

Supporting Statement A

Attachment 9

NHLBI Advisory Council Minutes

NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

MEETING MINUTES May 29, 2003

- I. Call to Order and Opening Remarks
- II. Review of Confidentiality & Conflict of Interest
- III. The Seventh Report on the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
- IV. Presentation of Award to Dr. Sidney Smith
- V. Accelerating Dissemination of Science-Based Information: Selected NHLBI Projects
- VI. Report on the NHLBI Grant Application in Excess of \$500,000
- VII. Board of Extramural Advisors Working Group
- VIII. Initiatives for Fiscal Years 2004/2005
- IX. Review of Applications

I. CALL TO ORDER AND OPENING REMARKS - Dr. Claude Lenfant

[Top of Page]

Dr. Claude Lenfant opened the meeting and welcomed the Council members to the 210th meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC). May is National High Blood Pressure Education Month and this year's theme is "Taking action now can prevent strokes, heart attacks, heart failure, kidney disease and blindness." The program is strongly encouraging community groups, civic and faith-based organizations, hospital outreach programs, public health departments, and workplaces to take action and renew activities to prevent and control high blood pressure.

Member Updates

Dr. Lenfant introduced a new Council member, Dr. Kim Eagle, who is the Albion Walter Hewlett Professor of Internal Medicine of the Health System Cardiovascular Center at the University of Michigan. He is also the Chief of Clinical Cardiology at the School of Medicine.

Dr. Pamela Steele, who has been an ex officio member representing the Department of Veterans Affairs, has moved to a new position in the Department and will no longer be able to serve on the Council. Council has appreciated her contributions over the past eight years. A new representative will hopefully be in place for September Council.

Drs. Alcalay, Austin, and Thomas did not attend the meeting.

Guests

Dr. Lenfant introduced two guest speakers. Dr. Aram Chobanian is the Dean and Provost of the Medical Campus, Boston University School of Medicine and was invited to present the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

Attachment 2

Dr. Sidney Smith is the Director of the Center for Cardiovascular Science and Medicine at the University of North Carolina Hospital and was invited to accept an award for his support of the Institute during his tenure as the Vice President for Science of the American Heart Association.

Personnel Announcements

Dr. Raynard Kington has been named as the Deputy Director of the National Institutes of Health as of February 10, 2003. He has assumed the position held by Dr. Ruth Kirschstein who served as NIH Deputy Director since 1993 as well as Acting NIH Director from January 2000 to May 2002. Dr. Kirschstein is now Senior Advisor to the NIH Director. Dr. Kington served as NIH Associate Director for Behavioral and Social Sciences Research and Director of the NIH Office Behavioral and Social Sciences Research since November 2000. He also served as the Acting Director for the National Institute on Alcohol Abuse and Alcoholism from January through September 2002. Dr. Kington came to NIH from the Centers for Disease Control and Prevention. As Director of the Division of Health Examination Statistics in the CDC's National Center for Health Statistics, he led the National Health and Nutrition Examination survey, a comprehensive, ongoing survey of the health status, health behaviors, and diet of people in the United States.

New Publications

Publications provided included the following:

- The May Public Interest Organization Newsletter from NHLBI
- The 7th Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure and related materials
- Materials on the Heart Truth Campaign

A community-based publication entitled "Improving Health, Changing Lives: Communities Taking Action" A brochure for the 2003 National Conference on Asthma which would be held June 19-21, 2003, in Washington, D.C.

A bumper sticker to promote the Institute's Hearts N' Parks Health Promotion Program which says: "Together We Make A Difference"

[Top of Page]

II. REVIEW OF CONFIDENTIALITY & CONFLICT OF INTEREST - Dr. Claude Lenfant

[Top of Page]

The Council was reminded that according to Public Law 92-463, the Federal Advisory Committee Act, the meeting of the NHLBAC would be open to the public except during consideration of grant applications. A notice of this meeting was published in the *Federal Register* indicating that it would start at 8:30 a.m. and remain open until approximately

12:00 p.m. Dr. Lenfant also reminded the Council members that they are Special Government Employees and are subject to departmental conduct regulations.

