

Roundtable Discussion During Digestive Disease Week

Participants:

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Transcription:

Bill Steiber: Konsyl Pharmaceuticals is very happy to present a round table discussion on a subject we feel is of major importance, and that is the long-term use of stimulant laxatives. The problem with this is that it has been demonstrated, studied and proven that long-term use of stimulant laxatives will result in what is called cathartic colon and literally will get to the point where a patient cannot have a normal bowel movement. Unfortunately there is nothing we can do about those patients who are already unable to have a normal bowel movement. However, we are concerned with are the patients have used a stimulant product longer than they should but they haven't gotten to the point of having a cathartic colon. We want to try to get the word out to the medical community, to the general population and to the pharmacists in the country about this danger and give them a plan of something to do about it. So let me introduce the participants. First of all we have Brian Sweeney, Division of Colon and Rectal Surgery University of Minnesota, St. Paul, Dr. Steven Pray, Bernhardt professor at Southwestern Oklahoma University, School of Pharmacy in Weatherford Oklahoma, and a local person Dr. Peter Sender. He is the Head of the Department of Gastroenterology in Harbor City, California and I'm very pleased and honored to have you gentlemen be a part of this because you can give different perspectives to the table, and I think this is going to be a discussion in which we establish what the problem is and then come back with a plan and say "What can the population do about it?" Konsyl is sponsoring this and Practical Gastroenterology is also the co-sponsor.

Let's start with the first discussion point, and to do this in the interest in time, if you basically agree with something that's already been said and just want to make a clarification, it will help to move things along. First of all, explain what you think of the idea that stimulant laxatives are dangerous if used over a long period of time. Dr. Pray, from a pharmaceutical standpoint, let's start with you.

Pray: There are a couple of things that always worry me about the prolonged use of stimulants. One is the unnatural way in which they work. I use a simple analogy with patients, and that is your bowel is like a train - you load the boxcars when you eat a meal, which is roughly three times a day, and those little meals start marching down until they are ready to be excreted as waste. The problem with stimulant laxatives is that they do take care of today's constipation but they don't stop there. Instead their action continues on up the colon until finally the patient excretes material that should have been excreted tomorrow. That starts the habituation cycle because the person typically thinks you have to have a bowel movement everyday. When there is no bowel movement tomorrow (because it was already excreted) they don't understand and assume that they are constipated again. So they interpret that as a new episode of constipation and take the stimulant again. In the most extreme cases, they can abuse stimulants for many years. No one ever tells them that the remedy is to stop abuse of the stimulants and bulk up your diet. Thus, the very unnatural method of action of stimulants leads directly to habituation. In addition to that issue, we're also going to cover other major issues with use of stimulants, the actual bowel damage they cause, and their potential for carcinogenicity. There was once an ingredient known

as danthron that is no longer available because of that issue. The FDA recently removed aloe, casanthranol, and cascara, so we're left with just a few stimulants under suspicion, which have never been cleared. Castor oil and senna may be carcinogenic, while bisacodyl has supposedly been cleared by the FDA. Those are the issues that bother me in use of stimulant laxatives

Steiber: Dr. Sweeney

Sweeney: I wholeheartedly agree. The way the body is designed is the best way for it to function; it cannot be a good situation when we start artificially creating bowel movements because the patient thinks they need to have one.

Sender: I agree. I ask these patients over a period time when their habituated to laxatives that they don't move their bowels independently without the stimulant and they frequently experience bloating and pain, especially if they can't get to the laxative, and it's a vicious cycle and we need to get them off of these which is what I think the purpose of this discussion is.

Steiber: Another question: What is the period of time a laxative can be safely used before seeing a physician? Again, Dr. Pray.

Pray: If the physician has directed use of a specific laxative, it's not pharmacist-directed self-care. However, pharmacists constantly counsel patients who are not being directed by a physician, so the Food and Drug Administration has clearly defined how long we can recommend that patients use laxatives without seeing a physician. Seven days is what the FDA recommends as the maximal pharmacist-assisted self-care time of use.

Sweeney: Occasionally I will prescribe a PEG product for a day or two in order to rapidly initiate a bowel movement.

Sender: From my viewpoint as a surgeon, I think there may be some artificial state that may alter the bowel function that might require a longer prescription, but I always start out with fiber products and water and so forth, and I'm thinking post-operative cases like rectal or abdominal surgery where patients are on narcotics, I'm thinking maybe two weeks would be the normal time they would be on a stimulant laxative.

Steiber: As we discussed, the public seems to believe that they need to have a bowel movement everyday because their mother told them so. Could we define to the public what a normal range is, or what defines constipation... Dr. Sender?

Sender: You're right that [people] perceive having a bowel movement [at different times] natural for them. Everyday would seem to be the norm, but there is a wide variation there. Some people with their bowels go once or twice a week and that's normal and they are comfortable doing that, and they don't have any symptoms or pressure gas bloating or go more often - then I would agree it's variable. But I think if they are not moving their bowels twice a week there is a problem. I would like to investigate that.

Steiber: But as long as it's consistent with their pattern, is there a problem?

Sender: If that's their life long pattern, you can see that from childhood, and there is nothing wrong.

