

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1027 CS Biomedical Research
SPONSOR(S): Hasner, Coley and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 1826

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee	9 Y, 0 N	Ciccone	Brown-Barrios
2) Health Care Appropriations Committee	15 Y, 0 N, w/CS	Massengale	Massengale
3) Health & Families Council	11 Y, 0 N, w/CS	Ciccone	Moore
4) _____	_____	_____	_____
5) _____	_____	_____	_____

SUMMARY ANALYSIS

House Bill 1027 w/CS provides legislative intent to provide funding for biomedical research grants in Florida with particular emphasis on cancer research and Alzheimer's disease research, and to promote economic development particularly in the biotechnology industry. The bill increases state funding for biomedical research, creates a new cancer research program, and amends several statutes that govern state-funding for biomedical research.

The bill establishes the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program within the Department of Health and provides grant monies to researchers seeking cures for cancer. The bill requires that state-funded biomedical research grants be awarded on a competitive basis after a peer review of proposals. The bill provides new and, in some cases, increased program reporting to the Governor and Legislature.

The bill revises the composition of the Florida Center for Universal Research to Eradicate Disease (CURED) advisory council and establishes four-year terms for advisory board members and requirements for the election of a chair.

The bill discontinues the automatic annual distribution of alcoholic beverage tax collections from the State Treasury for the Center for Universal Research to Eradicate Disease, the James and Esther King Biomedical Research Program, and the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and authorizes the Legislature to annually appropriate funds for these centers and the program. The bill requires the Department of Health to submit an annual report on the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program. The bill requires the annual operating budget for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute be submitted to the Governor and Cabinet, Senate President, House Speaker and State Board of Education chair and require additional information regarding the center's expenditure of funds and research.

The bill includes appropriations from the General Revenue Fund as follows:

- \$6 million to the James and Esther King Biomedical Research Program.
- \$9 million to William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.
- \$15 million to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

The bill provides for an effective date of July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Limited Government—The bill adds a new grant program and expands the administrative and oversight responsibility of the Department of Health.

Empower families—Florida families should benefit from greater access to information and health care services derived from cancer and Alzheimer's disease clinical trials and resultant new therapies.

B. EFFECT OF PROPOSED CHANGES:

The bill revises state funding for biomedical research to end automatic distributions from the State Treasury for a specified program and centers and instead authorizes annual appropriations for the program and centers. The bill increases accountability requirements in awarding biomedical research grants and revises several statutes governing state-funded biomedical research.

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

Currently the Biomedical Research Trust Fund expends monies for the purposes of the James and Esther King Biomedical Research Program. The bill expands the use of Biomedical Research Trust Fund money to include the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program. The funds awarded in grants from these programs can be expended over a period of up to three years.

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

The James and Esther King Biomedical Research Program is located within the Department of Health. The Biomedical Research Advisory Council (BRAC) is created within the James and Esther King Biomedical Research Program and carries out the mission of the program. This bill reduces the number of Governor's appointments to the 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 council's duties are expanded to award cancer research grants under the newly-created Bankhead-Coley Program. The bill replaces the automatic \$6 million distribution from alcoholic beverage tax collections with a \$6 million annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund.

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

The Florida Center for Universal Research to Eradicate Disease (CURED) is located within the Department of Health. The CURED advisory council carries out the mission of the center. 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 Florida Research Consortium rather than all 43 members of the consortium board of directors. The bill deletes two members representing entities that no longer exist. The bill establishes 4-year terms for advisory board members and requirements to elect a chair and for periodic board meetings. The bill replaces the automatic distribution of up to \$250,000 of alcoholic beverage tax collections from the \$6 million appropriated to the James and Esther King Biomedical Research Program for the center's operating costs with an annual appropriation.

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 within the Department of Health, and provides that grants be awarded towards cures for cancer by the Biomedical Research Advisory Council. The bill establishes application procedures for research grants

including that grant proposals be awarded on the basis of scientific merit by a peer-review panel. The bill appropriates \$9 million to the Biomedical Research Trust Fund for grants.

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

The Florida Cancer Council is located within the Department of Health. The purpose of the council is to establish the state as a center of excellence for cancer research. 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 effect of this change is to expand the types of facilities that may be awarded grants. Grant-funding decisions would be based on a peer-review system according to specific criteria.

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

The Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute is located at the University of South Florida. The purpose of the center is to encourage research, education, treatment, prevention and the early detection of Alzheimer's disease. The bill revises the information contained within the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute's annual report to include a description of the expenditure of all funds, information concerning research conducted or funded by the center, and the expected or actual result of such research. The bill requires the center's chief executive officer to submit an annual operating budget to the Governor, Cabinet, President of the Senate, Speaker of the House of Representatives, and State Board of Education chair. The bill establishes procedures that the center must follow when awarding research grants including that proposals be awarded on the basis of scientific merit by a peer-review panel. The bill limits the membership of the board of directors to 16 from the current possible 21 members. The bill replaces the automatic \$15 million distribution from alcoholic beverage tax collection with a \$15 million annual appropriation from the General Revenue Fund to the Grants and Donations Trust Fund within the Department of Elder Affairs.

