

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL 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: The Professional Staff of the Health Regulation Committee

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BILL: SPB 7004

INTRODUCER: For consideration by the Health Regulation Committee

SUBJECT: Biomedical research programs

DATE: October 22, 2009

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson		<b>Pre-meeting</b>
2.				
3.				
4.				
5.				
6.				

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**I. Summary:**

The proposed committee bill saves from repeal the James and Esther King Biomedical Research Program (King Program) and the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program). The proposed committee bill also establishes a 4-year staggered term of membership for the Biomedical Research Advisory Council, requires the Department of Health (DOH) to adopt rules to administer the biomedical research programs, specifies a recurring source of funding for the King Program and the Bankhead-Coley Program, authorizes the DOH to receive restricted or unrestricted gifts to further the goals of the programs, and repeals obsolete provisions and other provisions pertaining to the Legislature’s review and reenactment of these two programs. Unless reenacted by the Legislature, authorization for the King Program and the Bankhead-Coley Program will expire on January 1, 2011.

This proposed committee bill substantially amends the following sections of the Florida Statutes: 215.5602 and 381.922.

**II. Present Situation:**

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

The Florida Legislature created the Florida Biomedical Research Program in 1999 within the DOH. The Florida Biomedical Research Program was renamed the James and Esther King Biomedical Research Program during Special Session B of the 2003 Legislature.

The purpose of the King Program is to provide an annual and perpetual source of funding to support research initiatives that address the health problems of Floridians in the areas of

tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.<sup>1</sup> The long-term goals of the program are to:

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

The King Program offers competitive grants to researchers throughout Florida to fulfill its goals. Grant applications from any university or established research institute<sup>2</sup> in this state will be considered for biomedical research funding under the King Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.<sup>3</sup>

The State Surgeon General, after consultation with the Biomedical Research Advisory Council (the Advisory Council), is authorized to award grants and fellowships on the basis of scientific merit<sup>4</sup> within the following three categories:

- Investigator-initiated research grants, which are designed to initiate research that can be subsequently funded from a national agency,
- Institutional research grants, which are intended to foster the development of new and promising research investigators so that they can undertake more independent research that would be competitive for national research funding as well as to attract talented researchers to Florida institutions, and
- Predoctoral and postdoctoral research fellowships.<sup>5</sup>

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<sup>1</sup> s. 215.5602, F.S.

<sup>2</sup> An established research institute is any Florida non-profit or foreign non-profit corporation covered under Chapter 617, F.S., with a physical location in Florida, whose stated purpose and power is scientific, biomedical or biotechnological research or development and is legally registered with the Florida Department of State, Division of Corporations. This includes federal government and non-profit medical and surgical hospitals, including veterans administration hospitals. See the Call for Grant Applications 2009-2010, page 7, available at:

[http://forms.floridabiomed.com/jek\\_call/King%20Call%2009-10.pdf](http://forms.floridabiomed.com/jek_call/King%20Call%2009-10.pdf) (Last visited on October 22, 2009).

<sup>3</sup> Grant award recipients have included the following institutions or investigators associated with these institutions: University of Miami (UM), University of Florida (UF), H. Lee Moffitt Cancer Center & Research Institute (Moffitt Cancer Center), University of Central Florida (UCF), M.D. Anderson Cancer Center, University of South Florida (USF), Florida State University (FSU), Roskamp Institute, Mayo Clinic, Florida Atlantic University (FAU), The Scripps Research Institute, Bay Pines VA Healthcare System, Florida Institute of Technology, and Nemours Children's Clinic.

<sup>4</sup> See the Grant Application and Processing section of Senate Interim Report 2010-219 for more information about assessing scientific merit.

<sup>5</sup> The DOH staff indicated that funding constraints have limited awarding fellowships. However, it is anticipated that fellowships may be available in the near future as a result of the infusion of funding to the King Program.

### **The William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program**

The Bankhead-Coley Program was created in 2006 by the Florida Legislature within the DOH.<sup>6</sup> The purpose of the Bankhead-Coley Program is to advance progress toward cures for cancer through grants awarded for cancer research.

