Summary Report:

THE NATIONAL CHOLESTEROL EDUCATION PROGRAM COORDINATING COMMITTEE MEETING

October 16, 2001
Marriott Tysons Corner
Vienna, Virginia

CONTENTS

HIGHLIGHTS

National Cholesterol Education Program (NCEP)
Coordinating Committee Meeting

October 16, 2001

- Dr. David Orloff reported on research and results relating to the possibility of statin drugs causing rhabdomyolysis. Data from the studies showed that cerivastatin carried a significantly higher risk of rhabdomyolysis than do the other statins, especially when used in combination with gemfibrozil. He stressed that results of at least five major trials demonstrate that statins reduce morbidity and mortality from coronary heart disease and are generally safe.

- Dr. James Cleeman reported on activities to promote the adoption of ATP III. This has included publishing the ATP III Executive Summary in the *Journal of the American Medical Association*, holding a press conference, and extensive media coverage. Tools and materials to speed up the implementation of the guidelines have been developed and posted on the NHLBI's ATP III Web page (http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm). These tools and materials include a patient brochure, the "Guidelines At-A Glance Quick Desk Reference," online 10-year risk calculators, an interactive guideline tool for Palm OS, and PowerPoint slides. The NCEP also cosponsored a national conference with the National Committee for Quality Assurance (NCQA) to assist in the implementation of the new guidelines.

- Drs. Scott Grundy, Stephen Havas, and Lewis Kuller presented the issue of reducing lifetime CHD risk in the individual at low short-term risk. They contrasted population-based approaches with medical high-risk approaches, noting benefits and drawbacks of both. They agreed that a population-based approach would be a good idea at this time.

- The Coordinating Committee members broke into small discussion groups to consider aspects of a possible population-based campaign to reduce cholesterol. They reconvened and expressed a consensus to move forward with such a plan.

WELCOME AND REPORT FROM THE COORDINATOR

Dr. James Cleeman

Dr. Cleeman called the meeting to order at 9 a.m. and welcomed the Coordinating Committee members and guests. He expressed the regrets of Dr. Lenfant, Chairman of the National Cholesterol Education Program (NCEP) Coordinating Committee, for not being able to attend due to an urgent development. Dr. Cleeman stated that he would inform Dr. Lenfant of the meeting's discussions.

Dr. Cleeman introduced several new Coordinating Committee participants: Ms. Pat Bonifer-Tiedt, the new official representative of the American Red Cross; Ms. Rose Marie Matulionis, representing the Association of State and Territorial Health Officials at this meeting; and Dr. Craig Spellman (for Dr. Clearfield), representing the American Osteopathic Association at this meeting. See Attachment A for a complete list of participants.

Because this was the first Coordinating Committee meeting since the tragic events of September 11, Dr. Cleeman thanked the members for attending, thereby following President Bush's suggestion that citizens resume their normal lives and activities, conducting them with courage. Dr. Cleeman stated that participating in the meeting, which aims to improve the health of the United States, is a fine way to show we will not be deterred from living in freedom and making the world a better place. He commended all for attending.

Dr. Cleeman expressed the sympathy of the Institute in light of the September 12 death of Dr. Richard Carleton, an outstanding contributor to the NHLBI and, particularly, to the National Cholesterol Education Program. Dr. Carleton and his contributions will be truly missed.

Dr. Cleeman described briefly the day's agenda [see Attachment B], reminded the attendees of upcoming Coordinating Committee meetings, and introduced the first presenter, Dr. David Orloff.

SAFETY OF STATINS—A VIEW FROM FDA

Dr. David Orloff

Dr. Orloff reported on research and results relating to the possibility of statin drugs causing rhabdomyolysis. He displayed a table that summarized the results of five major statin trials conducted over a 5-year period using three different drugs, involving over 15,000 patients with various LDL cholesterol levels and risk levels. Statin therapy resulted in a 20 to 25 percent reduction in CHD morbidity and mortality, with no observed increase in non-cardiovascular mortality or cancer. Only one case of rhabdomyolysis occurred in the large, 5-year statin trials in a patient who underwent major surgery after discontinuing statin treatment and developed post-operative rhabdomyolysis. Across the trials, the rates of myopathy (defined as a CK > 10 X ULN with symptoms) were low (<1 percent) and indistinguishable from those of the placebo groups. Dr. Orloff stated that the absolute benefits of using statins outweigh the risks, and the absolute benefits increase as the absolute risk for cardiovascular disease increases. The risk/benefit ratio of statins will be augmented when individuals at high risk in both primary and secondary prevention are selected for treatment.

Dr. Orloff presented a slide showing U.S. reports of fatal rhabdomyolysis culled from the FDA database for the various statins since they were introduced. Cerivastatin, the most recently released statin and the least prescribed drug, was responsible for over half of the 74 fatal cases of rhabdomyolysis. Considering all fatal cases involving statins, a number of accompanying factors were found, including older age, underlying chronic disease such as diabetes or chronic renal insufficiency, and use of combination therapy such as cyclosporine, itraconazole, erythromycin, and mibefradil. There is an increased risk for rhabdomyolysis in association with combined use of gemfibrozil and some or all of the statins. In addition, the combination of niacin and statin may also increase risk for rhabdomyolysis.

