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1	A bill to be entitled
2	An act relating to biomedical research; amending s.
3	20.435, F.S.; specifying use of funds deposited in the
4	Biomedical Research Trust Fund; revising a time limit
5	relating to certain undisbursed balances of appropriations
6	from the trust fund; amending s. 215.5601, F.S.;
7	conforming a cross-reference; amending s. 215.5602, F.S.;
8	revising the purposes and long-term goals of the James and
9	Esther King Biomedical Research Program; providing for
10	certain funds appropriated for the program to be deposited
11	into the Biomedical Research Trust Fund; specifying use of
12	such funds; renaming the Biomedical Research Advisory
13	Council the Biomedical Research Commission; revising
14	membership of the commission; providing that the
15	commission serves as an exclusive source of biomedical
16	research grant and fellowship awards; requiring the
17	commission to create committees for specified purposes;
18	requiring the commission to adopt policies and procedures
19	regarding the committees and to receive input from outside
20	sources; revising responsibilities of the commission;
21	creating a future requirement for the commission to submit
22	priorities for funding research related to tobacco-related
23	and nontobacco-related diseases to the State Surgeon
24	General; requiring the State Surgeon General to provide
25	commission funding priorities to the Legislature;
26	providing restrictions on the State Surgeon General;
27	providing criteria for ranking priorities; authorizing the
28	State Surgeon General to award grants or fellowships;
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providing for the award of grants or fellowships upon a 29 30 specific appropriation; prohibiting the funding of research projects not in compliance with the requirements 31 of the section; providing restrictions on the 32 recommendation or award of grants or fellowships by other 33 programs and entities; providing for future reductions of 34 35 limits on annual administrative expenses; revising 36 requirements relating to the commission's annual progress 37 report; providing a future expiration date for the commission to award grants for the Bankhead-Coley Program; 38 revising provisions relating to appropriations; extending 39 the expiration date of the program; amending s. 381.79, 40 F.S.; providing for the expiration of a provision relating 41 to the distribution of funds from the Brain and Spinal 42 Cord Injury Program Trust Fund; amending s. 381.853, F.S.; 43 44 providing a requirement for the Florida Center for Brain Tumor Research relating to the use of state funds for 45 biomedical research; amending s. 381.855, F.S.; providing 46 additional program functions for the Florida Center for 47 48 Universal Research to Eradicate Disease; requiring the center to disseminate certain information if an 49 appropriation is made; conforming references to changes 50 made by the act; amending s. 381.911, F.S.; conforming 51 references to changes made by the act; amending s. 52 381.922, F.S., relating to the William G. "Bill" Bankhead, 53 54 Jr., and David Coley Cancer Research Program; creating a future requirement for the commission to submit priorities 55 for funding cancer research to the State Surgeon General; 56 Page 2 of 35

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57 requiring the State Surgeon General to provide commission 58 funding priorities to the Legislature; providing 59 restrictions on the State Surgeon General; providing criteria for ranking priorities; authorizing the State 60 Surgeon General to award grants; providing for the award 61 of grants upon a specific appropriation; prohibiting the 62 63 funding of research projects not in compliance with the requirements of the section; conforming references to 64 65 changes made by the act; revising process and provisions relating to future peer review of grant applications to 66 conform to the changes to the biomedical research program 67 made by the act; deleting a provision requiring the 68 Division of Statutory Revision within the Office of 69 Legislative Services to certify certain language and 70 citations related to the program; deleting a provision 71 72 requiring future legislative review of the program; revising the expiration date of the program; amending s. 73 430.502, F.S.; requiring the Department of Elderly 74 75 Affairs, in consultation with the Alzheimer's Disease Brain Bank, to evaluate the need for additional memory 76 disorder clinics in the state; conforming references to 77 changes made by the act; deleting obsolete language; 78 amending ss. 430.503, 430.504, 458.324, and 459.0125, 79 80 F.S.; conforming references to changes made by the act; amending s. 1004.445, F.S.; providing for the future 81 82 repeal of specified provisions to conform to changes made by the act; reducing appropriations for fiscal year 2008-83 2009; providing for and specifying use of future 84 Page 3 of 35

