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1 A bill to be entitled
2 An act relating to biomedical research funding; amending
3 s. 20.435, F.S.; deleting a reference to conform to the
4 provisions of this act; amending s. 215.5602, F.S.;
5 revising provisions relating to the James and Esther King
6 Biomedical Research Program; revising provisions relating
7 to program funds and funding; revising long-term goals of
8 the program; revising membership provisions relating to
9 the Biomedical Research Advisory Council; providing that
10 the council serves as the exclusive source of certain
11 biomedical research grant and fellowship awards; requiring
12 the council to create committees; providing requirements
13 for the committees; revising duties of the council;
14 deleting references to conform to the provisions of this
15 act; revising a requirement relating to the council's
16 annual progress report; prohibiting the use of funds for
17 certain research with human embryonic stem cells; amending
18 s. 381.853, F.S.; deleting a requirement for the Florida
19 Center for Brain Tumor Research to develop a competitive
20 grant process relating to brain tumor research; amending
21 s. 381.921, F.S.; specifying that certain cancer research
22 funding shall be for research other than biomedical
23 research; amending ss. 381.912, 381.92, and 381.98, F.S.;
24 deleting references to conform to the provisions of this
25 act; repealing s. 381.855, F.S., relating to the Florida
26 Center for Universal Research to Eradicate Disease;
27 repealing s. 381.922, F.S., relating to the William "Bill"
28 Bankhead, Jr., and David Coley Cancer Research Program;
29 providing an effective date.

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

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

20.435 Department of Health; trust funds.--

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

(h) Biomedical Research Trust Fund.

1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to s. 215.5601 and any other funds appropriated by the Legislature. Funds shall be used for the purposes of the James and Esther King Biomedical Research Program ~~and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program~~ as specified in ss. 215.5602 and, 288.955, ~~and 381.922~~. The trust fund is exempt from the service charges imposed by s. 215.20.

2. Notwithstanding the provisions of s. 216.301 and pursuant to s. 216.351, any balance in the trust fund at the end of any fiscal year shall remain in the trust fund at the end of the year and shall be available for carrying out the purposes of the trust fund. The department may invest these funds independently through the Chief Financial Officer or may negotiate a trust agreement with the State Board of Administration for the investment management of any balance in the trust fund.

3. Notwithstanding s. 216.301 and pursuant to s. 216.351, any balance of any appropriation from the Biomedical Research Trust Fund which is not disbursed but which is obligated pursuant

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59 | to contract or committed to be expended may be carried forward
 60 | for up to 3 years following the effective date of the original
 61 | appropriation.

62 | 4. The trust fund shall, unless terminated sooner, be
 63 | terminated on July 1, 2008.

64 | Section 2. Section 215.5602, Florida Statutes, is amended
 65 | to read:

66 | 215.5602 James and Esther King Biomedical Research
 67 | Program.--

68 | (1) There is established within the Department of Health
 69 | the James and Esther King Biomedical Research Program funded by
 70 | the proceeds of the Lawton Chiles Endowment Fund pursuant to s.
 71 | 215.5601 and the Biomedical Research Trust Fund within the
 72 | Department of Health pursuant to s. 20.435(1)(h). The purpose of
 73 | the James and Esther King Biomedical Research Program is to
 74 | provide an annual and perpetual source of funding for biomedical
 75 | ~~in order to support~~ research initiatives that address the health
 76 | care problems of Floridians, including tobacco-related diseases
 77 | ~~in the areas of tobacco-related cancer, cardiovascular disease,~~
 78 | ~~stroke, and pulmonary disease~~. The long-term goals of the program
 79 | are to:

80 | (a) Improve the health of Floridians by researching better
 81 | prevention, diagnoses, treatments, and cures for the most deadly
 82 | and widespread diseases, including cancer, cardiovascular
 83 | disease, stroke, and pulmonary disease, diabetes, autoimmune
 84 | disorders, and neurological disorders, including Alzheimer's
 85 | disease, epilepsy, and Parkinson's disease.

