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This year, we are proud to be collectively celebrating our 25<sup>th</sup> anniversary: a quarter of a century spent promoting and expanding the ideas, philosophies, and central tenets of personalized and functional medicine.

Throughout this exciting and dynamic event in Hollywood, you will have the opportunity to participate in extensive and interactive discussions, connect with like-minded professionals, and—most importantly—experience and internalize the evidence-based research presented by experts and thought-leaders in preventative medicine. We are proud to offer an event that represents an elite medical education platform: a conference during which multidisciplinary health practitioners are collaboratively redefining and reshaping medicine. It is our hope that you leave this conference armed with new clinical protocols and skills, and the arsenal of tools necessary to immediately and effectively implement them into your practice, while simultaneously improving patient care and maximizing the potential of your practice.

Our medical approach is rooted in cutting-edge science and personalized care, both utilized to prevent and reverse the effects of age-related diseases. We believe that when healthcare practitioners view the patient holistically, and do not solely focus on surface-level symptoms, the benefits are enormous.

As this brand of medicine continues to grow, we hope you will also reaffirm your support of this specialty. Your attendance at this event is all a part of the transformation necessary for the future of medicine, and we applaud you for helping to lead the evolution of healthcare.

With warm regards,



Ronald Klatz,  
MD, DO  
President, A4M

A handwritten signature in black ink, appearing to read 'Ron Klatz'.



Robert Goldman,  
MD, PhD, DO, FAASP  
Chairman, A4M

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2. Name badge must be worn at all times during show hours and official events.
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4. This event is open to healthcare professionals and their invited guests only.
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# SPRING CONGRESS 2017

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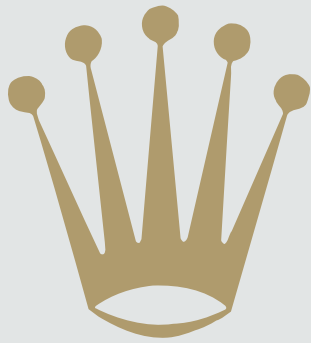
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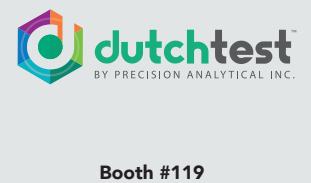
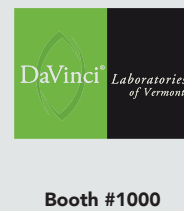
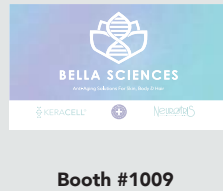
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# A Case Report of a 53-Year-Old Female with Rheumatoid Arthritis and Osteoporosis: Focus on Lab Testing and CAM Therapies

By Kara Fitzgerald, ND

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## ABSTRACT

A 53-year-old female presented with rheumatoid arthritis and osteoporosis. Additional conditions and symptoms included Raynaud syndrome, fatigue, irritable bowel syndrome associated constipation (IBS-C), gastroesophageal reflux (GERD), menopausal symptoms, chronic urinary tract and upper respiratory infections, and weight gain. She was taking Arthrotec 75° (a combination of diclofenac and misoprostol – for pain and inflammation), Fosamax Plus D° (alendronate with vitamin D3 – recently prescribed because of low bone density), and Catapres° (clonidine – for menopausal symptoms). Against the advice of her rheumatologist, she had recently discontinued taking Plaquenil° (hydroxychloroquine), methotrexate, and prednisone, due to significant side effects. Lab tests to identify underlying imbalances and to direct treatment were ordered. Treatment included dietary, nutritional, hormonal, and mind/body support. After one year of therapy, the patient experienced improvement with all of her presenting conditions and symptoms, which enabled her to discontinue several medications. She became versed in identifying and avoiding the environmental triggers of her disease, including foods (dairy, wheat, eggs, and soy), molds, and emotional stress. Antinuclear antibodies were normalized. She experienced a 7.5-percent improvement in left trochanteric bone density – comparable to bisphosphonate therapy. Mild improvements were also noted in the spine and bilateral femoral neck. (Altern Med Rev 2011;16(3):250-262)

Patient Medical History and Initial Visit Findings NV was 53 years old when she presented with a four-year diagnosis of inflammatory arthritis (IA), which had been made by her rheumatologist. She complained of nearly constant swelling, stillness, and pain, with occasional numbness and tingling in her hands, wrists, and elbows. At the visit, she reported her pain using a visual analog scale (VAS) as 8/10 (0 = no pain; 10 = greatest pain) and stated that the morning pain was frequently unbearable, rating it as 9/10-10/10. The pain did not respond well to medication and lasted most of the morning. She had been using diclofenac 75 mg and misoprostol 200 mcg, twice a day for pain for about one year, with minimal relief. Because of the swelling in her fingers, she had been unable to wear her wedding ring for approximately one year. Although she thought she noted a worsening of IA symptoms when she ate dairy products, she continued to consume them.

NV recalled the onset of her arthritic symptoms, about 6.5 years earlier, coincided with the development of mold, which had been found after flooding in her basement. NV did not know what type of mold it was. She and her husband moved from the home two months after the start of her symptoms, and she experienced a full remission immediately after the move. She did not receive medical attention for her complaints at that time. Two years later, after the loss of a close aunt, NV experienced a return of all her arthritic symptoms. She was referred to a rheumatologist who, according to NV, diagnosed her with inflammatory arthritis and prescribed hydroxychloroquine, methotrexate, and prednisone. She did not recall the dosages of the medications. While they did help her arthritis, she was

unable to tolerate the side effects of the medications (reflux, photosensitivity, and alopecia). She discontinued the medications against the advice of her rheumatologist and refused new medications. NV was also taking Arthrotec 75<sup>®</sup> (combination of the non-steroidal anti-inflammatory drug [NSAID] diclofenac with the synthetic prostaglandin misoprostol added to prevent NSAID-induced gastric ulcers), alendronate with D3 (Fosamax Plus D<sup>®</sup> – prescribed– prescribed because of low bone density), and clonidine (Catapres<sup>®</sup> – for menopausal symptoms).

NV reported that laboratory results within the past six months showed a pronounced elevation of antinuclear antibodies (ANA) and erythrocyte sedimentation rate (ESR); rheumatoid factor (RF) was negative. She reported that her ANA had been consistently positive since she was first tested by the rheumatologist, about four and a half years earlier.

NV also reported severe fatigue and rated it at 9/10, (1 = no fatigue, 10 = severe fatigue), with the afternoons being the most difficult time of day. She awoke feeling tired and unrefreshed, a situation that she attributed to IA and insomnia secondary to hot flashes. Although NV took clonidine (0.2 mg qhs) for menopausal hot flashes at night, it was only mildly helpful.

Patient-reported medical history included chronic urinary tract infections (UTIs), Raynaud syndrome in both hands and occasionally in the feet upon exposure to cold

temperatures, a recent diagnosis of osteoporosis, irritable bowel syndrome with severe constipation (IBS-C; 1-2 bowel movements per week), and gastroesophageal reflux disease (GERD). She had gained 30 pounds over the past four years. She had undergone a radical hysterectomy (uterus, ovaries, fallopian tubes, and cervix) due to severe uterine fibroids when she was 32 years old, at which time the hot flashes and insomnia developed. NV had taken multiple antibiotics over the years for UTIs and upper respiratory tract infections.

NV's past family and social history included stressors from caring for ailing parents. Her father, age 86, had type 2 diabetes and had experienced two myocardial infarctions. Her mother had died at age 85. Prior to her death, she had undergone three hip replacements to treat severe osteoporosis. She had had a complete thyroidectomy, but was unable to recall the medical reasons why this procedure was done.

NV had retired from nursing after 20 years. Her primary form of exercise involved training dogs. She was the primary caregiver of her father, who was living in her home. While they were very close, she found the caregiving highly stressful. She had a strong marriage and a number of good, supportive friends.

NV's diet and nutritional history also included multiple stressors. She skipped breakfast, drank black tea daily, and frequently had double cheeseburgers from a fast food restaurant for lunch. Dinner was frequently eaten out, and

most recently had included Mexican chicken with rice, chips, and salsa. NV craved salty and sweet foods and drank diet soda daily.

At first visit, NV was 5'6" tall and weighed 170 lbs. Her body mass index was 27.4. There was marked swelling, warmth, and reported tenderness in her metacarpal phalangeal joints and her proximal interphalangeal joints bilaterally with passive and active range of motion. There was limited digital flexion bilaterally. Her capillary refill rate was normal, with no evidence of digital cyanosis or ulceration. Her wrists and elbows were warm, with mild edema and tenderness to palpation; active

**Table 1. Results of ANA, hs-CRP, RF, and Thyroid Testing**

Test	Initial	6-month Follow-up	1-year Follow-up	Reference Range
Antinuclear Antibodies (ANA)	1:2860 (H)	1:2560 (H)	<1:40	<1:40
hs-CRP	5 (H)	5.6 (H)	N/A	< 1 mg/dL
Rheumatoid Factor	N/A	24 (H)	< 14	<14 IU/mL
Thyroid Stimulating Hormone	1.48	3.45	0.85	0.40-5.50 IU/mL
Free T3	2.5	2.1	2.7	2.0-4.4 pg/mL

H denotes value considered to be high for the indicated test. N/A indicates test not done.

and passive range of motion were within normal limits, but painful with passive and active range of motion. Her neck was supple, with no masses. Her thyroid was of normal size, smooth without masses, and not tender. Her heart demonstrated a regular rate and rhythm, with no murmurs or rubs noted; her lungs were clear to auscultation bilaterally. Blood pressure was 112/72 mm HG.

## LABORATORY TESTS AND FINDINGS

The list below summarizes the lab tests ordered for this patient and the clinical rationale for selecting these tests.

Complete blood count (CBC), comprehensive metabolic panel (CMP) with lipids, and thyroid panel (Table 1): Obtained to rule-out infection, anemia, and thyroid disease, and to check kidney and liver function.

Antinuclear antibodies (Table 1): ANAs are frequently elevated in inflammatory arthritis and indicate level of disease activity. They are useful for tracking treatment efficacy.

High-sensitivity C-reactive protein (hs-CRP)(Table 1): hsCRP is a standard acute phase reactant protein used to monitor general inflammation.

Rheumatoid factor: RF is an autoantibody, most relevant to rheumatoid arthritis.

Deoxypyridinoline (DPD) (Table 2): A marker of bone resorption tracked by a urine test to help monitor treatment efficacy for osteoporosis. Variability in serial testing is reduced by using the same lab and by testing at the same time of day.

Vitamin D (Table 2): Low levels are associated with increased inflammation and with increased incidence of numerous diseases.<sup>1</sup>

Food-Specific IgG4 antibodies (Table 3): Food reactions have been associated with inflammatory arthritis.<sup>2,3</sup> Multiple IgG4 reactions suggest intestinal hyperpermeability, also a factor in inflammatory arthritis. Removing o" ending foods may reduce pain and inflammation.

Multiprofile panel (amino acids) and essential elements (Table 4), essential fatty acids (Table 5), organic acids (Table 6), and oxidative stress markers: Obtained to detect nutrient deficiencies or imbalances that might be contributing to inflammation (only significant findings are discussed below).

Stool test (assessment of GI inflammation, microbiota, and pancreatic exocrine function) (Table 7): GI imbalances have been identified as involved in the pathogenesis of rheumatoid arthritis.<sup>4</sup>

Initial and subsequent findings on all lab tests are noted in the tables below. (Note: Complete blood count, comprehensive metabolic profile [also known as a complete blood chemistry panel], and lipid testing were within normal lab reference ranges and are not presented in Table 1.)

Bone densitometry obtained by DEXA scan (DXA) within the previous two weeks prior to the initial visit demonstrated left trochanter osteoporosis, with a T-score of -2.7 (a score below -2.5 is indicative of osteoporosis by World Health Organization [WHO] standards) (Table 2). As a result, she had been started on alendronate.

**Table 2. Results of Bone DPD, DXA, and Vitamin D Testing**

Test	Initial	6-month Follow-up	1-year Follow-up	Reference Range
Deoxypyridinoline (DPD)	4.9	7.7 (H)	5.7	≤ 7.4 nm/millimole creatinine
DXA T score (left trochanter)	-2.7	N/A	-2.5	+1 to -1 normal; -1 to -2.5 osteopenia; < -2.5 osteoporosis
25-Hydroxyvitamin D	27	N/A	N/A	10-64 ng/mL

H denotes value considered to be high for the indicated test. N/A indicates test not done.

## INITIAL DIAGNOSIS

Although NV stated she had previously been diagnosed by her rheumatologist as having inflammatory arthritis, her clinical presentation strongly suggested rheumatoid arthritis (RA) as defined by 2010 American College of Rheumatology/European League Against Rheumatism (ACR-EULAR)

collaborative initiative classification criteria.<sup>5</sup> These findings include involvement of greater than 10 joints (including at least one small joint), abnormal CRP, and greater than six weeks symptom duration.

NV's presentation also fit the older American Rheumatism Association diagnosis of RA, including morning stiffness lasting at least one hour, arthritis of three or more joint areas, hand joint involvement, and symmetrical distribution.

Anti-cyclic citrullinated peptide antibody (anti-CCP), a relatively new blood test used to help confirm a diagnosis of rheumatoid arthritis, was not conducted because, at the time patient first presented (2006), anti-CCP was not widely available. In 2010, anti-CCP testing was made a substantial part of the 2010 ACR-EULAR classification criteria for RA.<sup>5</sup>

Other potential issues revealed during initial testing or self-reported by the patient during intake included: osteoporosis (verified by DXA scan), Raynaud syndrome (patient self-reported), fatigue (patient self-reported), IBS-C (patient self-reported), GERD (patient self-reported), menopausal symptoms (patient self-reported), chronic UTIs (patient self-reported), several food sensitivities (verified with food-specific IgG4 antibodies) (Table 3), inflammation (verified with hs-CRP), oxidative stress (verified with testing for oxidative stress markers), and dysbiosis (verified with stool testing).

## INTERVENTION

The initial focus was on reducing gastrointestinal and systemic inflammation and treating nutrient deficiencies identified via laboratory tests (Tables 4-6), and clinical assessment specific to the patient. This was achieved by prescribing a gastrointestinal anti-inflammatory medicinal food (which included antioxidants, vitamins and minerals, hypoallergenic rice protein, glutamine, anti-inflammatory botanicals and active constituents), dietary supplements, and intravenous (IV) nutrients. Omega-3 fatty acids

(EPA and DHA) were given to correct insufficiencies identified on plasma fatty acid testing. Vitamin D was supplemented to increase vitamin D levels to a more desirable range. A proteolytic enzyme compound was given to help reduce the inflammatory proteins associated with RA and because evidence suggests proteolytic enzymes can reduce inflammatory mediators in rheumatic diseases.<sup>6</sup> CoQ10 and L-carnitine were supplemented to correct insufficiencies detected in lab testing. An anti-inflammatory oligoantigenic diet based on food-specific IgG4 antibody findings (Table 3) was prescribed. This diet also emphasized increasing monounsaturated fatty acid intake. Because stool testing (Table 7) identified dysbiosis, a botanical antimicrobial formula was given to reduce the number of opportunistic bacteria. A digestive enzyme formula was used to improve digestion of food and assimilation of nutrients. Selected nutrients – minerals, amino acids, B vitamins, vitamin C, and glutathione – were delivered intravenously (IV) to achieve rapid repletion. Nutrient IVs are suggested to be effective at improving fatigue, which was a chief complaint of the patient.<sup>7</sup>

Protocol for supplementation is listed below; all supplementation was oral unless otherwise indicated.

- Anti-inflammatory medicinal food, 2 scoops every morning
- EPA/DHA concentrate 3,000 mg, 1 tsp/day
- Vitamin D 2,000 IU, 1 drop/day
- Proteolytic enzymes, 3-6 tablets three times daily between meals as needed for pain (includes pancreatin, bromelain, papain, trypsin, chymotrypsin, lipase, rutin)
- CoQ10 100 mg, 1 tab/day
- L-Carnitine 500 mg, 2 tabs/day
- Antimicrobial botanicals, 3 capsules twice daily (includes wormwood, oleuropein, berberine, grapefruit seed extract, thyme, uva ursi extract,

Due to space constraints, this article may be missing tables that support the research. For in depth information and additional research, please visit <https://www.a4mwc.com/wp-content/uploads/2017/02/A-Case-Report.pdf>





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## MODULE II

### **A Metabolic & Functional Approach to Cardiovascular Disease**

The causes, mechanisms, diagnosis, and management of cardiovascular and cardiometabolic diseases including CHD, CHF, hypertension, metabolic syndrome, dyslipidemia, atherosclerosis, and renal disease are covered in this module. Topics include cardiovascular pathophysiology and biology, inflammation, oxidation, hormones, adipokines, stress, nutrition and nutrigenomics, glycemic control, environmental factors and toxicology, infections, and risk factor testing.

## MODULE III

### **A Metabolic & Functional Approach to Neurology**

This module reviews the most recent developments in the field of neurology utilizing a metabolic approach to the prevention, management, and treatment of neurologic diseases. The course will cover pathophysiology and the role of neurotransmitters, inflammatory and degenerative disorders, neurovascular diseases, psychological and psychiatric syndromes, the gut-immune-brain connection, and healthy brain function.

