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Committee on Health Regulation

BIOMEDICAL RESEARCH PROGRAMS - PERFORMANCE, OUTCOMES, AND FINANCIAL MANAGEMENT

Issue Description

In 2006, legislation was enacted to provide funding to support grants for biomedical research in this state. It was anticipated that sustained funding for biomedical research over a period of years would lead to an alleviation of human suffering from diseases such as cancer and Alzheimer's disease. The Legislature intended to dramatically reduce Florida's inordinately high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in Florida, making this state a world-class leader in cancer research and treatment. The Legislature further intended to stimulate economic development, particularly in the biotechnology industry, through investment in this state's biomedical research.

Accordingly, the Legislature established the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program) and enhanced funding for the existing James and Esther King Biomedical Research Program (King Program). The 2006 Legislature required a review of the performance, outcomes, and financial management of these two programs during the 2010 Regular Session of the Legislature. The 2010 Legislature will determine the most appropriate funding source and means of funding these programs. The statutes establishing these two programs expire January 1, 2011, unless reviewed and reenacted by the Legislature before that date.

Background

The James and Esther King Biomedical Research Program

The Florida Legislature created the Florida Biomedical Research Program in 1999 within the Department of Health (the DOH). The Florida Biomedical Research Program was renamed the James and Esther King Biomedical Research Program during Special Session B of the 2003 Legislature.

The purpose of the King Program is to provide an annual and perpetual source of funding to support research initiatives that address the health problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.¹ The long-term goals of the program are to:

- Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease.
- 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.
- Improve the quality of the state's academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers.
- 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.
- Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

The King Program offers competitive grants to researchers throughout Florida to fulfill its goals. Grant applications from any university or established research institute² in this state will be considered for biomedical

¹ s. 215.5602, F.S.

research funding under the King Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.³

The State Surgeon General, after consultation with the Biomedical Research Advisory Council (the Advisory Council), is authorized to award grants and fellowships on the basis of scientific merit⁴ within the following three categories:

- Investigator-initiated research grants, which are designed to initiate research that can be subsequently funded from a national agency,
- Institutional research grants, which are intended to foster the development of new and promising research investigators so that they can undertake more independent research that would be competitive for national research funding as well as to attract talented researchers to Florida institutions, and
- Predoctoral and postdoctoral research fellowships.⁵

Within these three categories of grants, the following grant mechanisms have been offered at various times:⁶

- Bridge Grant (offered in 2007 – 2009). This is a 1-year grant of up to \$200,000 to provide interim support for promising tobacco-related research projects that have been highly rated by national panels of scientific peer reviewers in recent federal competitions, but not funded due to budgetary constraints. Researchers use the Bridge period to collect preliminary data and improve their national applications based on peer review feedback. At the conclusion of the Bridge Grant, the researcher must submit a revised application to the federal funding agency that denied funding on the first submission;
- Investigator-Initiated Research Grant (offered in 2001). This grant was available for up to 25 months in the total amount of \$400,000;
- New Investigator Research Grants (offered in 2001, and each year from 2004 – 2009). This 3-year grant of up to \$450,000 fosters development of new Florida-based investigators by helping them undertake independent research that promises to become competitive for national research funding. Projects are conducted under the mentorship of a senior investigator. Proposals must address an important biomedical or behavioral problem relevant to tobacco-related disease;
- Small Business Technology Transfer Grant (offered in each year from 2003 – 2006, and 2008, and renamed Technology Transfer/Commercialization Partnership Grant for 2009). This is a 1-year grant that ranges from \$50,000 to \$100,000 to help biomedical researchers at Florida universities or research institutions collaborate with Florida-based small businesses to initiate private sector commercialization of technology or fund efforts towards technology transfer. One objective is to establish the scientific merit and feasibility of the proposed research and development efforts so that the project may become competitive for further industry investment or national-level development funding. In 2009, the grant could be used to develop training materials for the dissemination of new and novel practices or treatments resulting from the research. It is expected that products and techniques resulting from these grants will be tested and commercialized in Florida; and
- Team Science Program Grant (offered in each year from 2004 – 2009). This is a \$1 million grant for 2 years. It requires recipient institutions to provide a minimum of 25 percent in matching funds. The purpose of the