86 | (b) Expand the foundation of biomedical knowledge relating
 87 | to the prevention, diagnosis, treatment, and cure of diseases

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88 related to tobacco use, including cancer, cardiovascular disease,
89 stroke, and pulmonary disease.

90 (c) Expand the foundation of biomedical knowledge relating
91 to the prevention, diagnosis, treatment, and cure of the most
92 deadly and widespread diseases unrelated to tobacco use,
93 including cancer, cardiovascular disease, stroke, pulmonary
94 disease, diabetes, autoimmune disorders, and neurological
95 disorders, including Alzheimer's disease, epilepsy, and
96 Parkinson's disease.

97 (d)-(e) Improve the quality of the state's academic health
98 centers by bringing the advances of biomedical research into the
99 training of physicians and other health care providers.

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

104 (f)-(e) Stimulate economic activity in the state in areas
105 related to biomedical research, such as the research and
106 production of pharmaceuticals, biotechnology, and medical
107 devices.

108 (2) Funds appropriated for the James and Esther King
109 Biomedical Research Program shall be the exclusive source of
110 state funds used exclusively for the award of grants and
111 fellowships as established in this section; for research relating
112 to the prevention, diagnosis, treatment, and cure of the diseases
113 set forth in this section ~~related to tobacco use, including~~
114 ~~cancer, cardiovascular disease, stroke, and pulmonary disease;~~
115 and for expenses incurred in the administration of this section.

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116 Priority shall be granted to research designed to prevent or cure
117 disease.

118 (3) There is created within the James and Esther King
119 Biomedical Research Program in the Department of Health the
120 Biomedical Research Advisory Council.

121 (a) The council shall consist of 29 ~~41~~ members, including:
122 the chief executive officer of Enterprise Florida, Inc., or a
123 designee; the chief executive officer of the Florida Division of
124 the American Cancer Society, or a designee; the chief executive
125 officer of the Florida/Puerto Rico Affiliate of the American
126 Heart Association, or a designee; ~~and~~ the chief executive officer
127 of the American Lung Association of Florida, or a designee; the
128 chief executive officer of the H. Lee Moffitt Cancer Center, or a
129 designee; the director of the University of Florida Shands Cancer
130 Center, or a designee; the chief executive officer of the
131 University of Miami Sylvester Comprehensive Cancer Center, or a
132 designee; the chief executive officer of the Mayo Clinic,
133 Jacksonville, or a designee; the president of the Florida Society
134 of Clinical Oncology, or a designee; the president of the
135 American College of Surgeons, Florida Chapter, or a designee; and
136 the chair of the Florida Dialogue on Cancer, or a designee. The
137 remaining 18 ~~8~~ members of the council shall be appointed as
138 follows:

139 1. The Governor shall appoint eight ~~four~~ members, two
140 members with expertise in the field of biomedical research, one
141 member from a research university in the state, one
142 representative of the Epilepsy Foundation, one representative of
143 the Florida Medical Foundation, two members from the Florida

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144 Cancer Council, and one member representing the general
 145 population of the state.

146 2. The President of the Senate shall appoint five ~~two~~
 147 members, one member with expertise in the field of behavioral or
 148 social research, one representative of BioFlorida, one
 149 representative of Pharmaceutical Research and Manufacturers of
 150 America, one representative of the South Coastal Region of the
 151 American Diabetes Association, and one representative from a
 152 cancer program approved by the American College of Surgeons.

153 3. The Speaker of the House of Representatives shall
 154 appoint five ~~two~~ members, one representative of the National
 155 Parkinson Foundation, one representative of the Alzheimer's
 156 Association, one representative of the Florida Research
 157 Consortium, one member from a professional medical organization,
 158 and one representative from a cancer program approved by the
 159 American College of Surgeons.

