



Health Care Appropriations Subcommittee

November 17, 2015
1:00 PM – 3:00 PM
Webster Hall (212 Knott)

Meeting Packet



The Florida House of Representatives

Appropriations Committee

Health Care Appropriations Subcommittee

Steve Crisafulli
Speaker

Matt Hudson
Chair

November 17, 2015

AGENDA

1:00 PM – 3:00 PM

Webster Hall

- I. Call to Order/Roll Call
- II. Overview and Update of Biomedical/Alzheimer's Research and the Florida Cancer Registry

Department of Health

Dr. Celeste Philip, MD, MPH, Deputy Secretary for Health and Deputy State Health Officer for Children's Medical Services

- III. Overview and Update on the Biomedical Research Advisory Council

Biomedical Research Advisory Council

Daniel Armstrong, Ph.D, Chair

- IV. Closing/Adjourn

BIOMEDICAL RESEARCH GRANT PROGRAMS

Health Care Appropriations Subcommittee

November 17, 2015

Celeste Philip, MD, MPH

Deputy Secretary for Health

Deputy State Health Officer for Children's Medical Services

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BACKGROUND

- Lawton Chiles Endowment Fund created in 1999 (Section 215.5601 F.S.)
- \$150 million investment set-aside used for research
- Annual proceeds support research
 - *James & Esther King* Biomedical Research Program (Section 215.5602 F.S.)
 - *Bankhead-Coley* Cancer Research Program (Section 381.922 F.S.)

BIOMEDICAL RESEARCH ADVISORY COUNCIL

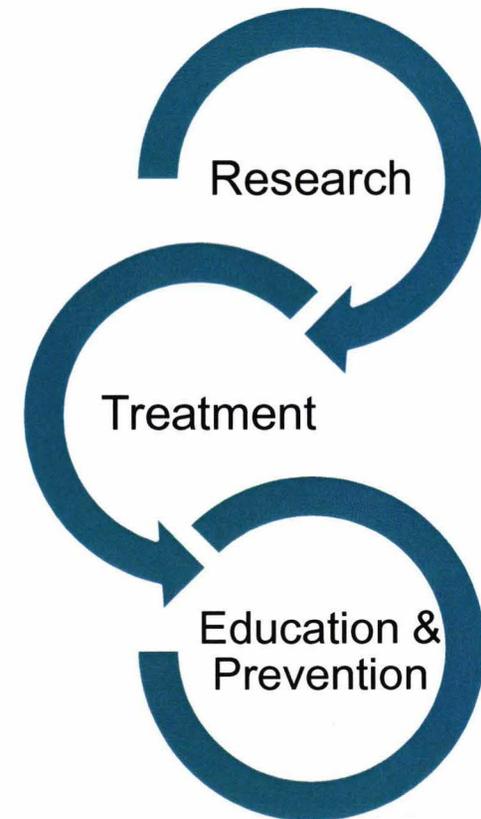
- Advises the State Surgeon General
- Membership – 3 year terms
 - Governor appoints 4 members
 - Senate President appoints 2 members
 - Speaker of the House appoints 2 members
 - American Cancer Society, American Heart Association, and the American Lung Association each appoint 1 member (appointments do not expire)
- Established Biomedical Research Agenda for State of Florida
 - Grant awards align with agenda



FL System for Cancer Research & Collaboration

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- Utilize a existing state infrastructure
 - C-CRAB, BRAC, PCAC, TAC, cancer registry, grant programs, NCI Program
- Create a state cancer research agenda
- Enhance collaborations between researchers and develop research networks
- Develop a state treatment plan and metrics to evaluate health impact of research
 - Cancer Centers of Excellence



