

**Florida Biomedical Research Advisory Council (Council)**  
**Strategic Planning Conference Call Minutes: Key**  
**Challenges to Translation – From Basic Science to T1**

October 13, 2009  
10:30 a.m. - 12:00 p.m.

Conference Call

**Council Members Present:**

Dr. Richard Bookman, Chair  
Dr. Randal Henderson  
Dr. Myra Hurt  
Dr. Sigurd Normann  
Dr. Edith Perez

Dr. Mary Lou Sole  
Dr. Herbert Weissbach, Vice-Chair

**Council Members Absent:**

Dr. Veena Antony  
Mr. Albert Latimer  
Dr. Penny Ralston

**Discussion Moderator:**

Ms. Jill Altshuler, AltshulerGray, Inc.

**Program Staff Members Present:**

Ms. Sherrie Hajek – DOH, OPHR  
Dr. Susan Phillips – DOH, OPHR  
Ms. Peggy Shults – Lytmos Group  
Mr. Chuck Wells – DOH, OPHR

**Speakers in Attendance:**

Ms. Debra Lappin, President of the Council for American Medical Innovation  
Dr. Nancy S. Sung, Senior Program Officer, Burroughs Welcome Fund

**Guests in Attendance:**

Mr. Paul Hull, American Heart Association  
Ms. Donna Lamb, Florida Hospital and Burnham Institute  
Mr. Christopher Streeter, AltshulerGray, Inc.

**Readings Distributed before this call:**

Butler, D. (2008). Crossing the valley of death. *Nature*, 453, 840-842.

Council for American Medical Innovation. (2009). Council for American Medical Innovation names Debra R. Lappin president. Retrieved from [http://www.americanmedicalinnovation.org/sites/CAMI/pdfs/20090723\\_lappin\\_president.pdf](http://www.americanmedicalinnovation.org/sites/CAMI/pdfs/20090723_lappin_president.pdf)

Khanna, N., et al. (2009). Translation of clinical research into practice: defining the clinical scientist. *Family Medicine*, 41(6), 440-443.

Kuehn, B. (2006). PhD programs adopt bench-to-bedside model to speed translational research. *JAMA*, 295(13), 1506-1507.

Lappin, Debra R., biography. Retrieved at <http://americanmedicalinnovation.org/debra-r-lappin>.

Ledford, H. (2008) The full cycle. *Nature*, 453, 843-845.

National Institutes of Health. (2009). *Decision Making in T1 Translational Research: Final Workshop Report*. Retrieved from [http://www.ncrr.nih.gov/publications/Decision\\_Making\\_in\\_T1\\_Translational\\_Research.pdf](http://www.ncrr.nih.gov/publications/Decision_Making_in_T1_Translational_Research.pdf)

Rosenberg, R. (2003). Translating biomedical research to the bedside. *JAMA*, 289(10), 1305-1306.

Sung, Nancy S, et. al. (2003) Central Challenges Facing the National Clinical Research Enterprise. *JAMA*. Vol. 289, No. 10.

Woolf, S. H., (2008). The meaning of translational research and why it matters. *JAMA*, 299(2), 211-213.

Zinner, D. & Campbell, E. (2009). Life-science research within US academic medical centers. *JAMA*, 302 (9), 969-976

**Questions to Consider (distributed before the call):**

1. It has been over six years since the publication of Sung et al. in *JAMA*, which introduced the concept of the two translational blocks. How has the framework held up/evolved since then? What is new or different since the article was published?
2. The pressure for ROI (i.e. medical innovation) in biomedical research funding is mounting. What strategies are funding organizations applying effectively to move basic science discoveries through the pipeline or to focus investments further upstream in the bench-to-bedside continuum?
  - a. What researcher behaviors (e.g. data sharing) should be incentivised and/or regulated through terms and conditions for funding?
  - b. What can the state do through funding, policy development or otherwise, to increase the chances that Florida's investments in basic science discoveries will ultimately be commercialized?
3. Biomedical research is underdeveloped in Florida compared to other large states, as reflected in substantially lower NIH funding per capita. How might this affect how best to deploy the Florida Biomedical Research Program funds for the targeted diseases, particularly vis-à-vis the blocks to translation?
  - a. Is it possible to invest strategically in basic research?
  - b. Is it possible to address T2 without a solid "installed base" of basic research? (i.e., is there a potential "leapfrog" strategy?)
  - c. What research infrastructure is necessary to successfully translate discoveries into human health benefit? Should FBRP funds be used to build this infrastructure in addition to/instead of on individual research projects?
  - d. Are there workforce issues (i.e. lack of M.D./Ph.D.s and other clinically-oriented practitioners) that can be reasonably impacted by a relatively small funding organization, and if so, over what kind of a horizon? Cultural and institutional disincentives?