Through 1999, 81 serious cases of rhabdomyolysis with cerivastatin were reported to the FDA. Cerivastatin had the fewest prescriptions but the highest reporting rate. Of the 81 cases, 20 cases involved cerivastatin alone and 61 cases were in combination with gemfibrozil. Dr. Orloff spoke briefly about the rhabdomyolysis cases reported with lovastatin, noting that about one-half of the cases with lovastatin in the first 2 years were in combination with gemfibrozil. The high reporting rate for rhabdomyolysis in association with lovastatin use early in its marketing history could possibly be because it is inherently less safe than the rest of the class; however, he noted the reporting rate of .06 of its close cousin simvastatin was not high, and was comparable to that for atorvastatin, fluvastatin, and pravastatin. Dr. Orloff explained that lovastatin was the first drug marketed and was marketed without any mention of myopathic risk on the label; therefore, rhabdomyolysis as an associated adverse event was alarming, and was probably more likely to be reported. He noted that complacency, on the other hand, tends to develop as drugs stay on the market. Cerivastatin, the last statin approved, would not have been expected to produce a vigorous response with regard to reporting of rhabdomyolysis, and yet, the

reporting rates for rhabdomyolysis with this statin have been markedly higher than for the other members of the class. Dr. Orloff cautioned that the studies are based on "reporting rates," which are not the same as true incidence rates; therefore, it is difficult to make comparisons across groups.

Dr. Orloff made the following concluding statements: (1) cerivastatin is distinctly less safe than other statins—alone or in combination with gemfibrozil; (2) the myotoxicity of cerivastatin was evident at relatively low doses with regard to LDL-C lowering; (3) cerivastatin was only intermediate in the class at the highest approved dose (0.8 mg) with regard to absolute LDL-C lowering potency, yet it was associated with the highest reporting rate for rhabdomyolysis; (4) there are differences in the metabolism of different statins that should guide recommendations for safe and effective use of the drugs, especially with potentially interacting agents. Dr. Orloff predicted the following actions (among others) for the future:

- Possibly altering the safety labeling for the statins.

- Providing physicians and patients with education concerning safe use of statins, including addressing combination therapy and early action needed in cases of suspected myopathy.

- Determining definitive mechanism(s) of statin-associated myopathy.

- Identifying risk factors related to drug/drug, drug/disease, and drug/gene interactions that impact on the safety of the drugs.

The FDA currently is reviewing its Adverse Event Reporting System data, and the Office of Drug Safety is conducting an epidemiological study to determine the incidence of rhabdomyolysis among users of statins and fibrates.

Dr. Kuller questioned why cerivastatin was approved in the first place and asked why increased use was not required before receiving FDA approval. Dr. Orloff replied that cerivastatin was approved because it was found to be "safe and effective," not because it was more potent on a per mg basis. It should be noted that cerivastatin was initially approved at doses of 0.2 and 0.3 mg daily. Subsequent, separate approvals were granted, first for the 0.4 mg dose and finally for the 0.8 mg dose. He acknowledged that exposure of patients to many drugs during development is small relative to the expected treatment populations but that several thousand patients were treated in cerivastatin clinical trials prior to approval. Approximately 750 patients were exposed to cerivastatin 0.8 mg in phase 3 trials, with nearly 500 receiving the drug for 52 weeks or more. In retrospect, there was a "signal" of myopathy risk seen in the 0.8 mg clinical trials database. On the basis of a number of cases of marked CK elevations, with and without symptoms, the drug was labeled at the time of the approval of 0.8 mg to warn against use of higher doses in elderly women. In the future, the FDA will be much less "tolerant" of signals that might portend a true myopathic risk, and signals of concern will lead to non-approval and/or further clinical trial exposures to exclude risk.

Dr. Preuss asked whether supplementation with coenzyme Q10 (CoQ10) can affect the rhabdomyolysis and whether CoQ10 or any other antioxidants have therapeutic benefit. Dr. Orloff did not have an answer for that particular question but cited a lack of data showing statins

depleting tissue CoQ10 levels. He was unaware of any studies examining whether administering CoQ10 reduces the risk of myopathy.

Dr. Pasternak asked whether the focus on gemfibrozil was due to exposure rates and whether the focus should extend to other fibrates. Dr. Orloff replied that pharmacokinetic studies of cerivastatin, simvastatin, and lovastatin show increased systemic exposure to drug when given in combination with gemfibrozil. Fenofibrate appears less prone to impact statin drug levels and therefore may be safer for statin-fibrate combination therapy. Dr. Pasternak asked whether we should change the way we monitor. Dr. Orloff replied that we probably need a better understanding of the natural history of rhabdomyolysis cases, and that we don't have enough information to suggest that we monitor CK levels rather than symptoms in our patients.

