Florida Senate - 2008

By Senator Peaden

2-03594A-08

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1	A bill to be entitled
2	An act relating to biomedical research; amending s.
3	20.435, F.S.; revising funding sources for the Biomedical
4	Research Trust Fund to conform to changes made by the act;
5	providing for segregation of trust funds based on the type
6	of research conducted; amending s. 215.5602, F.S.,
7	relating to the James and Esther King Biomedical Research
8	Program; providing for the prevention, diagnosis,
9	treatment, and cure of specified diseases as a long-term
10	goal of the research program; providing for the expansion
11	of the foundation of biomedical knowledge relating to the
12	prevention, diagnosis, treatment, and cure for specified
13	diseases; requiring that funds appropriated for the
14	research program be used for research relating to the
15	prevention, diagnosis, treatment, and cure of various
16	diseases; requiring that other funds appropriated for the
17	research program be credited to the Biomedical Research
18	Trust Fund; renaming the Biomedical Research Advisory
19	Council the Biomedical Research Commission; revising the
20	membership of the commission; requiring the biomedical
21	research program to serve as the exclusive source for
22	awarding grants and fellowships; requiring the commission
23	to create other committees; requiring the commission to
24	adopt procedures for assigning commission members to
25	committees; requiring the commission to advise the State
26	Surgeon General as to the direction and scope of the
27	research program; providing responsibilities of the
28	commission; requiring the State Surgeon General to award
29	grants and fellowships after consultation with the

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30 commission; requiring the State Surgeon General to submit 31 to the Legislature lists of priorities for funding tobacco 32 and non-tobacco-related diseases based on recommendations 33 of the commission; providing restrictions on the State 34 Surgeon General; providing for the award of grants or 35 fellowships upon a specific appropriation; providing that funding is only available to research projects that go 36 37 through a certain process; providing criteria for ranking 38 priorities; providing for the terms of the grants; 39 requiring other programs, boards, commissions, councils, 40 advisory groups, and committees to cease awarding 41 biomedical research grants or fellowships and to make 42 recommendations to the Biomedical Research Commission and 43 its committees; requiring the State Surgeon General, in 44 consultation with the commission, to appoint a peer review 45 panel; requiring that priority scores be forwarded to the commission and the committees; requiring the commission, 46 the committees, and the peer review panel to establish 47 48 rigorous guidelines for ethical conduct with regard to 49 conflicts of interest; reducing the limits on 50 administrative expenses; requiring the commission to 51 submit its recommendations and annual progress report to 52 the Governor, the State Surgeon General, the Legislature, 53 and the Florida Center for Universal Research to Eradicate 54 Disease; requiring the commission to award grants for 55 cancer research through the William G. "Bill" Bankhead, 56 Jr., and David Coley Cancer Research Program; providing an 57 expiration date; providing appropriations; revising 58 provisions relating to sunset of the program; amending s.

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59 381.79, F.S.; providing an expiration date for the 60 appropriation for spinal cord injury and brain injury research; amending s. 381.853, F.S.; requiring the Florida 61 62 Center for Brain Tumor Research to apply through the James 63 and Esther King Biomedical Research Program if the center seeks to conduct biomedical research using state funds; 64 65 amending s. 381.855, F.S.; providing additional program 66 functions for the Florida Center for Universal Research to 67 Eradicate Disease; requiring the center to disseminate information about diseases and conditions to Floridians 68 and providers if an appropriation is made; deleting 69 70 references to conform to changes made by this act; 71 amending s. 381.911, F.S.; deleting references to conform 72 to changes made by this act; repealing s. 381.912, F.S., 73 relating to the Cervical Cancer Elimination Task Force; 74 repealing s. 381.92, F.S., relating to the Florida Cancer 75 Council; repealing s. 381.921, F.S., relating to Florida 76 Cancer Council's mission and duties; amending s. 381.922, 77 F.S.; deleting cross-references to conform to changes of 78 this act; requiring the State Surgeon General to submit to 79 the Legislature a priority list for cancer research 80 funding by the Legislature; prohibiting the State Surgeon 81 General from rejecting or modifying the commission's 82 recommendations under certain circumstances; providing 83 ranking criteria for the commission; prohibiting the 84 provision of state funds for research that was not applied 85 for, reviewed, and recommended; requiring the commission, 86 the committees, and the peer review panel to establish 87 rigorous guidelines for ethical conduct with regard to