160
 161 In making these appointments, the Governor, the President of the
 162 Senate, and the Speaker of the House of Representatives shall
 163 select primarily, but not exclusively, Floridians with biomedical
 164 and lay expertise in the general areas of cancer, cardiovascular
 165 disease, stroke, ~~and~~ pulmonary disease, diabetes, autoimmune
 166 disorders, and neurological disorders, including Alzheimer's
 167 disease, epilepsy, and Parkinson's disease. The appointments
 168 shall be for a 3-year term and shall reflect the diversity of the
 169 state's population. An appointed member may not serve more than
 170 two consecutive terms.

171 (b) The council shall serve as the exclusive source of
 172 awarding or recommending the award of grants or fellowships for

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173 biomedical research in the state using state-appropriated funds.
 174 This paragraph shall not preclude another grant or fellowship
 175 program in the state from awarding grants from funds received
 176 from private or federal sources where permitted by state law.

177 (c)1. The council shall create a committee responsible for
 178 each of the following research areas:

- 179 a. Tobacco-related diseases.
- 180 b. Cancer, including brain tumor research.
- 181 c. Stroke.
- 182 d. Cardiovascular disease.
- 183 e. Pulmonary disease.
- 184 f. Diabetes.
- 185 g. Autoimmune disorders.
- 186 h. Alzheimer's disease.
- 187 i. Parkinson's disease.
- 188 j. Neurological disorders, including epilepsy.

189 2. The committees shall be comprised of council members and
 190 shall focus on issues and proposed research related to that
 191 committee. The committees shall report findings and make
 192 recommendations to the council regarding the award of grants and
 193 the areas of focus or need for future grants and fellowships.

194 (d)-(b) The council shall adopt internal organizational
 195 procedures as necessary for its efficient organization, including
 196 procedures for assigning council members to committees and
 197 coordination between the council and committees.

198 (e)-(e) The department shall provide such staff,
 199 information, and other assistance as is reasonably necessary to
 200 assist the council, including its committees, in carrying out its
 201 responsibilities.

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202 (f) ~~(d)~~ Members of the council shall serve without
 203 compensation, but may receive reimbursement as provided in s.
 204 112.061 for travel and other necessary expenses incurred in the
 205 performance of their official duties.

206 (4) The council, after consulting with its committees,
 207 shall advise the Secretary of Health as to the direction and
 208 scope of the biomedical research program. The responsibilities of
 209 the council may include, but are not limited to:

210 (a) Providing advice on program priorities and emphases.

211 (b) Providing advice on the overall program budget.

212 (c) Participating in periodic program evaluation.

213 (d) Assisting in the development of guidelines to ensure
 214 fairness, neutrality, and adherence to the principles of merit
 215 and quality in the conduct of the program.

216 (e) Assisting in the development of appropriate linkages to
 217 nonacademic entities, such as voluntary organizations, health
 218 care delivery institutions, industry, government agencies, and
 219 public officials.

220 (f) Developing criteria and standards for the award of
 221 research grants.

222 (g) Developing administrative procedures relating to
 223 solicitation, review, and award of research grants and
 224 fellowships, to ensure an impartial, high-quality peer review
 225 system.

226 (h) Developing and supervising research peer review panels.

227 (i) Reviewing reports of peer review panels and making
 228 recommendations for research grants and fellowships.

229 (j) Developing and providing oversight regarding mechanisms
 230 for the dissemination of research results.

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231 (5) (a) Applications for biomedical research funding under
 232 the program may be submitted from any university or established
 233 research institute in the state. All qualified investigators in
 234 the state, regardless of institution affiliation, shall have
 235 equal access and opportunity to compete for the research funding.

