2008

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 relating to tobacco-
23	related and nontobacco-related diseases to the State
24	Surgeon General; requiring the State Surgeon General to
25	provide 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; providing 39 for nonapplicability of James and Esther King Biomedical 40 Research Program requirements to specified programs and 41 the use of certain operating funds appropriated to 42 universities; extending the expiration date of the 43 44 program; amending s. 381.79, F.S.; providing for the expiration of a provision relating to the distribution of 45 funds from the Brain and Spinal Cord Injury Program Trust 46 47 Fund; amending s. 381.853, F.S.; providing a requirement for the Florida Center for Brain Tumor Research relating 48 to the use of state funds for biomedical research; 49 amending s. 381.855, F.S.; providing additional program 50 functions for the Florida Center for Universal Research to 51 Eradicate Disease; requiring the center to disseminate 52 53 certain information if an appropriation is made; 54 conforming references to changes made by the act; amending s. 381.911, F.S.; conforming references to changes made by 55 the act; amending s. 381.922, F.S., relating to the 56 Page 2 of 33

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William G. "Bill" Bankhead, Jr., and David Coley Cancer 57 58 Research Program; creating a future requirement for the 59 commission to submit priorities for funding cancer research to the State Surgeon General; requiring the State 60 Surgeon General to provide commission funding priorities 61 to the Legislature; providing restrictions on the State 62 63 Surgeon General; providing criteria for ranking 64 priorities; authorizing the State Surgeon General to award 65 grants; providing for the award of grants upon a specific appropriation; prohibiting the funding of research 66 projects not in compliance with the requirements of the 67 section; conforming references to changes made by the act; 68 revising process and provisions relating to future peer 69 review of grant applications to conform to the changes to 70 the biomedical research program made by the act; deleting 71 72 a provision requiring the Division of Statutory Revision within the Office of Legislative Services to certify 73 certain language and citations related to the program; 74 75 deleting a provision requiring future legislative review 76 of the program; revising the expiration date of the program; amending ss. 458.324 and 459.0125, F.S.; 77 conforming references to changes made by the act; amending 78 s. 1004.445, F.S.; providing for the future repeal of 79 80 specified provisions to conform to changes made by the act; reducing appropriations for fiscal year 2008-2009; 81 82 providing for and specifying use of future appropriations; repealing s. 381.0404, F.S., relating to the Center for 83 Health Technologies; repealing s. 381.85, F.S., relating 84 Page 3 of 33

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85	to biomedical and social research; repealing s. 381.912,
86	F.S., relating to the Cervical Cancer Elimination Task
87	Force; repealing s. 381.92, F.S., relating to the Florida
88	Cancer Council; repealing s. 381.921, F.S., relating to
89	the Florida Cancer Council; repealing s. 381.98, F.S.,
90	relating to the Florida Public Health Foundation, Inc.;
91	repealing s. 381.981, F.S., relating to health awareness
92	campaigns; repealing s. 1004.435, F.S., relating to cancer
93	control and research; providing for severability;
94	providing an effective date.
95	
96	Be It Enacted by the Legislature of the State of Florida:
97	
98	Section 1. Paragraph (h) of subsection (1) of section
99	20.435, Florida Statutes, is amended to read:
100	20.435 Department of Health; trust funds
101	(1) The following trust funds are hereby created, to be
102	administered by the Department of Health:
103	(h) Biomedical Research Trust Fund.
104	1. Funds to be credited to the trust fund shall consist of
105	funds deposited pursuant to s. 215.5601 and any other funds
106	appropriated by the Legislature. Funds shall be used for the
107	purposes of the James and Esther King Biomedical Research
108	Program and the William G. "Bill" Bankhead, Jr., and David Coley
109	Cancer Research Program as specified in ss. 215.5602, 288.955,
110	and 381.922. The trust fund is exempt from the service charges
111	imposed by s. 215.20.

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112	2. Funds deposited into the trust fund pursuant to s.
113	215.5601 and any other funds appropriated by the Legislature as
114	specified in s. 215.5602(12)(a) for research related to tobacco-
115	related diseases shall be used exclusively for the purpose of
116	awarding grants and fellowships for research regarding the
117	prevention, diagnosis, treatment, and cure of tobacco-related
118	diseases by the James and Esther King Biomedical Research
119	Program.
120	3. Funds deposited into the trust fund pursuant to the
121	William G. "Bill" Bankhead, Jr., and David Coley Cancer Research
122	Program as specified in s. 381.922 shall be used for the purpose
123	of awarding grants for cancer research by the William G. "Bill"
124	Bankhead, Jr., and David Coley Cancer Research Program.
125	4. All other funds deposited into the trust fund shall be
126	used for the purpose of awarding grants and fellowships for
127	biomedical research regarding the prevention, diagnosis,
128	treatment, and cure of the most deadly and widespread
129	nontobacco-related acute, chronic, and degenerative diseases by
130	the James and Esther King Biomedical Research Program as
131	specified in s. 215.5602(2)(b) and (12)(b).
132	5.2. Notwithstanding the provisions of s. 216.301 and
133	pursuant to s. 216.351, any balance in the trust fund at the end
134	of any fiscal year shall remain in the trust fund at the end of
135	the year and shall be available for carrying out the purposes of
136	the trust fund. The department may invest these funds
137	independently through the Chief Financial Officer or may
138	negotiate a trust agreement with the State Board of

