ACG 2007 Annual Scientific Meeting Program Slated

Simultaneous sessions, featured lectures, optional breakfast sessions and FAQs

Making plans for ACG 2007? We hope so. If not, you’ll miss a dynamic, comprehensive educational program designed to deliver you the latest clinical updates. In the last issue of ACG Update we highlighted features of the Postgraduate Course. In this issue we highlight the Annual Scientific Meeting, a three-day meeting that is free to ACG members.

The educational program begins on Monday, October 15. Kicking off the program is the Presidential Address and President’s Plenary Session, which will feature the best and brightest presenters and their cutting-edge research. Simultaneous Symposia follow the plenary session and include “Top Down or Step Up Therapy in Crohn’s Disease: Which is Right?” and “Complications from Cirrhosis: We’re Making Progress.”

A break is offered between sessions to have lunch and view the many posters being presented. If you want to keep the learning coming, attend one or both of the FAQ sessions, Esophagus and Pancreas, which will be offered during the lunch break. The FAQ on Esophagus will be presented by Philip O. Katz, MD, FACG and the FAQ on Pancreas will be presented by Peter A. Banks, MD, MACG. FAQs offer a significant amount of interaction with the presenter with Q&A.

Monday afternoon features simultaneous plenary sessions and the ever popular The American Journal of Gastroenterology Lec-

ACG Releases New DVD
Colonscopc polypectomy, and laparoscopic colectomy

Advances in medicine now provide physicians with a growing array of options for patient interventions short of open surgery. Colonoscopic Polypectomy and Laparo-scopic Colectomy provides presentations from leaders in their field regarding procedures that are minimally invasive compared to traditional surgery. Each presentation provides an overview of the procedure, offers recommendations and reviews the pros and cons as it relates to patient outcomes. Video and still images from each procedure are highlighted throughout.

Douglas K. Rex, MD, FACG, presents Resection of Large Sessile Polyps, while Bryan Butler, MD, FACS, presents Highlights of Laparoscopic Colectomy.

Members may purchase a copy online for only $5.00 shipping and handling. Visit www.acg.gi.org for more information.
FROM THE PRESIDENT

ASCs, SGR, Colon Cancer Screen for Life Act–We’re Busy!

By David A. Johnson, MD, FACG

It’s been a busy legislative year as ACG continues to work on your behalf on issues impacting GI practice. We’ve had dozens of ACG members visiting Capitol Hill with ACG staff to meet with Congressional leaders regarding the Colon Cancer Screen for Life Act, the ASC rule, and the SGR formula.

The Colon Cancer Screen for Life Act was reintroduced in both the House and Senate on April 19, 2007. Sponsoring the Bill in the Senate were long-time supporters Senators Benjamin Cardin (D-MD), Susan Collins (R-ME), Joseph Lieberman (I-CT), Lindsey Graham (R-SC), and Ben Nelson (D-NE). Since its reintroduction, and as we went to press, a total of 12 Senators are now co-sponsoring the Bill. In the House, long-time supporters including Representatives Richard Neal (D-MA), Phil English (R-PA), Edolphus Towns (D-NY), Tom Latham (R-IA), and Carolyn McCarthy (D-NY) introduced the bill. At press time, a total of 54 Representatives are now co-sponsoring the Bill. There is still much action that needs to take place to get this important bill passed. You can help by contacting your Representative and Senators in Congress. ACG’s National Affairs section of its website allows you to send a letter that reiterates the importance of this bill and requests your Congressional leaders join their colleagues in support of it as well. You can send the draft letter as written or edit it as you see fit. To send your letter or to find out who your Senators or representatives are, visit the National Affairs section of the ACG website, www.acg-gi.org.

The Colon Cancer Screen for Life Act isn’t the only item on ACG’s legislative agenda. We continue to work to turn around the proposed ASC rule both in Congress and at CMS, and for a permanent, long-term fix for the SGR formula.

The SGR formula may see a fix for two years, if House Ways and Means Committee Chair Pete Stark’s (D-CA) proposal for cuts in Medicare are passed. There are winners and losers in his proposal and you can expect a fight from all sides to keep their piece of the Medicare pie. Bills have been introduced to put in place a permanent fix as well, but the costs are very significant. We’ll be following this closely and will share information as it becomes available.

The proposed final ASC rule may come out as soon as this month. You will recall the original proposal would cut GI payments in the ASC by about 30%. The College has been working tirelessly to turn this around and we believe that, with the help of some 1,200 comments sent in by ACG members in response to our call to action, that CMS is aware that they have created a serious GI specific problem that needs to be addressed.

Outside of the legislative/regulatory arena, ACG actively participated in two recent exciting initiatives. On May 8 ACG, along with the American College of Obstetricians and Gynecologists (ACOG), the Monahan Center, the CDC, the EIF and ASGE, announced an educational campaign targeted to OB/Gyn’s to encourage their patients to seek colorectal cancer screening consistent with screening guidelines. Since many OB/Gyn’s are the de facto primary physician for many women, it is only fitting to educate our colleagues in obstetrics and gynecology on the importance of following recommended screening options for colorectal cancer and the importance for patients who are...
ACG Joins Alliance to Prevent Colorectal Cancer

Partnership promises to reach women with lifesaving message

Standing: L to R: ACG President David A. Johnson, MD, FACG; Douglas Laube, MD (President, ACOG); Benjamin Greer, MD (ACOG); Mark Pochapin, MD, FACG (Medical Director, Jay Monahan Center). Seated: John Petrini, MD (ASGE President-Elect), Judy Ketchik (Entertainment Industry Foundation Vice President).

in recent memory to target women so they will hear and heed the call-to-action to get screened for colorectal cancer,” said ACG President David A. Johnson, MD, FACG.

