

## Meeting Minutes

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

June 12, 2006

#### I. **CALL TO ORDER**

The Chairman of the National Commission on Digestive Diseases (NCDD), Stephen P. James, called to order the first meeting of the Commission at 9:00 a.m. on Monday, June 12, 2006 in the Monticello Ballroom of the Crystal City Marriott, Arlington, Virginia.

#### **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)

BARBARA L. BASS, M.D., The Methodist Hospital, Houston, Texas

RICHARD S. BLUMBERG, M.D., Brigham & Women's Hospital, Boston

JOHN M. CARETHERS, M.D., University of California, San Diego

MAURICE A. CERULLI, M.D., New York Methodist Hospital, Brooklyn

EUGENE B. CHANG, M.D. University of Chicago

MITCHELL B. COHEN, M.D., Cincinnati Children's Hospital Medical Center,  
Cincinnati, Ohio

MARGARET M. HEITKEMPER, Ph.D., R.N., University of Washington, Seattle

JANE M. HOLT, National Pancreas Foundation, Boston

DAVID A. LIEBERMAN, M.D., Oregon Health Sciences University, Portland

NANCY J. NORTON, B.S., International Foundation for Functional Gastrointestinal  
Disorders, Milwaukee

PANKAJ J. PASRICHA, M.D., University of Texas Medical Branch, Galveston

DANIEL PODOLSKY, M.D., Massachusetts General Hospital, Boston

KENTON M. SANDERS, Ph.D., University of Nevada School of Medicine, Reno

ROBERT S. SANDLER, M.D., M.P.H., University of North Carolina, Chapel Hill

JOANNE A.P. WILSON, M.D., Duke University Medical Center, Durham

#### **COMMISSION MEMBERS ABSENT**

BRUCE R. BACON, M.D., St. Louis University School of Medicine, Missouri

#### **EX OFFICIO MEMBERS PRESENT**

ALEXIS BAKOS, Ph.D., R.N., National Institute of Nursing Research (NINR)

BETH P. BELL, M.D., M.P.H., Centers for Disease Control and Prevention (CDC)

BROOKS D. CASH, M.D., MC, CMDR USN, National Naval Medical Center

CHHANDA DUTTA, Ph.D., National Institute on Aging (NIA)

NANCY EMENAKER, Ph.D., R.D., National Cancer Institute (NCI) [substituting for  
John Milner, PhD, NCI]

DAVID P. GOLDMAN, M.D., M.P.H., United States Department of Agriculture (USDA)  
 RAJ K. GOYAL, M.D., VA Boston Healthcare System  
 GILMAN GRAVE, M.D., National Institute of Child Health and Human Development (NICHD)  
 BRIAN HARVEY, M.D., Ph.D., Food and Drug Administration (FDA)  
 JAY H. HOOFNAGLE, M.D., NIDDK  
 CHRISTINE A. KELLEY, Ph.D., National Institute of Biomedical Imaging and Bioengineering (NIBIB)  
 JAG H. KHALSA, Ph.D., National Institute on Drug Abuse (NIDA)  
 MARGUERITE KLEIN, M.S., R.D., National Center for Complementary and Alternative Medicine (NCCAM)  
 DENNIS LANG, Ph.D., National Institute of Environmental Health Sciences (NIEHS)  
 GRIFFIN P. RODGERS, M.D., M.A.C.P., NIDDK  
 MICHAEL ROGERS, Ph.D., National Institute of General Medical Sciences (NIGMS)  
 ANNETTE ROTHERMEL, Ph.D., National Institute of Allergy and Infectious Diseases (NIAID)  
 FRANCISCO S. SY, M.D., Dr.P.H., National Center on Minority Health and Health Disparities (NCMHD)  
 SAM ZAKHARI, Ph.D., National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Also Present:

JAY 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:

Sara Arnold, Health and Medicine Counsel of Washington	Mike Hall, American Liver Foundation
Anne Bicha, American Gastroenterological Association (AGA)	Eleanor Hoff, NIDDK
A. J. Bownas, The Hill Group	Michael Kalutkiewicz, AGA
Michelle Cissell, M.A.Cissell Consulting	Nakia Kelly, The Hill Group
Leslie Curtis, NIDDK	Kathy Kranzfelder, NIDDK
Dale Dirks, Digestive Disease National Coalition	Gavin Lindberg, Crohn's and Colitis Foundation of America
Jessica Duncan, AGA	Megan Miller, NIDDK
Richard Farishian, NIDDK	Anne-Louise Oliphant, American College of Gastroenterology
Carol Feld, NIDDK	Helyn Oscanyan, The Hill Group
Winnie Feldman-Lindauer, Celiac Sprue Association	Kimberly Parker, Congressman Bobby Rush (D-IL) Chief of Staff
	Judith Podskalny, NIDDK
	Stacey Poole, TAP Pharmaceuticals
	Sharon Pope, NIDDK