Dr. Grundy asked whether the NCEP should disseminate to physicians information on how to use statins, or whether this was someone else's responsibility. Dr. Orloff replied that the FDA and marketers of the products have an obligation to do this, but label warnings have generally been ineffective and it might be beneficial for the NCEP to reinforce messages to physicians.

COORDINATOR'S REPORT: ACTIVITIES TO PROMOTE THE ADOPTION OF ADULT TREATMENT PANEL III (ATP III) REPORT

Dr. James Cleeman

Dr. Cleeman reported on the activities that are being conducted to speed the adoption of ATP III into practice. The ATP III executive summary was published in the *Journal of the*

American Medical Association and received extensive media coverage. It was estimated that between May 15, 2001 and July 19, 2001, about 500 million audience impressions occurred. Dr. Cleeman described the additional support materials developed, including the patient brochure "High Blood Cholesterol, What You Need to Know," the Executive Summary, the "Guidelines At–A–Glance Quick Desk Reference," and a bookmark listing the electronic tools available on the ATP III Web page. These products were included in an Opinion Leader Dissemination Kit that was produced and funded outside the Institute and was distributed to more than 65,000 physicians nationally.

Dr. Cleeman showed, using visuals, how the NHLBI is presenting and promoting the ATP III materials on its Web page (http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm). The site includes full versions of the Executive Summary, the "Guidelines At–A–Glance Quick Desk Reference," an online risk calculator, and an interactive guideline tool for Palm OS® devices. Dr. Cleeman spoke about the conference held on June 3–5, 2001, in Washington, DC, jointly sponsored by NHLBI and the National Committee for Quality Assurance (NCQA) and attended by more than 300 professionals. He noted that NCQA recently established a HEDIS performance measure for LDL lowering in secondary prevention in consultation with NHLBI. He expressed hope that a performance measure for cholesterol lowering in primary prevention would be developed in the future.

Dr. Cleeman demonstrated the Palm tool by inserting data on a fictional person, after which the program calculated 10-year risk and recommended treatment according to LDL level and risk category. He presented highlights of the "Live Healthier, Live Longer" Web site

(http://www.nhlbi.nih.gov/chd/) and the popular Cholesterol Month Web site (http://hin.nhlbi.nih.gov/cholmonth/).

Dr. Cleeman fielded comments on ways in which member organizations are speeding implementation of the new guidelines.

Dr. Pasternak said that the American College of Cardiology and the American Heart Association (AHA) are incorporating ATP III recommendations in their guidelines, including the guidelines on women and heart disease, secondary prevention, and treatment of stable angina or acute myocardial infarction. The AHA will hold a satellite conference on ATP III for professionals on January 16, 2002, and many ATP III panel members will be involved. Dr. Grundy added that the AHA has scheduled a major session on ATP III at its national conference in November 2001.

Dr. Kuller stated that the American College of Preventive Medicine has made cardiovascular disease a priority and that two sessions on prevention of cardiovascular disease will be held at its next conference. Dr. Cleeman noted that the American Dietetic Association would also include a session on ATP III at its next conference. Committee members noted a number of recent meetings and conferences that included discussion of ATP III: Endocrine Society (Dr. Garber); National Black Nurses Association (Dr. Burnes-Bolton); National Medical Association (Dr. Clark); American Academy of Family Physicians (Dr. Ganiats); American Pharmaceutical Association (Dr. McKenney); and the Society for Nutrition Education (Ms. Lansing).

Dr. Preuss asked whether future guidelines might address the recommended amounts of *trans* fatty acids in the diet. Dr. Cleeman stated that *trans* fatty acids are mentioned in the current guidelines, and the recommendation is to keep them at a low level. The guidelines do not mention a specific level to seek or maintain.

REDUCING LIFETIME CHD RISK IN THE INDIVIDUAL AT LOW SHORT-TERM RISK: PRESENTATION OF THE ISSUE

Drs. Scott Grundy, Stephen Havas, and Lewis Kuller

Dr. Grundy explained that the purpose of this session was to determine whether ATP III should be extended or whether new approaches should be developed to prevent or treat atherosclerosis in patients who are at long-term risk. He said his presentation would focus on ATP III, whereas the other speakers' presentations would focus on where NCEP should go in the future.

Dr. Grundy explained that the scope of the NCEP efforts has included three main areas: the clinical approach for adults in the ATP guidelines, the population approach in 1990, and a coordination of the clinical approach and population approach for children and adolescents in 1991. He noted that general consensus has been that there should be a better connection between the clinical and population approaches. This was attempted in the ATP III report, but now would be a good time to further develop this idea. He reminded members that LDL cholesterol remains the primary target of therapy in the ATP III guidelines and that LDL cholesterol has been reclassified so that an LDL cholesterol < 100 mg/dL is now optimal. He reviewed the classification of LDL cholesterol according to the new guidelines.