**Opening Comments:**

Dr. Richard Bookman welcomed everyone to the call and turned the floor over to Jill Altshuler of AltshulerGray, Inc. who will be moderating these three strategic planning conference calls as well as the strategic planning retreat in November. Dr. Bookman disclosed that he has been working with Ms. Altshuler for a long time. This is an open meeting that is being recorded. Mr. Paul Hull will be attending the strategic planning retreat in place of Dr. Normann; he is listening on this conference call as a member of the public.

Ms. Jill Altshuler noted that the strategic planning retreat offers the opportunity for the Council to step back and think about the future of the Programs. The goal is to meet statutory goals. As preparation for the retreat, AltshulerGray will conduct a survey of Council members reflecting on progress made to date. This will also be a chance to look outside of the Council at trends within the wider research enterprise. To that end, we will have expert guests on each of the three conference calls leading up to the retreat.

For this first call, two experts have been invited to participate: Ms. Debra Lappin, President of the Council for American Medical Innovation, and Dr. Nancy S. Sung, Senior Program Officer, Burroughs Wellcome Fund.

### **Dr. Nancy Sung comments:**

Four dramatic changes in translational research landscape since JAMA paper:

- Clinical research transformed from cottage industry to major focus. Prime example is NIH CTSA grant.
  - CTSA's meant to pull all clinical resources together at an institution, provide an academic home for clinical research, and provide easier access for investigators to start human studies. Drives continuity from basic to clinical to population health.
  - Florida needs CTSA(s) to participate in this dialogue (UF has one, UM application just submitted).
  - FL should consider state-level "confederation" of CTSA's with the goal of bridging the gap between individual CTSA institutions and the national consortium. UNC-Duke held up as example of one such successful partnership.
  - FL funds can help leverage CTSA funds across all FL CTSA's (and non-CTSA institutions) and "do CTSA right".
  - CTSA institutions must develop metrics for success (e.g. more studies, more papers, leveraging additional NIH funds).
  
- Shortage of investigators – the problem persists but has evolved.
  - AAMC figuring out how to integrate training from medical school to residency to fellowship. Have pilot program within CTSA.
  - AAMC and Howard Hughes defined scientific competencies needed for medical students. Will affect MCAT review, so those coming in will be prepared to gain these competencies.
  - Shortage affects all players, not just principal investigators (PIs). However, PIs have seen most improvement in terms of programs coming online to address their numbers.
  - A new type of investigator is needed, one with clinical insight, medical training, and a bioinformatics background.
  - Neither UM nor UF has Medical Sciences Training Program (MSTP). UNC has had MSTP program for awhile, but used private money to establish track record.
    - FL funds could be used to help FL institutions establish the required track record to then leverage MSTP funding, particularly as one of the statutory goals deals with the FL academic health centers.
    - Could focus programs on niches of computational and comparative effectiveness tracks.
    - Could provide stipend support for those on training grants (similar to NIH K12 or K30 mechanisms).

- High cost and slow results of clinical research
  - Questions raised about how research is conducted: are randomized clinical trials the only way? Can we develop more rapid methods of discovery? FDA Critical Path Initiative is looking at these issues.
  - Possible partners in developing new research landscapes:
    - Pharma – blockbuster model not sustainable. Personalized medicine going to fragment markets, but could be the future.
    - Non-profit patient groups, particularly in rare diseases like cystic fibrosis and multiple myeloma.
    - Venture philanthropy
- Clinical research once faced a lack of funding – that has changed
  - CTSA's
  - Stimulus/ARRA money (over \$10 billion into NIH).
    - FL funds could help bridge the gap when stimulus monies expire in 2010, similar to bridge grant programs FL has already undertaken.
  - Venture philanthropy groups (e.g. gift matching)
  - Private foundations (though recent downturn has hurt this funding stream)

**Ms. Debra Lappin comments:**

- Infrastructure support very important to maintain clinical research in the face of enormous change.
- Adopting a more entrepreneurial / business model for clinical research is a key goal. Issues include:
  - How do we retain recruits?
  - Defining incentives to invest in medical innovation.
  - Defining the new role of academia to move medical innovations forward. Academia allows the sort of serendipitous discovery needed. How do we take basic lab ideas and apply industry milestone-based standards?
- Example: Institute for Advancing Medical Innovation - \$16M co-funded platform by Kauffman and Kansas University endowment. This sort of platform is the future. Allows industry to mentor academic scientists. Relates strongly to CTSA architecture.
- National Health Council looked at entrepreneur environment. How are we going to shore up the valley of death?
  - How do issues of wellness and lifestyle fit into the entrepreneurial model? Should FL funds be used for this sort of research since it's often under-funded (particularly with regard to effectiveness research as opposed to health delivery and service, which is funded by foundations)?
  - FL should end up with significant funds from the Sebelius prevention and wellness monies.
- How do we teach basic scientists the tools necessary to translate their discoveries?
  - Institute for Advancing Medical Innovation is addressing many of these questions.
  - Burroughs-Wellcome fund has a week-long program set up for how to run a lab.
  - Northwestern business school has put together business training program for scientists