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DIRECT APPROPRIATIONS

| | FY11/12 | FY12/13 | FY13/14 | FY14/15 | FY15/16 |
|--|---------------------|---------------------|---------------------|---------------------|---------------------|
| James and Esther King Research Program | \$7,200,000 | \$7,150,000 | \$10,000,000 | \$10,000,000 | \$10,000,000 |
| Bankhead-Coley Research Program | \$10,000,000 | \$5,500,000 | \$10,000,000 | \$10,000,000 | \$10,000,000 |
| <u>Direct Appropriations</u> | | | | | |
| McKnight Brain Institute | \$0 | \$0 | \$500,000 | \$500,000 | \$500,000 |
| Moffitt Cancer Center | \$5,000,000 | \$5,000,000 | \$7,050,000 | \$25,490,638 | \$25,160,937 |
| Shands Cancer Center | \$5,000,000 | \$7,500,000 | \$7,050,000 | \$18,509,362 | \$18,839,063 |
| Sylvester Cancer Center | \$5,000,000 | \$7,500,000 | \$7,050,000 | \$16,000,000 | \$16,000,000 |
| Sanford Burnham Medical Institute | \$0 | \$3,000,000 | \$5,600,000 | \$5,600,000 | \$0 |
| Torrey Pines Institute | \$0 | \$0 | \$3,000,000 | \$3,000,000 | \$0 |
| Vaccine and Gene Therapy Institute | \$0 | \$0 | \$0 | \$3,000,000 | \$0 |
| <u>Endowed Cancer Research</u> | | | | | |
| Moffitt Cancer Center | \$0 | \$0 | \$3,333,333 | \$0 | \$0.00 |
| Shands Cancer Center | \$0 | \$0 | \$3,333,333 | \$0 | \$0 |
| Sylvester Cancer Center | \$0 | \$0 | \$3,333,334 | \$0 | \$0 |
| Mayo Clinic Jacksonville | | | | \$2,000,000 | \$2,000,000 |
| Total | \$32,200,000 | \$35,650,000 | \$59,750,000 | \$93,600,000 | \$82,000,000 |

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CANCER RESEARCH GRANT FUNDING

- \$82 million for FY 2015-16:
 - \$10 million - tobacco-related diseases (King)
 - \$10 million – cancer (Bankhead-Coley)
 - \$60 million – Florida Consortium of National Cancer Institute-designated Cancer Centers (3)
 - \$2 million - Research Endowed Chairs (2)

GRANT AWARD PROCESS

1. Funding announced
2. Letter of Intent due from research center
3. Online system open to receive applications
4. Peer reviewers for grant applications identified
5. Application due
6. Peer review complete
7. Advisory council members meet and discuss results and make recommendations
8. Chair presents funding recommendations to State Surgeon General
9. Awards letters sent and announced through press release
10. Grants start