² An established research institute is any Florida non-profit or foreign non-profit corporation covered under Chapter 617, F.S., with a physical location in Florida, whose stated purpose and power is scientific, biomedical or biotechnological research or development and is legally registered with the Florida Department of State, Division of Corporations. This includes federal government and non-profit medical and surgical hospitals, including veterans administration hospitals. See the Call for Grant Applications 2009-2010, page 7, available at:

<http://forms.floridabiomed.com/jek_call/King%20Call%2009-10.pdf> (Last visited on August 18, 2009).

³ Grant award recipients have included the following institutions or investigators associated with these institutions: University of Miami (UM), University of Florida (UF), H. Lee Moffitt Cancer Center & Research Institute (Moffitt Cancer Center), University of Central Florida (UCF), M.D. Anderson Cancer Center, University of South Florida (USF), Florida State University (FSU), Roskamp Institute, Mayo Clinic, Florida Atlantic University (FAU), The Scripps Research Institute, Bay Pines VA Healthcare System, Florida Institute of Technology, and Nemours Children's Clinic.

⁴ See the Grant Application and Processing section of this report for more information about assessing scientific merit.

⁵ The DOH staff indicated that funding constraints have limited awarding fellowships. However, it is anticipated that fellowships may be available in the near future as a result of the infusion of funding to the King Program.

⁶ See the King Program Annual Reports, available at: <http://www.floridabiomed.com/annual_other.html#annualreports> (Last visited on August 18, 2009).

Team Science Program grant is to provide support for broad-based, often multidisciplinary research programs with well-defined major objectives or themes addressing the prevention, diagnosis, treatment, or cure of tobacco-related disease that will result in an application at the national level to continue the research program over the long term. A project under this grant generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of the overall objective. The grants consist of at least three, but no more than five, interrelated yet individual research projects that are directed toward well-defined research program goals.

The William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program

The Bankhead-Coley Program was created in 2006 by the Florida Legislature within the DOH.⁷ The purpose of the Bankhead-Coley Program is to advance progress toward cures for cancer through grants awarded for cancer research.

The research funded under the Bankhead-Coley Program is intended to emphasize the goals of the Florida Cancer Council⁸ as those goals support the advancement of cures for cancer. The Florida Cancer Council was established in 2004 within the DOH for the purpose of making the state a center of excellence for cancer research. The duties of the Florida Cancer Council include:

- Efforts to significantly expand cancer research capacity in the state by:
 - Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state;
 - Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
 - Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
 - Encouraging the employment of bioinformatics⁹ in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;
 - Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
 - Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research;
- Efforts to improve both research and treatment through greater participation in clinical trials networks by:
 - Identifying ways to increase adult enrollment in cancer clinical trials;
 - Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
 - Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and
 - Creating opportunities for the state’s academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks; and
- Efforts to reduce the impact of cancer on disparate groups by:
 - Identifying those cancers that disproportionately impact certain demographic groups; and
 - Building collaborations designed to reduce health disparities as they relate to cancer.

Applications for funding cancer research from any university or established research institute in the state will be considered under the Bankhead-Coley Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.¹⁰ Proposals that foster

⁷ s. 381.922, F.S., (Ch. 2006-182, L.O.F.).

⁸ See ss. 381.92 and 381.921, F.S.

⁹ Bioinformatics includes using computers to collect and analyze biochemical and biological information, especially related to molecular genetics and genomics. See <<http://www.merriam-webster.com/dictionary>> (Last visited on August 24, 2009).

