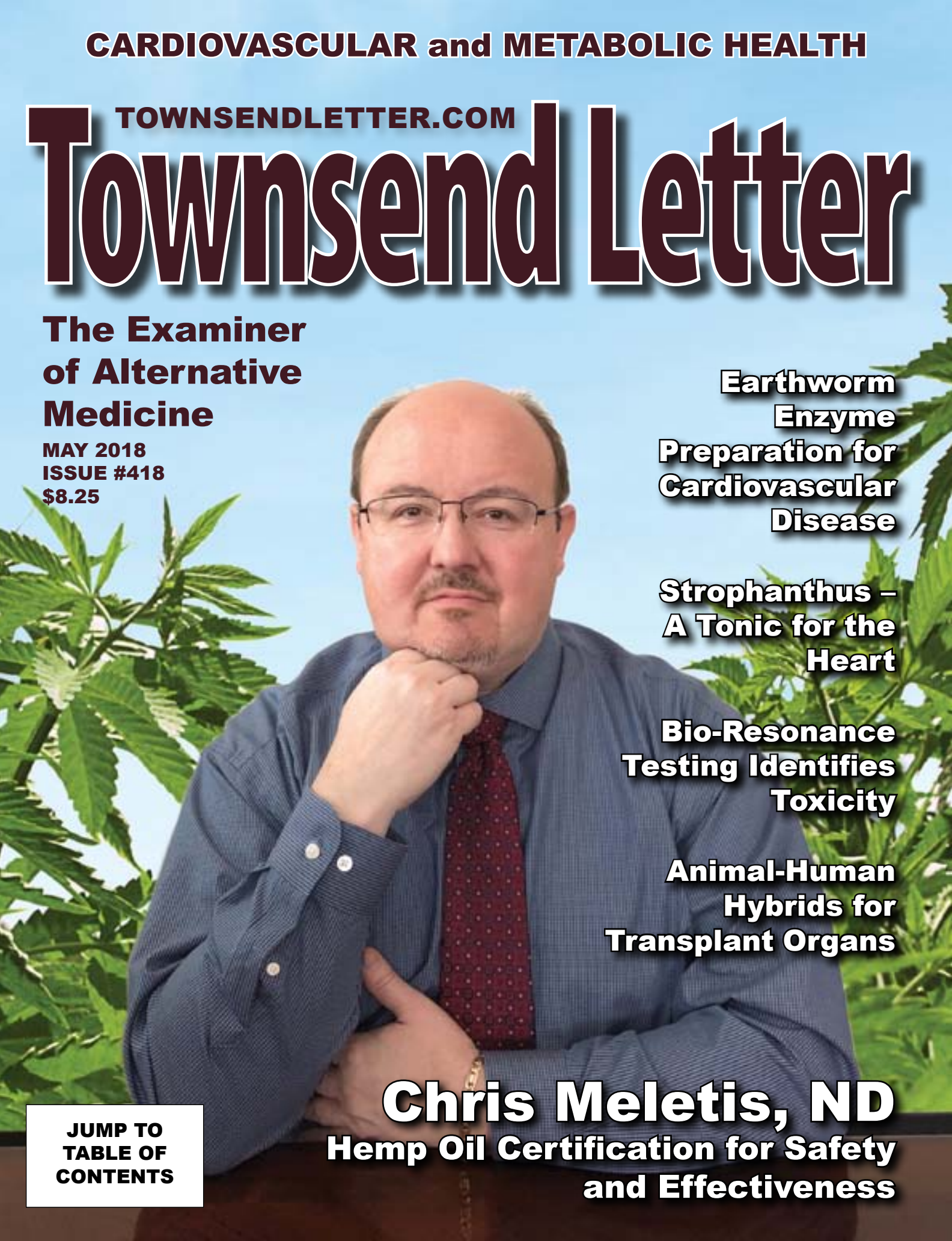
CARDIOVASCULAR and METABOLIC HEALTH

TOWNSENDLETTER.COM

Townsend Letter

The Examiner of Alternative Medicine

MAY 2018
ISSUE #418
$8.25



Earthworm Enzyme Preparation for Cardiovascular Disease

Strophanthus – A Tonic for the Heart

Bio-Resonance Testing Identifies Toxicity

Animal-Human Hybrids for Transplant Organs

Chris Meletis, ND

Hemp Oil Certification for Safety and Effectiveness

JUMP TO TABLE OF CONTENTS

Thank you for purchasing this issue of *TOWNSEND LETTER*

On the cover (next page) you will find a button that will take you directly to the table of contents. Once there, you can click page numbers that take you directly to articles. Click on "return to table of contents" at the bottom of each page to take you back to the TOC.

Most web and email addresses are clickable within the articles and in the calendar. We do not guarantee the accuracy of each address/URL, or that it is clickable.

Please don't overlook our advertisers, without their support *Townsend Letter* would not exist. Take the time to discover companies you might not be familiar with, many of whom offer special pricing for *Townsend Letter* subscribers. An advertiser list is printed on page 86 with clickable page numbers that will take you directly to their ad(s).

Subscription Rates and Options

Prices valid through 12/31/2020

Name _____ Email/Phone _____

Address _____

City/State/Zip _____

Payment accepted in US funds, payable by check / money order / credit card / or billed via PayPal

Payment by: Visa/MC/AMEX/Discover # _____ Expiration date: _____

Signature _____

Click here to subscribe online

	Description	Print Version	E-Edition	Combined
US Addresses (except WA state)	1-year Domestic US	$76.99	$66.99	$91.99
	2-year Domestic US	136.99	116.99	166.99
	6-month Domestic US	45.99	41.99	–
	1-year Student Domestic US	56.99	41.99	66.99
Washington State Residents	1-year Washington state (w/tax)	86.99	74.99	99.99
	2-year Washington state (w/tax)	146.99	127.99	183.99
	6-month Washington state (w/tax)	33.99	46.99	–
	1-year Washington Student (w/tax)	56.99	46.99	66.99
1st Class	1-year First Class Domestic US	96.99	66.99	111.99
	2-year First Class Domestic US	176.99	116.99	206.99
International Rates	1-year International (US$)	105.99	66.99	120.99
	2-year International (US$)	202.99	116.99	232.99
	6-month International (US$)	63.99	41.99	–
	1-year International student (US$)	76.99	41.99	93.99

SPECIAL RECEPTION ROOM OFFER:
Purchase a 2nd subscription for your waiting room

$57.99 US addresses – $87.99 International
Offer valid with current existing subscription

E-Edition Single Issue: $15.00

E-Edition Single Issue WA State (includes tax): $16.00

Single Print Issues: cover cost (for each issue), plus shipping charges, applicable taxes, and $3 per-order handling fee.

Townsend Letter
911 Tyler Street | Port Townsend WA 98368
info@townsendletter.com
360.385.6021 | 360.385.0699 (fax)
www.townsendletter.com

Snoring Problems

NoZovent®
the anti-snoring device

- Easier to breathe
- Easy to use
- Clinically proven
- Eliminate the feeling of stuffy nose from colds and allergies

Available from major distributors such as *Threshold, Emerson Ecologics, and Super Natural.*

Developed by a leading Swedish ENT doctor.

These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Scandinavian Formulas

Sellersville, PA 18960 • **P:** 215-453-2507 800-688-2276
F: 215-257-9781 • scandinavianformulas.com

The First and Only CBD Formula Produced Exclusively for Doctors.

*Douglas Laboratories® is a registered trademark of Atrium Innovations, Inc. and not affiliated with TruGen3®
† This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Personalized labeling available

- The only hemp oil product in the professional channel lab-tested using ICH standards that support and validate two-year shelf life.
- Exclusive VESIsorb® Technology provides up to 6x more CBD hemp oil bioavailability †
- Solvent-free SMB chromatography extraction for undetectable THC levels (unlike lipid-based and other extraction methods used in substandard CBD products that retain THC).
- 25mg of CBD & 6mg of beta-caryophyllene

Your Patients Deserve the Best.

TruEase® is truly today's best-in-class CBD product for discriminating Health Care Professionals. A TruGen3® exclusive, TruEase® delivers an ideal concentration of CBD, enabling bioactives like betacaryophyllene (BCP) to deliver synergistic interaction between phytocannabinoids and terpenes. This superior ratio of 4:1 (CBD:BCP) supports each other's function perfectly as BCP is directly linked to activating CBD in the body via CB2 receptors. (Beware inferior CBD products with zero levels of BCP and low-potency hemp oil (as little as 5% CBD, compared to 60% found in TruEase®).

TruGen3® continues Douglas Laboratories' family legacy, with our third generation and more than half-century of nutraceutical experience. All TruGen3 products are produced under the highest ethical standards and available only through Health Care Professionals.

Contact us today for FREE SAMPLES and to find out how you can put our innovative, one-of-a-kind products to work for your patients, and your practice, today.

Seeing is Believing

See for Yourself at www.trugen3.com/vesisorb

Patented VESIsorb® technology is clinically proven to provide up to 6X more bioavailability via multiple PK studies measured in human subjects.†

Competing Softgel

Formula does not go into solution; note separation of ingredients.

VESIsorb® Softgel

100% in solution; completely homogenous colloidal solution for optimal absorption.

TruGen3®

Three Generations of Truth in Nutrition

www.trugen3.com 1-844-387-8436

Going to ***bed*** and going to ***sleep*** are two different things.

Give your patients the sleep they need with two NEW PheniTropic™ products from Biotics Research!

Chronic stress has been linked to a number of life-threatening health conditions and is believed to be the cause of more than 75% of all doctor visits. High stress levels not only negatively impact our mental and physical health, they can also be a key contributing factor for sleep problems suffered by approximately 1/3 of all Americans.

Biotics Research Corporation now offers two new products, **PheniTropic™ PM** and **PheniTropic™ Ultra PM**. These superior nutritional supplements target neurotransmitter health, promoting an overall relaxation response, and support improved sleep and mood.

BIOTICS® RESEARCH CORPORATION

800-231-5777
www.bioticsresearch.com

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

METHYLATION SUMMIT

INTEGRATING METHYLATION INTO CLINICAL TREATMENT PLANS

CHICAGO JULY 13-15, 2018


Matthew Pratt-Hyatt, PhD


Nicole Bijslma, ND, LAc


David Quig, PhD


Debby Hamilton, MD, MPH


Andrew Rostenberg, DC


Carrie Jones, ND


Stephanie Seneff, PhD


Carolyn Ledowsky, ND
Director of MTHFR Support Australia


Sara Wood, ND

Are your toughest to treat patients not improving even while following your standard successful treatment protocol?

Do you wonder why some patients improve while others do not?

Why do so many patients experience such difficult Herxheimer reactions?

Why can some patients not overcome detoxification challenges?

Think Methylation. Dysfunctional methylation impairs the body's detoxification process, and it may be the answer to the aforementioned questions. Beyond methylation genetics, many otherwise "healthy" patients experience methylation issues. This widespread problem is a result of the environmental impact on our methylation pathways, and it impacts a significant number of your patients and the general population. Whatever the cause(s), understanding why it is happening AND how to fix it is essential. **Effective treatment goes way beyond just adding methylated B vitamins.**

EXPERIENCED FACULTY

The experienced faculty includes practitioners who specialize in methylation impairment and researchers with many published papers. The faculty is on the cutting edge of evidence-based integrative medicine, including the most recent methylation research, advanced diagnostics and proven treatment protocols.

REGISTER EARLY & SAVE!

Early Bird Special:
$449 until April 30, 2018
After April 30, 2018: $549

Sponsored by
Researched Nutritionals® solutions for life
MTHFRSUPPORT

Price includes Pre-Conference Methylation Basics Online course, Saturday breakfast & lunch, Sunday breakfast.

