PSG Rumblings
SPRING 2022
PENNSYLVANIA SOCIETY OF GASTROENTEROLOGY / NEWSLETTER

President's Message / David L. Diehl, MD, FACP, FASGE

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@DavidDiehlMD

Shall we talk about something other than COVID?!

I am certain that you all are beyond done with more COVID-related chatter, so the only thing I will say remotely related to COVID is that we are looking forward optimistically for the ability to resume a more normal life in the months to come. Barring unforeseen new pathogenic variants of SARS-CoV-2 in the Spring and Summer, we are on track to be able to meet in person at our Annual Meeting for the first time in 2 years.

The meeting is being held at the Hershey Hotel from September 9th through 11th. Program chair Shyam Thakker, MD is planning an outstanding line-up of speakers, and the PSG Education Task Force should also be commended for providing key help with this effort. As is usual for the annual PSG meeting, we meet in the morning for lectures, networking, reviewing posters, and visiting with industry sponsors. The afternoons are free to pursue family-friendly activities at several attractions in the Hershey area. We always extend a special invitation and perks for GI Fellows, including lodging stipend and the opportunity to compete for prize money for their submission of a research poster. "GI Jeopardy" for GI Fellows is again on the schedule this year, allowing fellows vie with other teams in this fun, rapid-fire quiz.

In my first few months as President, I have been reflecting on how to grow into this role and figure out what I would like to accomplish during my 2-year term of office. One important early "win" that I am proud of is the adoption a Diversity and Inclusion statement for the PSG. I am grateful to Rich Moses for expert "wordsmithing", and for the guidance of Ariel Jones and Heather Wilson, PSG and PAMed administrators, who have extensive practical expertise in this area. The board unanimously supported adopting the statement, and this has been a huge step forward for the PSG. The Diversity statement is included elsewhere in this edition of Rumblings; please check it out!

PSG/SOCIAL: @PAGastroSoc

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Another new development is the opening of PSG membership to West Virginia gastroenterologists. West Virginia does not have its own GI society, and the proximity of this state to Pennsylvania does suggesting the possibility of expansion of membership. When PSG Board member Shyam Thakkar started working in West Virginia, discussions about expansion started in earnest. We are soon going to be reaching out to the gastroenterologists in West Virginia, inviting them to join the PSG. Shayam and his colleague Justin Kupeck will be key collaborators in helping with this effort.

Another initiative that I would like to pursue is a renewed effort to increase PSG membership. To this end, I have had discussions with our membership chairmen: Richard Moses from the East, Mitul Patel from the central region and Randy Brand from the West. One goal we felt was of primary importance is to get all Pennsylvania and West Virginia GI fellows to join the PSG. Randy has been successful at doing this at his program and has set a laudable example for the rest of us. The PSG will be reaching out to GI Fellowship Program Directors to get them to understand the importance of the PSG, to be followed by a reach out to all the GI fellows in the Commonwealth and West Virginia. I am grateful to Karen Krok and Kim Chaput for each being an important part of this effort and will rely on them heavily as this initiative moves forward.

Another initiative that we are planning on pursuing is a series of PSG-sponsored educational Webinar events. Some of them will be disease-based topics, some more broad topics in GI and practice management, and we are also planning an important Webinar on Diversity issues. Please be on the lookout for announcements of these events! I also expect that a regular cadence of Webinar events will raise the PSG profile as well as generate content to stimulate our Social Media effort.

I am grateful for the abundant expertise that exists on the PSG board and membership, and I will continue to rely on them as my Presidential term evolves. If anyone who reads this is interested in getting more involved with the PSG through committees and task forces, please let me know. But for everyone else, please know that your support of PSG in the form of simply being a member is huge, and thanks!

David L. Diehl, MD, FACP, FASGE
President
Pennsylvania Society of Gastroenterology

Remembering Frank W. Jackson, MD
Former PSG president

Dr. Frank Jackson

Frank W. Jackson, MD passed away September 29, 2021, at the age of 88. Born June 23, 1933 in Pittsburgh, PA he was the middle of three boys in the family.

After graduating from Peabody High School in Pittsburgh, he attended Princeton University with a major in Biology, and then completed medical school was completed at Johns Hopkins (class of 1959). While a medical student, he and his recently wedded wife Joaquine spent a summer providing medical care, traveling by car, boat, bike, mule, or foot to the townspeople of the remote town of Twillingate in the northern reaches of Newfoundland. He completed a one-year internship at the old Bellevue Hospital in New York City where he contracted and recovered from tuberculosis, before returning to Pennsylvania where he completed training in Internal Medicine and then Gastroenterology at the University of Pennsylvania.