Sweeney: Very simply, constipation is infrequent bowel movements or difficult defecation. As Peter said, I've had patients go once a week and say they feel fine. More often I experience patients with painful defecation. They don't want to go, or they strain and push and nothing is coming out. There is straining, pain and bleeding. Some people say they go three times a day but, "I just have to force and push." They describe constipation because of the straining or the pain.

Pray: As I was going through the medical literature, I noticed physicians suggesting the normal range of bowel movements as 3 a day to 3 a week. It's very individual. I always try to ask my patients what their normal frequency is before I recommend a specific product.

Steiber: What do you feel are some of the most common reasons the general public uses stimulant laxative more than what you've recommended or what the package labels recommends?

Sweeney: I think it's the habits people get into and their diets. I tell my patients that when I was a kid, I ate sugar cereals low in fiber and white bread. Having six kids, I'm trying to get them to eat high fiber cereals, whole wheat bread fruits and vegetables. I also think there is an environmental issue surrounding bowel function. I think it's very important. I talk to schoolteachers and they say the kids don't want to go to the bathroom while at school. They think the bathrooms are gross and they wait until they get home to go. Over a long period of time, suppressing this call to stool I believe can be harmful. This may ultimately initiate their need for a laxative.

Sender: I think that some of the pressure might come from society and what they see on TV and in the print ads, and they're told they should take Benefiber because it's easy to take and they have the perfect bowel movement that essentially doesn't get in their way. And in some ways they are promoting stimulants on TV, and people get caught up in this. Everybody is so busy now a day - they get in their car everyday for 2 hours at least in LA, and there is a lot of pressure on them to not let it get in the way of their day. I think companies take advantage of that.

Pray: The medical literature tells us that 63 million people define themselves as constipated at any one time. Undoubtedly a great deal of that is perception, and as we said, people want to wake up and they want to shower, shave, shampoo and defecate, and they want to be clean inside and outside. Unfortunately delivering a 10-pound bowel is their definition of being cleaned. And that widespread misconception is one we must address. A second misconception is fostered by the unfortunate fact that, in the U.S., over-the-counter products can be bought in virtually any location---in airports, beauty shops, hotel lobbies, vending machines and gas stations. This leads to the myth that if it's over-the-counter it's safe as water. Any dose, anytime, no need to see a doctor, no need to read the label, do whatever I want. Advertising agencies further spread that misconception by refusing to place any type of warning in their ads for nonprescription products. Pharmacist intervention in nonprescription product sales becomes critical, because I feel that unsupervised sales are a large contributor to this problem. When the patient purchases a stimulant laxative at a convenience store or a gas station, there is no professional to stress label reading and to communicate the dangers inherent in use.

Steiber: Unless they read the labels

Pray: Surveys demonstrate convincingly that many patients simply refuse to read the directions of nonprescription products to see the warnings or limitations.

Steiber: There is data out there that long-term use of stimulants can permanently damage your colon. You can never have a normal bowel movement again. What is your opinion, and how do you convey to your patients this kind of situation?

Sweeney: I believe there is a time when irreversible damage has occurred. In a Colorectal Surgical practice we see patients with intractable constipation. They undergo transit studies and evaluation of anorectal function in the anorectal physiology lab. There are occasional surgical options in these intractable patients.

Steiber: There is data out there that indicates that this is the case.

Sender: I see patients that come in with these symptoms that don't take "laxatives." They'll take an herbal supplement, or tea, or an herb of some kind, and they do a colonoscopy and they've got a black colon and they can't move their colon at all. They aren't really taking laxatives, they are taking tea. But yet they hurt themselves to the point where they end up having to see Dr. Sweeney for the ultimate care. These are dangerous times we live in, and people have access to all kinds of things - a lot of them not FDA approved.

Pray: What you alluded to addresses the 1994 federal law (the Dietary Supplement Health and Education Act) that removed the FDA's ability to deal with products that are purported to be "dietary supplements." Unapproved products can now be marketed as safe "fiber" products without proving safety or efficacy. Until we have a national move to put responsibility back into nonprescription products, we will continue to see irresponsible products marketed.

The issue of lack of information about unproven dietary supplements such as Benefiber is difficult to communicate to the lay public. When testifying as an expert witness, I use this analogy. If you could conceivably place all the patients who have experienced dangers from products of unproven safety and efficacy and fill a large room, it would be completely dark if there were no reports of the adverse effects. But, if you had perfect data the room would be completely lighted. In medicine, we deal with a large number of case studies, which is the equivalent of opening a small window into the room, just light enough to see those few patients. The rest of the patients remain unknown unless they report their adverse effects to someone. This dark room is equivalent to the information vacuum we are placed in when companies market products such as Benefiber, which has never been proven safe and effective through the FDA OTC review.

And my point is, why should a patient use a product with questionable safety and efficacy when we know there are FDA-approved products that are going to accomplish the same goal?

Steiber: Often times, people believe that if it says it's natural that it must be good or safe.

Sender: You hear of people taking Aloe Vera, which I think comes as a tea. I think that should be avoided. That's also a stimulant laxative and think of the other brands. Basically, if someone tells me they are taking an herbal tea and I see melanosis, I basically tell them to stop taking the tea.

