## CHAMBER ACTION

<u>Senate</u> <u>House</u>

Representative Bean offered the following:

## Amendment (with title amendment)

Remove everything after the enacting clause and insert: Section 1. Subsection (6) of section 381.006, Florida Statutes, is amended to read:

381.006 Environmental health.--The department shall conduct an environmental health program as part of fulfilling the state's public health mission. The purpose of this program is to detect and prevent disease caused by natural and manmade factors in the environment. The environmental health program shall include, but not be limited to:

(6) A public facilities function, including sanitary practices relating to state, county, municipal, and private institutions serving the public; jointly with the Department of Education, publicly and privately owned schools; all places used 622583

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for the incarceration of prisoners and inmates of state institutions for the mentally ill; toilets and washrooms in all public places and places of employment; any other condition, place, or establishment necessary for the control of disease or the protection and safety of public health.

The department may adopt rules to carry out the provisions of this section.

Section 2. Subsection (1) of section 381.86, Florida Statutes, is amended to read:

381.86 Institutional Review Board. --

(1) The Institutional Review Board is created within the Department of Health 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.

Section 3. Section 381.98, Florida Statutes, is amended to read:

381.98 The Florida Public Health <u>Institute</u> <del>Foundation</del>, Inc.; establishment; purpose; mission; duties; board of directors.--

(1) The Florida Public Health <u>Institute</u> Foundation, Inc., referred to in this section as "the corporation," is established for the purpose of <u>advancing the knowledge and practice of public health</u>, including <u>disseminating breakthrough findings in biomedical research and promoting health awareness in this state and providing services to the Department of Health</u>.

- (2) The corporation's mission includes disseminating information about innovative biomedical research and clinical trials in this state as well as making Floridians and their treatment providers aware of specified diseases and conditions and available methods of preventing, diagnosing, treating, and curing those diseases and conditions.
- (2)(3) The purpose and objective of the corporation is shall be to operate exclusively for charitable, scientific, and educational purposes; to protect and improve the health and well-being of Florida's people and environment through partnerships committed to program innovation, education, applied research, and policy development; and to engage in charitable programs dedicated to improving the health of Floridians.
- (3)(4) The corporation shall be established as a not-for-profit entity qualifying under s. 501(c)(3) of the Internal Revenue Code. The corporation 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 mission-related activities of the corporation. The corporation shall have all of the powers conferred upon corporations organized under chapter 617.
- (4)(5) The corporation's duties include procuring funds necessary for accomplishing the purpose and mission of the corporation. The corporation shall strive to complement, supplement, and enhance the missions of the various organizations, entities, and departments represented on its

board by serving as the lead corporation in the state for promoting public health awareness.

- (5)(6) The affairs of the corporation shall be managed by an executive director appointed by a board of directors.
- (6) The board of directors shall be elected in accordance with the bylaws of the corporation and must include, but need not be limited to:
  - (a) The State Surgeon General or his or her designee.
- (b) A representative of the Florida Public Health

  Association former member of the Senate appointed by the President of the Senate.
- (c) Representatives of local health departments, with at least one representative from the southern, central, and northern areas of the state A former member of the House of Representatives appointed by the Speaker of the House of Representatives.
- (d) Representatives from institutions of higher learning A representative of the American Heart Association.
- (e) Representatives from the private health care, business, or foundation community A representative of the American Cancer Society, Florida Division, Inc.
- (f) A representative of the American Lung Association of Florida.
- (g) A representative of the American Diabetes Association, South Coastal Region.
  - (h) A representative of the Alzheimer's Association.
- (i) A representative of the Epilepsy Foundation. 622583

	Amendment No.
100	(j) A representative of the National Parkinson Foundation.
101	(k) A representative of the March of Dimes, Florida
102	<del>Chapter.</del>
103	(1) A representative of the Arthritis Foundation, Florida
104	<del>Chapter.</del>
105	(m) A representative of the American Liver Foundation.
106	(n) A representative of the Florida Council for Behavioral
107	Healthcare, Inc.
108	(o) A representative of the Florida Alcohol and Drug Abuse
109	Association.
110	(p) A representative of Pharmaceutical Research and
111	Manufacturers of America.
112	(q) A representative of the Florida Public Health
113	Association.
114	(r) A representative of the Florida Association of County
115	Health Officers.
116	(s) A public health academician selected by the State
117	Health Officer.
118	(t) A representative of the Florida Academy of Family
119	Physicians.
120	(u) Three consumers who have demonstrated an interest in
121	protecting the public health appointed by the Florida Public
122	Health Association.
123	(v) A representative of the Florida Association of Health
124	<del>Plans.</del>
125	(7) The majority of board members must be nonstate

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employees.

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(7) Members of the board of directors shall serve for 2 year terms and shall serve without compensation. Each organization represented on the board of directors shall cover the expenses of its representative.

