

## **Prescript-Assist™: *Updated Synopsis of Clinical Experience***

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The purpose of this report is to synopsise our involvement with, and clinical findings, regarding Prescript-Assist™ (Safer-Medical Inc. /SMI), which dates back to the latter part of 2000. The following sections provide: a general background regarding the rationale for our early involvement, clinical observations, and more recent observations during the formal clinical trial (Bittner, Croffut & Stranahan, 2005).

### ***Background***

Prescript-Assist™ had yet to be fully developed in the latter part of 2000. Rather, its “core ingredient” – a broad spectrum of Soil Based Microorganisms (SBOs) identified as *FloraStat*, comprised the entirety of the product. We conducted a six-month evaluation to establish some baseline observations, and found that it performed well against a number of gastric issues; however, there were the initial, and typical clinical matters involved with dosing and related costs. As a proponent of both cost-containment in healthcare and complementary/integrative medicine “when necessary and where applicable”, these were of particular concern as there are many cases where added supplementation/expense is neither necessary, nor applicable. “Probiotics,” in this regard, present a special point of interest, as we had previously tried numerous formularies. Typically, these were in cases where (1) on-going antibiotic therapies present clinical GI issues (as probiotics appear promising for mitigating side effects during treatment) or, (2) subsequently in attempts at correcting longer term issues following antibody treatments (i.e., those deleterious effects upon the GI tract with the introduction of abnormal levels and/or types of micro-flora, e.g., *Candida*). We generally had observed only a modest degree of success with these probiotic products (and this appeared to drop off, sometimes sharply dropping with time on product). Our early involvement with Prescript-Assist™ and its predecessor was toward finding a probiotic that better met our immediate and longer term clinical requirements.

Our role – in the development of Prescript-Assist™ has been “singular”: *To provide clinical evaluations as it evolved through successive formulary additions, modifications and deletions to its constituents, other than the SBOs.* During this period, the evolving formulary has been provided at no/ minimal cost; important, as the greater part of our practice involves Medicare/Medicaid patients; many are in both difficult health and financial straits. Our patients often present with a myriad of gastrointestinal issues, particularly when complicating factors include advancing age, previous medication/substance misuse, or poor dietary habits (later arguably due to low incomes). Predominantly, my patients are women – as our practice involves both the performance of gynecological surgery and delivery/ obstetrical care.

### ***Clinical Observations***

Our evaluations have confirmed that Prescript-Assist™ (P-A) can be effectively employed in the following three areas. These include:

- 1 *Alleviation of antibiotic induced gastritis* (during antibiotic therapy) – 30-count bottle/15 day (BID),
- 2 *GI tract general “reconditioning” (for post-antibiotic and/or simple indeterminate gastritis)* – a 60-count bottle/30 day (BID);
- 3 *IBS and other chronic gastric issues where P-A has been seen to be remarkably effective* – 90-count bottle (1-4 caps/day, where 2 caps BID often provides quicker results).

Clinical evaluations have also pointed toward a much broader applicability than noted above – though results are considered preliminary. These include *Ulcerative Colitis* and *Diverticulosis* where general remissions have typically occurred in 30 days or less (including two, of the several cases, that had persisted for more than 20-years of treatment). *Similar results have been seen with Crohns, IBD, Vaginitis (Yeast), “Leaky Gut Syndrome”, GERD* (GERD observations, it should be noted, are surprising with no directly anticipated mechanism(s)-of-action). Positive side-effects often have included improvements in skin conditions (e.g., acne and more complicated dermatoses), as well as apparent reductions in responses to food borne allergies (not including lactose allergies). P-A, in our experience, certainly is applicable to the three conditions noted above and appears to have considerable, though preliminary, promise for an increasing number of other conditions (e.g., Crohns, IBD etc).

Assessments of the longer-term effectiveness of P-A were made during my clinical evaluations. For these purposes, patients – after varied periods following cessation of symptoms – have been asked to go off P-A (with the length of those periods dependant upon reemergence of symptoms). One of the more remarkable cases involved a female

patient 81years, who had suffered from chronic Diverticulosis for (circa) 20 years (verified by colonoscopy). She presented to our clinic on/ or about March of 2003, whereupon we started her on P-A, 1 cap BID, for 30 days. At a follow-up visit in three months, she remained symptom free. Though she did not want to discontinue P-A (not infrequent among patients in remission from chronic conditions), I asked her to preclude its use, and if she were to become symptomatic, to contact our office; to date, she has not. In some cases (e.g., involving IBS), where symptoms have been alleviated, we have observed their return after varied periods off P-A (e.g., week(s) to months off product). Symptom free periods, it is noteworthy, appear somewhat related to the time on P-A, with longer symptom-free periods off P-A following longer periods on P-A. We have found that P-A 1 cap (BID) will provide symptom-free maintenance for patients for very extended periods (years) – thus P-A appears to maintain its efficacy well beyond that experienced with other probiotics).