In 1965, Dr. Jackson and his wife moved to Harrisburg, PA to join the Cowley Medical Group, a prominent, multi-specialty medical practice in the community. He established his career in Gastroenterology while also maintaining a small Internal Medicine primary care practice, patient relationships of which became lifelong. He founded his own Gastroenterology practice in 1974 and maintained a private GI practice, Jackson Gastroenterology, until he retired from the practice of Medicine in 2003. His son, F. Wilson Jackson, MD, joined the practice in 1999.

Dr. Jackson's career paralleled the growth and impact of the endoscope and pharmaceutical innovation on Gastroenterology. He was endlessly fascinated to bring endoscopic findings into the clinical arena of office-based patient care. A restless intellect, he made numerous contributions to medicine. He was a founding medical director of a cardiac rehab program in the mid and late 1970's, a first of a kind in the nation and well before cardiac rehab became a mainstay of patient management. Around the same time and before the use of computer-interpreted EKGs, he designed a handheld device to facilitate interpretation of EKGs with measurements of PR and QT intervals. He sold the device to a pharmaceutical company and promptly took his wife and five kids on a memorable ski trip to Switzerland. He later pioneered and patented a compact, benchtop device that enabled rapid, efficient, and consistent quality H&E stains (**Neat Stain**). Recognizing the potential of computer assisted learning, he founded in the 1980's an outpatient rehab program (**American Rehab Center**) that focused on patient-centric, educational programs around diabetes, congestive heart failure, hypertension and obesity. Around the same time, he established **Chek-Med Systems**, a company that focused on educational material for patient medications. Passionate about patient education, he broadened the company's portfolio on a wide range of diets and GI diseases, creating a subsidiary company, **Meducate**. With the advent of the internet, this patient educational material became the foundation of one of the most widely read patient resource for GI diseases, medications, and diets.

Ever a champion for patients and health care efficiency, Dr. Jackson was an early advocate to move routine endoscopy out of the hospital and into ambulatory surgical centers. He founded the first free-standing ASC in the Commonwealth of Pennsylvania in 1995. Many of the rules and regulations of ASCs had not yet been established and worked hard to help the Pennsylvania Department of Health to create these standards. He was an early champion of propofol sedation in endoscopy dating back to the mid 1990's. Somewhat unapologetically, he found hospital-based patient care inefficient and unnecessarily costly, not only for routine endoscopy but also ambulatory and acute patient care. He created one of the first dedicated, office-based GI infusion centers shortly after the FDA approval of infliximab. He spent the later part of his career managing and exploring how a wide range of acute GI patient disorders could be managed within the office and structured his practice to enable ambulatory care for many acute GI symptoms, effectively creating a GI specific, urgent-care clinic within his office for his patients to use.

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Remembering Frank W. Jackson, MD *continued from page 3*