The obstetricians and gynecologists enlisted ACG among several other groups in part because of the important role of Dr. Mark Pochapin, a member of the College’s Public Relations Committee, who serves as Medical Director of the Jay Monahan Center for Gastrointestinal Health. The Monahan Center was established in memory of Katie Couric’s late husband Jay, who died of colorectal cancer. Other partners include the American Society for Gastrointestinal Endoscopy and the Entertainment Industry Foundation, the organization that has worked so actively with Ms. Couric to raise the profile of colorectal cancer screening. Couric’s public service messages are a centerpiece for the ACOG initiative, which will reach women with materials and through their OB/GYN physicians.

In his remarks at the ACOG press event in San Diego, which garnered media coverage including an item via the UPI wire service, Dr. Johnson made the point that there is a dangerous public misperception that colorectal cancer is a ‘man’s disease.’ “It is painfully apparent, with the nearly 75,000 new cases per year developing in women, that colorectal cancer strikes both women and men,” said Johnson.

The College is grateful to the ACOG and its partners and looks forward to a productive partnership and to supporting the ongoing efforts to reach women and educate them about the importance of colorectal screening.

President’s Message

continued from page 2

50 or older or even sooner for high risk patients. The other initiative was the First National Summit on Obesity Policy, which took place May 8-9. Obesity has become an epidemic in this country and its impact on the healthcare system is being felt by everyone. I’ve been actively pursuing this issue for some time and believe gastroenterology can play a role in improving patient health by reducing obesity in the U.S. You can find out more information about the Summit in the article on this page.

Other activities highlighted in this issue of the ACG Update include the North American Conference of GI Fellows. The course was held in April and several GI fellows were awarded grants to attend the ACG 2007 Annual Scientific Meeting and Postgraduate Course. See the article on page 12 for more information.

In addition, the ACG Institute has announced the award winners for the Junior Faculty Awards and Clinical Achievement Awards. In total, nearly $700,000 is being awarded this year (see page 5 for further information).

Have you made your plans yet for ACG 2007, October 12-17? Registration and housing are open and I encourage everyone to register early for the best selection of learning luncheons, breakfast sessions, and optional Friday courses. If you are an ACG member, you should attend the Annual Scientific Meeting, which runs Monday-Wednesday, October 15-17. The Annual Scientific Meeting is free for ACG members and is one of the excellent benefits of membership in the College. Connect with colleagues at the meeting, stay abreast of clinical updates, and see the latest in technology and therapeutics in the exhibit hall. To learn about the Annual Scientific Meeting educational agenda, see the article on page 1. For more information on all the educational program and events taking place at the meeting, visit the ACG 2007 website at www.acgmeetings.org.
ACG 2007 Trainee Events in Philadelphia

Whether you need assistance preparing for your future in gastroenterology, are looking for a job, or would like to showcase your knowledge and have a good time at the GI Jeopardy competition, consider participating in the trainee-specific programs below.

Trainees’ Luncheon: What I learned my first year in practice
Saturday, October 13
12:40 pm – 1:55 pm
Ticket required. Cost is $25
Before you enter your first year of practice, learn from the experience of someone who just recently completed his first year. Larry E. Clark, MD, will discuss lessons learned from personal interactions, financial matters, prioritizing busy schedules, and focusing on quality of life issues for newly practicing gastroenterologists.

GI Jeopardy: Buzz in your training program
Saturday, October 13
5:30 pm – 7:00 pm
ACG’s favorite quiz show is back again in 2007. The preliminary round of competition begins online. Who will be the teams this year? You’ll have to attend ACG 2007 to find out. For more information on GI Jeopardy, see below.

Job Forum: Where candidates and employers meet
Sunday, October 14 – Tuesday, October 16
8:00 am – 5:00 pm
Wednesday, October 17
8:00 am – 12:30 pm
Looking for a job? ACG’s Job Forum offers valuable networking opportunities. The Job Forum includes a mechanism for the exchange of CVs and a message service to connect employers and job candidates. Visit www.acgmeetings.org to take advantage of this opportunity and register online.

Trainees’ Forum
Sunday, October 14
5:30 pm – 7:00 pm
If you’re looking for tools to find the right job environment after graduation, the annual Trainees’ Forum may be just what you need. The program includes presentations by experienced physicians and others from academia, the military, experts on job placement, and recent graduates who will provide insights into the process of finding a job and negotiating a contract. Available to all trainees in gastroenterology and hepatology at no charge.

Are You Ready for GI Jeopardy?
Become a contestant in ACG’s favorite quiz show starting July 16

Every year, GI Jeopardy has proven to be one of the most anticipated events at ACG’s Annual Postgraduate Course, and it will be back again in 2007. This exciting program is designed as a friendly competition among GI training programs from across the country. The competition begins July 16, 2007 with a preliminary online round open to all GI training programs. The five highest scoring programs from the preliminary round will be invited to send teams of two trainees to compete in front of a live audience on October 13, 2007 at the ACG Postgraduate Course being held in Philadelphia, Pennsylvania.

Last year’s GI Jeopardy finalists were supported by more than 300 lively audience members, giving the event a real game show atmosphere. Each member of the team that wins the competition will be awarded a $1,000 travel award to the 2008 ACG Annual Meeting and Postgraduate Course in Orlando plus a trophy for their program.

We encourage your training program to participate in this fun and educational event. Visit the Trainees’ section of the ACG website for further details on how to participate, or contact Maria Susano at the ACG office (301-263-9000 or msusano@acg.gi.org).
ACG Plays Key Role in Launching First National Summit on Obesity Policy

On May 8-9, 2007, in Washington, DC, members of Congress, TV personality and cardiothoracic surgeon Dr. Mehmet Oz, representatives of a wide range of consumer advocacy and disease groups, and ACG met to develop policy recommendations for federal lawmakers on how to address the nation’s obesity epidemic. ACG was the only specialty society on the summit’s steering committee.