The research funded under the Bankhead-Coley Program is intended to emphasize the goals of the Florida Cancer Council<sup>7</sup> as those goals support the advancement of cures for cancer. The Florida Cancer Council was established in 2004 within the DOH for the purpose of making the state a center of excellence for cancer research. The duties of the Florida Cancer Council include:

- Efforts to significantly expand cancer research capacity in the state by:
  - Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state;
  - Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
  - Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
  - Encouraging the employment of bioinformatics<sup>8</sup> 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; and
- 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.

Applications for funding cancer research from any university or established research institute in the state will be considered under the Bankhead-Coley Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the

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<sup>6</sup> s. 381.922, F.S., (Ch. 2006-182, L.O.F.).

<sup>7</sup> See ss. 381.92 and 381.921, F.S.

<sup>8</sup> Bioinformatics includes using computers to collect and analyze biochemical and biological information, especially related to molecular genetics and genomics. See <<http://www.merriam-webster.com/dictionary>> (Last visited on October 22, 2009).

research funding.<sup>9</sup> The State Surgeon General, after consultation with the Advisory Council, is authorized to award grants and fellowships on the basis of scientific merit<sup>10</sup> within the following three categories:

- Investigator-initiated research grants,
- Institutional research grants, and
- Collaborative research grants, including those that advance the finding of cures through basic or applied research.

### **Program Funding**

Initially, the King Program was funded with income from \$150 million of principal in the Lawton Chiles Endowment Fund.<sup>11</sup> In 2004, the Legislature appropriated additional funding, through a distribution from alcoholic beverage surcharge taxes. In 2006, the Legislature substituted a six million dollar annual appropriation commitment from the General Revenue Fund to fund the Biomedical Research Trust Fund within the DOH for purposes of the King Program.<sup>12</sup> However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the King Program was reduced to \$4.5 million.<sup>13</sup> During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed \$25 million, was to be transferred into the Biomedical Research Trust Fund for the King Program for the 2009-2010 fiscal year.<sup>14</sup> Of the funds appropriated for the King Program, up to \$250,000 per year is designated to operate the Florida Center for Universal Research to Eradicate Disease.<sup>15</sup>

The Bankhead-Coley Program was established with a commitment for an appropriation of \$9 million per year from the General Revenue Fund.<sup>16</sup> However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the Bankhead-Coley Program was reduced to \$6.75 million.<sup>17</sup> During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed

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<sup>9</sup> Grant award recipients have included the following institutions or investigators associated with these institutions: UM, UF, Moffitt Cancer Center, Florida International University, FAU, USF, M.D. Anderson Cancer Center, FSU, Mayo Clinic, Florida Institute of Technology, UCF, Florida Hospital Cancer Institute, and The Scripps Research Institute.

<sup>10</sup> *Ibid* 4.

<sup>11</sup> s. 215.5601, F.S. The Lawton Chiles Endowment Fund's principal originated from a portion of the state settlement received from its lawsuit with tobacco companies.

<sup>12</sup> Ch. 2006-182, Laws of Florida (L.O.F.).

<sup>13</sup> Ch. 2009-5, L.O.F.

<sup>14</sup> Ch. 2009-58, L.O.F.

<sup>15</sup> The purpose of the Florida Center for Universal Research to Eradicate Disease is to coordinate, improve, expand, and monitor all biomedical research programs within the state; facilitate funding opportunities; and foster improved technology transfer or research findings into clinical trials and widespread public use. See s. 381.855, F.S.

<sup>16</sup> s. 381.922(5), F.S.

<sup>17</sup> Ch. 2009-5, L.O.F.

\$25 million, was to be transferred into the Biomedical Research Trust Fund for the Bankhead-Coley Program.<sup>18</sup>

Chapter 2009-58, Laws of Florida, provided that 5 percent of the revenue deposited into the Health Care Trust Fund pursuant to s. 210.011(9), F.S., related to the cigarette surcharge and s. 210.276(7), F.S., related to the surcharge on tobacco products, are to be reserved for research of tobacco-related or cancer-related illnesses. The sum of the revenue reserved, however, may not exceed \$50 million in any fiscal year. The Legislature did not specify an amount to be appropriated annually, after the 2009-2010 fiscal year, for the King Program or the Bankhead-Coley Program from these reserves.