Pray: If you carry out an Internet search, you'll see there are millions of herbal sites, and I'd say unless an herb or dietary supplement is FDA-approved, avoid it. Because of the retrogressive 1994 federal law that approved sales of dietary supplements, we don't know if the dietary supplements and herbs are safe and effective. This is an entire realm of nonprescription products that should be avoided until they are FDA-approved.

Steiber: Can any of you give an estimated number of the US population that has reached this stage of having a lethargic colon where they can't have the normal bowel movement?

Pray: I found some data when I was conducting research for my textbook that 1.8% of Americans use laxatives daily or every other day. That tells us that there are millions of patients habituated to laxatives. At least 25% of laxative sales are stimulant laxatives, so enormous numbers of patients are victims of stimulant laxative abuse. The FDA doesn't actively collect data on this, but my guess is several million people reach the stage of permanent colon damage and are physically addicted, or psychologically addicted to stimulant laxatives, or both.

Steiber: Following up on the 25% that are stimulant laxatives - is that 25% dollars or units?

Pray: I believe it was in terms of dollar sales.

Steiber: And stimulant laxatives can be less expensive, therefore they are selling many more units. Therefore, the safer bulking units, even though they have a higher price tag, are selling fewer units. Any other thoughts on the number?

Sender: I think the point is, as we age things slow down physiologically, and you hear the story the old folks are having white toast and not enough activity and it's important we keep the old folks on a nice dietary and activity level.

Pray: When I attempt to intervene to stop long-term abuse of stimulants, the patient will often look at me as though I'm crazy. It is frequently an age issue, "You're younger than me, so don't tell me what works for me!" Too, they may have already tried to resume normal, unstimulated bowel function, but were unsuccessful because of the unnatural way that stimulants act, as previously described. The long-term abuse leads patients to purchase the large sizes. An elderly lady once brought a gallon of mineral oil to my counter and asked if we had anything bigger than this! There is the continuing misconception that stimulant laxatives are safe to take in any dose for any period of time whatsoever.

Steiber: How often do you get people seeking advice about these things, or is it just about the bigger size?

Pray: If we try to communicate that they are using an unsafe laxative, they are often resistant to our advice. If it's a first-time user we can get in and make some points. But it is usually pinned to the age of the patient. It's sad that it's true, but the longer they continue stimulant abuse, the longer they are habituated.

Generally, once the pharmacist steps away from the prescription-filling area to go out to help patients in the nonprescription aisles, we are asked question after question - they grab your elbow and grab your coat to get your attention, and you discover they have some very profound health issues.

Steiber: Other experiences we've had as well: the consumers, the public - constipation isn't a topic they talk about all the time very freely. That's why I think sometimes, certainly in your case or family practice, it's an "oh-by-the-way". You go for a sinus infection and then they mention a problem with constipation and that's all they want to say about it. So it's good if you can get them early going down the right path than continually down the wrong one and I agree with Brian when he says people do get older, and as they get older they need a little push (that's what the surgeons call it), and use a product that is partial stimulant. Another question about starting right, we've done some work with the pediatric gastroenterologist and the tendency seems to be the biggest problems are little boys rather than little girls. And it's been explained to me that little boys get busy playing and they get too busy doing what they want to do and they just let that moment pass by, and it's interesting as you get older the problem does shift to females in terms of perception that they need to have that bowel movement and perception that they've got to do something about and something about it now.

Sender: Again, I think everybody goes to the schools, and I'm not so sure if guys particularly care what the bathroom looks like in the high school, but I do think girls do. It'd be a neat study to do - how many kids use the restroom in high school and how many just wait until they get home. It's a long day; there's not enough time to go between classes. You're in class at 7am and you're not home until 6pm and nothing's happened all day.

Steiber: Anything else? I think we've fairly clearly defined what the problem is in terms of the nature, size, and causes.

Questions from the audience:

Q: Have you thought about speaking at Assisted Living Facilities? My mother called me just the other day and told me that they had a speaker come in and talk to them about fiber. They are so into taking care of themselves, they love it.

Steiber: Whenever we have a doctor or pharmacist who says “I really know your product is the best product out there. My mother is in assisted living, would you mind giving her a trade size?” I am always so willing to do that because I know that she’s going to tell seven other people about it. The only difficulty that I’ve run into personally with my mother-in-law who is in assisted living, is that if you don’t have doctor’s orders, whether its OTC or prescription, they will take it away from the resident.

Q: I don’t think OTC is often discussed. I think they have to specifically ask, “What are you doing about your bowels?” I work in a hospital and it amazes me how many people are not asked about their norms. In some of the hospitals, the physicians want them to have a bowel movement every day and they don’t ask, “How often is your norm?” And if your norm is three days, they’re trying to treat them now to have a bowel movement every day. The nurses are the same - they’re telling the doctors to make sure you have a bowel movement every day.