Dr. Grundy reviewed the natural history of coronary artery disease, emphasizing that it is not an all-or-nothing phenomenon; atherosclerosis builds up over time, thereby offering opportunities for intervention at several levels. He stated that LDL cholesterol is a primary factor at each stage in the development of atherosclerosis and noted that lowering LDL cholesterol, even in the presence of advanced CHD, can reduce the risk for coronary syndromes. Therefore, LDL cholesterol remains the primary target of treatment.

Dr. Grundy reviewed the two types of prevention: (1) short-term, or a period of less than 10 years, which targets LDL cholesterol lowering in patients with advanced atherosclerotic disease and attempts to prevent plaque rupture, and (2) long-term prevention. While long-term prevention has always been a part of the clinical guidelines, now may be a good time to pay more attention to how it is implemented. Dr. Grundy explained that the category of short-term risk is divided into highest risk and moderately high-risk categories, both of which are potential candidates for drug therapy. The category of long-term risk is divided into those at moderate risk and those at lower risk. He reviewed the ATP III cutpoints for considering drug therapy and therapeutic lifestyle changes for the various risk categories.

Dr. Grundy stated that the ATP III guidelines reach a limit in clinical management for persons who are not at immediate risk but may be at long-term risk. These persons should be followed more closely clinically, with a lipoprotein measurement completed at least every 2 years. Except for clinical follow-ups and emphasis on the public health approach, a special program for these at-risk patients is not available. Dr. Grundy suggested special categories of candidates who are potential targets for long-term prevention, including young adults (men <45 years, women <55 years), persons with borderline-high or high LDL-cholesterol levels who

are otherwise at low risk, persons with other risk factors, persons who are overweight or obese, and members of high-risk populations who deserve increased clinical attention. Dr. Grundy added that many of the categories tie in with target populations of other NHLBI programs.

Dr. Grundy recommended several population approaches to consider, including improving professional education, expanding screening for risk factors, expanding the role of allied health professionals, encouraging modes for intervention outside the clinical setting, and reimbursing long-term prevention measures.

Dr. Grundy said that the NCEP must pay more attention to persons at long-term risk and that there are many opportunities for the NCEP to develop new programs, improve education, and be more effective in preventing atherosclerosis in the first place, thereby reducing CHD risk in the long run.

Dr. Havas contrasted the high-risk-patient strategy and the population approach. The high-risk strategy addresses the smallest number of people at the highest risk. Benefits include cost-effectiveness, motivation of the provider and patient, and lack of interference by outside parties. Disadvantages to the high-risk approach include medicalizing issues, failing to address the larger problem, the cost of medications, the inability to accurately assess risk, and sending the implicit message that people do not need to change.

A population-based approach seeks to change behavior in the rest of the population, most of whom have lower risk, in hopes of preventing them from acquiring risk factors and eventually disease. The population-based approach has a large potential to prevent people from becoming

high risk and is nonpharmacological, thereby decreasing risk. Disadvantages to this approach include the fact that patients and public will be less motivated, costs are higher, and benefit-to-risk ratio is modest.

Dr. Havas presented data that demonstrated the increasing prevalence of risk factors with age, a rise that is not inevitable, and stated that a population-based approach results in far greater reductions in mortality. He presented the following data on the prevalence of modifiable risk factors in the U.S. population: 80 percent have an unhealthy diet, 80 percent fail to meet physical activity guidelines; 50 percent have high and borderline-high cholesterol levels; 50 percent are obese or overweight; 40 percent have high or borderline-high blood pressure; 25 percent smoke; 30 percent have low or borderline-low HDL; 8 percent are diabetic; and about 6 percent are borderline diabetic. All of these modifiable risk factors increase steeply with age.

Dr. Havas stated that education and policies to reduce the incidence of risk factors and disease are needed, and that these must be started in childhood and continued through old age. He suggested using a population-based approach that includes the following:

- Routine counseling for all persons, not just for those at high risk
- Improvement in the food supply (better labeling and improved choices)
- Promotion of healthier foods
- Improvement in restaurants (increased identification and smaller portions)

- Promotion of exercise in schools and worksites

Dr. Havas stressed the arbitrariness of defining low risk and high risk. This lack of clarity argues for the use of a broad population approach. He encouraged the development of a unified message as part of any approach. He pointed out that a successful population approach was used by the National High Blood Pressure Education Program to limit sodium in the diet.

Dr. Havas concluded that (1) effective population-based strategies can reduce the increased prevalence of risk factors seen with age, (2) most of the population is at higher than optimal risk, and (3) a combination of strategies will maximize reduction in mortality; but to do this, we need a comprehensive, integrated population approach, in which clinicians should play a major role.