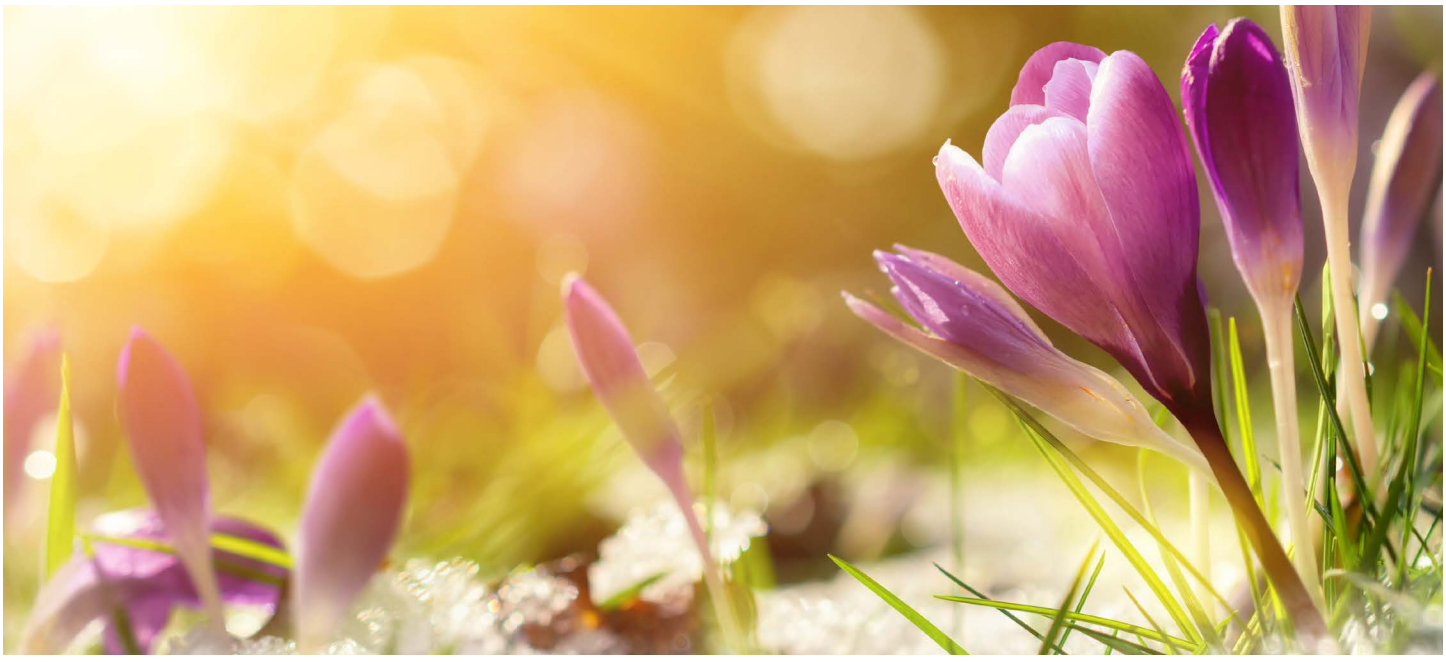
With continued expansion, **Chek-Med Systems** became **GI Supply**. Dr. Jackson held over a dozen patents that focused primarily on the field of gastroenterology. Perhaps the best-known invention of his was **Spot** endoscopic tattoo, which is used throughout the world and is a market leader. He developed this after many interesting discussions with the proprietor of a local tattoo shop! He innovated or improved on endoscopic bite blocks, an H pylori rapid urease test (**HP Fast** and **hpOne**), rapid peristaltic paracentesis pump for ascites (**RP Pump**), carbon dioxide based endoscopically delivered cryotherapy (**Polar Wand**) for treatment of dysplastic Barrett's, GAVE and radiation proctitis, biliary and pancreatic stents (**Winged Stent**), post-procedure endoscopic cleaning kits (**GI Tote**) and even designed an endoscopy cart to hold and store endoscopic instruments with a dedicated work space. He had an uncanny ability to partner with creative, like-minded people to develop medical device products and in doing so, established lifelong friendships.

In the early 2000's, he became curious about the microbiome, its yet not fully explored potential and its role in health and disease. His research led him to believe that prebiotics had much greater potential than the commercially more popular probiotics. He founded **Jackson GI Medical** and developed a series of prebiotic products under the tradename **Prebiotin** and went on to write a book on the subject, entitled Prebiotics not Probiotics.

Dr. Jackson was a long-standing member of the Pennsylvania Society of Gastroenterology and served as president from 1998–1999. As president, he organized an "how-to" conference on building ambulatory endoscopy centers which was attended by numerous PSG members nearly all of whom went on to build their own ASC's throughout our Commonwealth. Dr. Jackson was a well-regarded voice to the Pennsylvania General Assembly where he successfully testified on behalf of the PSG on a large range of GI specific legislative bills.

He was predeceased by his first wife in 1998. He remarried and is survived by her as well as his five children. Importantly, he greatly valued the friendships forged amongst PSG members and its leadership. They became not only fast-friends but also trusted colleagues whose council and camaraderie he valued.

—F. Wilson Jackson, MD



FIT UPDATE: The Obesity Epidemic and the Role of the Endoscopist

Travis Magdaleno, DO

In one way or another over the past two years, the COVID pandemic has impacted just about every life on earth. Early on, lifestyle changes were obvious: people were no longer dining out or leaving their house, forced to seek shelter, bringing daily routines to a halt. Gradually however life has returned, taking some shade of normalcy as each season passes. Weight gain is a scar from the pandemic that many people have encountered. We are definitely seeing more patients who have gained weight over the last year. This has been referred to as the "COVID 15" (or 20!)

Obesity impacts hundreds of millions of individuals worldwide[1]. It can be associated with chronic comorbidities including diabetes, obstructive sleep apnea, hypertension and can lead to significant mortality. Depending on your practice location, your institution may have a designated weight loss clinic/ center. In my health network, for example, there is a multidisciplinary weight management program that includes registered dietitians, behavioral health therapists, bariatric surgeons, and bariatric medicine physicians. To be evaluated in this program, patient's BMI must be over 30. Initial consultation includes discussion about different treatment pathways including dietary changes, meal replacements, weight loss medications, and finally surgical options. Bariatric endoscopy is emerging as another alternative to surgery.