REGISTER BY PHONE
1 805 693 1802 Option 1

REGISTER ONLINE
ResearchedNutritionals.com/methylation-summit

From the Publisher

Chelation Therapy for Cardiovascular Disease Gains Respect

When I was "introduced" to alternative medicine in February 1977, in Baton Rouge, Louisiana, by a district manager of Standard Process Vitamins, I was told to visit Ray Evers, MD, in Cottonwood, Alabama. Evers operated a clinic that provided intensive intravenous chelation therapy. He converted a barn into a treatment center with more than 60 beds. Patients received IV chelation daily – some received it on a continuous basis overnight. Evers didn't limit his use of chelation to patients with cardiovascular disease. He felt it was an appropriate treatment for most degenerative conditions: heart and peripheral vascular disease, cerebrovascular disease, degenerative arthritis, neurologic disorders, diabetes, cancer, and more. Evers did rounds on his patients twice daily – early in the morning and late in the afternoon operating his

continued on page 6 ➤

Superior Cardiovascular and Metabolic Support*

from Allergy Research Group®

Pycnogenol® 100

Original French Maritime Pine Bark Extract

Item #77270
30 vegetarian capsules
100 mg per capsule

Unique combination of procyanidins, bioflavonoids, and phenolic acids, with more than 400 published studies and review articles that demonstrate its safety and efficacy.* Supports normal capillary wall strength and permeability, circulation, endothelial function, and brain function.*

Berberine 500

Metabolic Support*

Item #77280
60 vegetarian capsules

Pure, concentrated berberine (97%). Supports normal, healthy blood sugar, cholesterol within normal levels, and normal balance of microbes in the respiratory and gastrointestinal tracts.* Obtained from non-GMO Indian barberry, and contains no common allergens.

Nattokinase NSK-SD®

Circulatory System Support*

Available in 36 mg, 50 mg and 100 mg potencies

Nattokinase NSK-SD®, was introduced to the US market by Allergy Research Group® in 2002. It has established standardization and quality levels for all nattokinases. Provides nutritional support for the maintenance and enhancement of normal healthy endogenous fibrinolysis.*

Lumbrokinase

Circulatory System Support*

30 or 60 delayed release phthalate-free vegicaps

Proteolytic enzymes, derived from the earthworm *Lumbricus rubellus*. Research has shown lumbrokinase to support healthy coagulation of blood within normal levels and enhance fibrinolytic activity, i.e. similar to nattokinase.*

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

AllergyResearchGroup®
Innovative Nutrition

800.545.9960
info@allergyresearchgroup.com
www.allergyresearchgroup.com

NSF GMP Registered

emerson QUALITY PROGRAM

natural partners

From the Publisher

➤ *continued from page 4*

facility more like a hospital than a clinic. I regret that I never made the trip to Cottonwood and did not get to observe Evers in action. Treating so many patients who were on their last legs would lead not infrequently to their passing and their relatives making a big fuss. Ultimately, the medical board in Alabama harassed Evers to the point where he had to move his operation to Mexico. Evers was never able to persuade the powers-to-be that chelation was sound medicine, efficacious, and safe.

In fact, despite a myriad of small studies that demonstrated effectiveness of chelation in treating cardiovascular disease, several larger studies done through the 1970s-1990s failed to confirm IV chelation's treatment benefit. Various medical journals seized upon the negative outcomes of these latter studies editorializing that chelation was unproven for the treatment of atherosclerotic conditions and unsafe (!) and should not be covered by Medicare or insurance. Quackbusters included chelation in their list of quack therapies. Practitioners who focused on chelation found themselves frequently under investigation by their local boards and were often forced to justify their care but still were sanctioned and occasionally delicensed. Without public or private funding, chelation practitioners continued to document chelation effectiveness in clinical studies that the mainstream journals ignored.

All of this changed with the completion of the National Institutes of Health TACT trial completed in 2012 and published in *JAMA* in 2013. As reviewed by Terry Chappell, MD, in the May 2017 issue of the *Townsend Letter,* TACT demonstrated significant benefit of intravenous EDTA chelation therapy in patients with atherosclerotic coronary artery disease. TACT revealed that chelation was an important treatment to prevent recurrence of cardiac events in patients with heart disease. Furthermore, it demonstrated even greater prevention in diabetic patients with atherosclerotic disease. Contrary to the editorials of the past, chelation was demonstrated to be safe, period. The American College of Cardiology and American Heart Association upgraded the evidence of chelation therapy to its classification of IIb. Such a classification matches the evidence for many therapies used in the treatment of heart disease. Despite the aforementioned, some critics remain unconvinced and attempt to dismiss the findings of the TACT trial trivializing its outcome with objections to methodology. Never mind that it was a ten-year study involving multiple institutions, randomized, and double-blinded. In fact, those

continued on page 8 ➤

DNA CONNEXIONS

DNA Connexions is a sophisticated laboratory specializing in the detection of microbial DNA. Polymerase chain reaction technology (PCR), with its high specificity and sensitivity, is the cornerstone of our testing methodology.

The Lyme Panel tests for four unique gene sequences found in *Borrelia burgdorferi*, in addition to 10 common tickborne co-infectors.

Visit link below to receive a free Patient Information brochure.

www.DNAConnexions.com/Townsend

➤ *continued from page 6*

chelation patients who concurrently received high potency multiple vitamin supplementation as part of their chelation protocol had the best outcomes.

When I initiated chelation therapy administration in the late 1970s, my patients were informed that chelation was worthless or worse. The insurance companies balked at covering my services and Medicare challenged any billings for chelation. If I brought up chelation to a cardiologist, the immediate response was that it is unproven. What a difference 30 years makes. Now cardiologists know that chelation is an effective and safe treatment, and patients who inform their cardiologist of their chelation treatment are acknowledged positively.

It is a shame that Evers died years before the TACT trial was completed. His work would have at last received the respect it deserved.

Terry Chappell, MD, Reviews Conventional and Alternative Treatments for Hypertension

As Dr. Chappell explains in his review of hypertensive therapies in this issue, the standards for defining hypertension dramatically changed on November 13, 2017. The American Heart Association and the American College of Cardiology set new guidelines for high blood pressure; instead of 140/90, cardiologists agreed that 130/80 should be the lower limit for hypertension. The lower reading meant that there would be an immediate 12% increase of hypertensive patients in the US. The AHA and ACC did not choose to seek consensus with family doctors who opted to retain the 140/90 limit. As noted by the Stanford Prevention Research Center, 29 million additional patients would require treatment, meaning addition prescription medication. Of course, integrative and naturopathic practitioners would argue that high blood pressure should not be managed with medication, but by lifestyle changes, exercise, herbal supplements, and other approaches. Chappell comprehensively reviews what should be done.

By and large high blood pressure can be managed with diet, salt reduction, mineral supplementation, stress reduction, and, if need be, a prescription drug. But sometimes these are not sufficient – the blood pressure remains elevated. The AMA approach is that if one drug is not completely effective, then a second drug is added. And if the two together are unsatisfactory, then a third drug is added, or a fourth, or more yet! Of course, such a strategy is likely to lead to one or more adverse effects. In fact, it is not infrequent for a patient to

continued on page 10 ➤

Tired of the Roller Coaster?

- ☑ Energy dragging?
- ☑ Sudden mood changes?
- ☑ Trouble concentrating?
- ☑ Sugar cravings?

Take control with SX-Fraction®

SX-Fraction® is a well-researched constituent found in the maitake mushroom that has been shown to support healthy blood sugar and insulin levels already within the normal range.*

Available through your health care professional, distributor or direct.

800-747-7418
Code TL518 – 20% Intro discount

MUSHROOM WISDOM®

emerson ECOLOGICS

natural partners

SCIENCE COMPLEMENTING ANCIENT WISDOM

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

➤ *continued from page 8*

be switched from one cocktail of anti-hypertensive drugs to another. Integrative physicians disdain such a strategy; in fact, a common goal for the practitioner and patient is to eliminate anti-hypertensive medications. But what if all these efforts fail and the patient continues to maintain an elevated blood pressure, especially in seeking this idealized limit of 130/80? Chappell offers a myriad of additional modalities that should be implemented in achieving normal blood pressure rather than stacking up medications.

Gary Huber, DO, Examines Testosterone's Role in Cardiovascular Health

Despite the fact that many patients are being screened with the Berkley Lipoprotein analysis, ultimately treatment is based on total cholesterol and LDL. When these are high, a statin drug is prescribed and, depending on the elevation of the triglyceride level, another drug or drugs are advised. However, as Gary Huber, DO, has written in March 2016,[1] elevated LDL cholesterol due to excessive fat in the diet is not the primary, much less, the sole cause of atherosclerotic heart disease. Yet this paradigm continues to be the chief consideration in treating the heart patient; failing to treat a diabetic with a statin to reduce their elevated LDL is considered malpractice. Huber emphasizes that it is not the LDL itself but its oxidation that causes the atherosclerosis. His explanation is that the oxidized LDL is captured by the blood vessel macrophages that transform into foam cells creating the plaque. Huber explains that the oxidized LDL creates an autoimmune process creating antibodies that hasten plaque formation. An elevation of these autoantibodies is predictive of major atherosclerotic events.

In 2015, Basaria and colleagues published a paper that raised alarms about the use of testosterone in patients who have atherosclerotic disease.[2] Basaria's work suggested that testosterone use posed a significant risk in men having heart disease. The paper was criticized by some for faulty methodology and statistical analysis. Nevertheless, there remains considerable concern in the conventional medical community about ad lib use of testosterone for "Low-T" not only because of cardiovascular concerns but also disputed worries about testosterone's role in initiating prostate cancer. Furthermore, the well documented benefits of testosterone in lessening the adverse effect of lipids in the atherosclerotic process, benefitting cardiovascular health, is being ignored.

Huber and Andrew Comb, RPh examine the truths and controversies in the medical literature and argue that testosterone definitely plays a role in cardiovascular health.

continued on page 12 ➤

Discover the Dr. Ohhira Difference!™

While most digestive health supplements contain only probiotics, Dr. Ohhira's exclusive formula is comprised of the three crucial components required for exceptional health, digestion and immune support: **PRE**biotics, **PRO**biotics, and **POST**biotics.* Dr. Ohhira's Probiotics™ award-winning, professional strength formula is the **ONLY 5-year fermented whole food supplement** that offers a truly exceptional probiotic containing three fundamental components:

PREbiotics—fermented fruits & vegetables that enrich the existing beneficial bacteria in the gut so they can thrive and poliferate *

PRObiotics—numerous strains of living probiotics including *Bifidobacterium* and *Lactobacillus*, which equates to a healthier microbiome and exceptional health for your patients*

POSTbiotics—amino acids, vitamins, minerals, and natural organic acids that are produced by the fermentation process and confirmed by science to be the most vital and health-promoting aspect of probiotic supplementation*

The final result is an organic, living fusion that merges and encourages the evolution of your exclusive internal bacteria. This, in turn, supports a healthy immune system and digestion of crucial micronutrients that the body needs to thrive and flourish.

ESSENTIAL FORMULAS®
PROFESSIONAL

DISTRIBUTED BY
emerson ECOLOGICS®

For More Information visit: www.essentialformulas.com/professionalformula • (972) 255-3918

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

From the Publisher

➤ *continued from page 10*

Our Cover Story: Chris Meletis, ND, Introduces Us to Certification for CBD Prescribing

While many states are legalizing the purchase of marijuana in retail stores and medical dispensaries, hemp oil cannabinoid (CBD) preparations with minimal THC content is being sold widely throughout the US. CBD hemp oil is touted to have significant medical benefit in many medical conditions including seizure disorders, pain management, anxiety and depression, musculoskeletal inflammation, and cancer. Unfortunately, hemp oil products are not regulated currently, and concentrations of CBD and THC may be mislabeled. It is not infrequent that the content of CBD is minimal compared to what is specified on the label. Furthermore, products may be adulterated with heavy metals, chemicals, and pesticides. An educational and regulatory group, the International Center for Cannabis Therapy (ICCT), is seeking to certify manufacturers and products to ensure proper labeling and safety of products. Chris Meletis, ND, has been named the Chief Medical Officer-USA of the ICCT, a role he will execute while continuing his naturopathic practice in Oregon. One of the main concerns for health practitioners is the lack of sufficient education for appropriate prescribing of CBD hemp oil. The ICCT will be offering an educational program by webinar modules leading to certification in CBD prescribing. The ICCT program will have a faculty of ICCT scientists and physicians who have researched the clinical use of cannabis and CBD. Practitioners will not only learn effective use of integrating CBD in a patient's medical program but also will be trained about legal regulations and marketing strategies.

Jonathan Collin, MD
Publisher

1. Huber G, Bankemper B. An integrative medical approach to reversing cardiovascular disease: Practicing beyond the standard of care. March 2016. Available at www.huperpm.com.
2. Basaria S, Harman S, et al. Effects of testosterone administration for 3 years on subclinical atherosclerosis progression in older men with low or low-normal testosterone levels; a randomized clinical trial. *JAMA,* 2015. 314(6) 570-581.