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139 Administration for the investment management of any balance in 140 the trust fund.

141 <u>6.3.</u> Notwithstanding s. 216.301 and pursuant to s. 142 216.351, any balance of any appropriation from the Biomedical 143 Research Trust Fund which is not disbursed but which is 144 obligated pursuant to contract or committed to be expended may 145 be carried forward for up to $5 \rightarrow$ years following the effective 146 date of the original appropriation.

147Section 2. Paragraph (e) of subsection (5) of section148215.5601, Florida Statutes, is amended to read:

149 215.5601 Lawton Chiles Endowment Fund.--

150

(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.
20.435(1)(h)5.2-

158 Section 3. Section 215.5602, Florida Statutes, is amended 159 to read:

160 215.5602 James and Esther King Biomedical Research161 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.
215.5601. The purpose of the James and Esther King Biomedical
Research Program is to provide an annual and perpetual source of
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167 funding in order to support research initiatives that address the health care problems of Floridians in the areas of tobacco-168 related cancer, cardiovascular disease, stroke, and pulmonary 169 170 disease and nontobacco-related acute, chronic, and degenerative 171 diseases, including cancer, cardiovascular disease, stroke, pulmonary disease, diabetes, autoimmune and genetic disorders, 172 and neurological disorders, including Alzheimer's disease, 173 174 epilepsy, and Parkinson's disease. The long-term goals of the 175 program are to: Improve the health of Floridians by researching better 176 (a) 177 prevention, diagnoses, treatments, and cures for the most deadly and widespread acute, chronic, and degenerative diseases, 178 including, but not limited to, tobacco-related diseases, cancer, 179 180 cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, 181 including Alzheimer's disease, epilepsy, and Parkinson's 182 183 disease. 184 Expand the foundation of biomedical knowledge relating (b) 185 to the prevention, diagnosis, treatment, and cure of tobaccorelated diseases related to tobacco use, including cancer, 186 187 cardiovascular disease, stroke, and pulmonary disease. 188 Expand the foundation of biomedical knowledge relating (C) 189 to the prevention, diagnosis, treatment, and cure of the most widespread acute, chronic, and degenerative diseases affecting 190 Floridians, including, but not limited to, cancer, 191 cardiovascular disease, stroke, pulmonary disease, diabetes, 192 autoimmune and genetic disorders, and neurological disorders, 193

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194 including Alzheimer's disease, epilepsy, and Parkinson's 195 disease.

196 <u>(d) (c)</u> Improve the quality of the state's academic health 197 centers by bringing the advances of biomedical research into the 198 training of physicians and other health care providers.

199 <u>(e) (d)</u> Increase the state's per capita funding for 200 research by undertaking new initiatives in public health and 201 biomedical research that will attract additional funding from 202 outside the state.

203 <u>(f)(e)</u> Stimulate economic activity in the state in areas 204 related to biomedical research, such as the research and 205 production of pharmaceuticals, biotechnology, and medical 206 devices.

207 (2) (a) Funds appropriated for the James and Esther King 208 Biomedical Research Program pursuant to the Lawton Chiles 209 Endowment Fund created in s. 215.5601 and additional funding 210 provided under paragraph (12)(a) for research related to 211 tobacco-related diseases shall be credited to the Biomedical 212 Research Trust Fund pursuant to s. 20.435 and shall be used 213 exclusively for the award of grants and fellowships related to 214 the prevention, diagnosis, treatment, and cure of tobacco-215 related diseases, including cancer, cardiovascular disease, stroke, and pulmonary disease and for expenses incurred in the 216 administration of this section. Priority shall be granted to 217 research designed to prevent or cure tobacco-related diseases. 218 (b) Beginning in fiscal year 2009-2010, and each fiscal 219 year thereafter, all other funds appropriated for the James and 220 Esther King Biomedical Research Program shall be credited to the 221 Page 8 of 33