We early informed Safer Medical (SMI) that two pharmacies associated with this clinic and the local hospital would be happy to carry FloraStat and later evolutions toward P-A. However, it has been SMI's intent to postpone commercialization until the formulary was fully developed, i.e., ensuring the broadest efficacy per dose at an affordable price. Pursuant to those objectives, we have watched P-A evolve from a very beneficial product, to one that a practitioner will only fully appreciate with experience. The final unique combination of probiotic and prebiotic components has realized its developmental goals. We then recently encouraged SMI to move to formal double-blind trials of its efficacy with an initial focus on IBS, and then with respect to the other conditions where promising results have been observed. (IBD etc as note above).

### ***Double-Blind Clinical Research***

IBS clinical trials were recently completed (Bittner et al., 2005). We were one of three participating physician groups involved with the conduct of the double blind, controlled trial for the Treatment Efficacy of Irritable Bowel Syndrome (IBS). Patients, selected for participation in this study, had to meet stringent IBS Rome II Criteria. This research, it is noteworthy, was not economically sponsored by SMI, other than providing Prescript-Assist™. Researchers, participating physician groups and others involved in the research received neither direct nor indirect compensations for their efforts. Prescript-Assist™ proved remarkably effective in this study as measured by the consistent statistical significances found (Bittner et al., 2005). I will add however, that these statistical results, though profound, do not fully capture the remarkable results seen in individual patients.

The most remarkable case – among patients at our clinic – was of a 52 year old female, with a three-year history of IBS with “uncontrollable diarrhea”. At the time she came to the clinic, her “diarrhea” had persisted (unabated) for three years of medication therapies provided by a succession of three other physicians. As it turned out when the blind was broken, she was enrolled to the trial in the Control (placebo) for the first two-week blinded period. She, not surprisingly, did not experience any relief and was quite concerned. As all patients, she was put on P-A for the second two weeks. Remarkably, she realized her “first solid bowel movement in three years” within 12 hours of initiating the crossover product (P-A). She continued on the crossover for the subsequent two-week period; however, she reduced her dosage and extended the duration of use, stretching the 28 capsules to a period in excess of 30 days, instead of the 14 (having concerns regarding product availability after the second two-weeks). When she contacted the clinic, she was ecstatic to say the very least. She then remained off the product for approximately 60 additional days, at which time the diarrhea began to reemerge (and she called for an appointment). We contacted SMI for product availability and supplied her with a 90 count bottle. She has subsequently remained symptom free, with only intermittent use during the preceding nine month period. Her medical history/ records have been provided to the Principal Investigator/authors, for their use, for possible inclusion in analyses of the results post-crossover, and as part of a long term follow-up of test subjects. This patient’s data – however it might have increased their statistical significance – were not included in the findings presented in the original report (Bittner et al., 2005).<sup>1</sup>

### **Summary**

Prescript-Assist™ (P-A)– a unique probiotic-prebiotic combination – has as its core ingredient a broad spectrum of Soil Based Microorganisms (SBOs). Our practice has been involved in P-A’s development and evaluation since 2000. Our clinical evaluations have confirmed that Prescript-Assist™ (P-A) may be effectively employed in the three areas: (1) *Alleviation of antibiotic induced gastritis* (during antibiotic therapy); (2) *GI tract general “reconditioning” (for post-antibiotic and/or simple indeterminate gastritis)*, and (3) *IBS and other chronic gastric issues where P-A appears to be remarkably effective (e.g., Ulcerative Colitis; Crohns, IBD; Vaginitis (Yeast), “Leaky Gut Syndrome”*. Prescript-Assist™ has been proven to be remarkably effective in a recently published double-blind study of IBS (Bittner et al., 2005).

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<sup>1</sup> This patient was one of two patients dropped from the formal study do to difficulties in contacting them; her breaking protocol – extending P-A availability – also removed her data from the analysis of the open label data (much to the considerable grumbling of the Principal Investigator).

## ***Acknowledgement***

Safer Medical, Inc. (SMI) provided both *FloraStat* and Prescript-Assist™ formulations at no/ minimal cost, to all patients involved in our clinical exploration of efficacy. As of this writing, we are neither: a stockholder in SMI, nor serve as a paid consultant; nor are involved with product commercialization. We are pleased however, to have been a participant in both the initial and more recent clinical trial, and do admit considerable satisfaction when our participating patients thank us.

## **Reference**

Bittner, Croffut

*SMI 001*