

Meeting Minutes

Department of Health and Human Services National Institutes of Health National Commission on Digestive Diseases

May 16, 2008

I. CALL TO ORDER

The Chairman of the National Commission on Digestive Diseases (NCDD), Stephen P. James, M.D. called to order the fifth meeting of the Commission at 4:00 p.m. on Friday, May 16, 2008 in the Westin Hotel in San Diego, CA.

A. ATTENDANCE – COMMISSION MEMBERS PRESENT

STEPHEN P. JAMES, M.D., National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)
BRUCE R. BACON, M.D., St. Louis University
BARBARA L. BASS, M.D., The Methodist Hospital, Houston
RICHARD S. BLUMBERG, M.D., Brigham & Women's Hospital
JOHN M. CARETHERS, M.D., University of California, San Diego
MAURICE A. CERULLI, M.D., New York Methodist Hospital
EUGENE B. CHANG, M.D. University of Chicago
MITCHELL B. COHEN, M.D., Children's Hospital Medical Center, Cincinnati
MARGARET M. HEITKEMPER, Ph.D., R.N., University of Washington
JANE M. HOLT, National Pancreas Foundation, Boston
DAVID A. LIEBERMAN, M.D., Oregon Health Sciences University
NANCY J. NORTON, B.S., International Foundation for Functional Gastrointestinal Disorders
PANKAJ J. PASRICHA, M.D., University of Texas Medical Branch
KENTON M. SANDERS, Ph.D., University of Nevada School of Medicine
JOANNE A.P. WILSON, M.D., Duke University Medical Center

COMMISSION MEMBERS ABSENT

DANIEL K. PODOLSKY, M.D., Massachusetts General Hospital
ROBERT S. SANDLER, M.D., M.P.H., University of North Carolina at Chapel Hill

EX OFFICIO MEMBERS PRESENT

RAJ K. GOYAL, M.D., VA Boston Healthcare System
JAY H. HOOFNAGLE, M.D., NIDDK
JOHN MILNER, Ph.D., National Cancer Institute
GRIFFIN P. RODGERS, M.D., Director, NIDDK

ADDITIONAL PRESENTERS IN ATTENDANCE

JAMES EVERHART, M.D., NIDDK
ROBERT HAMMOND, Ph.D., Executive Director, NCDD

B. ATTENDANCE – NIH STAFF AND GUESTS

In addition to Commission members, others in attendance included NIH staff representatives and interested members of the public. Attendees included the following:

Edward Doo, M.D., NIDDK
Aimee Frank, American Gastroenterological Association (AGA)

Frank Hamilton, M.D., M.P.H., NIDDK
Carina May, the Hill Group
Marjorie Merrick, Crohn's and Colitis Foundation of America
Megan Miller, Ph.D., NIDDK
William F. Norton, International Foundation for Functional Gastrointestinal Disorders
Michael Roberts, AGA
Lynn Robinson, AGA
Lisa Zamosky, Elsevier Society News Group

II. WELCOME, TODAY'S GOALS, AND APPROVAL OF NOVEMBER 2007 MINUTES

Dr. Stephen James, the Director of the Division of Digestive Diseases and Nutrition at NIDDK and Chairman of the Commission, welcomed Commission members and the public to the fifth meeting of the National Commission on Digestive Diseases. The primary goal of this meeting was for the Commission to discuss the draft long-range research plan entitled "Opportunities and Challenges in Digestive Diseases Research: Recommendations of the National Commission on Digestive Diseases" and to identify any remaining gaps or issues to be resolved before the research plan is finalized. Members were reminded that they have signed conflict of interest statements. The minutes of the November 2007 meeting were approved unanimously.

Dr. Griffin Rodgers, Director of the NIDDK, commended Commission members on the progress they have made in developing a draft plan to address opportunities and challenges in digestive diseases research. The Commission has now convened five highly productive, public meetings since its charter was issued by Dr. Elias Zerhouni, Director of the NIH, in 2005. In that time, the Commission identified 12 critical topic areas in digestive diseases research and established working groups to solicit external expertise and input. These topics were developed into a research plan that includes content on the state of the science and recommendations for research goals to address critical challenges in digestive diseases. In recognition of their time and efforts, Dr. Rodgers presented each appointed member of the Commission with a certificate of appreciation signed by Dr. Zerhouni and Dr. James.

III. REPORT ON BURDEN OF DIGESTIVE DISEASES IN THE UNITED STATES

Dr. James Everhart updated the Commission on the report on the burden of digestive diseases in the U. S. This report is expected to be released in final form at approximately the same time as the Commission's plan for digestive diseases research, which will include information from the report. The burden of disease report includes chapters on major digestive diseases, the national endoscopy database, and the costs of digestive diseases. The report covers a wide range of diseases, such as gastrointestinal infections, viral hepatitis, chronic liver disease, hemorrhoids, hernias, cancers of the digestive system, and others. Key elements include ambulatory care data from the National Ambulatory Medical Care survey, hospitalization data from the Healthcare Costs Utilization Project, mortality data in terms of years of potential life lost, and mortality trends.