## MODULE IV

### **A Metabolic & Functional Approach to Gastroenterology**

Comprehensive metabolic, functional, and nutritional approaches to gastrointestinal dysfunction and disease are reviewed in this module. Physiology and pathophysiology, GI microbiome and dysbiosis, gut permeability, hormones, diet, inflammatory bowel diseases, celiac disease and gluten sensitivity, the gut-immune-brain connection, irritable bowel syndrome, and other digestive and glandular disorders are highlighted.

## MODULE V

### **A Metabolic & Functional Approach to Nutrition & Exercise**

This module focuses on the role of nutrition and exercise in metabolic medicine with an emphasis on guidelines, protocols, and clinical applications. Nutritional biochemistry, aging, metabolism, diet and nutritional supplements, weight gain, weight loss and maintenance, exercise/sports and activity, nutrigenomics, proteomics, and metabolomics, and cancer risk are discussed.

## MODULE VI

### **A Metabolic & Functional Approach to Toxicology & Detoxification**

This module covers symptoms, disorders and diseases associated with exposures of heavy metals, pesticides, chemicals, drugs, nutrients, the natural environment, and other toxic causes of oxidative stress. This course describes the pathophysiology of toxic exposure, methods to prevent and avoid exposure including nutritional and lifestyle approaches, early detection, lab testing, and treatment protocols. Metabolic, digestive and antioxidative detoxification phases and processes are detailed.

## MODULE VII

### **A Metabolic & Functional Approach to Inflammation & Autoimmune Disease**

This module focuses on inflammatory disorders, autoimmune diseases, allergies, cancer, and the gut-immune-brain connection. Cellular and molecular biology of immunity, the cellular stress response, oxidation, genetic damage, inflammation, etiology of disease including environmental and lifestyle factors, and the risk for cancer development are reviewed. Clinical approaches to patient evaluations, testing, and disease management are provided.

## MODULE VIII (NON-CME)

### **Clinical Practice Protocols**

This review course examines patient case histories with a range of metabolic symptoms, disorders, or diseases that are covered in Modules I-VII. This clinical intensive course provides the tools to prevent, detect, diagnose, treat, and manage a variety of patient conditions that are commonly and uncommonly observed in the clinical setting. The goal is to provide comprehensive metabolic, functional, and nutritional approaches towards disease management that enable the Fellow to practice Metabolic Medicine confidently and effectively.



# A Natural Product Telomerase Activator Lengthens Telomeres in Humans:

## A randomized, double blind and placebo controlled study

By **Laura Salvador, MD**, Anti-aging Group Barcelona, Barcelona, Spain 08017, **Gunasekaran Singaravelu, PhD**, T. A. Sciences Inc., NY 10170, **Calvin B. Harley, PhD**, Independent consultant, Murphys, CA 95247, **Peter Flom, PhD**, Peter Flom Consulting, NY 10024, **Anitha Suram, PhD**, and **Joseph M. Raffaele, MD**, PhysioAge Systems, LLC, NY 10019

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### SUMMARY

TA-65 is a small molecule telomerase activator. The current study summarizes the findings on telomere length changes from a randomized, double blind, placebo controlled study of TA-65 over a one year period. The study was conducted on 117 relatively healthy CMV positive subjects aged 53-87 years old. Subjects taking the low dose of TA-65 (250 units) significantly increased telomere length over the 12 months period ( $530 \pm 180$  bp;  $p=0.005$ ) while subjects in the placebo group significantly lost telomere length ( $290 \pm 100$  bp;  $p=0.01$ ). The high dose of TA-65 (1000 units) showed a trend of improvements in telomere length compared to the placebo group; However the improvements did not reach statistical significance. Telomere length changes in the low dose group were similar for both median and 20th percentile telomere lengths. The findings suggest that TA-65 can lengthen telomeres in a statistically and possibly clinically significant manner.

### INTRODUCTION

TA-65 was discovered as a chemically defined small molecule activator of telomerase in the year 2000.<sup>1,2</sup> Interest in TA-65 as a telomerase activator is largely driven by the potential health benefit of telomere maintenance. This report provides the first evidence from a randomized, double blind, placebo controlled study that dietary supplementation with TA-65 has the ability to lengthen telomeres and potentially improve health outcomes in humans, with no observed safety concerns.

### CYTOMEGALOVIRUS (CMV) INFECTS THE MAJORITY OF THE POPULATION WORLDWIDE ASYMPTOMATICALLY.

Here we investigated whether TA-65 can alleviate telomere attrition in CMV+ subjects, to support our previous observational study finding that TA-65 appears to preferentially lengthen critically short telomeres in CMV+ subjects.<sup>1</sup> The current study is aimed at understanding telomere length changes in CMV+ subjects taking the telomerase activator TA-65 in comparison to the placebo group.

### MATERIALS AND METHODS STUDY DESIGN

This is a randomized, double blind, placebo controlled, parallel group study with three arms. Subjects were randomized to placebo, low dose, or high dose groups using a random number table. The Principle Investigator and subjects were blinded until the completion of the study. Following initial screening (168 subjects), a total of 117 subjects were recruited and 97 subjects completed the study. Forty-five subjects received TA-65: 23 subjects received one TA-65 capsule (250 units) and three placebo capsules; 22 subjects received four TA-65 capsules, each consisting of 250 units of TA-65 (i.e. 1000 units/4 capsules). Fifty-two 52 subjects received four placebo capsules. The study involved 104-day cycles consisting



of 90 days of taking product or placebo, followed by 14 days of abstinence from taking the test materials. The trial was run for a period of one year. The subjects had 6 visits during the study: pre-selection, day 0 (baseline), at 3 months, 6 months, 9 months and 12 months (final visit). The capsules were taken on an empty stomach in the morning.

The study was conducted in Barcelona, Spain. Inclusion criteria were subjects with IgG antibodies positive for CMV, aged between 53 and 87 years old and who were able to sign informed consent. Exclusion criteria were subjects with active carcinoma, a prior history of cancer, severe infectious diseases (Hepatitis C, Hepatitis V, HIV and syphilis), autoimmune diseases, hormonal therapy, prior intake of TA-65, or nutritional supplements enriched with Omega-3. The male to female ratio was 1.25.

## BLOOD COLLECTION

Blood was collected 5 times during the study: at day 0, at 3, 6, 9 and 12 months. Blood was tested for the clinical biomarkers, and an aliquot was used to isolate peripheral blood mononuclear cells (PBMC) for the high-throughput measurement of telomere length by fluorescent in situ hybridization (FISH).

## MEASUREMENT OF TELOMERE LENGTH

Median telomere length in PBMC was measured by Life Length (Spain) using the high throughput (HT) Q-FISH technique. This method is based on a quantitative fluorescence in situ hybridization method modified for cells in interphase.<sup>3</sup>

## CLINICAL LABORATORY ASSAYS

During visits at baseline and at the end of visits at 3, 6, 9 and 12 months after initiation of the test products (placebo or TA-65), vitals were checked and blood was drawn from each subject. Assays for a comprehensive metabolic panel, hematology panel, lipid panel, inflammatory markers and immune cells were carried out at Labco, Spain.

## STATISTICAL ANALYSIS: MULTILEVEL MODEL

Since each person was measured multiple times, the errors from a regression model would not be independent. To deal with this, we used a multilevel model. Because

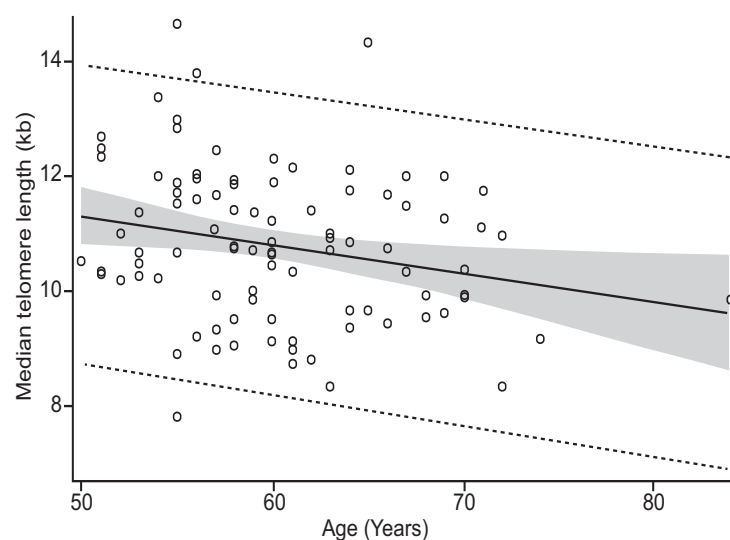
we were interested in nonlinear and possibly non-monotonic relationships between time and median telomere length, we used month as a categorical variable. We included time, group and their interaction in the model. The interaction term is most important, since it indicates whether the effect of time on median telomere length was different in the different groups.

## RESULTS

### Median telomere length: baseline characteristics

We used a linear regression model to analyze cross-sectional data of telomere lengths of all 97 subjects at baseline. Telomere length at baseline ranged from 7 to 15 kilo base pairs (kb) for the subjects aged from 53 to 87 years, and was inversely correlated with age ( $R\text{-Square} = 0.056$ ). The cross sectional rate of decline in telomere length for the baseline population was  $50 \pm 21$  bp/year. Figure 1 shows the distribution of telomere length of the study participants at baseline.

Figure 1



### Average change in the median telomere length for TA-65 group and placebo group

Median telomere length (TL) was measured in placebo group, low dose TA-65 (250 units) group and high dose TA-65 (1000 units) group at baseline, 3 months, 6 months, 9 months and 12 months (see Table 1). At baseline, there were no significant differences in TL among the three groups, although the range of lengths was bigger for the placebo group.

**TABLE 1: AVERAGE OF MEDIAN TELOMERE LENGTHS AT 5 VISITS.**

The average telomere length in Placebo, low dose TA-65 (250 units) and high dose TA-65 (1000 units) groups at baseline and at the end of 3, 6, 9 and 12 months in kilo base pairs (kb) with standard deviation (s.d.).

Group	Average of median telomere length (s.d.) in kb				
	Baseline	3 months	6 months	9 months	12 months
Placebo	11.03 (1.49)	11.00 (1.38)	11.19 (1.28)	10.85 (1.36)	10.74 (1.55)
TA-65 (250 Units)	10.57 (1.12)	10.92 (1.30)	10.89 (1.30)	10.92 (1.23)	10.81 (1.40)
TA-65 (1000 Units)	10.44 (1.04)	10.86 (1.40)	10.59 (1.32)	10.61 (1.11)	10.22 (1.19)

### Change in the median telomere length for TA-65 group vs placebo group: multilevel analysis

The effect of greatest interest was the interaction effect between time and group. The main effect of time tests whether the placebo changed over time, while the main effect of group tests whether the groups were different at baseline. While both must be accounted for, our interest is in whether the three groups behaved differently over time and this is tested by the interaction (Group and Time interaction). It is important to distinguish between the raw data (shown in table 1) and the parameter estimates by the multilevel analysis (shown in table 2).

The telomere lengths at baseline among the three groups were not significantly different as estimated by the group effect (Table 2). In the placebo group, there was a decrease in median TL at 9 and 12 months compared with baseline (Table 2 and Figure 2). At 9 months the decrease was  $170 \pm 90$  bp ( $p = 0.07$ ) and at 12 months the decrease was  $290 \pm 100$  bp ( $p = 0.01$ ).

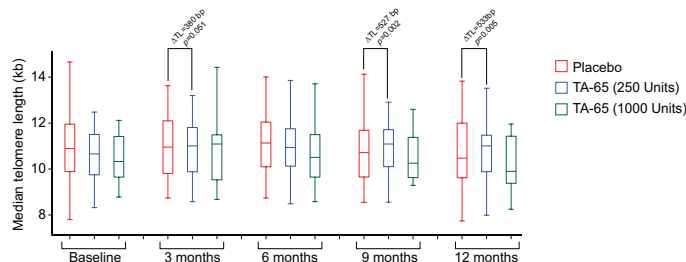
In the low dose TA-65 (250 unit) group, there was an increase in median TL at 3 months followed by relative stability (Table 2). Compared to the placebo group, the effect of time was significantly different in the TA-65 groups. The effect of low dose TA-65 (250 units) on median TL was significantly higher at 9 months (median TL was  $530 \pm 170$  bp longer,  $p = 0.002$ ), and 12 months (again, median TL was  $530 \pm 180$  bp longer,  $p = 0.005$ ) and borderline significantly higher at 3 months (median TL was  $380 \pm 190$  bp longer,  $p = 0.05$ ) but not significant at 6 months (Table 2 and Figure 2).

**TABLE 2: MULTILEVEL MODEL ANALYSIS OF MEDIAN TELOMERE LENGTH CHANGES COMPARED TO BASELINE.**

Placebo, low dose TA-65 (250 units) and high dose TA-65 (1000 units) groups are compared at baseline (0 months), and at the end of 3, 6, 9 and 12 months for median telomere length. The data show change in telomere length in comparison to the reference group(s). Results were adjusted for age and sex.

Effect	Group	Time (months)	Change in TL (kb)	Standard Error	P value
Group effect	Placebo	At baseline	Reference group		
	TA-65 (250 Units)		-0.47	0.32	0.15
	TA-65 (1000 Units)		-0.24	0.33	0.47
Time effect	Placebo	0	Reference group		
		3	-0.02	0.11	0.82
		6	0.16	0.09	0.07
		9	-0.17	0.09	0.07
		12	-0.29	0.10	0.01
Group and time effect	TA-65 (250 Units)	0	Reference group		
		3	0.38	0.19	0.05
		6	0.16	0.16	0.34
		9	0.53	0.17	0.002
		12	0.53	0.18	0.005
	TA-65 (1000 Units)	0	Reference group		
		3	0.25	0.20	0.22
		6	-0.13	0.17	0.46
		9	0.22	0.17	0.20
		12	-0.06	0.19	0.77

**Figure 2**



The high dose TA-65 (1000 units) showed a trend of improvement in telomere length compared to the placebo group, but the improvements did not reach statistical significance. It is not known why in this study the high dose TA-65 (1000 units) group appeared to change in a random manner. This may have resulted from a compliance issue with subjects who took the higher dose.

Change in telomere length of the short telomeres (20th percentile) for TA-65 group and placebo group.

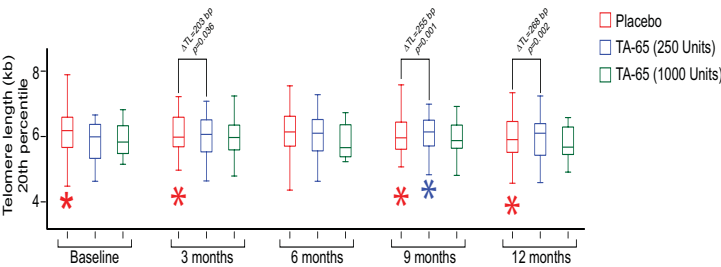
The shortest quintile of telomere lengths (< 20th percentile) were represented in table 3.

In the placebo group, there was a gradual decrease in average shortest quintile telomere length with time, as expected (Table 3). However, telomere length of the 20th percentile in the low dose TA-65 (250 units) group increased at 3 months and was then relatively stable. In the high dose TA-65 (1000 units) group, there was no consistent change in the 20th percentile telomere length (see Table 3).

**TABLE 3: AVERAGE OF 20TH PERCENTILE TELOMERE LENGTHS.** The average 20th percentile telomere length in Placebo, low dose TA-65 (250 units) and high dose TA-65 (1000 units) group at baseline and at the end of 3, 6, 9 and 12 months in kilo base pairs (kb) with standard deviation (s.d.).

Group	Average of 20 <sup>th</sup> percentile telomere length (s.d) in kb				
	Baseline	3 months	6 months	9 months	12 months
Placebo	6.14 (0.71)	6.08 (0.64)	6.17 (0.62)	6.01 (0.66)	5.97 (0.68)
TA-65 (250 units)	5.84 (0.68)	5.98 (0.78)	5.98 (0.81)	5.96 (0.72)	5.93 (0.49)
TA-65 (1000 units)	5.93 (0.49)	6.01 (0.64)	5.83 (0.52)	5.92 (0.52)	5.77 (0.52)

Figure 3



**KEY CHANGES IN THE SAFETY MARKERS**

There were no clinically significant changes in the safety markers during the study as judged by the physician (Joseph M. Raffaele). Immune cell bio markers were unfortunately inappropriately run and hence could not be used.

**DISCUSSION**

We tested a cohort of CMV+ subjects for the effect of TA-65 on telomere length. The telomere lengths were measured using HT Q-FISH with automation to handle large numbers of human samples and to improve consistency. Loss of 290 bp/year in the placebo group is indeed large, but a large loss is to be expected in a group that is 100% CMV positive and consists of older individuals aged >

60yrs. The accelerated attrition is supported by: (1) CMV infection- which causes significant shortening of telomere length in the age group of >60 years<sup>4</sup> and (2) CMV seropositivity increases the oligoclonal expansion of the immune cells with age.<sup>5</sup>

Analysis of the 20th percentile group showed trends similar to that of the overall group, but there was no consistent change in the high dose TA-65 (1000 units) group. The cause of no significant change over time in the high dose TA-65 group is unknown and unexpected. However, there was a trend in the observational studies<sup>1,2</sup> that high doses partially reverse some of the positive effects of TA-65.