Endoscopic treatments for obesity have been in use for a few years, however widespread adoption has been hampered mainly by the lack of insurance coverage. Only a select number of patients can front the thousands of dollars often required. However, an endoscopic solution to obesity is an attractive option as it is less invasive compared to surgery. It can also fill a role as an option for patients who do not qualify for surgery based on BMI but who have plateaued on medical treatment for weight loss. Currently there are multiple endoscopic options, including devices and procedures, that a gastroenterologist can utilize for patients with obesity.

Intragastric Balloons (IGB)

Intragastric balloons act to occupy space in the stomach and have been available for many years.. They reduce the available space for food storage and induce a sensation of early satiety. Early versions were introduced in the 1980s; currently there are 3 FDA approved balloons on the market. The balloons have capacities from 250mL to 800mL. Non-endoscopic placement is a feature of one device. The biggest drawback of IGB is lack of sustained weight loss. From multiple studies, they appear to work best in the short term (up to 2 years) before weight regain is observed.[2] Other studies suggest IGBs are best served as a bridge therapy to surgery or used in patients who would benefit from mild/modest weight loss in conjunction with behavior therapy.[3] The most common side effects were mild such as abdominal pain, nausea/ vomiting, and balloon deflation. Rare but serious adverse events including balloon slippage through the pylorus and gastric perforation have been observed.[3]

Aspiration Devices

These devices resemble a percutaneous gastrostomy tube, however instead of feeding, they are used for aspirating up to 30% of gastric material after a meal. The AspireAssist System was FDA approved for patients with a BMI of 35-55 kg/m2 who failed to achieve weight loss with non-surgical alternatives. A multicenter randomized controlled trial comparing the aspiration device to lifestyle changes noted a 37.2% vs 13% excess body weight loss (EWL) over 1 year.[4] A similar trial was performed in Europe and patients were monitored over a 4-year period which noted sustained results, as well as improvement in metabolic parameters including blood pressure, HbA1c, and triglyceride levels.[5] Most adverse events occurred within one week after placement, and included peristomal granulation, abdominal pain, and nausea/vomiting. Rare but serious adverse events were also noted and included peritonitis, prepyloric ulcer, and buried bumper syndrome. Unfortunately,

The Obesity Epidemic and the Potential Role of the Endoscopist *continued from page 5*

the AspireAssist will no longer be available after early April 2022 due to financial impacts the company suffered related to the COVID-19 pandemic.

Endoluminal Bypass Devices

Barrier devices are interesting products which mimic the anatomy of a Roux-en-Y gastric bypass surgery. It's simply a windsock-like device that is endoscopically placed and anchors itself in the duodenal bulb. When deployed it extends approximately two feet into the small bowel. After meals, gastric contents are then passed through the pylorus, directly through the barrier device preventing key nutrient-mucosa interactions early in the digestion process. The contents are then eventually emptied into the jejunum where they are joined by pancreatic and biliary secretions. Early small pilot trials noted an EWL of 23.6% after 12 weeks, and interestingly, all diabetic patients did not require their diabetic medications during the study period.[6] More recent prospective larger trials have shown an average EWL of about 47% after one year of use.[7] There is one device approved in Europe, called the Endobarrier (duodeno-jejunal bypass sleeve) and is endoscopically removed after one year. This device has not yet been approved by the FDA for use in the United States however there are ongoing active trials.

Transpyloric Shuttle

This is a large spherical balloon which is attached by a catheter to a smaller cylindrical bulb. The device is endoscopically placed and when seated properly, the catheter traverses the pylorus along with the smaller bulb leaving the larger balloon to obstruct the pylorus. As the stomach contracts, the shuttle moves proximally into the antrum, allowing the passage of gastric contents into the duodenum. This concept of the device is to delay gastric emptying by inducing an intermittent gastric outlet obstruction. A prospective open-label single-centered study noted a 6-month EWL of 50.0 +/- 26.4%. There is one FDA approved device in the US. Although studies do suggest modest weight loss, a large number of included patients experienced some form of an adverse event including abdominal pain, nausea, and vomiting, not unexpected given the mechanism of the device.[7]
Magnetic Entero-Enteral Bypass