Townsend Letter
ISSN 1940-5434
Subscriptions • Editorial • Advertising
360/385-6021
24 Hr. Fax – 360/385-0699

911 Tyler Street
Pt. Townsend, Washington 98368-6541 USA
www.townsendletter.com | info@townsendletter.com

Editor-in-Chief Jonathan Collin, MD
Publisher Jonathan Collin, MD
Editor Jule Klotter
Contributing Medical Editor Alan Gaby, MD
Managing Editor Barbara Smith
Circulation Manager Joy Reuther-Costa
Managing Assistants Julie Reuther; Jill Tomasi
Advertising Projects & Accounts Barbara Smith, Joy Reuther-Costa, Jonathan Collin

Published by
Townsend Letter for Doctors & Patients, Inc.
Jonathan Collin, President
Deborah Nissen-Collin, Vice-President

Disclosure: The *Townsend Letter for Doctors & Patients* publishes information about alternative medicine written by researchers, health practitioners, and patients. As a forum for the entire alternative medicine community, we present information discussing a wide variety of alternative and integrative medicine practices. In addition to publishing original research and literature abstracts and reviews, we encourage case studies and anecdotal reports. Detailed anecdotal reports are not viewed as proof but as possibilities that need further investigation. All authors are required to submit their reports to other professionals for review and include proof of peer-review with article submission.

The editors of the *Townsend Letter* recommend that all patients (and physicians) review further reports provided in the article's references and investigate the practitioner's techniques before undertaking an alternative diagnosis, examination, or treatment. Please discuss such treatments and examinations with a reputable health practitioner in your community. If you do use an alternative treatment discussed in the *Townsend Letter*, we would appreciate your report of the outcome, any side effects, and costs.

Pathways to Healing

by Elaine Zablocki

MD Chef Tweaks Recipes to Support Health

Erica Leazenby, MD, practiced within a large hospital system in Indianapolis for 18 years and then decided to explore other ways of practicing medicine. "I felt burned out from the systematic routine, seeing four to six patients an hour," she recalls. "I prescribed medications but was frustrated after seeing that my patients weren't necessarily feeling better." Eventually she resigned from practice and traveled throughout the United States, attending various CME courses and conferences, looking for inspiration and ways to develop a different business model for medical practice.

During this transitional period, she attended the Institute for Functional Medicine (IFM) introductory course. "This was a complete paradigm shift for me, and it really resonated,"she says. "I learned you could identify and address some of the root causes of illness. I knew I had found my new medical career."

For example, in her earlier training she looked at rheumatoid arthritis primarily as a joint disorder, and Hashimoto's thyroiditis primarily as a thyroid illness. In contrast, functional medicine looks at the underlying autoimmune problems. Functional medicine considers lifestyle, diet, stresses, exposures to various toxins – all the underlying causes that may lead to a specific symptom. "I learned that really sitting down with the patient, taking a detailed history, considering all the various factors that affect this particular patient, is an essential first step in the healing process," Leazenby says.

MD Goes to Cooking School

Leazenby completed her initial coursework at IFM during 2015. Over the next couple of years, she continued studying with them, eventually completing the seven required courses for IFM certification. During this transitional period, she also spent six months at the Natural Gourmet Institute for Culinary and Healing Arts in Manhattan. This sophisticated culinary training institute offers a solid grounding in traditional skills, combined with an unusual focus on the healing qualities of foods. "We had to learn our basic knife skills and so on. At the same time this school is based on 80% plant-based foods," she says. "I chose this school because I realized the key to health and longevity lies in eating a whole-foods, mostly plant-based diet. I wanted to learn a range of cooking methods so plant-based food tastes delicious."

The culinary training emphasized ways to make food tasty without relying on salt and unhealthy fats. "I learned how to cook any vegetable so it is flavorful and nutritious. In addition, we learned how to adapt older recipes," she says. "In this age we see many food sensitivities, so we need to adapt foods for people with very specific needs."

New Form of Practice, Plus Cooking Classes

After developing so many new skills, Leazenby decided to explore a new form of healthcare. She calls her new practice "Relish Health." Her website states, "We believe food is medicine. The lifestyle choices that you make, especially related to diet, can dramatically affect your risk and expression of illness. You are unique and have individual dietary needs. Relish Health combines the joy and art of cooking with the science of food, nutrition and medicine."

In her new practice, Leazenby sees patients three days a week. An initial consultation usually takes 90 minutes,

Erica Leazenby, MD

with 45 minute follow-ups. Because her practice is limited, she doesn't need support staff. She doesn't take insurance. She sends people home with a specialized receipt, a super bill, that patients can submit to their insurance for reimbursement. "It was a difficult decision, whether or not to accept insurance," she says. "I realized if I wanted to spend this amount of time with my patients, I had to follow a different system."

Since she schedules three days of office-based practice, she has time to offer cooking classes and demonstrations in a wide variety of settings. "I find these cooking classes bring me the greatest joy," she reflects. "They are my tool to prevent future burnout."

Her cooking classes and workshops take place in many different settings. At a local hospital she may do a cooking demonstration with 30 to 50 people in the audience. She may do a smaller hands-on cooking class in a church basement or in someone's home. She's even been able to incorporate cooking demonstrations into resident training and continuing medical education lectures.

Often her practical culinary workshops are organized around a particular theme.

➤

➤

For example, a recent class focused on brain health, the connections between food and mood, and particular foods and recipes that support brain health. Another useful topic is blood sugar management and the glycemic index. "This topic is so useful for people who may have high blood sugar or polycystic ovarian syndrome or just get woozy in the afternoon because they had a high glycemic lunch," she says. "We all benefit when we understand how the foods we eat can sustain energy, balance blood sugars, and reduce inflammation."

Leazenby notes that some people with specific health conditions may need a specialized diet in response to that condition. "The diets I typically prescribe include the elimination diet, FODMAP diet, and ketogenic diet. Sometimes I may suggest a balanced Mediterranean diet when the main focus is blood sugar and hypertension management," she says. "The key thing is to put the whole picture together, to perceive the main underlying issues, and then address those issues."

Some people who attend her cooking classes have later become patients, in order to focus more closely on their own health concerns. We asked Leazenby whether any recent cases demonstrate the special benefits of a thorough intake interview at the start of the diagnostic process. She recalls one person who was supposed to have rheumatoid arthritis. After doing a thorough history and work-up, Leazenby discovered that she actually had ulcerative colitis and that was probably the cause of her joint pain. This led to a more appropriate treatment plan.

In another case, a person had many digestive problems and had tried multiple therapies without relief. Leazenby asked when the pain had started, which brought up memories of deeply emotional family issues. "With my previous training I don't know whether I would have asked that sort of question," Leazenby says. "Now I take the time for a thorough discussion of all possible factors, and often that does lead to more effective treatments."

As a practitioner, Leazenby emphasizes that so many different elements support core wellness. Food, exercise, sleep, stress, relationships, love. "They are all important. My own particular passion is food, so that's where I focus my educational efforts. I offer cooking classes and demonstrations because I really want to increase literacy about nutrition in my own community. But of course all aspects are important. In my office-based practice we do address all these related issues."

Resources

Relish Health Website
https://www.relishhealthmd.com/
Relish Health Cooking Classes, Demonstrations
https://www.relishhealthmd.com/events/
The Institute for Functional Medicine
https://www.ifm.org/
Institute for Functional Medicine Certification Program
https://www.ifm.org/certification-membership/certification-program/
Natural Gourmet Institute for Culinary and Healing Arts
https://naturalgourmetinstitute.com/

Elaine Zablocki is the former editor of CHRF News Files. ◆

To help support heart healthy cholesterol levels, recommend Pantesin.*

A pure and highly absorbable form of Pantethine (an active form of Vitamin B5) Pantesin® works at the cellular level, enhancing enzyme and metabolic activity to help the body maintain a healthy blood lipid ratio.* A pure, vegetarian, allergen-free ingredient, Pantesin is backed by more than three decades of research showing it to be safe and effective.* Recommend Pantesin with confidence as a smart addition to your patients heart health program.

Pantesin®

For more information visit
www.pantesin.com

Follow Pantesin®

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Look for Pantesin® Pantethine in these fine brands.

Endurance Products Company · HCP Formulas · Integrative Therapeutics · pure encapsulations — Your Trusted Source — · Protocol for Life Balance · AllergyResearchGroup® · Thorne Research

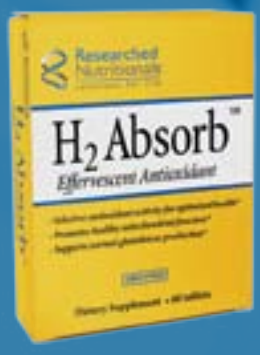
MITOCHONDRIA

- ✓ Phospholipid membrane repair*
- ✓ Krebs cycle support*
- ✓ Clinically researched

CYTOKINE SUPPORT

- ✓ Promotes healthy cytokine activity*
- ✓ Highly absorbable polyphenol blend*
- ✓ Nrf-2 support*

ANTIOXIDANT



- ✓ Targets hydroxyl radical group*
- ✓ Crosses blood-brain barrier & cell membrane*
- ✓ Nrf-2 support, which promotes healthy glutathione level*

DETOX

- ✓ Clinically researched
- ✓ Supports detox pathways*
- ✓ Promotes healthy mitochondrial function & NK cell function*

Joseph Burrascano Jr., MD

"Due to the research basis of these formulations, I think these products would be an important part of a practitioner's arsenal."

*These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure or prevent any disease.

IN THIS ISSUE May 2018 | #418

ON THE COVER: Chris D. Meletis – Hemp Oil Certification for Safety and Effectiveness (pg. 38) Earthworm Enzyme Preparation for Cardiovascular Disease (pg. 52) Strophanthus – A Tonic for the Heart (pg. 57) Bio-Resonance Testing Identifies Toxicity (pg. 21) Animal-Human Hybrids for Transplant Organs (pg. 73)

OncANP 2018: Capable Hands

by Jacob Schor, ND

The Oncology Association of Naturopathic Physicians held its 7th annual conference in mid-February 2018. This conference continues to be, for me, the most interesting and thought-provoking conference of the year. Speakers are selected by a committee that includes some of the best presenters in our profession, and the relatively narrow focus on naturopathic oncology allows some of our selected speakers to dive deep into particular topics while other speakers survey the breadth of our field.

OncANP Residency Committee responsible for the OncANP Residency Toolkit (L to R: Michael Traub, ND, DHANP, FABNO; Dave Allderdice, ND, FABNO; Gurdev Parmar, ND, FABNO; Chad Aschtgen, ND, FABNO – not picured: Dan Lander, ND, FABNO)

Dr. Eric Marsden opened the conference with a highly detailed discussion on managing intravenous infusions treatment (IVIT) for advanced cancer patients. In addition to the basic vitamin C IVs most of us are now familiar with, he also covered infusional hydrochloric acid, viscum, colloidal silver, and glycyrrhizic acid. Marsden is an analytical sort with extensive experience administering some 40,000 infusions to patients over the years. The first topic discussed in depth was prevention of thromboembolic events (VTE), that is avoiding blood clots triggered by treatment. VTE risk is significantly higher in advanced cancer patients. For example, in pancreatic cancer patients, VTE risk is 4.5 times that of a person without cancer.

Weakened immune function along with accessing ports to administer drugs and other intravenous treatments puts cancer patients at higher risk for infection. Marsden reviewed the way he treats these infections and perhaps, more importantly, the procedures he follows to prevent them. He also discussed how to prevent and address cachexia.

I was the second speaker of the conference. My assumption is that the scheduling committee wanted to get it over with asap. That was my feeling as well. Speaking at conferences leaves me anxious enough that I can't pay attention to what anyone else says until I've gotten my lecture over and done with. I tend to view public speaking as a standup comedy act and like to see my audience smiling and laughing out loud. I spoke on the quest to trigger spontaneous remission in cancer patients, a somewhat serious topic, and one not particularly designed for laughter-provoking punch lines. Thus, I lowered my expectations for being the funniest lecture of the conference and hope my lecture nudged at a few paradigms.

Erin Sweet followed my act with a thoroughly academic review of a study in progress conducted by Leanna Standish, ND, at Bastyr University and Robyn Andersen, PhD, MPH, at Fred Hutchinson. They are conducting an observational study on whether naturopathic oncology interventions effect the quality of life of breast cancer patients. They have already had over a dozen studies published using data drawn from these women. Does what we do really work? These researchers will be the first to know. Stay tuned. Dr Standish is scheduled to deliver a webinar for OncANP members in the near future on how to take part in a web-based outcome reporting effort that Bastyr University is conducting: https://redcap.bastyr.edu/redcap/surveys/?s=XKR9Y3HDLC.