## **Discussion: What sort of investments should FL make?**

- Infrastructure vs. research
  - One reasonable answer might be let NIH fund research and let FL funds go toward infrastructure.
    - Debra suggests 80% in infrastructure and 20% to fund projects. For projects, define targets / milestones such as 5-year path to clinical trials.
    - Nancy cautions that FL should not neglect support to individual scientists with great ideas who are not doing big science. It's the sort of funding not under CTSA's.
    - From American Cancer Society (ACS) perspective, interested in striking balance between research and helping FL build capacity and infrastructure to recruit and retain talent.
  
- Is basic research funding needed?
  - Need to pick desired impact – translational progress rests on a foundation of basic research. However, particularly in T2, it's not necessary to have a basic science engine. Basic science could be sought through collaboration.
  - Lesson from 1970s war on cancer was that a lack of basic knowledge can derail a research engine.
  - Many foundations do invest primarily in the basic arena. Therefore, clinical / translational may be the gap that needs to be filled.
  - Council should review FL basic portfolio in tobacco-related research (for King Program) to establish a baseline for where FL basic science engine stands / where more funding might be beneficial.
  
- Next steps
  - Council should discuss how this information fits in with statutory goals, using them to define some direction and boundaries.
  - Should take the current pulse of the legislature as well.
  - Using resources listed below, develop example models for how other states, academic institutions, foundations, and companies are grappling with these same issues.

## **Discussion Summary: Possible uses of FL funds**

- Collaboration
  - Create state-level “confederation” of CTSA's, filling gaps and leveraging NIH funds to “do CTSA right”
- Training and retention
  - Fund training programs to establish the track record needed to apply for MSTP funds.
    - Fits in with statutory goal regarding academic health centers
    - Could focus on niches of computational and comparative effectiveness tracks
    - Could provide stipend support for those on training grants (K12, K30)
  - Provide funds to attract / retain researchers at FL institutions
  - Provide basic scientists and labs with the tools and knowledge to translate their discoveries into the clinical arena
- Research funding
  - Create bridge funds to cover research costs once stimulus funds expire (2010)

- Fund comparative effectiveness research
- Fund research projects with industry-like milestones
- Provide research funding for scientists with great ideas who don't do "big science"

**Possible resources (contributed by Dr. Sung and Ms. Lappin):**

**T1**

Education and training

AAMC/Howard Hughes Medical Institute Scientific Foundation for Future Physicians

- Partnered to examine the natural science competencies that a graduating physician needs to practice science-based medicine

AAMC Medical School Objectives Project (MSOP)

- Designed to reach general consensus within the medical education community on the skills, attitudes, and knowledge that graduating medical students should possess.

Research

FDA Critical Path Initiative – information on developing a new model for research

<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>

Flinn Foundation

<http://www.flinn.org/>

- A privately endowed, philanthropic grantmaking organization established to improve the quality of life in Arizona to benefit future generations.

The Translational Genomics Research Institute

<http://www.tgen.org/index.cfm>

- The Translational Genomics Research Institute (TGen) is a non-profit 501(c)(3) organization focused on developing earlier diagnostics and smarter treatments.

Council for American Medical Innovation

<http://www.americanmedicalinnovation.org/>

**T2**

IOM Roundtable on Evidence-based medicine

<http://www.iom.edu/en/Activities/Quality/EBM.aspx>

Mt. Sinai Health Care Foundation

<http://www.mtsinaifoundation.org/who/index.html>

Kauffman Foundation

[http://www.kauffman.org/Section.aspx?id=Advancing\\_Innovation](http://www.kauffman.org/Section.aspx?id=Advancing_Innovation)

- Projects focusing on university innovation, commercialization, university-industry collaboration

Kansas Bioscience Authority

<http://www.kansasbioauthority.org>

Donaghue Foundation

<http://www.donaghue.org/>

**Other resources**

Georgia Research Alliance

<http://www.gra.org>

Kansas University's Institute for Advancing Medical Innovation (\$16M platform co-funded by Kauffman)

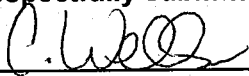
<http://www2.kumc.edu/iami/>

ARRA funds for Prevention and Wellness

**Open Discussion and Closing:**

Dr. Bookman thanked everyone for their participation and the conference call concluded at noon.