The bulk of the evidence suggests that TA-65 lengthens telomeres by increasing telomerase activity. The results from the current study are consistent with the previous observations regarding the lack of any toxicity associated with the intake of TA-65. We did not find any product-related toxicities, as assessed by the biochemical markers of liver, kidney, and metabolic functions.

**ACKNOWLEDGEMENT**

We thank Life Length (Spain) for the measurement of telomere lengths.

**AUTHOR DISCLOSURE STATEMENT**

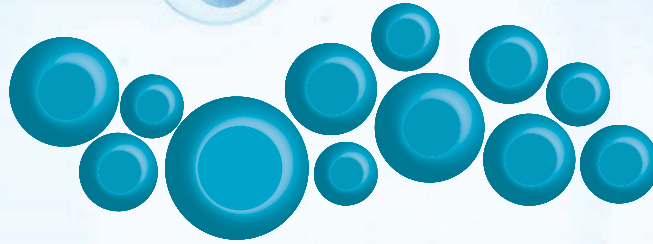
Laura Salvador, clinical investigator of the study, was supported by funding from T.A. Sciences Inc. Gunasekaran Singaravelu and Anitha Suram are employees of T.A. Sciences Inc. Calvin Harley, Peter Flom and Joseph Raffaele consult for TA Sciences Inc. ■

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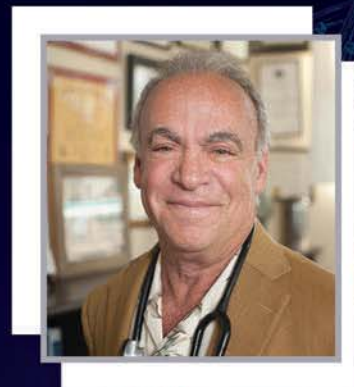


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# IMOs and HMOs, Novel Ingredients with Prebiotic Properties

By Lewis Chang, PhD, Medical Affairs, Metagenics, Inc.

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## OVERVIEW ON PREBIOTICS

The definition of prebiotics has been revised several times in the past 20 years. The most current definition was described in 2010 by the International Scientific Association for Probiotics and Prebiotics (ISAPP) as "...a selectively fermented ingredient that results in specific changes in the composition and/or activity of the gastrointestinal microbiota, thus conferring benefit(s) upon host health."<sup>1</sup>

Simply put, prebiotics are nondigestible substances that function as food for the gut microbiota, and they fuel growth or activity of health-promoting bacteria that live in the gut. In light of recent breakthroughs in technologies and the understanding of diet-microbiome-host interactions, experts have indicated that it is time to revise the 2010 ISAPP definition to make it more clinically relevant. They proposed to define prebiotics as "...a nondigestible compound that, through its metabolism by microorganisms in the gut, modulates composition and/or activity of the gut microbiota, thus conferring a beneficial physiological effect on the host."<sup>2</sup>

Classic prebiotics that have been previously identified include inulin, fructo-oligosaccharides (FOS), oligofructose (OF), transgalacto-oligosaccharides (tGOS), also spelled as galacto-oligosaccharides (GOS), and lactulose.<sup>1</sup> Recent research has identified new compounds that also have prebiotic effects. They include (but are not limited to) isomalto-oligosaccharides (IMOs), polydextrose, soybean oligosaccharides, lactosucrose, glucans, or glucooligosaccharides (GLOS), and xylooligosaccharides (XOS).<sup>1</sup>

## Mechanisms of prebiotics

Prebiotics confer health benefits via various mechanisms of actions:<sup>3,4</sup>

- Modulation of the gut microbiota composition, such as the stimulation of beneficial bifidobacteria and lactobacilli. They help restore a diverse gut microbiota which is important for host health.
- Production of short-chain fatty acids (SCFAs), such as butyrate, propionate and acetate. SCFAs are an energy source, have immunological and metabolic effects, and reduce intestinal pH which inhibits the growth of pathogenic bacteria.

- Anti-adhesive function. Some prebiotics prevent adhesion of pathogenic microbes to intestinal linings by mimicking the binding sites of those microbes.

## OVERVIEW ON ISOMALTO-OLIGOSACCHARIDES (IMOS)

IMOs are a mixture of short-chain carbohydrates (i.e., oligosaccharides) that have digestion-resistant properties. The majority of IMOs consists of 3 to 6 glucose units linked together by digestion-resistant  $\alpha$ 1-6 linkages. IMOs are found in nature, such as honey, but also in various fermented foods such as miso, sake, and soy sauce.<sup>5</sup> IMOs can also be commercially produced from starch (e.g., tapioca) via enzymatic reactions.

## Properties of IMOs

Research has demonstrated that IMOs exert health benefits in humans. The properties of IMOs are summarized below.

PROPERTY	DESCRIPTION OF EVIDENCE
<b>(Partial) resistance to digestion</b>	Unlike starch, which is broken down rapidly in the upper gastrointestinal tract, IMOs resist digestive enzymes and are broken down slowly. <sup>6</sup> Undigested IMOs reach colon where they are fermented by resident microbiota. <sup>7</sup>
<b>Selective bifidogenic effects</b>	In human studies, ingestion of IMOs has been shown to (1) increase the levels of Bifidobacteria, Lactobacilli, and Eubacteria; <sup>8</sup> (2) increase Bifidobacteria numbers in feces; <sup>9</sup> and (3) increase fecal bacteria mass. <sup>10</sup>
<b>Beneficial effects on bowel functions</b>	Ingestion of IMOs has been shown to relieve constipation and increase number of bowel movements. <sup>10,11</sup>
<b>Beneficial effects on serum lipids</b>	Ingestion of IMOs has been shown to lower total cholesterol and triglycerides and increase HDL-C in hemodialysis patients. <sup>11</sup>
<b>Low glycemic index</b>	The glycemic index of IMOs was evaluated at $34.66 \pm 7.65$ . <sup>12</sup>

Well known in Asia (especially Japan) as "functional oligosaccharides" for decades, IMOs are becoming a promising ingredient in the prebiotic market in the Western countries.

## OVERVIEW ON HUMAN MILK OLIGOSACCHARIDES (HMOs)

It was more than 100 years ago when researchers first noticed that breast-fed infants had higher survival rate and better health than bottle-fed infants. Thanks to decades of work and discoveries, we now know that one of the reasons human milk is unique is because it contains high concentrations of oligosaccharides that are scarcely present in bovine milk (and bovine milk-based infant formula). There are 5-15 g/L of oligosaccharides in human milk but only 0.05 g/L in bovine milk.<sup>13</sup>

Structurally, an oligosaccharide is a sugar polymer consisting of a small number of simple carbohydrates linked together. HMOs are a mixture of different kinds of oligosaccharides, and they resist digestive enzymes in the stomach.

### HMOs are more than just prebiotics

HMOs meet the criteria of prebiotics. Once ingested, the great majority (~99%) of HMOs can reach colon and provide a growth advantage for beneficial bacteria such as *Bifidobacterium longum* subsp. *infantis* and *Bifidobacterium bifidum*.<sup>14,15</sup> Historically HMOs were called “bifidus factor.”

HMOs also have other important biological functions that go beyond prebiotics. These biological properties are summarized here:

PROPERTY	DESCRIPTION OF EVIDENCE
<b>Resistance to digestion</b>	HMOs resist digestive enzymes in the stomach and upper small intestine and thus can reach distal small intestine and colon intact. <sup>16,17</sup>
<b>Selective bifidogenic effects</b>	HMOs promote the growth of the beneficial <i>Bifidobacterium longum</i> subsp. <i>infantis</i> and <i>Bifidobacterium bifidum</i> . <sup>14,15</sup>
<b>Production of short-chain fatty acids</b>	<i>Bifidobacteria</i> consume HMOs and produce short-chain fatty acids that create an environment favoring the growth of commensal bacteria over potential pathogens. <sup>18</sup>
<b>Antiadhesive antimicrobials</b>	Serving as decoy receptors, HMOs block pathogens such as <i>Campylobacter jejuni</i> from adhering to host intestinal epithelial cells, thereby reducing risks of infections and diarrhea. <sup>19,20</sup>
<b>Modulators of intestinal epithelial cell responses</b>	HMOs affect certain gene expressions in epithelial cells. The reprogramming modulates the cell surface, resulting in reduced binding of pathogenic bacteria to epithelial cells. <sup>21</sup>
<b>Immune modulators</b>	HMOs affect lymphocyte maturation resulting in a more balanced Th1/Th2-cytokine production. <sup>22</sup> HMOs also reduce leukocyte rolling and adhesion to endothelial cells and leukocyte activation. <sup>23,24</sup>

## Regarding 2'-fucosyllactose (2'-FL)

More than 100 types of oligosaccharides have been identified in human milk, and the most abundant type is 2'-FL. Researchers have confirmed that 2'-FL alone possesses the biological properties summarized in the table above. That is, 2'-FL functions as a prebiotic utilized by the beneficial bifidobacteria in the gut, preventing pathogenic microorganisms from sticking to host intestinal epithelial cells (which increases the risk of infection and diarrhea), and influencing host immune responses.<sup>13,25</sup> 2'-FL can now be produced for commercial use via a fermentation process.

A recent double-blind, randomized controlled trial demonstrated that consumption of 2'-FL for 2 weeks is sufficient to beneficially modulate the microbiota in adults.<sup>26</sup> Another randomized controlled trial found that infants given formula supplemented with 2'-FL exhibited lower levels of inflammatory cytokine profiles, similar to those of breast-fed infants.<sup>27</sup> Other health benefits of 2'-FL in humans require additional ongoing research and will take some time, but experimental research using animal models have shown that 2'-FL quenches *Campylobacter jejuni*-induced inflammation, attenuates the severity of necrotizing enterocolitis, and improves cognitive abilities in both young and adult animals.<sup>28-31</sup>

## SUMMARY

Conflicting information regarding prebiotics found on the Internet likely has caused a lot of confusion even among health-conscious consumers. In a recent scientific survey of adult patients at two urban medical centers, researchers found that 38% of those patients were consuming some forms of prebiotics, but only 7% of them could correctly define the meaning of prebiotics from a list of answers.<sup>32</sup> It is hoped that this overview brings some clarity on prebiotics, and also provides recent clinical evidence for supporting the use of novel ingredients including IMOs and HMOs in food products. ■



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# SERMORELIN & ASSOCIATED PEPTIDES:

## Restoring Growth Hormone in Aging

By Anthony J. Campbell, PharmD

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### INTRODUCTION

There are few things in life as relentless as aging. It is an inescapable part of life; ever pursuing us from the moment we draw our first breath to the day we breathe our last. Patiently, aging slowly chips away at one's youthful vigor and vitality, gradually deteriorating things such as lean body mass, bone density, aerobic exercise capacity, and cognitive function to name a few. Because of the aggressive and unprovoked assault on human longevity, aging may be categorized by some as an adversary; a disease necessitating eradication. Truthfully, however, aging is as normal a life process as is breathing and while it does take its toll and demands its dues over time, aging should not be viewed as an ailment in need of a cure. Yet, due to increased frailty and because many of the traditional signs of aging appear to mirror the features associated with the distinct clinical entity of Adult Growth Hormone Deficiency (AGHD), providing growth hormone (GH) directly to individuals as they age would appear to be the most direct and obvious route to restoring declining levels of GH. However, due to the wide array of potential side effects in older adults (i.e. edema, arthralgia, elevated blood glucose, etc.) it is typically undesired and many times contraindicated. Moreover, while initiating therapy at lower doses may decrease the likelihood of developing these common side effects, its use for anti-aging purposes (outside of controlled clinical research studies) is currently prohibited by US Federal law, 21 U.S.C. §333(e). Nevertheless, with the discovery and implementation of GH secretagogues in aged individuals – (i.e. Growth Hormone Releasing Hormone [GHRH], Growth Hormone Releasing Peptides [GHRP], and similar mimetics – the signs and symptoms of aging have recently become vulnerable to an alternative method of having their deleterious effects on the body decreased and slowed in rate of appearance.

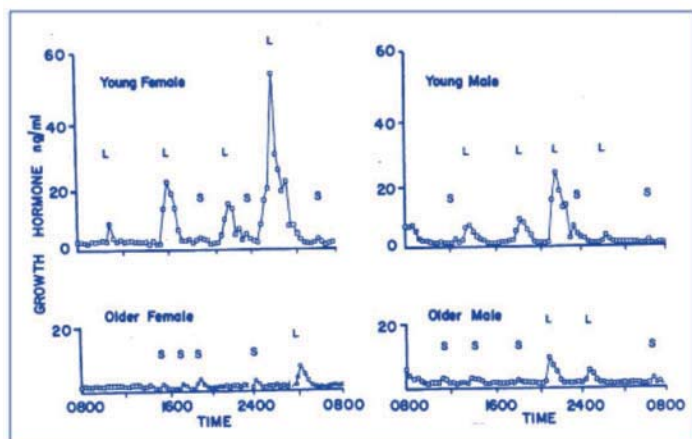
### GROWTH HORMONE SECRETION AND REGULATION

A substantial number of studies and published literature indicate that while there is an exponential decline in GH secretion after puberty, there is a progressive and nearly linear rate of decline of GH secretion after the third decade of life in otherwise normal, healthy adults. In clinical literature, Melmed reports that GH secretion typically peaks at puberty at about 150µg/kg/day, then gradually and relentlessly decreases to approximately 25µg/kg/day by the age of 55.<sup>1</sup> Of particular interest is the fact that while the amplitude, or strength, of recurring GH pulses throughout the day are significantly reduced in older individuals, the frequency, or number of pulses, remain nearly unchanged; moreover, the nocturnal pulsatile release of GH secretion is most significantly reduced in an aged individual (Figure 1). It has been reported in the literature that there are as many as 10 pulses of GH secretion per day, each lasting approximately 90 minutes with a separation of about 2 hours with the highest secretory activity occurring within an hour after the onset of deep sleep.<sup>2(p.122-123)</sup> Due to this physiologic occurrence, many protocols utilizing GHRH and/or GHRP therapy call for a once-daily dose provided prior to bedtime. The release of GH subsequently stimulates the production of insulin-like growth factor-1 (IGF-1), which in addition to mediating many of GH's positive effects, happens to be a potent inhibitor in the negative feed-back loop of growth hormone releasing hormone (GHRH) and GH secretion. Therefore, because IGF-1 production is primarily regulated by GH, the consequence is a decrease in GH secretion via this negative feed-back loop (Figure 2). Perhaps for this reason, many clinicians find that treated patients will initially see IGF-1 levels surge, only to plateau or decrease with continued, uninterrupted use. This will be discussed a bit later as well as potential modalities to prevent this phenomenon from occurring or at least limit the severity of inhibition. In addition to IGF-1, there are three hypothalamic factors regulating GH secretion: (i) Somatostatin, a non-competitive inhibitor of GH secretion; (ii) GHRH, the principal stimulator for GH production/release; and (iii) Ghrelin, secreted by the stomach, an endogenous ligand to the GH secretagogue re-

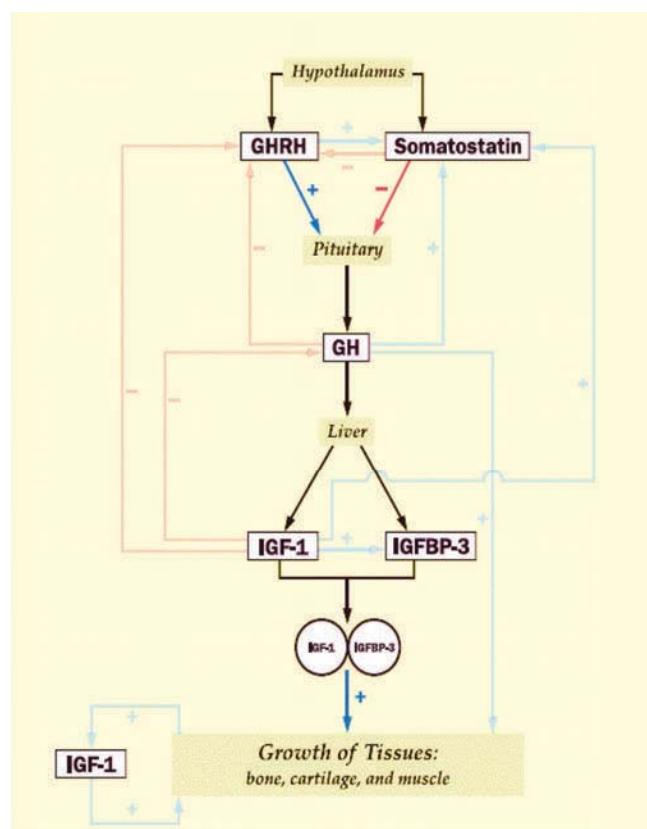
ceptor.<sup>2</sup>(p.122) Intertwined with one another and combined with other peripheral factors (e.g. exercise, sleep, food intake, stress, and body composition), all of these elements are involved in an intricate symphony regulating the physiologic patterns of pulsatile GH secretion.