The next two lectures looked at pain management. The first was given by Drs. Wright and Green who spoke on persistent breast pain and distress in breast cancer survivors. They asked us to consider improving our screening and broaden our approaches for treating these issues for the good reason that survival improves significantly for women with support networks, relaxation counseling, and yoga. Specifically, they discussed a few large RCT's where stress reduction counseling offered breast survivors a 45-55% reduction in recurrence and decreased mortality in 10-12 year follow up. The second pain talk was given by our old friend Dr. Eric Yarnell and was on the herbal formulas he uses for pain. With this particularly interested and attentive audience, Dr. Yarnell was able to go into great depth on prescribing the herbs corydalis, aconite, pulsatilla, and hyoscyamus. Yarnell is the owner of Heron Herbs; and what many conference attendees failed to notice was that at their tradeshow vendor booth, Eric had a fair number of samples of herbal pain formulas. This one particularly curmudgeonly conference attendee happily cleaned up at the end of the trade show.

These lectures were followed by a 'sponsored lecture' given by Dr. Michael Morse, MD, from Duke University. He spoke about his research on a product made by Oliventures inc., an extract rich in tyrosols made from olives. He did a decent job of convincing us that swallowing their pills would have an impact equivalent to consuming several liters per week of extra virgin olive oil (EVOO). Given that in the PREDIMED trial a single liter of EVOO per week was associated with a 68% decline in breast cancer incidence, this caught my attention. Dr. Morse presented unpublished data that suggests these tyrosol-rich extracts might reduce inflammatory markers and aromatase inhibitor arthralgia in women with

➤

Cynthia Bye, ND, FABNO
Recipient of the 2018 President's Award
Oncology Association of Naturopathic Physicians

by Heather Wright, ND, FABNO

Heather Wright, ND (left), presents award to Cynthia Bye, ND, FABNO (right)

It was extremely difficult to select the recipient of the OncANP President's Award this year – first because I've so little experience being presidential and second because so much powerful work has been done in the last year by our committees. Dr. Eric Marsden from Toronto, Ontario, led the committee that created the recently released "Principles of Care" document (POC) to our membership. This accomplishment was a huge and time-consuming task and is so important to our profession that he was an obvious choice for this award. In fact, considering the enormous efforts his large committee put into this task, it might have been reasonable to include all the members as well. Competing with this though are the efforts of Gurdev Parmar, Chad Ashtagen, and Michael Traub who created the OncANP Residency Toolkit, which provides the instructions and tools needed for clinic directors to start up a residency-training program. Anything that increases our ability to train clinicians in naturopathic oncology should be awarded. And then there is the PR committee with Christina Shannon, Sharon Gurm, and Heidi Vincent who advanced our public relations by creating professional, written powerpoint and other presentations that capture our message in a consistent way so that we can all be better ambassadors of naturopathic oncology. This list of worthy contributors must also include our membership committee – Kirsten West, Heidi Lucas, and Sonja Fung who have been producing our monthly newsletter and promoting opportunities through the creation of a member benefits package. Lastly, we have the research committee, led by Dugald Seely, who for the second year in a row added an incredibly successful research poster component to the OncANP conference. This adds a step in the right direction for our colleagues who create professional presentations of their pre-publication projects and novel proposals. Suffice to say there were a number of deserving competitors for this award and that I agonized at making my choice.

One person stood out though, a person who was quietly working behind the scenes and not on a committee. At her own expense, and working over several years, she built a team of professionals and experts to support her mission. She has created what I hope will prove to be an exceptional resource and model that stands to significantly support the continuation and sustainable development of our clinical practices. This one person noticed that as naturopathic doctors retired, their practices were being closed. All their patients lost their source of integrative health care and the provider their source of income.

At the same time, there were capable clinicians fresh out of school, some of whom carry hefty debt burdens, looking to start a practice. These young doctors were forced to re-invent the wheel, so to speak, while other older practices with existing patient bases were closing. I was in Seattle last Fall at a professional meeting when a colleague came up to me and said, "I'd like to speak with you some time about this project I've been working on. It's a business model," she said, "for naturopathic doctors planning to retire. It helps provide information, so they can bring on new grads and residents and not close their practice." She presented me with a professional-looking manuscript. She said she'd partnered with a Washington State University program of fourth-year business and marketing students to create a detailed and well-illustrated analysis of naturopathic practices. Basically, it's an argument for old docs to take on new docs into their practices and various financial analyses on how this could be financially advantageous to both parties.

Choosing the recipient of this year's award has been hard. Fulfilling this role as the association's president is challenging. It is even harder to believe that this dedicated, hardworking individual named Cynthia Bye, ND, FABNO, saw this need and worked for several years to amass the information needed to create this professional transition tool for the benefit of our profession. I'm honored to provide this award to her today.

From Cynthia's website (http://cynthiabye.com/):

> Cynthia works in Vancouver, Washington, at her clinic Journey to Wellness. She received her undergraduate degree in pre-med from Bowling Green State University in Ohio. She then went on to get her doctorate in naturopathic medicine from the National College of Naturopathic Medicine in Portland, Oregon, where she completed her thesis on breast cancer. She completed a residency at Cancer Treatment Centers of America in Tulsa, Oklahoma. Dr. Bye is a Fellow of the American Board of Naturopathic Oncology (FABNO). She is a board member of the Complementary and Alternative Medical Practitioners (CAMP), and on the advisory board for the Ovarian Cancer Alliance of SW Washington and Oregon. She is a past board member of the American Association of Naturopathic Physicians. Dr. Bye works with cancer patients and those who want to reduce their risk factors for cancer through a holistic and complementary approach.

➤

breast cancer. Regardless of being a sponsored presentation, a lecture about a compound that promises these things caught my attention.

President Heather Wright, ND, FABNO, enjoying lectures

That was day one, and while some people might hope I go lecture by lecture through entire the conference, such a plan strikes me as tedious, both to write and to read. Suffice to say that the following two days continued along the same vein of useful, inspiring, and occasionally mind-shifting presentations.

I am lobbying the speakers to write articles for this journal based on their lectures and hopefully this will happen over the coming months. These include in particular Ian Biers, Judith Boice, Lise Alschuler, and others.

I do want to single out Ian Bier's lecture as I've been meaning to go back and read his notes again. He reviewed common lab tests that are under appreciated, tests that possess prognostic value in cancer and might be useful in monitoring patients. Some of these mentioned tests caught this listener by surprise as they are routinely run as part of chemistry screening panels. Most of us are aware that monitoring lymphocyte and neutrophil ratios is useful, but I suspect few know to watch gamma-glutamyl transpeptidase (ggt) levels just as carefully.

Research Poster Presentations: (L to R: Chad Aschtgen, ND, FABNO; Mark Carney, ND; Gurdev Parmar, ND, FABNO; Michael Whitney, ND, FABNO)

As useful as the information from these speakers might prove to be in practice, what was more interesting was the range of projects that association members are moving forward on. Drs. Gurdev Parmar, Chad Aschtgen and Michael Traub have created a manual for residency training in naturopathic oncology. They have successfully created systems in their own practices that bring new doctors in and train them up to be full-time associates. Practicing naturopathic oncology has grown into such a specialty with such a complex field of knowledge that many believe residency training is needed for a practitioner to practice naturopathic oncology effectively and safely. Providing opportunities for this sort of training is crucial as the prevalence of cancer increases. Increasing quantity and quality of residencies is fast becoming the most important thing our association can do.

The other urgent task at hand is increasing public awareness of naturopathic oncology. There are a large number of patients who seek the science-informed integrative approach to oncology that we offer who have no idea that OncANP or even naturopathic doctors exist. Tina Kaczor, ND, FABNO, has created the Naturopathic Oncology Foundation, a 501c3 non-profit, which is soliciting donations and initiating projects to make our specialty more visible to the public.

Finally at the end of the conference, Heather Wright, ND, FABNO, current president of the OncANP acknowledged an important challenge in both our specialty and in naturopathic practices in general when she selected Cynthia Bye as this year's recipient of the President's Award. Dr. Bye has created a transition model that will help experienced colleagues, who want to retire, find younger doctors to transition into their practices. Dr. Wright's presentation acknowledged how important Cynthia's work may prove to be for the health of the profession. Dr. Bye described her self-assigned project to me in an email in November 2017:

> I worked with four fourth-year business and marketing students. My goal was to do a transition model to take the experience of successful docs who want to retire and match them with new docs to help them thrive in private practice. I spent six months working with and directing the students as to the goals, and then gave them the resources to use to put the information together. Essentially, I was the project manager. Given that none of my students even knew what naturopathic medicine was, I spent a lot of time helping them get up to speed both from a ND business model stand point and helping them to understand the naturopathic market. As I started talking with other health care professionals that had retired – ND, DC, dentists – I kept hearing the same thing, "I tried to bring on an associate and they sucked my brain dry" and either left or went down the street to start their own practice taking many patients with them. So, a large percentage of retiring docs just closed their doors. Given the large failure rate of new docs in any profession, I found this to be a shame. Thus, this model was born.... I love my profession and want to bring naturopathic medicine to more people. In my humble opinion the best way to do this is to help new docs become successful.

I found these efforts that look toward our shared futures to be the most exciting part of the conference.

The 8th Annual OncANP conference will be held at the Hilton San Diego Resort and Spa on February 15-17, 2019. Visit our website at www.oncanp.org to stay up to date with our call for abstracts and registration. ◆

Long TIme OncANP Members: Davis Lamson, Jacob Schor and Michael Traub

FCT® in the Coronary Care Unit of a University Hospital and Heart

by Savely Yurkovsky, MD

As heart disease retains its infamous leadership in killing Americans, the following cases suggest that this leadership might be owed to the very main paradigm, chemical-pharmaceutical medicine, that is attempting to solve it.

FCT Saves My 92-Year-Old Mom from Scientific Cardiologists

In the spring of 2015, my vigorous 92-year-old mother, a Boston resident, slipped and fractured her hip. Following this, she received excellent care from an orthopedic surgeon and medical staff in a local university teaching hospital. The surgeon marveled, how fast she was healing, and I skipped telling him that this was likely due to homeopathic Arnica, received prior to the surgery. Yet, her subsequent recovery was suddenly derailed due to an IV fluid overload following the surgery. Between the overload and her 92-year-old heart with aortic valve stenosis, it became a big problem; under the circumstances, the domino effect ended up in a heart attack and congestive heart failure. She began gasping for breath and was transferred to the CCU, where high doses of diuretic and other medications, were administered 24/7. Among these was a beta-blocker drug because, in spite of its known side effects of causing congestive heart failure due to reducing heart rate and contraction, some study showed that due to these actions there was somewhat better survival rate among congestive heart failure patients by, allegedly, sparing the heart muscle from wearing itself out faster. While I knew that such benefit, even if for real, could be clearly detrimental particularly in elderly people whose heart contraction is already weaker, I decided to play a Good Joe to her heart specialists team and see the benefit for myself. And the team treated me as such.

The only problem was that neither this comradery nor the slew of drugs was doing little to end the crisis, which kept progressing. Her lungs sounded more congested, the chest x-rays looked it too, and breathing was more labored, all in spite of increasing doses of a diuretic orally and IV. Logistically, I started sensing a reality of my mother dying by heroic scientific death, thanks to a piece of paper with some beta-blocker study on it. Indeed, my bio-resonance testing* was confirming a severe intolerance to this drug by her heart. Since the combination of myocardial infarction, severe aortic stenosis, and persistent congestive heart failure carries a very high mortality rate—even among much younger people, never mind the seniors in their 90s—I diplomatically suggested to the team's head attending cardiologist that the beta-blocker be reduced or, better, stopped.

Following this, I apparently stripped myself of a Good Joe immunity and was told in less than a cordial manner that based on high scientific standards of evidence-based medicine, as supported by that "positive study," that the drug was clearly a lifesaver for Mom and, also, if I am so smart, I should take over my mother's care, myself. But to prove me outright ignorant in the matter, he will dispatch the ultimate judge in the field, some big specialist in congestive heart failure. The next day, as my mother continued struggling and, likely, making reservations in Heaven for herself, the dispatched big specialist charged in with a small army of subordinates. In no time she issued the same scientific verdict, that the beta-blocker was clearly the best thing that ever happened in my mom's life. "We have a study, the real evidence," said the specialist, "that proves you wrong."

