

Minutes
Health Research Advisory Committee
July 20, 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

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

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

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

Not in attendance

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

Department of Health (DOH) Staff Present:

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

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

Dawn Houff, MBA, Program Analyst, Health Research Program

Terri Matio, Director of the Bureau of Administrative and Financial Services

Holli Senior, Special Assistant to Secretary of Health

Michael Suchanick, Deputy Secretary for Administration

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

Ming Gan, Intern, Office of Legal Counsel

Others in Attendance

John Anthony, Tobacco CURE Manager, Pennsylvania State University

Sarah A. Copley, Senior Associate, Greenlee Partners, LLC

Brian P. Smith, Director, Compliance, The Hospital & Healthsystem Association of Pennsylvania

Call to Order

Secretary Murphy called the meeting to order at 2:33 p.m. on Monday, July 20, 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. She invited all those present in person and via teleconference to introduce themselves for the record. Secretary Murphy then announced that the primary purpose of the meeting was to solicit feedback for setting research priorities and to determine if the committee has any preliminary recommendations regarding the approach to establishing research priorities for the 2015-16 state fiscal year.

Minutes of the November 4, 2014 Meeting

Secretary Murphy called for a motion to accept the minutes of the meeting held on November 4, 2014. Dr. Smith-Whitley moved to accept the minutes of the meeting. Dr. Davis seconded the motion, and the motion passed without objection.

Review of Health Research Priorities and Funding

Secretary Murphy then reviewed the health research priorities and the actions the Department has taken regarding the tobacco research funds.

Secretary Murphy stated that over the past year, the 2014-15 funds were issued under a Request for Applications for both the formula and nonformula funds. Formula grants were awarded for clinical, health services and/or biomedical research priorities and nonformula grantees were selected to provide research on the approved priority of Big Data.

In May of this year, the Department was notified of the release of the 2013-14 tobacco funds that were previously on hold due to the master agreement arbitration. These funds are now available for both formula and nonformula research. The formula funds from 2013-14, along with the 2015-16 formula funds, will be announced in the same RFA that will be released later this year. The nonformula funds received from 2013-14 will be added to the grants awarded for Big Data. Subsequent to the identification of Big Data as the nonformula priority for State Fiscal Year (SFY) 2014-15, the Department identified an expanded access research study using a pharmaceutical grade Cannabidiol (CBD) compound as a second nonformula priority for SFY 2014-15. As soon as the priority is finalized, the Department will post it on the CURE website, issue an RFA to solicit applications and select an applicant to carry out the research. The sum of \$2,000,000 will be released in this RFA for this priority.

For the current 2015-16 year, at a subsequent meeting the Committee needs to discuss and approve the priorities that should be funded by both the formula and nonformula grants.

Solicitation of Feedback on the Best Methods of Setting Nonformula Research Priorities, Using Established Guidelines

The Secretary requested ideas and recommendations from the Committee regarding possible improvement in the operation of the Health Research Advisory Committee (HRAC) and the process of selecting nonformula priorities. Secretary Murphy also stated that the Department would accept any recommendations that the Committee would like to make for next year's priorities, but that another meeting would be held in early fall to discuss 2015-16 funding.

Dr. Parmacek commented that he as well as several other members of the HRAC had been Committee members since the inception of the Program. He indicated that for the first ten years after the CURE Act that there were a couple of HRAC meetings per year that were attended by most Committee members in person. In the past, the Committee took public comment concerning ideas for projects that led to a robust discussion about the pros and cons of different priorities that really focused on the health of Pennsylvanians. Dr. Parmacek further stated that he believed that due to a whole host of issues including transitional and budget issues that occurred about two or three years ago, a conference call-in system evolved for the Committee, which in Dr. Parmacek's opinion really did not take advantage of the Committee members' expertise. That led to the final evolution, which was the Department recommending their own project last year, which largely was not discussed although attempts were made to contact individual Committee members to discuss it. Dr. Parmacek further stated that he believed that the Committee members have remarkable expertise and true dedication to the nonformula priority selection process because they have seen the results from the process. He stated that underrepresented minorities were included in medical research, which is not only a priority for the Commonwealth, but also for the nation, and this was done remarkably well through the Program in the past. Dr. Parmacek stated that he is committed to moving forward and participating as much as possible in the priority selection process because he has seen the results in the past when the Committee was able to follow the original process and would welcome moving back in that direction.

Secretary Murphy thanked Dr. Parmacek for his comments and indicated that she would try to ascertain the philosophy of past meetings by reviewing the minutes to get a better sense of what took place.