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conflicts of interest; deleting a provision concerning 88 89 certification by the Division of Statutory Revision of the 90 Office of Legislative Services related to the program; deleting a provision concerning future Legislative review 91 92 of the program; revising the sunset date for the program; 93 repealing s. 381.98, F.S., relating to the Florida Public 94 Health Foundation, Inc.; repealing s. 381.981, F.S., 95 relating to Health awareness campaigns; amending s. 96 430.502, F.S.; requiring the Department of Elderly Affairs 97 to evaluate the need for more memory disorder clinics in 98 the state; deleting cross-references to conform to changes 99 made by this act; amending ss. 430.503, 430.504, and 100 458.324, F.S.; deleting a reference and cross-references 101 to conform to the changes made by this act; amending s. 102 459.0125, F.S.; redefining the term "medically viable"; 103 deleting a cross-reference to conform to the changes made 104 by this act; repealing s. 1004.435, F.S., relating to 105 cancer control and research and the Cancer Control and 106 Research Commission; amending s. 1004.445, F.S.; providing 107 an expiration date for the appointment of a council by the 108 not-for-profit corporation that governs the Johnnie B. 109 Byrd, Sr., Alzheimer's Center and Research Institute; 110 providing an expiration date for applying for funding for 111 Alzheimer's disease research through the Johnnie B. Byrd, 112 Sr., Alzheimer's Center and Research Institute; providing 113 an expiration date for the appropriation of funds from the 114 General Revenue Fund to the Grants and Donations Trust 115 Fund within the Department of Elderly Affairs for the 116 Johnnie B. Byrd, Sr., Alzheimer's Center and Research

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117 Institute; revising an appropriation of funds from the 118 General Revenue Fund to the Grants and Donations Trust 119 Fund within the Department of Elderly Affairs for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research 120 121 Institute; providing an appropriation of funds from the General Revenue Fund to the Grants and Donations Trust 122 123 Fund within the Department of Elderly Affairs for the 124 Johnnie B. Byrd, Sr., Alzheimer's Center and Research 125 Institute for the purpose of providing assistance to 126 memory disorder clinics; requiring the Johnnie B. Byrd, 127 Sr., Alzheimer's Center and Research Institute to apply 128 for funding through the James and Esther King Biomedical 129 Research Program; providing for severability; providing an 130 effective date. 131

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

134 Section 1. Paragraph (h) of subsection (1) of section135 20.435, Florida Statutes, is amended to read:

20.435 Department of Health; trust funds.--

137 (1) The following trust funds are hereby created, to be138 administered by the Department of Health:

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(h) Biomedical Research Trust Fund.

140 1. Funds to be credited to the trust fund shall consist of 141 funds deposited pursuant to s. 215.5601 and any other funds 142 appropriated by the Legislature. Funds shall be used for the 143 purposes of the James and Esther King Biomedical Research Program 144 and the William G. "Bill" Bankhead, Jr., and David Coley Cancer 145 Research Program as specified in ss. 215.5602, 288.955, and

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381.922. The trust fund is exempt from the service charges 146 147 imposed by s. 215.20. 148 2. Funds deposited to the trust fund pursuant to s. 149 215.5601 and any other funds appropriated by the Legislature as 150 specified in ss. 215.5602(12)(a) and 288.955 or elsewhere for 151 research related to tobacco-related diseases shall be used 152 exclusively for the purpose of awarding grants and fellowships 153 for research regarding the prevention, diagnosis, treatment, and 154 cure of tobacco-related diseases by the James and Esther King 155 Biomedical Research Program. 156 3. Funds deposited to the trust fund pursuant to the 157 William G. "Bill" Bankhead, Jr., and David Coley Cancer Research 158 Program as specified in s. 381.922 shall be used for the purpose 159

of awarding grants for cancer research by the James and Esther
 King Biomedical Research Program.
 <u>4. All other funds deposited to the trust fund shall be</u>

162 used for the purpose of awarding grants and fellowship for 163 biomedical research regarding the prevention, diagnosis, 164 treatment, and cure of the most deadly and widespread non-165 tobacco-related acute, chronic, and degenerative diseases by the 166 James and Esther King Biomedical Research Program as specified in 167 ss. 215.5602(2)(b) and 215.5602(12)(b).

168 <u>5.2.</u> Notwithstanding the provisions of s. 216.301 and 169 pursuant to s. 216.351, any balance in the trust fund at the end 170 of any fiscal year shall remain in the trust fund at the end of 171 the year and shall be available for carrying out the purposes of 172 the trust fund. The department may invest these funds 173 independently through the Chief Financial Officer or may 174 negotiate a trust agreement with the State Board of

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

177 <u>6.3.</u> Notwithstanding s. 216.301 and pursuant to s. 216.351, 178 any balance of any appropriation from the Biomedical Research 179 Trust Fund which is not disbursed but which is obligated pursuant 180 to contract or committed to be expended may be carried forward 181 for up to 3 years following the effective date of the original 182 appropriation.

183 Section 2. Section 215.5602, Florida Statutes, is amended 184 to read:

185 215.5602 James and Esther King Biomedical Research 186 Program.--

187 There is established within the Department of Health (1)188 the James and Esther King Biomedical Research Program funded by the proceeds of the Lawton Chiles Endowment Fund pursuant to s. 189 190 215.5601. The purpose of the James and Esther King Biomedical 191 Research program is to provide an annual and perpetual source of 192 funding in order to support research initiatives that address the 193 health care problems of Floridians in the areas of tobacco-194 related cancer, cardiovascular disease, stroke, and pulmonary 195 disease, and non-tobacco-related acute, chronic, and degenerative 196 diseases, including cancer, cardiovascular disease, stroke, 197 pulmonary disease, diabetes, autoimmune and genetic disorders, 198 and neurological disorders, including Alzheimer's disease, 199 epilepsy, and Parkinson's disease. The long-term goals of the 200 program are to:

(a) Improve the health of Floridians by researching better
 prevention, diagnoses, treatments, and cures for <u>the most deadly</u>
 and widespread acute, chronic, and degenerative diseases,

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204 <u>including, but not limited to, tobacco-related diseases,</u> cancer, 205 cardiovascular disease, stroke, and pulmonary disease, <u>diabetes</u>, 206 <u>autoimmune and genetic disorders</u>, and <u>neurological disorders</u>, 207 including Alzheimer's disease, epilepsy, and Parkinson's disease.