"Excuse me, doctor, for a naive question, but was my mother or other 92-year-olds with a myocardial infarction, severe aortic stenosis, and congestive heart failure a part of this study?" Short silence followed as the herd mentality can neither handle nor tolerate anything that even faintly resembles individualized medical care. They simply get lost as if struck by a foreign language. "We will continue the beta-blocker," the specialist uttered through her teeth, storming out of the room. "We are discontinuing the beta-blocker," I advised my mother's nurse seconds later, exercising my legal right as her health proxy. Yet, following my bold move, the next day brought no roses, as my mother remained just as breathless. The attending cardiologist helped matters little, when after being told of what I did, he refused to hear further update on Mom's condition, obviously as a complete waste of time for such a hopeless basket case under the circumstances. This didn't do much good to my brother's spirits, who had witnessed the entire ordeal for days.

"Are you sure you know what you are doing?" he asked gingerly, while seeing little gain from losing scientific community support.

"I hope I am," I uttered while resuming bio-resonance testing in

➤

* Energetic test that works through bio-physical level of human body and can noninvasively determine causes of disease of internal organs

➤

a hope to find the next cause of the stubborn problem. However, the good old test did not show anything new but still the same old villain, beta-blocker, impairing Mom's heart. It was either still circulating in her blood or remained in her heart muscle. Next step: treat poison with same poison, but only in its energetic form in order to help the body to finally part with the drug or any toxin or infection. After a good nurse supplied me with the real one, I prepared its energetic counterpart. Done. Yet, still no parade that day, either, but the same struggle. However, the next day brought the first signs of hope as Mom looked less breathless and her lungs no longer sounded like Niagara Falls. Her blood oxygen level jumped up, heart rate came down indicating its decreased stress state. The next 24 hours were all good news: IV diuretic was discontinued, the oral one decreased, and the chest x-ray, finally, looked clean. The next morning, she left CCU for the rehab facility to work out her hip.

Today, at age 95, mom is doing well. Unfortunately, and ironically, just a year following her ordeal, her much younger attending cardiologist who deemed her to be hopeless died. Speaking of another piece of heart 'science,' for many years Mom had high cholesterol in a hefty 300 range for which her local internist kept pushing statins. Yet, she never took them, upon my unscientific advice to ignore and never even bother checking cholesterol, as I don't mine, and just keep doing FCT. Perhaps just as ironically, a recent analysis declared failure of the conventional, gold-standard, evidence-based medicine to meet its high expectations for medical practice.[1]

When Statins Kill?

In my book, *The Power of Digital Medicine*, I presented a case of a heart patient who ignored the bio-resonance testing findings that a cholesterol-lowering drug was harming his liver. "I feel good and my cardiologist said the drug was necessary. Why listen to some strange test?" was the reaction. Yet, months later he no longer felt good and was delivered by an ambulance with intense pain in his liver to an ER where blood test and diagnosis confirmed the harm. After the drug was stopped, he gradually recovered. However, in this tragic case of an 80-year-old man, there was no recovery.

This case was even more tragic because as he was aging, under FCT care, he was gaining vigor, being full of energy, working a full-time job, and wanting to buy a Harley Davidson motorcycle at a tender age of 78. However, after dropping out of FCT maintenance visits, he returned with a very unusual disease for his age, acute myelocytic leukemia, that normally strikes young children. His son, a biological dentist and a patient of mine, said that the oncologist prognosis was six to eight weeks survival. My bio-resonance testing detected general environment pollutants and statin drug in his bone marrow, and he received their homeopathic-energetic counterparts. Since the patients on long-term FCT very rarely develop cancer or any serious diseases, I examined his chart for possible oversight on my part. Yet, instead, I have found just the opposite, warning him decades back that bio-resonance testing red-flagged his statin drug as harming him. Unfortunately, the same logic, "my cardiologist said it was necessary," prevailed again. Not to force a patient into something uncomfortable and scary for him and for liability reasons, I didn't press the issue further. Which facts made me suspect that it was the statin, even more than pollutants, that caused this leukemia?

1. Finding any toxin in the bone marrow in the presence of its overt disease links it to that disease.
2. Following the first two FCT remedies, his oncologist (not being aware of FCT treatment, due to the family wish) stated that the leukemia displayed an unusual (e.g., for chemotherapy alone) regression.
3. Following the next bio-resonance retesting, only the statin was still detected in the bone marrow, which speaks for its deep poisonous nature for the organ.

Savely Yurkovsky, MD, a pediatrician, internist, and cardiologist, has evolved a novel medical model that interfaces important knowledge from biology, medicine, toxicology, and physics. Its primary focus is on the most important aspect of chronic diseases – its causes – along with the most effective diagnostic and therapeutic means to address these. This has transformed the often-imprecise medical interventions into a far more effective, exact, and predictable science. He has founded a teaching organization, SYY Integrated Health Systems, Ltd., which provides training in this medical system under the concept of FCT®, Field Control Therapy. This concept as medicine of the future was suggested by Professor Emeritus of Materials Science at Stanford University, William A Tiller, PhD. Dr. Yurkovksy has presented FCT at many professional symposia in both the US and Europe, including the annual Bio-terrorism 2005 conference: "Unified Science & Technology for Reducing Biological Threats & Countering Terrorism" with affiliation to the Homeland Security Office and Harvard Medical School, among others.

Dr. Yurkovsky has been nominated for the prestigious Bravewell Leadership Award for "significant contributions to the field of medicine" and "compelling vision for the future of medicine" in 2005. He has authored numerous articles and the book, *The Power of Digital Medicine* that was endorsed by prominent scientists from MIT, Columbia, and Stanford Universities and contributed a chapter on homeopathy to the textbook of *Integrative Gastroenterology*, edited by the chief of integrative gastroenterology at Johns Hopkins University medical school, Gerard Mullin, MD.

Dr. Yurkovsky maintains a private practice with a cause-based approach to diseases, covering from pediatrics to geriatrics, located in Chappaqua, New York.

4. As a clinical confirmation to this, after a stronger homeopathic-energetic statin, his oncologist reported that the leukemia displayed a further dramatic regression.
5. While seemingly paradoxically, my search on statins and bone marrow showed just the opposite: their potential to prevent this very leukemia by suppressing the corresponding triggering genetic mechanisms! Yet, a science of hormesis puts a different spin on all pharmaceuticals, conventional and alternative, through its nasty rule of "the dose makes the poison." Thereby, a beneficial substance may suddenly become a poison, based on cumulative effect, and cause the same disease that it seems to prevent in a lab. And vice versa, that minute poisons may heal. Did the statin at some point become too much of a good thing for that anti-leukemia pathway and cause the very disease it was supposed to prevent? Very likely! If not, why then, did it not prevent his leukemia?
6. What sealed the verdict, this unusual-for-adults leukemia (particularly the elderly) peaked and continued to grow in incidence within a year after statins were introduced in the 1980s!

Following his unusual progress, I pleaded with the family to convince his oncologists to back off from the usual high-dose chemotherapy protocol because the bone marrow's natural recovery on FCT and the organ, itself, will be destroyed by it more than by leukemia. However, as usual, the herd mentality prevailed, and they said it was necessary to prevent the usual recurrence of leukemia, based on their books. This ultimately killed him, as his poisoned-by-the-drugs bone marrow could not produce sufficient white blood cells to resist vicious strains of common hospital infections; and he died of pneumonia. Instead of the expected six to eight weeks, he lived almost a year.

Reversed Heart Disease, Without Heart Medications

A reader may review my *Townsend Letter* report of an FCT patient with known coronary artery disease, severe diabetes, obesity, and junk food consumer who without any heart medications or supplements, surprisingly displayed clean heart arteries.[2]

Adding more paradoxes for our scientific cardiovascular medicine, the recent studies have demonstrated decreased mortality rates among acute myocardial infarction patients when interventional cardiologists leave town.[3] Another study shows that an average cardiologist does not even know what a healthy heart diet is.[4]

The bottom line, as in any disease: Addressing well its real causes remains the ultimate science.

References

1. Horwitz RI et al. From Evidence Based Medicine to Medicine Based Evidence. *Amer J Med.* 2017;130(11):1246-50.
2. Yurkovsky S. FCT documented case of an apparently reversed heart disease in a junk food addict with obesity and diabetes, thanks to cause-based approach to chronic diseases. *Townsend Letter.* May 2015; 84-7.
3. Jena AB et al. Acute Myocardial Infarction Mortality During Dates of National Interventional Cardiology Meetings. *Journal of the American Heart Association*. 2018.
4. Devries S, et al. A Deficiency of Nutrition Education and Practice in Cardiology. *Amer J Med.* November 2017;130 (11):1298-1305.

◆

What's in Your Coffee? The Good, the Bad, and the Ugly

by Steven M. Helschien, DC

Introduction

Multiple studies have shown that coffee is a superfood, containing vast amounts of nutrients, and antioxidants – phytochemicals and phenols.[1] It contains more antioxidants than any other food, including berries, dark chocolate, and kale. The antioxidants in coffee provide many health benefits, including preventing disease and increasing cognitive function. But that is if the coffee is high grade and produced to retain the nutrients and antioxidants. If not, the coffee will usually contain unhealthy chemicals and compounds, due to poor-quality farming, handling, and roasting methods. These unhealthy chemicals and compounds can be found in many leading brands of coffee. As a result, many consumers experience negative side-effects from these coffees. As you can see, when it comes to what's in your coffee, there is the good, the bad, and the ugly.

Coffee Quality

To ensure that a cup of coffee is nutrient and antioxidant rich requires some key factors, including the following:

Farming: Premium coffee is organically grown in high altitudes**.** The premium species of coffee that ranks highest for nutrition density, pleasing flavor, and low acidity is the Arabica bean, which grows best at higher altitudes.

Coffee plants thrive in a certain temperature, amount of rainfall, sunlight, and altitude. Tropical mountains provide the ideal climate for growth and altitude that slows the maturation of the coffee bean in a way that improves its denseness and flavor. The soil is more fertile and porous at higher elevations in the mountains, making it ideal for coffee growing, and the higher altitudes also reduce the number of pests. One of the coffee farmers' greatest threats is the coffee berry borer, which cannot survive at high altitudes.

Organic farming of coffee plants works in harmony with nature to ensure that consumers are not ingesting the chemicals from pesticides and herbicides but also to create resilient, nutrient-dense soil to grow the healthiest plants.[2]

Harvesting: Handpicked when the berries are mature, premium coffee beans are sorted for defects and repeatedly tested for mold, microorganisms, and toxins.

Coffee is harvested either by hand picking or machine stripping. Handpicked cherries are picked at their peak – when they are mature and a bright deep red. Machine stripping picks all of the cherries, whether they are ripe or not. The coffee bean is the seed inside the cherry. The seeds or beans are removed from the cherry and dried. The beans are then sorted for any defects and tested for molds or toxins.

Roasting: A premium roast decreases acrylamide and maximizes chlorogenic acids and other antioxidant compounds.

In the beginning of the roasting process, acrylamide is formed and is broken down later in the roast, so if the bean is under-roasted there will be higher levels of acrylamide, which is unhealthy. Over-roasted coffee may form polycyclic aromatic hydrocarbons (PAHs), some of which are carcinogenic, and will also diminish antioxidant compounds. As the bean is roasted, healthy chlorogenic acids and other desirable antioxidant compounds diminish. So, there is a balance that needs to be struck in order to roast for the healthiest beans.

Transportation and storage: Premium coffees and their environments are consistently tested for mold and toxins. If coffee has been grown and handled under strict standards and testing, including during transportation and storage, consumers can reap the rewards of an abundance of nutrients and antioxidants.

The Good

These premium coffees have an abundance of antioxidants:

Plant Phenols are powerful antioxidants found in coffee, similar to the antioxidants found in berries and include flavonoids and lignans. Studies show that plant phenols can protect the body from cellular damage and diseases, including cardiovascular disease and cancers.[3] They also help in breaking down carbohydrates in the body, which aids in weight loss.[4]

Chlorogenic Acid is a powerful antioxidant, anti-inflammatory, and antibacterial compound. It can also enhance insulin function in the body, which means it's able to fight diabetes. Chlorogenic acid has been shown to prevent the growth of tumors and slow the growth of existing tumors. Chlorogenic acid may also reduce triglyceride levels and decrease blood cholesterol. Chlorogenic acid also reduces bile stagnation, which causes adverse effects in the liver, kidneys, and gallbladder and can cause cancer and stone formation.[5]

Quinine. Coffee is especially rich in one potent type of antioxidant known for its ability to kill off diseases called quinine. The magical part about quinine is that it becomes more potent after coffee beans are roasted. When quinine combines with magnesium, another element found naturally in coffee, they have a positive effect on blood sugar levels and boost athletic performance.