This is an incisionless and permanent bypass procedure which utilizes the placement of two ringed magnets within the proximal and distal small bowel. Placement requires a simultaneous push enteroscopy and colonoscopy with ileal intubation. Using fluoroscopy to ensure symmetrical magnetic overlap, the ringed magnets are deployed within adjacent loops of bowel. Over the proceeding days, shear pressure creates ischemic changes of the intestinal wall between the magnets, and the tissue undergoes necrosis leaving an enteric fistula. After mucosal erosion, the magnetic rings link up and are expelled. This creates a partial jejunal diversion. The initial human pilot study was performed in 2017 and enrolled 10 patients. The anastomosis was patent at 2, 6, and 12 month endoscopic assessments. Metabolic profiles significantly improved over one year duration with an average EWL of 40.2% at 12 months.[8]

Endoscopic Sleeve Gastroplasty

This procedure utilizes endoscopic suturing to mimic the anatomy of a surgical sleeve gastrectomy. It consists of the placement of multiple transmural gastric sutures in a specific pattern which when tightened, reduces the size of the gastric body along the greater curvature. The gastric fundus typically remains undisturbed. Compared to its surgical counterpart, as the fundus and body are not resected, the hormonal benefits including decreased ghrelin are not seen. However, despite this, considerable weight loss is still observed trials, with a two-year EWL of 60.4%.[9] Adverse events largely include abdominal discomfort, nausea/vomiting. Serious adverse events have been described including perigastric hematoma and gastric leak.

Duodenal mucosal resurfacing (DMR)

One company (Fractyl Health) has developed an ablation device which accomplishes what is called "duodenal mucosal resurfacing". This induces local hormonal changes in the duodenum which can lower glucose levels, and is being investigated as a treatment for type II diabetes mellitus. Limited clinical studies have been done outside the United States and have been encouraging, although there is limited follow-up[10]. In addition, the exact "dose" of mucosal ablation has not been worked out, nor whether the treatment has to or can be repeated if necessary.

The clinical effect appears to be less related to weight-loss than to glucose control, which itself is an important goal. The term "metabolic endoscopy" has been coined to describe an endoscopic treatment which can treat diabetes[11].

Summary

There have been significant advances in the field of bariatric endoscopy since the original introduction of the Garren-Edwards intragastric balloon more than 20 years ago. More data is required to determine long-term outcomes of these interventions, and to decide which technique or device should be applied to which patient. As the rate of obesity (and type II diabetes) in the United States continues to increase, it is anticipated that there will be an increase in patient interest in these options. In this regard, an important issue of insurance coverage for any bariatric endoscopic procedure will need to be addressed. However, it seems clear that there will be an emerging role for bariatric endoscopic procedures moving forward.

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PRACTICE MANAGEMENT: Should you hire a practice management consultant to optimize your reimbursements?

By R. Fraser Stokes, MD
PSG Practice Management Chairman

@fraserstokes

One of the challenges facing gastroenterologists today is getting fair reimbursement from health insurance companies. Most practitioners simply accept the reimbursement rates assigned by insurers without questioning whether these rates are competitive in the current market.

Six months ago, our practice received a notice from one of our major insurers that our rates were going to be substantially reduced, and that if we didn't respond to their letter within a short period of time that these decreased rates would be our new standard for the next several years. This raised major red flags for our business. Accepting these rates would certainly be damaging to the fiscal health of our practice. Accepting similar rates from our other major insurers would threaten our practice's very survival.

This forced us to negotiate with the insurer. We felt at a disadvantage in this negotiation because we did not know what other GI practices in our state were being given for our common billing codes. In addition, we didn't have extensive experience with the negotiation process, didn't know how hard to push, and didn't fully understand the leverage that we had. Furthermore, our GI physicians and administrative team were very busy and didn't have the time to dedicate to this process. Conversely, health insurance companies know exactly what each practice is reimbursed and have a dedicated staff armed with effective strategies to minimize reimbursement rates

There are different ways to deal with this challenge. Some practices are approaching nearby hospital systems inquiring about a potential buyout whereby the hospital would ensure the physicians would no longer need to worry about insurer negotiation. Another trend is for practices to join supergroups, which often have private equity backing. These organizations have a team of administrators with expertise in contract negotiation that are fully committed to doing battle with insurers.

Another option is to engage the services of a consulting firm specializing in revenue cycle enhancement. These companies do a thorough review of the top 10-15 billing codes a practice has sent to their five largest insurers.

Reimbursements for each code are reviewed, and then compared with what they have identified as competitive rates for a similar practice. A report is generated that estimates potential revenue gain by effective contract negotiation. In addition, advice is given to potential changes in language in a contract so that the practice can be in a more favorable position.