Pray: To confirm something you said, surveys show that when a physician says, “Tell me what medications you’re on,” they usually neglect to mention nonprescription products because of the perception that they are not real medications. Further, when they are asked about use of herbals and dietary supplements, the patients often ask, “Are those drugs too?” Patients often think that medications are in these three distinct groups (prescription products, nonprescription products, and dietary supplements), making it difficult to get a good and complete medication history from them. They are also often embarrassed to tell the physician or pharmacist that they are taking unregulated medications obtained in a health food store.

Sender: Well, what I usually try to do if a patient is taking an herbal is tell them to look at the label to see if there’s something like Senna in that or Cascara or aloe or something like that, and I’ll say, “You shouldn’t be taking this.” Now hopefully these herbals are labeled, although I can’t vouch for all of them. Some of them have nothing.

Pray: Manufacturers are supposed to label the ingredients at the very least. The 1994 law requires a statement on the container of every dietary supplement to the effect that it is not known to be effective for diagnosis, treatment, cure or prevention of any disease. What else is left? That’s the double-talk that the 1994 law allows, but patients don’t understand or overlook the whole affair. They often think that someone, somewhere is approving dietary supplements for safety and efficacy when the sad truth no one, nowhere, is checking these products.

Steiber: But if it’s in the laxative section, many pharmacies just mix the OTC drugs and supplements all together.

Q: As a college student, I was wondering what you think about laxative abuse in terms of weight loss.

Pray: In high school and college that is definitely a concern with sales of stimulant laxatives. In the pharmacy where I’ve worked part-time for 23 years, we placed Dulcolax behind the counter because we had young ladies abusing it as part of the anorexia/bulimia syndrome. That forced them to ask the pharmacist for the product, allowing us to see if it’s an extremely thin young lady attempting the purchase, or if it is repeated purchases. If so, we could refuse the sale.

Sender: And I think it’s probably an underappreciated problem, it’s not talked about.

Steiber: Are there any other questions?

Q: What would be a way in which you would want to disengage your patients who are using stimulants to get them to a safer form of bowel normalization to treat chronic constipation?

Sweeney: These patients first must be evaluated for obstructing mechanical lesions such as neoplasms or inflammatory strictures. Also, chronic medical conditions such as hypothyroidism need to be screened for. After proper evaluation has been complete, then disengagement can begin.

Sender: I think that's a very good question. I think when we've done the documentation, we've done the colonoscopy, and we see that they've used laxatives (and we can tell that by the way the colon looks), I know we're in for a problem because that patient is not going to go to the bathroom without taking a laxative. I can tell him to take all the fiber, take Konsyl 3 times a day, gradually build up, etc., but they're still going to have a problem. I usually tell them that. I tell them, "You're going to get worse before getting better." But as you know, I'm not at home with them. I can't really tell if they're not taking their laxatives. So that's why I was happy to see the SennaPrompt come onto the market. I use that now as a bridge between their laxative and the Konsyl that I want them to use. But what that will do, if they take it as directed, is give them some stimulant relief and at the same time transition them into the natural fiber that I want them to be taking. I see that after a period of time, I repeat that exam and that colonoscopy they no longer have the melanosis, so I know it's working.

Q: That black colon you referred to, is that a function of the stimulant laxative?

Sender: Actually the stimulants can contain an anthracin dye. And it will actually stain the mucosa. It's a colored pigment that is deposited in the mucosa and when this happens it actually denatures the lining of the colon and damages the smooth muscle fibers, and the nerves themselves do not promote peristalsis at this point. This is caused by the laxative so it's actually damaging the lining of the colon.

Q: If they do eventually stop the use of stimulant laxatives, over a period of time does that lining reestablish itself?

Sender: Yes it does. There's a cellular turnover in which the healthy cells will replace the diseased ones, and if they're not using the stimulant, it won't deposit in the cell. Now I'm not sure where in the cell that it actually deposits, but probably in the organelles.

Q: Can you see that all the way through the colon or is it just in the hemispheres?

Sender: You can't see it all the way through; it's usually predominantly right-sided colon and the secum is the most stained area. It progressively lessens toward the rectum but you can see rectal involvement as well. Generally there's a trend from the proximal to distal colon.

Pray: When I was writing the first edition of my textbook, the problem was referred to as pseudomelanosis coli. It was thought to be simply a marker of stimulant abuse, but FDA has now recognized it as a well-known marker of carcinogenicity increasing the risk by a factor of three! That caused the FDA to prohibit phenolphthalein, casanthranol, cascara sagrada, and aloe. Senna has not yet been cleared. Castor oil may also carry the risk of carcinogenicity, although bisacodyl has been cleared for now.

Steiber: How often is it very successful to just say "I want to get you off the stimulants and put you on fiber"? Are most patients likely to say, "I'll go find another doctor that will keep me on them"?

Pray: The graded withdrawal method of treating addictions such as laxative dependence has a well-accepted predecessor in smoking cessation. There are smoking cessation products that bridge the nicotine addict from smoking to non-smoking through the use of patches, gum or lozenges. All temporarily provide a blood nicotine level to remove the behaviors associated with smoking. We all know it's difficult to quit any addiction "cold turkey" so it seems as though a product such as SennaPrompt may bridge patients from laxative dependence much the way

smoking cessation products do. As Dr. Sweeney said, if you simply say “No More”, many patients will continue the abuse. My patients might go to another pharmacy, or buy the stimulants at a convenience store because I haven’t told them what they want to hear. Therefore, graded withdrawal seems to me a more valid concept for halting stimulant dependence for these folks.