(8) The corporation, in consultation with the Department of Health and the Florida Center for Universal Research to Eradicate Disease, shall facilitate communication between biomedical researchers and health care providers each month according to the health awareness schedule established by the Florida Public Health Foundation, Inc., in order to ensure ongoing dialogue between researchers, treatment providers, and the department.

(8) (9) The corporation and the Department of Health shall enter into partnerships with providers of continuing education for health care practitioners, including, but not limited to, hospitals and state and local medical organizations, to ensure that practitioners are aware of the most recent and complete diagnostic and treatment tools.

(9) (10) The corporation may provide personnel to the Department of Health for the purpose of performing duties and responsibilities outlined in private and public grants received by the Department of Health. These personnel are not state employees and are not entitled to retirement credit and other benefits provided to state employees under chapters 110 and 112. These personnel shall perform services under pursuant to an agreement between the corporation and the Department of Health.

(10) (11) The corporation may purchase goods, services, and property for use by the Department of Health. These purchases 622583

are not subject to the provisions of chapters 253, 255, and 287, nor to the control or direction of the Department of
Environmental Protection or the Department of Management
Services.

(11) (12) The corporation shall provide an annual report concerning its activities and finances to the Florida Center for Universal Research to Eradicate Disease and shall provide copies of the annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

Section 4. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read:

- 20.435 Department of Health; trust funds.--
- (1) The following trust funds are hereby created, to be administered by the Department of Health:
  - (h) Biomedical Research Trust Fund.
- 1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to s. 215.5601 and any other funds appropriated by the Legislature. Funds shall be used for the purposes of the James and Esther King Biomedical Research Program and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program as specified in ss. 215.5602, 288.955, and 381.922. The trust fund is exempt from the service charges imposed by s. 215.20.
- 2. Funds deposited into the trust fund pursuant to s.

  215.5601 and any other funds appropriated by the Legislature as specified in s. 215.5602(12)(a) for research related to tobaccorelated diseases shall be used exclusively for the purpose of awarding grants and fellowships for research regarding the 622583

- prevention, diagnosis, treatment, and cure of tobacco-related
  diseases by the James and Esther King Biomedical Research
  Program.
  - 3. Funds deposited into the trust fund pursuant to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program as specified in s. 381.922 shall be used for the purpose of awarding grants for cancer research by the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.
  - 4. All other funds deposited into the trust fund shall be used for the purpose of awarding grants and fellowships for biomedical research regarding the prevention, diagnosis, treatment, and cure of the most deadly and widespread nontobacco-related acute, chronic, and degenerative diseases by the James and Esther King Biomedical Research Program as specified in s. 215.5602(2)(b) and (12)(b).
  - 5.2. Notwithstanding the provisions of s. 216.301 and pursuant to s. 216.351, any balance in the trust fund at the end of any fiscal year shall remain in the trust fund at the end of the year and shall be available for carrying out the purposes of the trust fund. The department may invest these funds independently through the Chief Financial Officer or may negotiate a trust agreement with the State Board of Administration for the investment management of any balance in the trust fund.
  - $\underline{6.3.}$  Notwithstanding s. 216.301 and pursuant to s. 216.351, 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 may 622583

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- be carried forward for up to 5/2 years following the effective date of the original appropriation.
- Section 5. Paragraph (e) of subsection (5) of section 214 215.5601, Florida Statutes, is amended to read:
  - 215.5601 Lawton Chiles Endowment Fund.--
  - (5) AVAILABILITY OF FUNDS; USES.--
  - (e) Notwithstanding s. 216.301 and pursuant to s. 216.351, all unencumbered balances of appropriations from each department's respective Tobacco Settlement Trust Fund as of June 30 or undisbursed balances as of December 31 shall revert to the endowment's principal. Unencumbered balances in the Biomedical Research Trust Fund shall be managed as provided in s.
- 223 20.435(1)(h)5.<del>2.</del>
- Section 6. Section 215.5602, Florida Statutes, is amended to read:
  - 215.5602 James and Esther King Biomedical Research Program.--
- (1) There is established within the Department of Health
  the James and Esther King Biomedical Research Program funded by
  the proceeds of the Lawton Chiles Endowment Fund pursuant to s.
  231 215.5601. The purpose of the James and Esther King Biomedical
  Research Program is to provide an annual and perpetual source of
- funding in order to support research initiatives that address
- 234 the health care problems of Floridians in the areas of tobacco-
- related cancer, cardiovascular disease, stroke, and pulmonary
- 236 disease and nontobacco-related acute, chronic, and degenerative
- 237 diseases, including cancer, cardiovascular disease, stroke,
- 238 pulmonary disease, diabetes, autoimmune and genetic disorders, 622583

- and neurological disorders, including Alzheimer's disease,
  epilepsy, and Parkinson's disease. The long-term goals of the
  program are to:
- (a) Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for the most deadly and widespread acute, chronic, and degenerative diseases, including, but not limited to, tobacco-related diseases, cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.
- (b) Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of <a href="tobacco-">tobacco-</a> related diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.
- (c) Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of the most widespread acute, chronic, and degenerative diseases affecting Floridians, including, but not limited to, cancer, cardiovascular disease, stroke, pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.
- (d) Expand the foundation of biomedical knowledge relating to the deadly and most widespread acute, chronic, and degenerative diseases and identify biomedical solutions regarding health disparities that exist in relation to these diseases.