Caffeine. A moderate amount of caffeine can increase mental clarity and focus. It has also been suggested that caffeine improves cognitive function and may prevent the development of Parkinson's and Alzheimer's disease.[6]

Tocopherols in coffee act similarly to plant phenols. Tocopherols act like antioxidants and assist in the synthesis of carbohydrates and lipids. Tocopherols found in coffee are particularly important for ocular and skin health. Tocopherols

can also inhibit the growth of gallbladder and kidney stones and may protect you against colorectal cancer.

The Health Benefits of Coffee

Studies have shown that coffee that is rich in anti-inflammatory properties provide a vast array of the following health benefits:

- Enhances brain function, including focus, concentration, cognitive function, and working memory;
- Reduces the risk of Alzheimer's, Parkinson's, and dementia;
- Increases energy;
- Protects the heart and cardiovascular system;
- Fights cancer. According to the American Institute for Cancer Research, the antioxidants, phytochemicals, phenols, and nutrients found in coffee, all play an important role in helping reduce the risks of many cancers,[7] including breast cancer, oral cancer, brain cancer, colorectal cancer, liver cancer, skin cancer, prostate cancer, and uterine cancer;
- Reduces the risk of type 2 diabetes;
- Protects the liver;
- Promotes weight loss;
- Improves sports performance;
- Helps fight depression and enhances mood;
- Reduces risk of retinal damage;
- Reduces risk of multiple sclerosis;
- Acts as a pain suppressant; and
- Promotes longevity.

According to studies from the *Annals of Internal Medicine*, coffee drinking lowers risks of premature death for women by 26% and for men by 20%.[8]

The Bad and the Ugly

Unfortunately, studies show that most coffee beans that have not been organically grown and properly sourced, processed, and tested contain mold, mycotoxins (the toxic substances produced by some types of mold), pesticides, and herbicides.

Coffee is one of the foods that is most susceptible to contamination by mycotoxins, and most coffee producers do not routinely test for these contaminants at every stage. Studies have shown that most conventional coffees test positive for pesticides and herbicides, and low-quality coffees test as high as 50% for mold.

A study published in the journal *Food Control* indicates that mycotoxin contamination could be widespread in commercially available coffees.[9]

Coffee Mold and Pesticide Exposure

Instead of providing energy, focus, and anti-inflammatory properties that prevent disease, coffee beans that have mold toxins and higher rates of pesticides are associated with health risks. The Agricultural Health Study of farmers and their families, which is a prospective study started in 1993, reports the farm communities exposed to higher rates of pesticides have higher rates of leukemia, non-Hodgkin lymphoma, multiple myeloma, and soft tissue sarcoma, as well as cancers of the skin, lip, stomach, brain, and prostate. Other negative outcomes include respiratory and neurological problems, as well as birth defects.[10]

Mold and Pesticide Allergy and Sensitivity Symptoms

The symptoms of coffee mold or pesticide allergy or sensitivity are similar to that of other allergies and sensitivities: ➤

Coffee

➤

- Irritated eyes, throat, mouth;
- Runny nose;
- Wheezing;
- Skin rash or eczema;
- Headache;
- Fatigue;
- Gastrointestinal upset; and,
- Diarrhea.

Symptoms beginning after a cup of coffee are especially suspect to an allergy for mold or chemicals in the coffee. The severity of symptoms depends on the individual.

People who are chemically sensitive and experience low-level exposures to pesticides and other chemicals, increasingly have symptoms of fatigue, headaches, nausea and dizziness. These chronic low-level exposures can lead to a compromised immune system.

Conclusion

Coffees can be very different. There is growing evidence that premium organic coffee is a healthy addition to a nutritious diet, unlike other coffees that may contain toxins, including pesticides. For the first time, the US Dietary Guidelines Advisory Committee reviewed the effects of coffee on health in 2015. The committee is a group of experts in nutrition and health, appointed by the Department of Health and Human Services and the US Department of Agriculture. They review the science behind what Americans should eat and submit a report to help the USDA make decisions about the next edition of the Dietary Guidelines for Americans. It seems, upon reviewing the scientific studies, the committee agreed that coffee has health benefits. "There is enough science on coffee to make a closer look worthwhile," said Tom Brenna, a food scientist at Cornell University and a member of the committee. "There was so much evidence out there," he said. "Instead of just five or six papers on the subject, there is a huge number."[11]

References

1. Stokel K. National Institutes of Health Discover Protective Effects of Coffee. *Life Extension Magazine*. September 2012.
2. Aubrey A. Is organic more nutritious? New study adds to the evidence. *NPR.org*. February 18, 2016.
3. Natella F, et al. Coffee drinking induces incorporation of phenolic acids into LDL and increases the resistance of LDL to ex vivo oxidation in humans. *AJCN*. September 2007;86(3):604-609.
4. Lin D, et al. An overview of plant phenolic compounds and their importance in human nutrition and management of type 2 diabetes. *Molecules*. 2016;21:1374.
5. Liang N, Kitts DD. Role of chlorogenic acids in controlling oxidative and inflammatory stress conditions. *Nutrients*, 2016;*8*(1):16.
6. Ritchie K, et al. Caffeine, cognitive functioning, and white matter lesions in the elderly: establishing causality from epidemiological evidence. *Journal of Alzheimer's Disease*. 2010;S161–S166.
7. Yu X, et al. Coffee consumption and risk of cancers: a meta-analysis of cohort studies. *BMC Cancer*. 2011;11:96.
8. Lopez-Garcia E, et al. The relationship of coffee consumption with total and disease-specific mortality: a cohort study. *AIM*. **2008;**148(12):904–914.
9. García-Moraleja A, et al. Simultaneous determination of mycotoxin in commercial coffee. *Food Control*. November 2015;30(57):282-92.
10. National Cancer Institute. Agricultural Health Study. Available at: https://www.cancer.gov/about-cancer/causes-prevention/risk/ahs-fact-sheet. Accessed February 19, 2018.
11. Brookshire B. Report offers stimulating recommendation on coffee. *Science News*. March 4, 2015.

◆

Dr. Steven Helschien (a.k.a. Dr. Coffee) is a coffee aficionado and believes that coffee is a powerhouse superfood. He is the founder of Level 1 Diagnostics (a cardiovascular testing program that uses advanced, noninvasive technology to detect and prevent cardiovascular disease), and Level 1 Therapeutics (a health and wellness program dedicated to supporting optimal health). Dr. Helschien is passionate about progressive health issues and encouraging people toward greater health and wellbeing.

9TH ANNUAL INTEGRATIVE MEDICINE FOR MENTAL HEALTH CONFERENCE

IMMH2018

SEPTEMBER 6-9
DALLAS TX
HYATT REGENCY DALLAS

Conference Overview

The Integrative Medicine for Mental Health Conference (IMMH) will give practitioners a holistic approach to successfully diagnose and treat underlying issues contributing to the manifestations of neurological, behavioral, and psychiatric disorders. Research has revealed that many disorders such as depression, bipolar disorder, anxiety, OCD, eating disorders, and autism spectrum disorders often have biomedical causes that contribute to symptoms, from nutritional deficiencies to chronic infections. Patients have better outcomes when these causes are addressed and treated through a combination of specialized testing and nutritional therapies, even in combination with traditional approaches. This year's conference will have more new speakers and new topics than ever before! **CME available!**

Who Should Attend?

- ★ Psychiatrists
- ★ Family Physicians and Physician Assistants
- ★ Doctors of Osteopathic Medicine
- ★ Nurses and Nurse Practitioners
- ★ Naturopathic Physicians
- ★ Nutritionists and Registered Dietitians
- ★ Chiropractic Physicians
- ★ Psychologists

Register by July 1 and SAVE $100!

Use promo code TOWN50 to save an additional $50!

Featured Speakers

Dale Bredesen, MD

★ The End of Alzheimer's: Uncovered Causes and Effective Treatment Strategies

Terry Wahls, MD

★ Dietary Approaches to Treating and Preventing Neurodegeneration

Ben Lynch, ND

★ Dirty Genes: MTHFR and Genetics in Mental Health

WWW.IMMH2018.COM

Professional Quality Sauna

for your home or office

The Relax® Sauna

Only portable sauna using medical grade technology.

The Relax Sit Up Sauna comes with this double radiator, using 40 semi-conductor chips.

Patented ceramic elements which no other sauna has

Hi-tech semi-conductor chips transform electricity into 95-99% pure Far Infrared Energy. (Most FIR saunas are only 30-60%)

The Table lamp is used for spot treatments on small problem areas.

200 watt Table Lamp - Sugg Retail $250

The Sit up Sauna is our most popular product due to its high level of efficiency & positive results.

1500 watt Sauna Sugg Retail $1300

(Lie down sauna available too. 1000 watt sugg retail $1300)

- Promotes cellular renewal and healing.
- For relaxation & improving one's mood.
- Elimination of metabolic waste & heavy metals.
- Improves blood circulation & micro-circulation.
- Increases metabolism & beautifies skin.

The Sky Eye Medical Lamp is used in hospitals & practioner's offices. It is approved by the FDA as a medical device.

(FDA number - 510(K): K053376)

800 watt Medical Lamp - Sugg Retail $1300

What makes the Relax Sauna different from other Far Infrared Saunas

The Relax Sauna succeeds when other infrared Saunas fail because of the Technology, and hence the greater amount and potency of the Relax Sauna. We give you 1500 watts at about 98% purity, giving you 1470 watts of Pure Far infrared Energy. The Relax Sauna uses advanced semi-conductor chip technology. The Relax Sauna is Very Effective, simple and convenient to use, Safe, and extremely reliable.

Many have had Great Success with Diabetes, using the Relax Sauna!

Many Doctors have reported to us their Great success using the Relax Sauna with their diabetes patients. We have also had a surprising amount of success stories with those with Neuropathy, Raynaud's syndrome and for those with diabetic ulcers and/or bed sores. The Powerful and Potent Relax Sauna succeeds where other infrared devices fail because of the Much Greater Potency of the Relax Sauna energy. Dr. Akpinar (surgeon general for the Nation of Hawaii, a medical doctor, an oriental medical doctor & acupuncturist, and a chi gong master) calls the Relax Sauna the only Chi Gong Sauna, and has had great success with many of his patients who use the Relax Sauna.

CALL 626.200.8454

Phill Wilson - Columbus Ohio

moment98@aol.com

For over 650 reviews, search for: "relax sauna testimonials" on youtube!

www.relaxsaunas.com

Mention you saw this ad in Townsend to get Professional Prices. Also Ask about Wholesale.

Shorts

briefed by Jule Klotter
jule@townsendletter.com

Electromagnetic Radiation Impact on Cardiovascular Health

In their 2017 invited editorial for the *European Journal of Preventive Cardiology,* Priyanka Bandara and Steven Weller argue for the need to include exposure to microwave radio frequency electromagnetic radiation as an environmental risk factor for cardiovascular illness. They begin by citing a 2017 study by Vernon et al that showed an increase in serious heart attacks among people without recognized, modifiable risk factors (high cholesterol, hypertension, diabetes and smoking). In that single-center retrospective study of consecutive ST elevation myocardial infarction patients, the incidence among people without risk factors increased from 11 percent in 2006 to 27 percent in 2014. Bandara and Weller reviewed medical literature and found ample evidence that "rapid and widespread deployment of wireless communication and surveillance infrastructure and the use of personal wireless devices" could be a significant factor in this unexplained increase.

Bandara and Weller report that 216 of 242 studies (89%) found increased oxidative stress and/or reduced antioxidant levels with radio frequency electromagnetic radiation (RF-EMR) exposure. Oxidative stress, which damages tissue and can alter signal transduction pathways, is a recognized contributor to cardiovascular disease (CVD). In addition, RF-EMR affects the autonomic system, increasing the sympathetic response. Healthy men (under age 50) exposed to RF-EMR during work showed autonomic dysregulation compared to unexposed controls. In lab experiments, RF-EMR exposure to cordless and mobile phones altered heart rate variability, a measure of autonomic balance. Moreover, RF-EMR disrupts voltage-gated calcium ion channels (VGCC). "The downstream effects of VGCC disruption may involve alteration of important functions of Ca2+/calmodulin-dependent enzymes (such as nitric oxide synthase and protein kinase II), influencing the pathophysiology of CVD," say Bandara and Weller. Some animal studies have also found multiple histopathological changes in the heart muscles of animals exposed to RF-EMR (Azab and Ebrahim).