¹⁰ Grant award recipients have included the following institutions or investigators associated with these institutions: UM, UF, Moffitt Cancer Center, Florida International University, FAU, USF, M.D. Anderson Cancer Center, FSU, Mayo Clinic, Florida Institute of Technology, UCF, Florida Hospital Cancer Institute, and The Scripps Research Institute.

collaboration 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, may be given preference for grant awards. The State Surgeon General, after consultation with the Advisory Council, is authorized to award grants and fellowships on the basis of scientific merit¹¹ within the following three categories:

- Investigator-initiated research grants,
- Institutional research grants, and
- Collaborative research grants, including those that advance the finding of cures through basic or applied research.

Funded projects began in January, 2007, with two grant mechanisms that could be deployed within an accelerated timeframe. The Bridge Grant provided interim support for promising cancer-related, investigator-initiated research projects that had been highly rated by national panels of peer reviewers in recent federal competitions, but not funded due to budgetary constraints. The second mechanism, the Shared Instrument Grants, supported Florida investigators who were conducting cancer-related research by improving access to state-of-the-art research instruments that can only be justified on a shared-use basis and for which meritorious cancer research projects were identified. Currently, the four grant mechanisms offered include:¹²

- Bridge Grants;
- Clinical Research Planning Grants, which are 1-year grants intended to increase the likelihood of success in research projects involving clinical investigations (clinical trials) of new drugs, biologics, and devices intended for licensure by the Food and Drug Administration, and behavioral studies;
- New Investigator Research Grants, which foster development of new investigators so that they can undertake independent research that will be competitive for national research funding. A senior researcher serves as a mentor, and projects must address an important cancer biomedical or behavioral problem;
- Specialized Programs of Research Excellence (SPORE) Planning Grants, which are designed to assemble and prepare strong interdisciplinary teams of Florida researchers to plan and compete successfully for National Cancer Institute (NCI) SPORE grants. Teams collect preliminary data and conduct and translate basic research findings from the laboratory to a clinical setting. These grants may provide support for up to 3 years and require recipient institutions to provide a minimum of 25 percent in matching funds.

Program Funding

Initially, the King Program was funded with income from \$150 million of principal in the Lawton Chiles Endowment Fund.¹³ In 2004, the Legislature appropriated additional funding, through a distribution from alcoholic beverage surcharge taxes. In 2006, the Legislature substituted a six million dollar annual appropriation commitment from the General Revenue Fund to fund the Biomedical Research Trust Fund within the DOH for purposes of the King Program.¹⁴ However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the King Program was reduced to \$4.5 million.¹⁵ During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed \$25 million, was to be transferred into the Biomedical Research Trust Fund for the King Program for the 2009-2010 fiscal year.¹⁶ Of the funds appropriated for the King Program, up to \$250,000 per year is designated to operate the Florida Center for Universal Research to Eradicate Disease.¹⁷

¹¹ *Ibid* 4.

¹² Bankhead-Coley Program 2008 Annual Report.

¹³ s. 215.5601, F.S. The Lawton Chiles Endowment Fund's principal originated from a portion of the state settlement received from its lawsuit with tobacco companies.

¹⁴ Ch. 2006-182, Laws of Florida (L.O.F.).

¹⁵ Ch. 2009-5, L.O.F.

¹⁶ Ch. 2009-58, L.O.F.

¹⁷ The purpose of the Florida Center for Universal Research to Eradicate Disease is to coordinate, improve, expand, and monitor all biomedical research programs within the state; facilitate funding opportunities; and foster improved technology transfer or research findings into clinical trials and widespread public use. See s. 381.855, F.S.

The Bankhead-Coley Program was established with a commitment for an appropriation of \$9 million per year from the General Revenue Fund.¹⁸ However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the Bankhead-Coley Program was reduced to \$6.75 million.¹⁹ During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed \$25 million, was to be transferred into the Biomedical Research Trust Fund for the Bankhead-Coley Program.²⁰

Any cash balance in the Biomedical Research Trust Fund at the end of a fiscal year remains in the trust fund to be available for carrying out the purposes of the trust fund. In addition, any balance of an appropriation from the Biomedical Research Trust Fund which has not been disbursed, but which is obligated, may be used for up to three years from the effective date of the original appropriation.