## GROWTH HORMONE BENEFITS AND THE ASSOCIATED RELATIVE RISK

It is true that a number of clinical trials have reported that by providing GH to adults with GHD, many of the features often associated with AGHD are significantly reversed or improved. Fat mass/volume is decreased, reductions in abdominal fat are obtained, and while there is little change in overall body weight, increases in lean body mass and skeletal muscle volume are observed signifying a shift away from fat to lean body mass. Additionally, there is no denying the thousands of published papers indicating better exercise capacity and cardiovascular function, improved bone mineral density, and enhanced quality of life in adults with GHD treated with GH. In spite of these advantageous findings, there remains an equal number of potential risks that have been described associated with the use of GH. In experimental trials,  $\approx 40\%$  of users reported clinical edema,  $\approx 20\%$  develop joint swelling and myalgia, and  $\approx 10\%$  develop carpal tunnel syndrome.<sup>3</sup> Additionally, many report hyperglycemia, hypertension, glucose intolerance and hyperinsulinemia.<sup>4</sup> Interestingly, a number of these adverse events can be attributed to incorrect dosing, in that they were much too high. In other words, they were the result of over-dosing and over-exposure to physiologic levels of GH. This is where the use of GHRH and other associated peptides have come to be advantageous as their mechanism of increasing GH preclude the potential for over-exposure or tachyphylaxis.



**Figure 1** Patterns of GH secretion in younger & older women and men. There is a marked age-related decline in GH secretion in both sexes and a loss of nighttime enhancement of GH secretion seen during deep sleep. This decrease is primarily due to a reduction in GH pulse amplitude, with little change in pulse frequency. L=large pulse, S=small pulse. [From Ho et al 1987]<sup>12</sup>



**Figure 2** Regulation of the GH/IGF-1 axis. Pituitary inhibition of GH secretion results from an increase in Somatostatin as well as decreased GHRH stimulation, both of which result from increased levels of circulating IGF-1. [Mayo Communiqué March 2006]<sup>13</sup>

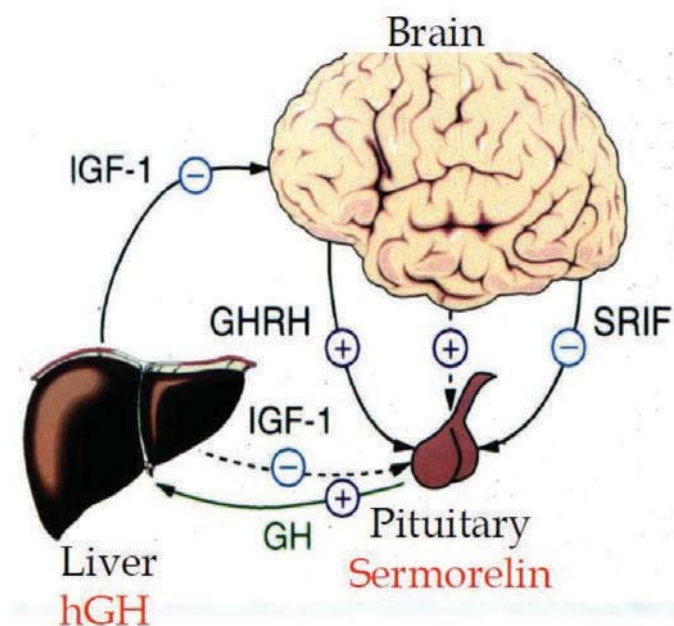
## GHRH: A BETTER METHOD OF INCREASING GROWTH HORMONE

### Physiologic and Clinical Advantages of GHRH

Rather than introducing exogenous and supraphysiologic doses of GH directly to the liver, GH secretagogues like GHRH (i.e. Sermorelin and others) stimulate the normal and physiologic secretion of GH in an intact and responsive pituitary (Figure 3). This normal and physiologic secretion results in a normal, time-separated, pulsatile release of GH, rather than prolonged elevation of exogenous exposure; thereby avoiding tachyphylaxis and preserving the capability for negative feed-back inhibition of GH by the rising levels of IGF-1.<sup>2</sup>(p.127) It is because of this normal, negative feed-back regulation that treatment with GHRH results in much less frequent and milder side effects as compared to those experienced strictly with GH use. The most frequent side effects associated with GHRH (e.g. Sermorelin) use in clinical trials were reported to be localized injection site reactions such as pain, swelling, or redness; occurring in approximately 16% of users. Other events such as headache, flushing, dysphagia, dizziness, hyperactivity, somnolence, and urticaria were reported in less than 1%.<sup>5</sup>

### SUGGESTED DOSING OF GHRH

In the complete sequence, hGHRH is a 44-amino acid chain. However, it is recognized that biological activity is induced solely utilizing only the first 29 amino acid sequence. It is this sequence, specifically GHRH(1-29)NH<sub>2</sub> or Sermorelin, that received FDA approval (e.g., Geref®, Serono) in October 1997 for the treatment of GHD in children. Oddly enough, it was subsequently withdrawn from the market in November 2002 due to the limited demand for the product, most likely due to the limited efficacy Sermorelin has in elevating GH in children (i.e. GHD deficient children require much higher levels of GH than what can be achieved by stimulating their own, already deficient production). In the normal aging adult, however, pituitary stimulation of GH production by Sermorelin has been demonstrated to clinically elevate GH and subsequent IGF-1 levels to at least the lower portion of the young adult normal range and by as much as 35%.<sup>2</sup>(p.127)



**Figure 3** Sermorelin activity is upon the pituitary, stimulating the production of GH under negative feed-back control. Exogenously provided hGH acts directly upon the liver and GH is increased outside of the feed-back control mechanism resulting in prolonged, supraphysiologic GH exposure.

Dosing protocols in clinical literature widely vary and, as such, an established, standardized dose effective for everyone has not been determined. Nevertheless, early clinical studies performed by Corpas and colleagues used twice daily subcutaneous GHRH doses of both 500mcg and 1000mcg which resulted in significant increases in GH peak amplitude ( $P < 0.05$ ), but also in mean 24-hour GH and IGF-1 ( $P < 0.001$  and  $0.005$ , respectively).<sup>6</sup> Likewise, later additional

studies performed by Vittone, et al utilized nightly subcutaneous GHRH doses of 2000mcg resulting in significantly increased nocturnal GH peak amplitude.

Furthermore, 33% of participants showed improved measurements of muscle strength and endurance ( $P < 0.04$ ).<sup>7</sup> Of particular interest, no significant adverse events were reported in either study. This is of importance because many of the currently employed dosing protocols utilize daily subcutaneous GHRH doses of  $\leq 300$ mcg giving practitioners and patients alike at least some semblance of certainty that the risk of experiencing an adverse event is quite low. As promising as many of the published clinical findings report the use of GHRH to be, there still remains some uncertainty as to the frequency of dosing. Due to either small sample sizes, short trial duration and/or variances in doses, it is still clinically unknown whether GHRH can be equally effective when administered once daily as opposed to daily divided doses. To date, however, nearly all studies involving the use of once-daily, evening subcutaneous injections of GHRH(1-29)NH<sub>2</sub> have proven to be well-tolerated, increasing 24-hour GH secretion, boosting circulating levels of IGF-1, and improve body composition in older patients.

Currently, typical dosing protocols for younger patients, in their 40's and early 50's, with good body composition have utilized single daily doses of 100 – 300mcg via subcutaneous injection administered one-hour prior to bedtime. This regimen very often results in sustaining youthful characteristics, health, and vitality without the use of additional hGH supplementation. In patients with excessive abdominal fat due to inactivity and increased weight gain (e.g. BMI > 30), a slightly different protocol may be considered. For example: 1-2u of hGH administered each morning for approximately 3 to 6 months until the patient's body composition has improved, followed by nightly injections of 200mcg to 300mcg of Sermorelin one hour prior to bedtime. This should provide the maintenance dose to sustain pituitary functional cells and increase hGH reserve and secretory volume. Although tachyphylaxis and IGF-1 mediated inhibition of GH is unlikely, one caveat to consider when evaluating a patient's declining response to daily GHRH therapy is the insertion of a short "drug-holiday" in the dosing protocol. Consider the provision of a 21/7 or 5/2 protocol (i.e. 21-consecutive days, followed by 7-days of rest or alternatively, a regimen of 5-consecutive days with 2-days off). This may be quite useful in order to maintain the continued benefits with chronic therapy, particularly in patients who have shown significant improvements initially only to find that later they begin to exhibit a plateau or declining effect of circulating IGF-1 levels.



## THE ESTROGEN FACTOR AND ORAL DOSING

Doses for females on oral estrogen replacement therapy (ERT) will likely require dosage adjustments (i.e. increased) to see a clinical improvement in IGF-1 as it has been reported in the literature that estrogen has a blunting effect of hGH upon the liver to produce IGF-1.<sup>8,9</sup> Curiously, this blunting effect is only associated with oral estrogen therapy, and is not seen in women using transdermal ERT. Therefore, in order to elicit clinically effective outcomes, women should be transitioned and stabilized from oral to topical ERT prior to initiating daily GHRH therapy. Lastly, there is an alternative for patients averse to daily injections. Due to the smaller molecular nature of GH secretagogues, at least one of them has been clinically shown that it can be administered orally and elderly patients can still benefit from increases in pulsatile GH secretion and IGF-1.<sup>10,11</sup> These results provide speculative hope that other GH secretagogues may also be equally effective via alternative routes such as sublingual, transdermal, or nasal delivery.

## GHRP: ELICITING ENHANCED OUTCOMES THROUGH DRUG-DRUG SYNERGISM

### Growth Hormone Releasing Peptides

Concurrent administration of GHRH and GHRP has been well documented and established to provide synergistic release of GH from the pituitary. While there are a number of GHRPs that have been researched and/or studied, the two that have garnered much attention and clinical use are GHRP2 and GHRP6. Others that have been used are Ipamorelin and Hexarelin, but are typically un-favored due to the former being a weaker GH promoter and the latter having a stronger, adverse effect on cortisol and prolactin. GHRP2/6 are both very potent at promoting GH release, yet have little to no effect on cortisol or prolactin. While several studies have concluded increases in GH secretion and IGF-1 are achievable with solitary use, concurrent use with GHRH is more than additive. This is, in part, due to the fact that GHRH is much less capable of increasing GH when physiologic levels of somatostatin are high and GHRP inhibits somatostatin. Recommended doses for GHRP 2 or 6 are typically around 150mcg as there is a receptor saturation point, and delivering more yields little benefit and may promote desensitization with chronic dosing.

## CONCLUSION

While the stimulation of GH with GHS – rather than direct GH replacement – clearly has the advantage of being more akin to mirroring a physiologic approach of increasing endogenous GH pulsatility and secretion, there still remain important and unanswered questions that need resolution before conclusive

statements about efficacy and benefits can be made. Defining measurable, therapeutic endpoints, measuring a reduction in frailty, and the safety of chronic, long-term GHRH therapy are a few of the clinical outcomes that have yet to be determined. Certainly, GHRH has been shown to afford a place in therapy for the aging adult, but much larger and extended clinical trials will need to be completed before it takes its place among routine medicine for the aged. Until then, closely monitored individuals under a physician's direct care can benefit from its availability via compounding pharmacies. ■

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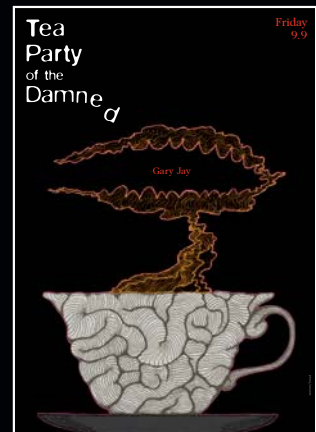
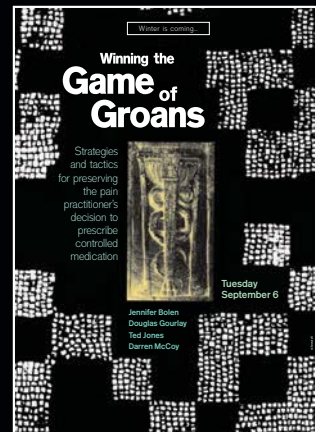
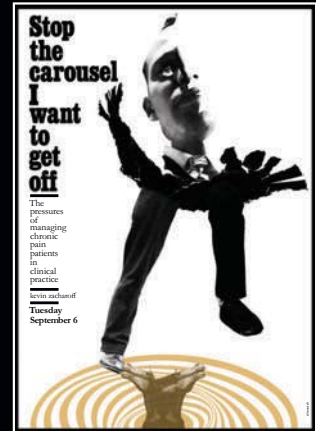
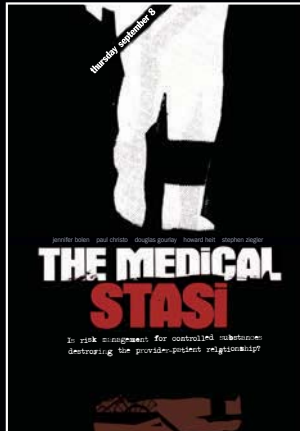
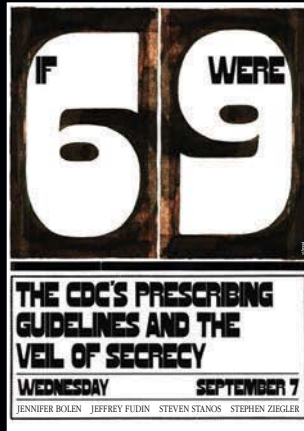
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# The Metabolic Code Making Inroads in Patient Care

By Bassel Haidar, CEO of Metabolic Code

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**BOCA RATON, FL;** Metabolic Code empowers health care providers to Deliver Better Health Outcomes and work more efficiently. The Metabolic Code cloud-based system offers a compelling point of care platform for practitioners to manage patients effectively. The platform aggregates biologic and self-reported data from each patient and generates an individualized care plan. This information is conveyed to the patient by the provider in a comprehensive report, which includes suggestions for nutrition, exercise and strategic dietary supplementation to correct metabolic imbalances and restore vitality. Providers can track patients longitudinally, assess interim outcomes and make adjustments between office visits. Metabolic Code represents the nexus between lifestyle medicine, technology and personalized care.

In a review of the underlying science, practical clinical application and market place innovation, George Washington University has agreed to include the Metabolic Code system in the Master's program in Integrative Medicine for all their students. Metabolic Code offers an information-rich teaching environment for students that accelerates their understanding of fundamental concepts in lifestyle medicine and ensures exposure to real world tools for future integrative practitioners. According to the American College of Preventive Medicine, "lifestyle medicine is a scientific approach to decreasing disease risk and illness burden by utilizing lifestyle interventions such as nutrition, physical activity, stress reduction, rest, smoking cessation, and avoidance of alcohol abuse. Lifestyle medicine is the recommended foundational approach to preventing and treating many chronic diseases."

"We are delighted to finalize this partnership with the Metabolic Code. This represents many years of hard work and sacrifice to produce a platform that creates efficiencies for practitioners while serving patients in their journey towards wellness. George Washington University has a strong interest in the educational and research opportunities that the

Metabolic Code provides, and together, we will improve the evidence base of lifestyle medicine and hopefully change the practice of medicine as well," says Andrew Heyman, MD, Program Director of Integrative Medicine, GWU.

The deployment of the Metabolic Code platform is an enormous research opportunity as physician practices adopt the system. Many challenges exist in the collection of medical outcomes data, especially in the field of health and wellness. Physician practices generally function independently of the conventional health care system, little industry oversight occurs, and dietary supplements are unregulated. The core of the Metabolic Code is a sophisticated technology that ensures cohesive clinical decision-making across participating practices, access to high quality products, and the extraordinary opportunity to track outcomes data among large populations.

Additionally, Metabolic Code has amassed an impressive array of partners to enable it to provide one-click lab ordering and posting, best in class medical grade supplements that can be delivered on a recurrent basis to patients, and access to clinical expertise through highly respected educational institution affiliations.

## **NATIONAL CLINICAL LABORATORIES**

Metabolic Code selected national clinical laboratories True Health Diagnostics, Quest Diagnostics, and Physicians Lab to analyze data from patient lab samples in conjunction with patient lifestyle questionnaires and personal biometric information to help determine an individual's greatest areas of metabolic risk. Practitioners then use that information to develop the most beneficial and engaging health plan for the patient.

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#### EDUCATIONAL INSTITUTIONS

James LaValle, Founder and Chairman of Metabolic Code and Andrew Heyman, MD and Chief Medical Officer of

Metabolic Code, are both sought-after thought leaders in integrative Medicine and speakers at the American Academy of Anti-Aging Medicine (A4M), where they teach a variety of continuing medical education courses (CME) with a focus on a systems biology approach to medicine, known as "the Triads".