RF-EMR exposure increases blood pressure and heart rate. For example, a 2015 study, led by Linda Saili, exposed Albino rabbits to WiFi signals (2.45 GHz) for one hour. This exposure increased the animals' heart rate (+22%) and arterial blood pressure (+14%). In addition, the researchers found that the WiFi exposure changed the action of epinephrine and dopamine. Bandara and Weller report that chronic occupational RF-EMR exposure is associated with increased CVD risk and change in the diurnal rhythms of blood pressure and heart rate.

Bandara and Weller refer to epidemiological evidence from chronically exposed populations near radio frequency transmitters (radio/TV/radar towers) before the explosion of cell towers and other man-made RF-EMR sources. Soviet research, according to a 1976 US Army medical intelligence document, found "a significantly higher incidence of coronary disease, hypertension, and disturbances of lipid metabolism" in engineers and officials exposed to microwaves compared to unexposed controls – even though family history of heart disease was about the same in the two groups. The US document also stated that being "more stringent in the enforcement of stringent exposure standards...could be unfavorable...on industrial output and military functions." Apparently, public health is less of a concern than industry and the military.

The World Health Organization linked the high incidence of heart attacks and cancers among people living in North

continued on page 32 ➤

KLAIRE LABS®

Target gb-X™

GUT-BRAIN AXIS

- 5 billion CFU probiotic blend clinically demonstrated to support positive mood†
- Powered by Ecologic BARRIER
- Protected by PROBIOACT® Technology

Target gb-X mechanisms of action[1]

- Strengthening of the epithelial barrier as evidenced by in vivo transepithelial electrical resistance (TEER)
- Decrease in mast cell-mediated intestinal permeability demonstrated in vitro
- Inflammatory modulating IL-10 production demonstrated in vitro
- Enzymatic digestion of lipopolysaccharides demonstrated in vitro

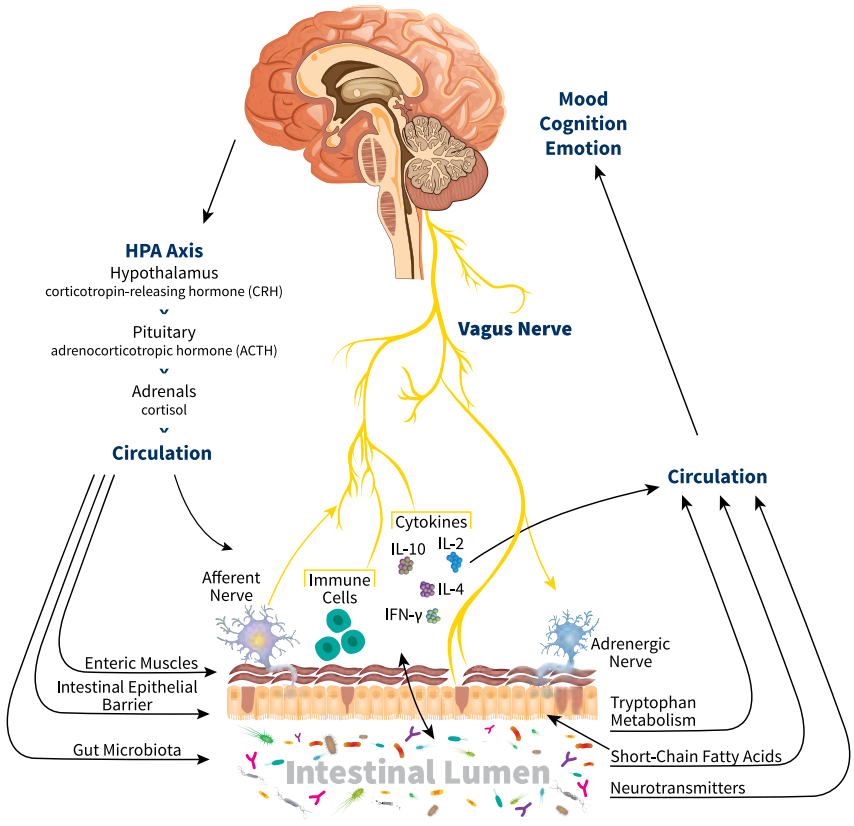
klaire.com | 888 488 2488

† These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

Introduction: the gut-brain axis

The gut-brain axis is a communication network that links the central nervous system (CNS) with the enteric nervous system. The anatomical network includes the brain and spinal cord, autonomic nervous system (ANS), hypothalamic-pituitary-adrenal (HPA) axis, and the innervation of the GI tract, or enteric nervous system.

Both neural and hormonal routes of communication allow the brain to influence intestinal activities, including activity of functional effector cells (i.e., immune cells, epithelial cells, enteric neurons, smooth muscle cells, interstitial cells, etc.). Gut microbiota also influence the CNS both directly and indirectly by supporting epithelial barrier function, modulating immune function, supporting healthy inflammation metabolism, and directly altering circulating neurotransmitter levels.



Product features

- **Powered by Ecologic BARRIER**
  A 9-strain probiotic blend shown to support tight junction integrity, influence regulatory cytokine production, inhibit mast cell activation, and suppress circulating lipopolysaccharides (bacterial endotoxins).†
- **Protected by PROBIOACT® Technology**
  A proprietary matrix designed to maximize shelf stability, minimize osmotic shock on rehydration, protect against gastric acid exposure, and enhance metabolic activity in the small intestine.†
- **Hypoallergenic, non-GMO, shelf stable, single-serving sachets**
  Free of the following common allergens: milk/casein, eggs, fish, shellfish, tree nuts, peanuts, wheat, gluten, and soybeans. No artificial additives, colors, flavoring, preservatives, sugar, or salicylates are used. Contains corn.

Target gb-X research

Target gb-X strains were specifically selected for their pronounced synergistic influence on the gut-brain axis as demonstrated by both human and animal studies.

Clinical findings

Steenbergen and colleagues studied the effects of Ecologic BARRIER in a 2015 randomized, triple-blind, placebo-controlled trial (n=40, non-smoking healthy young adults, mean age 20 years) at a dose of 5 billion CFU per day. Consumption of Ecologic BARRIER significantly reduced overall cognitive reactivity to sad mood, in particular aggressive and ruminative thoughts, as assessed by the Leiden index (LEIDS-R).†[2] Heightened cognitive reactivity to normal, transient changes in sad mood is an established marker of vulnerability to more serious mood alterations in otherwise healthy individuals, and is therefore considered an important target for interventions.

Animal studies

In a 2016 laboratory study, 40 male rats were randomized to either a control or high-fat diet for 10 weeks.[3] After five weeks, the rats received either placebo or the Ecologic BARRIER probiotic blend. Forced swim test results demonstrated, independent of diet, Ecologic BARRIER significantly improved mood in the treatment group by 34%.†[3] In addition, the probiotic group had decreased levels of inflammatory cytokines and increased indole-3-propionic acid, a potential neuroprotective agent.

Conclusion

Target gb-X with Ecologic BARRIER is the first probiotic clinically shown to support healthy mood.† Supplied as convenient, single-serving, shelf stable sachets, Target gb-X is suitable for supporting the gut-brain axis through intestinal barrier integrity and healthy immune/inflammatory response.†

PURITY | POTENCY | PERFORMANCE

*One time 10% single order discount

[1] Van Hemert S, Ormel G. Influence of the multispecies probiotic Ecologic Barrier on parameters of intestinal barrier function. *Food and Nutrition Sciences*. 2014, 5, 1739-1745.
[2] Steenbergen L, et al. A randomized controlled trial to test the effect of multispecies probiotics on cognitive reactivity to sad mood. *Brain Behav Immun*. 2015 Aug;48:258-64.
[3] Abildgaard A, et al. Probiotic treatment reduced depressive-like behavior in rats independently of diet. *Psychoneuroendocrinology*. 2017 May;79:40-48.

Shorts

➤ *continued from page 29*

Karelia, Finland, to a nearby Soviet early warning radar station. The North Karelian lifestyle intervention program, which increased consumption of antioxidant-rich fruits and vegetables and decreased smoking rates, brought improved health. "The success of the North Karelia project...supports our hypothesis that chronic exposure to RF-EMR causes CVD via redox mechanisms of [oxidative stress]," write Bandara and Weller, "which can be countered, albeit not fully, with increased dietary intake of antioxidants." Because oxidative stress affects inflammation, neutrophil infiltration, platelet aggregation, and endothelial integrity, Bandara and Weller say that reducing RF-EMR exposure would be prudent for patients recovering from a heart attack – although no studies have been conducted yet.

"It is clearly time to investigate the potential role of RF-EMR exposure from common wireless device use on CVD," say Bandara and Weller. "Noting that existing research findings are influenced by the funding source, fresh directives are necessary for objective high quality research to expand current primary and secondary prevention strategies." Perhaps, new research can find strategies for mitigating the harmful effects – if industry and enabling government agencies stop trying to obscure the problems.

Azab AE, Ebrahim SA. Exposure to Electromagnetic Fields Induces Oxidative Stress and Pathophysiological Changes in the Cardiovascular System (abstract). *Journal of Applied Biotechnology & Bioengineering.* 2017;4(2).

Bandara P, Weller S. Cardiovascular disease: Time to identify emerging environmental risk factors. *European Journal of Preventive Cardiology.* 2017: 24(17): 1819-1823.

Saili L, et al. Effects of acute exposure to WIFI signals (2.45 GHz) on heart variability and blood pressure in Albinos rabbit. *Environmental Toxicology and Pharmacology.* 2015;40:600-605.

Vernon ST, et al. Increasing proportion of ST elevation myocardial infarction patients with coronary atherosclerosis poorly explained by standard modifiable risk factors (abstract). *European Journal of Preventive Cardiology.* 2017;24(17):1824-1830.

Virgin Coconut Oil and Cardiovascular Disease

Does virgin coconut oil (VCO) contribute to cardiovascular disease (CVD), or is it beneficial? Coconut oil, like butter, palm oil, and animal fat, primarily consists of saturated fat. Although not suitable for deep frying because of its low smoke point, VCO is fine for single-use, shallow frying as it resists oxidation and polymerization during heating, according to a 2016 review by Laurence Eyres and colleagues. Eyres et al urge readers not to conflate coconut oil with medium-chain triglyceride oils. Lauric acid, the predominant fat in coconut oil, behaves more like a long-chain fatty acid in terms of absorption and how it is metabolized.

When compared to unsaturated plant oils, the consumption of coconut oil increases HDL, LDL, and total cholesterol levels, according to the Eyres review: "Overall, the weight of the evidence to date suggests that replacing coconut oil with cis unsaturated fats would reduce CVD risk. Therefore, this review does not support popular claims purporting that coconut oil is a healthy oil in terms of reducing the risk of CVD." However, Thai researchers report that publicity about the saturated fat-cardiovascular correlation has led to a decline in coconut oil consumption over the past 20 years in Thailand, but the incidence of CVD has increased during the same time period.

Chinwong et al conducted a randomized crossover trial with healthy Thai volunteers that compared dietary coconut oil with a placebo. During the eight-week study, 32 participants added 15 ml of virgin coconut oil or 2% carboxymethylcellulose solution twice a day to their normal diet. Unlike studies that compare coconut oil to unsaturated plant oils, this study found that VCO increased HDL cholesterol but not LDL or total cholesterol. The results only apply to healthy, young (18-25 years) Thais; more research is needed to see if people with CVD, metabolic syndrome, or different ethnic backgrounds have the same response.

Virgin coconut oil is more than a fat; it also has antioxidant properties. A 2016 rat study by Indian researchers compared VCO to copra oil (CO), a common edible oil made from dried coconut and used in south India. While the fatty acid profile of the two are the same, VCO contains more polyphenolic antioxidants, such as caffeic acid, ferulic acid, syringic acid, catechin, and epigallocatechin. For this experiment, rats in the two treatment groups were given a high-fructose diet (60%), known to promote insulin resistance and fatty liver, and either VCO or copra oil. The control group ate a reference diet that included groundnut oil, which is high in unsaturated fatty acids and low in antioxidant polyphenols. After four weeks, blood glucose levels in the control group increased 26 percent, compared to 46 percent for the copra oil group, and just 17 percent for the VCO group. Moreover, the rats fed virgin coconut oil showed less liver damage and steatosis than the CO-fed rats. The authors say, "These results suggest that VCO could be an efficient nutraceutical in preventing the development of diet-induced insulin resistance and associated complications possibly through its antioxidant efficacy."