Q: Dr. Pray, why do you feel that fiber-bulky diets are so much safer than stimulants?

Pray: I’ve been preaching fiber for decades now. I started teaching OTC products in 1976. Fiber supplementation made sense then and it makes more sense now because we’ve collected so much more data. Fiber has always seemed to me to be the answer. First, it’s not carcinogenic, in sharp contrast to the stimulants, further, there are serious physiological problems with mineral oil, but with fiber products we have a high margin of safety. They don’t force an unnatural bowel movement as other laxatives do. Fiber is the closest thing to our natural physiology. You eat three times a day; if you take a fiber supplement 3 times a day, it’s the substitute for the fiber we’re not getting. It’s the closest to getting back to what we should be eating all along. Also, while some people call them fiber laxatives, they don’t really product a laxation. Instead, fiber supplementation gives patients a normalcy of bowel movements. There’s so much going for them and so little against them that it seems to be the natural category to recommend.

Sweeney: Regarding the physiology of the colon and rectum, transit through the lumen is facilitated by bulkier stools. I’m convinced that diverticular disease and a lot of anorectal problems can be prevented with a regular fiber supplement or high-fiber diet.

Sender: The less the colon has to work, the less pressure it needs to pass a bowel movement, the less forceful the peristalsis, the better it is for the colon. In fact, that’s probably what causes diverticulosis - the extreme pressures used in these low fiber, low roughage diets. I think that bulking agents do help. Certainly with hemorrhoids and any pressure effect like diverticula, I’ve seen colons that look like Swiss cheese. Although the bulking agents won’t heal the diverticula that you’ve already got, they will prevent a worsening of the condition so that you won’t develop more diverticulosis. So you sort of keep what you’ve got, and in some cases that’s a good thing because any worsening and you’ll end up needing surgery or having a bleed or some problem like that.

Sweeney: Using the term “laxative” for fiber products I feel is misleading. I call them “bowel normalizers” instead of laxatives. I know they have to be categorized as something, but I think that “laxative” is actually a misinterpretation of what the products actually are.

B: From a manufacturer’s standpoint, we have called our product a bowel normalizer or a bulking agent for years and years, and finally our friends at the FDA said, “No, this has to fit into a category. You can call it a bulk laxative, but you can’t call it a bowel normalizer.” I fought this and we held out as long as we could. There was a study done at Baylor in Dallas in which they took healthy patients, induced diarrhea in them with phenolphthalein and then said, “Let’s see what agents help to normalize the stool the best.” They used wheat bran, calcium polycarbophil, and psyllium. The first two did not work, did not do anything. The psyllium did work, so they went on to study 3 grams versus 6 grams. With the additional grams, the viscosity of the stool got more and better formed. In effect, it can work for both constipation and for nonspecific diarrhea.

Q: One thing that we don’t discuss with patients is the fermentation. When I educate patients on a high-carb diet, I tell them how it is very helpful that the bacteria ferments and creates a product that is the ideal food for the colon. It is a symbiotic relationship in keeping your colon healthy by providing fiber. I also use the analogy of a thermos: fiber keeps hard stool soft and soft stool a little more firm. I think the fermentation will have healthful benefits in terms of short-term; they don’t appreciate that as much.

Steiber: Thank you. We emphasize that quite a bit especially in view of some television ads that started out that way by saying that X product did not cause fermentation. That’s the first time I

saw the ad and I said, "They don't understand what it should be doing." Then they just changed it to say that it mixed easier. Since then, you have this issue where people do not having enough fiber in their diet. How do you go about getting them to do that? Peter.

Sender: We have a high-fiber diet that we suggest, and I tell patients that these are the things that we'd like you to take, and you can pick and choose what you like. There's going to be something in there that's going to agree with them. I don't force this on them, but I say, "Pick something out of these categories that you like and go with that. And in addition I want you to take a fiber supplement." It's always a combination of the two. Your point about the government telling us that these are laxatives is a problem. It puts me in a bind, so I usually say that I want the patient to avoid laxatives and take a bulking agent instead. This is the way that I promote it in my office so that they'll get both the high-fiber diet and the fiber supplement.

Sweeney: I tell my patients, "I know that you get up in the morning, have your Starbucks coffee, and go down to the gas station and get a sausage and cheese biscuit, because I do too. I try to eat a diet high in fiber, but first thing in the morning I have 6 grams of psyllium fiber as a kick-start. If you can get 25-30 grams of fiber into your diet in what you eat, then by all means do that." But most people are probably more like me. I try to be practical and say, "Just take the supplement first thing in the morning and work on your diet the rest of the day." I usually show my patients all the different samples of fiber supplements and tell them what they'll get for each sample. I tell them that this is what I do everyday.

Pray: I mention to patients that they should be eating a proper diet, but many of my patients have not seen a physician so I try to tell them that if they can't do it by diet here are some fiber supplements, psyllium is probably one you'll want to choose, you can take it three times a day. See what that does for you after a couple of weeks and we just hope that they will try that.