JAMES AND ESTHER KING BIOMEDICAL RESEARCH PROGRAM

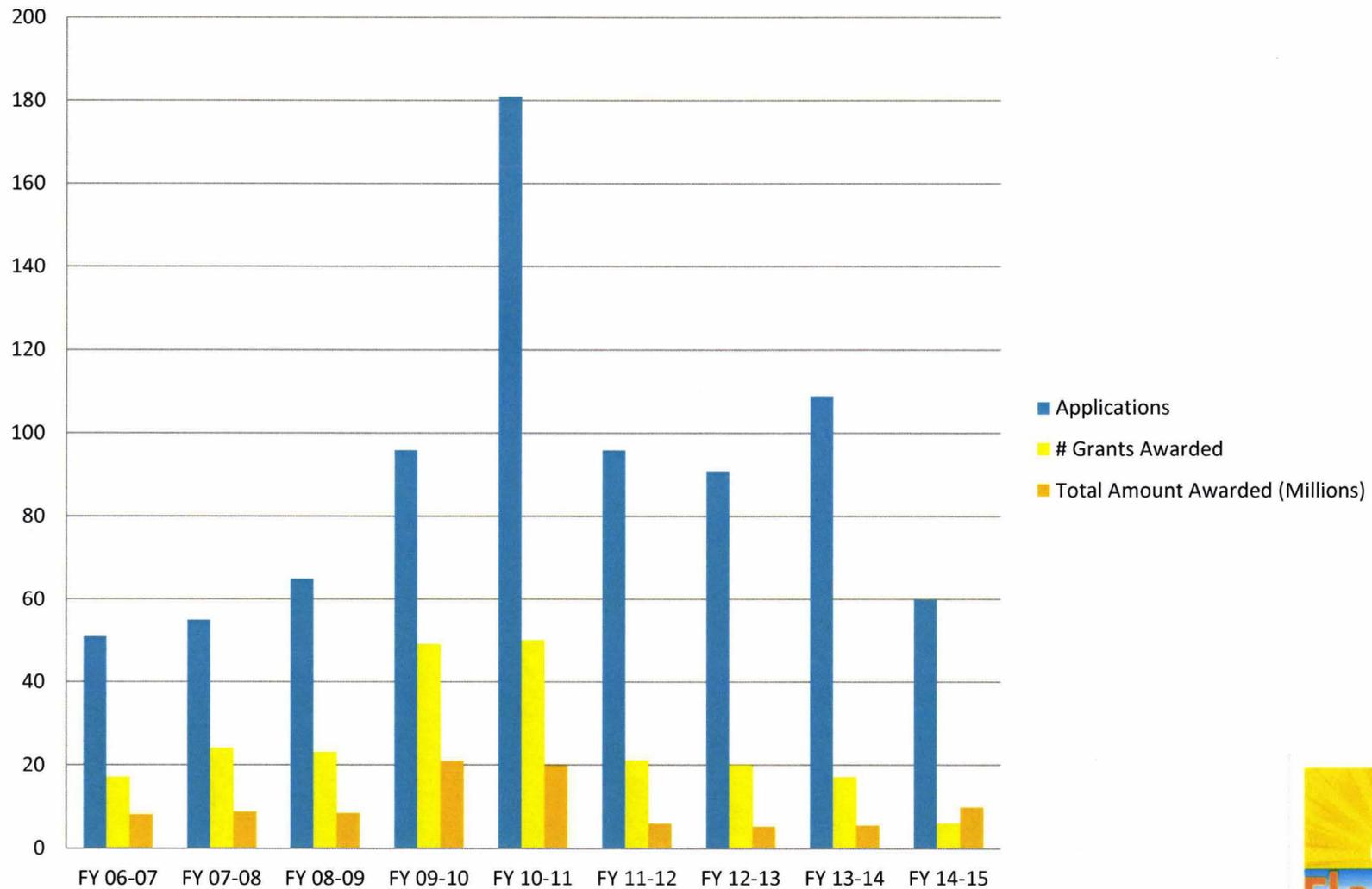
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- Priority: research to prevent and cure tobacco-related disease
- Goals:
 - Improve the health of Florida's families
 - Expand the foundation of biomedical knowledge
 - Improve the quality of the state's academic health centers
 - Increase research funding
 - Stimulate economic activity and through a statewide research network, become the premier destination for cancer care

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KING APPLICATIONS AND FUNDED PROJECTS



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BANKHEAD-COLEY CANCER RESEARCH PROGRAM