(b) Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

(c) Expand the foundation of biomedical knowledge relating
 to the prevention, diagnosis, treatment, and cure of the most
 widespread acute, chronic, and degenerative diseases affecting
 Floridians, including, but not limited to, cancer, cardiovascular
 disease, stroke, pulmonary disease, diabetes, autoimmune and
 genetic disorders, and neurological disorders, including
 Alzheimer's disease, epilepsy, and Parkinson's disease.

219 <u>(d) (c)</u> Improve the quality of the state's academic health 220 centers by bringing the advances of biomedical research into the 221 training of physicians and other health care providers.

(e) (d) Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional funding from outside the state.

226 <u>(f)(e)</u> Stimulate economic activity in the state in areas 227 related to biomedical research, such as the research and 228 production of pharmaceuticals, biotechnology, and medical 229 devices.

(2) (a) Funds appropriated for the James and Esther King
 Biomedical Research Program <u>pursuant to the Lawton Chiles</u>
 Endowment Fund in s. 215.5601 and additional funding provided in

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233 s. 215.5602(12)(a) or elsewhere in law for research related to 234 tobacco-related diseases shall be credited to the Biomedical 235 Research Trust Fund pursuant to s. 20.435 and shall be used 236 exclusively for the award of grants and fellowships related to the prevention, diagnosis, treatment, and cure of diseases 237 238 related to tobacco use, including cancer, cardiovascular disease, 239 stroke, and pulmonary disease, and for expenses incurred in the 240 administration of this section. Priority shall be granted to 241 research designed to prevent or cure tobacco-related disease. 242 (b) Beginning in the 2009-2019 fiscal year and each fiscal year thereafter, all other funds appropriated for the James and 243 244 Esther King Biomedical Research Program shall be credited to the 245 Biomedical Research Trust Fund pursuant to s. 20.435 and shall be 246 used exclusively for the award of grants and fellowships as established in this section; for research relating to the 247

248 prevention, diagnosis, treatment, and cure of the most deadly and 249 widespread acute, chronic, and degenerative non-tobacco-related 250 diseases affecting Floridians related to tobacco use, including 251 cancer, cardiovascular disease, stroke, and pulmonary disease, 252 diabetes, autoimmune and genetic disorders, and neurological 253 disorders, including Alzheimer's disease, epilepsy, and 254 Parkinson's disease, + and for expenses incurred in the 255 administration of this section. Priority shall be granted to 256 research designed to prevent or cure disease.

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

(a) The council shall consist of <u>15</u> 11 members, including:
the chief executive officer of the Florida Division of the
American Cancer Society, or a designee; the chief executive

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262 officer of the Greater Southeast Florida/Puerto Rico Affiliate of 263 the American Heart Association, or a designee; and the chief 264 executive officer of the American Lung Association of Florida, or a designee; the chief executive officer of the South Coastal 265 Region of the American Diabetes Association, or a designee; and 266 267 the president of the Florida Medical Association, or a designee. 268 The remaining 10 8 members of the commission council shall be 269 appointed as follows:

The Governor shall appoint <u>13</u> four members <u>as follows:</u>
 two members <u>having</u> 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.

274 2. The President of the Senate shall appoint three two 275 members, one member having with expertise in the field of 276 behavioral or social research and two representatives from 277 volunteer health organizations operating in this state which focus on Alzheimer's disease, Parkinson's disease, epilepsy, 278 279 stroke, or autoimmune or genetic disorders one representative 280 from a cancer program approved by the American College of 281 Surgeons.

3. The Speaker of the House of Representatives shall appoint <u>three</u> two members, <u>two representatives from volunteer</u> <u>health organizations operating in this state which focus on</u> <u>Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or</u> <u>autoimmune or genetic disorders, one member from a professional</u> <u>medical organization</u> and one representative from a cancer program approved by the American College of Surgeons.

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290 In making these appointments, the Governor, the President of the 291 Senate, and the Speaker of the House of Representatives shall 292 select primarily, but not exclusively, Floridians with biomedical 293 and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and 294 295 genetic disorders, and neurological disorders, including 296 Alzheimer's disease, epilepsy, and Parkinson's disease. The 297 appointments shall be for a 3-year term and shall reflect the 298 diversity of the state's population. An appointed member may not 299 serve more than two consecutive terms.

(b) Beginning July 1, 2009, and each year thereafter, the
 biomedical research program shall serve as the exclusive source
 of awarding grants or fellowships for biomedical research in the
 state using state funds. This paragraph does not preclude another
 grant or fellowship program in the state from awarding grants
 from funds received from private or federal sources where
 permitted by state law.