The consultant then works behind the scenes to advise a practice on specific points to be covered during a negotiation. A detailed plan is generated with scripted advice which is used for the laborious process of a single contract negotiation, which can take up to two months.

The consulting firm can advise which insurer tends to under-reimburses for which codes. Their review of a practice's major contracts can also avoid missing an important deadline, and negotiate increased reimbursement to account for rising overhead costs or cost of living increases.

When doing a contract negotiation, it's essential to know the value of a practice in a community in terms of local competition, number of lives covered, and other practice-specific details.

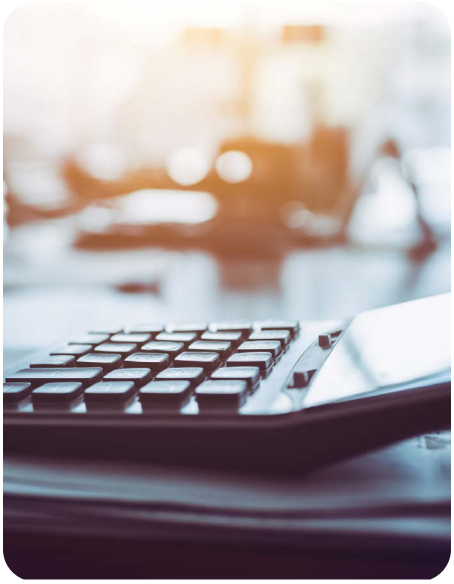
Practice consultants create a current and complete inventory of all payor agreements, which is critical to manage and track multiple and complex insurance agreements, all with different terms, notification

requirements, rate modification language, etc. A practice needs to have the ability to say "no" to an unacceptable contract offer and know the financial consequences with a cost benefit analysis.

Typical fees for these consultants are about $5,000 per contract review and $10,000 for negotiation assistance. However it is not unreasonable to expect a 10-20x return on this investment. The initial contract review process usually takes 4-6 weeks.

Some of these consulting firms do more than just assist with contract work, and they can provide help for a practice's entire revenue cycle, from preregistration to fee collection, as they try to negotiate maximal reimbursement for Gi services rendered.

As contracts become more complex, and there is more pressure by payors to lower reimbursement, it can be great to have an experienced consultant by your side to help with contract review and with the re-negotiation process.



Legal Corner

Richard E. Moses, DO, JD

What you need to know about employment contracts in the COVID era

@therealgidoc

It is no surprise that the healthcare environment for gastroenterologists is rapidly changing. In the past 1-2 years, we have seen GI practice consolidations and acquisitions, new GI practice start-up ventures, private equity partnerships, and the continued fading of smaller private practices . GI fellows coming out of training most commonly opt for employment. Contract negotiations have become more limited as these larger GI practice entities have gained more control of the employment environment.

We are also entering the 3rd year of the COVID-19 pandemic. The pandemic has created challenges for employers particularly larger consolidated healthcare systems. Some of these challenges include decreased revenue, restrictions in patient flow despite rising overhead costs, and the need to have healthcare delivery in different locations (in-hospital and remote). In many cases, this has created a situation where employers have needed to reassign or terminate their employed physicians. This situation in which employer feels that they need more control over their employees, has created important changes, and often restrictions in what was previously relatively standard employment contracts policies. This can lead to important limitations for the physician to negotiate contracts.

The purpose of this article is to call your attention to some important employment contract issues, which have changed recently. This will allow you to consider the implications, and knowledgably discuss them with your healthcare attorney, prior to signing your employment contract.

Employers may demand unilateral changes to compensation and work hours

Be aware that there are contract clauses that give the employer broad latitude in reassigning your work location, hours of work (including requiring work during off-hours and weekends), and control of call schedule. In addition, some contracts give employers the option of unilaterally altering compensation by raising the productivity threshold bonus or directly modifying base salary. This could be triggered based on productivity, profitability, or refusal to move to another location. Employment termination clauses may contain the same or similar language. Be aware that some of these contracts allow a unilateral need determination.

"Without Cause" notice

"Without cause" notice clauses are common in employment contracts. Historically, these have allowed the employer to terminate physicians convicted of a moral issue, felony or other causes. Often, these allow termination after 60-90 days allowing the physician time to seek new employment. However, some employers include a clause to allow a "without cause" action with no notice. This can trigger a restrictive covenant clause (non-compete clause) which restrict the physician from obtaining employment near the practice.

"Force Majeure" clause

The "Force Majeure" clause frees both parties from obligation or liability when an extraordinary circumstance occurs beyond the control of the parties. This could include war, a strike, riot, crime, epidemic or sudden legal changes that prevents one or both parties from fulfilling their obligations under the contract. The COVID pandemic has resulted in frequent use of this previously uncommonly invoked clause. Employers have recently used the clause to impact incentives tied to performance more so than salary directly. It may also be used as a reason for employment termination.