Background

Cancer Research:

The emphasis that Florida places on cancer research is evidenced in the high-profile cancer related programs and funding strategies that have been established over the years. In addition, Florida recognizes the importance of a coordinated and collaborative approach to biomedical research. The scientific, humanitarian and economic value that is derived from a coordinated state, federal, and academic and private effort can not be overstated. Ultimately, biomedical research contributes to a healthier population and biomedical discoveries and the resultant products or treatments contribute to the economy of the area in which they are produced. For both health and economic reasons, governments are interested in furthering the work of biomedical researchers and in helping researchers collaborate and share resources.

Efforts in Florida relating to the coordination and development of medical research and disease prevention include the James and Esther King Biomedical Research Program, the Florida Center for Universal Research to Eradicate Disease, the Florida Cancer Council, and the Florida Dialogue on Cancer.

The James and Esther King Biomedical Research Program

The 1999 Legislature established the Lawton Chiles Endowment Fund ¹ as a result of its settlements 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, Florida Statutes, establishes the James and Esther King Biomedical Research Program funded from interest earnings on the endowment fund, and provides that funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. The Biomedical Research Advisory Council within 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 Florida Center for Universal Research to Eradicate Disease

Section 381.855, Florida Statutes, creates the Florida Center for Universal Research to Eradicate Disease within the Department of Health. 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 to expedite the discovery of cures for diseases. Summit attendees are required to cover, or obtain sponsorship for, the costs of their attendance.

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

¹ Section 215.5601, F.S., ch. 99-167, Laws of Florida

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

The Florida Cancer Council

In 2004, the Legislature created the Florida Cancer Council within the Department of Health for the purpose of making Florida a center of excellence for cancer research.² Section 381.921, Florida Statutes, provides the overall mission of the Florida Cancer Council and stipulates that 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 work toward dramatically improved cancer research and treatment in Florida through a number of specific efforts including expanding cancer research capacity in Florida, improving research and treatment through greater participation in clinical trials networks, and reducing the impact of cancer on disparate groups of persons.

The Florida Cancer Council membership is representative of Florida cancer centers, hospitals, and patient groups. The council is authorized to 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 and technical and professional income from the mission-related activities of the council.

The council membership is as follows:

- The Chairman of the Florida Dialogue on Cancer, who serves as the council chairman.
- 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 shall be 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.
- 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 two-year terms concurrent with the terms of the presiding officers who make the appointments. Appointments made by the Governor are two-year terms, and the Governor may reappoint directors. Members of the council or any subsidiaries serve without compensation and each organization represented covers the expenses of its representatives.

The council issues an annual report to the 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 contains policy and funding recommendations regarding cancer research capacity in Florida and related issues.

² Section 381.92, Florida Statutes, s.10, ch. 2004-2 Laws of Florida

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, and 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 the following:

- 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.
- Identify and promote the replication of best practices in providing access to cancer prevention, education, and screening, diagnosis, and treatment programs for all Floridians 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.

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. Alzheimer's disease is the most common form of irreversible dementia—symptom escalation varies from person to person and includes confusion, personality and behavior changes and impaired judgment. Most people with Alzheimer's disease become unable to care for themselves.

There is no known cure for Alzheimer's disease; however, certain medications can help relieve symptoms or slow the progression of the disease. Approximately 100,000 victims die and 360,900 new cases of Alzheimer's disease are diagnosed each year in the United States. According to the Alzheimer's Association, the number of Americans with the disease has doubled since 1980 and current estimates reflect 4.5 million Americans have Alzheimer's disease. By 2050, it is estimated that 14 million Americans will have this disease. There are currently 396,000 people with Alzheimer's disease in Florida.

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

Section 1004.43, Florida Statutes, establishes the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida. The institute is governed by a not-for-profit corporation in accordance with an agreement with the State Board of Education. The corporation is managed by a board of directors consisting of the President of the University of South Florida and the chair of the State Board of Education, or his or her designee, five representatives of the state university system, and between 9-14 additional directors who are not medical doctors or state employees. The institute is administered by a chief executive officer, who serves at the pleasure of the board of directors.

The mission of the Byrd Alzheimer's Research Center is to collaborate with researchers throughout the State of Florida and the wider global research community to develop treatment to cure and prevent this disease. The Byrd Alzheimer's Research Center will conduct state of the art research in addition to serving as the site for coordinating and facilitating the state's various efforts to diagnose, treat and prevent the disease. Funding for the institute is generated through state and federal grants and other fundraising efforts.

C. SECTION DIRECTORY:

Section 1. Provides legislative intent.

Section 2. Amends s. 20.435, F.S., adding the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program to the list of purposes of the Biomedical Research Trust Fund.