307 (c) The commission shall create committees to focus on 308 disease specific areas, including, but not limited to, tobacco-309 related diseases, cancer, stroke, cardiovascular disease, 310 pulmonary disease, diabetes, autoimmune or genetic disorders, 311 Alzheimer's disease, epilepsy, and Parkinson's disease.

312 <u>(d) (b)</u> The <u>commission</u> council shall adopt internal 313 organizational procedures as necessary for its efficient 314 organization, including policies and procedures regarding the 315 <u>creation and composition of the committees, reporting and</u> 316 <u>recommendations by the committee to the commission regarding the</u> 317 <u>award of grants and fellowships, coordination between the</u> 318 commission and committees, and the methods for receiving input

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319 from outside individuals, organizations, or entities regarding 320 the prioritization of research.. 321 (e) (c) The department shall provide such staff, 322 information, and other assistance as is reasonably necessary to 323 assist the commission council in carrying out its 324 responsibilities, including those of its committees. 325 (f) (d) Members of the commission council shall serve 326 without compensation, but may receive reimbursement as provided 327 in s. 112.061 for travel and other necessary expenses incurred in the performance of their official duties, including committee 328 329 meetings. 330 (4) The commission council shall, after considering the 331 recommendations of its committees, advise the State Surgeon 332 General as to the direction and scope of the biomedical research 333 program. The responsibilities of the commission council may 334 include, but are not limited to: Establishing Providing advice on program priorities and 335 (a) 336 emphases. 337 Establishing Providing advice on the overall program (b) 338 budget and making recommendations to the State Surgeon General

and the Legislature for future appropriations.

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(c) Participating in periodic program evaluation.

341 (d) <u>Developing Assisting in the development of guidelines</u>
342 to ensure fairness, neutrality, and adherence to the principles
343 of merit and quality in the conduct of the program.

(e) <u>Developing</u> Assisting in the development of appropriate
 linkages to nonacademic entities, such as voluntary
 organizations, health care delivery institutions, industry,
 government agencies, and public officials.

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348 (f) Developing criteria and standards for the award of 349 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 peer, science-based review system.

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(h) Developing and supervising research peer review panels.

355 (i) Reviewing reports of peer review panels and making356 recommendations for research grants and fellowships.

357 (j) Developing and providing oversight regarding mechanisms358 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) For the 2008-2009 fiscal year, grants and fellowships
shall be awarded by the State Surgeon General, after consultation
with the commission council, on the basis of scientific merit, as
determined by an open competitive peer review process that
ensures objectivity, consistency, and high quality.

369 (c) Beginning in 2010 and each year thereafter, the State 370 Surgeon General shall submit to the Legislature by February 1 371 priority lists for both tobacco and non-tobacco-related 372 biomedical research funding by the Legislature based on the 373 recommendations made by the commission after peer-review and scoring of the applications received. Recommendations to the 374 375 Legislature shall be in the form of a list from the State Surgeon 376 General of the commission's ranking by order of priority from the

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377	proposal having the highest priority through the proposal having
378	the lowest priority, including the recommended dollar amount and
379	duration for each proposal. Unless the commission recommends
380	funding for an entity that is ineligible to receive funding under
381	the program, the State Surgeon General may not reject or modify
382	the commission's recommendations. Successful grant and fellowship
383	applications shall be awarded by the State Surgeon General based
384	upon the recommendations of the commission and the final funding
385	decision made by the Legislature. Funding for grant and
386	fellowship applications for tobacco-related research shall be
387	based upon funds available pursuant to ss. 215.5601,
388	215.5602(2)(a), and 216.5602(12)(a).
389	(d) Beginning in the 2009-2010 fiscal year and each fiscal
390	year thereafter, the commission's overall rank for grant or
391	fellowship applications shall be based on the score awarded to
392	the proposal by peer reviewers on the basis of scientific merit
393	through an open competitive peer review process that ensures
394	objectivity, consistency, and high quality, and the commission's
395	determination of the following:
396	1. The projected impact that the proposed research will
397	have on the most deadly and widespread diseases affecting
398	Floridians at the time the grant or fellowship is awarded;
399	2. The likelihood or possibility that the proposed research
400	will result in new treatment modalities or technology during the
401	term of the grant or fellowship; and
402	3. Whether the research proposed offers an efficient use of
403	state funds in order to prevent or cure disease.
404	(e) The following types of applications shall be considered
405	for funding:

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406 1. Investigator-initiated research grants. 407 2. Institutional research grants. 408 3. Predoctoral and postdoctoral research fellowships. 409 (f) Upon a specific appropriation, the council shall award grants for terms of 1 to 5 years. State funds may not be provided 410 411 for research that was not applied for, reviewed, and recommended 412 in accordance with this section. 413 (g) Except for the William G. "Bill" Bankhead, Jr., and 414 David Coley Cancer Research Program that expires June 30, 2011, 415 as set forth in s. 381.922, beginning July 1, 2009, and each year 416 thereafter, any program, board, commission, council, advisory 417 group, agency, or entity created by state law that awards or 418 recommends the award of grants or fellowships for biomedical 419 research shall cease awarding grants or fellowships using state 420 funds and, instead, shall make recommendations to the commission 421 and its committees for the prioritization and award of grants and 422 fellowships through the James and Esther King Biomedical Research 42.3 Program. This section does not apply to the World Class Scholars, 424 Centers of Excellence, or State University Research 425 Commercialization Assistance Grant Programs as set forth in s. 42.6 1004.226.