More information can be found at [www.metaboliccode.com](http://www.metaboliccode.com)

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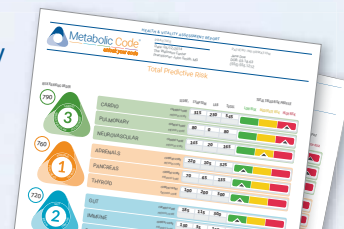
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# Probiotics, the Gut Microbiota, and Healthful Aging

By Marina MacDonald, PhD and Stephen Olmstead, MD

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## SUMMARY

The gastrointestinal microbiota is a complex microecological system consisting of over trillions of microorganisms. It may be considered a vital organ acquired during infancy. As with all other organs, the gut microbiota ages resulting in diminished microbial diversity, reduced Bifidobacterium populations, and increased pathogen numbers. Age-related shifts in intestinal microbial populations increase the susceptibility of the elderly to infections such as *Clostridium difficile*-associated disease. The loss of Bifidobacterium and other beneficial microbes is associated with a decline in innate and adaptive immune function termed “immunosenescence.” This renders older people vulnerable to infection, cancer, and autoimmune disease. Immunosenescence causes a low-grade systemic inflammation termed “inflamm-aging.” Healthy centenarians have robust Bifidobacterium populations that mediate anti-inflammatory effects. Multispecies Bifidobacterium and *Lactobacillus* probiotics show great potential to support healthy, diverse gut microbiota during aging and evidence suggests they may reduce the risks of infection, cancer, and chronic inflammatory diseases often encountered in the elderly.

## AGING AND DYSBIOSIS

The gastrointestinal tract is home to trillions of microorganisms, including any of 15,000 to 36,000 microbial species.<sup>1,2</sup> Each individual hosts around 160 different species that essentially constitute an organ within the body that has a profound effect on gastrointestinal function, immune modulation, and metabolic balance.<sup>3</sup> This gut microbiota is acquired during birthing, matures during infancy, changes during childhood, and ages just as does every other organ system.<sup>4-7</sup> Aging is associated with diminished gastric acid production, increased gastric pH, delayed gastric emptying, and decreased gastrointestinal motility, all of which can negatively affect the microbiota.<sup>8,9</sup> These physiologic changes, together with a lifetime of poor diet and repeated exposures to antibiotics and non-steroidal anti-inflammatory drugs, contribute to a shift from a diverse, balanced microbiota to a dysbiotic gut microbiota characterized by a loss of microbial diversity and heightened pathogen numbers.<sup>10,11</sup> The most important characteristic of age-related gut dysbiosis is the decline in the abundance, diversity, and adhesive properties of Bifidobacterium species.<sup>10,12-15</sup> Bifidobac-

teria have important anti-infective and immunomodulatory functions.<sup>16-18</sup> Diminished diversity and numbers of gastrointestinal Bifidobacterium are increasingly viewed as associated with an increased susceptibility to gastrointestinal and systemic infections as well as age-related inflammatory conditions.<sup>19,20</sup> Other dysbiotic findings prevalent in the aging gastrointestinal tract include decreased numbers of butyrate-producing species such as *Faecalibacterium prausnitzii* and reduced populations of *Clostridium* clusters IV and XIV leading to increased inflammatory cytokine levels.<sup>12,22-24</sup> The reduction in beneficial species with age is accompanied by an increase in the relative proportions of potentially harmful species such as Proteobacteria, Fusobacterium, and pathogenic clostridia.<sup>11,12,22,25</sup> The elderly have increased numbers of *Clostridium difficile*, especially in people receiving antibiotic therapy.<sup>26-28</sup> In one study, 21% of hospitalized elderly subjects tested positive for *C. difficile* as compared with 1.6% of elderly subjects in the community.<sup>29</sup> Age-related shifts in bacterial populations increase the susceptibility to *C. difficile* in older people. Elderly patients with *C. difficile*-associated diarrhea (CDAD) have greatly reduced numbers of Bacteroides, Bifidobacterium, and Prevotella<sup>26</sup> and a marked reduction in microbial diversity.<sup>29</sup> Since similar but less pronounced gut microbial composition changes have been observed in elderly individuals as a whole, it has been suggested that age-related shifts in bacterial populations could increase the susceptibility to *C. difficile* in aging individuals.<sup>30</sup> Recent successes with fecal microbiota transplantation underscore the importance of a healthy microbiota in eliminating *C. difficile*.<sup>31</sup> Organ failure incidence and ICU mortality in the elderly is significantly higher in patients with profound reductions in microbiota size and diversity, especially when associated with a massive presence of enterococci and with antibiotic use.<sup>32,33</sup> Similar but more extensive changes in the gut microbiota have been observed in critically ill patients with severe systemic inflammatory response syndrome (SIRS), suggesting that an abnormal intestinal microbiota may affect the inflammatory response after severe sepsis, trauma, and shock.<sup>34</sup> Although considerations of diet and ethnicity complicate the definition of an “aged” gut microbiota,<sup>14,35</sup> these data indicate that intestinal microbiota composition and diversity has a significant effect on health maintenance and disease incidence during aging.<sup>10</sup>

## IMMUNOSENESCENCE AND INFLAMM-AGING

The loss of a robust and diverse Bifidobacterium population as well as reduced numbers of other beneficial microbes coupled with an increase in pathogenic microbial species leads to a decline in immunologic function and an increase in systemic inflammation. A gradual decline in both innate and adaptive immune function associated with aging has been called “immunosenescence”<sup>36-38</sup> while an age-related increase in chronic, low-level inflammation is termed “inflamm-aging.”<sup>40-42</sup> Immunosenescence is associated with an increased susceptibility to infections and a weakened immunization response rendering elderly individuals more susceptible to infection, autoimmune disease, and cancer. Inflamm-aging, which often accompanies immunosenescence, has been implicated in the pathogenesis of major diseases such as cardiovascular disease, type 2 diabetes, Alzheimer’s disease, Parkinson’s disease, osteoporosis, rheumatoid arthritis, and cancer.<sup>43-45</sup> Inflamm-aging is predictive of mortality independent of pre-existing morbidity.<sup>41,42</sup> Even in the absence of acute infection, interleukin-6 (IL-6), TNF, and C-reactive protein (CRP) levels increase with age.<sup>46</sup> These inflammatory cytokines are strongly associated with frailty in the elderly.<sup>47,48</sup> Unlike acute inflammation, inflamm-aging is characterized by a relative decline in adaptive immunity and T-helper 2 (Th2) responses, together with persistent activation of cells of the mononuclear phagocyte lineage.<sup>21,49,50</sup> Senescent CD8+ T cells also produce more proinflammatory cytokines than their more “youthful” counterparts.<sup>51</sup> In prospective studies, CRP, an independent predictor of mortality,<sup>52</sup> predicted the risk of myocardial infarction, stroke, peripheral arterial disease, and other chronic age-related diseases including Alzheimer’s and Parkinson’s disease.<sup>46,53-55</sup> Proinflammatory cytokines interfere with processing and production of amyloid beta peptide, the pathological hallmark feature of Alzheimer’s disease, suggesting that inflamm-aging may be a “prodrome” to Alzheimer’s disease.<sup>56</sup> In patients with rheumatoid arthritis, IL-6 and other cytokines may contribute to autoimmunity, resulting in joint damage.<sup>57,58</sup> Animal studies suggest that a particular dysbiotic microbiota is required to trigger, if not drive, systemic autoimmunity leading to inflammatory arthritis.<sup>59</sup> An age-related increase in gut wall permeability to microorganisms and microbial constituents reflected by an increase of circulating antibodies against commensal gut bacteria, may contribute to low-grade systemic inflammation.<sup>60,61</sup> Aging is associated with impaired regulatory T cells (Treg) modulation of IL-10 production.<sup>62</sup> Gut microbiota composition regulates the ratio of Treg cells to effector T cells thereby influencing intestinal immunity, tolerance, and susceptibility to inflammatory diseases and allergies.<sup>63,64</sup> Several probiotic bacteria, including Bifidobacterium bifidum and B. infantis in humans and indigenous Clostridium species in mice have been shown to induce Treg cells and IL-10 production and produce anti-inflammatory effects.<sup>65-69</sup>

## THE GUT MICROBIOTA – A KEY TO HEALTHFUL AGING

One of the important keys to healthful aging and longevity is to develop and maintain an immune system that minimizes chronic inflammation without compromising the body’s ability to respond to pathogens and neoplastic cells.<sup>41</sup> Individuals who live to be 100 years old have well-conserved immune parameters such as preserved T cell repertoire and, despite showing some inflammation markers, avoid or delay major inflammation-driven, age-related diseases.<sup>70,71</sup> A study that compared stool samples from centenarians with those of younger adults suggests that healthy centenarians can maintain a balanced, diverse gut microbiota with health-producing properties. The numbers of Bifidobacterium species in healthy centenarians ranged from 53% to 87% of all anaerobes compared to the average of 40% in healthy younger people.<sup>72</sup> Bifidobacterium strains isolated from healthy centenarians enhanced both immune and intestinal function in healthy mice following oral administration.<sup>72,73</sup> These findings provide tantalizing evidence that healthy centenarians are characterized by a gastrointestinal microbiota containing more numerous, diverse Bifidobacterium populations that possess valuable immunomodulatory properties than are even present in younger healthy people. Furthermore, studies show that preserved immune function modulated by a balanced gut microbiota is a characteristic of healthy elderly people at any age.<sup>21</sup>

## PROBIOTICS TO SUPPORT A HEALTHY AGING GUT MICROBIOTA

Probiotic consumption can shift the gastrointestinal microbiota composition in elderly people from an overabundance of pathogenic species towards a more beneficial, diverse microecosystem.<sup>74-78</sup> Probiotics affect the microbiota directly by modulating its microbial composition through the production of bacteriocins, hydrogen peroxide, lactic acid, and short-chain fatty acids.<sup>79</sup> As gut bifidobacteria populations tend to diminish with age, probiotic administration containing ample Bifidobacterium numbers and diverse species represents a strategy to support aging gastrointestinal microbiota. Combining large numbers of Bifidobacterium with Lactobacillus probiotics may be the optimal approach.<sup>80</sup> The benefits to this type of support are borne out by the use of probiotics in the treatment of C. difficile in the elderly. Meta-analyses of clinical studies have shown that probiotic intervention is more effective than placebo in ameliorating C. difficile symptoms and/or preventing C. difficile-associated disease.<sup>81-83</sup> In elderly patients, consumption of Lactobacillus-containing cheese reduced C. difficile populations as compared with a run-in period.<sup>77</sup> The probiotic effect was associated with enhanced innate immune function manifested by improved cytotoxicity of NK

cells and an increase in phagocytic activity.<sup>84</sup> In a study of probiotics versus placebo in hospitalized patients with an average age of 74 only 12% of the probiotic group developed diarrhea as compared with 34% in the placebo group.<sup>85</sup> The ability of lactobacilli to persist through antibiotic treatment accentuates their value as probiotics against antibiotic-associated diarrhea.<sup>13,86</sup> In another study, a probiotic formula containing 10 bacterial strains at a combined dose of 10 billion CFU/day was administered as adjunctive therapy during *C. difficile* infection.<sup>80</sup> The adjunctive use of probiotics resulted in complete resolution of *C. difficile* in adults in the clinical setting. The investigators postulated that only a multistrain probiotic mixture could fully address the needs of patients with *C. difficile* infection.

## PROBIOTICS AND THE PREVENTION OF IMMUNOSENESCENCE

The ability of probiotics to modulate and support healthy immune system function is well established.<sup>87-89</sup> Probiotics influence the numbers and function of cells responsible for innate and acquired immunity and produce anti-inflammatory effects. Species that modulate immune cell function in vitro and/or in vivo include *B. bifidum*,<sup>90,91</sup> *B. breve*,<sup>92</sup> *B. infantis*,<sup>93,94</sup> *B. lactis*,<sup>95</sup> *B. longum*,<sup>96</sup> *L. acidophilus*,<sup>68,97</sup> *L. casei*,<sup>98,99</sup> *L. gasseri*,<sup>100,101</sup> *L. plantarum*,<sup>102,103</sup> and *L. rhamnosus*.<sup>68,104</sup> Bifidobacterium strains produce a more anti-inflammatory profile (IL-10), modulate regulatory T cells, and are associated with anti-inflammatory effects.<sup>18,105,106</sup> Many different Lactobacillus strains promote Th1 cytokines (IL-12) and probiotics from the Lactobacillus genera have the greatest ability to reduce the incidence and/or symptoms of common cold or respiratory tract infections.<sup>95</sup> The anti-inflammatory effects of probiotics are not limited to their influence on immune cells.<sup>107</sup> Probiotic microorganisms may also counteract inflammation-aggravating bacteria, which will decrease the inflammatory tone of the system and improve the gut mucosa barrier function.<sup>108</sup> This reduces translocation of proinflammatory microbial components from the gut lumen out into the body. The ability of many Lactobacillus strains to improve the gut mucosa barrier function is a subject of intense investigation, since a strong epithelial barrier lowers the risk of systemic inflammation due to a chronic immune reaction of pro-inflammatory components originating from the gut microbiota.<sup>109-112</sup> The stimulation of CD8+ T cells and NK cells by various probiotic compositions suggests that probiotics enhance the immune defense against viral infections and tumors.<sup>113-118</sup> Dietary supplementation with probiotics can modulate innate and adaptive immune responses both locally and systemically and mixtures of Lactobacillus and Bifidobacterium may produce a balanced effect, consistent with the view that the immune system responds to whole suites of bacteria.

## CONCLUSION

Probiotics are increasingly being recognized as immune-modulating nutritional factors, and interest in their impact on the immune response of the elderly has grown in recent years. Chronic probiotic consumption represents a strategy to maintain a robust, diverse microbiota with age and to support against immunosenescence. Research shows that probiotic molecules can induce beneficial changes in the host via enhancement of gut epithelial barrier function, competitive exclusion and inhibition of pathogens, and balanced modulation of immune cell behavior and cytokine profiles. Evidence suggests a promising role for probiotics to improve age-related immune system defects and to reduce infectious disease severity and cancer incidence in the elderly. Each probiotic strain produces a different set of molecular and cellular responses, such that mixtures of probiotics are likely to be more effective than single strains. In an older person, a composition of Lactobacillus and Bifidobacterium probiotics with the numbers weighted heavily in favor of the Bifidobacterium species is likely to be most effective. Probiotics require an adequate dosage and a prolonged supplementation period to have greatest benefit. Due to the transient nature of probiotic colonization, microbiota composition is likely to regress if probiotic administration ceases, so chronic consumption is required for ongoing effect. ■

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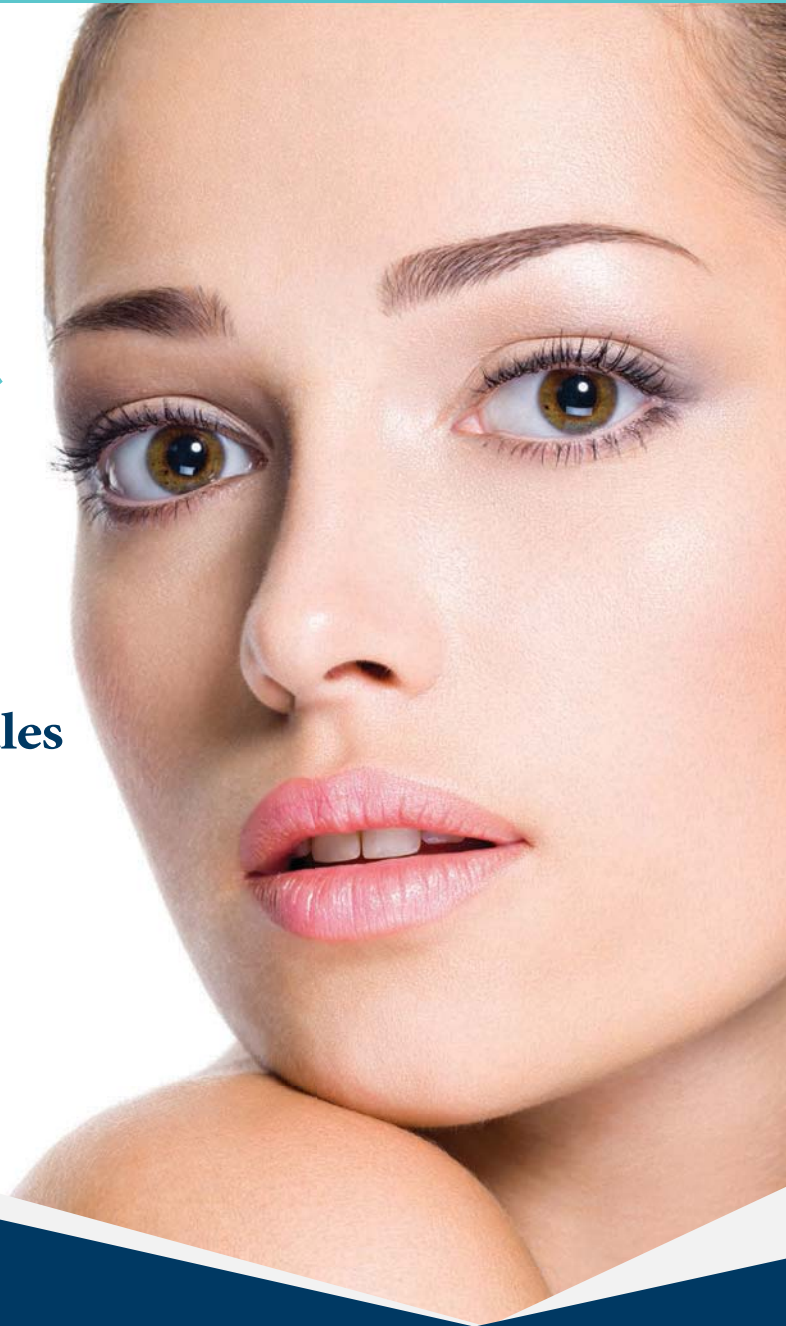


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# The Role of the Endothelial Glycocalyx in the Pathogenesis of Atherosclerosis:

## A New Frontier in Cardiovascular Health

By Derrick DeSilva Jr, MD, Jeffrey Gladden, MD, FACC, Chen Chen, PhD, Jon Ward, MA

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Much recent work on the pathogenesis of atherosclerosis has focused on the “response to injury theory”. In brief, the theory holds that atherosclerosis may be understood as an inflammatory response to insults occurring to the endothelium.<sup>1</sup>

When the endothelium is healthy, atherosclerosis does not occur. When the endothelium is damaged, it produces surface-adhesion molecules causing monocytes and t-lymphocytes to stick to its surface, which then penetrate the endothelium into intima. As low density lipoprotein (LDL) particles follow the path, they enter the intima and begin to oxidize. This sets the stage for foam cell formation and plaque development. The resulting plaque then builds up and, when internally inflamed or externally eroded, can be a threat to rupture its contents into the arterial flow, potentially triggering a blood clot that if large enough, or not lysed quickly enough, can occlude the artery to various degrees causing anything from mild to devastating downstream ischemia. Indeed, it is the clotting in response to plaque disruption, not the plaque accumulation in the arteries per se, that poses the real threat. 75% of heart attacks occur at arteries that are less than 50% blocked, while mild plaquing escapes traditional stress tests 80% of the time.