Any cash balance in the Biomedical Research Trust Fund at the end of a fiscal year remains in the trust fund to be available for carrying out the purposes of the trust fund. In addition, any balance of an appropriation from the Biomedical Research Trust Fund which has not been disbursed, but which is obligated, may be used for up to three years from the effective date of the original appropriation.

### **Biomedical Research Advisory Council<sup>19</sup> and Peer Review Panel<sup>20</sup>**

The purpose of the Advisory Council is to advise the State Surgeon General as to the direction and scope of the King Program. The Advisory Council is also required to consult with the State Surgeon General concerning grant awards for cancer research through the Bankhead-Coley Program.<sup>21</sup>

In order to ensure that proposals for research funding within the King Program and the Bankhead-Coley Program are appropriate and evaluated fairly on the basis of scientific merit, a peer review panel of independent, scientifically qualified individuals is appointed to review the scientific content of each proposal to establish a [scientific]<sup>22</sup> priority score.<sup>23</sup> To eliminate conflicts of interest, peer reviewers come from outside the state of Florida. Reviewers are experts in their fields from universities, government agencies, and private industry who are matched according to application topic and area of expertise. The priority scores must be considered by the Advisory Committee in determining which proposals will be recommended for funding to the State Surgeon General.

Meetings of the Advisory Council and the peer review panel are subject to chapter 119, F.S., relating to public records; s. 286.011, F.S., relating to public meetings; and s. 24, Article I of the State Constitution relating to access to public meetings and records.

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<sup>18</sup> Ch. 2009-58, L.O.F.

<sup>19</sup> s. 215.5602(3), F.S.

<sup>20</sup> s. 215.5602(6) and (7), and s. 381.922(3)(b), F.S.

<sup>21</sup> s. 381.922(3)(a), F.S. However, s. 215.5602(11), F.S., contains an inconsistency with respect to the responsibility of the Advisory Council concerning awarding grants for cancer research.

<sup>22</sup> The King Program requires a *scientific* priority score in s. 215.5602(6), F.S. The Bankhead-Coley Program requires a priority score in s. 381.922(3)(b), F.S.

<sup>23</sup> A Bridge Grant application is ranked solely by the priority score or percentile assigned to its qualifying federal proposal in an eligible federal review process.

## Program Administration and Grant Management

The Office of Public Health Research within the DOH manages both the King Program and the Bankhead-Coley Program with support from the Advisory Council and Lytmos Group, LLC (Lytmos), pursuant to contract.

The law authorizes, but does not require, the DOH, after consultation with the Advisory Council, to adopt rules as necessary to implement these programs.<sup>24</sup> The DOH has not adopted rules to implement these programs. Instead, the DOH publishes, on its website, the procedures for implementing these two programs.<sup>25</sup> The Joint Administrative Procedures Committee recently contacted the DOH concerning unadopted rulemaking.<sup>26</sup>

The *GrantEase*<sup>TM</sup> online system is used by grantees to access grant information and submit progress reports, invoices, financial reports, and change requests during the life of the grant. At least once during the grant period, the grantee is subjected to on-site monitoring for both scientific and administrative purposes.

## Mandatory Review

The 2006 Legislature required a review of the performance, outcomes, and financial management of these two programs during the 2010 Regular Session of the Legislature. The 2010 Legislature will determine the most appropriate funding source and means of funding these programs. The statutes establishing these two programs expire January 1, 2011, unless reviewed and reenacted by the Legislature before that date.