Dr. Dwight Davis seconded the comments made by Dr. Parmacek. He stated that there were some very important conversations and thought provoking ideas that came out of the Committee's early face-to-face meetings when guests were allowed to present ideas to the Committee for research activities. Dr. Davis further indicated that he thought that a wealth of good ideas came out of those discussions and some very innovative projects. Dr. Davis further expressed that he understood that issues arise that are out of the Committee's control in terms of what happens with respect to the operation of State government and the Department, but if this area is to remain successful, the Committee should not lose sight of past practices that allowed the Committee to do a much better job of coming up with good ideas for projects than has occurred recently.

Secretary Murphy asked if past HRAC meetings were held in Harrisburg, if they were rotated and where the meetings involving public input were held.

Dr. Davis responded that most of the meetings in the past were held in Harrisburg. He indicated that although the Harrisburg location makes it difficult for traveling for some of the members, he believed that all of the Committee members were committed enough to try to attend meetings in person in the future as long as enough lead time was given for scheduling. Dr. Davis also pointed out that the location of future meetings should allow for a good representation from the public and other investigators at the meetings.

Dr. Levine concurred with the statements made by Drs. Parmacek and Davis. Dr. Levine indicated when he had read of the CURE funds being used to support a clinical trial for cannabinoid oil in children with intractable seizures that he had written to Secretary Murphy to express his concerns. He pointed out that although it is a perfectly legitimate clinical test for a severe disorder in children, it is not commonwealth specific. There are children with intractable seizures throughout the nation and parents who lobby for cannabinoid oil throughout the nation. Dr. Levine also stated that it was not the fact that the study was not Pittsburgh centric which most concerned him, but the fact that he was not consulted as a member of the Health Research Advisory Committee nor he believed was Dr. Parmacek.

Dr. Parmacek stated that it was correct that he was not consulted regarding the use of CURE funds to support a clinical trial for cannabinoid oil in children with intractable seizures.

Dr. Levine further commented that there may have been other people consulted, but that the Committee as a whole was not consulted and there was no Committee consensus reached. He appreciated that this may have been a result of the changing administration, but hoped that in the future the commonwealth used the Health Research Advisory Committee as it was intended and as had been the case throughout all of the years since Dr. Levine had started as a founding member of the Committee.

Dr. Davis indicated that for those members that were contacted, such as himself, about the clinical trial for cannabinoid oil in children with intractable seizures he would not use the term, consulted. Dr. Davis stated that it was clear to him when he was contacted that he was not being asked for an opinion but was being told that the decision had already been made.

Dr. Smith-Whitley indicated that she concurred with Dr. Parmacek's comments. Dr. Smith-Whitley also stated that she thought that the Committee could really benefit by conducting future committee meetings the way that they had been done previously in the sense that the Committee had an open forum and very thoughtful discussions including input from experts from throughout the state on topics that were of interest to the Committee. Dr. Smith-Whitley also emphasized that a very positive aspect of past meetings was that the Committee had an opportunity to hear back from some of the grant recipients. This allowed the Committee to be informed about how the grants that the Committee had proposed previously were actually being conducted. Dr. Smith-Whitley further stated that she thought that that was useful information for the Committee going forward to see if things were phrased the right way and to see if the research projects went forward the way that the Committee had intended. Dr. Smith-Whitley hoped that in the

restructuring of meetings that the Committee would continue to have some feedback on the progress and performance of grants that were previously funded.

Secretary Murphy asked the floor how frequently meetings were held in the past. She also asked with regard to the meetings with presentations concerning the solicitation of ideas for research priorities from the public, if the Committee met on a regular basis.

Dr. Levine commented that from the beginning, the Committee held two meetings per year, usually in Harrisburg. Two meetings were held outside of Harrisburg; one in Pittsburgh and the other in Philadelphia. In response to Dr. Parmacek's comments, Dr. Levine believed that what was needed was one major meeting each year in Harrisburg. He was not sure that a second meeting was necessary if the Committee worked both intelligently and parsimoniously in the first meeting. If a second meeting was necessary it could be done perhaps by skype or by phone conference. Dr. Levine emphasized that it would be critical to have one meeting for as many hours as needed and he proposed that the Committee start doing that as of next year perhaps even rotating meeting locations.

Dr. Levine then made a motion that the Committee have one in-person meeting per year for as many hours as would be needed focusing on an agenda similar if not identical to the 7/20/2015 agenda and that the Committee consider rotating that meeting among Philadelphia, Harrisburg and Pittsburgh, and if another meeting is necessary that that meeting be done by skype or by telephone conference. Dr. Parmacek seconded the motion, and the motion passed without objection.