Needless to say, this means that merely measuring the serum levels of LDL and HDL is inadequate to assess event risk. To interrupt the cycle, clinicians need to be primarily concerned with the health of the endothelium.

The injury-response theory is gaining widespread acceptance, but it begs an important question: What causes the injury to the endothelium in the first place? Multiple candidates have been cited such as:

- Direct trauma causing physical injury
- Turbulence in the blood flow, for example at artery bifurcations
- Excessive blood glucose levels
- Circulation of free radicals
- TMAO (trimethylamine-N-oxide)
- Higher than normal concentrations of LDL or VLDL
- High blood pressure
- Circulating toxins
- Deterioration of the NO system

All of these explanations have value, but they miss a critical factor in endothelial health which merits more attention than it has received in the current literature. That factor is the endothelial glycocalyx.

### THE ENDOTHELIAL GLYCOCALYX

Popular accounts of the endothelium inaccurately describe it as “the inner lining” of the blood vessels. Here is Wikipedia:

“Endothelium is a type of epithelium that lines the interior surface of blood vessels and lymphatic vessels, forming an interface between circulating blood or lymph in the lumen and the rest of the vessel wall.”

What is missing from these accounts is the glycocalyx, a slippery smooth gel coating of the endothelium that positions an additional layer between the endothelium and the circulating blood. This is the true interface. In other words, it is the endothelial glycocalyx—not the endothelial cells themselves—that has (or should have) direct contact with the circulating fluids and particles.

When we help doctors explain the endothelial glycocalyx to patients, we sometimes liken it to the non-stick surface of a

frying pan. The analogy is useful because it highlights the protective function of this important structure. A healthy glycocalyx ensures that LDL particles “slip by” without contacting the endothelium. Conversely, when the endothelial glycocalyx is compromised (which happens very easily), the endothelium becomes susceptible to injury impairment and LDL penetration. Important clinical implications follow. To prevent atherosclerosis, we must protect the endothelium from injury and preserve its vital functions. To protect endothelial function, we must support its existing natural protection, the endothelial glycocalyx. In layman’s terms: if you want to stop food sticking to your saucepan, take care of the non-stick coating! If you want the infrastructure of the endothelium to work, you need to protect its surface.

### A CLOSER LOOK AT THE GLYCOCALYX

The endothelial glycocalyx is a thin gel-like layer that coats the entire luminal side of the vascular endothelium. It is a meshwork mainly of glycoproteins, proteoglycans and glycosaminoglycans at a thickness of approximately 1  $\mu\text{m}$  magnitude.<sup>2-4</sup> Syndecans and glypicans are the core proteins of heparan sulfate (a glycosaminoglycan) proteoglycans bound to endothelial cells identified in the glycocalyx. Glycoproteins such as selectins and integrins are also anchored on endothelial cells while some other soluble proteins and proteoglycans simply dock in glycocalyx.<sup>5</sup>

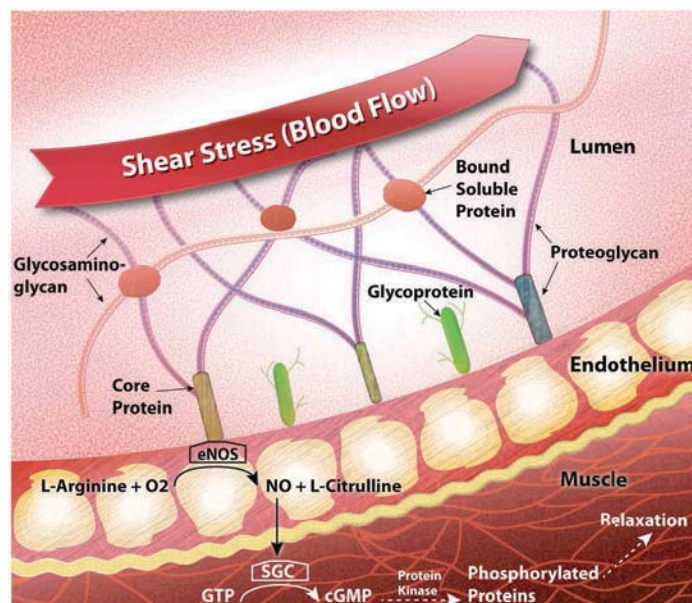
Extensive research has revealed the importance of glycocalyx-mediated endothelial function in vascular and microvascular health.

### FOR EXAMPLE, THE ENDOTHELIAL GLYCOCALYX:

- Regulates vascular permeability and fluid balance due to the large size and negative charge of glycosaminoglycans.<sup>6,7</sup>
- Provides a physical barrier against inadvertent adhesion of platelets and leukocytes to the vascular wall.<sup>8</sup>
- Regulates coagulation as many of mediators of coagulation pathway are buried inside the glycocalyx under normal physiological condition.<sup>5</sup>

Most intriguingly, the glycocalyx is found to be a mechano-sensor and -transducer of the shearforce inside blood vessels.<sup>3</sup> The signal is believed to be transduced to endothelial nitric oxide synthase (eNOS) via heparan sulfate in the glycocalyx to either up- or down-regulate the synthesis of nitric oxide (NO) in response to the blood flow.<sup>9,10</sup>

Figure 1 illustrates the chemical structure of the endothelial glycocalyx and its signal transduction to eNOS and subsequently sGC (soluble guanylyl cyclase) to induce smooth muscle relaxation via shear stress.



**Figure 1.** Structure of the endothelial glycocalyx and its activation of vascular muscle relaxation via NO in response to increased shear force

### DAMAGE TO THE ENDOTHELIAL GLYCOCALYX

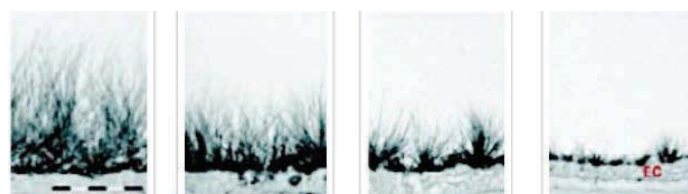
The endothelial glycocalyx is a delicate structure and can be damaged by several common mechanisms involved in the pathogenesis of atherosclerosis. These include high blood glucose,<sup>11</sup> oxidative stress,<sup>12</sup> and inflammation.<sup>4</sup> It is known that high-sugar diets, cigarette smoking, stress, and aging can all degrade the glycocalyx.

Hyperglycemia is a major cause for disruption of the endothelial glycocalyx.<sup>11,13</sup> In fact, individuals with hyperglycemia and diabetes are known to have less endothelial glycocalyx.<sup>14</sup> Such a change may explain the endothelial dysfunction and increased microvascular permeability that lead to major complications in the diabetic population.<sup>15,16</sup>

There are several other disease conditions identified so far to be associated with a compromised endothelial glycocalyx:

- Coronary heart disease<sup>17</sup>
- Renal diseases<sup>18</sup>
- Lacunar stroke (a small vessel disease)<sup>19</sup>
- Severe trauma<sup>20</sup>

These electron-microscope images show the deterioration of the endothelial glycocalyx:





## CLINICAL INTERVENTIONS

Given the vital role the endothelial glycocalyx plays in the pathology of many vascular and micro-vascular related diseases, it has naturally become a target for pharmaceutical intervention.<sup>21,22</sup> However, glycocalyx drug development is still in its infancy, and no substantial progress has been made to date.<sup>23</sup>

A dietary supplement has been tested and shown to have measurable benefits for a compromised glycocalyx in healthy subjects. Brand-named Arterosil, its primary ingredient is rhamnan sulfate derived from rare marine algae. Rhamnan sulfate has a similar chemical structure to heparan sulfate found abundantly in the human endothelial glycocalyx, and may exert its bioactivity by regenerating the glycocalyx.

In an early clinical trial, the positive impact on the glycocalyx was established by measuring recovery of RHI (reactive hyperemia index) in 20 healthy human subjects following a high sugar, high-fat meal. Results were compared with and without consumption of ArterosilHP. The study confirmed a significant improvement in glycocalyx RHI recovery with the supplement.

Important safety data were obtained for complete metabolic panel (CMP), thyroid stimulating hormone (TSH), complete blood count (CBC), and partial thromboplastin time (PTT) from the trial. No significant changes were observed for any of these tests after 4 weeks of ArterosilHP supplementation. There was also no serious adverse event reported during the study, and the product was well tolerated by all subjects.

## THE GLYCOCALYX AND ARTERIAL ELASTICITY: A NEW FRONTIER

The clinical significance of arterial elasticity is well established: Central arterial stiffness has been shown to be an independent predictor of cardiovascular morbidity and mortality.<sup>24</sup> While the prognostic value of this measure is widely accepted, the causes of arterial stiffness are still subject to debate. Some research suggests that the issue is not limited to the larger arteries themselves, but may extend to the micro-vascular system.<sup>25</sup> Other studies indicate the role of endothelial function in determining the degree of arterial elasticity.<sup>26</sup>

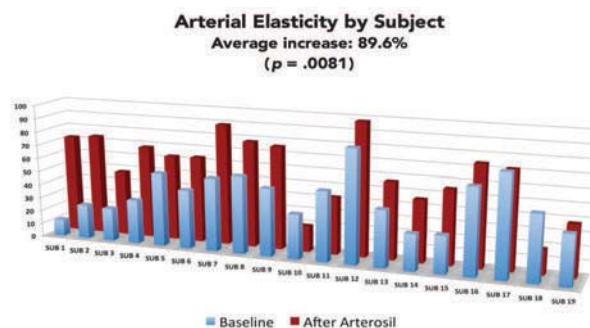
One useful contribution to this debate may prove to be a new focus on the endothelial glycocalyx. Because the glycocalyx serves to protect the integrity of the endothelium, and hence of the arterial wall, it stands to reason that a healthy glycocalyx might be associated with good arterial elasticity.

We conducted a pilot study to test patients for arterial elasticity — among other markers — before and after the consumption of ArterosilHP.

Nineteen healthy human subjects (11 females age 22 to 64 and 8 males age 30 to 60) were randomly recruited for the single blinded clinical study, which was conducted at an independent cardiology center on the Baylor Medical Campus in Plano, Texas. Their vascular health condition was evaluated utilizing MaxPulse, an FDA approved Class II device. The MaxPulse utilizes accelerated plethysmography technology with data being gathered by way of a finger probe. This technology, also known as pulse wave analysis, includes multiple factors including wave type, arterial elasticity, eccentric constriction and remaining blood volume valuations.

In this study, the baseline reading was taken at approximately 2 hours (+/- 30 minutes) post consumption of a breakfast of the subject's choice. Immediately after the baseline reading one capsule of ArterosilHP was swallowed. A post-dose reading was taken every 30 minutes for 3 hours, for a total of 7 readings (baseline, 30 min, 60 min, 90 min, 120 min, 150 min & 180 min +/- 5 minutes). The patients were kept in a quiet ambient environment. No food or liquid (other than small amounts of water as needed) was consumed during the 3 hour testing period.

## THE RESULTS ARE SUMMARIZED IN THE TABLE BELOW:



In sum, 78.9% of subjects experienced an increase in arterial elasticity. The average percentage increase in arterial elasticity was 89.6% (*p* = .0081). The mean time to maximum increase was 118 minutes. There was concurrent improvement in remaining blood volume and eccentric contraction. In this preliminary study, we were able to demonstrate that ArterosilHP improves arterial elasticity in healthy human subjects. It is likely this acute beneficial effect is a result of improved glycocalyx and its mediated endothelial func-



tions. These new data are in agreement with our previous findings that ArteriosilHP helps regenerate the endothelial glycocalyx and restore compromised endothelial functions. Clearly there is a need for further studies to validate these early results.

We know that arterial stiffness indicates adverse changes of blood vessel structure and function, and poses a significant threat to patients' cardiovascular health.<sup>27</sup> If it transpires that rebuilding the glycocalyx has a rapid and positive impact on arterial elasticity, this could suggest a valuable clinical intervention, both for patients presenting disease conditions and for those seeking preventative care.

## ABOUT THE PRIMARY AUTHOR

Dr. Derrick DeSilva is a practicing internist with a wide range of medical interests. He serves as Senior Attending Staff at the Department of Medicine, Raritan Bay Medical Center (RBMC) in Perth Amboy, New Jersey. He also serves on the teaching faculty of the JFK Medical Center in Edison, New Jersey. Dr. DeSilva serves as Chairman of the Planning Committee for the Age Management Medicine Group (AMMG) and is a Past President of the American Nutraceutical 7 Association. He has been a recipient of the Alan Mintz Award for Excellence in Clinical Age Management Medicine, and he has received the Best Doctor Award by Castle Connolly for the past 15 consecutive years. Dr. DeSilva is host of "Ask the Doctor" on WCTC Radio, a medical correspondent for Cablevision (News 12 New Jersey) and host of "12 to Your Health". ■

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# TETRAHYDROCUCURMIN: The Ultimate Metabolite of the Curcuminoids

MICHAEL JURGELEWICZ, DC, DABCN, DCBCN, CNS

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There are only a few natural products that have demonstrated the wide range of protective properties as curcumin. Some of the challenges with curcumin are its poor solubility, low intestinal absorption, rapid metabolism, and rapid systemic elimination.<sup>1</sup>

In order to achieve any significant absorption from curcumin, special technology is necessary to successfully facilitate this. Some manufacturers make the curcumin particles very fine so it can be soluble in water. While this can be effective, it results in a very low amount of curcumin per capsule, as most of the material is needed to increase absorption. Another method is the use of phospholipids to assist in allowing curcumin to across the intestinal wall, which is also an impressive and efficacious technique. Unfortunately, this only yields approximately 20% curcumin per capsule, making it difficult to deliver a sound, therapeutic dose. Also, other curcumin products may use piperine (an alkaloid derived from pepper) to increase bioavailability. The problem is that piperine is a common allergen and stomach irritant, and it increases curcumin's absorption by inhibiting the glucuronidation pathway of the liver.<sup>2,3</sup>

Turmeric's three main bioactive components are curcumin, desmethoxycurcumin, and bisdemethoxycurcumin. These curcuminoids have many biological effects, including anti-inflammatory, antioxidant, antitumor, antibacterial, and antiviral properties. However, the poor circulating bioavailability of the curcuminoids limits their biological effects in vivo.<sup>4</sup> Recently, there has been significant attention on tetrahydrocurcumin, which is the most powerful metabolite of the curcuminoids.<sup>5</sup>

Tetrahydrocurcumin is not typically found in turmeric extract powders containing 95% curcuminoids used in dietary supplement products, but it appears in the plasma following ingestion of curcuminoids.<sup>6</sup> Tetrahydrocurcumin plays an important role in the antioxidant mechanism of curcumin and has been shown to be the most potent antioxidant of the curcuminoids.<sup>7</sup> In a January 2014 study in the *Nutrition Journal*, several trademarked curcumin formulas were analyzed for their bioavailability. Although all of these formulations did enhance absorption of the curcuminoids, none of them significantly produced tetrahydrocurcumin in vivo.<sup>6</sup>

The free radical scavenging ability was compared in a series of studies of various curcuminoids including curcumin, bisdemethoxycurcumin, and tetrahydrocurcumin.<sup>8</sup> As a result, tetrahydrocurcumin was demonstrated as being the most effective, followed by curcumin and bisdemethoxycurcumin.