Biomedical Research Advisory Council²¹ and Peer Review Panel²²

The purpose of the Advisory Council is to advise the State Surgeon General as to the direction and scope of the King Program. The Advisory Council is also required to consult with the State Surgeon General concerning grant awards for cancer research through the Bankhead-Coley Program.²³ The responsibilities of the 11-member²⁴ Advisory Council include, but are not limited to:

- Providing advice on the program priorities and emphases;
- Providing advice on the overall program budget;
- Participating in periodic program evaluation;
- Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the King Program;
- Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials;
- Developing criteria and standards for the award of research grants;
- Developing administrative procedures relating to solicitation, review, and award of research grants and fellowships, to ensure an impartial, high-quality peer review system;
- Developing and supervising research peer review panels;
- Reviewing reports of peer review panels and making recommendations for research grants and fellowships; and
- Developing and providing oversight regarding mechanisms for the dissemination of research results.

In order to ensure that proposals for research funding within the King Program and the Bankhead-Coley Program are appropriate and evaluated fairly on the basis of scientific merit, a peer review panel of independent, scientifically qualified individuals is appointed to review the scientific content of each proposal to establish a [scientific]²⁵ priority score.²⁶ To eliminate conflicts of interest, peer reviewers come from outside the state of Florida. Reviewers are experts in their fields from universities, government agencies, and private industry who are matched according to application topic and area of expertise. The priority scores must be considered by the

¹⁸ s. 381.922(5), F.S.

¹⁹ Ch. 2009-5, L.O.F.

²⁰ Ch. 2009-58, L.O.F.

²¹ s. 215.5602(3), F.S.

²² s. 215.5602(6) and (7), and s. 381.922(3)(b), F.S.

²³ s. 381.922(3)(a), F.S. However, s. 215.5602(11), F.S., contains an inconsistency with respect to the responsibility of the Advisory Council concerning awarding grants for cancer research.

²⁴ Three members of the Advisory Council are designated in statute, with the Governor, President of the Senate, and Speaker of the House of Representatives appointing the remaining members. See s. 215.5602(3), F.S.

²⁵ The King Program requires a *scientific* priority score in s. 215.5602(6), F.S. The Bankhead-Coley Program requires a priority score in s. 381.922(3)(b), F.S.

²⁶ A Bridge Grant application is ranked solely by the priority score or percentile assigned to its qualifying federal proposal in an eligible federal review process.

Advisory Committee in determining which proposals will be recommended for funding to the State Surgeon General.

Both the Advisory Council and the peer review committee are required to follow rigorous guidelines for ethical conduct and to adhere to a strict policy concerning conflicts of interest. A member of the Advisory Council or peer review panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body, or as an employee, or with which the member has entered into a contractual arrangement.

Meetings of the Advisory Council and the peer review panel are subject to chapter 119, F.S., relating to public records; s. 286.011, F.S., relating to public meetings; and s. 24, Article I of the State Constitution relating to access to public meetings and records.

Findings and/or Conclusions

Program Administration and Grant Management

Administration

The Office of Public Health Research within the DOH manages both the King Program and the Bankhead-Coley Program with support from the Advisory Council and Lytmos Group, LLC (Lytmos), pursuant to contract. The administration of the program has continually evolved and become more comprehensive throughout the years. Initially, a program manager, a grant manager, and a technical consultant staffed the King Program.²⁷ In 2004, Lytmos was retained to administer the King Program.²⁸ The contract with Lytmos was renewed in 2007 for an additional 3-year period, subject to the availability of funds. To the extent possible, the King Program and the Bankhead-Coley Program are administered in parallel.

Administrative expenses may not exceed 15 percent of the total funds available to the King Program in any year. Administrative expenses have ranged from 5 percent in fiscal years 2001-2002 through 2003-2004 to 11 percent in fiscal year 2007-2008 for an average of 7.3 percent.²⁹ Up to 10 percent of the appropriated funds for the Bankhead-Coley Program may be used for administrative expenses. Since its inception, administrative expenses have averaged 8.6 percent per year.³⁰ The money that was available for administrative costs which was not used for that purpose has been redirected for additional direct research project support.