- (e) (c) 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.
- $\underline{\text{(f)}}$  (d) 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.
- (g) (e) Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.
- Biomedical Research Program pursuant to the Lawton Chiles
  Endowment Fund created in s. 215.5601 and additional funding
  provided under paragraph (12)(a) for research related to
  tobacco-related diseases shall be credited to the Biomedical
  Research Trust Fund pursuant to s. 20.435 and shall be used
  exclusively for the award of grants and fellowships related to
  the prevention, diagnosis, treatment, and cure of tobaccorelated diseases, including cancer, cardiovascular disease,
  stroke, and pulmonary disease and for expenses incurred in the
  administration of this section. Priority shall be granted to
  research designed to prevent or cure tobacco-related diseases.
- (b) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, all other funds appropriated for the James and Esther King Biomedical Research Program shall be credited to the Biomedical Research Trust Fund pursuant to s. 20.435 and shall be used exclusively for the award of grants and fellowships as 622583

established in this section; for research relating to the prevention, diagnosis, treatment, and cure of the most deadly and widespread acute, chronic, and degenerative nontobaccorelated diseases affecting Floridians related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease, and for expenses incurred in the administration of this section. Priority shall be granted to research designed to prevent or cure disease.

- (3) There is created within the Department of Health the Biomedical Research Commission Advisory Council.
- (a) The <u>commission</u> <u>council</u> shall consist of <u>15</u> <u>11</u> members, including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief executive officer of the <u>Greater Southeast Florida/Puerto Rico</u> Affiliate of the American Heart Association, or a designee; and the chief executive officer of the American Lung Association of Florida, or a designee; the chief executive officer of the South <u>Coastal Region of the American Diabetes Association</u>, or a <u>designee</u>; and the president of the Florida Medical Association, or a <u>designee</u>. The remaining <u>10</u> <del>8</del> members of the <u>commission</u> <u>council</u> shall be appointed as follows:
- 1. The Governor shall appoint four members, two members with expertise in the field of biomedical research, one member from a research university in the state, and one member representing the general population of the state.

- 2. The President of the Senate shall appoint three two members, one member with expertise in the field of behavioral or social research and two members representing volunteer health organizations operating in the state that focus on Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or autoimmune and genetic disorders one representative from a cancer program approved by the American College of Surgeons.
- 3. The Speaker of the House of Representatives shall appoint three two members, two members representing volunteer health organizations operating in the state that focus on Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or autoimmune and genetic disorders one member from a professional medical organization and one member representing representative from a cancer program approved by the American College of Surgeons.

- In making these appointments, the Governor, the President of the Senate, and the Speaker of the House of Representatives shall select primarily, but not exclusively, Floridians with biomedical and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease. The appointments shall be for a 3-year term and shall reflect the diversity of the state's population. An appointed member may not serve more than two consecutive terms.
- (b) Except for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program that expires June 30, 2011, 622583

pursuant to s. 381.922, beginning in fiscal year 2009-2010, and each fiscal year thereafter, funds appropriated for the James and Esther King Biomedical Research Program shall serve as the exclusive source of awarding grants or fellowships for biomedical research in the state using state funds. This paragraph does not preclude another grant or fellowship program created by state law from awarding grants from funds received from private or federal sources if permitted by state law.

- (c) The commission shall create committees to focus on disease-specific areas, including, but not limited to, tobaccorelated diseases, cancer, stroke, cardiovascular disease, pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.
- (d) (b) The commission council shall adopt internal organizational procedures as necessary for its efficient organization, including policies and procedures regarding the creation and composition of the committees, the submission of reports and recommendations by committees regarding the awarding of grants and fellowships, coordination between the commission and committees, and the methods for receiving input from individuals, organizations, or entities that are not members of the commission or its committees regarding the prioritization of research.
- (e) (c) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the commission council in carrying out its responsibilities, including those of its committees.