Selected highlights of the data described in the report are:

- In 2004, 72 million ambulatory care visits had a first diagnosis of a digestive disease; almost 105 million visits had a digestive disease listed on the record.
- Between 1995 and 2004, ambulatory care visits for digestive diseases increased 33 percent, compared to a 17 percent increase for any disease or condition. Similarly, hospitalizations for digestive diseases increased 35 percent over a slightly shorter time, compared to a 13 percent increase for all hospitalizations.
- In 2004, approximately 10 percent of all deaths in the U.S. were due to digestive disease as the underlying cause. This rate has been declining since 1979 in part due to changes in the way diseases

are reported, but also because deaths from colorectal cancer, which is the leading cause of death from digestive disease, have been declining.

- In 2004, there were 1.5 million ambulatory care visits for peptic ulcer disease (12th among all digestive diseases), 489,000 hospitalizations (6th), 3,700 deaths (10th), and 20,000 years of potential life lost. These rates have all been trending downward in recent years.
- An estimated 21,500 new cases of gastric cancer were reported in 2004; the age-adjusted incidence of this cancer has been declining and the 5-year survival rate has also improved.
- Deaths from gallstones have declined; in addition, a steady decrease in gallbladder cancer mortality has been observed since 1979.
- Hospitalizations for gastrointestinal infections have increased, due in part to the increased incidence of *C. difficile* infection.
- In 2004, GERD accounted for 18.3 million ambulatory care visits and 3.2 million hospitalizations; both rates were the highest among digestive diseases.
- Around 16,000 new cases of primary liver cancer were reported in 2004, making it the fourth leading cause of digestive system cancer. The incidence of primary liver cancer has been increasing since the mid-'80s; 5-year survival has improved modestly to 8 percent.

Dr. Everhart invited the Commission members to submit written comments on the draft burden of digestive diseases report.

IV. POWERPOINT PRESENTATION: OVERVIEW OF THE COMMISSION'S OPERATIONS AND MAJOR THRUST OF THE RESEARCH PLAN

Three draft slide sets outlining the Commission's operational processes and major recommendations for research goals were prepared for the members' use as an outreach tool to raise awareness of the research plan. The first slide set details the history of the Commission, key elements of the charter, the Commission's website, lists of appointed and *ex officio* members, and a timeline of major events. A slide will be added to explain the process by which the Commission and its working groups developed its recommendations. The other slide sets listed either: (1) a summary of the research goals for each topic in the research plan on opportunities and challenges in digestive diseases research, or (2) the exact wording of every research goal for each topic. Commission members can use these slides to assemble presentations tailored to their specific needs and interests. The slide sets will also be made available to the public through the Commission's website.

V. NEXT STEPS TO ACHIEVE THE GOALS OF THE RESEARCH PLAN

Dr. James discussed suggestions that the recommendations for research goals in the Commission's research plan should be prioritized and that a timeline for implementation should be set. The original charge to the working groups had been to develop goals that would fit into short (1-3 years), intermediate (4-6 years), and long (7-10 years) timeframes. However, that structure for the research goals proved to be unwieldy and was abandoned in favor of developing a series of goals with supporting objectives that collectively span the 10-year timeline of the research plan. There was also a concern that prioritizing the research goals could detract from the inclusiveness of the plan, which addresses research opportunities for a large number of digestive diseases. However, the Commission was interested in identifying "special opportunities" that meet criteria such as the burden of disease, scientific opportunity, and the potential impact on disease. The Commission discussed the feasibility of applying such parameters to a wide variety of research topics, including basic science related to the digestive system, in a way that would highlight a few common areas of interest in the context of the richly detailed research plan. A group of Commission members will be organized to develop ideas for special opportunities that could be

highlighted and to evaluate the most appropriate means of incorporating the resulting items into the research plan.

The Commission discussed organizational structures that could be used for monitoring implementation of the research plan over the next decade. The Digestive Diseases Interagency Coordinating Committee and the Digestive Diseases and Nutrition subcouncil of the NIDDK Advisory Council were mentioned as possible entities that could perform this function. However, it is important to note that many of the 27 NIH Institutes and Centers support digestive diseases research in addition to NIDDK; therefore, input could be sought from advisory councils or groups associated with all relevant NIH Institutes and Centers.

Dr. James explained that suggestions for identifying funding mechanisms and developing a professional judgment budget for implementation of the research plan are outside the scope of the Commission's authority as outlined in its establishing charter. However, groups or individuals outside the Commission would not be limited in using the research plan as a tool for identifying their own priorities for digestive diseases research and optimal approaches to achieving them.

VI. FINAL DISCUSSION

The Commission's research plan is expected to be finalized during the summer of 2008. The final printed version of the research plan will include an index to allow for cross-referencing of topics that are relevant to multiple chapters. Members were also invited to submit suggestions for additional research goals or topics that could be cross-referenced in the body of the research plan.

VII. ADJOURNMENT

Dr. James thanked Commission members and all attendees for their time and participation. The fifth meeting of the Commission was adjourned at 7:00 p.m. on May 16, 2008.

I hereby certify that to the best of my knowledge, the foregoing summary minutes are accurate and complete.



Stephen P. James, M.D.
Director, Division of Digestive Diseases and Nutrition, National Institute of Diabetes and Digestive and
Kidney Diseases
Chairman, National Commission on Digestive Diseases