**Respectfully submitted on behalf of Dr. Richard Bookman, Chair**

 1-29-10

**Chuck Wells, Assistant Director**

**Office of Public Health Research**

**Strategic Planning Conference Call Minutes:  
T2 Dissemination / Implementation Issues and Health  
Disparities**

**Conference Call**

**Council Members Present:**

Dr. Veena Antony  
Dr. Richard Bookman, Chair  
Dr. Randal Henderson  
Mr. Albert Latimer  
Dr. Sigurd Normann  
Dr. Penny Ralston  
Dr. Mary Lou Sole  
Dr. Herbert Weissbach, Vice-Chair

**Council Members Absent:**

Dr. Myra Hurt  
Dr. Edith Perez

**Discussion Moderator:**

Ms. Jill Altshuler, AltshulerGray, Inc.

**Program Staff Members Present:**

Ms. Sherrie Hajek – DOH, OPHR  
Dr. Susan Phillips – DOH, OPHR  
Ms. Peggy Shults – Lytmos Group  
Mr. Chuck Wells – DOH, OPHR

**Speakers in Attendance:**

Ms. Cynthia Vinson, National Cancer Institute  
Dr. Jamila Rashid, Office of Minority Health,  
Health and Human Services

**Guests in Attendance:**

Mr. Mike Devine, FL CURED  
Mr. James Mosteller, American Heart Association  
Ms. Maria Serrano (for Ms. Donna Lamb), Florida  
Hospital and Burnham Institute  
Mr. Christopher Streeter, AltshulerGray, Inc.

**Readings Distributed before this call:**

Brownson, R.C., et al. (2006). Translating scientific discoveries into public health action: how can schools of public health move us forward? *Public Health Reports*, 121, 97-103.

Department of Health & Human Services. (2008) The effect of racial and ethnic discrimination/bias on health care delivery (DHHS Publication No. PA-08-083).

Eliminating Disparities in Clinical Trials (EDICT). Introduction to policy recommendations.

Fagan, P., et al. (2004). Eliminating tobacco-related health disparities: directions for future research. *Am J Public Health*, 94, 211-217.

Institute of Medicine. (2009). Report Brief: Initial national priorities for comparative effectiveness research.

National Cancer Institute. (2008). About designing for dissemination (D4D) definitions. Retrieved from <http://cancercontrol.cancer.gov/d4d/definitions.html>.

Saul, S. (2005, June 24). FDA approves a heart drug for African-Americans. *The New York Times*. Retrieved at <http://www.nytimes.com/2005/06/24/health/24drugs.html>.

Westfall, J., et al. (2007). Practice-based research-“blue highways” on the NIH roadmap. *JAMA*, 297(4), 403-406.

### **Questions to Consider (distributed before the call):**

1. What is the state of the field of dissemination and implementation science, and how is it relevant/being applied to cancer, cardiovascular disease, stroke, and pulmonary disease? How can Florida invest most strategically in this emerging field to make a difference in the quality of care delivered in the state?
2. One of the statutory goals of the King program is to “Bring advances into the training of physicians and other health care providers in Florida.” What are the ways the program can best meet that goal? What mechanisms have worked elsewhere?
3. Comparative effectiveness research has been allocated \$1.1 billion of the American Recovery and Reinvestment Act (ARRA). How can Florida best participate in these efforts, leveraging its investments in the King and Bankhead-Coley programs? (Note: goal of King program is to “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.”)
4. One of the goals of the Bankhead-Coley program is to “Identify ways to increase adult enrollment in cancer clinical trials.” What are some approaches that have worked elsewhere? How in particular to increase the participation of minority populations?
5. A goal of the Bankhead-Coley Program is to “Reduce the impact of cancer on disparate groups.” Additionally, with Florida’s diverse population, the burden of diseases related to tobacco use (King Program focus) among minority populations is high.
  - ◆ What can be done within the research infrastructure to make a difference (e.g. minority supplements to reverse under representation)?
  - ◆ Is there more that we need to know about health disparities (i.e. health disparities research agenda), particularly as it relates to Florida’s cancer and tobacco burden?
  - ◆ What have we already learned about health disparities that calls for action (i.e. translational research)?

### **Opening Comments:**

Dr. Richard Bookman welcomed everyone to the call. The focus of this call is the second translational block and beyond.

Ms. Jill Altshuler introduced the guest experts for this first call: Ms. Cynthia Vinson, National Cancer Institute, and Dr. Jamila Rashid, Office of Minority Health, Health and Human Services.