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222 Biomedical Research Trust Fund pursuant to s. 20.435 and shall 223 be used exclusively for the award of grants and fellowships as established in this section; for research relating to the 224 225 prevention, diagnosis, treatment, and cure of the most deadly 226 and widespread acute, chronic, and degenerative nontobacco-227 related diseases affecting Floridians related to tobacco use, 228 including cancer, cardiovascular disease, stroke, and pulmonary 229 disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, 230 231 and Parkinson's disease, + and for expenses incurred in the 232 administration of this section. Priority shall be granted to research designed to prevent or cure disease. 233

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

236 The commission council shall consist of 15 11 members, (a) 237 including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief 238 executive officer of the Greater Southeast Florida/Puerto Rico 239 240 Affiliate of the American Heart Association, or a designee; and the chief executive officer of the American Lung Association of 241 242 Florida, or a designee; the chief executive officer of the South 243 Coastal Region of the American Diabetes Association, or a designee; and the president of the Florida Medical Association, 244 or a designee. The remaining 10 & members of the commission 245 council shall be appointed as follows: 246

247 1. The Governor shall appoint four members, two members248 with expertise in the field of biomedical research, one member

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266

from a research university in the state, and one member representing the general population of the state.

251 2. The President of the Senate shall appoint <u>three</u> two 252 members, one member with expertise in the field of behavioral or 253 social research and <u>two members representing volunteer health</u> 254 <u>organizations operating in the state that focus on Alzheimer's</u> 255 <u>disease, Parkinson's disease, epilepsy, stroke, or autoimmune</u> 256 <u>and genetic disorders</u> one representative from a cancer program 257 approved by the American College of Surgeons.

258 The Speaker of the House of Representatives shall 3. 259 appoint three two members, two members representing volunteer health organizations operating in the state that focus on 260 Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or 261 262 autoimmune and genetic disorders one member from a professional 263 medical organization and one member representing representative 264 from a cancer program approved by the American College of 265 Surgeons.

267 In making these appointments, the Governor, the President of the 268 Senate, and the Speaker of the House of Representatives shall 269 select primarily, but not exclusively, Floridians with 270 biomedical and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, 271 autoimmune and genetic disorders, and neurological disorders, 272 including Alzheimer's disease, epilepsy, and Parkinson's 273 274 disease. The appointments shall be for a 3-year term and shall reflect the diversity of the state's population. An appointed 275 member may not serve more than two consecutive terms. 276

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277	(b) Except for the William G. "Bill" Bankhead, Jr., and
278	David Coley Cancer Research Program that expires June 30, 2011,
279	pursuant to s. 381.922, beginning in fiscal year 2009-2010, and
280	each fiscal year thereafter, funds appropriated for the James
281	and Esther King Biomedical Research Program shall serve as the
282	exclusive source of awarding grants or fellowships for
283	biomedical research in the state using state funds. This
284	paragraph does not preclude another grant or fellowship program
285	created by state law from awarding grants from funds received
286	from private or federal sources if permitted by state law.
287	(c) The commission shall create committees to focus on
288	disease-specific areas, including, but not limited to, tobacco-
289	related diseases, cancer, stroke, cardiovascular disease,
290	pulmonary disease, diabetes, autoimmune and genetic disorders,
291	and neurological disorders, including Alzheimer's disease,
292	epilepsy, and Parkinson's disease.
293	(d) (b) The commission council shall adopt internal
294	organizational procedures as necessary for its efficient
295	organization, including policies and procedures regarding the
296	creation and composition of the committees, the submission of
297	reports and recommendations by committees regarding the awarding
298	of grants and fellowships, coordination between the commission
299	and committees, and the methods for receiving input from
300	individuals, organizations, or entities that are not members of
301	the commission or its committees regarding the prioritization of
302	research.
303	(e) (c) The department shall provide such staff,
304	information, and other assistance as is reasonably necessary to
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305 assist the commission council in carrying out its responsibilities, including those of its committees. 306 307 (f) (d) Members of the commission council shall serve 308 without compensation, but may receive reimbursement as provided 309 in s. 112.061 for travel and other necessary expenses incurred 310 in the performance of their official duties, including attending 311 committee meetings. The commission council shall, after considering the 312 (4)recommendations of its committees, advise the State Surgeon 313 314 General as to the direction and scope of the biomedical research program. The responsibilities of the commission council may 315 include, but are not limited to: 316 Establishing Providing advice on program priorities 317 (a) 318 and emphases. 319 (b) Evaluating Providing advice on the overall program 320 budget and making recommendations to the State Surgeon General 321 and the Legislature regarding future appropriations. 322 Participating in periodic program evaluation. (C) 323 (d) Developing Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles 324 325 of merit and quality in the conduct of the program. 326 (e) Developing Assisting in the development of appropriate 327 linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, 328 government agencies, and public officials. 329 Developing criteria and standards for the award of 330 (f) 331 research grants.

