



ACG Institute for Clinical Research and Education  
Annual Report 2006-2007



ACG INSTITUTE FOR CLINICAL RESEARCH & EDUCATION  
AMERICAN COLLEGE OF GASTROENTEROLOGY

**mission**

The primary mission of the ACG Institute is to advance the field of clinical gastroenterology through education and research. Consistent with that mission, the ACG Institute for Clinical Research and Education serves as a forum in which to build on the goals of the College and to promote research in clinical gastroenterology, to educate physicians and the public, and to provide resources to support young clinical investigators who as they develop careers in academic gastroenterology, enrich knowledge and treatments in digestive diseases.



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## ACG INSTITUTE COMES INTO ITS OWN

### SUCCESS OF CAPITAL CAMPAIGN RESULTS IN EXPANDED FUNDING FOR EXCELLENT CLINICAL RESEARCH AND NEW EDUCATIONAL PROGRAMS

#### 2006 - 2007

The ACG Institute is pleased to announce the outstanding success of the Institute's Capital Campaign, which through recent generous gifts in 2007 stands well beyond the \$16 million mark. Launched in 2002, the original goal of \$12 million was surpassed several years ago, reflecting the generous and visionary support of ACG members and contributors from the pharmaceutical and device sectors.

From the beginning, the ACG Institute set an ambitious goal and the College is proud of the unprecedented support for the Institute and its mission. Generous gifts from several companies this year are capstones for this remarkable campaign. Highlights of the Campaign in 2007 include new pledges of support from Procter & Gamble and Salix at major gift levels, and significant commitments to the Institute from Prometheus, Shire, and Given Imaging. These gifts underscore the importance of the Institute in the life of the College.

From a position of burgeoning financial strength, the Institute has been able to achieve a significant boost in its support for patient-oriented research and to expand its educational programming. In 2007, the ACG Institute awarded \$950,688 in support for clinical GI including three career development awards through ACG's Junior Faculty Development Award. As part of this investment in excellent clinical GI research, \$264,652 was awarded pursuant to a Request for Applications issued by the Institute under the Colorectal Cancer Prevention Action Plan.

The Colorectal Cancer Prevention Action Plan reflects the College's longstanding commitment to improving colorectal cancer screening. The ACG Institute issued an RFA for the second of a planned series of RFAs for a grant of up to \$150,000. In developing the RFA, the Institute recognized that in spite of multiple efforts to promote colorectal cancer screening, utilization rates remain low and adherence to surveillance guidelines is highly variable. ACG's goal was to promote research geared toward improving the quality of colorectal cancer screening and/or surveillance, with the ultimate goal of reducing colorectal cancer incidence and mortality.

In total, ten applications were received. While the original plan was to fund a single outstanding research protocol, the quality of the proposals submitted led the ACG Board of Trustees to fund two proposals: one from researcher Cynthia Ko, MD at the University of Washington for her project "Colonoscopy Quality and Outcomes in Clinical Practice, and a second to Linda Rabeneck, MD, MACG of Sunnybrook Regional Cancer Centre in Toronto to investigate "New or Missed Colorectal Cancer After Colonoscopy."

At the same time, the Institute has introduced highly successful educational programs that offer valuable educational offerings to practicing clinicians. Dr. Edgar Achkar, working with Dr. Philip Katz and Dr. Kenneth DeVault, introduced the "ACG Saturday with GI Experts" series this year, highlighting the Institute's commitment to top-tier educational offerings and to creating practical clinical updates to meet the needs of busy GI clinicians.

The ACG Institute is proud of its growth and success in attracting funding for its important mission, and is pleased to report to members of the College on its activities and accomplishments.