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85	appropriations; repealing s. 381.0404, F.S., relating to
86	the Center for Health Technologies; repealing s. 381.85,
87	F.S., relating to biomedical and social research;
88	repealing s. 381.912, F.S., relating to the Cervical
89	Cancer Elimination Task Force; repealing s. 381.92, F.S.,
90	relating to the Florida Cancer Council; repealing s.
91	381.921, F.S., relating to the Florida Cancer Council;
92	repealing s. 381.98, F.S., relating to the Florida Public
93	Health Foundation, Inc.; repealing s. 381.981, F.S.,
94	relating to health awareness campaigns; repealing s.
95	430.501, F.S., relating to the Alzheimer's Disease
96	Advisory Committee; repealing s. 1004.435, F.S., relating
97	to cancer control and research; providing for
98	severability; providing an effective date.
99	
100	Be It Enacted by the Legislature of the State of Florida:
101	
102	Section 1. Paragraph (h) of subsection (1) of section
103	20.435, Florida Statutes, is amended to read:
104	20.435 Department of Health; trust funds
105	(1) The following trust funds are hereby created, to be
106	administered by the Department of Health:
107	(h) Biomedical Research Trust Fund.
108	1. Funds to be credited to the trust fund shall consist of
109	funds deposited pursuant to s. 215.5601 and any other funds
110	appropriated by the Legislature. Funds shall be used for the
111	purposes of the James and Esther King Biomedical Research
112	Program and the William G. "Bill" Bankhead, Jr., and David Coley
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113 Cancer Research Program as specified in ss. 215.5602, 288.955, 114 and 381.922. The trust fund is exempt from the service charges 115 imposed by s. 215.20. 116 2. Funds deposited into the trust fund pursuant to s. 117 215.5601 and any other funds appropriated by the Legislature as specified in s. 215.5602(12)(a) or other provisions of law for 118 119 research related to tobacco-related diseases shall be used exclusively for the purpose of awarding grants and fellowships 120 121 for research regarding the prevention, diagnosis, treatment, and 122 cure of tobacco-related diseases by the James and Esther King 123 Biomedical Research Program. 3. Funds deposited into the trust fund pursuant to the 124 125 William G. "Bill" Bankhead, Jr., and David Coley Cancer Research 126 Program as specified in s. 381.922 shall be used for the purpose 127 of awarding grants for cancer research by the William G. "Bill" 128 Bankhead, Jr., and David Coley Cancer Research Program. 4. All other funds deposited into the trust fund shall be 129 130 used for the purpose of awarding grants and fellowships for 131 biomedical research regarding the prevention, diagnosis, 132 treatment, and cure of the most deadly and widespread 133 nontobacco-related acute, chronic, and degenerative diseases by 134 the James and Esther King Biomedical Research Program as 135 specified in s. 215.5602(2)(b) and (12)(b). 5.2. Notwithstanding the provisions of s. 216.301 and 136 pursuant to s. 216.351, any balance in the trust fund at the end 137 of any fiscal year shall remain in the trust fund at the end of 138 the year and shall be available for carrying out the purposes of 139 the trust fund. The department may invest these funds 140 Page 5 of 35

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141 independently through the Chief Financial Officer or may
142 negotiate a trust agreement with the State Board of
143 Administration for the investment management of any balance in
144 the trust fund.
145 <u>6.3.</u> Notwithstanding s. 216.301 and pursuant to s.

146 216.351, any balance of any appropriation from the Biomedical 147 Research Trust Fund which is not disbursed but which is 148 obligated pursuant to contract or committed to be expended may 149 be carried forward for up to $5 \rightarrow$ years following the effective 150 date of the original appropriation.

Section 2. Paragraph (e) of subsection (5) of section215.5601, Florida Statutes, is amended to read:

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154

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.

161 20.435(1)(h)<u>5.</u>2.

162 Section 3. Section 215.5602, Florida Statutes, is amended 163 to read:

164 215.5602 James and Esther King Biomedical Research165 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.
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169 215.5601. The purpose of the James and Esther King Biomedical 170 Research Program is to provide an annual and perpetual source of funding in order to support research initiatives that address 171 172 the health care problems of Floridians in the areas of tobacco-173 related cancer, cardiovascular disease, stroke, and pulmonary 174 disease and nontobacco-related acute, chronic, and degenerative diseases, including cancer, cardiovascular disease, stroke, 175 pulmonary disease, diabetes, autoimmune and genetic disorders, 176 and neurological disorders, including Alzheimer's disease, 177 epilepsy, and Parkinson's disease. The long-term goals of the 178 179 program are to: Improve the health of Floridians by researching better 180 (a) prevention, diagnoses, treatments, and cures for the most deadly 181 182 and widespread acute, chronic, and degenerative diseases, including, but not limited to, tobacco-related diseases, cancer, 183 184 cardiovascular disease, stroke, and pulmonary disease, diabetes, 185 autoimmune and genetic disorders, and neurological disorders, 186 including Alzheimer's disease, epilepsy, and Parkinson's 187 disease. Expand the foundation of biomedical knowledge relating 188 (b) 189 to the prevention, diagnosis, treatment, and cure of tobacco-190 related diseases related to tobacco use, including cancer, 191 cardiovascular disease, stroke, and pulmonary disease. (c) Expand the foundation of biomedical knowledge relating 192 to the prevention, diagnosis, treatment, and cure of the most 193 widespread acute, chronic, and degenerative diseases affecting 194 Floridians, including, but not limited to, cancer, 195 cardiovascular disease, stroke, pulmonary disease, diabetes, 196 Page 7 of 35

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197 <u>autoimmune and genetic disorders, and neurological disorders,</u> 198 <u>including Alzheimer's disease, epilepsy, and Parkinson's</u> 199 <u>disease.</u>

200 <u>(d) (c)</u> Improve the quality of the state's academic health 201 centers by bringing the advances of biomedical research into the 202 training of physicians and other health care providers.

203 <u>(e) (d)</u> Increase the state's per capita funding for 204 research by undertaking new initiatives in public health and 205 biomedical research that will attract additional funding from 206 outside the state.