Without changes, over 73% of American adults will be overweight by 2008, increasing their risk of colon and esophageal cancers, NFALE, aggravating GERD and creating GI challenges for any such patients who undergo bariatric surgery. Clearly, this epidemic has a huge impact on the clinical practice of gastroenterology. Furthermore, the burden of obesity is adding significantly to the nation’s healthcare bill. As keynote speaker Senator Tom Harkin (D-IA) stated, “Fat is a fiscal issue.”

The Summit made recommendations in three areas: nutrition, physical activity and changes to the healthcare system. The Summit recommended that the federal government “recognize obesity as a complex disease, with strong adverse health effects, establish diagnosis codes, and require coverage for prevention, screening, diagnosis and multi-treatment programs that are coupled to measurement of health outcomes.” The Summit also recommended that the federal government increase “support for basic, clinical, epidemiological and health services research focused on obesity across all agencies of the federal government to bring it in line with investments aimed at solving other major medical problems.”

In addition to ACG staff, the ACG was ably represented by Dr. David Greenwald, MD, FACP, who alerted attendees to the link between obesity and various GI disorders. The Summit was just the beginning of an ongoing cross-disciplinary effort to push federal policymakers to develop and implement policies that will address this growing national crisis.

Visit www.obesitysummit.org for more information.

ACG Institute Provides Over $686,000 for Research Grants

The ACG Institute for Clinical Research and Education is pleased to announce the award of $686,036 in support of clinical research in gastroenterology. Selected for funding were eleven Clinical Research proposals totaling $236,036. In addition, the Institute selected three Junior Faculty Development Award winners, increasing the total number of awardees to fourteen. Since the inception of the ACG Institute in 1994, the generous support of industry and ACG members has allowed the Research Committee to provide over $7.9 million to 417 physicians in support of research directly relating to the clinical gastrointestinal practice. The proposals awarded funding in 2007 are listed below.

**ACG 2007 Junior Faculty Development Awards**
(A two-year grant of $75,000 per year for each of two years)

- Brian Behm, MD, University of Virginia — *Pravastatin in Active Crohn’s Disease*
- Gregory Sayuk, MD, Washington University School of Medicine — *The Effect of Somatic Symptom Burden on Central Pain Responses in Irritable Bowel Syndrome*
- Marcelo Vela, MD, Medical University of South Carolina — *Impedance pH and Electron Microscopy to Evaluate Endoscopy-Negative Reflux Disease*

**ACG 2007 Clinical Research Awards**

- 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, FACP, Mayo Clinic Rochester — *Effect of Fluoxetine on Serotonin Metabolism and Intestinal Transit on Constipation Predominant IBS (C-IBS)*
- Joseph Leung, MD, FACP, UC Davis Medical Center — *Use of Mechanical Simulator for Evaluation of Trainee Performance in Papillotomy*
- IlcheNONEVSKI, MD, Cleveland Clinic Foundation — *Eosinophilic Esophagitis: The Role of Pro-Inflammatory Mdiators to Eosinophil 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 Entopathy*

**Pilot Studies**

- Herbert L. Bonkovsky, MD, FACP, 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's popular Regional Postgraduate Courses provide the perfect mix of education and relaxation. Earn your CME and enjoy a little R&R, while making new connections and strengthening current collegial bonds.

- Top-notch faculty discuss latest advances in clinical gastroenterology diagnosis, management and treatment.
- Weekend format means less time away from your practice.
- Depending on the course offerings, attendees can earn 11–18 AMA PRA Category 1 Credits™.
- Ample time is allowed to enjoy recreational and social offerings in family-friendly settings.

Education. Networking. Relaxation.
The American College of Gastroenterology's Regional Courses offer it all.

September 7-9, 2007
ACG/VGS/ODSGNA Regional Postgraduate Course
The Williamsburg Lodge, Williamsburg, Virginia

September 13-15, 2007
ACG/TSGE Regional Postgraduate Course
The Gaylord Texan Resort, Grapevine, Texas

register for these courses at
www.acg.gi.org
“Scoring” and the ACG Policy

In Washington, the most important score among policy wonks is not the result of Washington Redskins’ touchdowns or Washington Nationals’ home runs, it’s the scoring done by the Congressional Budget Office, Office of Management and Budget (OMB) and Office of the Actuary within the Centers for Medicare and Medicaid (CMS).

The scoring that keeps the policy cognoscenti up at night can be defined as “the process for estimating budget authority, outlay, revenue and deficit levels resulting from Congressional actions” (e.g., the cost of implementing a particular bill or provision.) The Congressional Budget Office (CBO) carries out this duty for Congress and the OMB prepares the President’s budget and costs out the effect of Executive Branch proposals. The Office of the Actuary within CMS estimates national spending on health care goods and services.

You’re probably thinking at this point that this is all well and good, but why should I care and for that matter, why does the ACG care? Because scoring affects nearly everything we try to achieve on policy matters for clinical GI.

In recent years, as federal deficits have once again become a source of national concern, scoring has always mattered. Indeed, it is nearly impossible to have a conversation with a Congressional office about a legislative matter without being asked if the legislation one is advocating has a “CBO score.” However, if anything, scoring is even more important today for two reasons, and it’s not just because none of DC’s professional sports teams seem to be able to make the play-offs!