Michael Roberts, AGA  
Jennifer Shevchek, American  
Association for the Study of Liver  
Diseases

Rucha Vyas, Health and Medicine  
Counsel of Washington  
Anne Wright, Circle Solutions, Inc.  
Andrew Wurtzel, American Society  
for Gastrointestinal Endoscopy

## **II. WELCOME, INTRODUCTIONS, AND TODAY'S GOALS**

### **A. WELCOME AND INTRODUCTIONS**

Dr. Stephen James, the Director of the Division of Digestive Diseases and Nutrition at NIDDK and Chairman of the Commission, welcomed all participants to the meeting. Appointed members of the Commission introduced themselves, and described their expertise relative to digestive diseases. Dr. James reminded members not to speak on behalf of the Commission over the next 2 years as the process unfolds. Any statements that emerge during the course of the Commission's work will be approved by the group as a whole.

### **B. CHARGE TO THE NATIONAL COMMISSION ON DIGESTIVE DISEASES**

Dr. Griffin Rodgers, Acting Director of NIDDK, welcomed the group on behalf of the Director, NIH. Dr. Rodgers discussed the NIH interest in digestive diseases research relative to its mission of improving human health and presented the overall charge to the Commission. The NIH aims to protect and improve human health by conducting and supporting basic and applied clinical research and health services research. These efforts lead to the acquisition and dissemination of new knowledge to prevent, diagnose, and treat human diseases and disabilities. Attention to digestive diseases research by the NIH stems from the significant public health burden of these diseases in the U.S. It is estimated that 60-70 million Americans are affected by digestive diseases with direct medical costs each year totaling more than \$86 billion. These diseases, which include but are not limited to gastrointestinal reflux disease, food borne illnesses, irritable bowel syndrome, inflammatory bowel diseases, hepatitis, pancreatitis, GI cancer, and others, are a major cause of morbidity and mortality.

In fiscal year (FY) 2005, the NIH invested approximately \$1.2 billion in research related to digestive diseases. The three largest institutes in terms of funding support for this field were NCI, NIDDK, and NIAID, but many of the 27 Institutes and Centers at NIH contributed to the overall investment. Significant advances in understanding the causes and mechanisms of digestive diseases and developing new therapies to combat these diseases have resulted from NIH-funded research programs. Digestive diseases research has also benefited from cross-disciplinary research efforts including the Human Genome Project, HapMap studies, and the NIH Roadmap.

Dr. Elias Zerhouni, NIH Director, established the Commission for the purpose of enhancing research on digestive diseases for the benefit of patients and their families.

Dr. Zerhouni has charged the Commission with two main tasks: (1) to conduct an overview of the state of the science in digestive diseases research and (2) to develop a 10-year plan for digestive diseases research that is consistent with the NIH research mission and aimed at the ultimate goal of improving the health of the nation through research. The Commission's primary focus will be to identify compelling research opportunities that, if pursued, would improve the lives and health of individuals affected by digestive diseases. To accomplish this task, the Commission was assembled with 16 appointed members who include extramural researchers, medical professionals, and patient advocates, as well as 19 *ex officio* members representing NIH Institutes and Centers and other Federal agencies with an interest in digestive diseases research. In addition to these members, other stakeholders will be able to participate in the activities of the Commission through involvement in public meetings and opportunities for input and comment throughout the planning process. The strategic plan developed by the Commission will serve as an important scientific guide to help define the NIH focus on digestive diseases research in the upcoming years.

### **C. MEETING GOALS**

Dr. James explained that this first meeting of the Commission is largely organizational. By the end of the day, the Commission should have agreed on the nature and general structure of the plan to be developed, including a general outline of the report content. The group will also discuss the process for obtaining input and writing the report within the 2-year timeframe of the Commission's charter.