B: When you say that often the people you are counseling are not seeing doctors that you're aware of - how often when Brian and Peter say, "I want you to take a bulking agent" do they want to come to you to get a different answer?

Pray: Quite often I'll ask them if a physician recommended a particular bulking agent, but most of the time that's not the case and I realize I'm on my own as a pharmacist. Then I try to refer them into the physician when necessary, but that's still very difficult because so many of these people want to avoid the physician. As pharmacists, we often tell patients they should not avoid the physician, but should make an appointment instead.

Q: Dr. Pray has referenced a textbook, one that is probably the Bible of OTC drugs – nonprescription products - and if you want to know anything about nonprescription products that textbook explains it all in a very, very good, orderly fashion. Everyone is deeply indebted to you for that. Which class of bulking agents do you believe offer the most benefit and why?

Pray: The FDA has approved several bulking agents, but some have significant drawbacks to their use. One is malt soup extract, although I've seldom seen that in pharmacies. I had to special order it to show it to my students. The liquid is thick, odorous and expensive so it's not a viable option. I'm not sure the powder and tablets are much better, but all dosage forms of malt soup extract lack cardioprotection as none can lower cholesterol. Polycarbophil and methylcellulose also lack cardioprotective effects. But that leaves psyllium, the only bulking agent that's proven to be a stool normalizer but also has a cardioprotective effect through lowering cholesterol. Bran also does that, but bran is not available as a supplement for stool normalizing. So psyllium is the only widely available bulking agent has a two-pronged health effect. To me that's a natural. Why would I want to recommend a bulking agent that gives the patient only one health benefit when I can recommend a supplement that gives you two benefits? Psyllium is the leader to me as far as stool normalization.

Steiber: I was at a conference down in New Orleans recently and they had some slides where they were there and hadn't been resolved. The other thing is, and again this is where TV gets into it, is when Fibercon does their ad on the nightly news they show the picture of Metamucil and it's thick and gunky. Then they show the two little Fibercon caplets. Going back and forth between the two gives the inference that the two caplets equal the dose of Metamucil, which obviously is not the case.

Sweeney: I show them how much Fibercon they'd need to take as an equivalent dose of psyllium. 500mg seems like a lot of fiber, but I point out that this is ½ gram.

Pray: I agree that the more bulking agent the better, so I go with the 6 gram formulation product such as Konsyl rather than the 3.4 grams product or solid dosage forms which are much less. If a patient wishes going to take tablets, he'll have to take 12 a day to equal one scoop of a product like Konsyl.

Steiber: We touched on this a little bit - in addition to the relief of constipation, what are some other conditions that you might not necessarily think of where the psyllium, as a natural fiber, can help a patient? You mentioned a cardiovascular effect.

Sweeney: It's a bulking agent, so you can suggest using psyllium for frequent loose stools.

B: With IBS, obviously if it's diarrhea dominant you could certainly use it. But if it's constipation dominant, I know you have some prescription options there.

Pray: We used to have it for diarrhea and then that was taken off the market because it did cause ischemic colitis in patients.

Sweeney: Pruritis ani is a common problem, usually in middle-aged men who drink a lot of coffee and eat spicy foods. It's a debilitating problem for people. My approach is very simple: The problem is seeping after bowel movements and stools that are pasty and hard to clean up after. The need to feel clean is there. I put people on a 6 gram dose of Konsyl, and they come back and say, "You know, I wish someone had told me about this ten years ago when I first had this problem." The result is an easy to pass stool with minimal clean up afterwards. Psyllium is also part of my conservative therapy for hemorrhoidal disease and anal fissures.

Pray: That's known as energy displacement. If you eat fiber instead, you aren't eating as much of the other foods, the high-protein, high-carb foods. Also, when you ingest fiber, it stimulates saliva as well as gastric acid, resulting in stomach distension that makes the patient feel full. Fiber slows the absorption of carbohydrates and fats in the diet. So there's several different ways that fiber helps with dieting. A dose of Konsyl 30 minutes before a meal might help us get rid of the waistline.

Steiber: Let's go on. There's a situation in which we talk about fiber, some of it being soluble, some of it being insoluble. All natural fibers are partially soluble, partially insoluble. Psyllium happens to be much more naturally soluble than it is insoluble, therefore it is hydrophilic and it loves liquid and works as a bulking agent so well. There are other products out there that end up and say that they're soluble but there's been some other things done to them to make them that way.

Pray: Konsyl and other psyllium products such as Metamucil have the advantage in being natural, derived from seed husks which I believe are sourced from India. This natural product has a cardioprotective effect. Citrucel is chemically altered, it's not cardioprotective and it's not natural. Fibercon is calcium polycarbophil, an insoluble rather than soluble fiber. Based on what I've heard here, doesn't always pass through the way it should. Benefiber is guar gum, altered from a natural source. But from what I've read, there's no evidence that it bulks stool and it's not approved by the FDA. It's marketed as a dietary supplement and therefore isn't scrutinized as

closely by the FDA. As a pharmacist I never want to recommend a product like that, that is intentionally trying to avoid FDA scrutiny. So all non-psyllium products have potential problems with use or are not cardioprotective. Psyllium falls out here as the best product for me.