CBO
First, the new Democratic Congressional majority has adapted “pay-go” budget rules. This means that all new spending or tax cuts must be offset by corresponding savings to the government. These are called “off-sets.” Over the years, even when there weren’t such rules in effect, Congress has already passed into law many of the easy offsets so it can be challenging to find more. Moving the goal post further down the field for new healthcare legislation is the fact that Democrats have placed a high priority on reauthorizing and expanding the State Children’s Health Insurance Program (SCHIP). The cost for doing so is estimated at $50 billion over five years. On the other hand, CBO has found that equalizing Medicare Advantage and fee-for-service payment rates would save $54 billion over five years and $149 billion over 10 years. Ways and Means Health Subcommittee Chairman Pete Stark is in favor of recouping this money, but the insurance industry is waging a full-scale frontal assault, placing their best players on the field against such a move and enlisting the support of lawmakers who represent rural or minority districts where such plans have been popular. Therefore, the Medicare Advantage excess payments may not be such easy offsets after all. Second, CBO uses what is called “static” rather than “dynamic” scoring. This means that it does not generally credit investments in up-front preventive care, e.g., colorectal cancer screening or disease management, in making its estimates. So, while we may think that it’s obvious that such screening not only saves lives but saves in avoided cancer treatment costs, CBO is reluctant to score such savings, presenting challenges for ACG’s efforts to increase utilization of and reduce barriers to Medicare beneficiaries’ access to colorectal screening through legislation like H.R. 1926/S. 1164, “The Colon Cancer Screen for Life Act.”

Official Washington, however, has CBO fatigue. For example, last year, former Speaker Newt Gingrich who, since leaving office, has become something of an expert on health information technology (HIT), testified before a Senate committee on the subject of HIT, but most of his testimony was a rant at CBO for failing to score savings from up-front investments in HIT. While the former Speaker is often a polarizing figure, on this issue he is not alone.

CBO has responded by creating a Panel of Health Advisors which held its first meeting in May. The panel, consisting of academic and healthcare experts, examined issues such as the comparative analysis of different treatment and health information technology. In the long run, such an effort may pave the way for CBO to more easily credit investments in prevention. Even in the short term, not all is hopeless as CBO can sometimes be persuaded to score cost savings if the literature on such savings is compelling.

SGR
The score is also a challenge to a long-term fix to the SGR problem. In December, through the “Tax Relief and Healthcare Act,” Congress paid for a freeze in SGR cuts for 2007 by requiring that the cost borne in 2008, effectively doubling payment cuts to 10% for 2008! However, CBO estimates that the cost of eliminating the SGR and replacing it with yearly Medicare physician payment increases based on a Medicare Economic Index measuring the rising yearly cost of physician care would cost $262 billion over 10 years. No wonder, despite the best of intentions among the Congressional health policy leadership, it seems that every year Congress seems to postpone action on SGR relief until the last possible minute and then adapts a stopgap solution. There is growing realization, however, that this approach only makes the problem worse in the long-run so this Congress may just be the one to pass such a long-term solution if offsets can be found.

What is ACG doing?
ACG is working to advance the “Colon Cancer Screen for Life Act.” We will work with the CBO to try to get a reasonable score for the bill so that cost considerations do not become a barrier to the enactment of this important legislation that would increase physician reimbursement for colorectal-cancer screening.
Indication
XIFAXAN (rifaximin) Tablets are indicated for the treatment of patients (≥12 years of age) with travelers’ diarrhea caused by noninvasive strains of Escherichia coli. XIFAXAN should not be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.

Safety Considerations
XIFAXAN should be discontinued if diarrhea symptoms get worse or persist more than 24-48 hours, and alternative antibiotic therapy should be considered.

In clinical trials, XIFAXAN was generally well tolerated. The most common side effects (vs placebo) were flatulence 11.3% (vs 19.7%), headache 9.7% (vs 9.2%), abdominal pain 7.2% (vs 10.1%), and rectal tenesmus 7.2% (vs 8.8%).

Licensed by Alfa Wassermann S.p.A. Please see accompanying brief summary of Prescribing Information.

The Point Of A Nonsystemic Antibiotic

Works In The Gut. And Only In The Gut.
Indication

XIFAXAN (rifaximin) Tablets are indicated for the treatment of patients (≥12 years of age) with travelers’ diarrhea caused by noninvasive strains of Escherichia coli. XIFAXAN should not be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.

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Licensed by Alfa Wassermann S.p.A.
Please see accompanying brief summary of Prescribing Information.
\textbf{NONSYSTEMIC}

\textbf{Xifaxan® (rifaximin) tablets 200 mg TARGETED GI ANTIBIOTIC}

The following is a brief summary only; see full Prescribing Information for complete product information.

\textbf{INDICATIONS AND USAGE}

XIFAXAN® Tablets are indicated for the treatment of patients (≥12 years of age) with travelers’ diarrhea caused by noninvasive strains of Escherichia coli. XIFAXAN Tablets are not used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.

\textbf{CONTRAINDICATIONS}

XIFAXAN® Tablets are contraindicated in patients with a hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any of the components in XIFAXAN Tablets.

\textbf{WARNINGS}

XIFAXAN® Tablets were not found to be effective in patients with diarrhea complicated by fever and/or blood in the stool or diarrhea due to pathogens other than Escherichia coli. XIFAXAN® Tablets are not effective in cases of travelers’ diarrhea due to Campylobacter jejuni. The effectiveness of XIFAXAN® Tablets in travelers’ diarrhea caused by Shigella spp. and Salmonella spp. has not been proven. XIFAXAN® Tablets should not be used in patients with Campylobacter jejuni, Shigella spp., or Salmonella spp. may be suspected as causative pathogens. XIFAXAN® Tablets should be discontinued if diarrhea symptoms get worse or persist more than 24-48 hours, and alternative antibiotic therapy should be considered.

Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is the primary cause of antibiotic-associated colitis.

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against \textit{Clostridium difficile}.

\textbf{PRECAUTIONS}

\textbf{General}

The use of antibiotics may promote the overgrowth of nonsusceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken.