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(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.

336 (h) Developing and supervising research peer review337 panels.

338 (i) Reviewing reports of peer review panels and making339 recommendations for research grants and fellowships.

340 (j) Developing and providing oversight regarding341 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.

354 (c) Beginning in fiscal year 2009-2010, and each fiscal
 355 year thereafter, the State Surgeon General shall submit to the
 356 Legislature by February 1 priority lists for the funding of both
 357 tobacco-related and nontobacco-related biomedical research by
 358 the Legislature based on the recommendations made by the
 359 commission after peer review and scoring of the applications

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360 received. Recommendations to the Legislature shall be in the 361 form of lists submitted by the State Surgeon General of the 362 commission's rank order of priority from the proposal with the 363 highest priority through the proposal with the lowest priority, 364 including the recommended dollar amount and duration for each 365 proposal. The State Surgeon General may not reject or modify the 366 commission's recommendations. Successful applicants shall be 367 awarded grants or fellowships by the State Surgeon General based 368 upon the recommendations of the commission and the final funding decision made by the Legislature. Funding for grant and 369 370 fellowship applications for tobacco-related research shall be 371 based upon funds available pursuant to paragraphs (2)(a) and (12)(a) and s. 215.5601. 372 373 Beginning in fiscal year 2009-2010, and each fiscal (d) 374 year thereafter, the commission's overall ranking of grant and 375 fellowship applications shall be based on the score awarded to 376 the proposal by peer reviewers on the basis of scientific merit 377 through an open competitive peer review process that ensures 378 objectivity, consistency, and high quality and the commission's 379 determination of the following: 380 The projected impact that the proposed research will 1. 381 have on the most deadly and widespread diseases affecting 382 Floridians at the time the grant or fellowship is awarded; 383 2. The likelihood or possibility that the proposed research will result in new treatment modalities or technology 384 385 during the term of the grant or fellowship; and Whether the research proposed offers an efficient use 386 3. 387 of state funds in order to prevent or cure disease. Page 14 of 33

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FLORIDA HOUSE OF REPRESENTATIVES	F	L	0	R		D	Α	Н		0	U	S	Е	0	F	F		E	Р	R	Е	S	Е	Ν	Т	Α	Т		V	Е	S
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388 The following types of applications shall be (e) 389 considered for funding: 390 Investigator-initiated research grants. 1. 391 2. Institutional research grants. 392 3. Predoctoral and postdoctoral research fellowships. 393 The State Surgeon General shall award grants or (f) 394 fellowships for terms of 1 to 5 years. State funds shall only be provided for research that was applied for, reviewed, and 395 396 recommended in accordance with this section. (g) 397 Except for the William G. "Bill" Bankhead, Jr., and 398 David Coley Cancer Research Program that expires June 30, 2011, 399 pursuant to s. 381.922, beginning July 1, 2009, and each fiscal 400 year thereafter, any program, board, commission, council, 401 advisory group, agency, or entity created by state law that awards or recommends the award of grants or fellowships for 402 403 biomedical research may not award grants or fellowships that 404 require the use of state funds and, instead, shall make any 405 recommendation to the commission and its committees for the 406 prioritization and award of grants and fellowships through the 407 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 <u>commission</u> 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

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415 commission and its committees council and must be considered in 416 determining which proposals shall be recommended for funding. The commission, the committees, council and the peer 417 (7)418 review panel shall establish and follow rigorous guidelines for 419 ethical conduct and adhere to a strict policy with regard to 420 conflict of interest. A member of the commission, committee, 421 council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, 422 423 entity, or agency with which the member is associated as a 424 member of the governing body or as an employee, or with which 425 the member has entered into a contractual arrangement. Meetings of the commission, committees, council and the peer review 426 panels shall be subject to the provisions of chapter 119, s. 427 428 286.011, and s. 24, Art. I of the State Constitution. 429 (8) The department may contract on a competitive-bid basis 430 with an appropriate entity to administer the program. Administrative expenses may not exceed 15 percent of the total 431 432 funds available to the program in any given year. Effective July 433 1, 2009, administrative expenses may not exceed 10 percent of 434 the total funds available to the program in any given year. 435 Effective July 1, 2011, administrative expenses may not exceed 5 436 percent of the total funds available to the program in any given 437 year. The department, after consultation with the commission 438 (9) council, may adopt rules pursuant to ss. 120.536(1) and 120.54 439 as necessary to implement this section. 440 In addition to its recommendations regarding 441 (10)appropriations for the award of grants and fellowships to the 442

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443 <u>State Surgeon General and the Legislature</u>, the <u>commission</u> 444 council shall submit an annual progress report on the state of 445 biomedical research in this state to the Florida Center for 446 Universal Research to Eradicate Disease and to the Governor, the 447 State Surgeon General, the President of the Senate, and the 448 Speaker of the House of Representatives by February 1. The 449 report must include:

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

452

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

453 (c) A list of publications in <u>peer-reviewed</u> peer reviewed
454 journals involving research supported by grants or fellowships
455 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.