- Priority: research to cure cancer and improve treatment options

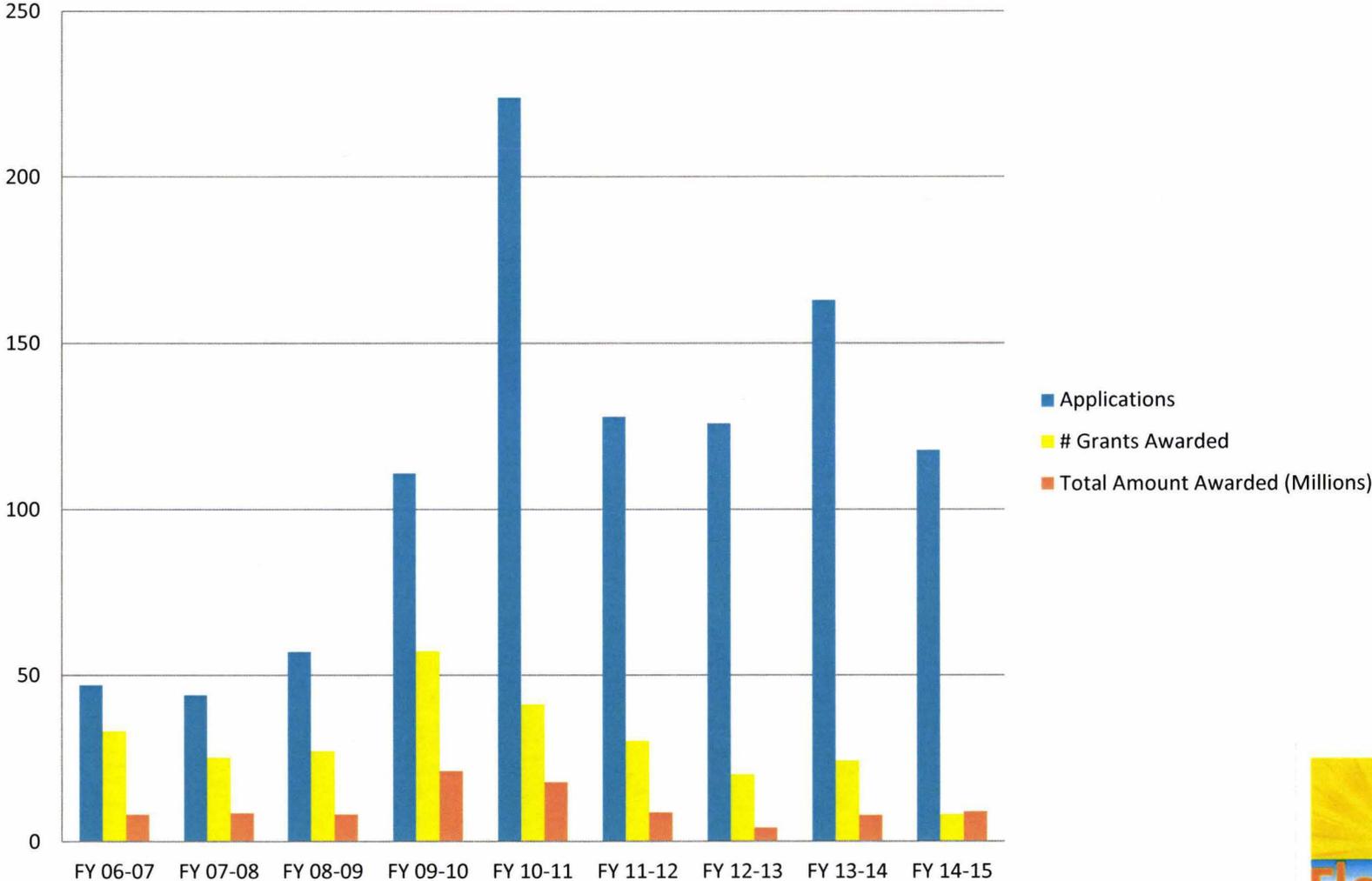
- Goals:
 - Expand cancer research capacity
 - Improve research and treatment through greater participation in clinical trials networks
 - Reduce the impact of cancer on disparate groups

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BANKHEAD-COLEY APPLICATIONS AND FUNDED PROJECTS

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GRANT FUNDING TO INSTITUTIONS SINCE 2004

| Names of Institutions That Have Been Funded | # of Grants |
|--|--------------------|
| Bay Pines VA Health Care System | 4 |
| Edward Waters College | 1 |
| Florida A&M | 1 |
| Florida Atlantic University | 9 |
| Florida Hospital Cancer Institute | 1 |
| Florida Institute of Technology | 1 |
| Florida International University | 9 |
| Florida State University | 32 |
| Haley VA Hospital | 2 |
| M.D. Anderson Cancer Center | 14 |
| Mayo Clinic | 28 |
| Miami VA | 2 |
| Moffitt | 78 |
| Nano Discovery Inc. | 1 |
| Nemours Childrens Clinic | 1 |
| Roskamp Institute | 1 |
| Saneron CCEL Therapeutics | 1 |
| Sanford-Burnham | 8 |
| The Scripps Research Institute | 4 |
| Torrey Pines Institute | 2 |
| University of Central Florida | 14 |
| University of Florida | 137 |
| University of Miami | 147 |
| University of South Florida | 41 |