\textbf{Information for Patients}

Patients should be advised that XIFAXAN® Tablets may be taken with or without food. Patients should be advised that XIFAXAN Tablets should be discontinued if their diarrhea persists for more than 24-48 hours or worsens, or if they have fever and/or blood in the stool that requires medical care.

\textbf{Drug-Drug Interactions}

Although in vitro studies demonstrated the potential of rifaximin to interact with cytochrome P450 3A4 (CYP3A4), a clinical drug-drug interaction study demonstrated that rifaximin did not significantly affect the pharmacokinetics of midazolam either presystemically or systemically. An additional clinical drug-drug interaction study showed no effect of rifaximin on the presystemic metabolism of an oral contraceptive containing ethinyl estradiol and norgestimate. Therefore, clinical interactions with drugs metabolized by human cytochrome P450 isoenzymes are not expected.

\textbf{ADVERSE REACTIONS}

\textbf{All Adverse Events With an Incidence ≥2% Among Patients Receiving XIFAXAN Tablets 600 mg/day, in Placebo-Controlled Studies}

| MedDRA Preferred Term | XIFAXAN® 600 mg/day (N = 280) | Tablets | Placebo | N = 228 |
|------------------------|-------------------------------|---------|---------|
| Flatulence             | 36 (13.2%)                    | 45 (19.7%) |
| Headache              | 31 (9.7%)                     | 21 (9.2%)  |
| Abdominal Pain NOS    | 23 (7.2%)                     | 22 (10.1%) |
| Rectal Tenesmus       | 23 (7.2%)                     | 20 (8.8%)  |
| Diflexion Urgency     | 19 (5.8%)                     | 21 (9.2%)  |
| Nausea                 | 17 (5.3%)                     | 19 (8.3%)  |
| Constipation           | 12 (3.8%)                     | 8 (3.5%)   |
| Pterygia               | 10 (3.1%)                     | 10 (4.4%)  |
| Vomiting NOS           | 7 (2.2%)                      | 4 (1.8%)   |

The following adverse events, presented by body system, have also been reported in ≤2% of patients taking XIFAXAN Tablets in the two placebo-controlled clinical trials where the 200 mg tablet three times a day dose was used. The following includes adverse events regardless of cause in relationship to drug exposure.

- Blood and Lymphatic System Disorders: lymphocytosis, monocytosis, neutropenia
- Ear and Labyrinth Disorders: ear pain, motion sickness
- Gastrointestinal Disorders: abdominal distension, diarrhea NOS, dry throat, fecal incontinence, nasopharyngitis NOS, pruritus, rectal bleeding, urinary tract infection
- Metabolic and Nutritional Disorders: anemia, dehydration
- Musculoskeletal: Connective Tissue, and Bone Disorders: arthralgia, muscle spasms, myalgia, neck pain
- Nervous System Disorders: abnormal dreams, dizziness, migraine
- Respiratory, Thoracic, and Mediastinal Disorders: dyspnea NOS, nasal passage irritation, nasopharyngitis, pharyngitis, pharyngolaryngeal pain, rhinitis NOS, rhinorrhea
- Skin and Subcutaneous Tissue Disorders: clamminess, rash NOS, sweating increased
- Vascular Disorders: hot flashes NOS

Postmarketing Experience

The following events have been reported with the use of rifaximin: exfoliative dermatitis, rash, angioedema, urticaria (rash, itching, and swelling of face and tongue and difficulty swallowing), urticaria, flushing, and pruritis, have been identified during postapproval use of XIFAXAN Tablets. These events occurred as early as or within 15 minutes of drug administration.

OVERTOXICITY

No specific information is available on the treatment of overdosage with XIFAXAN Tablets. In clinical studies at doses higher than the recommended dose (>600 mg/day), adverse events were similar to the recommended dose (200 mg taken three times a day) and to placebo. In the case of overdose, discontinuation of XIFAXAN Tablets, treatment symptomatic, and institute supportive measures as required.

Rx Only

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January 2007

REFERENCES


Infections and Infestations: dystrophy NOS, respiratory tract infections, upper respiratory tract infection NOS

Injury and Poisoning: sunburn

Investigations: aspartate aminotransferase increased, blood in stools, eosinophilic leukocytosis

Metabolic and Nutritional Disorders: anorexia, dehydration

Musculoskeletal: Connective Tissue, and Bone Disorders: arthralgia, muscle spasms, myalgia, neck pain

Nervous System Disorders: abnormal dreams, dizziness, migraine

Respiratory, Thoracic, and Mediastinal Disorders: dyspnea NOS, nasal passage irritation, nasopharyngitis, pharyngitis, pharyngolaryngeal pain, rhinitis NOS, rhinorrhea

Skin and Subcutaneous Tissue Disorders: clamminess, rash NOS, sweating increased

Vascular Disorders: hot flashes NOS

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\textbf{Works In The Gut. And Only In The Gut.}
You Are Incompetent and You Don’t Really Know It

By Chalmers M. Nunn, Jr, MD

Dr. Nunn is a member of the ACG Practice Management Committee.

Unconsciously Incompetent

All of us have been through outstanding medical training. Most of us go straight from a very competitive collegiate environment to medical school and then directly into residency and fellowship programs, all the while immersing ourselves in textbooks, the literature, research and patient care. It was all-consuming and in reality a very protected environment.

Our mentors were academics with a very specialized and focused view of the world. They were very left-brained and linear people who often taught in the manner of a bully. I think my corpus colossum was cut during my internship thus isolating my right brain. I liken it to a horse with blinders on for about 10 years, only able to see one way, straight ahead. Atrophy set in quickly.

When we first entered practice our new mentors were our partners who also came from the left-brained environment I described. I would venture to say most business discussions centered on call, vacation and how to divide income. This does not really move the ball forward.