Steiber: I think we've pretty much agreed on that. One thing I will say is that if you're thinking about your health, then that's got to be the obvious conclusion. But we all are creatures of wanting things to be somewhat easy. A gastroenterologist told me many years ago, he said, "Bill, what everybody wants is one pill they can take that will make this problem go away forever." Unfortunately that doesn't exist. So the products like Benefiber and Citrucel, while they aren't natural soluble fibers, they are very easy to mix even though they have lesser amounts of fiber in them, they also are easier to mix and that becomes a deciding factor and leads the physician to say this is what I want you to go out and buy.

Break

Steiber: One issue that is always important, and we kind of touched on it when I said that patients choose products because they're easy to take, is compliance. It doesn't matter how good the medication is, if the patients won't comply then it's not going to do them any good. Do you believe that it is better to give them a specific recommendation, or are you of the school where you give them a bunch of samples and let them choose what to take?

Sweeney: I'm very specific about recommendations: take 6 grams of psyllium powder a day. Konsyl is the brand that I recommend and take personally.

Sender: I recommend Konsyl as well and I give them a sample in the office and say, "mix this with at least 8 ounces of juice or water and drink it down right away." When given to them that way, most patients tolerate it very well. And if they can't, I tell them to try the easy mix formulation.

Steiber: When we see doctors at the various medical meetings, and actually, even if I'm in a pharmacy or drugstore somewhere and somebody's mulling over what to take, I'll talk to them and say, "we have a product that has more fiber. Yes, it appears that it is more expensive because of the price tag and the smaller bottle, but good things come in small packages. And we provide more fiber than almost 180 doses of the other product." I always tell them that when mixing it, we provide a shaker cap and if you'll mix it up, (and we suggest mixing primarily with juice because when you mix it with water, it's not going to be very pretty and if it's not going to have any taste to it) shake it, and drink about half of it down, it's not that bad. And if they want to add a little but more juice halfway and put the top on shake it again, they should go ahead. Because the biggest compliance problem with the psyllium products is that people say they don't like the way it tastes. What they actually mean is that they don't like the way it feels in their mouth. They don't like the gritty beginning and gelatinous end.

Sender: And so the shaker cup makes a big, big difference.

Sweeney: I agree with that. I don't have any data, but I think that the shaker cup increases compliance. I'll have patients come back into the office and say, "Do you have any extras of those shaker cups? We're going on a trip."

Your point about the juice - I always tell my patients, "Juice is a great thing." I use Tropicana Pure Premium No Pulp because if you add in the pulp *and* the grit, it really gets thick. Suggestions like this help with compliance too.

Sender: With all the different juices out there now, you don't have to get tired of taking orange flavor everyday of your life.

Pray: In general, when the pharmacist recommends products, our patients follow our recommendations. I also speak from personal experience when I can add that to my counseling session. I use every tool I can to enhance compliance.

Steiber: I think I have seen some studies, and I might be off on the exact percentage, but I believe that the percentage of non-compliance (now this encompasses everything from just not taking the medication or not being able to get the medication to not taking all the antibiotics for your condition that you're supposed to - all of those are considered non-compliance) is something around 50% of patients. So obviously there is a big interest around compliance because otherwise what you just told them is going out the window. There have also been some studies that I have seen where they have looked at compliance when a specific recommendation is made. They found that the patient is more likely to comply than when you don't tell them exactly what to take. From a doctor's perspective, it's like they feel the patient deserves to have a choice. But I think that having a specific recommendation is probably the most important thing to do if you want compliance.

Another side issue – we were talking before about the caplets and the capsules. What would you say are the advantages and the drawbacks of using those? Peter?

Sender: Well, I really don't recommend caplets because of the number you would have to take, and I'm even going to stick with Konsyl capsules. I tell them that the formulation should be the powder formulation, but if they absolutely can't take the powder formulation - and I tell them to mix it in whatever they prefer also; you can put it in coffee if you want as long as it's 8 oz. - go ahead and take the capsules. However, you'll really have to take a lot of them over the day. Some people, when they hear "12 capsules" they'll say, "I'll bite the bullet and go with this one dose in the morning and just hold my nose to get it down." I also give them a sample, and the sample comes with the shaker and they usually take that and then I tell them go pick up a canister after you get the sample and take that home and you'll have the pre-measured scoop in that to use. But if they just won't do it then I'll go with the psyllium capsules.

Pray: People sometimes say they can't swallow tabs or capsules, so we are locked into a powdered liquid. We also have issues of compliance because of the large numbers of tablets or capsules needed, so I try to discuss that with the patients and let them make up their own minds. Patients will either accept a liquid or a powder or prefer a tablet or a capsule in a solid form. All I can really do in my position is point out the advantages and disadvantages of each and let them make up their own mind.