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SYMPOSIUM, PATENTS AND PRESENTATIONS

- 2015:
 - Inaugural Cancer Research Symposium held at UCF on September 18th

- 2012-present:
 - 13 patents
 - 83 presentations
 - 214 published peer-reviewed journal articles

BREAST CANCERS (BEST) STUDY

- Black women: diagnosed at younger age, more aggressive breast cancer
- Total participants= 491
- Benefit to participants: Screening, genetic counseling and testing
- Disseminated results to community
- Involved Florida's cancer registry
- Follow on funding: \$903,000

INVESTIGATION OF GENETIC RISK ASSESSMENT FOR INHERITED BREAST CANCER

- New grant with focus on Hispanic population
- 1,100 participants recruited during first quarter of grant
- Goal is to improve care given to women with BRCA gene changes

ADDRESSING TOBACCO HEALTH DISPARITIES VIA GROUP INTERVENTION

- Focus on racial/ethnic minorities and cessation- 37 consenting participants have already been recruited
- Studying the effect of cognitive behavioral therapy on transdermal nicotine patches.
- Seeks to work toward eliminating disparities in quitting success

ED AND ETHEL MOORE ALZHEIMER'S DISEASE RESEARCH PROGRAM

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ED AND ETHEL MOORE ALZHEIMER'S DISEASE RESEARCH PROGRAM

- Section 381.92 *Florida Statutes* (2014)

- Peer-reviewed funding for research leading to prevention of or a cure for Alzheimer's disease
 - \$3,000,000 for FY 2014-15
 - \$3,000,000 for FY 2015-16

RESEARCH GRANT FUNDING

2014-15 ALZHEIMER'S DISEASE GRANTS

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| Institution | Grant Amount |
|-----------------------------|--------------|
| Mayo Cancer Clinic | \$ 500,000 |
| University of Miami | \$ 500,000 |
| Mayo Cancer Clinic | \$ 500,000 |
| University of Florida | \$ 250,000 |
| University of Florida | \$ 225,000 |
| University of Miami | \$ 200,000 |
| University of South Florida | \$ 200,000 |
| Mayo Cancer Clinic | \$ 200,000 |
| University of Miami | \$ 200,000 |
| University of South Florida | \$ 112,500 |
| University of South Florida | \$ 112,500 |
| Total = 11 | \$ 3,000,000 |

Grant application cycle for FY 2015-16 is currently in process.

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CANCER REGISTRY



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CANCER REGISTRY - BACKGROUND

- Florida's legislatively-mandated, statewide, population-based cancer registry
 - Section 385.202 *Florida Statutes*

- Implemented in 1981

- Incidence only registry
 - Collects information on newly diagnosed cancer cases

- Currently the second largest central registry in the country

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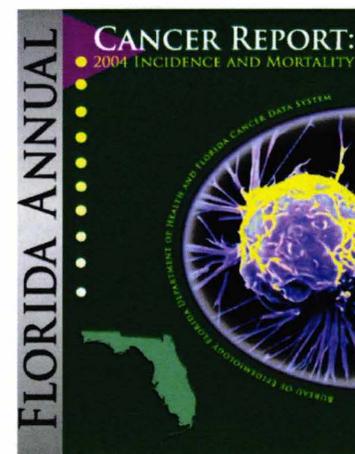
CANCER REGISTRY - SOURCES

- Cancer records from hospitals, radiation therapy centers, ambulatory surgery centers, laboratories, and dermatologists
- Link with data from Agency for Health Care Administration and Vital Statistics
- Record review/validation (23,000 ~ 11%)
- Emerging data sources
 - Reports from oncologists, hematologists, and urologists (billing claims data)
 - Physicians and electronic health record vendors (Meaningful Use Stage 2)

CANCER REGISTRY – USERS

- Local and State
 - Researchers
 - Prevention, outreach, and education programs
 - Healthcare professionals
 - Policy makers
 - Florida residents