(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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434 <u>commission and its committees</u> council and must be considered in 435 determining which proposals shall be recommended for funding.

436 The commission, the committees, council and the peer (7) 437 review panel shall establish and follow rigorous guidelines for 438 ethical conduct and adhere to a strict policy with regard to 439 conflict of interest. A member of the commission, a committee, 440 council or a panel may not participate in any discussion or 441 decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the 442 443 governing body or as an employee, or with which the member has 444 entered into a contractual arrangement. Meetings of the 445 commission, the committees, council and the peer review panels 446 shall be subject to the provisions of chapter 119, s. 286.011, 447 and s. 24, Art. I of the State Constitution.

(8) The department may contract on a competitive-bid basis
with an appropriate entity to administer the program.
Administrative expenses may not exceed 15 percent of the total
funds available to the program in any given year. Effective July
<u>1, 2009, administrative expenses may not exceed 10 percent of the</u>
total funds available to the program in any given year.

(9) The department, after consultation with the <u>commission</u>
council, may adopt rules <u>pursuant to ss. 120.536(1) and 120.54</u> as
necessary to implement this section.

(10) <u>In addition to its recommendations to the State</u>
Surgeon General and the Legislature to appropriate funds for the
award of grants and fellowships, the commission the council shall
submit an annual progress report on the state of biomedical
research in this state to the Florida Center for Universal
Research to Eradicate Disease and to the Governor, the State

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2-03594A-08 20082752 463 Surgeon General, the President of the Senate, and the Speaker of 464 the House of Representatives by February 1. The report must 465 include: 466 A list of current research projects supported by grants (a) 467 or fellowships awarded under the program. 468 A list of recipients of program grants or fellowships. (b) 469 A list of publications in peer-reviewed peer reviewed (C) 470 journals involving research supported by grants or fellowships 471 awarded under the program. 472 (d) The total amount of biomedical research funding 473 currently flowing into the state. 474 New grants for biomedical research which were funded (e) 475 based on research supported by grants or fellowships awarded 476 under the program. 477 (f) Progress in the prevention, diagnosis, treatment, and 478 cure of the most deadly and widespread acute, chronic, and 479 degenerative diseases affecting Floridians, including diseases 480 related to tobacco use, including cancer, cardiovascular disease, 481 stroke, and pulmonary disease, diabetes, autoimmune and genetic 482 disorders, and neurological disorders, including Alzheimer's 483 disease, epilepsy, and Parkinson's disease. 484 The commission council shall award grants for cancer (11)485 research through the William G. "Bill" Bankhead, Jr., and David 486 Coley Cancer Research Program created in s. 381.922. This 487 subsection expires June 30, 2011. 488 (12) (a) Beginning in fiscal year 2006-2007, the sum of \$6 million is appropriated annually from recurring funds in the 489 General Revenue Fund to the Biomedical Research Trust Fund within 490

491 the Department of Health for purposes of the award of grants and

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492 <u>fellowships by the</u> James and Esther King Biomedical Research
493 Program <u>for research relating to tobacco-related diseases</u>
494 pursuant to this section. From these funds up to \$250,000 shall
495 be available for the operating costs of the Florida Center for
496 Universal Research to Eradicate Disease.

497 Beginning in the 2009-2010 fiscal year and each fiscal (b) 498 year thereafter, the Legislature may appropriate funds from 499 recurring funds in the General Revenue Fund to the Biomedical 500 Research Trust Fund within the Department of Health for purposes 501 of the award of grants and fellowships by the James and Esther 502 King Biomedical Research Program for research concerning the most 503 deadly and widespread non-tobacco-related acute, chronic, and 504 degenerative diseases pursuant to this section. Any research 505 grant or fellowship awarded for Alzheimer's research pursuant to this section shall be named a "Johnnie B. Byrd, Sr., Alzheimer's 506 507 Grant." Any research grant or fellowship awarded for cancer 508 research pursuant to this section shall be named a "Bankhead-509 Coley Cancer Grant."

(13) By June 1, <u>2014</u> 2009, the Division of Statutory Revision of the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of this section, which is scheduled to expire January 1, <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 <u>2015</u> 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.

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

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381.79 Brain and Spinal Cord Injury Program Trust Fund.--(3) Annually, 5 percent of the revenues deposited monthly

527 in the fund pursuant to s. 318.21(2)(d) shall be appropriated to 528 the University of Florida and 5 percent to the University of 529 Miami for spinal cord injury and brain injury research. The amount to be distributed to the universities shall be calculated 530 based on the deposits into the fund for each quarter in the 531 532 fiscal year, but may not exceed \$500,000 per university per year. 533 Funds distributed under this subsection shall be made in 534 quarterly payments at the end of each quarter during the fiscal 535 year. This subsection expires June 30, 2009.