- <u>(f)(d)</u> Members of the <u>commission</u> <u>council</u> shall serve without compensation, but may receive reimbursement as provided in s. 112.061 for travel and other necessary expenses incurred in the performance of their official duties, including attending <u>committee meetings</u>.
- (4) The <u>commission</u> <u>council</u> shall, <u>after considering the</u> <u>recommendations of its committees</u>, advise the State Surgeon General as to the direction and scope of the biomedical research program. The responsibilities of the <u>commission</u> <u>council may</u> include, but are not limited to:
- (a) <u>Establishing</u> <del>Providing advice on</del> program priorities and emphases.
- (b) <u>Evaluating Providing advice on</u> the overall program budget <u>and making recommendations to the State Surgeon General</u> and the Legislature regarding future appropriations.
  - (c) Participating in periodic program evaluation.
- (d) <u>Developing</u> Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the program.
- (e) <u>Developing</u> Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials.
- (f) Developing criteria and standards for the award of research grants.
- (g) Developing administrative procedures relating to solicitation, independent peer review, and award of research

grants and fellowships, to ensure an impartial, high-quality, science-based peer review system.

- (h) Developing and supervising <del>research</del> peer review panels.
- (i) Reviewing reports of peer review panels and making recommendations for research grants and fellowships.
- (j) Developing and providing oversight regarding mechanisms for the dissemination of research results.
- (5)(a) Applications for biomedical research funding under the program may be submitted from any university or established research institute in the state. All qualified investigators in the state, regardless of institution affiliation, shall have equal access and opportunity to compete for the research funding.
- (b) <u>Beginning in fiscal year 2008-2009</u>, grants and fellowships shall be awarded by the State Surgeon General, after consultation with the <u>commission council</u>, on the basis of scientific merit, as determined by an open competitive peer review process that ensures objectivity, consistency, and high quality.
- (c) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, the State Surgeon General shall submit to the Legislature by February 1 priority lists for the funding of both tobacco-related and nontobacco-related biomedical research by the Legislature based on the recommendations made by the commission after peer review and scoring of the applications received. Recommendations to the Legislature shall be in the form of lists submitted by the State Surgeon General of the 622583

commission's rank order of priority from the proposal with the	
highest priority through the proposal with the lowest priority,	
including the recommended dollar amount and duration for each	
proposal. The State Surgeon General may not reject or modify the	
commission's recommendations. Successful applicants shall be	
awarded grants or fellowships by the State Surgeon General based	
upon the recommendations of the commission and the final funding	
decision made by the Legislature. Funding for grant and	
fellowship applications for tobacco-related research shall be	
based upon funds available pursuant to paragraphs (2)(a) and	
(12) (a) and s. 215.5601.	

- (d) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, the commission's overall ranking of grant and fellowship applications shall be based on the score awarded to the proposal by peer reviewers on the basis of scientific merit through an open competitive peer review process that ensures objectivity, consistency, and high quality and the commission's determination of the following:
- 1. The projected impact that the proposed research will have on the most deadly and widespread diseases affecting

  Floridians at the time the grant or fellowship is awarded;
- 2. The likelihood or possibility that the proposed research will result in new treatment modalities or technology during the term of the grant or fellowship; and
- 3. Whether the research proposed offers an efficient use of state funds in order to prevent or cure disease.
- (e) The following types of applications shall be considered for funding:

- 1. Investigator-initiated research grants.
- 2. Institutional research grants.
- 3. Predoctoral and postdoctoral research fellowships.
- (f) The State Surgeon General shall award grants or fellowships for terms of 1 to 5 years. State funds shall only be provided for research that was applied for, reviewed, and recommended in accordance with this section.
- (g) Except for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program that expires June 30, 2011, pursuant to s. 381.922, beginning July 1, 2009, and each fiscal year thereafter, any program, board, commission, council, advisory group, agency, or entity created by state law that awards or recommends the award of grants or fellowships for biomedical research may not award grants or fellowships that require the use of state funds and, instead, shall make any recommendation to the commission and its committees for the prioritization and award of grants and fellowships through the James and Esther King Biomedical Research Program.
- (6) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the State Surgeon General, in consultation with the <a href="commission">commission</a> council, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its scientific priority score. The priority scores shall be forwarded to the <a href="commission">commission</a> and its committees council and must be considered in determining which proposals shall be recommended for funding.

- review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest. A member of the commission, committee, council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee, or with which the member has entered into a contractual arrangement. Meetings of the commission, committees, council and the peer review panels shall be subject to the provisions of chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.
- (8) The department may contract on a competitive-bid basis with an appropriate entity to administer the program.

  Administrative expenses may not exceed 15 percent of the total funds available to the program in any given year. Effective July 1, 2009, administrative expenses may not exceed 10 percent of the total funds available to the program in any given year.

