Minutes
Health Research Advisory Committee
August 24, 2015
Health and Welfare Building, Room 129
Commonwealth Avenue and Forster Street
Harrisburg, Pennsylvania

Committee Members:

Attendance in person

Karen M. Murphy, PhD, RN, Secretary of Health and Chair of the Committee, Commonwealth of Pennsylvania

Participation via teleconference

Dwight Davis, MD, Professor of Medicine and Medical Director, Cardiac Rehabilitation Program, Pennsylvania State University School of Medicine

Karen Wolk Feinstein, PhD, President and Chief Executive Officer of the Jewish Healthcare Foundation

Lewis Kuller, MD, DrPH, Professor of Epidemiology and University Professor of Public Health, Graduate School of Public Health, University of Pittsburgh

Arthur Levine, MD, Senior Vice Chancellor for Health Sciences and Dean of the School of Medicine, University of Pittsburgh

Michael Parmacek, MD, Frank Wister Thomas Professor of Medicine, Chair, Department of Medicine and Director of the Penn Cardiovascular Institute, University of Pennsylvania School of Medicine

Lisa Staiano-Coico, PhD, President, The City College of New York

Not in attendance

Kim Smith-Whitley, MD, Associate Professor of Pediatrics, Division of Hematology, The Children's Hospital of Philadelphia

Department of Health (DOH) Staff Present:

Executive Staff

Carolyn Byrnes, Special Assistant to Secretary of Health

Lauren Hughes, MD, Deputy Secretary for Health Innovation

Loren Robinson, MD, Deputy Secretary for Health Promotion and Disease Prevention

Michael Suchanick, Deputy Secretary for Administration

Legal

Keith Fickel, Esq., Senior Counsel, Office of Legal Counsel

Alison Taylor, Esq., Chief Legal Counsel, Office of Legal Counsel

CURE Program/Health Research Office Staff

Cathy Becker, MPH, Program Administrator, Health Research Office

Sylvia Golas, DMD, MPH, Program Administrator, Health Research Office

Sirisha Reddy, JD, MS, Program Manager, Health Research Office

Others in Attendance

John Anthony, Tobacco CURE Manager, Pennsylvania State University
Sarah A. Copley, Senior Associate, Greenlee Partners, LLC
Mary M. Kennan, Government Affairs, Webber Associates
Brian P. Smith, Director, Compliance, The Hospital & Healthsystem Association of Pennsylvania

Call to Order

Secretary Murphy called the meeting to order at 10:33 a.m. on Monday, August 24, 2015, in Room 129 of the Health and Welfare Building in Harrisburg, Pennsylvania. Secretary Murphy welcomed Committee members, Department of Health staff, and members of the public to the meeting. Secretary Murphy announced that the primary purpose of the meeting was to finalize research priorities for nonformula grants for the 2015-16 state fiscal year.

Minutes of the July 20, 2015 Meeting

Dr. Levine moved to accept the minutes of the meeting held on July 20, 2015. Dr. Davis seconded the motion and the motion passed.

Finalization of Research Priorities for Nonformula Funds for State Fiscal Year 2015-16

Secretary Murphy presented the issue of combining the two categories of nonformula funds. There are two funding categories in Act 77: (1) clinical research and health services research and (2) "Other research", which includes clinical research, health services research and biomedical research. If two priorities are recommended, there is more flexibility in funding proposals if these two nonformula funding categories are combined as in the past. If the categories are not combined, half of the funding must be allocated to the first category and half to the second category. Proposals submitted to the first category which only allows for clinical and health services research could not include any biomedical research. Also, if the Department did not receive enough proposals deemed worthy of funding in a category, the funds could not be used. If the two categories are combined, all of the nonformula funds can be used and all proposals can incorporate biomedical research components. In this case, at least 50 percent of the funds must be spent on clinical and health services research.

Secretary Murphy called for a motion that the two nonformula categories be combined by including these statements in the priorities: "For the purpose of priority setting, the Health Research Advisory Committee recommends combining the two nonformula funding categories of clinical and health services research and other research. At least 50 percent of the funds must be spent on clinical research and/or health services research." Dr. Parmacek made the motion as requested; Dr. Davis seconded the motion and it was passed.