The Office of Public Health Research and the Lytmos are jointly responsible for:

- Program planning and development. This involves funding cycle and call³¹ preparation, researching grant programs and initiatives, developing and refining the two programs' policies and procedures, and creating program materials;
- Application processing;
- Scientific peer review management. This includes recruiting reviewers, making panel and review assignments, and developing evaluation materials;
- Decision support. This entails analyzing and reporting on competition statistics and data, providing funding decision aids, and providing direct support to the Advisory Council;
- Applicant and grantee support. This includes providing ongoing program and technical support from application through project work to grant completion and close out;
- Administrative and programmatic monitoring. This includes: evaluating and monitoring financial reports and budget changes; reviewing scientific and technical progress reports and conducting site visits with the

²⁷ Florida Biomedical Research Program Annual Report dated February 1, 2003.

²⁸ Lytmos provides consulting, business, and technology solutions for grant-making entities. See: <http://www.lytmos.com/index.asp> (Last visited on August 18, 2009).

²⁹ The King Program 2008 Annual Report.

³⁰ *Ibid* 12.

³¹ The Call for Grant Applications outlines, among other things, the technical and administrative requirements associated with a grant application, identifies allowed and disallowed costs, general eligibility criteria, and the specific grant mechanism's eligibility criteria.

assistance of scientific peer reviewers to monitor scientific progress against the research aims; processing project protocol change requests; ensuring compliance with human and animal use assurances, if applicable; financial and scientific overlap monitoring;³² and processing continuation and no-cost extension requests;

- Program evaluation and improvements. This involves ongoing monitoring and implementation of process and performance enhancements, strategic planning, working with the Advisory Council to compare the programs against benchmarks, such as federal granting policies and procedures, and reviewing and updating long-term goals; and
- Technical support, which includes managing the automated application process, grant management systems support, grantee technical assistance, and website development and maintenance. Both programs are essentially fully automated.

The law authorizes, but does not require, the DOH, after consultation with the Advisory Council, to adopt rules as necessary to implement these programs.³³ The DOH has not adopted rules to implement these programs. Instead, the DOH publishes, on its website, the procedures for implementing these two programs.³⁴ The Joint Administrative Procedures Committee recently contacted the DOH concerning unadopted rulemaking.³⁵

Grant Application Review and Processing

Grant applications are required to be submitted through the online application system. Each timely-submitted application undergoes a preliminary administrative review to verify mandatory eligibility requirements and the completeness of the application. Peer reviewers assess the scientific merit of applications, using a standard rating format, in addition to providing comments on the project proposal. Three to seven independent peer reviewers are assigned to eligible applications. During the review process, reviewers are not able to see critiques by the other reviewers assigned to the same application. For most grant mechanisms, the high and low scientific merit scores are dropped. Peer reviewers rate the proposals for scientific merit for the following criteria:

- Scientific and technical quality of the proposed project or activity;
- Significance, approach, and feasibility of the research plan;
- Qualifications of the principal investigator to carry out the proposed project;
- Available resources and environment;
- Relationship of the project to either the advancement toward prevention, diagnosis, treatment, and cure of tobacco-related diseases for the King Program or the search for prevention, diagnoses, treatment, and cures of cancer for the Bankhead-Coley Program; and
- Conditions required for the particular grant mechanism.

The Advisory Council considers the results of the peer review in a manner that is blind to the identity of the investigator and institutional identities. Advisory Council members may take into account other programmatic interests, such as the balance of support among grant mechanisms and the availability of funds, in forming a set of funding recommendations to the State Surgeon General.

All funding decisions of the State Surgeon General are final. However, applicants may request a re-consideration pursuant to a written statement outlining the substantive concern and basis for the concern. Applications are classified either as funded, fundable but unfunded, or unfundable. Re-consideration may position the proposal into a more highly ranked classification in the event that additional funding becomes available.