  Effective July 1, 2011, administrative expenses may not exceed 5 percent of the total funds available to the program in any given year.
- (9) The department, after consultation with the <u>commission</u> council, may adopt rules <u>pursuant to ss. 120.536(1) and 120.54</u> as necessary to implement this section.
- (10) <u>In addition to its recommendations regarding</u>

  <u>appropriations for the award of grants and fellowships to the</u>

  <u>State Surgeon General and the Legislature</u>, the <u>commission</u>

  <u>council</u> shall submit an annual progress report on the state of 622583

biomedical research in this state to the Florida Center for Universal Research to Eradicate Disease and to the Governor, the State Surgeon General, the President of the Senate, and the Speaker of the House of Representatives by February 1. The report must include:

- (a) A list of <u>current</u> research projects supported by grants or fellowships awarded under the program.
  - (b) A list of recipients of program grants or fellowships.
- (c) A list of publications in <u>peer-reviewed</u> <del>peer reviewed</del> journals involving research supported by grants or fellowships awarded under the program.
- (d) The total amount of biomedical research funding currently flowing into the state.
- (e) New grants for biomedical research which were funded based on research supported by grants or fellowships awarded under the program.
- (f) Progress in the prevention, diagnosis, treatment, and cure of the most deadly and widespread acute, chronic, and degenerative tobacco-related and nontobacco-related diseases affecting Floridians diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.
- (11) The <u>commission</u> <u>council</u> shall award grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created in s. 381.922. <u>This</u> subsection expires June 30, 2011.

- (12) (a) Beginning in fiscal year 2006-2007, the sum of \$6 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for purposes of the award of grants and fellowships by the James and Esther King Biomedical Research Program for research relating to tobacco-related diseases pursuant to this section. From these funds up to \$250,000 shall be available for the operating costs of the Florida Center for Universal Research to Eradicate Disease.
- (b) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, the Legislature may appropriate funds from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for purposes of the award of grants and fellowships by the James and Esther King Biomedical Research Program for research of the most deadly and widespread nontobacco-related acute, chronic, and degenerative diseases pursuant to this section. Any research grant or fellowship awarded for Alzheimer's research pursuant to this section shall be named a "Johnnie B. Byrd, Sr. Alzheimer's Grant." Any research grant or fellowship awarded for cancer research pursuant to this section shall be named a "Bankhead-Coley Cancer Grant."
- (13) This section does not apply to the 21st Century World Class Scholars, Centers of Excellence, or State University

  Research Commercialization Assistance Grant Programs established under s. 1004.226; to the University Major Gifts Program established under s. 1011.94; or to the use of general operating funds appropriated to universities.

(14) (13) By June 1, 2014 2009, the Division of Statutory Revision of the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of this section, which is scheduled to expire January 1, 2016 2011.

(15)(14) The Legislature shall review the performance, the outcomes, and the financial management of the James and Esther King Biomedical Research Program during the 2015 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.

 $\underline{\text{(16)}}$  (15) This section expires January 1,  $\underline{\text{2016}}$   $\underline{\text{2011}}$ , unless reviewed and reenacted by the Legislature before that date.

Section 7. Subsection (3) of section 381.79, Florida Statutes, is amended to read:

381.79 Brain and Spinal Cord Injury Program Trust Fund. --

(3) Annually, 5 percent of the revenues deposited monthly in the fund pursuant to s. 318.21(2)(d) shall be appropriated to the University of Florida and 5 percent to the University of Miami for spinal cord injury and brain injury research. The amount to be distributed to the universities shall be calculated based on the deposits into the fund for each quarter in the fiscal year, but may not exceed \$500,000 per university per year. Funds distributed under this subsection shall be made in quarterly payments at the end of each quarter during the fiscal year. This subsection expires June 30, 2009.

Section 8. Paragraph (h) is added to subsection (4) of section 381.853, Florida Statutes, to read:

381.853 Florida Center for Brain Tumor Research. --

- (4) The Florida Center for Brain Tumor Research is established within the Evelyn F. and William L. McKnight Brain Institute of the University of Florida.
- (h) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, if the center seeks to conduct biomedical research using state funds, the center shall apply for funding through the James and Esther King Biomedical Research Program pursuant to s. 215.5602.
- Section 9. Paragraph (a) of subsection (5) of section 381.855, Florida Statutes, is amended, and paragraphs (n), (o), (p), and (q) are added to subsection (3) of that section, to read:
- 381.855 Florida Center for Universal Research to Eradicate Disease.--
- (3) There is established within the Department of Health the Florida Center for Universal Research to Eradicate Disease, which shall be known as "CURED."
- (n) The center shall identify ways to attract new research talent and attendant national grant producing researchers to research facilities in this state.
- (o) If funds are specifically appropriated by the Legislature, the center shall disseminate information to Floridians and treatment providers about specified diseases and conditions and available methods of preventing, diagnosing, treating, and curing those diseases and conditions.
- (p) The center shall provide information regarding research needs in the state to the Biomedical Research 622583