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

The Commission's report will include an update of data on the national burden of digestive diseases in the U.S. Dr. Jay Everhart from the NIDDK Division of Digestive Diseases and Nutrition reviewed past efforts on this topic. For example, Dr. Everhart edited a comprehensive report entitled "Digestive Diseases in the United States: Epidemiology and Impact," which was published in 1994. Among the more recent reports is one entitled "The Burden of Gastrointestinal Disease" published by the American Gastroenterological Association (AGA) in 2001; a summary of this report was published in the journal *Gastroenterology* in 2002 (vol. 12:1500-1511). This report was commissioned by the AGA Public Policy Committee for the purpose of determining the impact of gastrointestinal (GI) conditions on the national population and identifying the relative economic burden of GI diseases. The medical costs and loss of productivity from 17 selected diseases were examined using multiple Federal and non-Federal data sources. For each disease, the report presented data on: prevalence; direct and indirect costs; total deaths and mortality rates (overall and by sex); and NIH research expenditures compared to total disease costs. An updated report—"Digestive and Liver Diseases Statistics, 2004"—was published in the journal *Gastroenterology* in 2004 (vol. 126:1448-1453). Dr. Everhart pointed out that these reports suggested trends in digestive disease burden over time. For example, acid-related disease, which was barely mentioned in reports of

the 1990s, was the largest single disease category in terms of direct medical costs in the 2001 AGA report. This shift was largely driven by the costs of acid reflux medications. Among other topics, the 2004 report more closely examined prescription drug costs and trends in utilization of anti-acid and gastroprotective agents.

Dr. Everhart noted that all previous reports on digestive diseases burden were limited by the availability of high-quality data. Economic data, particularly in terms of indirect costs, can be difficult to obtain. In the past, no information has been available for endoscopy and its indications, but new resources now exist that could be utilized for the next update. Limited data are available on topics like access to care, health disparities, or regional variation. Some diseases such as celiac disease or gastroparesis have poor national data, but may yet be important to include in future analyses.

In September 2005, the Digestive Diseases Interagency Coordinating Committee (DDICC) met to discuss the need and purpose, scope, and resources needed for an updated report on the burden of digestive diseases. Importantly, the planned update will focus on data tabulation for the purpose of supporting the work of the NCDD. This report should not be considered “epidemiological research” that will result in better understanding of diseases or, by itself, identify significant questions for future research. Moreover, tabulation will be limited by the quality of the data, which varies across digestive diseases. However, the update will be aided by the increasing numbers of well-trained epidemiologists who recognize the public health implications of digestive diseases and are performing sophisticated, hypothesis-driven research. The technological revolution of recent years has also facilitated the accessibility and ease of analysis of data related to disease burden.

The updated report on disease burden needs to be completed in a short time so that the data can be used by the Commission during its 2-year process. For this reason, the report will be largely tabular and restricted to the most common diseases as well as diseases of special interest or ones that appear to be increasing in significance. Metrics to be analyzed include incidence, prevalence, health care utilization, restricted and limited activity days, mortality, and cost. As appropriate, the report might also examine time-trends of some measures, population disparities by age, sex, or race, and, when possible, the impact on children.

Commission members suggested several topics that might be relevant for the update on disease burden such as: eosinophilic gastrointestinal diseases; infectious diseases, including food borne illnesses; quality of life issues; and pediatric conditions, including intestinal failure, complex motility disorders, and feeding disorders. These recommendations will be taken under consideration; however, it is important to realize that diseases or metrics chosen for the report will ultimately be determined by the data that are available and not necessarily by what are the most important topics. The Commission was encouraged to develop recommendations for future epidemiological research in the course of its work.

#### **IV. ACTION PLAN FOR LIVER RESEARCH: OVERVIEW AND UPDATE**

Dr. Jay Hoofnagle, Director of the Liver Disease Research Branch of NIDDK, reported on the development and implementation of the Action Plan for Liver Disease Research<sup>1</sup> at NIH. In 2003, in response to Congressional and lay interest, a Liver Disease Research Branch was created within the NIDDK Division of Digestive Diseases and Nutrition to bring greater visibility and focus to liver disease research and to ensure growth and excellence in NIH-funded liver-related research. The initial charge to the Branch was to establish a Liver Disease Subcommittee of the DDICC and, through that subcommittee, to formulate a trans-NIH Action Plan for Liver Disease Research. The Action Plan was to provide an overview of the current status of liver disease research and to outline the major challenges and needs for future research. The ultimate goal is to reduce the burden of liver and biliary diseases in the U.S. through research.