Our college friends who went into business spent the same 10 years developing skills and experiences that have benefited them in our capitalistic society. They have had business success and failure and have learned what it takes to be efficient, productive and in general make the whole greater than the sum of the parts. At the end of my 10 year experience I may be way ahead in clinical skills, but I am far behind in the general skills of life and business.

I went into practice in 1985. The demands placed upon the practitioner have dramatically changed since then. It has evolved from a professional and guild oriented world where I once had control to an environment where the customer (and often this is not the patient) is king and there are many customers. Quality, pay for performance, E&M, schedules, income statements, balance sheets, employee morale, consumerism, EHR, CPOE, etc., are the buzz words and acronyms of today. To make this new life work you have to become the President/CEO/manager of the world around you. You can no longer just see the patients and go home and feel good about it.

I am not a cynic and do not imply that what has happened is bad. In fact I would dare say quality and productivity are much better today than they have ever been, but are you prepared to deal with this new world and make the best of it for yourself and your profession and your patients?

For those of you who are not prepared, I suspect you are very unhappy. We live in an environment that is complex with high levels of stress and anxiety. There was a recent issue of Physician Executive published by the American College of Physician Executives that surveyed physicians and it clearly pointed out that morale is low in our profession. Physicians are typically control-oriented and part of this morale problem is the fact that we feel we have lost control over our work and lives. Either we should change fields or somehow gain some control over what we do. To do this, you need a new skill set, and business skills may be just the prescription.

I, like you, was well prepared clinically when I entered practice, but I was unconsciously incompetent when it came to business skills and the tools needed to make it in this evolving medical environment. I was frustrated and perturbed and really didn’t know why. After nine years of practice I became consciously incompetent. I realized I did not have the skill set to deal with the new problems I was facing so I made a change.

Conscious Incompetence

It was 1993. Managed care was hitting its stride and I became acutely aware of how overhead can kill a practice. I felt I needed to do something differently to deal with these new complexities, so I made a switch to full time management and left a flourishing practice. I became the VPMA of the local hospital and obtained a Masters Degree in medical management at Carnegie Mellon. I think this awareness of my being consciously incompetent is the first step toward change.

I don’t think a full time management career is what most physicians are interested in or need, but the skills that will help you cope come from the business sector. These skills would include finance, marketing, negotiation, organizational dynamics, quality, how to run a meeting, managing people, etc. I argue that every physician needs business skills to survive in today’s practice environment.

Conscious Competence

If you are able to acquire these skills, your view of the world and its complexities will change. You will no longer feel as angry and hopeless, but empowered. Many people have these skills naturally and may already be en-
40 Fellows Were Honored at NACGF Conference
Three received Distinguished Achievement Awards

A total of 40 fellows attended the North American Conference of Gastroenterology Fellows from April 12-15, 2007 in San Diego, California. At the three-day conference, participants presented their research work, networked with other fellows from across the U.S. and Canada, and participated in a variety of lectures from a distinguished faculty of gastroenterologists. Led by Program Chair, Sunanda V. Kane, MD, MSPH, FACC, along with co-chairs David A. Johnson, MD, FACC and Philip O. Katz, MD, FACC, the fellows also received coaching on presentation skills. In late 2006, all gastroenterology fellows in the U.S. and Canada were invited to submit up to three abstracts for NACGF. A total of 174 abstracts were submitted this year. Fellows whose abstracts were selected for either oral or poster presentation were invited to attend NACGF and had their travel expenses covered by the ACG.

Three fellows were also recognized with Distinguished Achievement Awards, which included a $1000 travel award to ACG 2007 at the Pennsylvania Convention Center in Philadelphia on October 12-17. The winners were Julie Casilloux, Hôpital Sainte-Justine, Quebec, Canada (“Predictive Factors of a Complex Evolution in Patients with Esophageal Atresia”), Aditi Kinkhabwala, New York University, New York, NY (“Prospective Evaluation of Helicobacter pylori Eradication Effects on Meal-Induced Changes in Plasma Ghrerin and Leptin”), and Ponni Perumalswami, New York University, New York, New York (“Hepatitis B Virus Coinfection Among American Patients with Chronic Hepatitis C Virus Infection: A Prospective Analysis of Prevalence and Viral Interactions”).

ACG is proud to offer this exceptional program for fellows. The program is sponsored by the ACG, endorsed by the Canadian Association of Gastroenterology, and supported by an unrestricted educational grant from Procter & Gamble.

College of Physician Executives offers some of the best training and networking for physicians—you can take classes at your own pace and with other physicians who have the same issues. The courses are taught by well selected business school professors, and physician ratings of these classes are consistently high. Visit their website at acpe.org to learn more. The ACG also has excellent resources as well, starting with the Annual Practice Management Course at the Annual Meeting as well as the College website and publications.

All physicians need this type of training but do not get it in medical school or residency programs. In fact we are programmed to be too left-brained when it is the right brain skills we need to develop. Take the plunge, become a better physician, seek business training and exposure. This will change your outlook and attitude. You won’t be the same again.
Beware of confusing fecal blood test G-code

This year CMS deleted the long established G-code you had used to bill for the screening fecal occult test – G0107 – but tossed in G0394 and left some people wondering how to use it. Descriptors for 82270 and G0394 are nearly identical [blood, occult test (e.g., guaiac); feces, consecutive collected specimens with single determination, for colorectal neoplasm (i.e., patient was provided three cards or single triple card for consecutive collection)].

CMS has yet to clarify the different between the codes, so to be on the safe side, Health Care Economics suggests sticking with the CPT code for screening tests (82270).

Other fecal occult blood test codes are more straightforward. Use 82272 when the physician collects a single (as opposed to consecutive) feces sample during a rectal exam at the office.