461 (f) Progress in the prevention, diagnosis, treatment, and cure of the most deadly and widespread acute, chronic, and 462 463 degenerative tobacco-related and nontobacco-related diseases 464 affecting Floridians diseases related to tobacco use, including 465 cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological 466 disorders, including Alzheimer's disease, epilepsy, and 467 468 Parkinson's disease. The commission council shall award grants for cancer 469 (11)

470 research through the William G. "Bill" Bankhead, Jr., and David Page 17 of 33

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471 Coley Cancer Research Program created in s. 381.922. <u>This</u>
472 subsection expires June 30, 2011.

Beginning in fiscal year 2006-2007, the sum of \$6 473 (12) (a) 474 million is appropriated annually from recurring funds in the 475 General Revenue Fund to the Biomedical Research Trust Fund 476 within the Department of Health for purposes of the award of 477 grants and fellowships by the James and Esther King Biomedical Research Program for research relating to tobacco-related 478 479 diseases pursuant to this section. From these funds up to 480 \$250,000 shall be available for the operating costs of the Florida Center for Universal Research to Eradicate Disease. 481 Beginning in fiscal year 2009-2010, and each fiscal 482 (b) year thereafter, the Legislature may appropriate funds from 483 484 recurring funds in the General Revenue Fund to the Biomedical 485 Research Trust Fund within the Department of Health for purposes

486 of the award of grants and fellowships by the James and Esther

487 <u>King Biomedical Research Program for research of the most deadly</u>

488and widespread nontobacco-related acute, chronic, and489degenerative diseases pursuant to this section. Any research

490 grant or fellowship awarded for Alzheimer's research pursuant to

491 this section shall be named a "Johnnie B. Byrd, Sr. Alzheimer's

492 Grant." Any research grant or fellowship awarded for cancer

493 research pursuant to this section shall be named a "Bankhead-

494 <u>Coley Cancer Grant."</u>

495 (13) This section does not apply to the 21st Century World 496 Class Scholars, Centers of Excellence, or State University 497 Research Commercialization Assistance Grant Programs established 498 under s. 1004.226; to the University Major Gifts Program

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499 established under s. 1011.94; or to the use of general operating 500 funds appropriated to universities.

501 (14)(13) By June 1, 2014 2009, the Division of Statutory 502 Revision of the Office of Legislative Services shall certify to 503 the President of the Senate and the Speaker of the House of 504 Representatives the language and statutory citation of this 505 section, which is scheduled to expire January 1, 2016 2011.

506 <u>(15)(14)</u> The Legislature shall review the performance, the 507 outcomes, and the financial management of the James and Esther 508 King Biomedical Research Program during the <u>2015</u> 2010 Regular 509 Session of the Legislature and shall determine the most 510 appropriate funding source and means of funding the program 511 based on its review.

512 (16) (15) This section expires January 1, 2016 2011, unless 513 reviewed and reenacted by the Legislature before that date. 514 Section 4. Subsection (3) of section 381.79, Florida 515 Statutes, is amended to read:

516 381.79 Brain and Spinal Cord Injury Program Trust Fund.--517 (3) Annually, 5 percent of the revenues deposited monthly in the fund pursuant to s. 318.21(2)(d) shall be appropriated to 518 519 the University of Florida and 5 percent to the University of Miami for spinal cord injury and brain injury research. The 520 521 amount to be distributed to the universities shall be calculated based on the deposits into the fund for each quarter in the 522 fiscal year, but may not exceed \$500,000 per university per 523 year. Funds distributed under this subsection shall be made in 524 quarterly payments at the end of each quarter during the fiscal 525 year. This subsection expires June 30, 2009. 526