Development of the Action Plan began with an analysis of the NIH grant portfolio for liver research in FY2002. In that year, NIH invested \$348.5 million for 1,646 grants and awards through 16 Institutes or Centers. These grants were classified into 16 topic areas that formed the basic structure of the Action Plan. Topic areas encompassed basic research, various liver diseases, and technology development. For each area, working groups were assembled that included extramural investigators, a member of the Liver Disease Subcommittee, NIDDK staff members, and lay volunteers. Each working group met by conference call to develop recommendations for 9-18 goals per topic area. Draft chapters based on these calls were prepared by NIDDK staff and reviewed through an iterative process by the original working group, a second group of NIH-funded investigators, industry researchers, and lay groups. Final recommendations were approved by the original working group members.

Development of the Action Plan focused on translation of basic research into clinical gains that would reduce the burden of disease. Research goals, which were intended to be representative and measurable, were categorized into a 3 by 3 matrix stratified by time [short-term (1-3 years), medium-term (4-6 years), long-term (7-10 years)] and level of risk or difficulty of attaining the goal (low, intermediate, high). Recommendations for specific funding mechanisms were avoided as much as possible. A total of 214 Research goals were developed for the 16 topic areas collectively. Several common themes emerged throughout the Action Plan, including: translation of recent basic research breakthroughs, development of appropriate and reliable animal models, standardization of nomenclature, and promotion of interdisciplinary research.

To aid implementation of the Action Plan, 10 “benchmark goals” were framed. These were not necessarily the most important goals, but rather ones that could serve as signposts for the success of the Action Plan. Every year, scientific progress in each of the goals, including the benchmark goals, will be assessed by the working groups. Commission members noted that the success of the Action Plan, particularly in the near-term, is associated to some degree with previous investments and activities in liver research. Since its publication, all liver-related initiatives (e.g., Requests for Applications,

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<sup>1</sup> The Action Plan for Liver Disease Research can be accessed at <http://liverplan.niddk.nih.gov>

Program Announcements, or meetings and workshops) produced by NIDDK alone or in collaboration with other NIH Institutes and Centers are now based on priorities as defined by the Action Plan. Within NIDDK, goals of the Action Plan are used to determine “special emphasis funding” for R01 grants that fall just outside the typical payline, but which are responsive and critical to the success of the Action Plan. The NCDD was encouraged to consider making recommendations about how its own plan could be implemented or evaluated after the close of the Commission’s term. Delegating responsibility for implementation to the DDICC is an option; although, many interest groups both within the NIH and in external organizations will be able to incorporate the Commission’s report into their future activities.

Dr. Hoofnagle mentioned some lessons learned in the development of the Action Plan that could inform the Commission’s efforts. Focusing the Action Plan so that it would have a real impact on lessening the burden of disease could be difficult because there often is simply not enough data available to understand the relative impact of various diseases. It was also important for the working groups to concentrate on developing scientific goals rather than potential funding mechanisms. Training of new investigators in liver disease research was not addressed in the Action Plan, although issues related to training and career development will be important considerations for the NCDD. Finally, coding of grants by disease can be inconsistent across NIH Institutes and Centers, which can affect the portfolio analysis.

## **V. RECENT AND CURRENT DIGESTIVE DISEASES RESEARCH: NIH INSTITUTES, CENTERS, AND OTHER FEDERAL AGENCIES**

Representatives of NIH Institutes or Centers and other Federal agencies with an interest in digestive disease research provided an overview of research activities within their organizations.

Stephen James, NIDDK: In FY2005, NIDDK spent more than \$322.7 million for 1,127 grants and awards related to digestive diseases, mostly through the Division of Digestive Diseases and Nutrition. These awards covered a wide range of topics—liver and biliary diseases, the gastrointestinal tract, the pancreas, obesity as it relates to digestive diseases, nutrient metabolism, and cross-cutting areas such as clinical trials, genetics, epidemiology, and training. Many topics of interest to NIDDK overlap with the priorities of other NIH Institutes. For example, NIDDK and the NCI each support research on pre-malignant conditions, such as dysplasia in Barrett’s esophagus. NIDDK employs a variety of funding mechanisms—consortia, multi-center clinical studies and trials, centers that provide core resources, and career development awards—to promote digestive diseases research. Through the DDICC, the NIDDK takes a leadership role in research planning activities related to digestive diseases.