Curcumin and tetrahydrocurcumin have distinct benefits over one another, and it would make sense to have both and not just one. It would be best to consume a bioavailable curcumin product that produces significant levels of this metabolite in vivo. Most studies have indicated that tetrahydrocurcumin exhibits a higher antioxidant activity, while curcumin exhibits both pro-oxidant and antioxidant properties.<sup>9</sup>

Several independent studies have reported the significant antioxidant effects of tetrahydrocurcumin.<sup>7,10,11</sup> One study evaluated the antioxidant activity of the curcuminoids and tetrahydrocurcumin and found that tetrahydrocurcumin had the strongest antioxidant activity among all curcuminoids and, therefore, must play an important role in the antioxidant mechanism of curcumin in vivo.<sup>6</sup>

A highly absorbed curcumin formula would be the best choice to reduce peripheral inflammation directly. This may include neurodegenerative diseases, cardiovascular diseases, osteoarthritis, various cancers, benign prostatic hypertrophy, diabetic microangiopathy and retinopathy, anterior uveitis, maculopathy, and glaucoma.

Tetrahydrocurcumin has been shown to have specific neuroprotective properties. One study demonstrated a protective effect of tetrahydrocurcumin against oligomeric amyloid- $\beta$ -induced toxicity.<sup>12</sup> This antioxidant activity may have a neuroprotective effect in Alzheimer's disease.

Oxidative stress has been associated with many diseases, including diabetes. A separate study demonstrated that tetrahydrocurcumin increased the total number of insulin binding sites, resulting in a significant increase in plasma insulin. Note that this effect was superior to that of curcumin.<sup>13</sup>

Tetrahydrocurcumin also demonstrates powerful cardioprotective properties. In a study in Hypertension Research, tetrahydrocurcumin alleviated hypertension and reversed the effects of aortic wall thickness and stiffness, and oxidative stress.<sup>14</sup> Therefore, tetrahydrocurcumin may be considered as a protective agent against cardiovascular alterations under nitric oxide-deficient conditions.

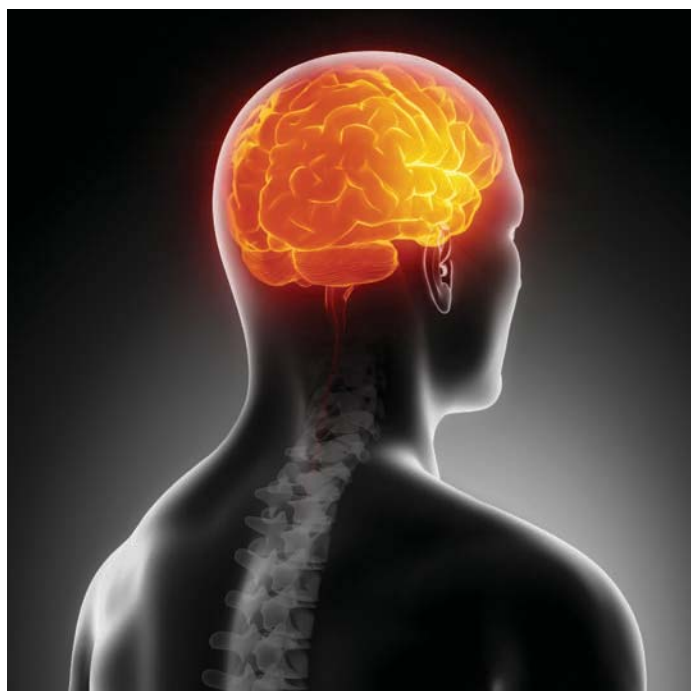
Curcumin is metabolized to tetrahydrocurcumin, and both of these compounds have distinct protective properties. Curcumin binds and modulates a wide array of targets, whereas tetrahydrocurcumin is a superior antioxidant but lacks some of the anti-inflammatory and pro-oxidant activities of curcumin.

Research demonstrates tetrahydrocurcumin has potent antioxidant properties, but if taken by itself, what does this metabolite get metabolized into? Will it appear as unconjugated tetrahydrocurcumin or some other metabolite? Will it have the same effect as what is being produced in vivo from the parent compounds?

It makes sense to use a curcumin formula that produces the potent metabolite, tetrahydrocurcumin, in vivo. It remains to be seen whether taking tetrahydrocurcumin is better than a formula that naturally produces significant levels of plasma tetrahydrocurcumin in vivo from the parent compounds. ■

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# ONDAMED:

## A Non-Disease Label Approach to Improving Body Functions Versus Treating Disease

By Rolf D. Binder, Inventor, & Silvia Binder, N.D., Ph.D.

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### SUMMARY

Disease labels do not help us cure our patients. Imagine an approach that would rapidly allow you to find the hidden physiological and emotional cause of your patient's symptoms, while simultaneously stimulating your patient's nervous system with focused therapeutic electromagnetic fields. This is a non-invasive method to help you, the therapist, find the source of your patient's symptoms within minutes, while simultaneously treating and stabilizing your patient.

### OVERVIEW

The human body works on the basis of biophysics and biochemistry. While traditional medicine has much to offer in the chemical sense, it lacks the therapeutic approach of physics. Practitioners use the noninvasive ONDAMED technology and the biofeedback loop to scan the body for underlying dysfunctions, such as inflammation, infections, scar tissue, and emotional trauma residing at a cellular level. These areas often prove to be the source of disease and symptoms that might be otherwise difficult to find. Identified areas are treated with focused pulsed electro-magnetic fields to stimulate tissue and the nervous system. Therapy with ONDAMED focused pulsed fields helps reduce local stress and improve metabolism and lymphatic flow resulting in reduced inflammation, pain and edema, while improving stress tolerance by reducing cortisol levels and by influencing the nervous system.

### MORE SPECIFICALLY:

ONDAMED is very unique in its ability to deliver specific resonant frequencies to the source of illness. While other devices deliver either a pulsed electromagnetic stimulus to a symptomatic region in order to reduce pain and swelling or affect abnormal brain electrophysiology, the ONDAMED approach is focused on what we discover about the illness and its location. Once discovery is completed, ONDAMED accurately delivers focused pulsed fields to the dysfunctional cellular/tissue areas which are found with the unique biofeedback loop.

ONDAMED's emotionally driven feedback helps locate the patient's weakened or dysfunctional areas such as inflammation, degenerated tissue or even more critical areas linked to experienced traumas, residing at a cellular level. Traumas that reside on a cellular level often prove to be the primary cause of disease and dysfunction.

It is quite impossible for either the practitioner or the patient to find such areas by themselves. The solution is "Emotional Biofeedback", which an ONDAMED practitioner receives when stimulating the patient's nervous system with specifically selected pulsed fields at an area which may be linked to an either recent or even old physiological, mental, or emotional trauma.

It is thought that by stimulating areas connected with experienced traumas, the focused fields reanimate the areas' functions.

Reanimating these areas' functions may help patients resolve the secondary indication or symptom(s), for which the patients had originally come to seek help. ONDAMED may be considered a combination of "emotional feedback therapy" and "focused electro-magnetic stimulus causing an induction within tissue".

Within minutes, the ONDAMED therapist finds the specific treatment stimuli for the patient, finds the actual location that is in most need to receive therapy and treats the discovered area by applying a systemic therapeutic stimulus. The stimulus energizes the flow of electrons across natural immune system inflammation barriers. These barriers are often undetectable or treatable in any other way, and include free radical scavengers.

When placing the nonintrusive applicator to a specific area, electrons and white blood cells are summoned to the area to start the repair process.

ONDAMED, therefore, jumpstarts the body's immune functions and directs the immune response to the area of dysfunction, which is often hidden or in "stealth mode" to the immune system. Cells and tissue in need of therapeutic stimulation can be oscillated by specific resonant frequencies selected from a wide range of 0.1 to 32,000 Hz. In standard electro-medical treatment, the tissue of least resistance will draw the current while potential dysfunctional tissue stays untreated.

ONDAMED applicators emit a focused field, which implements a vector driven current induction to access the tissue of dysfunction.

A vector driven current induction allows stimulation of tissue dependent on the position of the applicator rather than the tissue's structure.

Tissue vibration can enable detoxification of unwanted heavy metals, waste and toxins, potentially resulting in improved metabolic functions. Nutrients, remedies and supplements can then be assimilated by "cleaner", or detoxified tissue and cells.

The lymphatic system (an important part of the immune system) can also be stimulated. Toxins and waste can then be discharged by stool, urine, sweat and the release of fluid in certain areas.

One of the first effects patients usually notice is a general feeling of relaxation due to the influence of ONDAMED's resonant stimulus on the entire central nervous system, particularly when the therapy calls for frequencies in the delta and theta ranges.

ONDAMED's wide range of personalized frequencies enables the targeted therapy of a wide range of issues; often issues with difficult abnormalities otherwise going undetected.



### **THE ONDAMED COMPLETE SOLUTION**

After all, it is the specific tissue of the individual that we treat and not just a symptom or disease. The ONDAMED System enables the practitioner to draw upon four prepared Modules and each Module can be considered application specific:

#### **Module 1:**

Selecting and using 2 specific pulsed fields relating to organs and organ systems.

#### **Module 2:**

Selecting and using 170 preset protocols to stimulate tissue with pre-programmed frequency combinations.

#### **Module 3:**

Selecting and using one (1) highly focused frequency to stimulate immune functions.

#### **Module 4:**

Selecting and using nutritionally related resonant frequencies.

From your research, you will find that the ONDAMED technology stands on its own due to its intelligence and personalization to each patient. The use of this 20+ year old invention allows the practitioner to obtain a larger diagnostic perspective of the patient complementing, yet going beyond standard diagnostics and offers the solution as to WHERE treatment is needed on the body and WHICH frequencies prove most significant for the patient.

The ONDAMED epigenetic impact is now being considered, and while we appreciate that no energy system or even medication can bring about a cure of any disease, ONDAMED shows that the body can effectively be stimulated to heal itself.

It has become recognized that the body's DNA, when fully able to express its protective (genes) mode by enabling the reduction of the excessive cellular histone acetylase DNA tightening, may become the 'holy grail' of healing most chronic diseases. Leading scientists are now in hot pursuit to determine if biological energy healing will become the final answer to histone acetylase reduction.

A multi-disciplinary collaborative program between Alfa-Gene Bioscience Inc., NJ, the Department of Biology, City University of New York and the Ondamed Companies in New York and Germany is now underway to study bio-interactive mechanisms of ONDAMED's focused electromagnetic fields with cell and/or tissue types in the physiological and disease state. Modern bio-medical engineering tools, novel stem cell technology, sophisticated cellular, molecular, and genetic techniques are utilized in our studies. The results will be published in the near future.

Finally, ONDAMED encompasses the individual's specific needs at the time of discovery by finding the patient-specific treatment stimulus, the exact location that needs stimulation and non-intrusively delivers the stimulus during the same session, often providing immediate results.

ONDAMED is both practitioner and patient friendly. ONDAMED "a better way to make you better" couldn't be easier to learn and use.

We invite you to learn more about integrating ONDAMED into your daily practice life.

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Rolf Binder: Inventor of the ONDAMED Technology and Founder of the ONDAMED companies in Germany and New York and The Binder Institute for Personalized Medicine in Germany. Binder worked as an electronics engineer in research and development of a German Biomedical technology company for twelve years. In 1993, Binder came up with a totally new approach with his own invention of the ONDAMED. His goal was to create a treatment modality for the medical field which offers a specific intervention driven by the patient's hidden emotional information linked to physiological stress and disease.

Silvia Binder is CEO of the Ondamed Companies in New York and Germany and the Founder of The Binder Institute for Personalized Medicine in Southern Germany. She was born in Germany, and grew up in Vienna, Austria, where she earned her degree in business. Her career led her to New York in 1989 where she lived for 22-years until moving back to Germany in 2010. Her personal story with her 5-year old son fueled her passion for integrative medicine. Silvia received her N.D. degree from the College of Naturopathy in London, U.K. followed by her Ph.D. degree in naturopathy. Silvia has been helping chronically ill patients from around the world, she is faculty of the American Academy of Anti-Aging Medicine, is on the Advisory Boards of the Medical Wellness Association and the Occidental Institute Research Foundation. She is involved with clinical studies at various university clinics, lectures around the world, and offers specialized courses on Integrative Personalized Medicine and Biomedical Information Therapy (Bio-IT) for healthcare practitioners. She is the author of several scientific publications and the book "Ondamed A story of love, healing, and medical revolution".

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AND OBESITY.<sup>1</sup>**

Poor glucose control and insulin resistance are two of the most pervasive biomarkers associated with chronic diseases affecting over 80% of Americans.<sup>2</sup> Insulin resistance occurs for a variety of reasons, but in most cases the struggle is that our diets tend to gravitate toward starchy foods with high sugar content. Researchers have suggested that an important factor of this epidemic is the increased intake of simple carbohydrates that are rapidly absorbed (particularly sugars).<sup>1</sup> ■ The issue with simple carbohydrates, like sugar, is that they are quickly converted into blood glucose. After consumption, the pancreas detects this sudden rise in glucose and tries to regulate it by excreting insulin into the bloodstream. A rise in insulin signals the body to stop burning stored fat and begin to burn circulating glucose. Until glucose levels return to normal, the body is more efficient at storing fat than burning it.<sup>2</sup> ■ A sensible diet and exercise plan is the cornerstone of metabolic management — however — *if we can begin to safely impact the absorption of glucose, help insulin receptors work more efficiently, and at the same time increase the amount of resistant starch that gets delivered to the large intestine (to feed the microbiome and modulate the gut hormones responsible for appetite) — we start to take a very big step toward health.* ►



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Recently, there has been a shift towards the reduction carbohydrate intake, particularly simple carbohydrates, as an approach to manage excess weight.<sup>5</sup> The digestion of carbohydrates begins with amylase secreted by the salivary glands. The alpha-amylase inhibitor properties of white kidney bean extract have been heavily studied with positive results in delaying the digestion and absorption of carbohydrates, thereby lowering their glycemic impact.<sup>5, 6, 7</sup> Carbohydrates that are resistant to digestion in the small intestine are delivered to the large intestine where they act more like dietary fiber — feeding the microbiome and upregulating GLP-1 which regulates satiety signaling. In a 12-week weight-loss and a subsequent 12 week weight-maintenance study, subjects were randomized to receive either a patented, proprietary extract of white kidney bean or a placebo.<sup>7</sup> All subjects adhered to a mildly hypocaloric diet and body

weight and other body composition parameters were measured at baseline and every 4 weeks thereafter.<sup>7</sup> At the end of the 12-week weight-loss period, the treatment group lost a mean of  $2.91 \pm 2.63$  kg in body weight compared with  $0.92 \pm 2.00$  kg in the placebo group.<sup>7</sup> During the weight maintenance phase, 36 out of 49 subjects were able to maintain their weight, even without dietary restrictions.<sup>7</sup>