[Top of Page]

III. THE SEVENTH REPORT ON THE JOINT NATIONAL COMMITTEE ON PREVENTION, DETECTION, EVALUATION, AND TREATMENT OF HIGH BLOOD PRESSURE - Dr. Aram Chobanian

[Top of Page]

Dr. Aram Chobanian who is the Dean and Provost of the Medical Campus at the Boston University School of Medicine presented the Seventh Report on the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, an important component of the Institute's National High Blood Pressure Education Program (NHBPEP). The NHBPEP began in 1973. Heart disease costs amount to \$350 billion each year and the most common primary diagnosis is hypertension. The report is based upon analyses of data from 30 trials, and includes a simpler classification for high blood pressure as well as new concise guidelines. Data from new trials indicate that two drugs are usually required to control high blood pressure and the report lists guidelines for drug use depending on the high blood pressure classification. These classifications includes a new level referred to as prehypertension (other levels are normal, Stage 1 hypertension, and Stage 2 hypertension). At this level lifestyle modifications such as smoking cessation, exercise, and healthy diet are recommended to try to prevent the progression to hypertension. Other factors such as increasing patient adherence to treatment regimens and public health approaches to reducing the prevalence of hypertension were presented. Educational materials for physicians, patients, and the public are available at the National High Blood Pressure Education Program web site at <http://www.nhlbi.nih.gov/about/nhbpep>.

Dr. Lenfant presented Dr. Chobanian with a special award for all his work over the years on this Committee.

[Top of Page]

IV. PRESENTATION OF AWARD TO DR. SIDNEY SMITH - Dr. Claude Lenfant

[Top of Page]

Dr. Lenfant presented a special award to Dr. Sidney Smith who is the Director of the Center for Cardiovascular Science and Medicine at the University of North Carolina Hospital. Dr. Smith was recognized for his exceptional contributions in strengthening the partnership between NHLBI and the American Heart Association during his tenure as the Vice President for Science of the American Heart Association.

[Top of Page]

V. ACCELERATING DISSEMINATION OF SCIENCE-BASED INFORMATION: SELECTED NHLBI PROJECTS - Dr. Gregory Morosco

[Top of Page]

Dr. Gregory Morosco is the Director of the NHLBI Office of Prevention, Education, and Control (OPEC). He presented an overview of the Institute's outreach programs, which include:

- the National High Blood Pressure Education Program
- the National High Cholesterol Education Program
- the National Heart Attack Alert Program
- the National Asthma Education and Prevention Program
- the NHLBI Obesity Education Initiative
- the Women's Heart Health Education Program
- the NHLBI Sleep Education Initiative

The tenets of these programs are that they:

Attachment 2

- are science-based
- have a tailored education and communication strategy
- involve national and local partnership approaches

Dr. Morosco introduced four individuals who are involved with the NHLBI high risk community partnerships.

Ms. Karen Donato, Coordinator of the NHLBI Obesity Education Initiative, gave a presentation on the Hearts N' Parks Program which was created in 2001 through a partnership with the National Recreation and Park Association. The objective of this program is to reverse the growing trend of obesity and the risk of coronary heart disease in the United States by encouraging Americans of all ages to attain a healthy weight, follow a heart-healthy eating plan, and engage in regular physical activity. Hearts N' Parks has expanded its network to 50 magnet center sites in 10 states.

Ms. Matilda Alvarado, Coordinator for Minority Outreach Efforts, discussed the Salud para su Corazon Initiative. This program was designed for Latinos and fosters heart health by training specific community members, called "promotores." These lay-health workers go back to their communities to educate people about healthy activities. In the past four years over 400 "promotores" have been trained and recently the program has begun to partner with other minority community groups in order to expand its influence to American Indian and Alaska Natives.

Ms. Carol Bryant Payne, a representative of the Department of Housing and Urban Development (HUD) presented Healthy Hearts in Housing, which is a cooperative project between the NHLBI and HUD. This program has developed a community specific cardiovascular health program in Baltimore's public housing communities. Public Housing residents are trained as community health workers and are paid to provide individual and group education and prevention activities relating to physical exercise, nutrition, smoking cessation, and other areas of cardiovascular health. The goal of the program is to engage every resident.

Ms. Terry Long, a Senior Manager for Health Communication and Public Information, showcased recent activities of the Heart Truth which is a campaign to make women more aware of the dangers of heart disease and the risk factors that lead to its development. Recently the Heart Truth released several TV and radio public service announcements and a print ad campaign targeting women with the message that "heart disease doesn't care what you wear." This message led to a partnership with Mercedes Benz and the fashion industry, which launched the Red Dress Campaign during New York's Fashion Week in February. The Red Dress Project has been promoted by First Lady Laura Bush and is symbolized by the Red Dress pin, which was created as the symbol for women and heart disease awareness, much like the pink ribbon associated with breast cancer.

Council complimented the presenters on the programs and were particularly impressed by their cultural sensitivity. Members acknowledged that changing behavior is very difficult especially with contrary messages being promoted by groups such as the fast food industry as well as with the variety of diets that have been advertised. Experts in obesity refer to the environment as "toxic" and one that poses a difficult challenge. Other issues include maintaining weight loss, smoking cessation, and being sensitive to various age groups, especially adolescents. NHLBI is currently considering partnering with the Department of Education to address the issues of fatty lunches in schools and the lack of exercise programs.

