A bill to be entitled

An act relating to biomedical research; providing

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legislative intent; amending s. 20.435, F.S.; authorizing the use of funds in the Biomedical Research Trust Fund for the purposes of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; amending s. 215.5601, F.S.; providing for deposit of certain proceeds of the Lawton Chiles Endowment Fund into the Biomedical Research Trust Fund for purposes of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; amending s. 215.5602, F.S.; revising the membership and the method for appointing members to the Biomedical Research Advisory Council; requiring the council to award grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; providing for the repeal of the James and Esther King Biomedical Research Program; requiring the Legislature to review the program prior to the repeal; providing for transition to new appointments; amending s. 381.855, F.S.; revising the membership of the advisory council for the Florida Center for Universal Research to Eradicate Disease; providing for terms of office and the filling of vacancies; providing for officers, meetings, and procedures; providing for transition to new appointments; amending s. 381.921, F.S.; revising a goal of the Florida Cancer Council; creating s. 381.922, F.S.; establishing the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program

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within the Department of Health; providing the purpose of the program; requiring the program to provide grants for cancer research; providing procedures for awarding cancer research grants; providing for peer review panels; providing requirements with respect to ethical conduct and conflicts of interest; providing for public records and meetings; requiring an annual report; providing for the repeal of William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; requiring the Legislature to review the program prior to the repeal; amending s. 381.98, F.S., revising the purpose, duties, and authority of the Florida Public Health Foundation, Inc.; revising the membership of the board of directors of the corporation; amending s. 430.41, F.S., providing for the Governor to certify certain funds for a certain number of years; amending s. 561.121, F.S.; redistributing certain funds collected from taxes on alcoholic beverages; amending s. 1004.445, F.S.; requiring certain information in the annual report; requiring an annual operating budget; providing procedures for awarding of Alzheimer's disease research grants; providing for peer review panels; providing requirements with respect to ethical conduct and conflicts of interest; providing for public records and meetings; providing for the repeal of Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; requiring the Legislature to review the center and institute prior

to the repeal; providing appropriations; providing effective dates.

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Be It Enacted by the Legislature of the State of Florida:

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It is the intent of the Legislature to provide funding to support grants for biomedical research in this state with the anticipation that sustained funding for biomedical research over a period of years will lead to an alleviation of human suffering from diseases such as cancer and Alzheimer's disease. It is the intent of the Legislature to dramatically reduce this state's inordinately high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in this state, making this state a world-class leader in cancer research and treatment. Further, it is the intent of the Legislature to address the debilitating and deadly effects of Alzheimer's disease by supporting research in Alzheimer's disease statewide through the awarding of research grants on a competitive basis. Additionally, it is the intent of the Legislature to stimulate dramatic economic development, particularly in the biotechnology industry, through investment in this state's biomedical research.

- Section 2. 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:

Page 3 of 23

(h) Biomedical Research Trust Fund.

- 1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to s. 215.5601. 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, and 288.955, and 381.922. The trust fund is exempt from the service charges imposed by s. 215.20.
- 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.
- 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 be certified by the Governor for up to 3 years following the effective date of the original appropriation.
- 4. The trust fund shall, unless terminated sooner, be terminated on July 1, 2008.
- Section 3. Paragraph (a) of subsection (5) of section 215.5601, Florida Statutes, is amended to read:

215.5601 Lawton Chiles Endowment Fund. --

(5) AVAILABILITY OF FUNDS; USES. --

- (a) Funds from the endowment which are available for legislative appropriation shall be transferred by the board to the Department of Financial Services Tobacco Settlement Clearing Trust Fund, created in s. 17.41, and disbursed in accordance with the legislative appropriation.
- 1. Appropriations by the Legislature to the Department of Health from endowment earnings from the principal set aside for biomedical research shall be from a category called the James and Esther King Biomedical Research Program and a category called the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program and shall be deposited into the Biomedical Research Trust Fund in the Department of Health established in s. 20.435.
- 2. Appropriations by the Legislature to the Department of Children and Family Services, the Department of Health, or the Department of Elderly Affairs from endowment earnings for health and human services programs shall be deposited into each department's respective Tobacco Settlement Trust Fund as appropriated.
- Section 4. Subsection (3) of section 215.5602, Florida Statutes, is amended, and subsections (11) through (14) are added to that section, to read:
- 215.5602 James and Esther King Biomedical Research Program.--

(3) There is created within the Department of Health the Biomedical Research Advisory Council.