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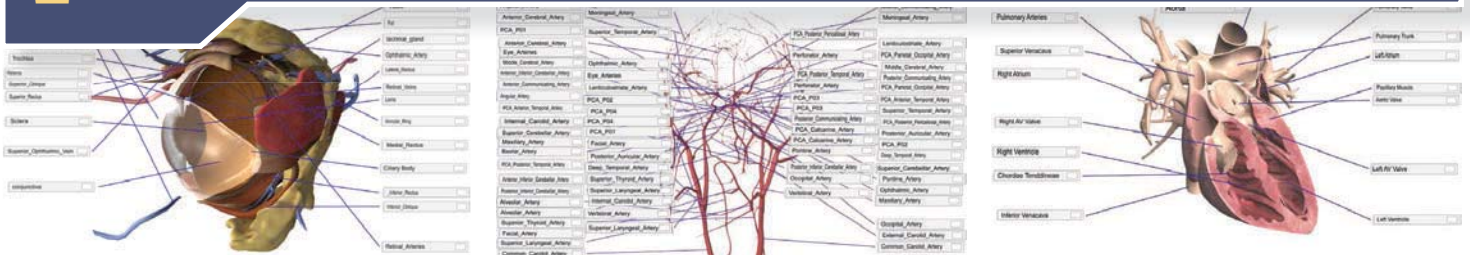
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Scan Results		Scan Test		Low		Normal		High		Positive		Negative		Low		Normal		High	
CLIENT	Doe John	234765275	6/20/1995	62	M	6'6"	178												
SCAN	3/8/2017	12:38:55 PM																	
PROVIDER	Acme Company	1234 5th Street, Burley Idaho	801-562-7493																
Scan Test																			
Blood Other		Albumin																	
Blood Other		Circulating Immune Complex(CIC)																	
Blood Other		Ferritin																	
Blood Other		Total Iron Binding Capacity																	
Blood Other		Serum Iron																	
Blood Other		Total Protein																	
Blood Other		Adhesion Degree of Shoulder Muscles																	
Blood Other		Age of Ligaments																	
Blood Other		Lumbar Circulation Limit																	
Blood Other		Lumbar Fiber Penetrating Dimension																	
Blood Other		Bone Alkaline Phosphatase																	
Blood Other		Apparent Bone Density																	
Blood Other		Long Bone Healing																	
Blood Other		Osteocalcin																	
Blood Other		Short Bone Cartilage Healing																	
Blood Other		Anatomical Calcium Loss																	
Blood Other		Bone Mineral Density																	
Blood Other		Degree of Bone Hyperplasia																	
Blood Other		Degree of Osteoporosis																	
Blood Other		Osteoclast Coefficient																	
Blood Other		Cerebral Arteriosclerosis																	
Blood Other		Functional Status of Cranial Nerve																	
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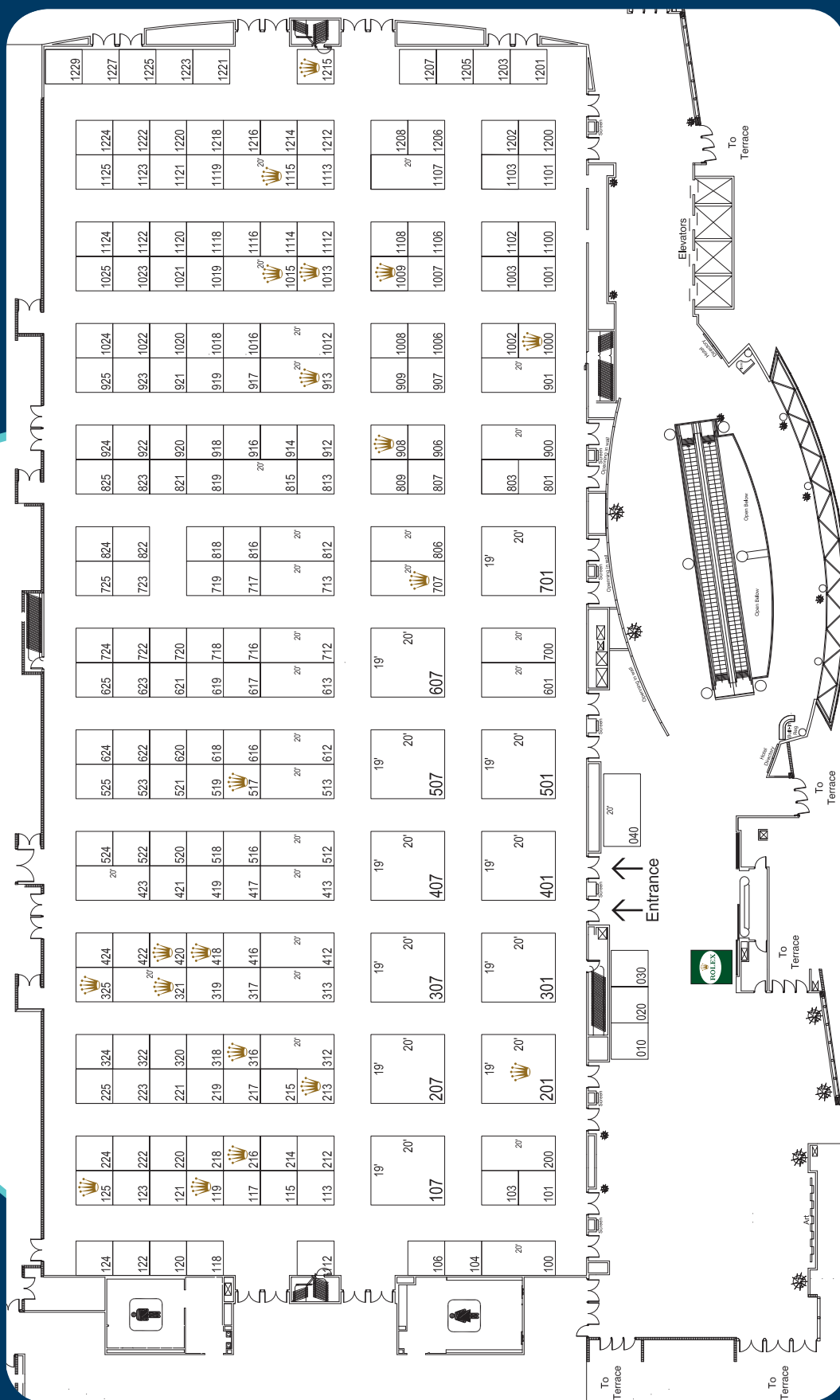
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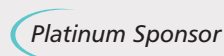
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Healeon Medical provides innovative medical devices, clinical expertise and and support for autologous point-of-care treatments.

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**HempMeds • Booth #1214**

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Ph: 866-273-8502 • Fax: 866-273-8502

Email: [info@hempmedspx.com](mailto:info@hempmedspx.com) • Website: [www.hempmedspx.com](http://www.hempmedspx.com)

Your Trusted CBD Source, HempMeds is the leading worldwide retailer and distributor of hemp CBD oil products, best known for its flagship product line, Real Scientific Hemp Oil™. The company offers 100% natural products derived from unique non-GMO European hemp cultivars using proprietary technologies. HempMeds® continues to lead across the globe, as the first legal CBD distributor in Brazil and Mexico.

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**High Tech Health International, Inc. • Booth #1206**

5621 Arapahoe Ave., Ste. D, Boulder, CO 80303 USA

Ph: 800-794-5355 • Fax: 303-449-9640

Email: [info@hightechhealth.com](mailto:info@hightechhealth.com) • Website: [www.hightechhealth.com](http://www.hightechhealth.com)

High Tech Health International pioneered detoxification via infrared sauna therapy and pH balance via alkaline water ingestion with the goal of maintaining body homeostasis. Today, 4,000+ health practitioners in 57 countries use and recommend the Thermal Life Sauna, Transcend Sauna and Ionizer Plus Electrolyzer to protect against toxicity, inflammation and acidity. High Tech Health most recently launched molecular hydrogen products with Vital Reaction.

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**High Tech Hydrogen International - Vital Reaction • Booth #1208**

5621 Arapahoe Ave., Ste. D, Boulder, CO 80303 USA

Ph: 800-794-5355 • Fax: 303-449-9640

Email: [info@hightechhealth.com](mailto:info@hightechhealth.com) • Website: [www.hightechhealth.com](http://www.hightechhealth.com)

Vital Reaction offers superior molecular hydrogen products that exhibit anti-inflammatory, anti-oxidant and anti-apoptotic properties. The Vital Reaction Inhaler generates hydrogen mixed gas for inhalation with the ability to penetrate biomembranes, including the blood brain barrier. The Vital Reaction Tablets deliver molecular hydrogen to the body's organs and tissues by super-saturating any non-carbonated beverage with the highest ppm in the least amount of time, providing the most benefits and convenience.

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**Hopkinton Drug, Inc. • Booth #416**

52 Main St., Hopkinton, MA 01748 USA

Ph: 800-439-4441 • Fax: 508-435-5983

Email: [pharmacy@rxandhealth.com](mailto:pharmacy@rxandhealth.com) • Website: [www.rxandhealth.com](http://www.rxandhealth.com)

Hopkinton Drug is a compounding pharmacy located in Hopkinton Massachusetts. In our state of the art compounding lab, we create hundreds of medications for practitioners working in but not limited to the following areas of medicine; Functional/Integrative, HRT, Endocrinology, Dermatology, Pain and Pediatrics. One of our specializations is working with those who diagnose and treat Lyme disease and mold illness. We work with practitioners nationwide and ship to most states.





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Ph: 786-403-3485 • Fax: 786-403-3485

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International Skin Care is providing high quality technology, and products that offer tailored cosmetic solutions to its clients. ISC is celebrating beauty through safe cosmetics, technological innovation, and non-toxic formulas. We focus our efforts towards providing our clients with the latest in high quality cosmetic technology. Our mission is to distribute skin care and other cosmetic treatments that will allow men and women to maintain a natural, youthful appearance by using safe, innovative, non-surgical, and non-invasive procedures.



### KBMO Diagnostics • Booth #318

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Email: info@kbmodiagnostics.com • Website: www.kbmodiagnostics.com

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### **LaserCap® Company • Booth #221**

3615 Superior Ave., Suite 4203D, Cleveland, OH 44114 USA

Ph: 855-424-7774 • Fax: 860-201-1846

Email: support@laser-cap.com • Website: www.laser-cap.com

LaserCap® Company was formed in 2006 by co-inventors Michael Rabin, MD and M.I.T.-trained optical physicist David Smith, PhD, in collaboration with Harvard-based photo medicine expert Michael Hamblin, PhD and internationally acclaimed hair restoration physician Robert Haber, MD, to develop innovative light-based devices for the Global Beauty & Health Industries. Its first commercial product LaserCap®, is for women and men with thinning hair or at risk for thinning hair. This is a condition that affects up to 50% of adult women and 80% of adult men. Their newest FDA cleared product innovation released in 2017 is the LaserCap® MC<sup>2</sup>™, providing maximum comfort and maximum coverage.

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### **Life Length • Booth #619**

Miguel Angel 11, 2º Floor., Madrid ES29 28010 Spain

Ph: +34 91 737 12 98 • Fax: +34 91 310 1753

Email: yfernandez@lifelength.com • Website: www.lifelength.com

Life Length, world leader in telomere measurement, is a U.S. Federal CLIA certified, internationally accredited clinical lab. We provide our proprietary Telomere Analysis Technology® (TAT®) to physicians. The TAT uniquely measures telomeres at the chromosomal level, providing the crucial measure for measuring cellular senescence and hence biological age. As an independent biomarker for many diseases, our TAT supports clinical decision-making in early detection and risk stratification.

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LivOn Laboratories has been the industry leader formulating high performance dietary supplements that offer genuine health benefits for the past thirteen years. LivOn Labs Lypo-Spheric™ Vitamin C was the world's first unidose Liposomal vitamin C gel. Each Lypo-Spheric™ product is formulated with one goal in mind: to provide you with effective doses of nutrients without the use of binders, fillers, artificial colors or artificial flavors. LivOn Labs' invites attendees to visit our booth and meet Thomas E. Levy MD, JD and sample our products.

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### **MasterPharm Compounding Pharmacy • Booth #219**

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Email: [answers@mcguffpharmacy.com](mailto:answers@mcguffpharmacy.com) • Website: [www.mcguff.com](http://www.mcguff.com)

McGuff Compounding Pharmacy Services provides a level of commitment and value that is unsurpassed. We are independently certified as ISO 9001:2008 compliant and accredited by the Pharmacy Compounding Accreditation Board (PCAB). We compound all dosage forms including sterile injections and deliver to all US states, territories and protectorates. Product quality and patient safety are our number one concern.



### MegaSporeBiotic • Booth #1207

1332 Waukegan Rd., Glenview, IL 60025 USA

Ph: 855-729-5090 • Fax: 224-521-1216

Email: [info@gomegaspore.com](mailto:info@gomegaspore.com) • Website: [www.gomegaspore.com](http://www.gomegaspore.com)

MegaSporeBiotic is dispensed by Microbiome Labs, which was born out of the desire to improve the tools that integrative physicians have to improve the health and well being of their patients. Microbiome Labs was founded by a practicing doctor and is dedicated to creating nutritional supplements with the highest quality, potency, and efficacy for health care professionals.



### Meridian Valley lab • Booth #620

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Ph: 855-405-8378 • Fax: 206-209-4200

Email: [info@meridianvalleylab.com](mailto:info@meridianvalleylab.com) • Website: [www.MeridianValleyLab.com](http://www.MeridianValleyLab.com)

Meridian Valley Lab is a world leader and pioneer in 24-hour urine hormone, food sensitivity, blood viscosity, and glucose control testing. Founded in 1976 by Jonathan Wright, MD, Meridian Valley Lab has always been at the forefront of laboratory testing in large part due to Dr. Wright's pioneering spirit and his fearless dedication to serving humanity. Every test ordered comes with a free consultation with Meridian Valley Lab's very own consulting physicians.



### Metabolic Code • Booth #307

5000 T-Rex Ave., Ste. 200, Boca Raton, FL 33431 USA

Ph: 561-972-9547 • Fax: 877-510-6816

Email: [msavage@metaboliccode.com](mailto:msavage@metaboliccode.com) • Website: [www.metaboliccode.com](http://www.metaboliccode.com)

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Metagenics was founded on a revolutionary idea-our genes do not pre-determine our health potential, and through nutrition, we can impact how our genes express themselves. Utilizing innovative research and novel technologies, we produce high-quality science-backed nutraceuticals and medical foods specially designed to support practitioners in their efforts to help patients achieve their health and wellness goals.

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People are turning to genetic testing to help find answers to their health and need an experienced practitioner to help them. MethylGenetic Nutrition Analysis online software is the tool you need to easily guide you through this seemingly complex process. MGNA creates nutritional pro-protocols, based upon one's unique DNA, lab work, and presenting symptoms, giving you the ability to Assess, Analyze and Design Support. This will take your practice into the future of care.

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1 Madison St., Ste. F6, East Rutherford, NJ 07073 USA

Ph: 800-747-7418 • Fax: 973-470-0017

Email: customerservice@mushroomwisdom.com • Website: www.MUSHROOMWISDOM.com

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Email: susan@humann.com • Website: www.HumanN.com

About HumanN, formerly Neogenis® Medical:

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## NeoMed Innovations LLC • Booth #1220

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### **Purium • Booth #1112**

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### **Quicksilver Scientific • Booth #815**

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Ph: 303-531-0861

Email: [front.desk@quicksilverscientific.com](mailto:front.desk@quicksilverscientific.com) • Website: [www.quicksilverscientific.com](http://www.quicksilverscientific.com)

Quicksilver Scientific was founded in 2005 in Lafayette, Colorado. Quicksilver Scientific is a CLIA certified laboratory specializing in superior liposomal delivery systems and blood metal testing for human health. We use state-of-the-art technology, including patented mercury speciation, for the most accurate, reliable testing available on the market. Our liposomal supplements incorporate Quicksilver Delivery Systems, which brings the power of intravenous therapy to oral delivery and dramatically increases absorption and effectiveness. Our line of products and protocols help restore the body's natural detoxification system and re-establish natural health and optimum functioning.



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Email: [corp@nuaxon.com](mailto:corp@nuaxon.com) • Website: [www.rebelherbs.com](http://www.rebelherbs.com)

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Refine USA, LLC located in Jacksonville, FL has been a market leader in manufacturing and distribution of premier aesthetic technologies for over a decade. We pride ourselves in designing and developing medical devices that meet the clinical and financial needs of aesthetic health care providers. The Rejuvaben® Automatic Therapy System, and the Purespin PRP® System are just a couple examples of our "market changing" technologies.



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REDEFINING MEDICINE

# 2017 Educational Schedule



## MAY

San Diego Marina Marriott  
San Diego, CA

**Symposium - Lab Interpretation**  
May 4-6, 2017

**Intro to Anti Aging Medicine Workshop**  
May 7, 2017

San Francisco Marriott Marquis  
San Francisco, CA

**Module III - Neurology**  
May 19-21, 2017

**Module V - Nutrition and Exercise**  
May 19-21, 2017

## JULY

West Palm Beach Hilton  
West Palm Beach, FL

**Pellet Workshop**  
July 28-29, 2017

**Sleep Workshop Part II**  
July 29, 2017

## AUGUST

Venetian/Palazzo - Las Vegas  
Las Vegas, NV

**Module VII - Autoimmune Disease & Inflammation**  
August 10-12, 2017

**IV Symposium/Chelation**  
August 11-12, 2017

**Chronic Infections Workshop Part II**  
August 12, 2017

## SEPTEMBER

Chicago Marriott Downtown  
Chicago, IL

**ABAARM & ABAHP Exams**  
September 13-16, 2017

**BHRT Symposium**  
September 14-16, 2017

**Module IV - Gastroenterology**  
September 14-16, 2017

**Module XVI-C - Cardio**  
September 14-16, 2017

**Module XX-A - Triad**  
September 14-16, 2017

**Aesthetic Module I - Injectables & Cosmeceuticals**  
September 14-16, 2017

## OCTOBER

Sheraton Boston Hotel  
Boston, MA

**Weight Symposium**  
October 6-7, 2017

West Palm Beach Hilton  
West Palm Beach, FL

**Pellet Workshop**  
October 20-21, 2017

**Advanced Symposium - Sexual Health**  
October 20 - 21, 2017

**Bio-Energetic Workshop**  
October 21, 2017

## DECEMBER

Venetian/Palazzo - Las Vegas  
Las Vegas, NV

**ABAARM/ABAHP Written Exams**  
December 13, 2017

**ABAARM Oral Exams**  
December 14-16, 2017

**World Congress**  
December 14-16, 2017

**Practice Enhancement Training**  
December 12-13, 2017

**Peptides Pre-Conference Workshop**  
December 13, 2017

**Obesity Management Pre-Conference Workshop**  
December 13, 2017

**Nitric Oxide Pre-Conference Workshop**  
December 13, 2017

**Module I - Endocrinology**  
December 14-16, 2017

**Module VIII - Clinical Practice Protocols**  
December 14-16, 2017

**Aesthetic Module II - Laser & Light**  
December 14-16, 2017

**Menopause/Andropause Workshop**  
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