Introduction to the Discussion of the Potential Nonformula Research Priorities for State Fiscal Year 2015-16

Secretary Murphy noted that the Department took the suggestions and recommendations made by the Health Research Advisory Committee for moving forward very seriously. She stated that the Department plans, with a new director of Health Services Research as well as two experts in Health Care Services Research, Dr. Robinson and Dr. Hughes, to abide by the time frame previously established, but to also have a much more active committee than perhaps in the past. Secretary Murphy further stated that the Department plans on reporting news of health services research across the country concerning how Pennsylvania is going to participate in Health Services Research for the betterment of the health of all Pennsylvanians. Secretary Murphy expressed the Department's commitment to improving the CURE program and to engaging the committee in a meaningful way. The Secretary then opened the floor for questions or comments about the information she had shared. There was no discussion by the committee on these points.

Discussion of Potential Priority Areas

Secretary Murphy turned to the discussion of possible priorities for nonformula funds. After confirming that the committee members had received all of the white papers that had been submitted, she asked the committee members to individually give feedback on the papers. Dr. Davis suggested as a process of procedure that the writers of the white papers give a two sentence comment on the papers they submitted.

Dr. Levine presented a brief overview of the Traumatic Brain Injury priority.

Traumatic Brain Injury Discussion – Dr. Davis noted that traumatic brain injury is a significant cause of falls in the frail elderly population. He also wished to add an additional bullet point for the committee's consideration for this priority: *"Developing non-subjective and quantitative imaging markers for diagnosis in longitudinal/long-term evaluation of the functional and structural changes in the brain in traumatic brain injuries during interventions/treatment."* Dr. Levine agreed.

Although Dr. Kuller concurred that traumatic brain injury and its relationship to Alzheimer's disease is a very important problem, he expressed concern that there is a very large amount of funding available ongoing right now in the area of traumatic brain injury in the United States and that given the limited amount of funds available there might be better priorities. He also stated that one of the major stumbling blocks in studying this at least in humans is imaging especially of Tau in the brain or measuring Tau or other markers in the blood. There are no markers right now in the blood that can tell you whether the injury has resulted in damaged nerves. Dr. Levine countered that although there is a lot of funding available for neuroscience research in general, there is little data that are focused narrowly on the relationship between acute traumatic brain injury and Alzheimer's disease. Dr. Kuller responded that he thought that the reason for this was that this was extraordinarily difficult to do right now because the methodology to study the problem is just evolving. Dr. Kuller further commented that in terms of understanding dementia and Alzheimer's disease in relationship to brain injury you either have to look at historical data or you have to look at data related to imaging and what's happening in the brain in relationship to Tau. He also stated that to study the relationship of brain injury to Alzheimer's disease you need both a long term longitudinal study and much better imaging which is just now evolving.

Dr. Levine stated that Dr. Kuller was hitting on a larger point which is important to all of these proposals and important to the concept of CURE which is should we or should we not use these limited funds to support anything that is supported by somebody else. Dr. Kuller responded that he was saying and other committee members had said in the past that if there is a lot of funding available from other sources that the committee should be cautious about using the Pennsylvania funds. He also stated that it had been the decision of the committee over the years that the priority of decisions was using the funds in the absence of available funds for this type of research. Dr. Kuller further stated that in reason to the lack of good studies of the relationship between brain injury and trauma and Alzheimer's disease is the fact that the future techniques to be able to separate these associations is just evolving and the longitudinal studies are going to take a long time to determine, but Dr. Kuller agreed that it is a very important problem.
Dr. Feinstein thought that the research sounded very good, but questioned how many proposals could be funded and how the amounts were determined. Dr. Murphy responded that each year the committee recommends topics and then the department selects the topic and then the requests for proposal goes out. The Department will not know the exact funding amount for 2015-16 until later in the calendar year, but believes that it will be approximately 9 to 10 million dollars. Dr. Feinstein inquired whether the committee member who writes the white paper that is selected conducts the research. Dr. Murphy responded that the institution actually receives the funding, but in the past there had been, to her understanding, committee members who have recommended topics that had researchers at their associated facilities that conducted the research. Ms. Becker clarified that once the research priority is established, then the Department issues a Request for Application to select the grantees. Dr. Parmacek further clarified that it is an open process and anybody can apply in the Commonwealth and the person that submits their proposal. Other people from their institution could apply, but there's certainly no linkage between who submitted the proposals and who applies and who receives funding. Dr. Levine pointed out that there have been circumstances in which the institution submitting the proposal did not win the grant. Dr. Parmacek concurred.
Dr. Davis asked if in the past the committee had selected two areas of funding. Dr. Levine responded yes. Dr. Kuller responded that very frequently the committee selected two areas, but there had been more money available in the past than there is now. So, now with 10 million dollars there was one priority, but in the past with 20 million dollars there were two priorities. Dr. Davis then inquired whether there was an estimate of the amount of funding available. Dr. Murphy responded that the estimate is 9 to 10 million dollars. Dr. Parmacek thought it was a very strong proposal and a very important area of research. He said that Dr. Kuller's comments were well taken but that Dr. Levine's counter point the number of projects that have been focused specifically on traumatic brain injury taking Alzheimer's out of the mix was probably relatively limited. Dr. Parmecek further pointed out the relationship between concussions and severe depression and suicide that has been highlighted because of the football experience. He also mentioned that the committee hasn't done anything like this in the past. Dr. Coico agreed with the previous comments. She also stated that if the committee were to only fund things that weren't being funded by anybody else that that would very severely limit the types of projects and proposals that we would be funding. Dr. Coico further agreed that the whole issue of traumatic brain injury and depression and traumatic brain injury given the major issues with sports teams in and around Pennsylvania is a very important project to fund.