207 <u>(f)(e)</u> Stimulate economic activity in the state in areas 208 related to biomedical research, such as the research and 209 production of pharmaceuticals, biotechnology, and medical 210 devices.

211 (2) (a) Funds appropriated for the James and Esther King 212 Biomedical Research Program pursuant to the Lawton Chiles 213 Endowment Fund created in s. 215.5601 and additional funding 214 provided under paragraph (12) (a) or other provisions of law for research related to tobacco-related diseases shall be credited 215 216 to the Biomedical Research Trust Fund pursuant to s. 20.435 and 217 shall be used exclusively for the award of grants and fellowships related to the prevention, diagnosis, treatment, and 218 219 cure of tobacco-related diseases, including cancer, cardiovascular disease, stroke, and pulmonary disease and for 220 expenses incurred in the administration of this section. 221 222 Priority shall be granted to research designed to prevent or 223 cure tobacco-related diseases.

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224 Beginning in fiscal year 2009-2010, and each fiscal (b) 225 year thereafter, all other funds appropriated for the James and 226 Esther King Biomedical Research Program shall be credited to the 227 Biomedical Research Trust Fund pursuant to s. 20.435 and shall 228 be used exclusively for the award of grants and fellowships as 229 established in this section; for research relating to the 230 prevention, diagnosis, treatment, and cure of the most deadly 231 and widespread acute, chronic, and degenerative nontobacco-232 related diseases affecting Floridians related to tobacco use, 233 including cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and 234 neurological disorders, including Alzheimer's disease, epilepsy, 235 236 and Parkinson's disease, + and for expenses incurred in the 237 administration of this section. Priority shall be granted to 238 research designed to prevent or cure disease.

(3) There is created within the Department of Health the
 Biomedical Research <u>Commission</u> Advisory Council.

241 The commission council shall consist of 15 11 members, (a) 242 including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief 243 244 executive officer of the Greater Southeast Florida/Puerto Rico 245 Affiliate of the American Heart Association, or a designee; and 246 the chief executive officer of the American Lung Association of Florida, or a designee; the chief executive officer of the South 247 Coastal Region of the American Diabetes Association, or a 248 designee; and the president of the Florida Medical Association, 249 or a designee. The remaining 10 & members of the commission 250 council shall be appointed as follows: 251

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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.

256 2. The President of the Senate shall appoint <u>three</u> two 257 members, one member with expertise in the field of behavioral or 258 social research and <u>two members representing volunteer health</u> 259 <u>organizations operating in the state that focus on Alzheimer's</u> 260 <u>disease, Parkinson's disease, epilepsy, stroke, or autoimmune</u> 261 <u>and genetic disorders</u> one representative from a cancer program 262 approved by the American College of Surgeons.

The Speaker of the House of Representatives shall 263 3. appoint three two members, two members representing volunteer 264 265 health organizations operating in the state that focus on Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or 266 267 autoimmune and genetic disorders one member from a professional medical organization and one member representing representative 268 269 from a cancer program approved by the American College of 270 Surgeons.

271 272 I

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

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280 reflect the diversity of the state's population. An appointed 281 member may not serve more than two consecutive terms.

Except for the William G. "Bill" Bankhead, Jr., and 282 (b) 283 David Coley Cancer Research Program that expires June 30, 2011, 284 pursuant to s. 381.922, beginning in fiscal year 2009-2010, and 285 each fiscal year thereafter, funds appropriated for the James 286 and Esther King Biomedical Research Program shall serve as the 287 exclusive source of awarding grants or fellowships for 288 biomedical research in the state using state funds. This 289 paragraph does not preclude another grant or fellowship program 290 created by state law from awarding grants from funds received 291 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, tobacco related diseases, cancer, stroke, cardiovascular disease,
 pulmonary disease, diabetes, autoimmune and genetic disorders,
 and neurological disorders, including Alzheimer's disease,
 epilepsy, and Parkinson's disease.

298 (d)(b) The commission council shall adopt internal 299 organizational procedures as necessary for its efficient 300 organization, including policies and procedures regarding the 301 creation and composition of the committees, the submission of 302 reports and recommendations by committees regarding the awarding of grants and fellowships, coordination between the commission 303 and committees, and the methods for receiving input from 304 individuals, organizations, or entities that are not members of 305 the commission or its committees regarding the prioritization of 306 307 research.

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308 (e) (c) The department shall provide such staff, 309 information, and other assistance as is reasonably necessary to assist the commission council in carrying out its 310 responsibilities, including those of its committees. 311 312 (f) (d) Members of the commission council shall serve 313 without compensation, but may receive reimbursement as provided 314 in s. 112.061 for travel and other necessary expenses incurred in the performance of their official duties, including attending 315 316 committee meetings. The commission council shall, after considering the 317 (4)recommendations of its committees, advise the State Surgeon 318 General as to the direction and scope of the biomedical research 319 program. The responsibilities of the commission council may 320 321 include, but are not limited to: 322 (a) Establishing Providing advice on program priorities 323 and emphases. 324 Evaluating Providing advice on the overall program (b) 325 budget and making recommendations to the State Surgeon General 326 and the Legislature regarding future appropriations. (C) 327 Participating in periodic program evaluation. 328 (d) Developing Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles 329 330 of merit and quality in the conduct of the program. (e) Developing Assisting in the development of appropriate 331 linkages to nonacademic entities, such as voluntary 332 organizations, health care delivery institutions, industry, 333 government agencies, and public officials. 334

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335 (f) Developing criteria and standards for the award of336 research grants.