"Claw Back"

There are some newer twists with employment contracts. One example is "claw-back". One version of this is that a bonus is promised to an employee, but if certain requirements are not met, part of the amount of the bonus is deducted ("clawed back"). One must be sure that the conditions that must be fulfilled to earn the entire bonus are reasonable. Some more punitive claw-back clauses might be encountered. For example, the contract might state that the provider must pay back overpayments after a payer audit. Although this could be a result of the employer's billing office error, contract language could hold the employee physician responsible.

Demand for "As Is" contract acceptance

A large employer may require that the contract to be accepted "as is": that is, without any contract changes. There may still be the opportunity for your healthcare attorney to get clarification of ambiguities and correct errors if you truly want that job. Working outside of your subspecialty has also been added to some employment contracts. It is determined at the discretion of the employer. This arose from COVID-related hospital/ICU staffing issues.

"Integration clause"

No matter what an employer promises, the promise must be in the contract to protect your rights. Contracts frequently have an "integration clause" specifying that the contract constitutes the complete agreement between the two parties and nullifies any other oral or written promise made to the employee. Promises made in an alternative document, such as an offer letter, will not be enforceable unless the alternative document specifically states that the commitment in that document is protected from the integration clause in the contract. This can be an uphill battle for your healthcare attorney.

Hire an experienced contract attorney!

The healthcare environment continues to change. There is a well-documented decline of independent physician employment with about 70 percent of U.S. physicians employed by hospitals or corporations. And during the first year of the pandemic, 48,400 physicians left independent practice for employment. The best approach to navigate the shifting healthcare employment environment is to hire an experienced healthcare attorney who is qualified to review, explain, and negotiate for you. This is the best way to protect your rights and negotiate for the best possible contract.

Ozanimod: A Novel Therapeutic Option for Treatment of Ulcerative Colitis

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Introduction:

The mainstay of therapy for mild-moderate ulcerative colitis (UC) includes 5-aminosalicylates, while treatment of moderate-severe disease generally involves the use of biologic agents (anti-TNF, anti-integrin, and anti-IL12/23 monoclonal antibodies) or small molecule inhibitors (JAK pathway)[1]. Many patients will have either a primary or secondary loss response to these medications[2] and approximately 15% of UC patients will require colectomy over the course of their lifetime[3]. In 2021, the FDA approved the use of ozanimod (brand name Zeposia), a sphingosine-1-phosphate (S1P) receptor modulator, for the treatment of moderate-severe UC[4].

Mechanism of Action

Though previously approved for relapsing and remitting multiple sclerosis, ozanimod is the first drug of its class to be approved for use in UC. S1P is an important molecule in signaling lymphocytes to leave lymph nodes and move towards inflamed tissue[5]. Ozanimod binds to the S1P receptor (specifically S1P1 and S1P5) which causes internalization and therefore limits the egress of T-lymphocytes from the lymph nodes, blocking lymphocyte trafficking[5]. Downstream, this |results in decreased inflammation at the affected tissue.

Efficacy Data

The first large, published report of ozanimod in UC was a Phase 2 trial (Touchstone) by Sandborn, et al in 2016[6]. In this dose-finding study, 197 patients were randomized 1:1:1 to receive ozanimod 0.5mg or 1mg or placebo daily for 32 weeks. The primary endpoint was clinical remission at 8 weeks (Mayo Clinic score ≤2, with no subscore >1). The primary outcome was achieved in 16% of patients receiving 1mg of ozanimod compared to 6% of patients receiving placebo (p=0.048). The 0.5mg dose did not reach significance. Similar results were seen at 32 weeks. This study resulted further study of the 1mg dose.

A landmark, phase 3, double blind, placebo-controlled study (True North) was published in September 2021 [7]. Like other recent drug trials in inflammatory bowel disease, this study was designed as both an induction and maintenance trial. Adult patients with moderate-severe UC (defined by Mayo score 6-12, a rectal bleeding subscore of 1 or higher, and a stool frequency subscore of 1 or higher) were randomized 2:1 to receive 1mg ozanimod daily or placebo. A second cohort of patients received open-label 1mg ozanimod. Patients who had a clinical response after 10 weeks in either cohort were re-randomized to receive 1:1 continued 1mg ozanimod or placebo for an additional 42 weeks (total 52 weeks). The primary outcome was the percentage of patients with clinical remission at week 10 (for the induction period) and at week 52 (for the maintenance period) as assessed by the three-component Mayo Score (rectal bleeding subscore of 0, stool frequency subscore of 1 or less, and endoscopy subscore of 1 or less). Additional secondary endpoints included clinical response, mucosal healing, histologic remission, and steroid-free remission among others. Safety assessments were also examined.