## GENEROUS DONORS

Capital Campaign pledges through October 1, 2007

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### NAMED GIFTS \$100,000 TO \$499,000

David Y. Graham Lectureship

Meretek and Otsuka in honor of David Y. Graham, MD, MACG

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### MAJOR GIFTS \$25,000 TO \$99,999

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*This list includes Capital Campaign pledges over \$1,000 as of October 1, 2007*

## COLORECTAL CANCER PREVENTION ACTION PLAN

*The ACG Colorectal Cancer Prevention Action Plan is an ambitious, multi-faceted effort approved by the ACG Board of Trustees in 2004. Under this plan, the College has earmarked significant resources to support large clinical research grants on specific clinically important topics in colorectal cancer prevention—research in improving the safety, effectiveness and acceptability of colonoscopy, and other colorectal cancer prevention strategies.*



*Charles J. Kahi, MD  
Roudebush VA Medical  
Center, Indianapolis, IN*

### **ACG's Ongoing Commitment to Improving CRC Screening**

For 2007, the ACG Institute issued a Request for Applications pursuant to the Action Plan for the second of a planned series of RFAs for a one-time grant of \$150,000. There was consensus among colorectal cancer experts involved in developing the RFA that the measurement of quality of performance of colorectal cancer screening tests was of critical importance. In the RFA, the Institute sought to promote research geared toward improving the quality of colorectal cancer screening and/or surveillance, with the ultimate goal of reducing colorectal cancer incidence and mortality.

Two proposals emerged from the grant review as top scoring protocols. The scores were so close, and both were so highly regarded, that a dilemma emerged. The top ranked proposals were a project from Dr. Cynthia Ko at the University of Washington (Colonoscopy Quality and Outcomes in Clinical Practice) and a project from Dr. Linda Rabeneck at Sunnybrook Regional Cancer Centre in Toronto (New or Missed Colorectal Cancer After Colonoscopy.)

At a recent ACG Board of Trustees meeting, Dr. Achkar presented the dilemma of these two excellent projects and opened this issue up for consideration by the Trustees. During the discussion, it became clear that the College's priority was to fund excellent clinical research on quality in colorectal screening, that both of these promising proposals met this criterion, and that the time was ripe for both.

After serious consideration of the budget for the research component of the Action Plan, it was the consensus of the ACG Board, in an unprecedented move, to fund both of these projects, drawing down some of the remaining funds originally slated for a third RFA.

In 2005 the College made its first award through the Action Plan when a one-time grant of \$100,000 was awarded for research on chromocolonoscopy in the detection of flat colorectal neoplasms to Charles Kahi, M.D. and his colleagues in Indianapolis.

Additionally, under the auspices of the Action Plan, the College has made a priority to provide financial support for ongoing, targeted patient and physician education efforts regarding colorectal cancer screening. The launch of this effort in 2005 included major national newspaper advertising, public awareness efforts at the local level addressing issues of quality endoscopy, as well as the development and dissemination of an excellent Colorectal Cancer Resource Kit for ACG members.



*Cynthia W. Ko, MD  
University of Washington  
Seattle, WA*



*Linda Rabeneck, MD, MACG  
Sunnybrook Cancer Centre  
Toronto, ONT, Canada*

## CLINICAL GI RESEARCH SUPPORT

### CAREER DEVELOPMENT & CLINICAL RESEARCH SUPPORT

The College continues to receive increasing numbers of excellent quality research proposals. Through the support of the ACG membership and partners in industry, the Institute has been able to raise enough money to fund a substantial number of proposals that promise to make a difference in the future of gastroenterology and patient care. The College can be rightfully proud of its mission to support clinical research in gastrointestinal diseases. ACG's ongoing support of clinical investigators, especially young investigators, in the face of the declining availability of federal funds, provides crucial support to talented researchers who are often at crucial junctions of their career.

#### Junior Faculty Development Award

The ACG Junior Faculty Development Award is a two-year grant designed to support a junior faculty member or mid-career clinical investigator of outstanding promise, and to assist in facilitating his/her progress into an independent, productive research career in gastroenterology or hepatology. In its tenth year in 2007, this award shows ACG's clear commitment to promote clinical research and scholarly activities. This is consistent with one of the ACG Institute's major goals of helping young people who want to develop careers in gastroenterology, and particularly clinical research, with mechanisms to provide funding of time and resources that otherwise might not be possible. In selecting candidates, ACG has enjoyed a clear pattern of success, as Junior Faculty Awardees stay in academic and research careers, publish their findings, present them at the Annual Scientific Meeting, and go on in their careers to secure prestigious NIH funding.