Dr. Kuller presented a brief overview of the Health Effects of Exposure to Toxic Chemicals from Fracking priority.

Health Effects of Exposure to Toxic Chemicals from Fracking Discussion – Dr. Levine thought that the proposal was terrific and agreed with all that Dr. Kuller had said. He pointed out, however, that just because of the financial implications of the fracking industry for the governor and for the legislature this particular proposal has a political context which the other ones don't have. He further stated that whether or not to support this priority despite the excellence of the science was going to have to be a political decision by Dr. Murphy and the governor's staff. Dr. Kuller agreed, but with one caveat, and that was that having knowledge and science goes a lot longer ultimately than just the political debate about whether fracking is good or bad for you. Dr. Kuller further commented that he wasn't proposing to prove that fracking has an adverse effect. What he was trying to do was say whether scientists in the state can provide the information about whether fracking has or doesn't have any health effects in the best science that is possible. Dr. Levine indicated that Dr. Kuller made a very important point and didn't disagree with anything that Dr. Kuller had said, but Dr. Levine wanted to note that when their own faculty published a paper recently on the incidence of prematurity in the fracking environment the political fallout from the publication of the article was intense. Dr. Levine further stated that he didn't have a judgement one way or the other. He felt that everything with regard to the science that Dr. Kuller said was correct, but that this one particular proposal because it is in a political context has got to be a judgement not just of this committee.

Dr. Davis concurred with all of the comments that Dr. Kuller made and the importance of trying to understand the health implications of fracking in the state. He also noted Dr. Levine's comments and stated that he thought all of the committee members were aware of the political implications of how this is viewed by various segments of the state. Dr. Davis stated that in his proposal Dr. Kuller had mentioned a couple of locales where there is some research activity going on in this area. Dr. Davis asked if there are some groups with a significant amount of research already going on in various areas looking at health effects of fracking. Dr. Kuller responded that there is no research in health effects of fracking. What he'd mentioned was that there are centers across the state in various universities with expertise in this technology that could be applied to the study of fracking. Dr. Kuller stated that we're not going anywhere in studying fracking and that the traditional metrics are not going to work. He further commented that good new scientific technology must be applied to this problem and it's an excellent opportunity that would give us an advantage in further work in studying the environmental adverse effects on a variety of developmental abnormalities, cancers, etc. Dr. Davis clarified that he thought that it is an important area for investigation with implications for the state and he understood the politics involved.

Dr. Feinstein said that she was wildly enthusiastic about the priority. She agreed with Dr. Levine and understood the problem and that the committee had to be sensitive, but that getting really good definitive credible information on this important priority is difficult.

Dr. Parmecek presented a brief overview of the Population Health Management in Healthcare Innovation priority.