82274 and G0328 are for the more involved fecal occult immunoassay tests. Those are more reliable for detecting blood specifically in the lower digestive track—a possible sign of cancer or a pre-cancerous condition—by eliminating false positives from other sources.

Modifier -59 — Distinct procedural service

The -59 Modifier is the second most incorrectly used modifier, just behind the -25 Modifier. So as a refresher, the requirements for the use of Modifier -59 are outlined below:

- Modifier -59 is used to report a procedure or service that was distinct or independent from other services performed on the same day.
- Modifier -59 is used to identify procedures/services that are not normally reported together, but are appropriate under the circumstances.
- Modifier -59 is the modifier of last resort (only use if NO OTHER modifier is appropriate).
- Do not use Modifier -59 with an E/M code.

Screening, diagnostic or therapeutic?

Your diagnosis coding depends on knowing whether a procedure is performed for screening, diagnostic or therapeutic purposes. For Medicare’s colorectal screening benefits, this is vital.

<table>
<thead>
<tr>
<th>Type of Service</th>
<th>Description</th>
<th>CPT</th>
<th>ICD</th>
<th>Tips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>A procedure or service provided to a patient who does not have symptoms or abnormal findings, or known disease.</td>
<td>G0105 (average risk)</td>
<td>V76.51 (special screening for malignant neoplasms, colon)</td>
<td></td>
</tr>
<tr>
<td>Diagnostic</td>
<td>A procedure or service provided to a patient to identify the cause of symptoms or abnormal findings, or to evaluate a known disease.</td>
<td>45378</td>
<td>Use colonoscopy findings or presenting signs and symptoms if colonoscopy is normal or findings to not explain the ‘medical necessity’ for the exam.</td>
<td>No additional procedures performed via the scope.</td>
</tr>
<tr>
<td>Therapeutic (surgical)</td>
<td>Removal, insertion, or repair of pathology found during a screening or diagnostic exam.</td>
<td>Appropriate colonoscopy code with biopsy or removal.</td>
<td>If exam began as screening: primary: V76.51 secondary: screening exam findings.</td>
<td>Exam may begin as screening and change to therapeutic if pathology is found. Additional procedures (biopsy, etc.) are done.</td>
</tr>
</tbody>
</table>

Even with possible reporting delays, NPIs still required by May 23

According to Part B News, one government entity is formally asking CMS to make the May 23rd deadline six months later, claiming widespread disruptions in claims filing could occur without a delay.

The National Committee on Vital and Health Statistics (NCVHS), which is part of HHS, is asking HHS Secretary Michael Leavitt to delay full implementation of the NPI until at least November 23, 2007, or six months after CMS releases its still-unseen policy on how it will share NPIs among providers.

But be careful! Even if this recommendation is adopted, you still should have obtained your NPI by May 23.

According to one committee member, Larry Green MD, “The committee still wanted May 23 to ‘have some meaning,’ which is why it’s recommending that all NPIs be obtained by that date.”

ACG is pleased to partner with Health Care Economics to provide GI coding information. Health Care Economics, LLC is a health care consulting firm specializing in the “business side of medicine,” including all areas of practice management, assisting in a buy-out, selling a practice, negotiating contracts with managed care providers and assisting practices to help prevent a Medicare audit. ACG members earn discounts from Health Care Economics. As an ACG member, you receive a special rate on consulting fees. There is a $25 fee for a single question related to one coding issue. For complex or multiple questions that require additional research, the fee is $25 plus $2 per minute after 15 minutes (normal rates are $200 per hour). You may also send your questions via fax to 317-558-6186 or contact Renee Hatfield, Senior Consultant, by e-mail at reneeh@forumcu.com. For more information on Health Care Economics, visit their website at www.forumcu.com.
Medicare coverage for a pre-operative visit with the physician prior to a screening colonoscopy and clarify the applicability of the Medicare deductible.

We will also aggressively monitor and respond to Congressional action to ensure that the offsets for Congressional priorities don’t come at the expense of you, the ACG members.

The ASC rule

No less troubling is the issue of measuring cost inside the walls of CMS. Why in CMS’ August 2006 proposed ASC rule does GI face the possibility of 30 percent cuts on procedures performed in an ASC? There are many factors in play, but chief among them is the agency’s very narrow definition of “budget-neutrality.” True, the 2003 Medicare Modernization Act required CMS to propose a new budget neutral ASC payment system, but CMS has defined this in a myopic way. First, CMS did not recognize savings that will accrue to Medicare as volume moves from the HOPD to the ASC, or costs that could be incurred if volume moves back to the HOPD in cases such as GI, where payment is too low. In an alternative analysis, CMS considered only the migration that could occur as the 14 new codes are implemented not the migration that could occur for all procedures that are already on the ASC list. Further, CMS is planning to add a significant number of new procedures to the list of approved ASC procedures, but not new money.

ACG is continuing to fight these Draconian proposed cuts and has met with CMS and many in Congress to persuade the agency to embrace a broader definition of budget neutrality. We’re not in the ninth inning yet so stay tuned!

We need you

While all the members of the Congressional “team” are forced to wear green eyeshades rather than helmets, cleats or hockey skates, they can sometimes be persuaded to overcome this nearsighted focus and see the whole field, if there is enough noise generated by the fans of one side or another of an issue. This means that we need you to take action. See the National Affairs section of the ACG website (www.acg.gi.org) for more information on how you can advance ACG public policy priorities such as the Screen for Life Act and push for Congress to weigh in with CMS to reconsider its ill-advised ASC rule.
Each: CLAZAL capsules contain 750 mg of balsalazide disodium, a prodrug that is enzymatically cleaved in the colon to produce mesalamine (5-aminosalicylic acid) and its metabolites. Each daily dose of CLAZAL (6.75 grams) is equivalent to 2.4 grams of mesalamine. Balsalazide disodium has the chemical name \( \text{CH}_3\text{NH}-\text{COCH}_2\text{CH}_{2}\text{CH}_{2}\text{NCO-NH-CO} \). The drug contains the following inactive ingredients: magnesium stearate. The sodium content of each capsule is approximately 86 mg.