Dr. Kuller stated that prevention of atherosclerosis is the primary concern. He explained that CHD cannot be prevented and controlled by a medical model alone, and, in fact, the high-risk approach has a relatively small impact on the rates of CHD within a population. Even if the highest risk population were treated with maximum success, we would not reduce the risk substantially in the lowest risk population. In addition, it is impossible to identify a majority of the individuals who will have a heart attack each year. A second approach is needed to balance the first (or clinical) approach. Dr. Kuller proposed that it be called "the prevention of atherosclerosis," and use a tag line such as "no plaque in the arteries" (resembling the dental campaign that encouraged no plaque on the teeth). A first step might be to declare an LDL cholesterol level of less than 100 mg/dL as optimal for all adults. This might be followed by an

educational campaign targeting the public and, to a lesser extent, the medical community. In addition, rather than setting up a program to prevent heart attacks, the NCEP might develop a program to prevent atherosclerosis—one that would prevent the development of the risk factors.

Dr. Kuller stated that although he liked the population approach in general, he favored an individualized at-risk approach in the population. Perhaps a combination of preventive medicine and a public health approach is needed. This type of approach would need the following: (1) a national consensus that an LDL cholesterol of <100 mg/dL is optimal; (2) a public health campaign for low cholesterol levels and for understanding the methods to prevent their rise with age; and (3) training and support of nutrition and behavioral scientists for program leadership. He stressed that this would not work with a medical model in the physician setting but must use a different approach. An ideal setting would be prevention centers, where high-quality behavioral scientists and nutritionists, along with public health officials, could take the lead in the prevention of atherosclerosis.

COORDINATING COMMITTEE DISCUSSION—REDUCING LIFETIME CORONARY HEART DISEASE (CHD) RISK IN THE INDIVIDUAL AT LOW SHORT-TERM RISK

Beginning a discussion of issues surrounding the idea of a population-based approach, Dr. Bronner urged that, in any campaign, information be delivered in culturally sensitive ways.

Dr. Yetley commented that past NCEP reports have been extremely useful to the FDA. The FDA would welcome future guidance for deciding how available data should be used to make recommendations for population-based strategies.

Dr. Steele agreed that a population-based approach is needed and cited the failure of health care institutions, despite the wide availability of information, to change the way workers and patients are fed. She wondered whether identifying everyone as the target of intervention would be more effective than identifying high-risk individuals.

Dr. Ganiats asked the group if the population-based approach would focus on cholesterol and heart disease only, or on additional goals.

Dr. Cleeman replied that today's discussion was intentionally left wide open. He listed the various approaches discussed, including a clinical approach, a preventive medicine approach, a population approach, and the importance of addressing multiple risk factors. He reminded the group that decisions about what should be done, how it should be done, and who needs to be involved do not have to be decided at this point. The purpose of this discussion is to brainstorm to determine priorities.

Dr. Garber agreed that a new and unique approach is needed, because the current approach has not solved our problems. He noted the rising incidence of diabetes.

Dr. Kuller listed similarities between the Dietary Approaches to Stop Hypertension (DASH), diabetic, and cholesterol-lowering diets. He felt it was important to focus on LDL

cholesterol because an approach that focused on lowering LDL cholesterol could result in a reduction in the incidence of weight gain and obesity, hypertension, diabetes, as well as elevation of LDL cholesterol and atherosclerosis. He stressed that atherosclerosis does not occur in the absence of LDL cholesterol.

Dr. Havas stated that it would be to the group's advantage to integrate the program with programs that are delivering similar messages.

Dr. Fedder urged the committee to study and learn from model programs used in the field of infectious diseases, whereby those at high risk are identified. He felt the clinical site should serve as a point of departure to identify who is at high risk.

Dr. Grundy wondered whether the NCEP should continue to focus at both the public health and clinical level only on cholesterol, or should the NCEP support other programs, such as the obesity initiative and the hypertension program. He questioned whether the NCEP could carry the larger message alone.

Dr. Bronner noted that data from the Food Survey demonstrated that the African-American community had poor food practices across the spectrum, regardless of education or income. She thought this demonstrated the need for an approach to educate the public, addressing cultural needs.

Dr. Giles stressed that education alone will not change behavior and that methods must be undertaken to make it easier to adopt healthy behavior. He felt we could learn a lot from the

anti-tobacco efforts in terms of policy and environmental strategies. He noted that environmental changes such as nutrition and physical activity will assist us in achieving the LDL cholesterol goal.

Dr. Clark suggested integrating NCEP messages into other health guidelines. He noted two areas that could easily be adapted by other health efforts, namely therapeutic lifestyle changes and the metabolic syndrome. Dr. Garber reminded the members that some behavioral changes can be made more easily than others—for example, changes in exercise are easier than changes in diet.

REPORTS FROM THE SMALL-GROUP DISCUSSIONS

Dr. Cleeman asked the Coordinating Committee members to break into smaller groups to discuss population approaches. Afterwards, the members reconvened as a group and the chairperson/facilitator of the small groups reported their group's discussions.

Group 3 Report

Dr. James McKenney

Dr. McKenney reported that his group considered a population approach to be the best answer to reducing cholesterol levels in the Nation. The group suggested developing a new population panel report, which would describe best strategies, include educational messages, and address issues such as environment (restaurants), food labels, and personal calorie-counting.