### **Ms. Cynthia Vinson comments:**

- NIH has been looking at dissemination research for last 5 years or so
  - Just finished 6<sup>th</sup> round of trans-NIH program announcement in implementation and dissemination research. Still difficult to decide what we should be focusing on / addressing.
- New program announcement by year's end – designed to help raise critical questions
  - What has to happen to go from bench to bedside to community?
  - What processes have to happen to move research into communities?
  - Touches on disparities in that research needs to be put into practice to help minorities.
- Difference between intervention vs dissemination research.
  - Dissemination research is built on intervention. Once a research team has studied an intervention / treatment and knows it's effective, it's taking that intervention and studying the mechanisms of dissemination – what has to be modified to move it into practice? It's a fine line between the two. Sometimes the intervention needs to be modified for the dissemination.
  - Dissemination studies can look at broader methods and processes, not just single intervention
  - Link between dissemination research and disparities – We realize dissemination is key to reducing health disparities – trying to make sure that interventions get put into practice is imperative to reducing disparities. Our website allows programs to be sorted by population.
  - Which of these areas can FBRP fund?
    - Could in theory run a competition asking state cancer research community to identify 5 blocks to dissemination. Could then fund dissemination research, but when that's done dissemination itself would be someone else's problem.
- Funded grants
  - Back in 2002, NCI started by funding supplements to NCI grants at \$100k
  - Grant awards now range: R01s at \$500k / yr; R21 and R13 from \$150k - \$300k
  - NIMH and NCI have funded most dissemination and intervention (DI) grants. NIHLB has funded many. Some institutes do their own DI research
  - Cynthia to provide list of all funded grant applications with abstracts
- Best grant applications exhibit a number of characteristics:
  - Established stakeholder participation
  - Include community ties
  - Team has expertise in research and dissemination
  - Strong evidence for intervention's effectiveness
  - Has strong qualitative component (e.g. sustainability)
  - Addressed a significant public health issue
- Metrics for success
  - 1<sup>st</sup> rounds of R01s are just now concluding
  - Tracking publications
  - One outcome has been dissemination / implementation meeting of OBSSR.
  - Changes in public health indicators not part of scope
- State-supported infrastructure vs research projects

- On the cancer side, trying to focus on established coalitions / networks for DI. Imperative that the state has some type of support for that.
- Dana Farber report on Cancer Control Planet re: challenges faced at local level highlighted the need to develop tools to identify evidence-based interventions and adapt them to local settings
- Cancer Control Planet
  - Check into FL plan on Cancer Control Planet website – Who in state is working with NIH on this?
- State's role in training
  - One program goal is to bring discoveries of research into training of healthcare professionals through network of Academic Health Centers (AHCs). Could states play intermediary role to AHCs?
  - We do have networks that reach out and do training. CDC also interested in DI but having state training at AHCs would be great. Our staff won't be doing as much training in future as funds have been cut.
- Optimal study design for DI research
  - Had to educate reviewers on process and stress that many applications would not include gold standard of randomized control trial.
  - Likely won't be one optimal study design – will depend on what's being disseminated.
- How do findings from dissemination research get implemented at NIH?
  - NCI has a mandate to disseminate research findings. We have to learn what has to happen to move the research into practice.
  - HHS set up such that NIH is the research enterprise and CDC is implementation arm.
- Other states as models?
  - TX is plowing forward at state level to identify and fund a research agenda. Would be an interesting group to investigate, specifically CPRIT.
  - CA has a rather big state research program.
  - UNC
  - U of Washington
  - UTMB
  - Harvard – doing MassConnect
  - UAB

**Dr. Jamila Rashid comments:**

- Our office was created in 1987 with a mission to look at health in racial / ethnic minorities and find policies to eliminate these disparities.
  - Most of our programs are on interventions – HIV, youth, ex-offenders, bi-lingual/bi-cultural, healthy baby.
- Have a very extensive database of resources for states looking to build capacity around health disparities which can be found at [www.omhrc.gov](http://www.omhrc.gov)
- Prevention and Wellness Initiative through CDC is being built with ARRA funds. This initiative is putting out the \$650M.

- Comparative Effectiveness Research (CER)
  - CER looks like it will be a growth area. Might be interesting for us to discuss at planning retreat to try and position FL to contribute to CER research and funding
  - Look at IOM recommendations to help focus on what priorities would be valuable to FL
- With disparities being such a complex program, how should Florida focus?
  - Often focus too much on race alone. Many other factors play into health disparities and it's important that we bring all these areas together – address all these problems.
- Most important thing that could be done is find ways to build a collaborative structure and not just see disparities as a health issue but rather one that includes education, housing, environment, etc.
- Youth under 30 and smoking needs more intervention study, Office of Women's Health is trying to focus in on this.