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

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554	(p) The center shall provide information regarding
555	research needs in the state to the Biomedical Research
556	Commission located in the James and Esther King Biomedical
557	Research Program.
558	(5) There is established within the center an advisory
559	council that shall meet at least annually.
560	(a) The council shall consist of one representative from a
561	Florida not-for-profit institution engaged in basic and clinical
562	biomedical research and education which receives more than \$10
563	million in annual grant funding from the National Institutes of
564	Health, to be appointed by the State Surgeon General from a
565	different institution each term, and one representative from and
566	appointed by each of the following entities:
567	1. Enterprise Florida, Inc.
568	2. BioFlorida.
569	3. The Biomedical Research <u>Commission</u> Advisory Council.
570	4. The Florida Medical Foundation.
571	5. Pharmaceutical Research and Manufacturers of America.
572	6. The Florida Cancer Council.
573	<u>6.</u> 7. The American Cancer Society, Florida Division, Inc.
574	7.8. The American Heart Association.
575	<u>8.</u> 9. The American Lung Association of Florida.
576	9.10. The American Diabetes Association, South Coastal
577	Region.
578	10. 11. The Alzheimer's Association.
579	<u>11.12. The Epilepsy Foundation.</u>
580	<u>12.13. The National Parkinson Foundation.</u>
581	14. The Florida Public Health Foundation, Inc.
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582 13.15. The Florida Research Consortium. 583 Section 7. Subsections (2), (3), and (4) of section 584 381.911, Florida Statutes, are amended to read: 585 381.911 Prostate Cancer Awareness Program.--586 For purposes of implementing the program, the (2)587 Department of Health and the Florida Public Health Foundation, 588 Inc., may: 589 Conduct activities directly or enter into a contract (a) 590 with a qualified nonprofit community education entity. Seek any available gifts, grants, or funds from the 591 (b) state, the Federal Government, philanthropic foundations, and 592 593 industry or business groups. A prostate cancer advisory committee is created to 594 (3) 595 advise and assist the Department of Health and the Florida 596 Public Health Foundation, Inc., in implementing the program. 597 (a) The State Surgeon General shall appoint the advisory 598 committee members, who shall consist of: 599 Three persons from prostate cancer survivor groups or 1. 600 cancer-related advocacy groups. 601 Three persons who are scientists or clinicians from 2. 602 public universities or research organizations. 603 Three persons who are engaged in the practice of a 3. 604 cancer-related medical specialty from health organizations 605 committed to cancer research and control. Members shall serve without compensation but are 606 (b) entitled to reimbursement, pursuant to s. 112.061, for per diem 607 and travel expenses incurred in the performance of their 608 609 official duties. Page 22 of 33

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

612 Section 8. Section 381.922, Florida Statutes, is amended 613 to read:

614 381.922 William G. "Bill" Bankhead, Jr., and David Coley
615 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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637 proposals, including those that advance the program's goals 638 enumerated in subsection (2), may be given preference. For fiscal year 2008-2009, grants shall be awarded by 639 (b) 640 the State Surgeon General, after consultation with the 641 Biomedical Research Commission Advisory Council, on the basis of 642 scientific merit through, as determined by an open, competitive 643 peer review process that ensures objectivity, consistency, and high quality. 644 645 (c) Beginning in fiscal year 2009-2010, and each fiscal 646 year thereafter, the State Surgeon General shall submit to the 647 Legislature by February 1 a priority list for cancer research funding by the Legislature based on the recommendations of the 648 649 commission after peer review and scoring of the applications 650 received. Recommendations to the Legislature shall be in the form of a list submitted by the State Surgeon General of the 651 652 commission's rank order of priority from the proposal with the 653 highest priority through the proposal with the lowest priority, 654 including the recommended dollar amount and duration for each 655 proposal. The State Surgeon General may not reject or modify the commission's recommendations. Successful applicants shall be 656 657 awarded grants by the State Surgeon General based upon the 658 recommendations of the commission and the final funding decision 659 made by the Legislature. (d) Beginning in fiscal year 2009-2010, and each fiscal 660 year thereafter, the commission's overall ranking of grant 661 662 applications shall be based on the score awarded to the proposal by peer reviewers on the basis of scientific merit through an 663 open competitive peer review process that ensures objectivity, 664

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FLORIDA HOUSE OF REPRESENTATIVE	FL	_ 0	RΙ	DΑ	ΗО	U S	SΕ	ΟF	RΕ	ΡR	E S	Е	N T	ΤА	Т	ΙV	Е	S
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665 consistency, and high quality and the commission's determination 666 of the following: 667 The projected impact that the proposed research will 1. 668 have on cancer research at the time the grant is awarded; 669 The likelihood or possibility that the proposed 2. 670 research will result in new treatment modalities or technology 671 during the term of the grant; and 672 3. Whether the research proposed offers an efficient use 673 of state funds in order to prevent or cure cancer. The following types of applications shall be 674 (e) considered for funding: 675 676 Investigator-initiated research grants. 1. 2. Institutional research grants. 677 678 3. Collaborative research grants, including those that advance the finding of cures through basic or applied research. 679 Beginning in fiscal year 2009-2010, and each fiscal 680 (f) 681 year thereafter, state funds shall only be provided for research 682 that was applied for, reviewed, and recommended in accordance 683 with this section. 684 (q) (b) In order to ensure that all proposals for research 685 funding are appropriate and are evaluated fairly on the basis of scientific merit, the State Surgeon General, in consultation 686 687 with the commission council, shall appoint a peer review panel of independent, scientifically qualified individuals to review 688 the scientific content of each proposal and establish its 689 priority score. The priority scores shall be forwarded to the 690 commission and its committees council and must be considered in 691 692 determining which proposals shall be recommended for funding.