(g) Developing administrative procedures relating to
solicitation, <u>independent peer</u> review, and award of research
grants and fellowships, to ensure an impartial, high-quality,
science-based peer review system.

341 (h) Developing and supervising research peer review342 panels.

343 (i) Reviewing reports of peer review panels and making344 recommendations for research grants and fellowships.

345 (j) Developing and providing oversight regarding346 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</u> council, on the basis of scientific merit, as determined by an open competitive peer review process that ensures objectivity, consistency, and high quality.

359 (c) Beginning in fiscal year 2009-2010, and each fiscal
 360 year thereafter, the State Surgeon General shall submit to the
 361 Legislature by February 1 priority lists for the funding of both
 362 tobacco-related and nontobacco-related biomedical research by

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363	the Legislature based on the recommendations made by the					
364	commission after peer review and scoring of the applications					
365	received. Recommendations to the Legislature shall be in the					
366	form of lists submitted by the State Surgeon General of the					
367	commission's rank order of priority from the proposal with the					
368	highest priority through the proposal with the lowest priority,					
369	including the recommended dollar amount and duration for each					
370	proposal. The State Surgeon General may not reject or modify the					
371	commission's recommendations. Successful applicants shall be					
372	awarded grants or fellowships by the State Surgeon General based					
373	upon the recommendations of the commission and the final funding					
374	decision made by the Legislature. Funding for grant and					
375	fellowship applications for tobacco-related research shall be					
376	based upon funds available pursuant to paragraphs (2)(a) and					
377	(12)(a) and s. 215.5601.					
378	(d) Beginning in fiscal year 2009-2010, and each fiscal					
379	year thereafter, the commission's overall ranking of grant and					
380	fellowship applications shall be based on the score awarded to					
381	the proposal by peer reviewers on the basis of scientific merit					
382	through an open competitive peer review process that ensures					
383	objectivity, consistency, and high quality and the commission's					
384	determination of the following:					
385	1. The projected impact that the proposed research will					
386	have on the most deadly and widespread diseases affecting					
387	Floridians at the time the grant or fellowship is awarded;					
388	2. The likelihood or possibility that the proposed					
389	research will result in new treatment modalities or technology					
390	during the term of the grant or fellowship; and					
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391 Whether the research proposed offers an efficient use 3. 392 of state funds in order to prevent or cure disease. The following types of applications shall be 393 (e) considered for funding: 394 395 1. Investigator-initiated research grants. 396 2. Institutional research grants. 397 3. Predoctoral and postdoctoral research fellowships. (f) The State Surgeon General shall award grants or 398 fellowships for terms of 1 to 5 years. State funds shall only be 399 400 provided for research that was applied for, reviewed, and 401 recommended in accordance with this section. 402 Except for the William G. "Bill" Bankhead, Jr., and (q) David Coley Cancer Research Program that expires June 30, 2011, 403 404 pursuant to s. 381.922, beginning July 1, 2009, and each fiscal year thereafter, any program, board, commission, council, 405 advisory group, agency, or entity created by state law that 406 awards or recommends the award of grants or fellowships for 407 408 biomedical research may not award grants or fellowships that 409 require the use of state funds and, instead, shall make any recommendation to the commission and its committees for the 410 411 prioritization and award of grants and fellowships through the 412 James and Esther King Biomedical Research Program. This section 413 does not apply to the 21st Century World Class Scholars, Centers 414 of Excellence, or State University Research Commercialization Assistance Grant Programs established under s. 1004.226. 415 To ensure that all proposals for research funding are 416 (6) appropriate and are evaluated fairly on the basis of scientific 417 merit, the State Surgeon General, in consultation with the 418 Page 15 of 35

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419 <u>commission</u> council, shall appoint a peer review panel of 420 independent, scientifically qualified individuals to review the 421 scientific content of each proposal and establish its scientific 422 priority score. The priority scores shall be forwarded to the 423 <u>commission and its committees</u> council and must be considered in 424 determining which proposals shall be recommended for funding.

425 (7) The commission, the committees, council and the peer review panel shall establish and follow rigorous guidelines for 426 427 ethical conduct and adhere to a strict policy with regard to conflict of interest. A member of the commission, committee, 428 429 council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, 430 entity, or agency with which the member is associated as a 431 432 member of the governing body or as an employee, or with which 433 the member has entered into a contractual arrangement. Meetings 434 of the commission, committees, council and the peer review panels shall be subject to the provisions of chapter 119, s. 435 436 286.011, and s. 24, Art. I of the State Constitution.

437 (8) The department may contract on a competitive-bid basis with an appropriate entity to administer the program. 438 439 Administrative expenses may not exceed 15 percent of the total 440 funds available to the program in any given year. Effective July 1, 2009, administrative expenses may not exceed 10 percent of 441 the total funds available to the program in any given year. 442 Effective July 1, 2011, administrative expenses may not exceed 5 443 444 percent of the total funds available to the program in any given 445 year.