Population Health Management in Healthcare Innovation – Dr. Davis agreed that it was a very important and timely topic. He suggested one additional bullet point for the committee's consideration for this priority: *What are the patient reported variances and determinants of health from a diversity of geographic settings and patient populations in the commonwealth that limit optimum healthcare outcome? The need to focus on patients who require additional support necessitates evidence based designs that are personalized to both the community and the social context with those patient populations in need*. Dr. Davis further commented that the bullet point emphasizes individualization as we look at how we better care for populations outside of the individual patient approach. Dr. Parmacek responded that one of the real strengths of this approach is that these new approaches are useful for addressing disparities in health care and variances in health care delivery.
Dr. Feinstein liked the priority very much, but wasn't sure how much of the research should be directed to how best to use various technological devices or whether it was broader. She further indicated that she would be more enthusiastic if it were broader and we could look at things like the effectiveness of community health workers or something like the new Total Accountable Care Organizations. Dr. Feinstein felt that if the priority were focused a little more broadly than just the behavioural economics of different technologies she would be very enthusiastic.
Dr. Levine commented that he thought that the priority was focused and that it was an excellent proposal that makes critical points in the context of the revolutionary changes in medicine and health care delivery, which are now beginning to be seen. He further stated that Dr. Parmecek's proposal focuses on rapidly developing ways to sense physiology particularly in people who are remote from hospitals and doctors. Given that Pennsylvania is a largely rural state, Dr. Levine thought this has particular importance. Dr. Levine also said that Dr. Parmecek points out in the priority that you can have sensors for an extended period of time, but if neither the client nor the provider acts on the data in those sensors they're meaningless and unfortunately many patients in this targeted population most severely at risk of chronic illness don't know how to use a sensor or won't use a sensor or won't act on the sensor, etc. Another point that Dr. Parmecek makes is that the challenge that we have is not simply to identify people who are at risk but people who given their risk might be manipulated by themselves or by their provider to intervene with that risk. Dr. Levine further stated that this combination of sensors and other devices particularly in a largely rural state coupled with our understanding of the social science of how both potential patients and potential providers act on the data goes to the very heart of what's happening in this revolution in health care in this country. Almost all of our health care dollars are spent on diseases and disorders which are largely preventable: smoking, eating, drinking and sexually transmitted diseases, etc., and so if such a proposal could lead in the commonwealth to a true benefit that would be a remarkable advance.

Dr. Murphy then moved on to the last two papers, but stated that the authors of the two white papers were not present at the meeting, today, but that the committee members had received the two papers in their packets for review prior to the meeting. She then opened the floor for comments on the Evaluation of Frailty Intervention for Elderly Patients with Heart Failure submitted on behalf of Thomas Jefferson.

Evaluation of Frailty Intervention for Elderly Patients with Heart Failure Discussion – Dr. Feinstein commented that she was anxious to hear what Dr. Kuller had to say because it was his area. Dr Kuller stated that he thought that it was an important area, but that it was very narrow and he wasn't sure where to go with this. He thought that a question of really enhancing the quality of medical care in the elderly frail population with heart failure was partially related to the last discussion of Dr. Parmecek's proposal. Rather than technology and adherence therapies and the use of new drugs, the big winners here really are development of new therapies for heart failure and improvement in identification and the determinants of frailty in the elderly and dealing with the added dimension in a huge number of these individuals of dementia, frailty and congestive heart failure in an elderly cohort. Dr. Kuller further commented that he thought that it was a very serious problem, but that it can't be solved with this proposal or any reasonable proposal at the present time. Dr. Murphy asked if any of the other committee members had a differing opinion.

There was no response so the Secretary moved on to open the floor for discussion of the white paper in the area of devices for enhancing health, health care and delivery – a translational agenda for precision health presented on behalf of Penn State University.

Devices for Enhancing Health, Health Care and Delivery – A Translational Agenda for Precision Health – Dr. Davis stated that he thought it was an important area, but thought that the proposal looked like it was woven into a bit of Dr. Parmecek's proposal as many of the questions being posed in the proposal might be at least components of looking at how it is that we look at real time information to help us to provide better care in a population base. Dr. Levine commented that he didn't think that there was anything in this proposal that wasn't in Dr. Parmecek's. Drs. Parmacek and Feinstein expressed agreement.

Dr. Murphy then opened the floor for comment around the table in the room before tallying the support of the committee in support of the white papers. Dr. Hughes expressed her appreciation of the efforts put into the white papers and agreed that each of them was critically important for different reasons. She further stated that being a health services researcher, a health policy person and wearing her new hat as the Deputy Secretary of Health Innovation gravitated toward the third one that the committee discussed on population health management and she appreciated the last two we discussed. Dr. Hughes further commented that she thought aspects of those proposals could be rolled up into that third one on population health management. She thought that moving forward especially as we reform how we pay for, deliver and coordinate care across the commonwealth it will be very important to understand the different approaches that are truly effective when it comes to population health management and integrating public health and primary care not only at the point of individual patient care, but also from the population health perspective. Dr. Hughes appreciated that this proposal was broad enough to get some interesting applications in the RFA process that can really drive this work forward across the state.