- National and International Reports



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FLORIDA REGISTRY - QUALITY

- North American Association of Central Cancer Registries (NAACCR)
 - Gold Certification: 13 consecutive years
- Centers for Disease Control and Prevention's National Program of Cancer Registries
 - Registry of Distinction
- National certifications are based on:
 - Data Completeness: 95% threshold
 - Data Quality
 - Data Timeliness



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CANCER REGISTRY - FUNDING

- Federal (Centers for Disease Control and Prevention) and State (GR)
- Cancer cases increasing
- More diverse sources of data
- Florida Cancer Data System (FCDS) able to maintain national certifications and monitor state cancer burden as a result of
 - Automation
 - Staff Experience
- Current cost per case is \$17.34 compared to the national average of \$58.01

RISK TO FL CANCER SURVEILLANCE

- FCDS' completeness has steadily decreased over the past several years
- In 2013, data submission had lowest case completeness rate of 95.6%
- Minimum national standard for state cancer registries = 95%

RISK TO FL CANCER SURVEILLANCE

- Completeness decline attributed to patients being diagnosed and treated outside the hospital setting
 - Ambulatory surgical facilities
 - Radiation treatment centers
 - Physician offices

FCDS MODERNIZATION PROPOSAL

- **Aligns with CCRAB Priorities/Florida Cancer Plan**
 - Cancer Plan Goal 1 – Collect all cancer cases in Florida ensuring data is timely and accurate

- **FCDS Modernization Proposal**
 - Goal 1: Increase Completeness
 - Goal 2: Increase Quality
 - Goal 3: Increase Data Use

FCDS MODERNIZATION FUNDING COSTS

- To accomplish all 3 Goals
- Total first year request: \$654,150
- Subsequent years: \$600,600
- Increased cost from \$17.34 to \$22.79 per case
 - Remains a fraction of the national average of \$58.01

THANK YOU



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FLORIDA'S BIOMEDICAL RESEARCH ADVISORY COUNCIL UPDATE

November 17, 2015

Daniel Armstrong, Ph.D.

Chair, Florida Biomedical Research Advisory Council

Department of Pediatrics/Mailman Center for Child Development/Sylvester
Cancer Center

University of Miami Miller School of Medicine

And

Holtz Children's Hospital



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AFFILIATIONS AND DISCLOSURES

- Department of Pediatrics and Sylvester Cancer Center, University of Miami Miller School of Medicine



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

- Holtz Children's Hospital at UM/Jackson Memorial Medical Center



- American Cancer Society (Board and representative to the Biomedical Research Advisory Council (BRAC))



- Disclosure

- Merck Consumer Care (unrelated to this presentation)

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Biomedical Research Grants 2010-Current

| Name of Institution: | Number of Awards: | Funding Amount: |
|--|-------------------|----------------------|
| University of Miami | 64 | \$29,112,497 |
| University of Florida | 47 | \$21,247,359 |
| Moffitt Cancer Center and Research Institute | 41 | \$23,372,113 |
| Mayo Clinic | 14 | \$8,989,271 |
| University of South Florida | 10 | \$4,676,367 |
| Florida State University | 13 | \$2,835,352 |
| Florida International University | 6 | \$2,286,275 |
| University of Central Florida | 6 | \$1,913,750 |
| Sanford-Burnham Medical Research Institute | 5 | 2,054,398 |
| M.D. Anderson Cancer Center | 4 | \$1,646,693 |
| Bay VA Healthcare System | 3 | \$1,142,773 |
| Scripps Research Institute | 3 | \$1,999,600 |
| Torrey Pines Institute for Molecular Studies | 2 | \$760,000 |
| Haley VA Hospital | 2 | \$200,000 |
| Miami VA Healthcare System | 2 | \$264,450 |
| Nemours Children's Clinic | 1 | \$374,901 |
| Florida A&M University | 1 | \$100,000 |
| Total: | 224 | \$102,975,799 |

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PUBLICATIONS BY FUNDED INVESTIGATORS

- 2012-13: 86 peer reviewed
- 2013-14: 74 peer reviewed
- 2014-15: 54 peer reviewed

STATE BIOMEDICAL RESEARCH STRATEGIC GOALS

- Conduct research with a focus on prevention and improved treatment or care delivery that contributes to decreased deaths in lung cancer by **15%**, breast cancer by **15%**, prostate cancer by **20%**, colon cancer by **25%**, and melanoma by **15%** within 10 years.
- Develop research that contributes to reductions in deaths due to lung cancer by **30%**, breast cancer by **30%**, prostate cancer by **30%**, colon cancer by **30%**, and melanoma by **30%** resulting from health disparities due to race, ethnicity, or income within 10 years.