Group 2 Report

Dr. Luther Clark

Dr. Clark reported that his group discussed targeting the message. One suggestion was to target the pediatric level. Another was to focus on education outside the medical community. But, cautioned Dr. Lasater, the NCEP should be careful not to set itself up for failure. Changing cholesterol management on a population level likely would be very difficult. Enlisting the aid of effective outside organizations would be important.

Group 1 Report

Dr. Scott Grundy

Dr. Grundy reported that his group felt that more discussion is necessary—by a small group of committee members. He proposed that the committee assign a small writing group to consider the issues and develop a proposal for a population campaign. This would be presented to the whole group and, eventually, to Dr. Lenfant.

Drs. Grundy, Havas, and Kuller agreed to form the writing group. Dr. Cleeman said that he would invite Dr. Van Horn (absent) to join the writing group as well. Dr. Cleeman also said that he would ask Dr. Lenfant when he might be able to consider a proposal by the committee. He would forward Dr. Lenfant's response to the writing committee members, allowing them to plan their time appropriately.

Dr. Cleeman asked for final comments from the committee members and from the invited guests. There were no additional comments.

OPEN FORUM—COMMENTS FROM INVITED GUESTS

No comments made during the open forum.

ADJOURNMENT

Dr. Cleeman thanked the Coordinating Committee members and guests for their contributions and adjourned the meeting.

ATTACHMENT A

PARTICIPANT LIST

National Cholesterol Education Program
Coordinating Committee Meeting
October 16, 2001

Participant List

COORDINATING COMMITTEE

Members Present

AMERICAN ACADEMY OF FAMILY PHYSICIANS
Theodore G. Ganiats, M.D.

AMERICAN ACADEMY OF INSURANCE MEDICINE
Gary Graham, M.D.

AMERICAN COLLEGE OF CARDIOLOGY
Richard C. Pasternak, M.D., F.A.C.C.

AMERICAN COLLEGE OF NUTRITION
Harry Preuss, M.D.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE
Lewis H. Kuller, M.D., Dr.P.H.

AMERICAN DIABETES ASSOCIATION, INC.
Alan J. Garber, M.D., Ph.D.

AMERICAN HEART ASSOCIATION
Scott M. Grundy, M.D., Ph.D.

AMERICAN OSTEOPATHIC ASSOCIATION
Craig Spellman, M.D. (for Dr. Clearfield)

AMERICAN PHARMACEUTICAL ASSOCIATION
James M. McKenney, Pharm.D.

AMERICAN PUBLIC HEALTH ASSOCIATION
Stephen Havas, M.D., M.P.H., M.S.

AMERICAN RED CROSS
Pat Bonifer-Tiedt, Sc.M., M.S.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
Rose Marie Matulionis (for Mr. Santos)

CITIZENS FOR PUBLIC ACTION ON BLOOD PRESSURE AND CHOLESTEROL, INC.
Gerald J. Wilson, M.A., M.B.A.

NATIONAL BLACK NURSES ASSOCIATION
Linda Burnes-Bolton, Dr.P.H., R.N., M.S.N., F.A.A.N.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
James I. Cleeman, M.D.

NATIONAL MEDICAL ASSOCIATION
Luther T. Clark, M.D.

SOCIETY FOR NUTRITION EDUCATION
Darlene Lansing, M.P.H., R.D.

SOCIETY FOR PUBLIC HEALTH EDUCATION
Donald O. Fedder, Dr.P.H., M.P.H.

Members Absent

AMERICAN ACADEMY OF PEDIATRICS
Ronald E. Kleinman, M.D.

AMERICAN ASSOCIATION OF OCCUPATIONAL HEALTH NURSES
Pamela Hixon, B.S.N., R.N., C.O.H.N-S.

AMERICAN COLLEGE OF CHEST PHYSICIANS
Gerald T. Gau, M.D.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
Thomas C. Peng, M.D.

AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE
Ruth Ann Jordan, M.D.

AMERICAN DIETETIC ASSOCIATION
Linda Van Horn, Ph.D., R.D.

AMERICAN HOSPITAL ASSOCIATION
Sandra Cornett, R.N., Ph.D.

AMERICAN MEDICAL ASSOCIATION
Yank D. Coble, Jr., M.D.

ASSOCIATION OF BLACK CARDIOLOGISTS
Karol Watson, M.D., Ph.D.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
Claude Lenfant, M.D.

Associate Member Absent

AMERICAN ASSOCIATION OF OFFICE NURSES
Joyce Logan

Liaison Representatives Present

NHLBI AD HOC COMMITTEE ON MINORITY POPULATIONS
Yvonne L. Bronner, Sc.D., R.D., L.D.

CENTERS FOR DISEASE CONTROL AND PREVENTION
Wayne Giles, M.D., M.P.H.