Dr. Murphy then asked the committee members to identify their priorities and indicated that she was open to any comments they might have. Dr. Davis stated that he believed that the committee had three very important topics being proposed with important implications for this state and for the population in the state, which made it difficult for him to select. Dr. Davis

further commented that the population proposal probably was very timely and selected it for his first priority. For his second priority Dr. Davis selected traumatic brain injury because he was concerned about how the third proposal would play out.
Dr. Feinstein chose the fracking priority as her first priority. She stated that she was very enthusiastic about the population health one as her second priority because it was an area that she knew a lot better than the neurological research, but she would like to see a broader approach that is not just limited to the efficacy of electronic devices but extends to the whole idea of what works and what doesn't work and how we start making it a serious research enterprise.
Dr. Kuller selected his own fracking proposal as his first priority and traumatic brain injury as his second priority.
Dr. Levine selected his own traumatic brain injury proposal as his first priority and his second priority was Dr. Parmecek's proposal. He also pointed out if one reads Dr. Parmacek's proposal carefully it is not focused exclusively on devices. It makes the extremely important point that the population most at risk probably can't be fit with devices and even if they were they probably wouldn't be able to deal with the data that accumulates from their devices. Dr. Levine went on to say that he didn't think that Dr. Parmacek's proposal was a narrow proposal at all.
Dr. Parmecek chose his own proposal as his first priority. He stated that his proposal is absolutely not just focused on the application of new devices. It's really trying to change and optimize behaviours of patients and also it could be viewed broader in terms of the context of setting up systems of care to optimize health outcomes. The other point Dr. Parmacek voiced was that he thought that the proposal compliments nicely the RFA put out last time on Big Data. Dr. Parmecek's choice for his second priority was traumatic brain injury.
Dr. Coico selected traumatic brain injury as her first priority and Dr. Parmecek's proposal for her second priority.
Dr. Murphy commented that she thought that they were all excellent recommendations, but she thought that the majority of the committee members had come down to two proposals, which were population health and traumatic brain injury.

Secretary Murphy then asked Ms. Becker if the Department would be able to choose two priorities. Ms. Becker commented that one of the things to keep in mind is each priority would have to be peer reviewed by a separate peer review panel. So, with 10 million dollars you could fund two research grants. So, if you have two priorities you'd have to have two panels. And Ms. Becker indicated that this has been done in the past as the members have pointed out but there was twice as much money. The Secretary then asked the committee if two priorities were selected to weigh in on the minimum amount of research funding that would be able to produce meaningful research. Dr. Levine responded that 5 million for each of the two priorities would be entirely reasonable, but if the Health Department decides that they want to give multiple grants within the five million then it's unreasonable. So, if we were to give one grant to one institution for five and the second grant for five million to a second institution, that would be fine. Dr. Coico agreed with Dr. Levine. Secretary Murphy clarified, "If we were going to give one five million dollar award in two topics that would suffice. If we were going to take the five million dollars on one topic and divide it up among multiple institutions you think that perhaps the outcome of that research wouldn't meet our objectives." Dr. Davis questioned whether or not having a few institutions working in collaboration with some of their local contacts would provide broader perspective on various aspects versus one institution being the center of activity. Dr. Levine responded if you look back at the record of how these monies have been spent since

the founding of the committee and look at the policy statement from the commonwealth it becomes evident that demonstrable collaboration especially amongst minority institutions, small institutions and increasingly industry is part and parcel of the CURE process. So, if two grants were given out to two institutions, Dr. Levine thought that the grants that would have the proposals would have to be written such that they clearly demonstrate the kind of collaboration that Dr. Davis described.

Closing remarks and next steps

Secretary Murphy thanked the committee for their feedback and stated that she was impressed by the submissions and that the Department would communicate with the committee. The Secretary further commented that the Department would really think about the priorities and the funding to be sure that we have met the objectives of the CURE research.

The Secretary pointed out that Section 90703 defines the selection of this committee and the appointment authorities and also specifies that the committee members continue to serve on the committee after their term of office ends until a qualified successor is appointed. She further stated that with the exception of Dr. Karen Feinstein the committee members were probably aware that their terms have ended and if they'd like to continue to serve on the committee then they should contact their respective appointment authority for their term to be renewed. Secretary Murphy reiterated that the Department values all of the committee members' guidance, ideas, and input to determine the research priorities and to improve the health of all Pennsylvanians and thanked everyone for coming to the meeting and for being very committed to improving the health of all Pennsylvanians.
We're adjourned. Thank you.

Adjournment
The meeting adjourned at 11:47 a.m.