236 (b) The council, after consulting with its committees,
 237 shall recommend the award of grants and fellowships for
 238 biomedical research to the Secretary of Health, who shall make
 239 the award ~~Grants and fellowships shall be awarded by the~~
 240 ~~Secretary of Health, after consultation with the council,~~ on the
 241 basis of scientific merit, as determined by an open competitive
 242 peer review process that ensures objectivity, consistency, and
 243 high quality. The following types of applications shall be
 244 considered for funding:

- 245 1. Investigator-initiated research grants.
- 246 2. Institutional research grants.
- 247 3. Predoctoral and postdoctoral research fellowships.

248 (6) To ensure that all proposals for research funding are
 249 appropriate and are evaluated fairly on the basis of scientific
 250 merit, the Secretary of Health, in consultation with the council,
 251 shall appoint a peer review panel of independent, scientifically
 252 qualified individuals to review the scientific content of each
 253 proposal and establish its scientific priority score. The
 254 priority scores shall be forwarded to the council and its
 255 committees and must be considered in determining which proposals
 256 shall be recommended for funding.

257 (7) The council, the committees, and the peer review panel
 258 shall establish and follow rigorous guidelines for ethical
 259 conduct and adhere to a strict policy with regard to conflict of

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260 interest. A member of the council or panel may not participate in
 261 any discussion or decision with respect to a research proposal by
 262 any firm, entity, or agency with which the member is associated
 263 as a member of the governing body or as an employee, or with
 264 which the member has entered into a contractual arrangement.
 265 Meetings of the council and the peer review panels shall be
 266 subject to the provisions of chapter 119, s. 286.011, and s. 24,
 267 Art. I of the State Constitution.

268 (8) The department may contract on a competitive-bid basis
 269 with an appropriate entity to administer the program.
 270 Administrative expenses may not exceed 15 percent of the total
 271 funds available to the program in any given year.

272 (9) The department, after consultation with the council,
 273 may adopt rules as necessary to implement this section.

274 (10) The council shall submit an annual progress report on
 275 the state of biomedical research in this state ~~to the Florida~~
 276 ~~Center for Universal Research to Eradicate Disease~~ and to the
 277 Governor, the Secretary of Health, the President of the Senate,
 278 and the Speaker of the House of Representatives by February 1.
 279 The report must include:

280 (a) A list of research projects supported by grants or
 281 fellowships awarded under the program.

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

283 (c) A list of publications in peer reviewed journals
 284 involving research supported by grants or fellowships awarded
 285 under the program.

286 (d) The total amount of biomedical research funding
 287 currently flowing into the state.

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288 (e) New grants for biomedical research which were funded
 289 based on research supported by grants or fellowships awarded
 290 under the program.

291 (f) Progress in the prevention, diagnosis, treatment, and
 292 cure of the most deadly and widespread diseases, including
 293 cancer, cardiovascular disease, stroke, pulmonary disease,
 294 diabetes, autoimmune disorders, and neurological disorders,
 295 including Alzheimer's disease, epilepsy, and Parkinson's disease
 296 ~~diseases related to tobacco use, including cancer, cardiovascular~~
 297 ~~disease, stroke, and pulmonary disease.~~

298 ~~(11) The council shall award grants for cancer research~~
 299 ~~through the William G. "Bill" Bankhead, Jr., and David Coley~~
 300 ~~Cancer Research Program created in s. 381.922.~~

301 (11)(12) Funds for the Biomedical Research Advisory Council
 302 shall be Beginning in fiscal year 2006 2007, the sum of \$6
 303 million is appropriated annually from recurring funds in the
 304 General Revenue Fund to the Biomedical Research Trust Fund within
 305 the Department of Health for purposes of the James and Esther
 306 King Biomedical Research Program pursuant to this section. From
 307 these funds up to \$250,000 shall be available for the operating
 308 costs of the James and Esther King Biomedical Research Program.
 309 None of the funds appropriated for biomedical research pursuant
 310 to this section shall be used for research with human embryonic
 311 stem cells that are derived by a process resulting from the death
 312 or destruction of the donor embryo or human cloning. If a grant
 313 or fellowship recipient awarded a grant or fellowship for
 314 biomedical research pursuant to this section uses state funds for
 315 embryonic stem cell research or human cloning, the grant or
 316 fellowship shall be immediately revoked and the council shall