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- 628 Commission located in the James and Esther King Biomedical 629 Research Program.
  - (q) The center shall identify ways to attract students from underserved communities for roles as health professionals and researchers.
  - (5) There is established within the center an advisory council that shall meet at least annually.
  - (a) The council shall consist of one representative from a Florida not-for-profit institution engaged in basic and clinical biomedical research and education which receives more than \$10 million in annual grant funding from the National Institutes of Health, to be appointed by the State Surgeon General from a different institution each term, and one representative from and appointed by each of the following entities:
    - 1. Enterprise Florida, Inc.
    - 2. BioFlorida.
    - 3. The Biomedical Research Commission Advisory Council.
    - 4. The Florida Medical Foundation.
    - 5. Pharmaceutical Research and Manufacturers of America.
    - 6. The Florida Cancer Council.
    - 6.7. The American Cancer Society, Florida Division, Inc.
    - 7.8. The American Heart Association.
- 650 8.9. The American Lung Association of Florida.
- 651 <u>9.10.</u> The American Diabetes Association, South Coastal Region.
- 653 10.<del>11.</del> The Alzheimer's Association.
- 654 11.<del>12.</del> The Epilepsy Foundation.
- 655 12.<del>13.</del> The National Parkinson Foundation.

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- 14. The Florida Public Health Foundation, Inc.
- 657 13.<del>15.</del> The Florida Research Consortium.
- Section 10. Subsections (2), (3), and (4) of section
- 381.911, Florida Statutes, are amended to read:
  - 381.911 Prostate Cancer Awareness Program. --
  - (2) For purposes of implementing the program, the Department of Health and the Florida Public Health Foundation, Inc., may:
  - (a) Conduct activities directly or enter into a contract with a qualified nonprofit community education entity.
  - (b) Seek any available gifts, grants, or funds from the state, the Federal Government, philanthropic foundations, and industry or business groups.
  - (3) A prostate cancer advisory committee is created to advise and assist the Department of Health and the Florida Public Health Foundation, Inc., in implementing the program.
  - (a) The State Surgeon General shall appoint the advisory committee members, who shall consist of:
  - 1. Three persons from prostate cancer survivor groups or cancer-related advocacy groups.
  - 2. Three persons who are scientists or clinicians from public universities or research organizations.
  - 3. Three persons who are engaged in the practice of a cancer-related medical specialty from health organizations committed to cancer research and control.
  - (b) Members shall serve without compensation but are entitled to reimbursement, pursuant to s. 112.061, for per diem

and travel expenses incurred in the performance of their official duties.

- (4) The program shall coordinate its efforts with those of the Florida Public Health Foundation, Inc.
- Section 11. Section 381.922, Florida Statutes, is amended to read:
- 381.922 William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program. --
- (1) The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, which may be otherwise cited as the "Bankhead-Coley Program," is created within the Department of Health. The purpose of the program shall be to advance progress towards cures for cancer through grants awarded through a peer-reviewed, competitive process.
- (2) The program shall provide grants for cancer research to further the search for cures for cancer.
- (a) Emphasis shall be given to the goals  $\underline{\text{that}}$  enumerated  $\underline{\text{in s. 381.921}}$ , as those goals support the advancement of such cures.
- (b) Preference may be given to grant proposals that foster collaborations among institutions, researchers, and community practitioners, as such proposals support the advancement of cures through basic or applied research, including clinical trials involving cancer patients and related networks.
- (3)(a) Applications for funding for cancer research may be submitted by any university or established research institute in the state. All qualified investigators in the state, regardless of institutional affiliation, shall have equal access and 622583

opportunity to compete for the research funding. Collaborative proposals, including those that advance the program's goals enumerated in subsection (2), may be given preference.

- (b) For fiscal year 2008-2009, grants shall be awarded by the State Surgeon General, after consultation with the Biomedical Research Commission Advisory Council, on the basis of scientific merit through, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality.
- year thereafter, the State Surgeon General shall submit to the Legislature by February 1 a priority list for cancer research funding by the Legislature based on the recommendations of the commission after peer review and scoring of the applications received. Recommendations to the Legislature shall be in the form of a list submitted by the State Surgeon General of the commission's rank order of priority from the proposal with the highest priority through the proposal with the lowest priority, including the recommended dollar amount and duration for each proposal. The State Surgeon General may not reject or modify the commission's recommendations. Successful applicants shall be awarded grants by the State Surgeon General based upon the recommendations of the commission and the final funding decision made by the Legislature.
- (d) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, the commission's overall ranking of grant applications shall be based on the score awarded to the proposal by peer reviewers on the basis of scientific merit through an 622583

- open competitive peer review process that ensures objectivity, consistency, and high quality and the commission's determination of the following:
- 1. The projected impact that the proposed research will have on cancer research at the time the grant is awarded;
- 2. The likelihood or possibility that the proposed research will result in new treatment modalities or technology during the term of the grant; and
- 3. Whether the research proposed offers an efficient use of state funds in order to prevent or cure cancer.
- (e) The following types of applications shall be considered for funding:
  - 1. Investigator-initiated research grants.
  - 2. Institutional research grants.
- 3. Collaborative research grants, including those that advance the finding of cures through basic or applied research.
- (f) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, state funds shall only be provided for research that was applied for, reviewed, and recommended in accordance with this section.
- (g) (b) In order to ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the State Surgeon General, in consultation with the commission council, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its priority score. The priority scores shall be forwarded to the

commission and its committees council and must be considered in determining which proposals shall be recommended for funding.