**Possible resources:**

<http://cancercontrolplanet.cancer.gov/>

<http://www.cprit.state.tx.us/>

[www.omhrc.gov](http://www.omhrc.gov)

**Open Discussion and Closing:**

Dr. Bookman thanked everyone for their participation and the conference call concluded at noon.

**Respectfully submitted on behalf of Dr. Richard Bookman, Chair**

C. Wells 1-29-10

**Chuck Wells, Assistant Director  
Office of Public Health Research**

**Florida Biomedical Research Advisory Council (Council)**

**November 3, 2009  
10:30 a.m. - 12:00 p.m.**

**Strategic Planning Conference Call Minutes:  
Models from other states and the from within the  
philanthropic community**

**Conference Call**

**Council Members Present:**

Dr. Richard Bookman, Chair  
Dr. Myra Hurt  
Dr. Sigurd Normann  
Dr. Penny Ralston  
Dr. Mary Lou Sole  
Dr. Herbert Weissbach, Vice-Chair

**Council Members Absent:**

Dr. Veena Antony  
Dr. Randal Henderson  
Mr. Albert Latimer  
Dr. Edith Perez

**Discussion Moderator:**

Ms. Jill Altshuler, AltshulerGray, Inc.

**Program Staff Members Present:**

Ms. Sherrie Hajek – DOH, OPHR  
Dr. Susan Phillips – DOH, OPHR  
Ms. Peggy Shults – Lytmos Group  
Mr. Chuck Wells – DOH, OPHR

**Speakers in Attendance:**

Ms. Kate Ahlport, Executive Director, Health Research Alliance  
Dr. Sharon Hesterlee, SVP, MDA Venture Philanthropy of the Muscular Dystrophy Association  
Dr. E. Shelton Earp, Director, UNC Lineberger Cancer Center and University Cancer Research Fund  
Dr. Robert E. McGehee, Fr., Director, Arkansas Biosciences Institute  
Dr. John P. Rosier, Director, Washington State Life Sciences Fund

**Guests in Attendance:**

Mr. Mike Devine, FL CURED  
Mr. Paul Hull, American Cancer Society  
Ms. Donna Lamb, Florida Hospital and Burnham Institute  
Mr. Christopher Streeter, AltshulerGray, Inc.

**Readings Distributed before this call:**

Arkansas Bioscience Institute. (2008). Annual Report.

DesRosier, John. (2009) Biography.

Earp, H. Shelton. Curriculum Vitae.

Hanson, S. et al. (2009) Venture philanthropy strategies to support translational research: workshop summary. Available from <http://www.nap.edu/catalog/12558.html>

Hesterlee, Sharon. Biosketch. (2008)

Life Sciences Discovery Fund. (2008). Investing in a healthy future for Washington. Retrieved from <http://www.lsdfa.org>

Life Sciences Discovery Fund. Frequently Asked Questions (FAQ) - 2009 Winter and Summer Commercialization Grants Competitions.

Life Sciences Discovery Fund. Frequently asked questions (FAQ) - LSDF 2009 Program Grant Competition.

Life Sciences Discovery Fund. Frequently asked questions (FAQ) - LSDF 2009 Project Grant Competition.

Muscular Dystrophy Association Venture Philanthropy. (2009). MVP Quarterly Update: Q2.

Muscular Dystrophy Association Venture Philanthropy. (2009). Turning research into treatments: Executive Summary. Retrieved from [http://www.mdavp.org/Business\\_Model/Executive\\_Summary.html](http://www.mdavp.org/Business_Model/Executive_Summary.html)

North Carolina Cancer Research Fund. (2009). Annual Report.

National Institutes of Health. (2006). State of the science conference statement on tobacco use: prevention, cessation, and control. *NIH Consensus and State of the Science Statements*, 23(3).

Tobacco Research Implementation Group, National Cancer Institute. (1998). Tobacco research implementation plan; priorities for tobacco research beyond the year 2000.

**Questions to Consider (distributed before the call):**

1. How have different funders approached investing in biomedical research?
  - How are investment priorities defined (strategic planning) and pursued?
  - What is the balance of spending on research “infrastructure” vs. projects?
  - What is the balance of basic vs. clinical vs. public health research?
  - What strategies do smaller funders use to leverage their dollars and make a difference within the nation’s research enterprise?
2. What can funders do to increase the likelihood that their investments will lead to improvements in human health?
  - How can funders facilitate the translation of basic science discoveries into new diagnostics/treatments and dissemination into practice?
  - How do funders measure success/impact of their investments?
3. How are funders positioning themselves to better access/leverage additional available funding (e.g, federal, philanthropic, industrial)? Is this an explicit part of the strategy?
4. How are funders addressing health disparities as part of their research agendas?
5. A goal of the Bankhead-Coley program is to “Identify ways to increase adult enrollment in cancer clinical trials.” Are other funders focusing on this?
  - What are some approaches that have worked?
6. Within the tobacco-related disease framework, where are the greatest needs? Greatest opportunities?
7. How does/should the approach taken by philanthropies to invest in biomedical research differ from government and industry?
  - What are the latest trends within philanthropies?
  - What lessons can be learned from how disease-focused philanthropic organizations have approached any/all of the above?