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317 | have the right to seek recovery of the funds used for such
 318 | unauthorized purposes ~~Florida Center for Universal Research to~~
 319 | ~~Eradicate Disease.~~

320 | (12)~~(13)~~ By June 1, 2009, the Division of Statutory
 321 | Revision of the Office of Legislative Services shall certify to
 322 | the President of the Senate and the Speaker of the House of
 323 | Representatives the language and statutory citation of this
 324 | section, which is scheduled to expire January 1, 2011.

325 | (13)~~(14)~~ The Legislature shall review the performance, the
 326 | outcomes, and the financial management of the James and Esther
 327 | King Biomedical Research Program during the 2010 Regular Session
 328 | of the Legislature and shall determine the most appropriate
 329 | funding source and means of funding the program based on its
 330 | review.

331 | (14)~~(15)~~ This section expires January 1, 2011, unless
 332 | reviewed and reenacted by the Legislature before that date.

333 | Section 3. Subsection (4) of section 381.853, Florida
 334 | Statutes, is amended to read:

335 | 381.853 Florida Center for Brain Tumor Research.--

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

339 | (a) The purpose of the center is to foster collaboration
 340 | with brain cancer research organizations and other institutions,
 341 | provide a central repository for brain tumor biopsies from
 342 | individuals throughout the state, improve and monitor brain tumor
 343 | biomedical research programs within the state, facilitate funding
 344 | opportunities, and foster improved technology transfer of brain

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345 | tumor research findings into clinical trials and widespread
 346 | public use.

347 | (b) The goal of the center is to find cures for brain
 348 | tumors.

349 | (c) Funds specifically appropriated by the Legislature for
 350 | peer-reviewed brain tumor research shall be awarded using a
 351 | competitive grant process developed by the center; however, the
 352 | funds may not be used to award grants for or related to
 353 | biomedical research.

354 | (d) The center shall hold an annual brain tumor biomedical
 355 | technology summit in the state to which scientists conducting
 356 | basic peer-reviewed scientific research from the state's public
 357 | and private universities, teaching hospitals, and for-profit and
 358 | nonprofit institutions are invited to share biomedical research
 359 | findings in order to expedite the discovery of cures. Summit
 360 | attendees shall cover the costs of such attendance or obtain
 361 | sponsorship for such attendance.

362 | (e) The center shall encourage clinical trials in the state
 363 | on research that holds the promise of curing brain tumors. The
 364 | center shall facilitate the formation of partnerships between
 365 | researchers, physicians, clinicians, and hospitals for the
 366 | purpose of sharing new techniques and new research findings and
 367 | coordinating the voluntary donation of brain tumor biopsies.

368 | (f) The center shall submit an annual report to the
 369 | Governor, the President of the Senate, the Speaker of the House
 370 | of Representatives, and the Secretary of Health no later than
 371 | January 15 that contains recommendations for legislative changes
 372 | necessary to foster a positive climate for the pursuit of brain

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373 | tumor research and the development of treatment modalities in the
374 | state.

375 | (g) The center shall be funded through private, state, and
376 | federal sources.

377 | Section 4. Subsection (1) of section 381.912, Florida
378 | Statutes, is amended to read:

379 | 381.912 Cervical Cancer Elimination Task Force.--

380 | (1) Effective July 1, 2004, the Cervical Cancer Elimination
381 | Task Force is established for the purpose of recommending
382 | strategies and actions to reduce the costs and burdens of
383 | cervical cancer in Florida. The task force shall present interim
384 | reports to the Florida Public Health Foundation, Inc., the
385 | Florida Cancer Council, ~~the Center for Universal Research to~~
386 | ~~Eradicate Disease~~, the Governor, the President of the Senate, and
387 | the Speaker of the House of Representatives on January 1, 2006,
388 | and July 1, 2007, with a final report due on June 30, 2008. After
389 | submitting its final report on or before June 30, 2008, the task
390 | force is dissolved.