Brooks Cash, Department of Defense (DOD): The DOD healthcare mission is to provide and maintain readiness to provide healthcare services and support to members of the Armed Forces during military operations. Because the Department also delivers routine

healthcare to military personnel and their families, DOD has an interest in many digestive diseases. DOD research activities are predominantly clinical in nature and offer an opportunity for enhanced collaboration with other agencies. Standardization of clinical database platforms with similar systems throughout the country could provide a means to improve outcomes analyses.

Nancy Emenaker, NCI: The NCI sponsors research on multiple cancers of the digestive system, including colorectal cancer, oral cancers, cancers of the pharynx, and pancreatic cancer among others. In FY2005, NCI granted more than 1,541 awards totaling \$390.3 million for research on these diseases. Within this portfolio are 236 clinical trials, which range from phase I (safety) to phase IV (post-market) studies. The NCI recently developed a national research agenda that led to the establishment of three Research Progress Groups to define priorities for research on colorectal cancer, pancreatic cancer, and stomach and esophageal cancers.

Annette Rothermel, NIAID: NIAID sponsors research on infectious digestive diseases of viral, bacterial, or parasitic origin in addition to immune-mediated digestive diseases that include food allergies, autoimmunity and mucosal immunity, and liver graft rejection. NIAID spent \$311 million in FY2005 to fund 727 projects related to these topics.

Dennis Lang, NIEHS: Although NIEHS activities have traditionally focused on toxicology as it relates to metabolism of drugs and environmental toxicants, the Institute is moving toward a new emphasis on human disease and clinical relevance. In FY2005, NIEHS spent \$29.4 million to support 115 projects relevant to digestive diseases mostly in the area of liver metabolism and liver injury from environmental chemicals and exposures.

Sam Zakhari, NIAAA: The NIAAA supports basic and clinical research on a variety of topics relevant to digestive diseases with an emphasis on alcohol metabolism and its effects on liver and pancreatic diseases. In FY2005, NIAAA allocated \$41.8 million for 136 research projects on liver disease, pancreatitis and pancreatic diseases, the stomach, and cancer of the digestive system.

Gilman Grave, NICHD: The NICHD mission encompasses research on many digestive diseases or conditions that affect children, such as shigellosis, neonatal taste development, hyperbilirubinemia, necrotizing enterocolitis, and others. NICHD spent \$17.7 million in FY2005 for 74 research projects related to digestive diseases.

Marguerite Klein, NCCAM: In FY2005, the NCCAM awarded \$6.4 million for 29 grants on digestive diseases research. More than half of this portfolio supported clinical research to investigate complementary or alternative therapies for digestive diseases including botanicals, probiotics, and other dietary supplements.

Chhanda Dutta, NIA: The NIA supports research that improves the health and well-being of older adults. The NIA digestive diseases research portfolio, comprising six grants for a



total of \$1.9 million in FY2005, focuses on understanding the aging processes that contribute to digestive diseases and the special needs of older adults.

Alexis Bakos, NINR: The NINR provided \$1.7 million in FY2005 for research on digestive diseases with an emphasis on studying patient outcomes and clinical research. In the area of digestive diseases, topics of interest to NINR include personalized self-management interventions to reduce symptom distress and improve quality of life, health disparities issues, and improvement in care and patient outcomes in children.

Jag Khalsa, NIDA: At NIDA, digestive diseases research focuses primarily on hepatic complications and gastrointestinal disorders of substance abuse, including HIV and Hepatitis C infections in the substance-abusing population. In FY2005, the Institute invested \$26 million in research projects to study these issues.

Christine Kelley, NIBIB: NIBIB, the most recently established Institute at the NIH, supports the development of new technologies to advance basic research and medical care. NIBIB spent \$1.0 million in FY2005 for six grants relevant to digestive diseases with an emphasis on the development of noninvasive or minimally-invasive imaging technologies that could be used to visualize organs or tissues of the digestive system.

Francisco Sy, NCMHD: The NCMHD funds research on minority health and health disparities through partnerships with other NIH Institutes and Centers and other Federal agencies as well as its own extramural program. An example of NCMHD-sponsored research in digestive diseases is a Center for Excellence in Health Disparities Research that studies liver cancer and viral hepatitis in minority populations.