[Top of Page]

VI. REPORT ON THE NHLBI GRANT APPLICATIONS IN EXCESS OF \$500,000 - Dr. Carl Roth

[Top of Page]

Attachment 2

Dr. Carl Roth, Associate Director for Scientific Program Operation at the NHLBI, presented data on the impact of the NHLBI policy for grants in excess of \$500,000. The NIH requires that all applications unsolicited by an RFA and requesting direct costs in excess of \$500,000 in any year must be approved by an individual institute before they can be submitted. This policy was instituted because of a steady rise in the cost of research grants that, if continued, would lead to a reduction in the number of grant awarded. The NHLBI policy stipulates that applications above \$500,000 but less than the P01 dollar cap (FY 2004 \$1.45 million; this figure is revised every fiscal year) need approval from the relevant Division Director. Applications in excess of the P01 cap must be reviewed by the Panel of Institute Officials, who may or may not approve submission of the application. The policy and the criteria are published on the NHLBI public website. Dr. Lenfant emphasized that the cost is important when evaluating the Institute's portfolio. This policy was first presented to the NHLBAC in May 1999 and was implemented for Fiscal Year 2000.

The percent of requests to submit applications over \$500,000 which were not accepted has been less than 20% for each of the past three years at NHLBI. Among the NHLBI divisions only the Division of Epidemiology and Clinical Applications (DECA) showed an appreciable number of requests that were not accepted. However, the average cost of requests submitted to DECA was significantly higher than those submitted to the other divisions. From FY 2000-2002 the mean lifetime direct costs for accepted requests was \$4.5 million, while the mean for denied requests was \$9.7 million. Final analysis showed that the number of grants submitted to the Institute requesting more than \$500,000 has not decreased since this process was initiated. This would be true even if the \$500,000 threshold for requests were raised annually to adjust for inflation.

[[Top of Page](#)]

VII. BOARD OF EXTRAMURAL ADVISORS WORKING GROUP - Dr. Claude Lenfant

[[Top of Page](#)]

The NHLBI Board of Extramural Advisors (BEA) is a working group of the Council. Council members who attended the April meeting of the BEA presented their impressions of it. Topics that were discussed during the meeting included the future supply of physician-scientists needed to continue medical research and patient privacy rights associated with donated biological samples. Much of the discussion was on SPARK II Working Group recommendations. Council members who attended the BEA strongly encouraged other Council members to attend.

[[Top of Page](#)]

VIII. INITIATIVES FOR FISCAL YEARS 2004/2005 - Dr. Claude Lenfant

[[Top of Page](#)]

Seventeen BEA Initiatives were presented to Council as well as one initiative on Diamond-Blackfan Anemia that did not go to BEA. The Diamond-Blackfan Anemia initiative resulted from patient advocacy groups' interest in increasing the Institute's portfolio of research on this rare disease. Each initiative is summarized below. Council concurred with the BEA Working Group evaluation overall and comments are noted below.

1. Title: Aldosterone Antagonists for the Treatment of Heart Failure with Preserved Systolic Function

Purpose: To evaluate the effectiveness, through a multi-center randomized trial, of aldosterone antagonist therapy in reducing all-cause mortality and re-hospitalization for heart failure in patients with preserved systolic function heart failure.

Attachment 2

Council was supportive of this initiative and noted that it presented a very significant opportunity.

2. Title: Asthma and Obesity

Purpose: To elucidate the mechanisms whereby obesity contributes to asthma onset and exacerbation and to translate this knowledge into new targets for intervention.

3. Title: Cardiac Conduction System Development and Disease

Purpose: To research the critical processes that direct the embryonic development of the cardiac conduction system, develop innovative approaches to understand the molecular mechanisms underlying the formation of the conduction system and the initiation of rhythm and rate in the heart, and apply this knowledge for therapeutic and preventive benefit.

4. Title: Cardiac Ischemia Reduction Through Stress Management

Purpose: To compare the efficacy of interventions for management of mental/emotional stress in patients with coronary artery disease (CAD), angina, and daily ischemia; and determine whether stress-reduction interventions can reduce daily ambulatory ischemia and thereby reduce CAD.

5. Title: Causes and Mechanisms of COPD Exacerbations:

Purpose: To develop in-home methods to quantify subclinical, as well as severe, Chronic Obstructive Pulmonary Disease (COPD) exacerbations and determine the causes and mechanisms of these events.

Council commented that this would be an important initiative if funds were available.

6. Title: Cellular and Molecular Effects of Airborne Particulate Matter in Heart, Lung, and Blood Systems

Purpose: To elucidate cellular and molecular mechanisms by which airborne particulate matter increases cardiopulmonary morbidity and mortality.