#### 2006 ACG Junior Faculty Development Awards

*\$75,000 Per Year for Each of Two Years*

**Albena Halpert, M.D.**

Boston Medical Center

*The Impact of Patient Education on Clinical Outcomes in Irritable Bowel Syndrome*

**Julie E. Polson, M.D.**

University of Texas Southwestern Medical Center

*Development of a Prognostic Scoring System for Acute Liver Failure*

**Claudia O. Zein, M.D., MSc**

Cleveland VA Medical Center

*Treatment Efficacy of Pentoxifylline in Patients with Non-Alcoholic Steatohepatitis: A Double-Blind Randomized Placebo-Controlled Trial*

#### 2007 ACG Junior Faculty Development Awards

*\$75,000 Per Year for Each of Two Years*

**Brian Behm, M.D.**

University of Virginia

*Pravastatin in Active Crohn's Disease*

**Gregory Sayuk, M.D.**

Washington University School of Medicine

*The Effect of Somatic Symptom Burden on Central Pain Responses in Irritable Bowel Syndrome*

**Marcelo Vela, M.D.**

Medical University of South Carolina

*Impedance pH and Electron Microscopy to Evaluate Endoscopy-Negative Reflux Disease*



## CLINICAL RESEARCH

### 2006 ACG Clinical Research Awards

*A One-Time Grant of up to \$35,000*

**John O. Clarke, M.D.**

Johns Hopkins Hospital

*Evaluation of Endoscopically-implantable On-demand Device To Stimulate The Lower Esophageal Sphincter*

**Hashem B. El-Serag, M.D., MPH**

Michael E. DeBakey Medical Center

*Statins and the Risk of Hepatocellular Carcinoma*

**Fritz Francois, M.D.**

New York University

*The Role of Gastric Leptin in Esophageal Pathology*

**Smita Halder, M.D.**

Mayo Clinic Rochester

*The Risk of GI And Non-GI Infections in Irritable Bowel Syndrome and Functional Dyspepsia*

**Meredythe A. McNally, M.D.**

MAYO CLINIC ROCHESTER

*Development of a Microscopic Colitis Disease Activity Index*

**Dawn Provenzale, M.D., FACC**

Duke University Medical Center

*Development of a Comprehensive Molecular Epidemiology Program for Clostridium Difficile-associated Diarrhea Using a Novel Automated Surveillance Methodology*

**Shaoyong Yu, M.D.**

Penn State University M.S. Hershey Medical Center

*Does Esophageal Mast Cell Activation Contribute to the Symptoms of Heartburn in Patients with Non-Erosive Reflux Disease (NERD) and Functional Heartburn?*

### 2006 Clinical Research Grants – Pilot Studies

**Laura Bianchi, M.D.**

Cleveland Clinic Foundation

*Determination of the Prevalence of Fundic Gland Polyp Dysplasia in Familial Adenomatous Polyposis*

**Ananya Das, M.D.**

Mayo Clinic Scottsdale

*Digital Image Analysis of Endoscopic Images for Differentiating Adenomatous Polyps From Non-Adenomatous Polyps Seen During Sigmoidoscopy/Colonoscopy*

**Ahmed Kandiel, M.D., M.P.H.**

Cleveland Clinic Foundation

*Stool Cmv DNA for Detection of CMV Infection Complicating IBD Colitis*

**Jeffrey A. Katz, M.D.**

University Hospitals of Cleveland

*Prevention of Antibiotic-Associated Diarrhea in Hospitalized Adults Receiving Lactobacillus Reuteri*

**Ioannis Oikonomou, M.D.**

*Role of Hepcidin in the Pathogenesis of Chronic Anemia in Patients with Ileal Pouch-Anal Anastomosis*

**Heather Patton, M.D.**

UC San Diego Medical Center

*A Single-center, Single-Blinded, Placebo-Controlled Pilot Study of IDB1016 (Siliphos) in Adult Diabetic Patients With Non-Alcoholic Steatohepatitis (NASH)*