536 Section 4. Paragraph (h) is added to subsection (4) of 537 section 381.853, Florida Statutes, to read:

381.853 Florida Center for Brain Tumor Research.--

(4) The Florida Center for Brain Tumor Research is
established within the Evelyn F. and William L. McKnight Brain
Institute of the University of Florida.

542 (h) Beginning in the 2009-2010 fiscal year and each fiscal
543 year thereafter, if the center seeks to conduct biomedical
544 research using state funds, the center shall apply for funding
545 through the James and Esther King Biomedical Research Program
546 pursuant to s. 215.5602.

547 Section 5. Paragraphs (n), (o), and (p) are added to 548 subsection (3) of section 381.855, Florida Statutes, and

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549 paragraph (a) of subsection (5) of that section is amended, to 550 read:

551 381.855 Florida Center for Universal Research to Eradicate 552 Disease.--

(3) There is established within the Department of Health the Florida Center for Universal Research to Eradicate Disease, which shall be known as "CURED."

556 (n) The center shall identify ways to attract new research 557 talent and attendant national grant producing researchers to 558 research facilities in this state.

(o) If funds are specifically appropriated by the
Legislature, the center shall disseminate information to
Floridians and treatment providers about specified diseases and
conditions and available methods of preventing, diagnosing,
treating, and curing those diseases and conditions.

564 (p) The center shall provide information regarding research 565 needs in the state to the Biomedical Research Commission located 566 in the James and Esther King Biomedical Research Program.

567 (5) There is established within the center an advisory568 council that shall meet at least annually.

(a) The council shall consist of one representative from a Florida not-for-profit institution engaged in basic and clinical biomedical research and education which receives more than \$10 million in annual grant funding from the National Institutes of Health, to be appointed by the State Surgeon General from a different institution each term, and one representative from and appointed by each of the following entities:

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1. Enterprise Florida, Inc.

577 2. BioFlorida.

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2-03594A-08 20082752 578 The Biomedical Research Commission Advisory Council. 3. 579 4. The Florida Medical Foundation. 580 5. Pharmaceutical Research and Manufacturers of America. 6. The Florida Cancer Council. 581 6.7. The American Cancer Society, Florida Division, Inc. 582 583 7.8. The American Heart Association. 584 8.9. The American Lung Association of Florida. 585 9.10. The American Diabetes Association, South Coastal 586 Region. 587 10.11. The Alzheimer's Association. 588 11.12. The Epilepsy Foundation. 589 12.13. The National Parkinson Foundation. 590 14. The Florida Public Health Foundation, Inc. 591 13.15. The Florida Research Consortium. 592 Section 6. Subsections (2), (3), and (4) of section 593 381.911, Florida Statutes, are amended to read: 594 381.911 Prostate Cancer Awareness Program.--595 (2) For purposes of implementing the program, the 596 Department of Health and the Florida Public Health Foundation, 597 Inc., may: 598 (a) Conduct activities directly or enter into a contract 599 with a qualified nonprofit community education entity. 600 Seek any available gifts, grants, or funds from the (b) 601 state, the Federal Government, philanthropic foundations, and 602 industry or business groups. 603 A prostate cancer advisory committee is created to (3) 604 advise and assist the Department of Health and the Florida Public 605 Health Foundation, Inc., in implementing the program.

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2-03594A-08 20082752 The State Surgeon General shall appoint the advisory 606 (a) 607 committee members, who shall consist of: 608 Three persons from prostate cancer survivor groups or 1. 609 cancer-related advocacy groups. 610 Three persons who are scientists or clinicians from 2. 611 public universities or research organizations. Three persons who are engaged in the practice of a 612 3. 613 cancer-related medical specialty from health organizations committed to cancer research and control. 614 615 (b) Members shall serve without compensation but are entitled to reimbursement, pursuant to s. 112.061, for per diem 616 617 and travel expenses incurred in the performance of their official 618 duties. (4) The program shall coordinate its efforts with those of 619 620 the Florida Public Health Foundation, Inc. 621 Section 7. Section 381.912, Florida Statutes, is repealed. 62.2 Section 8. Section 381.92, Florida Statutes, is repealed. 623 Section 9. Section 381.921, Florida Statutes, is repealed. 624 Section 10. Subsections (2), (3), (5), (6), (7), and (8) of 625 section 381.922, Florida Statutes, are amended to read: 62.6 381.922 William G. "Bill" Bankhead, Jr., and David Coley 627 Cancer Research Program. --628 (2)The program shall provide grants for cancer research to 629 further the search for cures for cancer. 630 Emphasis shall be given to the goals enumerated (a) 631 381.921, as those goals that support the advancement of such 632 cures. 633 (b) Preference may be given to grant proposals that foster 634 collaborations among institutions, researchers, and community

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635 practitioners, as such proposals support the advancement of cures
636 through basic or applied research, including clinical trials
637 involving cancer patients and related networks.

(3) (a) Applications for funding for cancer research may be
submitted by any university or established research institute in
the state. All qualified investigators in the state, regardless
of institutional affiliation, shall have equal access and
opportunity to compete for the research funding. Collaborative
proposals, including those that advance the program's goals
enumerated in subsection (2), may be given preference.