Dr. Levine then suggested that the Committee more aggressively seek suggestions from the public as to what the nonformula funding priorities might be. Dr. Levine stated that he did not know to what extent the Department had solicited the public, but thought that the Committee benefited from having people in the room during meetings. Dr. Levine recalled that in the past there had been only a few people from the public at meetings, and he questioned how well this information was disseminated.

Secretary Murphy stated that she would review what the historical practice has been in terms of notification of the meetings as well as time to accept public comment and the protocols surrounding that process.

Recommendation of 2015-2016 Formula Grant Research Priority

Secretary Murphy indicated that the research priorities for formula funds have remained unchanged since the inception of the program. The formula grant research priorities are clinical, health services, and/or biomedical research as defined by Act 77. Dr. Levine made a motion that the formula priorities be accepted as in the past. Dr. Davis seconded the motion, and the motion passed without objection.

Discussion of 2015-16 Nonformula Grant Research Priorities

Dr. Levine asked Secretary Murphy if the discussion of 2015-16 nonformula research priorities was being held to a later date. Secretary Murphy responded in the affirmative as she understood from the Committee's earlier discussion that the Committee wished to defer discussion of nonformula funds to a future in-person meeting. Dr. Levine then asked what the timeline would be for holding an in-person meeting considering the Department's deadlines for having the priorities set and for the money being committed. Secretary Murphy stated that the nonformula priorities would need to be set by September 1st so that 2015-16 funding could be used. Dr. Levine commented that it would be difficult to schedule an in-person meeting in the month of August due to scheduling conflicts. Dr. Staiano-Coico agreed with Dr. Levine and suggested that a considerable time had already been blocked off for the present meeting (7/20/1015) that perhaps it would be better to continue to have a nonformula priority discussion and then start best practices with in-person meetings for the following year. The Committee agreed to begin discussing the 2015-16 nonformula priorities at the present teleconference meeting. To start the discussion of possible priorities for nonformula funds, Secretary Murphy asked each Committee member if they had any recommendations for research priorities. Drs. Davis and Smith-Whitley reiterated the need for public input in the selection of the nonformula priorities. In response, Dr. Staiano-Coico asked if it would be possible to have these discussions and to allow four weeks for public input based on what would be discussed at the present meeting. Dr. Staiano-Coico also suggested in the interest of time that public input could be solicited electronically. She stated her concern that if the Committee waited until September and the start of best practices, that the Committee risked not having enough time to set the priorities by the needed deadlines. Dr. Davis commented that he understood Dr. Staiano-Coico's concern and indicated that he was in agreement with the discussion of nonformula priorities at the present meeting.

Dr. Levine recommended a priority that would relate to acute traumatic brain injury, especially in young people with a focus on concussions and the trajectory that may lead to chronic traumatic encephalopathy and ultimately to neurodegenerative diseases like Alzheimer's.

Secretary Murphy recommended a priority for consideration related to healthcare innovation in improving population health and the integration of population health, public health and healthcare delivery systems.

Dr. Parmacek volunteered to assist Secretary Murphy in writing the healthcare innovation in improving population health and the integration of population health, public health and healthcare delivery system white paper. Dr. Levine volunteered to write the traumatic brain injury white paper.

Secretary Murphy then asked the Committee if they would find it beneficial if the Department solicited additional 2015-16 nonformula priority recommendations from medical schools and research institutions across Pennsylvania. Dr. Parmacek commented that he did not know if it would be possible to do this given the time constraints, but that it would be a worthwhile endeavour.

After further discussion, Secretary Murphy summarized the Committee's agreed upon plan and time schedule for setting the 2015-16 priorities. Before the next meeting Dr. Levine would work on the white paper for Traumatic Brain Injury, and the Department would work with Dr.

Parmacek on the white paper for Healthcare Innovation. The Department would contact medical research institutions across the Commonwealth to solicit other white papers for 2015-16 nonformula funding. The Department would ask that all white papers be returned by August 15th. The Department will then disseminate all of the white papers to the entire Committee, and then another Health Research Advisory Committee meeting will be held in Harrisburg the week of August 22nd, which may be attended by members either telephonically or in-person to further discuss and finalize the 2015-16 nonformula research priorities.

New Business

Dr. Murphy announced that Dr. Lauren Hughes, Deputy Secretary of Health Innovation, will be participating in the Health Research Advisory Committee in the near future.

Adjournment

The meeting was adjourned at 3:23 p.m.