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693 (h) (c) The commission, the committees, council and the 694 peer review panel shall establish and follow rigorous guidelines 695 for ethical conduct and adhere to a strict policy with regard to conflicts of interest. A member of the commission, a committee, 696 697 council or the panel may not participate in any discussion or 698 decision with respect to a research proposal by any firm, 699 entity, or agency with which the member is associated as a 700 member of the governing body or as an employee or with which the 701 member has entered into a contractual arrangement. Meetings of the commission, the committees, council and the peer review 702 703 panels are subject to chapter 119, s. 286.011, and s. 24, Art. I 704 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 \$9 710 (5) 711 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund 712 713 within the Department of Health for purposes of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program 714 715 and shall be distributed pursuant to this section to provide grants to researchers seeking cures for cancer, with emphasis 716 given to the goals enumerated in s. 381.921. From the total 717 funds appropriated, an amount of up to 10 percent may be used 718 719 for administrative expenses.

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720 (6) By June 1, 2009, the Division of Statutory Revision of 721 the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of 722 723 Representatives the language and statutory citation of this 724 section, which is scheduled to expire January 1, 2011. 725 (7) The Legislature shall review the performance, the 726 outcomes, and the financial management of the William G. "Bill" 727 Bankhead, Jr., and David Coley Cancer Research Program during 728 the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the 729 730 program based on its review. 731 (6) (8) This section expires June 30 January 1, 2011, unless reviewed and reenacted by the Legislature before that 732 733 date. 734 Section 9. Subsection (1) and paragraph (a) of subsection 735 (2) of section 458.324, Florida Statutes, are amended to read: 736 458.324 Breast cancer; information on treatment 737 alternatives.--738 (1)DEFINITION. -- As used in this section, the term "medically viable," as applied to treatment alternatives, means 739 740 modes of treatment generally considered by the medical 741 profession to be within the scope of current, acceptable 742 standards, including treatment alternatives described in the written summary prepared by the Florida Cancer Control and 743 744 Research Advisory Council in accordance with s. 1004.435(4)(m). COMMUNICATION OF TREATMENT ALTERNATIVES. -- Each 745 (2)physician treating a patient who is, or in the judgment of the 746 747 physician is at high risk of being, diagnosed as having breast Page 27 of 33

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748 cancer shall inform such patient of the medically viable 749 treatment alternatives available to such patient; shall describe 750 such treatment alternatives; and shall explain the relative 751 advantages, disadvantages, and risks associated with the 752 treatment alternatives to the extent deemed necessary to allow 753 the patient to make a prudent decision regarding such treatment 754 options. In compliance with this subsection:

755

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

756 1. Orally communicate such information directly to the757 patient or the patient's legal representative;

758 2. Provide the patient or the patient's legal 759 representative with a copy of <u>a</u> the written summary prepared in 760 accordance with s. 1004.435(4)(m) and express a willingness to 761 discuss the summary with the patient or the patient's legal 762 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.

767

768 Nothing in this subsection shall reduce other provisions of law769 regarding informed consent.

770Section 10.Subsection (1) and paragraph (a) of subsection771(2) of section 459.0125, Florida Statutes, are amended to read:

459.0125 Breast cancer; information on treatmentalternatives.--

774 (1) DEFINITION.--As used in this section, the term 775 "medically viable," as applied to treatment alternatives, means Page 28 of 33

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776 modes of treatment generally considered by the medical 777 profession to be within the scope of current, acceptable 778 standards, including treatment alternatives described in the 779 written summary prepared by the Florida Cancer Control and 780 Research Advisory Council in accordance with s. 1004.435(4)(m).