CLINICAL PHARMACOLOGY: Balsalazide disodium is delivered intact to the colon where it is enzymatically cleaved to release equimolar quantities of mesalamine, which is the therapeutically active portion of the molecule, and 4-aminobenzoyl-ß-alanine. The recommended dose of 6.75 gram/dose, for the treatment of active disease, provides 2.4 grams of free 5-aminosalicylic acid to the colon. The 4-aminobenzoyl-ß-alanine carrier moiety released when balsalazide disodium is cleaved is only minimally absorbed and largely excreted. The mechanism of action of 5-aminosalicylic acid is unknown, but appears to be topical rather than systemic. Systemic production of arachidonic acid metabolites, both through the cyclooxygenase pathways, i.e., prostaglandins, and through the lipoxygenase pathways, i.e., leukotrienes and hydroxyeicosatetraenoic acids, is increased in patients with chronic inflammatory bowel disease, and it is possible that 5-aminosalicyclic acid derivatives information by blocking production of arachidonic acid metabolites in the colon.

Metabolism: CLAZAL capsules contain granules of balsalazide disodium which is delivered to the colon on reaching the colon, bacterial azoreductases cleave the compound to release 5-aminosalicyclic acid, the therapeutically active portion of the molecule, and 4-aminobenzoyl-ß-alanine.

Absorption: In healthy individuals, the systemic absorption of intact balsalazide was very low and variable. The mean Cmax occurs approximately 3-2 hours after single oral doses of 3 grams or 6 grams. The absolute bioavailability of this compound was not determined. In a study of ulcerative colitis patients receiving balsalazide disodium, for one year, systemic drug exposure, based on mean AUC values, was up to 80 times greater (80 ng·h/ml to 480 ng·h/ml), after equivalent multiple doses of 1.5 grams twice daily when compared to healthy subjects who received the same dose. There was a large intersubject variability in the plasma concentration of balsalazide versus time profiles in all studies, thus its half-life could not be determined. The effect of food on the absorption of this compound was not studied.

Distribution: The binding of balsalazide to human plasma proteins was 299%.

Elimination: Less than 1% of an oral dose was recovered as parent compound, 5-aminosalicylic acid, and its metabolites in the urine of healthy subjects after single and multiple doses of COLAZAL, while up to 25% of the dose was recovered as 4-aminobenzoyl-ß-alanine. In a study with 10 healthy volunteers, 65% of a single 2.25 gram dose of COLAZAL, while 25% of the dose was recovered as 4-aminobenzoyl-ß-alanine. In a study with 80 healthy volunteers, 65% of a single 2.25 gram dose of COLAZAL, while 25% of the dose was recovered as 4-aminobenzoyl-ß-alanine and the 4-aminobenzoyl-ß-alanine metabolites in urine, while <1% of the dose was recovered as parent compound. In a study that examined the disposition of balsalazide in patients who were taking 3.6 grams of COLAZAL daily for more than one year and who were in remission from ulcerative colitis, approximately 6% of an oral dose was excreted as intact balsalazide in the urine. Less than 4% of the dose was recovered as 4-aminosalicyclic acid and the 4-aminobenzoyl-ß-alanine was deleted from the urine. The urinary recovery of the N-acetylated metabolites comprised 20-25% of the dose. No local recovery studies were performed in this population.

CLAZAL Capsules are indicated for the treatment of mildly to moderately active ulcerative colitis in adult patients. Each daily dose of COLAZAL disodium and CG isolated in black.

NDC 65649-101-02 Bottles of 280 capsules

Bioclin: 20° to 25° (68° to 77°); excursions permitted between 15° and 30°C (59° and 86°F). See USP Controlled Room Temperature. Rx only

Manufactured for Salix Pharmaceuticals, Inc., Montrose, CO 72700

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6075, Guilford 2005


The following adverse events, presented by body system, have also been infrequently reported by patients taking COLAZAL during clinical trials (N = 510) treatment of active ulcerative colitis or from foreign post-marketing, reports. In most cases it relationship to COLAZAL has been established. Body as a Whole: Abdominal enlargement, chest pain, chills, dizziness, edema, elevated transaminases, fever, hypokalemia, pruritis ani, skin rash, swelling, headache, nausea, vomiting, abdominal distention. Constipation: constipation, acute constipation, acute ulcerative colitis, and from foreign post-marketing, reports. In most cases it relationship to COLAZAL has been established. Body as a Whole: Abdominal enlargement, chest pain, chills, dizziness, edema, elevated transaminases, fever, hypokalemia, pruritis ani, skin rash, swelling, headache, nausea, vomiting, abdominal distention. Constipation: constipation, acute constipation, acute ulcerative colitis, and from foreign post-marketing, reports. In most cases it relationship to COLAZAL has been established.
SAFETY CONSIDERATIONS

COLAZAL does not relieve symptoms in all patients; your patients’ results may vary. In four well-controlled clinical trials, patients receiving a COLAZAL dose of 6.75 g/day most frequently reported the following events (reporting frequency ≥3%): headache (8%), abdominal pain (6%), diarrhea (5%), nausea (5%), vomiting (4%), respiratory infection (4%), and arthralgia (4%). Withdrawal from therapy due to adverse events was comparable to placebo. COLAZAL is contraindicated in patients with a hypersensitivity to salicylates. Safety and effectiveness of COLAZAL beyond 12 weeks have not been established.