- (a) The council shall consist of 11 nine members, including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief executive officer of the Florida/Puerto Rico 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 Governor shall appoint the remaining eight six members of the council 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 two members, one member with expertise in the field of behavioral or social research and one representative from a cancer program approved by the American College of Surgeons.
- 3. The Speaker of the House of Representatives shall appoint two members, one member from a professional medical organization and one representative from a cancer program approved by the American College of Surgeons.
 - 4. One member from a research university in the state.
- 5. One member representing the general population of the state.

In making these his or her 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. The Governor's appointments shall be for a 3-year term and shall reflect the diversity of the state's population. An appointed A council member appointed by the Governor may not serve more than two consecutive terms.

- (b) The council shall adopt internal organizational procedures as necessary for its efficient organization.
- (c) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the council in carrying out its responsibilities.
- (d) Members of the council 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.
- (11) The council shall award grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created in s. 381.922.
- (12) 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.

(13) The Legislature shall review the performance, the outcomes, and the financial management of the James and Esther King Biomedical 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.

- (14) This section expires January 1, 2011, unless reviewed and reenacted by the Legislature before that date.
- Advisory Council for the James and Esther King Biomedical
 Research Program that were not made in accordance with s.

 215.5602, Florida Statutes, as amended by this act, shall expire
 June 30, 2006, but such appointees may continue to serve until
 their successors are appointed. This section shall take effect
 upon this act becoming a law.
- Section 6. Subsection (5) of section 381.855, Florida Statutes, is amended, and subsections (6) and (7) are added to that section, to read:
- 381.855 Florida Center for Universal Research to Eradicate Disease.--
 - (5) There is established within the center an advisory council that shall meet at least annually.
- (a) The council shall consist of <u>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 Secretary of Health from a</u>

Page 8 of 23

213	different institution each term, and the members of the board of
214	directors of the Florida Research Consortium and at least one
215	representative from and appointed by each of the following
216	<u>entities</u> :
217	1. The Emerging Technology Commission.
218	1.2. Enterprise Florida, Inc.
219	2.3. BioFlorida.
220	3.4. The Biomedical Research Advisory Council.
221	4.5. The Florida Medical Foundation.
222	5.6. Pharmaceutical Research and Manufacturers of America.
223	7. The Florida Tri Agency Coalition on Smoking OR Health.
224	<u>6.8.</u> The Florida Cancer Council.
225	7.9. The American Cancer Society, Florida Division, Inc.
226	8.10. The American Heart Association.
227	9.11. The American Lung Association of Florida.
228	10.12. The American Diabetes Association, South Coastal
229	Region.
230	11.13. The Alzheimer's Association.
231	12.14. The Epilepsy Foundation.
232	13.15. The National Parkinson Foundation.
233	14.16. The Florida Public Health Foundation, Inc.
234	15.17. The Florida Research Consortium Scripps Florida or
235	the entity formed in this state by The Scripps Research
236	Institute .
237	(b) Members of the council shall serve without
238	compensation, and each organization represented shall cover all

Page 9 of 23

expenses of its representative.

(6) Members shall be appointed to 4-year terms of office. The members of the advisory council shall annually elect a chair from among the members of the advisory council. Any vacancy on the advisory council shall be filled in the same manner as the original appointment.

(7) The advisory council shall meet at least annually, but may meet as often as it deems necessary to carry out its duties and responsibilities. The advisory council may take official action by a majority vote of the members present at any meeting at which a quorum is present.

Section 7. All appointments to the advisory council for the Florida Center for Universal Research to Eradicate Disease which were not made in accordance with s. 381.855, Florida Statutes, as amended by this act, shall expire June 30, 2006, but such appointees may continue to serve until their successors are appointed. This section shall take effect upon this act becoming a law.

Section 8. Subsection (1) of section 381.921, Florida Statutes, is amended to read:

381.921 Florida Cancer Council mission and duties.--The council, which shall work in concert with the Florida Center for Universal Research to Eradicate Disease to ensure that the goals of the center are advanced, shall endeavor to dramatically improve cancer research and treatment in this state through:

(1) Efforts to significantly expand cancer research capacity in the state by:

(a) Identifying ways to attract new research talent and attendant national grant-producing researchers to Florida based cancer research facilities in this state;

- (b) Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
- (c) Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
- (d) Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;
- (e) Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
- (f) Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research.
- Section 9. Section 381.922, Florida Statutes, is created 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 funded by the proceeds of the Lawton Chiles Endowment

Page 11 of 23

Fund pursuant to s. 215.5601. 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 enumerated 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 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. Grants shall be awarded by the Secretary of Health, after consultation with the Biomedical Research Advisory Council, on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:
 - 1. Investigator-initiated research grants.
 - 2. Institutional research grants.