(b) For the 2008-2009 fiscal year, grants shall be awarded
by the State Surgeon General, after consultation with the
Biomedical Research <u>Commission</u> Advisory Council, on the basis of
scientific merit <u>through</u>, as determined by an open, competitive
peer review process that ensures objectivity, consistency, and
high quality.

651 (c) Beginning in the 2009-2010 fiscal year and each fiscal 652 year thereafter, the State Surgeon General shall submit to the 653 Legislature by February 1 a priority list for cancer research 654 funding by the Legislature based on the recommendations made by 655 the commission after peer review and scoring of the applications 656 received. Recommendations to the Legislature shall be in the form 657 of a list from the State Surgeon General of the commission's 658 ranking by order of priority from the proposal having the highest 659 priority through the proposal having the lowest priority, 660 including the recommended dollar amount and duration for each 661 proposal. Unless the commission recommends funding for an entity 662 that is ineligible to receive funding under the program, the 663 State Surgeon General may not reject or modify the commission's

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664	recommendations. Successful grant and fellowship applications
665	shall be awarded by the State Surgeon General based upon the
666	recommendations of the commission and the final funding decision
667	made by the Legislature.
668	(d) Beginning in the 2009-2010 fiscal year and each fiscal
669	year thereafter, the commission's overall rank for grant or
670	fellowship applications shall be based on the score awarded to
671	the proposal by peer reviewers on the basis of scientific merit
672	through an open competitive peer review process that ensures
673	objectivity, consistency, and high quality, and the commission's
674	determination of the following:
675	1. The projected impact that the proposed research will
676	have on cancer research at the time the grant is awarded;
677	2. The likelihood or possibility that the proposed research
678	will result in new treatment modalities or technology during the
679	term of the grant; and
680	3. Whether the research proposed offers an efficient use of
681	state funds in order to prevent or cure cancer.
682	(e) The following types of applications shall be considered
683	for funding:
684	1. Investigator-initiated research grants.
685	2. Institutional research grants.
686	3. Collaborative research grants, including those that
687	advance the finding of cures through basic or applied research.
688	(f) Beginning in the 2009-2010 fiscal year and each fiscal
689	year thereafter, state funds may not be provided for research
690	that was not applied for, reviewed, and recommended in accordance
691	with this section.
692	(g)(b) In order to ensure that all proposals for research

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693 funding are appropriate and are evaluated fairly on the basis of 694 scientific merit, the State Surgeon General, in consultation with 695 the commission council, shall appoint a peer review panel of 696 independent, scientifically qualified individuals to review the 697 scientific content of each proposal and establish its priority 698 score. The priority scores shall be forwarded to the commission 699 and its committees council and must be considered in determining 700 which proposals shall be recommended for funding.

701 (h) (c) The commission, the committees, council and the peer 702 review panel shall establish and follow rigorous guidelines for 703 ethical conduct and adhere to a strict policy with regard to 704 conflicts of interest. A member of the commission, a committee, 705 council or panel may not participate in any discussion or 706 decision with respect to a research proposal by any firm, entity, 707 or agency with which the member is associated as a member of the 708 governing body or as an employee or with which the member has 709 entered into a contractual arrangement. Meetings of the 710 commission, the committees, council and the peer review panels 711 are subject to chapter 119, s. 286.011, and s. 24, Art. I of the 712 State Constitution.

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

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721	appropriated, an amount of up to 10 percent may be used for
722	administrative expenses.
723	(6) By June 1, 2009, the Division of Statutory Revision of
724	the Office of Legislative Services shall certify to the President
725	of the Senate and the Speaker of the House of Representatives the
726	language and statutory citation of this section, which is
727	scheduled to expire January 1, 2011.
728	(7) The Legislature shall review the performance, the
729	outcomes, and the financial management of the William G. "Bill"
730	Bankhead, Jr., and David Coley Cancer Research Program during the
731	2010 Regular Session of the Legislature and shall determine the
732	most appropriate funding source and means of funding the program
733	based on its review.
734	(6)(8) This section expires June 30, 2011 January 1, 2011,
735	unless reviewed and reenacted by the Legislature before that
736	date.
737	Section 11. Section 381.98, Florida Statutes, is repealed.
738	Section 12. Section 381.981, Florida Statutes, is repealed.
739	Section 13. Subsection (3) of section 430.502, Florida
740	Statutes, is amended to read:
741	430.502 Alzheimer's disease; memory disorder clinics and
742	day care and respite care programs
743	(3) The Department of Elderly Affairs The Alzheimer's
744	Disease Advisory Committee must evaluate the need for additional
745	memory disorder clinics in the state. The first report will be
746	due by December 31, 1995.
747	Section 14. Subsection (2) of section 430.503, Florida
748	Statutes, is amended to read:

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749 430.503 Alzheimer's Disease Initiative; fees and 750 administrative expense.--

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

763 Section 15. Section 430.504, Florida Statutes, is amended 764 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, or 768 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 is 772 confidential and exempt from the provisions of s. 119.07(1). Such 773 information may not be disclosed publicly in such a manner as to 774 identify a person who receives services under s. 430.501 or s. 775 430.503, unless that person or that person's legal guardian 776 provides written consent.