Michael Rogers, NIGMS: The mission of the NIGMS is to support research that will promote a fundamental understanding of basic life processes and the development of tools and techniques with application to multiple medical areas. For this reason, NIGMS has not identified a discrete portfolio of digestive diseases research, although the Institute supports several research projects in basic biochemistry, genetics, and cell biology, as well as the more clinical area of trauma and burn injury, of interest to this field. Examples of relevant research include: the role of nickel biochemistry in bacteria of the gut; control of cell proliferation in the developing stomach; and amino acid transport in the intestinal tract.

Beth Bell, CDC: The CDC generates and maintains large population-based surveys and vital statistics databases, including the National Death Index. The agency conducts population-based surveillance and applied epidemiological research and studies to enhance disease prevention. Several areas related to digestive diseases fall within the CDC's purview, including surveillance for viral hepatitis and foodborne pathogens; prevention of viral hepatitis and its sequelae; detection and response to outbreaks of foodborne illnesses; and monitoring and promotion of colorectal cancer screening.

Brian Harvey, FDA: As part of a recent reorganization, the FDA created a new division with responsibility for all digestive disease treatments other than viral hepatitis therapies.

Future clinical trials of new agents to treat digestive diseases should be designed with appropriate focus on issues such as safety and duration of treatment so that FDA approval can be sought for digestive disease indications.

David Goldman, USDA: The Food Safety and Inspection Service (FSIS) of the USDA ensures the safety of meat, poultry, and egg products in the U.S. In collaboration with the FDA, FSIS is responsible for meeting the food safety goals of the Healthy People 2010 program. FSIS scientists investigate food borne illnesses; perform quantitative microbial risk assessment; and study emerging zoonoses—disease transmission between species—that might result in food-borne transmission.

Raj Goyal, Department of Veterans Affairs (VA): The VA, which conducts research important to the care of veterans exclusively through an intramural program, spent \$6.2 million for digestive diseases research in FY2005. The unique infrastructure of the VA system, including electronic medical records for its entire patient population, affords exceptional opportunities for cooperative clinical studies, retrospective clinical data mining, and health sciences and rehabilitation research.

## VI. **CONTENT AND FORMAT OF FINAL REPORT**

Dr. James presented a draft list of possible topic areas that could form the basic outline of the Commission's report. The list included both cross-cutting scientific themes as well as organ/disease specific categories. The intent was that working groups would be established to further develop a set of recommendations within each theme area. Using the draft list as a starting point for discussion, the Commission was asked to outline a final report that would be comprehensive, yet manageable within a 2-year timeframe. Ideally, the final report will not be an extensive list of ideas but rather will present a series of important and well-thought-out opportunities and goals that can guide future research planning in relevant Federal agencies.

Through extensive discussion, the Commission agreed on the need to include patient- or disease-oriented themes in addition to basic science and cross-cutting topics within the structure of the final report. While it may not be possible or feasible to specifically address every digestive disease affecting humans, diseases can be categorized by common etiology, mechanisms, or other considerations. A report structure with a clearly identifiable clinical orientation would facilitate communication of the Commission's recommendations to audiences outside the NIH, such as Congress, digestive disease investigators, patient groups, and the lay public. Patient-oriented topics could extend beyond a disease-based approach to include wellness, prevention, detection, behavior, quality of life, and other issues that are integral to healthcare. The Commission also noted the importance of including fundamental, basic research that has the potential to uncover diseases that are currently unknown but which may be hidden in general symptoms.

Dr. James proposed that the report start with a general chapter on digestion and the function and development of the digestive tract. That introduction would be followed by

a series of chapters organized by organ-specific themes as well as clinically oriented and cross-cutting topics. Several potential themes that could form the basis of those chapters were proposed by the Commission, including:

- Functional gastrointestinal disorders;
- Disorders of function, motility, and pain;
- Gastrointestinal cancers;
- Enteric infectious diseases;
- Digestive tract physiology and development;
- Technology development—e.g., endoscopy, imaging;
- Regeneration and repair, including end organ failure, transplantation, tissue engineering;
- Enteric neurobiology—e.g., obesity, inflammation;
- Obesity, including bariatric surgery;
- Immune-mediated diseases—e.g., food allergies, celiac disease, eosinophilic esophagitis and gastroenteritis, certain liver diseases;
- Inflammatory bowel diseases;
- Diseases of the esophagus, including the oropharynx, GERD, swallowing disorders, motility disorders, Barrett’s esophagus, esophageal infections;
- Diseases of the pancreas;
- Symptom management;
- Quality of life research;
- Epidemiology or health services research.