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(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.

449 In addition to its recommendations regarding (10)appropriations for the award of grants and fellowships to the 450 451 State Surgeon General and the Legislature, the commission 452 council shall submit an annual progress report on the state of 453 biomedical research in this state to the Florida Center for 454 Universal Research to Eradicate Disease and to the Governor, the 455 State Surgeon General, the President of the Senate, and the Speaker of the House of Representatives by February 1. The 456 457 report must include:

(a) A list of <u>current</u> research projects supported by
grants or fellowships awarded under the program.

460

(b) A list of recipients of program grants or fellowships.

461

(c) A list of publications in <u>peer-reviewed</u> peer reviewed

462 journals involving research supported by grants or fellowships463 awarded under the program.

(d) The total amount of biomedical research fundingcurrently 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 diseases affecting Floridians
diseases related to tobacco use, including cancer,

473 cardiovascular disease, stroke, and pulmonary disease<u>, diabetes</u>, Page 17 of 35

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474 <u>autoimmune and genetic disorders, and neurological disorders,</u> 475 <u>including Alzheimer's disease, epilepsy, and Parkinson's</u> 476 <u>disease</u>.

(11) The <u>commission</u> 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. <u>This</u>
subsection expires June 30, 2011.

Beginning in fiscal year 2006-2007, the sum of \$6 481 (12) (a) million is appropriated annually from recurring funds in the 482 General Revenue Fund to the Biomedical Research Trust Fund 483 484 within the Department of Health for purposes of the award of grants and fellowships by the James and Esther King Biomedical 485 Research Program for research relating to tobacco-related 486 487 diseases pursuant to this section. From these funds up to 488 \$250,000 shall be available for the operating costs of the 489 Florida Center for Universal Research to Eradicate Disease.

490 Beginning in fiscal year 2009-2010, and each fiscal (b) 491 year thereafter, the Legislature may appropriate funds from 492 recurring funds in the General Revenue Fund to the Biomedical 493 Research Trust Fund within the Department of Health for purposes 494 of the award of grants and fellowships by the James and Esther 495 King Biomedical Research Program for research of the most deadly and widespread nontobacco-related acute, chronic, and 496 497 degenerative diseases pursuant to this section. Any research grant or fellowship awarded for Alzheimer's research pursuant to 498 this section shall be named a "Johnnie B. Byrd, Sr. Alzheimer's 499 Grant." Any research grant or fellowship awarded for cancer 500

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501 <u>research pursuant to this section shall be named a "Bankhead-</u> 502 Coley Cancer Grant."

503 (13) By June 1, <u>2014</u> 2009, the Division of Statutory
504 Revision of the Office of Legislative Services shall certify to
505 the President of the Senate and the Speaker of the House of
506 Representatives the language and statutory citation of this
507 section, which is scheduled to expire January 1, <u>2016</u> 2011.

(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.

(15) This section expires January 1, 2016 2011, unless
reviewed and reenacted by the Legislature before that date.
Section 4. Subsection (3) of section 381.79, Florida
Statutes, is amended to read:

518 381.79 Brain and Spinal Cord Injury Program Trust Fund.--519 (3) Annually, 5 percent of the revenues deposited monthly in the fund pursuant to s. 318.21(2)(d) shall be appropriated to 520 521 the University of Florida and 5 percent to the University of Miami for spinal cord injury and brain injury research. The 522 523 amount to be distributed to the universities shall be calculated based on the deposits into the fund for each quarter in the 524 fiscal year, but may not exceed \$500,000 per university per 525 year. Funds distributed under this subsection shall be made in 526 quarterly payments at the end of each quarter during the fiscal 527 year. This subsection expires June 30, 2009. 528

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529 Section 5. Paragraph (h) is added to subsection (4) of section 381.853, Florida Statutes, to read: 530 381.853 Florida Center for Brain Tumor Research.--531 The Florida Center for Brain Tumor Research is 532 (4) 533 established within the Evelyn F. and William L. McKnight Brain 534 Institute of the University of Florida. 535 (h) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, if the center seeks to conduct biomedical 536 research using state funds, the center shall apply for funding 537 538 through the James and Esther King Biomedical Research Program pursuant to s. 215.5602. 539 540 Section 6. Paragraph (a) of subsection (5) of section 381.855, Florida Statutes, is amended, and paragraphs (n), (o), 541 542 and (p) are added to subsection (3) of that section, to read: 381.855 Florida Center for Universal Research to Eradicate 543 544 Disease.--545 There is established within the Department of Health (3) 546 the Florida Center for Universal Research to Eradicate Disease, which shall be known as "CURED." 547 The center shall identify ways to attract new research 548 (n) 549 talent and attendant national grant producing researchers to 550 research facilities in this state. 551 If funds are specifically appropriated by the (0) Legislature, the center shall disseminate information to 552 Floridians and treatment providers about specified diseases and 553 conditions and available methods of preventing, diagnosing, 554 treating, and curing those diseases and conditions. 555