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777Section 16. Subsection (1) and paragraph (a) of subsection778(2) of section 458.324, Florida Statutes, are amended to read:

458.324 Breast cancer; information on treatment
alternatives.--

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

788 (2) COMMUNICATION OF TREATMENT ALTERNATIVES.--Each 789 physician treating a patient who is, or in the judgment of the physician is at high risk of being, diagnosed as having breast 790 791 cancer shall inform such patient of the medically viable 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 the 800 patient or the patient's legal representative;

2. Provide the patient or the patient's legal representative with a copy of the written summary prepared in accordance with s. 1004.435(4)(m) and express a willingness to discuss the summary with the patient or the patient's legal representative; or

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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.

811 Nothing in this subsection shall reduce other provisions of law 812 regarding informed consent.

813 Section 17. Subsection (1) and paragraph (a) of subsection
814 (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).

824 COMMUNICATION OF TREATMENT ALTERNATIVES .-- It is the (2)825 obligation of every physician treating a patient who is, or in 826 the judgment of the physician is at high risk of being, diagnosed 827 as having breast cancer to inform such patient of the medically 828 viable treatment alternatives available to such patient; to 829 describe such treatment alternatives; and to explain the relative 830 advantages, disadvantages, and risks associated with the 831 treatment alternatives to the extent deemed necessary to allow 832 the patient to make a prudent decision regarding such treatment 833 options. In compliance with this subsection:

834

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

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835 1. Orally communicate such information directly to the 836 patient or the patient's legal representative;

2. Provide the patient or the patient's legal representative with a copy of 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.

847 Nothing in this subsection shall reduce other provisions of law 848 regarding informed consent.

849Section 18.Subsections (7), (8), and (12) of section8501004.445, Florida Statutes, are amended to read:

851 1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and 852 Research Institute.--

853 The board of directors of the not-for-profit (7)854 corporation shall create a council of scientific advisers to the 855 chief executive officer comprised of leading researchers, 856 physicians, and scientists. The council shall review programs and 857 recommend research priorities and initiatives to maximize the 858 state's investment in the institute. The members of the council 859 shall be appointed by the board of directors of the not-for-860 profit corporation. Each member of the council shall be appointed 861 to serve a 2-year term and may be reappointed to the council. 862 This subsection expires June 30, 2009.

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

873 874

1. Investigator-initiated research grants.

2. Institutional research grants.

875 3. Collaborative research grants, including those that876 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.

882 To ensure that all proposals for research funding are (C) 883 appropriate and are evaluated fairly on the basis of scientific 884 merit, the board of directors of the not-for-profit corporation, 885 in consultation with the council of scientific advisors, shall 886 appoint a peer review panel of independent, scientifically 887 qualified individuals to review the scientific content of each 888 proposal and establish its scientific priority score. The 889 priority scores shall be forwarded to the council and must be 890 considered by the board of directors of the not-for-profit

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891 corporation in determining which proposals shall be recommended 892 for funding.

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

907

(e) This subsection expires June 30, 2009.

908 (12) (a) For the 2008-2009 fiscal year, Beginning in fiscal 909 year 2007-2008, the sum of \$7 million \$13.5 million is 910 appropriated annually from recurring funds in the General Revenue 911 Fund to the Grants and Donations Trust Fund within the Department 912 of Elderly Affairs for the Johnnie B. Byrd, Sr., Alzheimer's 913 Center and Research Institute at the University of South Florida 914 for the purposes as provided under paragraph (6)(a), conducting 915 and supporting research, providing institutional research grants 916 and investigator-initiated research grants, developing and operating integrated data projects, and providing assistance to 917 918 statutorily designated memory disorder clinics as provided under 919 s. 430.502. Not less than 80 percent of the appropriated funds

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920 shall be expended for these purposes, and not less than 20 921 percent of the appropriated funds shall be expended for peer-922 reviewed investigator-initiated research grants. <u>This paragraph</u> 923 expires June 30, 2009.

(b) Beginning July 1, 2009, and each year thereafter, the 924 925 sum of \$5 million is appropriated annually from recurring funds 926 in the General Revenue Fund to the Grants and Donations Trust 927 Fund within the Department of Elderly Affairs for the Johnnie B. 928 Byrd, Sr., Alzheimer's Center and Research Institute at the 929 University of South Florida for the purposes of providing assistance to statutorily designated memory disorder clinics as 930 931 provided under s. 430.502 and for the education, treatment, 932 prevention, and early detection of Alzheimer's disease. In order 933 to receive state funds for research, the Johnnie B. Byrd, Sr., 934 Alzheimer's Center and Research Institute shall apply for funding 935 through the James and Esther King Biomedical Research Program 936 pursuant to s. 215.5602.

937 Section 19. <u>If any provision of this act or the application</u> 938 <u>thereof to any person or circumstance is held invalid, the</u> 939 <u>invalidity does not affect other provisions or applications of</u> 940 <u>the act which can be given effect without the invalid provision</u> 941 <u>or application, and to this end the provisions of this act are</u> 942 <u>severable.</u>

943

Section 20. This act shall take effect July 1, 2008.