781 COMMUNICATION OF TREATMENT ALTERNATIVES.--It is the (2)782 obligation of every physician treating a patient who is, or in 783 the judgment of the physician is at high risk of being, 784 diagnosed as having breast cancer to inform such patient of the medically viable treatment alternatives available to such 785 786 patient; to describe such treatment alternatives; and to explain 787 the relative advantages, disadvantages, and risks associated with the treatment alternatives to the extent deemed necessary 788 789 to allow the patient to make a prudent decision regarding such treatment options. In compliance with this subsection: 790

791

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

792 1. Orally communicate such information directly to the793 patient or the patient's legal representative;

794 2. Provide the patient or the patient's legal 795 representative with a copy of <u>a</u> the written summary prepared in 796 accordance with s. 1004.435(4)(m) and express her or his 797 willingness to discuss the summary with the patient or the 798 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.

803

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

Section 11. Subsections (7), (8), and (12) of section
1004.445, Florida Statutes, as amended by chapter 2007-332, Laws
of Florida, are amended to read:

809 1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and
810 Research Institute.--

The board of directors of the not-for-profit 811 (7)812 corporation shall create a council of scientific advisers to the chief executive officer comprised of leading researchers, 813 physicians, and scientists. The council shall review programs 814 and recommend research priorities and initiatives to maximize 815 the state's investment in the institute. The members of the 816 817 council shall be appointed by the board of directors of the not-818 for-profit corporation. Each member of the council shall be 819 appointed to serve a 2-year term and may be reappointed to the 820 council. This subsection expires on June 30, 2009.

821 Applications for Alzheimer's disease research (8)(a) 822 funding may be submitted from any university or established 823 research institute in the state. All qualified investigators in 824 the state, regardless of institutional affiliation, shall have 825 equal access and opportunity to compete for the research 826 funding. Grants shall be awarded by the board of directors of 827 the not-for-profit corporation on the basis of scientific merit, as determined by an open, competitive peer review process that 828 ensures objectivity, consistency, and high quality. The 829 following types of applications shall be considered for funding: 830 Investigator-initiated research grants. 831 1.

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832

2. Institutional research grants.

833 3. Collaborative research grants, including those that834 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.

840 (C) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific 841 842 merit, the board of directors of the not-for-profit corporation, in consultation with the council of scientific advisors, shall 843 appoint a peer review panel of independent, scientifically 844 845 qualified individuals to review the scientific content of each proposal and establish its scientific priority score. The 846 847 priority scores shall be forwarded to the council and must be considered by the board of directors of the not-for-profit 848 849 corporation in determining which proposals shall be recommended 850 for funding.

The council of scientific advisors and the peer review 851 (d)852 panel shall establish and follow rigorous guidelines for ethical 853 conduct and adhere to a strict policy with regard to conflict of interest. All employees, members of the board of directors, and 854 855 affiliates of the not-for-profit corporation shall follow the same rigorous guidelines for ethical conduct and shall adhere to 856 the same strict policy with regard to conflict of interest. A 857 member of the council or panel may not participate in any 858 859 discussion or decision with respect to a research proposal by Page 31 of 33

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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.

866

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

867 (12)(a) Beginning in fiscal year 2008-2009 2007-2008, the 868 sum of \$3.75 \$13.5 million is appropriated annually from recurring funds in the General Revenue Fund to the Grants and 869 870 Donations Trust Fund within the Department of Elderly Affairs for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research 871 Institute at the University of South Florida for the purposes as 872 873 provided under paragraph (6)(a), conducting and supporting 874 research, providing institutional research grants and 875 investigator-initiated research grants, developing and operating 876 integrated data projects, and providing assistance to 877 statutorily designated memory disorder clinics as provided under 878 s. 430.502. Not less than 80 percent of the appropriated funds shall be expended for these purposes, and not less than 20 879 880 percent of the appropriated funds shall be expended for peer-881 reviewed investigator-initiated research grants.

(b) Beginning in fiscal year 2009-2010, and each fiscal
year thereafter, the sum appropriated in paragraph (a) shall be
used for programs that fulfill the mission of the institute in
education, treatment, prevention, and early detection of
Alzheimer's disease, developing and operating integrated data
projects, and providing assistance to statutorily designated

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888	memory disorder clinics. If the institute intends to conduct
889	research using state funds, it shall compete for funding through
890	the James and Esther King Biomedical Research Program pursuant
891	to s. 215.5602.
892	Section 12. Sections 381.0404, 381.85, 381.912, 381.92,
893	<u>381.921, 381.98, 381.981, and 1004.435, Florida Statutes, are</u>
894	repealed.
895	Section 13. If any provision of this act or the
896	application thereof to any person or circumstance is held
897	invalid, the invalidity does not affect other provisions or
898	applications of the act which can be given effect without the
899	invalid provision or application, and to this end the provisions
900	of this act are declared severable.
901	Section 14. This act shall take effect July 1, 2008.

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