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556 The center shall provide information regarding (p) 557 research needs in the state to the Biomedical Research 558 Commission located in the James and Esther King Biomedical 559 Research Program. 560 There is established within the center an advisory (5)561 council that shall meet at least annually. 562 (a) The council shall consist of one representative from a 563 Florida not-for-profit institution engaged in basic and clinical biomedical research and education which receives more than \$10 564 million in annual grant funding from the National Institutes of 565 566 Health, to be appointed by the State Surgeon General from a 567 different institution each term, and one representative from and appointed by each of the following entities: 568 569 1. Enterprise Florida, Inc. 2. BioFlorida. 570 571 3. The Biomedical Research Commission Advisory Council. The Florida Medical Foundation. 572 4. Pharmaceutical Research and Manufacturers of America. 573 5. 574 6. The Florida Cancer Council. 6.7. The American Cancer Society, Florida Division, Inc. 575 576 7.8. The American Heart Association. 8.9. 577 The American Lung Association of Florida. 578 9.10. The American Diabetes Association, South Coastal 579 Region. 10.11. The Alzheimer's Association. 580 581 11.12. The Epilepsy Foundation. 12.13. The National Parkinson Foundation. 582 The Florida Public Health Foundation, Inc. 583 Page 21 of 35

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584 13.15. The Florida Research Consortium. 585 Section 7. Subsections (2), (3), and (4) of section 381.911, Florida Statutes, are amended to read: 586 587 381.911 Prostate Cancer Awareness Program.--588 For purposes of implementing the program, the (2)589 Department of Health and the Florida Public Health Foundation, 590 Inc., may: Conduct activities directly or enter into a contract 591 (a) 592 with a qualified nonprofit community education entity. Seek any available gifts, grants, or funds from the 593 (b) state, the Federal Government, philanthropic foundations, and 594 595 industry or business groups. A prostate cancer advisory committee is created to 596 (3) 597 advise and assist the Department of Health and the Florida 598 Public Health Foundation, Inc., in implementing the program. 599 (a) The State Surgeon General shall appoint the advisory 600 committee members, who shall consist of: 601 Three persons from prostate cancer survivor groups or 1. 602 cancer-related advocacy groups. Three persons who are scientists or clinicians from 603 2. 604 public universities or research organizations. 605 Three persons who are engaged in the practice of a 3. 606 cancer-related medical specialty from health organizations committed to cancer research and control. 607 Members shall serve without compensation but are 608 (b) entitled to reimbursement, pursuant to s. 112.061, for per diem 609 and travel expenses incurred in the performance of their 610 official duties. 611 Page 22 of 35

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612 (4) The program shall coordinate its efforts with those of
 613 the Florida Public Health Foundation, Inc.

614 Section 8. Section 381.922, Florida Statutes, is amended 615 to read:

616 381.922 William G. "Bill" Bankhead, Jr., and David Coley617 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 peerreviewed, competitive process.

(2) The program shall provide grants for cancer researchto further the search for cures for cancer.

(a) Emphasis shall be given to the goals <u>that</u> 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

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639 proposals, including those that advance the program's goals 640 enumerated in subsection (2), may be given preference. For fiscal year 2008-2009, grants shall be awarded by 641 (b) 642 the State Surgeon General, after consultation with the 643 Biomedical Research Commission Advisory Council, on the basis of 644 scientific merit through, as determined by an open, competitive 645 peer review process that ensures objectivity, consistency, and high quality. 646 647 (c) Beginning in fiscal year 2009-2010, and each fiscal 648 year thereafter, the State Surgeon General shall submit to the 649 Legislature by February 1 a priority list for cancer research 650 funding by the Legislature based on the recommendations of the 651 commission after peer review and scoring of the applications 652 received. Recommendations to the Legislature shall be in the form of a list submitted by the State Surgeon General of the 653 654 commission's rank order of priority from the proposal with the 655 highest priority through the proposal with the lowest priority, 656 including the recommended dollar amount and duration for each 657 proposal. The State Surgeon General may not reject or modify the commission's recommendations. Successful applicants shall be 658 659 awarded grants by the State Surgeon General based upon the 660 recommendations of the commission and the final funding decision 661 made by the Legislature. (d) Beginning in fiscal year 2009-2010, and each fiscal 662 year thereafter, the commission's overall ranking of grant 663 664 applications shall be based on the score awarded to the proposal by peer reviewers on the basis of scientific merit through an 665 666 open competitive peer review process that ensures objectivity,

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667 consistency, and high quality and the commission's determination 668 of the following: 669 The projected impact that the proposed research will 1. 670 have on cancer research at the time the grant is awarded; 671 The likelihood or possibility that the proposed 2. 672 research will result in new treatment modalities or technology 673 during the term of the grant; and 674 3. Whether the research proposed offers an efficient use 675 of state funds in order to prevent or cure cancer. The following types of applications shall be 676 (e) considered for funding: 677 678 Investigator-initiated research grants. 1. Institutional research grants. 679 2. 680 3. Collaborative research grants, including those that advance the finding of cures through basic or applied research. 681 682 (f) Beginning in fiscal year 2009-2010, and each fiscal 683 year thereafter, state funds shall only be provided for research 684 that was applied for, reviewed, and recommended in accordance 685 with this section. 686 (q) (b) In order to ensure that all proposals for research 687 funding are appropriate and are evaluated fairly on the basis of scientific merit, the State Surgeon General, in consultation 688 689 with the commission council, shall appoint a peer review panel 690 of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its 691 priority score. The priority scores shall be forwarded to the 692 commission and its committees council and must be considered in 693 694 determining which proposals shall be recommended for funding. Page 25 of 35