**Lisbeth Selby, M.D.**

University of Kentucky

*Functional Bowel Disease in First Degree Relatives of IBD Patients*

**Anne Wolf, M.D.**

Brigham & Women's

*Effect of INR on Rebleeding Following Endoscopic Therapy for Non-Variceal Upper Gastrointestinal Hemorrhage*

## 2007 ACG Clinical Research Awards

*A One-Time Grant of up to \$35,000*

### **Neena S. Abraham, MD, MSCE**

Baylor College of Medicine  
Patient and Physician Preferences for High-Risk NSAID Prescription

### **David Bruining, MD**

Mayo Clinic Rochester  
*Clinical Benefit of CT Enterography in Crohn's Disease: Impact on Patient Management and Multi-Modality Modeling of Active Crohn's Disease*

### **Hesham Elgouhari, MD**

The Cleveland Clinic Foundation  
*Detection of Caspase Activity in the Plasma of Patients with Various Liver Diseases as a Novel Biomarker of Disease Severity*

### **Amy E. Foxx-Orenstein, DO, FACC**

Mayo Clinic Rochester  
*Effect of Fluoxetine on Serotonin Metabolism and Intestinal Transit on Constipation Predominant IBS (C-IBS)*

### **Joseph Leung, MD, FACC**

UC Davis Medical Center  
*Use of Mechanical Simulator for Evaluation of Trainee Performance in Papillotomy*

### **Ilche Nonevski, MD**

Cleveland Clinic Foundation  
*Eosinophilic Esophagitis: The Role of Pro-Inflammatory Mediators to Eosinophilic Infiltration and Muscle Contraction*

### **Thomas Schiano, MD**

Mount Sinai Medical Center  
*Hepatic Progenitor Cells: Their Possible Role in Severe Recurrent Hepatitis C and Associated Allograft Loss Post-Liver Transplantation*

### **Mamata Sivagnanam, MD**

University of California San Diego  
*The Genetic and Molecular Basis of Congenital Tufting Enteropathy*

## 2007 Clinical Research Grants – Pilot Studies

### **Herbert L. Bonkovsky, MD, FACC**

University of Connecticut Health Center  
*A Pilot Study to Assess DNA Methylation Patterns in Alcoholics and Controls: The DMAC Study*

### **Jhony Doumit, MD**

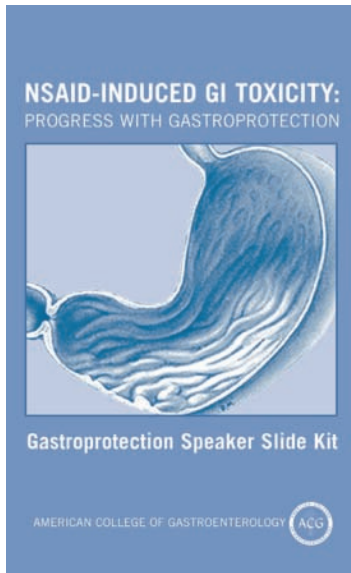
Cleveland Clinic Foundation  
*Role of Vitamin K in Bone Loss in Patients with Ileal Pouch-Anal Anastomosis*

### **Anish Sheth, MD**

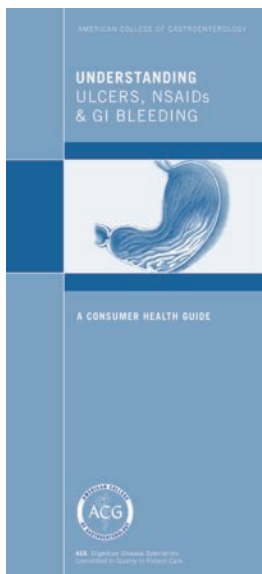
Yale University School of Medicine  
*The Effect of Synbiotic Therapy on the Hyperdynamic Circulatory State of Cirrhosis*

## ACG EDUCATION PROGRAMS FOR PATIENTS & PHYSICIANS

The ACG Institute for Clinical Research and Education is proud of the many excellent educational initiatives it sponsors to educate physicians, patients and the public about important advances in digestive health.