7. Title: Cellular and Molecular Imaging of the Cardiovascular, Pulmonary, and Hematopoietic Systems

Purpose: To develop non-invasive cellular and molecular probes to image specific cellular or molecular targets and events in the cardiovascular, pulmonary, and hematopoietic systems.

in vivo; and develop imaging techniques, or adapt current imaging technologies, to use these probes to image heart, lung, and blood systems at the cellular or molecular level.

Council was enthusiastic about this initiative and recommended that it include bone marrow and that it make clear what was to be imaged. The collaborative aspect was especially praised.

8. Title: Cis-Activation of Fetal Hemoglobin Genes For Treatment of Sickle Cell Disease and Cooley's Anemia

Purpose: To examine the regulatory contributions of cis-acting DNA sequences to the activation of fetal hemoglobin genes during human development.

9. Title: Disease Risk in Relatives of Persons with Heart and Lung Diseases Phase I

Attachment 2

Purpose: To develop clinically relevant approaches for increasing awareness, screening, treatment, and prevention of familial heart and lung disorders and their risk factors in relatives of persons with these disorders.

10. Title: Glycan Function in Hematologic, Cardiovascular, and Pulmonary Systems

Purpose: To investigate the contribution of glycans to hemostasis, thrombosis, hematopoiesis and transplantation-based therapies; and explore the role of extracellular matrix glycoproteins in vascular and pulmonary function and disease.

11. Title: Immunopathogenesis of Pulmonary Sarcoidosis

Purpose: To explore the inciting or initial mechanisms leading to granulomatous inflammation in the lungs.

Council highly recommended this initiative since little progress has been made with this disease.

12. Title: Inflammation and Thrombosis

Purpose: To examine the interplay between inflammation and thrombosis, and encourage translation of this knowledge to the management of thromboembolic disorders utilizing novel anti-inflammatory agents.

Council supported this initiative.

13. Title: Interventions to Improve Hypertension Control Rates in African Americans

Purpose: To evaluate interventions that will effect changes in medical care delivery leading to an increase in the proportion of treated African American patients whose blood pressure is controlled to below levels specified by the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC) guidelines.

Council endorsed this initiative.

14. Title: Lipid Standardization for NHLBI Supported Programs

Purpose: To support the Center for Disease Control and Prevention (CDC)-NHLBI Lipid Standardization Program that provides lipid standardization for NHLBI-funded studies.

15. Title: Molecular Mechanisms Underlying Diamond-Blackfan Anemia and Other Congenital Bone Marrow Failure Diseases

Purpose: To encourage research into the genetics and basic mechanisms on Diamond-Blackfan Anemia and other inherited or congenital bone marrow failure diseases.

Council supported this initiative.

16. Title: Partnership Programs for Reducing Cardiovascular Health Disparities

Purpose: To promote and expedite improved cardiovascular disease (CVD) outcomes in minority populations.

Attachment 2

Council recommended this initiative.

17. Title: Rates and Patterns of Diagnosis of Common Sleep Disorders

Purpose: To use existing large population based cohort studies to investigate the validity of sleep diagnoses in the health care setting, evaluate the basis for upward trends in the diagnosis of common sleep disorders, and investigate the patterns of sleep disorder diagnoses in relation to co-morbid conditions and in respect to ethnicity, gender, age, and socioeconomic status.

18. Title: Strategies to Improve Cardiac Surgery Neurocognitive Outcomes

Purpose: To improve clinical neurocognitive outcomes following cardiac surgery by developing and implementing protocols designed to evaluate therapeutic strategies to optimize neurocognitive function following either conventional or less invasive coronary artery bypass surgery (CABG).

Council recommended this initiative if there were sufficient funds and suggested that coronary revascularization be incorporated in addition to surgical methods.

Women's Health Initiative

Also during this session, Dr. Barbara Alying, Deputy Director of the NHLBI, presented plans for the Institute to continue its financial commitment to the Women's Health Initiative. Potential funding would continue this program through 2010. Other institutes would be invited to participate and it would be open to investigators outside the current study.

Council recommended continuing these studies.

CLOSED PORTION

[Top of Page]

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2).

There was a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

LOAN REPAYMENT PROGRAM

[Top of Page]

The Council members were provided with the results of the Loan Repayment Working Group. There was a brief discussion and Council concurred with the recommendations.

VIII. REVIEW OF APPLICATIONS

[Top of Page]

The Council considered 989 applications requesting \$1,563,378,284 in total direct costs. The Council recommended 987 applications with total direct costs of \$1,546,758,808. A summary of applications by activity code may be found in Attachment B.

ADJOURNMENT

The meeting was adjourned at 5:50 p.m. on May 29, 2003.

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete.

Claude Lenfant, M.D.

Director

National Heart, Lung, and Blood Advisory Council

on June 30, 2003