391 | Section 5. Subsection (3) of section 381.92, Florida
392 | Statutes, is amended to read:

393 | 381.92 Florida Cancer Council.--

394 | (3) The council shall issue an annual report to ~~the Center~~
395 | ~~for Universal Research to Eradicate Disease~~, the Governor, the
396 | Speaker of the House of Representatives, and the President of the
397 | Senate by December 15 of each year, with policy and funding
398 | recommendations regarding cancer research capacity in Florida and
399 | related issues.

400 | Section 6. Section 381.921, Florida Statutes, is amended to
401 | read:

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402 381.921 Florida Cancer Council mission and duties.--The
 403 council, ~~which shall work in concert with the Florida Center for~~
 404 ~~Universal Research to Eradicate Disease to ensure that the goals~~
 405 ~~of the center are advanced,~~ shall endeavor to dramatically
 406 improve cancer research and treatment in this state through:
 407 (1) Efforts to significantly expand cancer research
 408 capacity in the state by:
 409 (a) Identifying ways to attract new research talent and
 410 attendant national grant-producing researchers to cancer research
 411 facilities in this state;
 412 (b) Implementing a peer-reviewed, competitive process to
 413 identify and fund the best proposals to expand cancer research
 414 institutes performing research other than biomedical research in
 415 this state;
 416 (c) Funding through available resources for those proposals
 417 for research other than biomedical research that demonstrate the
 418 greatest opportunity to attract federal research grants and
 419 private financial support;
 420 (d) Encouraging the employment of bioinformatics in order
 421 to create a cancer informatics infrastructure that enhances
 422 information and resource exchange and integration through
 423 researchers working in diverse disciplines, to facilitate the
 424 full spectrum of cancer investigations;
 425 (e) Facilitating the technical coordination, business
 426 development, and support of intellectual property as it relates
 427 to the advancement of cancer research; and
 428 (f) Aiding in other multidisciplinary research-support
 429 activities as they inure to the advancement of cancer research.

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430 (2) Efforts to improve both research and treatment through
 431 greater participation in clinical trials networks by:

432 (a) Identifying ways to increase adult enrollment in cancer
 433 clinical trials;

434 (b) Supporting public and private professional education
 435 programs designed to increase the awareness and knowledge about
 436 cancer clinical trials;

437 (c) Providing tools to cancer patients and community-based
 438 oncologists to aid in the identification of cancer clinical
 439 trials available in the state; and

440 (d) Creating opportunities for the state's academic cancer
 441 centers to collaborate with community-based oncologists in cancer
 442 clinical trials networks.

443 (3) Efforts to reduce the impact of cancer on disparate
 444 groups by:

445 (a) Identifying those cancers that disproportionately
 446 impact certain demographic groups; and

447 (b) Building collaborations designed to reduce health
 448 disparities as they relate to cancer.

449 Section 7. Subsections (8) and (12) of section 381.98,
 450 Florida Statutes, are amended to read:

451 381.98 The Florida Public Health Foundation, Inc. ;
 452 establishment; purpose; mission; duties; board of directors.--

453 (8) The corporation, in consultation with the Department of
 454 Health ~~and the Florida Center for Universal Research to Eradicate~~
 455 ~~Disease~~, shall facilitate communication between biomedical
 456 researchers and health care providers each month according to the
 457 health awareness schedule established by the Florida Public

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458 Health Foundation, Inc., in order to ensure ongoing dialogue
459 between researchers, treatment providers, and the department.

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

465 Section 8. Sections 381.855 and 381.922, Florida Statutes,
466 are repealed.

467 Section 9. This act shall take effect July 1, 2007.