Steiber: Let's say you have a patient who has been on stimulants for a year. The doctor tells them that we are going to do a transition and we're going to get you on SennaPrompt first, because it has psyllium in it but it also has senna in it. We are going to do this for a short period of time. After that we're going to move to Konsyl, which is a bulk fiber. That's when often times you will hear, "I can't take that powder." What I have heard doctors say is, "Well, you can take this powder once a day for about a quarter a day, or you can take 12 of these capsules a day for about a dollar a day. I don't care which one you do but you'll have to do one or the other, and probably for the rest of your life." That usually will get across to people that this is what they need to do and there are no excuses.

Steiber: Dr. Sweeney, I am going to start with you on this one since you have a doctor among gastro neurologist who is known as "The King of Gas", Dr. Michael Levitt. He doesn't do all the gas studies, but he does a great number of gas studies. Give us your opinion on the common idea that some fiber agents cause gas while others don't.

Sweeney: Patient complaints related to flatus are usually the odor of gas or the quantity of gas. There are two sources of intestinal gas - swallowed air and fermented residue. If you have a fermentable fiber there is going to be a gas byproduct. On the same fiber product, some patients

will have what they describe as a lot of problems with gas, and some patients will have no problems with gas.

Sender: Yeah, patients that take these bulking agents do feel a sensation of bloating and they report that they do have more gas, and it's mostly flatulence rather than irritation with their belching, so they are passing it from below. I have been recommending flaxseed oil capsules in these patients that I suppose acts almost as a surfactant that will bind the bubbles. They seem to get some relief with this, so I have fewer complaints with that than when I tell them, "well if you are going to have this problem, get the flaxseed oil capsules." They are really horse pills. They are big pills. But when the patients take them, they have fewer complaints of "gas".

Pray: I included a chapter in my book on flatulence. The medical literature concludes that a lot of people complaining of flatulence do not have excess flatulence at all. Rather, is the movement of gas through the bowel that causes an unacceptable cramping. So I may tell patients to endure any minor discomfort because the benefits are far greater than this minor problem. The patient can also take simethicone to coalesce the gas bubbles and ease their elimination. I personally find it difficult to say the problem with flatulence would decrease with time because I am not sure bacterial fermentation is less active certain specified period.

Steiber: One thing we have the label of Konsyl is a little section called "easy does it." Here, we suggest that when you first start taking it, when you haven't had a lot of fiber in your regular diet, you should take only half a teaspoon for a week to ten days to let the body get used to it. After that you can move on to the full dose. And I often say to physicians, "It's not any different than if you didn't have much fiber in your diet and then you went out and ate half a pound of broccoli. You would have the same kind of sensation."

We are coming down towards the end of our discussion, and I first of all want to say that I really appreciate everyone's participation. Dr. Pray, would you like to emphasize anything in particular from your article that is going to be published in *US Pharmacists Magazine*?

Pray: As far as fiber goes, most people eat less than half, and probably far less than half, the fiber they should according to all the current recommendations. People should increase fiber ingestion or take a supplement. Supplementation is probably the most realistic thing to do for most patients, but especially those on the Atkins diet. The Atkins diet is notoriously low in fiber and may be unhealthy due to its high-fat content. Again, underscoring the importance of what we are doing today, it is critical to get the correct amount of fiber.

Steiber: Dr. Sender, Dr. Sweeney, would you like to add anything or clarify anything on Dr. Friedman's article that was in the March issue of *Gas Neurology* of 2006?

Sweeney: It is very clear and to the point.

Sender: It really is an excellent article, and I think that one of the take home messages is that not only the people who have chronic constipation or have diarrhea issues should be taking this but even the youngsters, the teens, the pre-teens, of both sexes, should probably be introduced to this. And I am not a pediatric gastro neurologist, so I don't deal with those patients, but I see what happens when they become adults and they don't have the proper balance in their diet. This would go a long way towards helping them achieve that and I think the word should go out.

Steiber: We are trying to do that, and we are now associated with a public relations agency, Gray & Rice in Boston, and the contents of this will also go to them. In addition, we are trying to get it into the pharmacy and medical community. We are going to try to get certain portions of this out to the general public that might not have sees this position; we're trying to make your job a little bit easier. But we are not going to take it to TV or anything like that. I really appreciate your participation today and the efforts that you made to get here.

Pray: I would also like to thank Bill and all their efforts at Konsyl pharmaceuticals because this is an important thing in our lives, and obviously in our patients' lives, and to just step back and look at it is important. I appreciate how you have gone through and looked at all positions, not only from a marketing standpoint, but also from a general standpoint. So again, thank you.

Steiber: Well, we thought it was really important to have a gastroenterologist and rectal surgeon speaking because they don't always agree. Also, I just want to add that this is something I have wanted to do for a long time. To get the medical and pharmacological groups together so that you can see that there certainly is some synergy here and the basic thinking is pretty similar - it just might come out in different ways. So any other questions or quick comments anybody would like to add?

Q: There is a new product out, in which Inulin is the active ingredient - I don't know if you have seen anything on this or not. It hasn't been marketed well, yet it is on the shelves...

Pray: Inulin is known as a functional food. I would like to have it submitted to the FDA as an actual medication. To my knowledge, that has not yet been done. Clinical data may demonstrate efficacy, but the gold standard for efficacy is FDA approval.

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