Page 12 of 23

3. Collaborative research grants, including those that advance the finding of cures through basic or applied research.

- (b) In order to ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the Secretary of Health, in consultation with the 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 council and must be considered in determining which proposals shall be recommended for funding.
- (c) The 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 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 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) 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.

- (6) 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.
- (7) This section expires January 1, 2011, unless reviewed and reenacted by the Legislature before that date.

Section 10. Subsection (1) of section 381.98, Florida Statutes, is amended, paragraph (v) is added to subsection (6), present subsection (10) is renumbered as subsection (12), and new subsections (10) and (11) are added to that section, to read:

- 381.98 The Florida Public Health Foundation, Inc.; establishment; purpose; mission; duties; board of directors.--
- (1) The Florida Public Health Foundation, Inc., referred to in this section as "the corporation," is established for the purpose of disseminating breakthrough findings in biomedical research and promoting health awareness in this state <u>and</u> providing services to the Department of Health.

(6) The affairs of the corporation shall be managed by an executive director appointed by a board of directors consisting of:

- (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 pursuant to an agreement between the corporation and the Department of Health.
- (11) The corporation may purchase goods, services, and property for use by the Department of Health. These purchases 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.
- Section 11. Subsection (3) is added to section 430.41, Florida Statutes, to read:
 - 430.41 Grants and Donations Trust Fund. --
- (3) Notwithstanding s. 216.301 and pursuant to s. 216.351, any balance of any general revenue appropriation to the Grants and Donations Trust Fund that is not disbursed but that is obligated pursuant to contract or committed to be expended may

Page 15 of 23

be certified by the Governor for up to 3 years following the effective date of the original appropriation.

Section 12. Subsection (1) of section 561.121, Florida Statutes, is amended to read:

561.121 Deposit of revenue. --

- (1) All state funds collected pursuant to ss. 563.05, 564.06, and 565.12 shall be paid into the State Treasury and disbursed in the following manner:
- (a) 1. Two percent of monthly collections of the excise taxes on alcoholic beverages established in ss. 563.05, 564.06, and 565.12 shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund to meet the division's appropriation for the state fiscal year.
- 2. Beginning July 1, 2004, there is annually distributed \$15 million to the Grants and Donations Trust Fund within the Department of Elderly Affairs, and these funds are annually appropriated to support a contract with the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida for the purposes of conducting research, developing and operating integrated data projects, and providing assistance to memory disorder clinics as established in s. 430.502.
- 3. Beginning July 1, 2004, there is annually distributed \$6 million to the Biomedical Research Trust Fund within the Department of Health, and these funds are annually appropriated to the James and Esther King Biomedical Research Program. From these funds, up to \$250,000 shall be available annually for the

Page 16 of 23

operating costs of the Florida Center for Universal Research to Eradicate Disease.

- 4. Beginning July 1, 2004, there is annually distributed \$9 million to be paid by warrant drawn by the Chief Financial Officer upon the State Treasury to Florida State University for the School of Chiropractic Medicine. Notwithstanding the provisions of chapter 216, until the School of Chiropractic Medicine is completely staffed and fully operational, these funds may be used for any purpose by the university.
- (b) The remainder of the funds collected pursuant to ss. 563.05, 564.06, and 565.12 collection shall be credited to the General Revenue Fund.

Section 13. Subsection (6) of section 1004.445, Florida Statutes, is amended, present subsections (8), (9), and (10) are renumbered as subsections (9), (10), and (11), respectively, and new subsections (8), (12), (13), and (14) are added to that section, to read:

1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.--

- (6) The institute shall be administered by a chief executive officer, who shall be appointed by and serve at the pleasure of the board of directors of the not-for-profit corporation, and who shall exercise the following powers and duties, subject to the approval of the board of directors:
- (a) The chief executive officer shall establish programs that fulfill the mission of the institute in research, education, treatment, prevention, and early detection of

Alzheimer's disease; however, the chief executive officer may not establish academic programs for which academic credit is awarded and which culminate in the conferring of a degree, without prior approval of the State Board of Education.