The dangers of NSAID-induced GI Injury was a focus of this 2005 educational program



### GERD BECOMES A HOUSEHOLD WORD

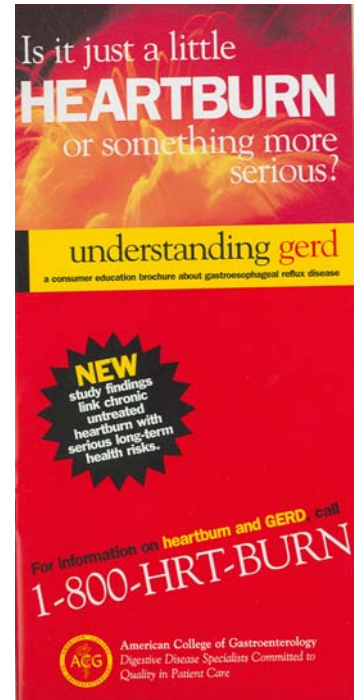
Among national health care organizations, including government and private sector entities, few can boast of an award-winning consumer education and awareness campaign that reached as many Americans, through as many varied channels, as the ACG GERD Campaign - and prompted them to take action. Well over one million heartburn sufferers contacted the College through its 1-800-HRT-BURN hotline, and millions of others received ACG GERD education materials through ACG member gastroenterologists, many of the nation's primary care physicians, and pharmacies nationwide. When ACG launched the GERD program in 1996, research revealed that consumers were unaware of the serious potential complications of chronic, untreated heartburn. Now GERD is a household word.

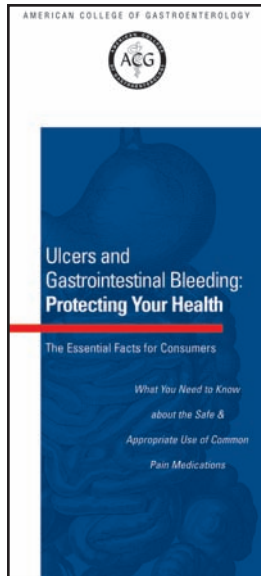
### IBS: DEMAND FOR INFORMATION

With the publication in November 2002 of evidence-based recommendations on the treatment of IBS as a supplement to *The American Journal of Gastroenterology*, the College laid the groundwork for a major physician and patient education campaign on IBS. In April 2003, the College introduced the patient component of this multi-media initiative with a wave of television advertising, a free telephone hotline 866-IBS-RELIEF and a Web site [www.ibsrelief.org](http://www.ibsrelief.org). The campaign enjoyed an immediate and dramatic response, as patients sought information from ACG.

### THE LITTLE KNOWN POTENTIAL DANGERS OF NSAIDS

The goal of this 2005 effort was to clarify in the minds of physicians and consumers alike appropriate options for pain management as alternatives to the COX-II class of therapies. Educational materials for primary care physicians, a slide program for a physician audience, and patient education tools were the highlights of this program which provided timely information about the potential serious complications associated with common over-the-counter and prescription pain medications.

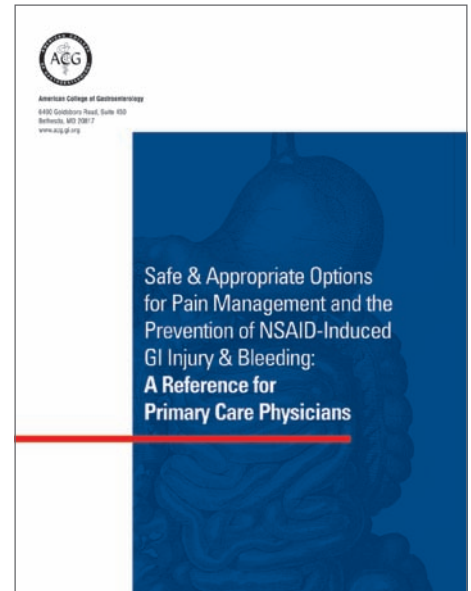




## NSAIDS TOOL KIT FOR PRIMARY CARE

The College developed this Tool Kit to help primary care physicians in understanding and communicating with patients about issues relating to chronic pain relief and risks of ulcers and GI bleeding. The essential message to primary care colleagues conveyed in the materials is that GI specialists, who are generally the physicians who are called upon to identify the source of GI bleeding and attend to patients on an urgent basis when GI bleeding occurs, are available to assist in evaluating the gastrointestinal risks in patients needing chronic pain relief.