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695 (h) (c) The commission, the committees, council and the 696 peer review panel shall establish and follow rigorous guidelines 697 for ethical conduct and adhere to a strict policy with regard to conflicts of interest. A member of the commission, a committee, 698 699 council or the panel may not participate in any discussion or 700 decision with respect to a research proposal by any firm, 701 entity, or agency with which the member is associated as a 702 member of the governing body or as an employee or with which the 703 member has entered into a contractual arrangement. Meetings of the commission, the committees, council and the peer review 704 705 panels are subject to chapter 119, s. 286.011, and s. 24, Art. I 706 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.

Beginning in fiscal year 2006-2007, the sum of \$9 712 (5) 713 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund 714 715 within the Department of Health for purposes of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program 716 717 and shall be distributed pursuant to this section to provide grants to researchers seeking cures for cancer, with emphasis 718 given to the goals enumerated in s. 381.921. From the total 719 funds appropriated, an amount of up to 10 percent may be used 720 721 for administrative expenses.

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722 (6) By June 1, 2009, the Division of Statutory Revision of 723 the Office of Legislative Services shall certify to the 724 President of the Senate and the Speaker of the House of 725 Representatives the language and statutory citation of this 726 section, which is scheduled to expire January 1, 2011. 727 (7) The Legislature shall review the performance, the 728 outcomes, and the financial management of the William G. "Bill" 729 Bankhead, Jr., and David Coley Cancer Research Program during 730 the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the 731 732 program based on its review. 733 (6) (8) This section expires June 30 January 1, 2011, unless reviewed and reenacted by the Legislature before that 734 735 date. Section 9. Subsection (3) of section 430.502, Florida 736 737 Statutes, is amended to read: 738 430.502 Alzheimer's disease; memory disorder clinics and 739 day care and respite care programs. --740 (3) The Department of Elderly Affairs shall consult with 741 the Alzheimer's Disease Brain Bank and model day care programs 742 to Alzheimer's Disease Advisory Committee must evaluate the need 743 for additional memory disorder clinics in the state. The first 744 report will be due by December 31, 1995. 745 Section 10. Section 430.503, Florida Statutes, is amended to read: 746 430.503 Alzheimer's Disease Initiative; fees and 747 748 administrative expense. --

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749 (1) Sections <u>430.502-430.504</u> <u>430.501 430.504</u> may be cited 750 as the "Alzheimer's Disease Initiative."

Provider agencies are responsible for the collection 751 (2)752 of fees for services in accordance with rules adopted by the 753 department. Provider agencies shall assess fees for services 754 rendered in accordance with those rules. To help pay for 755 services received pursuant to the Alzheimer's Disease 756 Initiative, a functionally impaired elderly person shall be 757 assessed a fee based on an overall ability to pay. The fee to be assessed shall be fixed according to a schedule to be 758 759 established by the department. Services of specified value may 760 be accepted in lieu of a fee. The fee schedule shall be developed in cooperation with the Alzheimer's Disease Advisory 761 762 Committee, area agencies on aging, and service providers.

763 Section 11. Section 430.504, Florida Statutes, is amended764 to read:

765 430.504 Confidentiality of information.--Information about 766 clients of programs created or funded under s. 430.501 or s. 767 430.503 which is received through files, reports, inspections, 768 or otherwise, by the department or by authorized departmental 769 employees, by persons who volunteer services, or by persons who 770 provide services to clients of programs created or funded under 771 s. 430.501 or s. 430.503 through contracts with the department 772 is confidential and exempt from the provisions of s. 119.07(1). Such information may not be disclosed publicly in such a manner 773 as to identify a person who receives services under s. 430.501 774 or s. 430.503, unless that person or that person's legal 775 776 quardian provides written consent.

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777 Section 12. Subsection (1) and paragraph (a) of subsection778 (2) of section 458.324, Florida Statutes, are amended to read:

458.324 Breast cancer; information on treatmentalternatives.--

(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).

788 (2) COMMUNICATION OF TREATMENT ALTERNATIVES. -- Each physician treating a patient who is, or in the judgment of the 789 790 physician is at high risk of being, diagnosed as having breast cancer shall inform such patient of the medically viable 791 792 treatment alternatives available to such patient; shall describe 793 such treatment alternatives; and shall explain the relative 794 advantages, disadvantages, and risks associated with the 795 treatment alternatives to the extent deemed necessary to allow 796 the patient to make a prudent decision regarding such treatment 797 options. In compliance with this subsection:

798

(a) The physician may, in his or her discretion:

799 1. Orally communicate such information directly to the800 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

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804 discuss the summary with the patient or the patient's legal 805 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.