Section 3. Amends s. 215.5602, F.S., relating to the membership of the Biomedical Research Advisory Council to create a new subsection (11) authorizing the council to award grants for cancer research through the Bankhead-Coley Cancer Research Program, and a new subsection (12) authorizing an annual appropriation to the James and Esther King Biomedical Research Program.

Section 4. Provides language regarding the expiration of certain appointments to the Biomedical Research Advisory Council; provides an effective date upon becoming law.

Section 5. Amends s. 381.855 (5) and creates new subsections (6), (7), and (8), F.S., relating to membership and term on the advisory council to the Center for Universal Research to Eradicate Disease (CURED); grant peer review process, and authorizing an annual appropriation to CURED for operating costs.

Section 6. Provides language regarding the expiration of certain appointments to the advisory council for the Center for Universal Research to Eradicate Disease (CURED).

Section 7. Amends s. 381.921 (1), F.S., relating to the mission and duties of the Florida Cancer Council.

Section 8. Creates s. 381.922, F.S., establishing the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.

Section 9. Amends s. 561.121 (1), F.S., and deletes language relating to certain automatic annual distributions of alcoholic beverage tax collections from the State Treasury.

Section 10. Amends s. 1004.445 (2) and (6), F.S., revising board of directors membership to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and creates new subsections (8) and (12) relating to research funding and authorizes an annual appropriation to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

Section 11. Provides language regarding the expiration of certain appointments to the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

Section 12. Provides a \$6 million appropriation for fiscal year 2006-07 from the General Revenue Fund to be deposited into the Biomedical Research Trust Fund for the James and Esther King Biomedical Research Program; provides a \$9 million appropriation for fiscal year 2006-07 from the General Revenue Fund to be deposited into the Biomedical Research Trust Fund for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, provides a \$15 million appropriation for fiscal year 2006-07 from the General Revenue Fund to be deposited into the Grants and Donations Trust Fund for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; provides for specific use of such funds.

Section 13. Provides an effective date of July 1, 2006, except as expressly provided in the act.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None

2. Expenditures:

The bill includes appropriations from the General Revenue Fund as follows:

- \$6 million to the Biomedical Research Trust Fund for the James and Esther King Biomedical Research Program., authorizing up to \$250,000 of that amount to be used for operating expenses of the CURED program.
- \$9 million to the Biomedical Research Trust Fund for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, authorizing up to 10 percent to be used for administrative expenses, and
- \$15 million to the Grants and Donations Trust Fund in the Department of Elderly Affairs for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, requiring not less than 80 percent of this amount to be distributed in research grants.

The Department of Health revised the original estimates to reflect the following:

<u>Estimated Expenditures</u>	1 st Year	2 nd Year (Annualized/Recur)
<u>Salaries:</u>		
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
<u>Expenses:</u>		
1 Std DOH professional pkg. w/maximum travel	\$19,090	\$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
Technical services contract	420,000	370,000
<u>Operating Capital Outlay</u>		
Computers	<u>2,100</u>	<u>- 0 -</u>
 Total Estimated Expenditures	 \$741,997	 \$687,720

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

By referring to research facilities as those that are "in this state," non-state universities, not-for-profit entities, researchers, biotechnology and pharmaceutical companies and others will benefit from this bill by receiving grants from which they may develop patented or licensed intellectual property. Further, new research talent and national grant-producing researchers should be attracted to cancer research facilities in this state.

D. FISCAL COMMENTS:

The bill discontinues the automatic distribution of alcoholic beverage tax collections from the State Treasury for the James and Esther King Biomedical Research Program and the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, and provides instead for an annual appropriation by the Legislature. The bill also discontinues the annual distributions of alcoholic tax collections for the Florida State University School of Chiropractic Medicine.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

This bill has no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

No additional rule-making is required for the Department of Health to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 17, 2006, the Health Care Appropriations Committee adopted a strike-all amendment that made the following changes:

- Added the Bankhead-Coley Cancer Research Program to the purposes of the Biomedical Research Trust Fund.
- Changed the number of appointments to the Biomedical Research Advisory Council by the President of the Senate and the Speaker of the House of Representatives from one to two.
- Added the awarding of grants by the Biomedical Research Advisory Council for cancer research for the purposes of Bankhead-Coley Cancer Research Program.
- Reduced the membership of the advisory council to the CURED from 18 to 16 members.
- Added a competitive, peer-reviewed grant application process to the Bankhead-Coley Cancer Research Program.
- Provided \$250,000 for CURED operating costs out of the \$6 million appropriation for Biomedical Research Trust Fund, and up to 10 percent of the \$9 million appropriation for administrative expenses for the Bankhead-Coley Cancer Research Program.

On March 28, 2006, the Health and Families Council adopted four amendments conforming the House Bill to the Senate Bill as follows:

- Corrected two statutory references.
- Removed potential reference to a public records exemption (addressed in separate bill)
- Specified use of funds appropriated for Alzheimer's research and related projects.

The analysis is written to reflect the bill as amended.