The kit included a concise reference guide for primary care physicians, article reprints, samples of patient education materials and re-order forms, as well as an overview of case law in the area of NSAIDs and GI injury.



## COLORECTAL CANCER PATIENT EDUCATION: A TOP PRIORITY

In 2007, ACG proudly introduced a new community education poster, “Colorectal Cancer: You Can Prevent It” developed by the ACG Public Relations Committee. The College is committed to educating Americans about the lifesaving potential of colorectal cancer screening.

Prominently featuring endoscopic images to educate about polyps and the “Anatomy of Colorectal Cancer,” the poster also offers information about various risk factors and screening options. While ACG’s recommendations on screening for African Americans are highlighted, the overall call-to-action urges adults over 50 to be screened for colorectal cancer, and emphasizes ACG’s position that colonoscopy is the “preferred screening strategy.”

## Colon Cancer... You Can Prevent It

### America's #2 Cancer Killer

- Colorectal cancer is the number 2 cancer killer in the United States, yet it is one of the most preventable types of cancer. Colorectal cancer is often curable when detected early.

### Risk Factors

- Lifetime risk of colorectal cancer is roughly equal in men and women.
- Colorectal cancer is most common after age 50, but it can strike at younger ages. The risk of developing colorectal cancer increases with age.



### Symptoms

Most early colorectal cancers produce no symptoms. This is why screening for colorectal cancer is so important. Some possible symptoms, listed below, do not always indicate the presence of colorectal cancer, but should prompt a visit with your physician and a check-up:

- New onset of abdominal pain
- Blood in or on the stool
- A change in stool color or shape
- A change in typical bowel habits, constipation, diarrhea

### Who is Considered High Risk?

Colonoscopy is recommended for individuals of any age who are at higher than average risk for developing colorectal cancer by virtue of:

- Personal history of colorectal cancer or colorectal polyps
- A strong family history of the disease
- Identified forms of colorectal polyps in cancer
- Predisposing genetic conditions such as familial adenomatous polyposis (FAP) or Crohn's disease or ulcerative colitis

Recommendations for how often colonoscopy should be performed vary for different subsets of high risk individuals, and they should consult with their physician.



### Colonoscopy: Preferred Screening Strategy

Colonoscopy is the preferred method of screening for colorectal cancer. The American College of Gastroenterology considers colonoscopy the “gold standard” for colorectal screening, because colonoscopy allows physicians to look directly at the entire colon and to identify suspicious growths. Colonoscopy is the only test that allows a biopsy or removal of a polyp at the very same time it is first identified.



### Colorectal Screening for African Americans

African Americans are diagnosed with colorectal cancer at a younger age than other ethnic groups, and African Americans with colorectal cancer have decreased survival compared with other ethnic groups.

Physicians experts from the American College of Gastroenterology in 2005 issued new recommendations to healthcare providers to begin colorectal cancer screening in African Americans at age 45 rather than 50 years.



Data support the recommendation that African Americans should begin screening at a younger age because of the higher incidence of colorectal cancer and a greater prevalence of proximal or right-sided polyps and cancer in this population. The recommendations were published in the March 2005 issue of the American Journal of Gastroenterology.



### The Anatomy of Colorectal Cancer Progression from Polyp to Cancer

Screening tests can find polyps so they can be removed before they turn into cancer

- Most colorectal cancers develop from polyps, which are abnormal growths in the colon.
- If polyps grow unchecked and are not removed, they may become cancerous.
- Screening tests can find precancerous polyps so they can be removed before they turn into cancer.
- The development of more than 75-90 percent of colorectal cancer can be avoided through early detection and removal of pre-cancerous polyps.\*

### What are the Screening Options?

Talk to your doctor about what screening tests are right for you.