STATE BIOMEDICAL RESEARCH STRATEGIC GOALS

- Improve screening accuracy, detection of high risk subgroups, and/or improved implementation of cancer screening program that result in a **20%** increase in early detection of cancer or preventable cancer within 10 years.
- Establish at least five Investigational New Drug(IND)/Investigational Device Exemption (IDE)s based on Florida investigator drug discovery, biologic, or other therapeutics that result in at least two multi-center collaborative clinical trials within 10 years.

STATE BIOMEDICAL RESEARCH STRATEGIC GOALS

- Design research protocols that lead to academic-industry development of five new biotechnology products/companies that subsequently obtain incremental commercial funding (beyond Florida funding) within 10 years.
- Reduce tobacco use in children and adolescents to less than 4% and adults to less than 15% within 10 years.
- Enhanced understanding of the relationship between obesity, healthy weight, and cancer.

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STATE BIOMEDICAL RESEARCH STRATEGIC GOALS

- Expand upon research that improves scientific understanding of causes and subsequent impact of cancer/cancer-treatment related morbidities in other systems (e.g, cardiovascular, pulmonary, endocrine, lymphatic, CNS, reproductive, developmental).

TACTICS TO BE CONSIDERED IN IMPLEMENTATION OF STRATEGIC PLAN

- Peer-reviewed statewide outcomes tracking study. (for tracking progress on strategic goals)
- Peer-reviewed grants for shared research infrastructure (e.g., genomics, imaging, biobanks, statewide bioinformatics, health disparities research network, enhance existing clinical trials infrastructure.
- Grants for targeted investigator recruitment and training.

TACTICS TO BE CONSIDERED IN IMPLEMENTATION OF STRATEGIC PLAN (TENTATIVE)

- Grants for investigator-initiated projects with high potential impact. (e.g., discovery, new drug, prevention and cancer control, health disparities, clinical trials, health services)
- Grants for different research models. (e.g., new investigators, team science, comparative effectiveness, bridge funding, technology transfer)
- Grants that optimize public-private partnerships in discovery science and health services research.
- Grants for conferences, cancer strategic plan summit.

FOCUS OF FUNDING OPPORTUNITY ANNOUNCEMENTS SINCE STRATEGIC PLAN

| | Lung | Colon | Breast | Prostate | Melanoma | Other Cancers | Lung Disease |
|--------------------|------|-------|--------|----------|----------|---------------|--------------|
| Health Disparities | | | 1 | | | | 2 |
| Discovery | 1 | | 1 | 1 | 1 | 1 | |
| Screening | 1 | | 1 | | | | |
| Drug Development | | | | | | | 1 |
| Translational | 1 | | | | | | |
| Clinical Trial | | | | | | | 1 |
| Infrastructure | | | | | | 2 | |

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DRIVING PRINCIPLES FOR AWARDS

- Intentionally create “Critical Mass” of research to address Strategic Goals.
- Create synergy among Florida investigators to more rapidly advance progress toward Strategic Goals.
- Use the biomedical research grant program to drive collaboration between investigators across Florida’s cancer research institutions.

BRAC NEXT STEPS

- Survey all prior Bankhead-Coley and King recipients.
 - Confirm all follow-on funding for funded projects (e.g., NIH, NSF, HRSA, major foundations)
 - Identify patents, licensed products, biotech companies, etc. resulting from Florida Funding
 - Identify any breakthroughs in screening, diagnosis, or treatment resulting from Florida Funding
 - Clinical trials
 - Drugs to market, inclusion in community treatment
- Map prior progress to Strategic Plan Goals.
- Use data to determine focus of future Funding Opportunity Announcements to focus on Strategic Goals.