Grantee Oversight

The *GrantEase*TM online system is used by grantees to access grant information and submit progress reports, invoices, financial reports, and change requests during the life of the grant. At least once during the grant period,

³² A project that is the subject of a grant application may not duplicate or significantly overlap, scientifically or financially, with other research projects in which the applicant is involved. Overlap, whether scientific, financial, or commitment of a project member's effort greater than 100 percent, is not permitted. Financial overlap occurs when duplicate or equivalent budget items are requested in an application but are already funded or provided for by another source. The research must not overlap with any research conducted by a New Investigator Research mentor.

³³ s. 215.5602(9), F.S.

³⁴ See: <<http://www.doh.state.fl.us/ExecStaff/biomed/ophrsitemap.html>>, (Last visited on August 18, 2009).

³⁵ Correspondence from the Joint Administrative Procedures Committee to the State Surgeon General dated August 6, 2009.

the grantee is subjected to on-site monitoring for both scientific and administrative purposes. Grants have a fixed payment schedule based on documented progress. Grantees must return to the DOH any overpayment of grant funds related to disallowed expenditures, funds unaccounted for due to non-submission of required deliverables, or other unused grant funds at the end of the grant period. Payment of the final invoice for a grant will occur after the end of the grant period once all required documentation and deliverables have been received and approved.

The DOH requires that a grantee agree to and comply with certain legally enforceable terms and conditions in order to receive and maintain grant awards. In addition to provisions related to deliverables, fiscal accountability, monitoring, and recordkeeping, the DOH manages these programs in accordance with the policies and procedures employed by the National Institutes of Health. With respect to provisions that apply to intellectual property, patent rights, inventions, and commercialization, the agreement provides that the DOH has a fully paid up, non-exclusive, non-transferable, irrevocable license to practice, have practiced, use or have used, the invention for or on behalf of the State of Florida.³⁶

Dedicated Funding Source

Chapter 2009-58, Laws of Florida, provided that 5 percent of the revenue deposited into the Health Care Trust Fund pursuant to s. 210.011(9), F.S., related to the cigarette surcharge and s. 210.276(7), F.S., related to the surcharge on tobacco products, are to be reserved for research of tobacco-related or cancer-related illnesses. The sum of the revenue reserved, however, may not exceed \$50 million in any fiscal year. The Legislature did not specify an amount to be appropriated annually, after the 2009-2010 fiscal year, for the King Program or the Bankhead-Coley Program from these reserves.

Outcomes

Currently, there are 64 active grants under the King Program, totaling \$26,630,590 and 63 active grants under the Bankhead-Coley Program, totaling \$20,791,024. This includes a total of 59 grants awarded to date for fiscal year 2009-2010.³⁷

One of the goals of the King Program and the Bankhead-Coley Program is to position Florida researchers for access to other external funding mechanisms to support their scientific work. Since the King Program's inception in 2001, additional external awards totaling \$90.4 million have been reported by the King Program grantees; with \$44.6 million reported by grantees for 2008.³⁸ By the end of 2008, Florida's total investment of \$27 million in the Bankhead-Coley Program has helped Bankhead-Coley grantees attract an additional \$29 million in funding into the state.³⁹

Presentations to colleagues at scientific seminars or conferences and publications in peer-reviewed journals are key indicators of contributions to the foundation of knowledge. Since 2001, grantees in the King Program have published cumulatively at least 310 peer-reviewed journal articles and book chapters, many of which were published in highly-rated journals.⁴⁰ In addition, grantees in the King Program have presented on their research a cumulative total of 646 times.⁴¹ The Bankhead-Coley Program grantees have 54 cumulative publications in peer-reviewed journals and have presented at 87 professional meetings.⁴²

Since 2001, the King Program grants have produced 31 patents filed, three of which were issued, and an additional 16 patents or inventions are planned or have been disclosed. At least five grants have lead to the creation of five new companies that created at least 45 new jobs. A study on the economic impact of research

³⁶ Florida Biomedical Research Programs: James and Esther King Biomedical Research Program and Bankhead-Coley Cancer Research Program Terms and Conditions.