A total of 1012 patients were enrolled in the trial. Approximately 90% of patients randomized completed the induction phase. Of the 557 patients that were enrolled in the maintenance phase, 184 patients who received ozanimod (80.0%) and 124 patients who received placebo (54.6%) completed the maintenance phase. Disease relapse was the most common reason for discontinuation.

At the conclusion of week 10, the ozanimod-treated group were more likely to be in clinical remission compared to the placebo patients (18.4% vs 6.0%, p<0.001). Ozanimod patients were also more likely to achieve clinical response (47.8% vs 25.9%), endoscopic improvement (27.3% vs 11.6%), and mucosal

healing (12.6% vs 3.7%) (for all p<0.001). In the maintenance phase, patients receiving ozanimod were more likely have achieved clinical remission at the end of 52 weeks (37.0% vs 18.5%, p<0.001). There were similar findings for the major secondary endpoints as well.

Side Effects/Safety

Prior phase 2 trials for both UC and Crohn's disease as well studies of patients using ozanimod for multiple sclerosis had identified several potential adverse effects. These include bradycardia, serious infections, macular edema, and elevated liver enzymes. The phase 3 True North trial found rates of adverse events similar to those seen in prior studies of ozanimod [7]. Given prior experience, particular attention was paid to rates of bradycardia and macular edema which were more common in ozanimod patients during the induction phase. There was no increased risk of malignancy and very few patients discontinued the drug due to an adverse event. Overall, the study authors deemed ozanimod to have a favorable safety profile [7].

Practical Considerations

The major advantage of ozanimod compared to most other advanced therapies available for patients with moderate-severe UC is the mode of delivery – this is an oral medication. This allows for improved quality of life for patients and may also decreases burden to healthcare system to avoid infusion centers [8]. As this is a small molecule, there is no risk of immunogenicity, and its short half-life may result in rapid onset of action and the ability to stop if there are side effects.

As a result of some safety concerns, there are several tests recommended prior to starting a patient on ozanimod that differs from other advanced therapies. All patients should get a CBC with lymphocyte count, liver function tests, an electrocardiogram, and varicella antibody serology. Patients with known diabetes are recommended to get a fundoscopic eye exam to assess for macular edema. Ozanimod is not recommended for patients with Mobitz type 2 or 3 AV block, other cardiac conduction abnormalities or macular edema. For other cautions, providers should review the FDA package insert. Additionally, ozanimod should be used with caution in pregnancy as there is not yet sufficient data to determine safety. Lastly, because of interactions with monoamine oxidase, patients should avoid significant quantities of tyramine-containing foods.

Insurance coverage for use of ozanimod for ulcerative colitis is currently spotty but will likely improve over time. There are resources available from Bristol Meyers Squibb for those interested in prescribing ozanimod but have difficulty with insurance.

Conclusions

Given that a sizeable number of patients have limited or loss of response to previously approved therapies, there still exists a large need for additional therapeutic options for the management of ulcerative colitis. Ozanimod, the first therapy in a new class of medications, is effective in the treatment of moderate-severe UC and has a favorable safety profile. In addition, it has the advantage of being a small molecule without immunogenicity and is given in an oral formulation. As providers gain familiarity with ozanimod, we will gain new insights into its proper positioning among the therapies already available.

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PSG Social Media Corner

We have been working hard to generate meaningful content on our social channels for PSG members and non-member physicians in the field. This month we highlighted St. Lukes's **Inaugural** Gastroenterology Symposium! **Keep your eye out for upcoming new content features** and be sure to let us know what you want to see on our social pages by commenting, liking, retweeting or direct messaging us. Remember to follow @PAGastroSoc on Facebook, Twitter and Instagram to see what our **Ambassadors** are up to! #PAGastro

Diversity & Inclusion: Our Future & Foundation for Growth

Diversity, equity, belonging, and engagement are at the core of the Pennsylvania Society of Gastroenterology's (PSG) values. The PSG encourages, welcomes, supports, and recognizes diverse opinions and voices of our members, staff, and business partners. We know it is important to intentionally foster understanding related to ethnicity, accessibility, age, gender, and sexual orientation. This will foster our commitment to collegiality and authentically connect us closer to our members, their patients, and the communities they serve

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