During the 2009-2010 interim, professional staff of the Senate Committee on Health Regulation performed the mandatory review of the King Program and the Bankhead-Coley Program as provided in ss. 215.5602 and 381.922, F.S. The recommendations in the resulting report<sup>27</sup> are that the Legislature re-enact the King Program and the Bankhead-Coley Program and further refine the statutory provisions governing these two programs. This proposed committee bill implements the committee's instruction to draft a proposed committee bill in accordance with the professional staff's recommendations.

### III. Effect of Proposed Changes:

**Section 1.** Amends s. 215.5602, F.S., related to the King Program to:

- Eliminate reference to funding the King Program with certain proceeds of the Lawton Chiles Endowment Fund and dedicate the 5 percent of revenue deposited into the Health Care Trust Fund from the cigarette and tobacco tax proceeds for the King Program and the Bankhead-Coley Program;

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<sup>24</sup> s. 215.5602(9), F.S.

<sup>25</sup> See: <<http://www.doh.state.fl.us/ExecStaff/biomed/ophrsitemap.html>>, (Last visited on October 22, 2009).

<sup>26</sup> Correspondence from the Joint Administrative Procedures Committee to the State Surgeon General dated August 6, 2009.

<sup>27</sup> Biomedical Research Programs – Performance, Outcomes, and Financial Management, dated September 2009, available at: <[http://www.flsenate.gov/data/Publications/2010/Senate/reports/interim\\_reports/pdf/2010-219hr.pdf](http://www.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-219hr.pdf)>, (Last visited on October 22, 2009).

- Clarify that up to \$250,000 of the funds appropriated for the King Program shall be available for operating costs of the Florida Center for Universal Research to Eradicate Disease to avoid an inconsistency regarding the exclusive use of the appropriations;
- Require the DOH to adopt rules to administer the programs;
- Change the length of membership on the Biomedical Research Advisory Council from 3 years to 4 years and establish a system to stagger membership on the council;
- Authorize the DOH to deposit restricted or unrestricted gifts into the Biomedical Research Trust Fund for purposes of the King Program; and
- Eliminate the 2009-2010 fiscal year appropriation, direction to the Division of Statutory Revision concerning the statutory citation of this section, the required Legislative review of the program, and the provision concerning expiration of the section, all of which will become obsolete upon enactment of this proposed committee bill.

**Section 2.** Amends s. 381.922, F.S., related to the Bankhead-Coley Program to:

- Designate the 5 percent of revenue deposited into the Health Care Trust Fund from the cigarette and tobacco tax proceeds for the King Program and the Bankhead-Coley Program as a funding source for the Bankhead-Coley Program;
- Authorize the DOH to deposit restricted or unrestricted gifts into the Biomedical Research Trust Fund for purposes of the Bankhead-Coley Program; and
- Eliminate the 2009-2010 fiscal year appropriation, direction to the Division of Statutory Revision concerning the statutory citation of this section, the required Legislative review of the program, and the provision concerning expiration of the section, all of which will become obsolete upon enactment of this proposed committee bill.

**Section 3.** Provides an effective date of July 1, 2010.

**Other Potential Implications:** Currently, 5 percent of revenue deposited into the Health Care Trust Fund from the cigarette and tobacco tax proceeds is reserved for research of tobacco-related or cancer-related illnesses. This proposed committee bill dedicates the entire 5 percent for the King Program and the Bankhead-Coley Program, subject to annual appropriations.

#### **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 the bill have no adverse impact on public records or open meetings issues under the requirements of Article I, Section 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. Fiscal Impact Statement:**

**A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

Continuing these two programs benefits both the private sector and the government sector of the state. Specifically, the King Program is leveraging research funding in the state for improvement of tobacco-related health conditions, expanding the foundation of biomedical knowledge, improving the quality of the state's academic health centers, increasing the state's per capita funding for research, and stimulating the economy. The Bankhead-Coley Program is expanding cancer research capacity in this state, improving research and treatment through clinical trials, and undertaking activities to reduce the impact of cancer on disparate groups. Dedicating a funding source for these programs provides continuity and expresses a commitment to improving Florida's position as a viable participant in the research community.

**C. Government Sector Impact:**

Refer to the private sector impact above.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Additional Information:**

**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.