- (b) The chief executive officer shall have control over the budget and the moneys appropriated or donated to the institute from private, local, state, and federal sources, as well as technical and professional income generated or derived from practice activities of the institute. However, professional income generated by university faculty from practice activities at the institute shall be shared between the institute and the university as determined by the chief executive officer and the appropriate university dean or vice president.
- (c) The chief executive officer shall appoint representatives of the institute to carry out the research, patient care, and educational activities of the institute and establish the compensation, benefits, and terms of service of such representatives. Representatives of the institute shall be eligible to hold concurrent appointments at affiliated academic institutions. University faculty shall be eligible to hold concurrent appointments at the institute.
- (d) The chief executive officer shall have control over the use and assignment of space and equipment within the facilities.
- (e) The chief executive officer shall have the power to create the administrative structure necessary to carry out the mission of the institute.

(f) The chief executive officer shall have a reporting relationship to the Commissioner of Education.

- (g) The chief executive officer shall provide a copy of the institute's annual report to the Governor and Cabinet, the President of the Senate, the Speaker of the House of Representatives, and the chair of the State Board of Education. The annual report shall describe the expenditure of all funds and shall provide information regarding research that has been conducted or funded by the center, as well as the expected and actual results of such research.
- (h) By August 1 of each year, the chief executive officer shall develop and submit to the Governor and Cabinet, the President of the Senate, the Speaker of the House of Representatives, and the chair of the State Board of Education an annual operating budget detailing the planned use of state, federal, and private funds for the fiscal year.
- (8) (a) Applications for Alzheimer's disease research funding may be submitted from any university or established research institute in the state. All qualified investigators in the state, regardless of institutional affiliation, shall have equal access and opportunity to compete for the research funding. Grants shall be awarded by the board of directors of the not-for-profit corporation on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality. 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.
- (b) Preference may be given to grant proposals that foster collaboration among institutions, researchers, and community practitioners because these proposals support the advancement of cures through basic or applied research, including clinical trials involving Alzheimer's patients and related networks.
- appropriate and are evaluated fairly on the basis of scientific merit, the board of directors of the not-for-profit corporation, in consultation with the council of scientific advisors, 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 council and must be considered by the board of directors of the not-for-profit corporation in determining which proposals shall be recommended for funding.
- (d) The council of scientific advisors and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest. All employees, members of the board of directors, and affiliates of the not-for-profit corporation shall follow the same rigorous guidelines for ethical conduct and shall adhere to the same strict policy with regard to conflict of interest. A member of the 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 council and the peer review panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

- (12) 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.
- (13) The Legislature shall review the performance, the outcomes, and the financial management of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute during the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the center and institute based on its review.
- (14) This section expires January 1, 2011, unless reviewed and reenacted by the Legislature before that date.
- Section 14. (1) The sum of \$6 million is appropriated from recurring general revenue funds to the Biomedical Research Trust Fund within the Department of Health for fiscal year 2006-2007 for purposes of the James and Esther King Biomedical Research Program pursuant to s. 215.5602, Florida Statutes. From these funds up to \$250,000 shall be available for the operating

costs of the Florida Center for Universal Research to Eradicate
Disease.

- (2) The sum of \$9 million is appropriated from recurring general revenue funds 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 for the 2006-2007 fiscal year, and shall be distributed pursuant to s. 381.922, Florida Statutes, to provide grants to researchers seeking cures for cancer, with emphasis given to the goals enumerated in s. 381.921, Florida Statutes. From the total funds appropriated, an amount of up to 10 percent may be used for administrative expenses.
- (3) The sum of \$15 million is appropriated from recurring general revenue funds to the Grants and Donations Trust Fund within the Department of Elderly Affairs for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida for fiscal year 2006-2007 for the purposes as provided under s. 1004.445(6)(a), Florida Statutes, conducting and supporting research, providing institutional research grants and investigator-initiated research grants, developing and operating integrated data projects, and providing assistance to statutorily designated memory disorder clinics as provided under s. 430.502, Florida Statutes. Not less than 80 percent of the appropriated funds shall be expended for these purposes and not less than 20 percent of the appropriated funds shall be expended for peer-reviewed investigator-initiated research grants.

Section 15. Except as otherwise expressly provided in this act and except for this section, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2006.

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Page 23 of 23