COORDINATING COMMITTEE FOR THE COMMUNITY DEMONSTRATION STUDIES
Thomas M. Lasater, Ph.D.

DEPARTMENT OF AGRICULTURE
Alanna Moshfegh, M.S., R.D.

FOOD AND DRUG ADMINISTRATION
Elizabeth Yetley, Ph.D.

NATIONAL CENTER FOR HEALTH STATISTICS
Clifford Johnson, M.P.H.

DEPARTMENT OF VETERANS AFFAIRS
Pamela Steele, M.D.

Liaison Representatives Absent

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY
Francis D. Chesley, Jr., M.D.

DEPARTMENT OF DEFENSE
Col. Robert Dana Bradshaw, M.D., M.P.H.

HEALTH RESOURCES AND SERVICES ADMINISTRATION
Celia Hayes, M.P.H., R.D.

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION
Kathryn Y. McMurry, M.S.

National Heart, Lung, and Blood Institute Staff

Terry Long
Gregory Morosco
Ann Taubenheim
Sue Shero
Janet Kelly

Support Contract Staff of the National Cholesterol Education Program

Donald Cunningham
Susan Keller
Joanne Karimbakas
Marcia Bache
Ezra Bourne
La'Shaune Lambert

ATTACHMENT B
MEETING AGENDA

National Cholesterol Education Program
Coordinating Committee Meeting
October 16, 2001

Marriott Tysons Corner
Vienna, Virginia

AGENDA

9:00	Welcome and Report from the Coordinator	Dr. James Cleeman
9:15	Safety of Statins: A View from FDA	Dr. David Orloff
9:45	Activities to Promote the Adoption of Adult Treatment Panel III—Coordinator's Report	Dr. James Cleeman
10:15	BREAK	
10:30	Reducing Lifetime CHD Risk in the Individual at Low Short-Term Risk: Presentation of the Issue	Dr. Scott Grundy Dr. Stephen Havas Dr. Lewis Kuller
11:15	Coordinating Committee Discussion: Reducing Lifetime CHD Risk in the Individual at Low Short-Term Risk	
12:00	LUNCH	
	Small-Group Discussions: Reducing Lifetime CHD Risk in the Individual at Low Short-Term Risk	
1:30	Reports from the Small-Group Discussions	
2:45	Open Forum: Comments from Invited Guests	
3:00	Adjournment	

ATTACHMENT C
SUMMARIES OF SMALL-GROUP DISCUSSIONS

National Cholesterol Education Program
Coordinating Committee Meeting
October 16, 2001

Small-Group Discussion—Group 3

Dr. James McKenney
(Chairperson/Facilitator)
Ms. Pat Bonifer-Tiedt
Dr. Gary Graham
Dr. Harry Preuss
Mr. Gerald Wilson
Ms. Rose Marie Matulionis
Ms. Janet Kelly (NHLBI)
Dr. Ann Taubenheim (NHLBI)
Ms. Marcia Bache (Contractor Staff)

Members of the group discussed approaches for reducing lifetime CHD risk in the individual at low short-term risk. The following are highlights from the discussion, including comments and suggestions:

- The group favored using a population approach to address reducing lifetime CHD risk.

- Create an updated population report or similar document that would include more recent statistics on cardiovascular disease, overweight, and obesity.

- Develop a strong educational message in addition to a clear-cut policy and environmental strategy.

- The group discussed at length overweight and obesity as they relate to CHD risk. All members agreed that overweight and obesity were issues that the NCEP should address. It was noted that while cholesterol and heart disease rates have decreased, the incidence of overweight and obesity in the population has dramatically increased.

- Formulate strategies or guidelines that would influence healthier eating habits and increase physical activity in schools, hospitals, worksites, communities, and government agencies.

- Group members felt there was a need to create an environment to support behavior change, especially in the food-labeling industry, grocery stores, and restaurants. Members suggested it would be productive to take an approach similar to that which the tobacco campaign has taken. Members felt the committee could partner with the NHLBI Obesity Education Initiative (OEI) to take the lead in this effort.

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Small-Group Discussion—Group 2

Dr. Luther Clark
(Chairperson/Facilitator)
Dr. Yvonne Bronner
Dr. Linda Burnes-Bolton
Dr. Donald Fedder
Dr. Theordore Ganiats
Dr. Wayne Giles
Ms. Darlene Lansing
Dr. Thomas Lasater
Ms. Alanna Moshfegh
Dr. Craig Spellman (substituting for
Dr. Michael Clearfield)
Dr. Elizabeth Yetley
Ms. Terry Long
Ms. Joanne Karimbakas (Contractor staff)

Members of the group discussed approaches for reducing lifetime CHD risk in the individual at low short-term risk. The following are highlights from the discussion, including comments and suggestions:

- Consider utilizing providers other than physicians to deliver the cholesterol message. Consider using technology, for example kiosks within physician's offices, to improve patient education.

- Attempt to change reimbursement patterns to encourage dietary counseling.