The list of potential themes will be further refined by the Commission through ongoing communication with Drs. James and Hammond after the meeting.

In terms of liver disease research, the Commission discussed the potential for overlap with the Action Plan for Liver Disease Research that was completed in December 2004. A working group could be established to identify updated information or gaps that would build on rather than duplicate recommendations from the Action Plan. For example, training and career development in liver disease research is a critical gap that was not included in the Action Plan, yet this topic is central to the Commission’s mandate.

The special case of nutrition and its relationship to digestive diseases was discussed by the Commission. Nutrition was specifically omitted from the NCDD charge because research planning in this area is overseen by an established committee<sup>2</sup>. Nonetheless, nutritional issues and nutrition science may be critically important to many digestive disease theme areas and will be incorporated into the Commission’s report as appropriate.

The Commission defined multiple issues to be considered by the working groups assigned to each theme area. It will be important for the working groups to identify unmet medical needs, scientific opportunities, and research priorities and to recommend cutting-edge science that will be needed to address those issues over the next 10 years. In

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<sup>2</sup> The Nutrition Coordinating Committee within the Division of Nutrition Research Coordination operates as an NIH-wide forum to review, stimulate, and encourage the support of nutrition research and training.

identifying gaps, working groups could address workforce needs, including opportunities for training and career development as well as the development of multidisciplinary teams. Working groups should look for ways to integrate research resources, such as proteomics or small molecule screening tools being developed through the NIH Roadmap, into each theme area. For all disease-oriented themes, addressing health disparities—in particular, the needs of children and special adult populations—will be a critical factor. Because of the diversity of diseases and research needs encompassed by each theme, experts who are invited to participate in the working groups will be expected to think broadly and to comment on issues that may extend beyond their individual research focus.

Each working group will include one or more appointed members of the Commission and will be charged with developing a draft chapter of the NCDD report in a standard format. A brief introduction and background section will highlight important scientific advances in the field. This will be followed by each group's research goals and recommendations for achieving those goals. Profiles of patients afflicted with digestive diseases may be included to draw attention to the impact of research on real people. Finally, the Commission discussed the possibility of attempting to prioritize goals that are developed within each theme. Commission members requested a more detailed grant list for the NIH portfolio in digestive diseases research as well as copies of prior strategic plans related to this field.

## **VII. OVERALL TIMELINE, GOALS, AND OPERATING PROCEDURES**

Dr. Robert Hammond, Executive Director of the NCDD, provided more information about the logistics of the working groups and presented a draft timeline for the Commission's activities over the next 2 years. Working groups aligned with each theme will be assembled for the purpose of providing expert advice to the Commission. Each group will include at least one NCDD member who will serve as the Chair in addition to 4-8 external advisors. These experts, who may include lay volunteers, will be nominated through an open and transparent process. Commission members will have an opportunity to approve the rosters for each group and were themselves encouraged to participate in multiple working groups. Working groups will be provided with clear instructions and templates for preparing their reports and will conduct their activities through conference calls and electronic mail.

Working groups will be appointed and begin their work in summer 2006 and continue to deliberate throughout early 2007. At upcoming NCDD meetings on November 6, 2006 and in spring 2007, the Commission will review proposed goals and recommendations as each group makes progress in its area. Assuming that all groups have completed their work by spring 2007, a draft NCDD report will be prepared and posted for public comment during summer 2007. The Commission will likely meet in fall 2007 and again in spring 2008 to finalize the report, approve the report for publication, and discuss plans for implementation.

## VIII. NEXT STEPS AND FINAL CLOSING POINTS

Dr. James invited Commission members to propose appropriate locations for future NCDD meetings and also asked members to give some thought as to how the public could contribute to the Commission's efforts. Washington, DC, and Chicago, IL, were suggested as possible future meeting locations. Members suggested holding an open forum for public comment or testimony, perhaps after the full draft report is completed. It was also noted that Digestive Disease Week will be held in Washington, DC, in May 2007. This event might afford an opportunity for a public forum if a suitable agenda can be developed. Commission members will vote on future meeting locations and dates.

## IX. ADJOURNMENT

Dr. James thanked Commission members and all attendees for their time and participation. The first meeting of the NCDD was adjourned at 4:42 p.m., June 12, 2006.

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



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