## **Opening Comments:**

Dr. Richard Bookman welcomed everyone to the call and yielded the floor to Ms. Jill Altshuler. This is the 3<sup>rd</sup> of three conference calls leading up to the strategic planning retreat. The 1<sup>st</sup> call focused on basic science and translational research. The 2<sup>nd</sup> call focused on the 2<sup>nd</sup> translational block and beyond. This call will look at process and strategy. We will hear from three other states and two philanthropic organizations; Dr. Rosier from Washington, Dr. McGehee from Arkansas, Dr. Earp from North Carolina, Kate Ahlport, Executive Director of the Health Research Alliance, and Dr. Sharon Hesterlee, Senior Vice President, MDA Venture Philanthropy of the Muscular Dystrophy Association.

Questions for speakers:

- Given that funding is limited, how did you approach identifying priorities / balancing spending?
- Projects vs infrastructure?
- Basic vs. clinical vs. downstream?

## **Dr. John P. Rosier, Director, Washington State Life Sciences Discovery Fund**

- Formed by state in 2005 by tobacco settlement bonus payments with a mission to improve health, foster economic development, and keep life sciences competitive.
- Board did a lot of the initial work with respect to balancing priorities.
- Focus is broader than tobacco-related but more on health and healthcare side. Goal is to make tangible return on investment.
- Program offers three types of grants
  - Program: seed launch of major new research initiatives around health or healthcare theme including both research and infrastructure; have awarded 9 so far from rural mental health to Phase I clinical cancer trial.
  - Project: range from evidence-based implementation to microfluidics. Not really basic research, more on early development side.
  - Commercialization: \$150k max award geared toward prototype development; these projects live or die on basis of commercial potential.
- Factors that contribute to award decisions
  - Categorize grants on discovery, development, delivery. Ideally, program would like to be more on delivery / true translational side.
  - Legislation allows geographical factors in making awards. Primarily, try to foster collaboration across the state. Several are in eastern, rural part of the state. Rural area also tends to be a test bed for grants in the Seattle area.
  - No specific effort to distribute funds across all state institutions
- Award granting process
  - All awards reviewed by AAAS, which comments on merits (scientific, healthcare, economic). For Commercialization awards, use local panel of business people.
  - Proposals placed into one of three rating categories – highly recommended, recommended, not recommended. Generally have more in the highest category than we have funding for.
  - 11 member board (4 legislators, 7 appointed by governor) makes final decisions.

### **Dr. Robert McGehee, Arkansas Biosciences Institute (ABI)**

- ABI is the agricultural and biomedical research arm of tobacco settlement.
- Total funding from settlement = \$70M / yr of which 23% goes to ABI (\$10-\$15M/yr).
  - ABI money is roughly equally split among 5 research-intensive universities in the state.
  - Each institution has a lot of leeway in how they use their ABI money.
- ABI board comprised of University of Arkansas president, chancellors / presidents of participating universities, and 5 legislatively-appointed members at large.
- Broad mission is to conduct biomedical research with some emphasis on tobacco-related disease; however, no strategic plan specifically targeting tobacco (Tobacco Cessation and Prevention program targets this).
  - Largest amount by far has gone to pilot studies to generate preliminary data for extramural grants (~2/3). Other 1/3 is for faculty recruitment / retention.
- Award granting process
  - RAND evaluates all programs within the tobacco settlement. They conduct annual site visits and quarterly phone conferences. Report annually back to legislature and ABI board of directors.
    - Additionally, external industry and scientific advisory board makes recommendations on projects. RAND reports are public.
  - Leverage factor for extramural money is key focus.
  - Started endowment as well.
  - Peer review done at university level.
  - Faculty recruitment decisions are largely internal to the universities. However, recruited investigators must be working in a position that will address legislative goals.