³⁷ Statistics received from the DOH Office of Public Health Research on July 22, 2009.

³⁸ *Ibid* 29.

³⁹ *Ibid* 12.

⁴⁰ Journals are rated or ranked according to an "impact factor" that is based on the number of professionals reading the journal on a regular basis.

⁴¹ *Ibid* 29.

⁴² *Ibid* 12.

throughout Florida's higher education institutions reported that for every dollar invested by the state, an increase in Gross Regional Product of \$10.89 results.⁴³

The King Program and the Bankhead-Coley Program have received the National Cancer Institute (NCI) designation as a funding organization with approved peer review and funding systems. This designation means that institutions can include cancer-related program awards⁴⁴ in the required research base for Cancer Center Support Grants and the NCI Cancer Center designation. Currently, the Moffitt Cancer Center and the Mayo Clinic in Jacksonville are designated Comprehensive Cancer Centers in Florida. When an institution earns the NCI designation as a Cancer Center, it is better able to: recruit talented scientists; improve the quality, quantity, and location for cancer patient treatment; promote collaboration of researchers with other institutions and industry; increase the number of local clinical trials; engage in prevention studies; expand treatment to underserved populations; and boost the regional economy through more grant money, more industry and biotechnology, and more high-paying jobs.

In addition, Florida academic healthcare providers are also benefiting from these programs. For example, both Ph.D. and M.D. investigators teach classes in medical schools, guide graduate and undergraduate research projects, and mentor students who will become the next generation of physicians and researchers.

Recommendations

Senate professional staff recommends that the Legislature re-enact the King Program and the Bankhead-Coley Program. These programs are achieving the goals established in statute and are benefiting the state in a variety of tangible and intangible ways. Specifically, the King Program is leveraging research funding in the state for improvement of tobacco-related health conditions, expanding the foundation of biomedical knowledge, improving the quality of the state's academic health centers, increasing the state's per capita funding for research, and stimulating the economy. The Bankhead-Coley Program is expanding cancer research capacity in this state, improving research and treatment through clinical trials, and undertaking activities to reduce the impact of cancer on disparate groups.

The 2009 Legislature identified a recurring source of funding for these two programs that will provide stability and solidify the state's commitment to invest in biomedical research. This will enhance Florida's competitive position for external funding opportunities and attracting additional biomedical and biotechnology industry to the state.

In addition, Senate professional staff recommends:

- Amending s. 215.5602(3), F.S., to stagger the terms of the Biomedical Research Advisory Council members to maintain continuity in institutional knowledge and to comply with s. 20.052(4)(c), F.S.^{45 46}
- That the Legislature consider providing specific authorization for the King Program and the Bankhead-Coley Program to receive unrestricted donations from public or private sources to further the goals of the two programs.
- Amending s. 215.5602(11), F.S., to clarify that the role of the Advisory Council is to recommend grant awards to the State Surgeon General rather than to make the grant award, which contradicts other provisions of law.
- Amending s. 215.5602, F.S., and s. 381.922, F.S., to require the DOH, after consultation with the Advisory Council, to adopt rules, as necessary, to implement the programs.

⁴³ Ibid 34, citing: Lynch T, Harrington J, Doyle C. *The Economic Impact and Benefit to Cost Ratio of Public and Private Higher Education Research in Florida*, Leadership Board for Applied Research and Public Services at Florida State University, Tallahassee, 2005.

⁴⁴ Shared Instrument Grants cannot be included.

⁴⁵ Section 20.052(4)(c), F.S., requires the members of an advisory body to be appointed for 4-year staggered terms, unless expressly provided otherwise in the State Constitution.

⁴⁶ Recommendation for Policy Change in the King Program 2006 Annual Report.