- (h)(c) The commission, the committees, council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest. A member of the commission, a committee, council or the panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement. Meetings of the commission, the committees, council and the peer review panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.
- (4) By December 15 of each year, the Department of Health shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report indicating progress towards the program's mission and making recommendations that further its purpose.
- (5) Beginning in fiscal year 2006-2007, the sum of \$9 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for purposes of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program and shall be distributed pursuant to this section to provide grants to researchers seeking cures for cancer, with emphasis given to the goals enumerated in s. 381.921. From the total

funds appropriated, an amount of up to 10 percent may be used for administrative expenses.

- (6) By June 1, 2009, the Division of Statutory Revision of the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of this section, which is scheduled to expire January 1, 2011.
- (7) The Legislature shall review the performance, the outcomes, and the financial management of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program during the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.
- (6) (8) This section expires <u>June 30</u> <del>January 1</del>, 2011, unless reviewed and reenacted by the Legislature before that date.
- Section 12. Subsection (1) and paragraph (a) of subsection (2) of section 458.324, Florida Statutes, are amended to read:

  458.324 Breast cancer; information on treatment alternatives.--
- (1) DEFINITION.--As used in this section, the term "medically viable," as applied to treatment alternatives, means modes of treatment generally considered by the medical profession to be within the scope of current, acceptable standards, including treatment alternatives described in the written summary prepared by the Florida Cancer Control and Research Advisory Council in accordance with s. 1004.435(4)(m).

- (2) COMMUNICATION OF TREATMENT ALTERNATIVES.--Each physician treating a patient who is, or in the judgment of the physician is at high risk of being, diagnosed as having breast cancer shall inform such patient of the medically viable treatment alternatives available to such patient; shall describe such treatment alternatives; and shall explain the relative advantages, disadvantages, and risks associated with the treatment alternatives to the extent deemed necessary to allow the patient to make a prudent decision regarding such treatment options. In compliance with this subsection:
  - (a) The physician may, in his or her discretion:
- 1. Orally communicate such information directly to the patient or the patient's legal representative;
- 2. Provide the patient or the patient's legal representative with a copy of <u>a</u> the written summary prepared in accordance with s. 1004.435(4) (m) and express a willingness to discuss the summary with the patient or the patient's legal representative; or
- 3. Both communicate such information directly and provide a copy of the written summary to the patient or the patient's legal representative for further consideration and possible later discussion.

Nothing in this subsection shall reduce other provisions of law regarding informed consent.

Section 13. Subsection (1) and paragraph (a) of subsection (2) of section 459.0125, Florida Statutes, are amended to read:

459.0125 Breast cancer; information on treatment alternatives.--

- (1) DEFINITION.--As used in this section, the term "medically viable," as applied to treatment alternatives, means modes of treatment generally considered by the medical profession to be within the scope of current, acceptable standards, including treatment alternatives described in the written summary prepared by the Florida Cancer Control and Research Advisory Council in accordance with s. 1004.435(4)(m).
- (2) COMMUNICATION OF TREATMENT ALTERNATIVES.--It is the obligation of every physician treating a patient who is, or in the judgment of the physician is at high risk of being, diagnosed as having breast cancer to inform such patient of the medically viable treatment alternatives available to such patient; to describe such treatment alternatives; and to explain the relative advantages, disadvantages, and risks associated with the treatment alternatives to the extent deemed necessary to allow the patient to make a prudent decision regarding such treatment options. In compliance with this subsection:
  - (a) The physician may, in her or his discretion:
- 1. Orally communicate such information directly to the patient or the patient's legal representative;
- 2. Provide the patient or the patient's legal representative with a copy of <u>a</u> the written summary prepared in accordance with s. 1004.435(4) (m) and express her or his willingness to discuss the summary with the patient or the patient's legal representative; or

3. Both communicate such information directly and provide a copy of the written summary to the patient or the patient's legal representative for further consideration and possible later discussion.

Nothing in this subsection shall reduce other provisions of law regarding informed consent.

Section 14. <u>Sections 381.0404, 381.85, 381.895, 381.912,</u> 381.92, 381.921, and 1004.435, Florida Statutes, are repealed.

Section 15. If any provision of this act or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are declared severable.

Section 16. This act shall take effect July 1, 2008.