810

811 Nothing in this subsection shall reduce other provisions of law812 regarding informed consent.

813Section 13.Subsection (1) and paragraph (a) of subsection814(2) of section 459.0125, Florida Statutes, are amended to read:

815 459.0125 Breast cancer; information on treatment
816 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).

COMMUNICATION OF TREATMENT ALTERNATIVES.--It is the 824 (2)825 obligation of every physician treating a patient who is, or in the judgment of the physician is at high risk of being, 826 827 diagnosed as having breast cancer to inform such patient of the medically viable treatment alternatives available to such 828 829 patient; to describe such treatment alternatives; and to explain the relative advantages, disadvantages, and risks associated 830 with the treatment alternatives to the extent deemed necessary 831 Page 30 of 35

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to allow the patient to make a prudent decision regarding suchtreatment options. In compliance with this subsection:

834

(a) The physician may, in her or his discretion:

835 1. Orally communicate such information directly to the836 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.

846

847 Nothing in this subsection shall reduce other provisions of law848 regarding informed consent.

Section 14. Subsections (7), (8), and (12) of section
1004.445, Florida Statutes, as amended by chapter 2007-332, Laws
of Florida, are amended to read:

852 1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and
853 Research Institute.--

(7) The board of directors of the not-for-profit
corporation shall create a council of scientific advisers to the
chief executive officer comprised of leading researchers,
physicians, and scientists. The council shall review programs
and recommend research priorities and initiatives to maximize
the state's investment in the institute. The members of the
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860 council shall be appointed by the board of directors of the not-861 for-profit corporation. Each member of the council shall be 862 appointed to serve a 2-year term and may be reappointed to the 863 council. This subsection expires on June 30, 2009.

864 (8)(a) Applications for Alzheimer's disease research 865 funding may be submitted from any university or established 866 research institute in the state. All qualified investigators in 867 the state, regardless of institutional affiliation, shall have 868 equal access and opportunity to compete for the research funding. Grants shall be awarded by the board of directors of 869 870 the not-for-profit corporation on the basis of scientific merit, as determined by an open, competitive peer review process that 871 ensures objectivity, consistency, and high quality. The 872 873 following types of applications shall be considered for funding:

874

875

2.

1. Investigator-initiated research grants.

Institutional research grants.

876 3. Collaborative research grants, including those that877 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.

(c) To ensure that all proposals for research funding are 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

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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.

894 (d) The council of scientific advisors and the peer review panel shall establish and follow rigorous guidelines for ethical 895 896 conduct and adhere to a strict policy with regard to conflict of 897 interest. All employees, members of the board of directors, and 898 affiliates of the not-for-profit corporation shall follow the 899 same rigorous quidelines for ethical conduct and shall adhere to the same strict policy with regard to conflict of interest. A 900 901 member of the council or panel may not participate in any 902 discussion or decision with respect to a research proposal by 903 any firm, entity, or agency with which the member is associated 904 as a member of the governing body or as an employee or with 905 which the member has entered into a contractual arrangement. 906 Meetings of the council and the peer review panels are subject 907 to chapter 119, s. 286.011, and s. 24, Art. I of the State 908 Constitution.

909

(e) This subsection expires on June 30, 2009.

910 (12) (a) Beginning in fiscal year 2008-2009 2007 2008, the 911 sum of \$5 \$13.5 million is appropriated annually from recurring 912 funds in the General Revenue Fund to the Grants and Donations 913 Trust Fund within the Department of Elderly Affairs for the 914 Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute 915 at the University of South Florida for the purposes as provided Page 33 of 35

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916 under paragraph (6) (a), conducting and supporting research, 917 providing institutional research grants and investigator-918 initiated research grants, developing and operating integrated data projects, and providing assistance to statutorily 919 920 designated memory disorder clinics as provided under s. 430.502. 921 Not less than 80 percent of the appropriated funds shall be 922 expended for these purposes, and not less than 20 percent of the appropriated funds shall be expended for peer-reviewed 923 924 investigator-initiated research grants.

Beginning in fiscal year 2009-2010, and each fiscal 925 (b) 926 year thereafter, the sum appropriated in paragraph (a) shall be 927 used for programs that fulfill the mission of the institute in education, treatment, prevention, and early detection of 928 929 Alzheimer's disease, developing and operating integrated data 930 projects, and providing assistance to statutorily designated 931 memory disorder clinics. If the institute intends to conduct 932 research using state funds, it shall compete for funding through 933 the James and Esther King Biomedical Research Program pursuant 934 to s. 215.5602.

 935
 Section 15.
 Sections 381.0404, 381.85, 381.912, 381.92,

 936
 381.921, 381.98, 381.981, 430.501, and 1004.435, Florida

937 <u>Statutes, are repealed.</u>

938Section 16. If any provision of this act or the939application thereof to any person or circumstance is held

940 invalid, the invalidity does not affect other provisions or

941 applications of the act which can be given effect without the

942 invalid provision or application, and to this end the provisions

943 of this act are declared severable.

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Section 17.	This	act	shall	take	effect	July	1,	2008.
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