#### Colonoscopy

For normal risk individuals, the American College of Gastroenterology recommends colonoscopy screening every 10 years beginning at age 50 (see new recommendations for African Americans).

#### Flexible Sigmoidoscopy & Fecal Occult Blood Test

An alternative strategy for average risk individuals is an annual stool test for blood, and a flexible sigmoidoscopy exam every 5 years. Unlike colonoscopy, this approach does not allow identification and removal of polyps in the entire colon.

\* Wilson S.J, et al. Prevention of colorectal cancer by colonoscopic polypectomy. The National Polyp Study Workgroup. N Engl J Med. 1993;329:973-977



American College of Gastroenterology  
Digestive Diseases: Opportunities Tailored to You in Patient Care  
www.acg.gi.org



## ABOUT THE ACG INSTITUTE

### Advancing Knowledge About Digestive Diseases Through Clinical Research

Founded in 1994, the ACG Institute for Clinical Research & Education has emerged as a major source of funding for clinical gastroenterology research, and an active and effective sponsor of educational programming for consumers and physicians alike. The Institute has succeeded dramatically in increasing the College's annual support for promising clinical, patient-care oriented GI research. Since its inception in 1994 and through 2007, the ACG Institute has awarded over \$7.9 million to 417 investigators in order to promote research directly related to the needs of clinical gastrointestinal practice.

The Institute enjoys an impressive track record in funding excellent clinical research marked by a consistent upward trend in support. At a time when funding from other sources is declining, the College, through the Institute, makes it a priority to fund clinical gastroenterology research.

### Enhancing Patient Care Through Physician Education

The Institute has staked a claim in the life of the College through the excellence of its educational initiatives. Whether educating consumers about screening for colorectal cancer or about serious GI disorders, or providing state-of-the-art educational tools for physicians to enhance their practice, the Institute has become an undisputed educational leader.

Under the auspices of the ACG Institute, many of the most distinguished clinicians, researchers and academics in the field of gastroenterology have contributed to the educational mission of the College by writing and editing an impressive array of physician and patient education tools. These programs run the gamut from scientific monographs on topics including managing GI complications of pregnancy, to special supplements on functional GI disorders and also on extra-esophageal manifestations of GERD in *The American Journal of Gastroenterology*, as well as educational tools for clinicians and their patients on the potential dangers of NSAIDs. The hallmark of the ACG Institute since its inception has been to share first-class educational materials with GI subspecialists, as well as primary care physicians, internal medicine specialists and family practitioners.

### Promoting Awareness of Digestive Health Through Public Education

Along with clinical research and physician education, public education is the third corner of the Institute's pyramid of strength. Using its own funds, without support from other partners, the Institute has made a major financial commitment to supporting patient education on colorectal cancer screening and prevention. Educating patients about the Medicare colorectal cancer screening benefit, and ensuring that American adults over 50 understand the importance of screening and early detection of colon cancer has been a primary focus of the Institute's educational mission. With the introduction of the Colorectal Cancer Prevention Action Plan in 2004, the ACG Institute has made a significant contribution to research efforts aimed at improving colonoscopy, and to enhancing public awareness of the lifesaving benefits of colorectal screening.

### Defining a Vision for the Institute Through Leadership

The ACG Institute is governed by a Board of Directors which answers to the ACG Board of Trustees. Charged with the oversight of the broad range of Institute-sponsored physician and patient programs, clinical research funding, as well as the financial health of the Institute, this group participated in an engaging day-long session reviewing key aspects of the Institute's multi-faceted activities.

The Institute Management Subcommittee, headed by the ACG Institute Director, was established in October 2005 as a result of Bylaws changes that formalized the structure, functions and leadership of the ACG Institute. Their role is to provide scientific and educational leadership for programs of the Institute; advise Institute Director on new initiatives; review proposed Institute programs and initiatives; and oversee status of ongoing Institute programs.