TITLE AMENDMENT

Remove the entire title and insert:

A bill to be entitled

An act relating to public health; amending s. 381.006, F.S.;
limiting application of the environmental health program of the

Department of Health to state institutions for the mentally ill 622583

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rather than all institutions used for the incarceration of prisoners and inmates; amending s. 381.86, F.S.; revising responsibilities of the Institutional Review Board; amending s. 381.98, F.S.; changing the name of the Florida Public Health Foundation, Inc., to the Florida Public Health Institute, Inc.; providing that the purpose of the institute is to advance the knowledge and practice of public health, including promoting health awareness in this state; providing for the objectives of the institute; requiring that the institute be established as a not-for-profit entity qualifying under s. 501(c)(3) of the Internal Revenue Code; providing for the duties of the institute; providing that affairs of the institute be managed by an executive director appointed by a board of directors; providing for membership on the board of directors; requiring the institute to present an annual report concerning its activities and finances to the Governor, the President of the Senate, and the Speaker of the House of Representatives; amending s. 20.435, F.S.; specifying use of funds deposited in the Biomedical Research Trust Fund; revising a time limit relating to certain undisbursed balances of appropriations from the trust fund; amending s. 215.5601, F.S.; conforming a crossreference; amending s. 215.5602, F.S.; revising the purposes and long-term goals of the James and Esther King Biomedical Research Program; providing for certain funds appropriated for the program to be deposited into the Biomedical Research Trust Fund; specifying use of such funds; renaming the Biomedical Research Advisory Council the Biomedical Research Commission; revising membership of the commission; providing that the commission 622583

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serves as an exclusive source of biomedical research grant and fellowship awards; requiring the commission to create committees for specified purposes; requiring the commission to adopt policies and procedures regarding the committees and to receive input from outside sources; revising responsibilities of the commission; creating a future requirement for the commission to submit priorities for funding research relating to tobaccorelated and nontobacco-related diseases to the State Surgeon General; requiring the State Surgeon General to provide commission funding priorities to the Legislature; providing restrictions on the State Surgeon General; providing criteria for ranking priorities; authorizing the State Surgeon General to award grants or fellowships; providing for the award of grants or fellowships upon a specific appropriation; prohibiting the funding of research projects not in compliance with the requirements of the section; providing restrictions on the recommendation or award of grants or fellowships by other programs and entities; providing for future reductions of limits on annual administrative expenses; revising requirements relating to the commission's annual progress report; providing a future expiration date for the commission to award grants for the Bankhead-Coley Program; revising provisions relating to appropriations; providing for nonapplicability of James and Esther King Biomedical Research Program requirements to specified programs and the use of certain operating funds appropriated to universities; extending the expiration date of the program; amending s. 381.79, F.S.; providing for the expiration of a provision relating to the distribution of funds 622583

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from the Brain and Spinal Cord Injury Program Trust Fund; amending s. 381.853, F.S.; providing a requirement for the Florida Center for Brain Tumor Research relating to the use of state funds for biomedical research; amending s. 381.855, F.S.; providing additional program functions for the Florida Center for Universal Research to Eradicate Disease; requiring the center to disseminate certain information if an appropriation is made; requiring the center to identify ways to attract students from underserved communities for roles as health professionals and researchers; conforming references to changes made by the act; amending s. 381.911, F.S.; conforming references to changes made by the act; amending s. 381.922, F.S., relating to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; creating a future requirement for the commission to submit priorities for funding cancer research to the State Surgeon General; requiring the State Surgeon General to provide commission funding priorities to the Legislature; providing restrictions on the State Surgeon General; providing criteria for ranking priorities; authorizing the State Surgeon General to award grants; providing for the award of grants upon a specific appropriation; prohibiting the funding of research projects not in compliance with the requirements of the section; conforming references to changes made by the act; revising process and provisions relating to future peer review of grant applications to conform to the changes to the biomedical research program made by the act; deleting a provision requiring the Division of Statutory Revision within the Office of Legislative Services to certify certain language and citations related to the program; 622583

## HOUSE AMENDMENT Bill No. CS/SB 2618

Amendment No.

deleting a provision requiring future legislative review of the program; revising the expiration date of the program; amending ss. 458.324 and 459.0125, F.S.; conforming references to changes made by the act; repealing s. 381.0404, F.S., relating to the Center for Health Technologies; repealing s. 381.85, F.S., relating to biomedical and social research; repealing s. 381.895, F.S., relating to relating to standards for compressed air used for recreational diving; repealing s. 381.912, F.S., relating to the Cervical Cancer Elimination Task Force; repealing s. 381.92, F.S., relating to the Florida Cancer Council; repealing s. 381.921, F.S., relating to the Florida Cancer Council; repealing s. 1004.435, F.S., relating to cancer control and research; providing for severability; providing an effective date.