Other general office expenses not included in standard package shown in fiscal: Blackberry service for one professional; DHL Courier Service; advertising in Florida Administrative Weekly; books, subscriptions, reference material; offices supplies; council supplies
2. Staff development is provided by Sterling Human Resource Focus Criteria
3. Council travel is included if approved for CURED Council members; Biomedical Research Advisory Council members travel is currently reimbursed; adding one member to existing council
4. Major services provided under contract include providing paperless, online grant application, peer review, and management system; developing and publishing annual Call for Grant Applications; providing technical assistance to applicants; accepting applications; conducting administrative review of applications; organizing peer reviewers; analyzing merit scores and presenting to council; verifying information for recommended applicants; creating mail merge files; providing grant management services including review of quarterly financial reports, processing grant amendments, monitoring progress of research projects by conducting site visits and obtaining peer review of

interim or annual narrative progress reports; tracking current and past grantees for new grant funding, publications and presentations; preparing and printing legislatively mandated annual report; developing and maintaining program website; preparing and maintaining program policies and operating procedures; providing support to council including logistics of meetings; providing support to department staff on technical aspects of program

5. The Program Administrator will prepare competitive solicitations; monitor contractor performance through weekly meetings, quarterly performance reports and performance standards; primary liaison for council members, intra-department activities, potential researchers or members of general public and other state or federal government officials; analyzes and monitors state and federal legislation, regulations, policy and funding trends; continuous program improvement; process mapping; developing strategic and action plans; coordinate departmental human research protections review as necessary

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

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

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## **VIII. Summary of Amendments:**

None.

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