### **Dr. E. Shelton Earp, UNC University Cancer Research Fund**

- Legislation written to create a fund to be used exclusively for cancer research at UNC hospitals and UNC Lineberger Comprehensive Cancer Center.
  - Funding of \$25M in year 1, \$40M in year 2, and \$50M / year in perpetuity.
  - Finalizing strategic plan now at beginning of year three.
  - Involvement of other institutions driven solely by strategic relevance.
- Strategic planning
  - Primarily faculty driven with a lot of input from deans. Went through questionnaires, meetings, focus groups. Decided to concentrate on three tiers with the last tier being three big bets: Genetics / genomics, drug discovery and development, and optimizing cancer outcomes (public health intervention, health outcomes, comparative effectiveness). These three areas will get ~1/2 the funds. Base area is Infrastructure tier funding recruitment in clinical excellence and facilities needed to do basic and clinical research. Final piece, Opportunity Fund, funds pilot projects (internal peer review), cutting-edge technology, and recruitment.
  - Big bet areas have major projects within them, e.g. cancer survivorship cohort enrolling 10,000 patients in next 5 years to follow their clinical / treatment data. Leverage this data to write grants. These big projects will have ~\$1.5M in funding.

- Governance
  - Oversight Committee at university level chaired by dean of medical school and other deans.
  - Top-level Governance Committee chaired by President of all universities and others by statute.
- Cancer center (developed through its core grant) and CTSA are linked in certain areas.
- Clinical trials network - Hope to open 5-6 sites over the next year. Have multi-site group in Chapel Hill which will do regulatory work and auditing. Partnering with large hospital-group practices. Would support some component for research nursing, databasing, and accrual. These trials more for later Phase II-type studies.

### **Health disparities**

- **UNC UCRF** – Very large part of our center. Recruited 4 minority faculty. Second-biggest project we're funding is CBCS III, which is aimed at population-based accrual of African American women vs Caucasian women with breast cancer. Spending \$1.5M a year to do this. Also have dissemination research core.
- **Washington State** - Haven't addressed programmatically, but the board is sensitive to the issue. For us, disparities is really about urban vs rural. Have award on rural mental health – how to adapt urban protocols for rural addictions. Evidenced-based surgical award enlisting all state hospitals.
- **ABI** – Don't have programmatic things in this area either. Do have several programs that target health disparities in the Delta, minority health initiative...

### **Research Dissemination vs Dissemination Research**

- **UNC UCRF**- We believe that to do research you have to have infrastructure in the communities. Some of the UCRF and CTSA funds are funding full-time employees in regions working on two-way dialogue with communities so that when projects are designed, we'll have their enthusiasm. Very muddy issue of funding infrastructure to produce a research base. Ultimately, we're doing more dissemination than dissemination research.
- **ABI** -That's exactly what we're doing in ABI. It's a very grey area: research / dissemination / both? A lot going to T2-type research and infrastructure building.

*Having heard how state programs have approached mission, how have philanthropic orgs achieved same goals?*

**Kate Ahlport, Executive Director of the Health Research Alliance and Dr. Sharon Hesterlee, Senior Vice President, MDA Venture Philanthropy of the Muscular Dystrophy Association**

- MDA is \$180M/yr funding research across a spectrum of neuro-muscular disease. All of the diseases covered are “rare”.
- Main funding program structured like NIH extramural research granting program.
- Market factors challenged strategy on translational research – particularly small market issues.
- 4-5 years ago, we realized there was a lack of translation of research into clinical practice – needed to align our efforts with our mission of developing cures.
  - As a result, developed direct funding for industry projects and translational projects in academic settings (development and Phase I studies).
  - Funded infrastructure grants uncoupled from specific research projects (e.g. clinical research networks, antibody repository).
- Created in 2009, MDA Venture Philanthropy is next evolution targeted at industry.
  - Translational research may not be the best fit for academia.
  - Funding focused on for-profit world.
  - Funded 6 projects at biotech companies. \$15M-18M.
  - Due diligence performed by both scientific and entrepreneurial review.
- Lesson for state: where’s the handoff from academia to industry and how do you facilitate this process?
- Conflicts of interest
  - All standing committee members have to disclose board relationships, academic relationships, etc. Also, tap into very large neuro-muscular community abroad for reviews.
- Goal - By 2012 have three new drugs on the market.

### **Possible resources:**

Carroll, J. (2008). Personalized medicine: from concept to reality. *Fierce Biotech*.

The Flinn Foundation. <http://www.flinn.org/>

Florida Cancer Research Policy Summit. (2009).

National Institutes of Health (NIH) Activity Codes. Retrieved June 29, 2009 from [http://grants.nih.gov/grants/funding/ac\\_search\\_results.htm](http://grants.nih.gov/grants/funding/ac_search_results.htm)

Personalized Medicine Coalition. (2009). The case for personalized medicine.

Surgeon General’s Report on Tobacco Disease. (2004).

U.S. Department of Health and Human Services. *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Executive Summary*. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2006.

**Open Discussion and Closing:**

Dr. Bookman thanked everyone for their participation and the conference call concluded at noon.

**Respectfully submitted on behalf of Dr. Richard Bookman, Chair**

 1-29-10

**Chuck Wells, Assistant Director**

**Office of Public Health Research**