- Initiate a broad-based public education campaign such as the successful "Know Your Number" message. Utilize NCEP member organizations to frame the messages and target specific populations with broad messages encouraging healthy eating.

- Utilize a balanced approach to implement the public health message, moving the focus away from simply losing weight and dieting to stressing healthy foods that taste good and are good for you.

- Take advantage of teachable moments; for example, after a heart attack, to discuss heart disease risk factors and the importance of lowering cholesterol.

- Encourage partnerships and consider utilizing a two-pronged approach. For example, addressing specific methods to lower cholesterol and provide a broader health message to encompass different diseases such as cancer and diabetes. Expand partnerships beyond the medical community to include governors, mayors, the food industry, school health organizations, and parks and recreation departments. Focus efforts on raising awareness and motivate various partnership organizations to implement strategies.

- Utilize educational models when deciding where resources will be deployed.

- Consider focusing on the school system; for example, use vending machines as a target, offering juice and water at reduced prices.

- The campaign should advocate policy and behavioral change and environmental influences. Groups should be encouraged to take action. For example, the National Black Nurses Association has established neighborhood walking groups to try to get people to be more active. A capacity-building project in Baltimore in conjunction

with Housing and Urban Development had children draw pictures that showed ways one could lower one's risk of heart disease.

- Different strategies should be used for different populations. Persons who have not had a cardiovascular event should be targeted, especially those 25–35 years of age.

- Focus on implementing environmental changes; for example, heart-healthy labels in restaurants, fruit juices and water in schools, and safe areas where persons can participate in physical activities. In addition, emphasize partnering with state agencies and increasing the number of physical education classes in schools.

- Implement and build on a large national campaign to show the benefit of reducing your cholesterol numbers. Consider a life-cycle approach that would illustrate how cholesterol changes at different points in your life. Develop strategies to formulate the basis of these changes.

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Small Group Discussion—Group 1

Dr. Scott Grundy
(Chairperson/Facilitator)
Dr. Alan Garber
Dr. Stephen Havas
Mr. Clifford Johnson
Dr. Lewis Kuller
Dr. Richard Pasternak
Dr. Pamela Steele
Dr. James Cleeman (NHLBI)
Dr. David Gordon (NHLBI)
Ms. Sue Shero (NHLBI)
Ms. Sue Keller (Contractor Staff)

Members of the group discussed reducing lifetime CHD risk in the individual at low short-term risk. The following comments and suggestions were made:

- Although two different approaches were discussed in the morning session, should a single approach or a combination of approaches be used?

- The group advocated a public health approach, in which the NCEP Coordinating Committee would ally itself with other NHLBI programs, such as the high blood pressure and obesity programs. NCEP might take the lead role, because of its proven record in the public health approach.

- The members felt the public health approach is important and perhaps offers the best opportunity to reduce the burden of atherosclerosis. However, they felt that a more individualized approach was needed—one in which health professionals would be more involved.

- LDL cholesterol should be the primary focus, regardless of the approach used.

- A better approach for integrating the message with those of other vascular disease risks, such as for high blood pressure, obesity, and cholesterol, is needed. ATP III took a big step by focusing on risk assessment with the purpose of targeting treatment to different groups.

- The members discussed whether the time was right for the NCEP to get together with other institutions and form a broad public health message regarding blood pressure, cholesterol, and obesity. The group felt the time was right, and stated that the Coordinating Committee would be the ideal messenger for delivering an integrated message, because of the buzz surrounding the NCEP.

- The members suggested forming a working group consisting of representatives from other programs, with the NCEP maintaining the lead role.

- The members felt it was important to offer broad public messages, such as cut down on eating animal fats and exercise more, in addition to specific messages that address blood pressure, cholesterol, and weight.

- The members felt that bringing the three programs together would be a good idea as long as the message advocated is scientifically sound.

- The message should encourage persons in the early years. There should be a special emphasis on getting the information out to the people, noting that information is already available but is not always getting out to the people.

- Dr. Cleeman thought the idea of some integration was appealing, but since this idea takes us beyond the scope of the program, details must be clearly articulated and first be presented to Dr. Lenfant.

- The group felt emphasis must be placed on getting individuals to change their eating and activity habits.

- The group suggested focusing on areas where there is already overlap with other programs, for example, weight, physical activity, and the metabolic syndrome.

- Dr. Grundy stated that the population approach in the past has not been a failure; average cholesterol levels in the population have declined, as have coronary event rates. Dr. Cleeman responded that we cannot be sure this trend will continue. Dr. Grundy agreed, and added that perhaps there is a need to reinforce the messages that are already out there.

- The group agreed that, because individuals have different cholesterol levels, the individualized approach is somewhat limited. People do not eat the same diet; therefore the focus should be on foods that are available to everyone (rather than on individual risk categories).

In summary, the small group agreed that Drs. Grundy, Havas, and Kuller would form a writing group; which would develop the proposal for a Working Group, including specification of the representation, the charter, and the specific purpose.

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