In a 2018 study, polyphenols isolated from virgin coconut oil helped protect rats from cadmium-induced dyslipidemia and oxidative stress. Cadmium (Cd), present in cigarettes and contaminated food, inhibits several enzymes involved in lipid metabolism. It significantly increases total cholesterol, low density cholesterol, and triglycerides and decreases HDL cholesterol. For this study, rats were pre-treated with VCO polyphenols for two weeks and then cadmium (5 mg/kg) was added for the next five weeks. The author report, "The co-administration of VCO polyphenol with Cd remarkably restored lipid profile and cardiovascular risk ratios and stabilized antioxidant defense systems comparable to control groups."

Virtually all research with virgin coconut oil focuses on cardiovascular biomarkers. As Thai researchers Chinwong et al, remark "further research should be conducted in the real-world practice among patients with low HDL-C levels, especially those at high risk of cardiovascular events."

Chinwong S, Chinwong D, Mangklabruks A. Daily Consumption of Virgin Coconut Oil Increases High-Density Lipoprotein Cholesterol Levels in Healthy Volunteers: A Randomized Crossover Trial. *Evidence-Based Complementary and Alternative Medicine.* 2017.

Eyres L, et al. Coconut oil consumption and cardiovascular risk factors in humans. *Nutrition Reviews.* 2016; 74(4):267-280.

Famurewa AC, Ejezie FE. Polyphenols isolated from virgin coconut oil attenuate cadmium-induced dyslipidemia and oxidative stress due to their antioxidant properties and potential benefits on cardiovascular risk ratios in rats. *Avicenna J Phytomed.* 2018;8(1):73-84.

Narayanankutty A, et al. Virgin coconut oil maintains redox status and improves glycemic conditions in high fructose fed rats. *J Food Sci Technol.* 2016;53(1):895-901.

Mercury and Heart Disease

"As heart rhythm and function are under autonomic nervous system control, it has been hypothesized that the neurotoxic effects of mercury might also impact cardiac autonomic function," write Giuseppe Genchi and colleagues in their 2017 review article. The researchers performed a literature search in an attempt to uncover the role that mercury exposure might play in cardiovascular disease.

In addition to its neurotoxic effects, mercury increases oxidative stress and decreases antioxidant activity. Mercury latches onto thiol (-SH) and selenium molecules, making these molecules unusable for antioxidant activities performed by the enzymes glutathione peroxidase, catalase, and superoxide dismutase. Mercury also inactivates paraoxonase, an extracellular antioxidative enzyme that supports beneficial HDL activity, and increases LDL oxidation. Mercury also contributes to inflammation, another contributor to CVD, by inducing arachidonic acid metabolite formation (e.g., prostaglandins, thromboxanes, leukotrienes).

Several epidemiological studies have linked mercury exposure, usually via contaminated food, to cardiovascular disease. Mercury, released into the atmosphere by coal-fired power plants and other industrial sources, ends up in soil and waterways – contaminating vegetables, animal products, and especially fish. Populations that rely on contaminated fish as a mainstay, such as those in Brazil's Amazon basin and Quebec, Canada's Inuit, have decreased heart rate variability and increased risk of high blood pressure, atherosclerosis, and heart attack.

Even though the mercury content in fish is a problem, fish are also important sources of omega-3 polyunsaturated fatty acids (PUFA) and selenium. Selenium, as mentioned above, is needed by the body's defensive antioxidant systems; and omega 3s are known to support cardiovascular health. "Many cardiovascular problems related to mercury are mitigated by the concomitant intake of fish, which contains omega-3 PUFA, and by intake of selenium," the authors explain.

A possible dose-response between mercury exposure and cardiovascular events is still being debated. In the meantime, Genchi and colleagues say, "Mercury toxicity should be evaluated in any patient with hypertension, coronary heart disease, cerebral vascular disease, or other vascular diseases and in patients who have clinical history of exposure or clinical evidence on examination of mercury overload."

Genchi G, et al. Mercury Exposure and Heart Diseases. *International Journal of Environmental Research and Public Health.* 2017.

Risk of Stopping Low-Dose Aspirin

Low-dose aspirin reduces the risk of heart attack, particularly in those who have already had one (secondary prevention). Once started, this therapy needs to be continued – unless bleeding or major surgery occurs – as patients who stop taking the aspirin have a >30% increased risk of a cardiovascular event, according to a 2017 Swedish population-based cohort study.

Aspirin is a prescription medication in Sweden, so researchers were able to see which patients over age 40 continued to take the low-dose aspirin (75 to 160 mg) prescribed for prevention of cardiovascular events. They looked for treatment breaks and permanent discontinuation after a year of continuous aspirin treatment from July 1, 2005 to December 31, 2009.

Patients who consistently maintained aspirin therapy had the lowest risk of a cardiovascular event. Those who stopped taking aspiring had a 37% higher risk of an event, an absolute risk of 13.5 events per 1000 person-years: "Put another way, on average, 1 of every 74 patients who discontinued aspirin had an additional cardiovascular event in 1 year." Those using aspirin for primary prevention had less risk (1 of every 146 primary patients) than those with established CVD (1 of every 36 secondary patients). Treatment with an oral anticoagulant or antiplatelet drug decreased the likelihood of an event when aspirin was discontinued. The authors say, "The risk increased shortly after discontinuation and did not appear to diminish over time."

This study did not look at possible confounding factors, such as socioeconomic status, lifestyle factors like smoking, or physical measures, including blood pressure. Also, the authors say there is a risk of reverse causation, "that is, patients about to die stop taking aspirin and then die anyway."

The widespread use of aspirin and the possibility of a rebound effect with discontinuation highlights a need for more research. The authors say, "Experimental studies have suggested a rebound effect after aspirin discontinuation, involving increased thromboxane levels possibly resulting from the pro-thrombotic effects of residual very low levels of aspirin." Does a rebound effect increase heart attack risk, even if a patient discontinues aspirin therapy for a short time because of surgery or other medical procedure? If so, would discontinuing gradually make a difference?

Sundström J, et al. Low-Dose Aspirin Discontinuation and Risk of Cardiovascular Events. *Circulation.* 2017;136:1183-1192.

◆

Literature Review & Commentary

by Alan R. Gaby, MD
drgaby@earthlink.net

Potassium May Improve Glucose Metabolism

Twenty-seven mostly obese African-American adults (mean age, 55 years; mean body mass index, 34.7 kg/m^2) with pre-diabetes and a serum potassium level of 3.3-4.0 mEq/L were randomly assigned to receive, in double-blind fashion, 1,564 mg per day of potassium (as potassium chloride) in capsule form in two divided doses per day or placebo (maltodextrin) for three months. Participants in both groups gained weight during the study, with an overall mean weight gain of 1.24 kg. At the end of the study, compared with baseline, the mean fasting blood glucose level fell by 1.1 mg/dl in the potassium group and increased by 6.1 mg/dl in the placebo group ($p = 0.03$ for the difference in the change between groups). There was a trend ($p = 0.086$) toward greater insulin sensitivity in the potassium chloride group than in the placebo group during an oral glucose tolerance test.

Comment: Potassium is known to play a role in glucose metabolism. The typical American diet contains suboptimal amounts of this mineral, which is found mainly in fruits and vegetables. A dietary survey of 12,581 adults in the United States revealed that less than 2% consumed at least 4.7 g per day of potassium (the current Adequate Intake level).[1] Population groups that tend to have relatively low potassium intake include teenage girls and young women, African Americans, and the elderly.

The results of the present study suggest that consuming adequate amounts of potassium could help prevent type 2 diabetes. Potassium supplementation might also improve glycemic control in some people with type 2 diabetes. However, potassium should be used with caution in diabetics, because hyperkalemia is common in this patient population, being observed in one study in 15% of patients attending a diabetes clinic.[2] Therefore, renal function and serum potassium should be determined in diabetic patients before recommending an increase in potassium intake through diet or supplements.

Chatterjee R, et al. Effects of potassium supplements on glucose metabolism in African Americans with prediabetes: a pilot trial. *Am J Clin Nutr*. 2017;106:1431-1438.

Potassium and Magnesium May Enhance Recovery After a Stroke

Two hundred ninety-one Taiwanese patients who had recently been discharged from the hospital after a stroke were studied. Exclusion criteria included poor renal function (glomerular filtration rate less than 60 ml per minute) and the use of potassium-sparing medicines. The patients were randomly assigned to receive, in double-blind fashion, regular salt, potassium-enriched salt (K salt: 50% NaCl, 50% KCl), or potassium- and magnesium-enriched salt (K/Mg salt: 42.85% NaCl, 42.85% KCl, and 14.3% magnesium sulfate heptahydrate) for six months. It was assumed that patients would consume about 6.5 g per day of table salt (in addition to soy sauce and other salt-containing condiments). At that level of intake, the daily amounts provided would be: regular salt, 2,555 mg of sodium; K salt, 1,278 mg of sodium and 1,701 mg of potassium; K/Mg salt, 1,094 mg of sodium, 1,752 mg of potassium, and 92 mg of magnesium. After adjustment for baseline neurologic status, as compared with the group consuming regular salt, the odds ratio of having good neurologic performance at six months was 1.60 for K salt ($p = 0.26$) and 2.21 for K/Mg salt ($p = 0.052$).

Comment: This study suggests that increasing potassium and magnesium intake while decreasing sodium intake may aid in the neurologic recovery of stroke patients. The results were only of borderline statistical significance, so a larger study should be conducted to confirm the findings. The extent to which each of these dietary changes (more potassium, more magnesium, and

less sodium) contributed to the observed benefit is not clear. In Taiwan, as in the United States, a large proportion of the population consumes suboptimal amounts of potassium and magnesium and excessive amounts of sodium.

Pan WH, et al. Intake of potassium- and magnesium-enriched salt improves functional outcome after stroke: a randomized, multicenter, double-blind controlled trial. *Am J Clin Nutr*. 2017;106:1267-1273.

Metformin Can Cause Vitamin B12 Deficiency

Three hundred ninety insulin-treated patients with type 2 diabetes were treated with metformin or placebo for 52 months. Compared with placebo, metformin significantly increased the mean serum concentration of methylmalonic acid. The increase in methylmalonic acid levels was associated with a significant increase in the severity of polyneuropathy.

Comment: Metformin is widely used to treat type 2 diabetes and polycystic ovary syndrome. This drug has been reported to inhibit the absorption of vitamin B12 in a dose-dependent manner. Discontinuation of the drug corrected vitamin B12 malabsorption in only about half of cases. In an earlier study of 390 patients with type 2 diabetes, the prevalence of vitamin B12 deficiency was significantly higher in patients treated with 850 mg of metformin three times per day for 4.3 years than in those given placebo (9.9% vs. 2.7%; p = 0.004).[3] In the new study, treatment with metformin increased serum concentrations of methylmalonic acid, which indicates a worsening of functional vitamin B12 status. The association between methylmalonic levels and severity of polyneuropathy suggests that metformin-induced vitamin B12 deficiency can increase the severity of diabetic neuropathy. Patients taking metformin should therefore have their vitamin B12 status monitored periodically or be treated prophylactically with vitamin B12 supplements.

Out M, et al. Long-term treatment with metformin in type 2 diabetes and methylmalonic acid: Post hoc analysis of a randomized controlled 4.3 year trial. *J Diabetes Complications*. 2018;32:171-178.

Anthocyanins Inhibit Platelet Aggregation

Sixteen healthy sedentary non-overweight Australian volunteers (mean age, 38 years) were randomly assigned to receive, in double-blind fashion, 320 mg per day of purified anthocyanins extract (from bilberry and black currant) or placebo for four weeks. After a two-week washout period, each person received the alternate treatment for an additional four weeks. Compared with baseline, anthocyanins significantly decreased ADP-induced platelet aggregation, whereas placebo had no effect.

Comment: Excessive platelet activity plays a role in the pathogenesis of cardiovascular disease, and drugs that inhibit platelet aggregation are frequently prescribed for patients who have or are at risk of developing heart disease. Several food-derived flavonoids, including anthocyanins and quercetin, have been shown to inhibit platelet aggregation. Other nutrients that inhibit platelet aggregation include omega-3 and omega-6 fatty acids, magnesium, vitamin B6, vitamin E, and vitamin C.[4] Many of these nutrients are present in relatively large amounts in a whole-foods plant-based diet. The cardioprotective effect of such a diet might be explained in part by inhibition of platelet aggregation, although a number of other mechanisms are likely involved as well.

Thompson K, et al. The effect of anthocyanin supplementation in modulating platelet function in sedentary population: a randomised, double-blind, placebo-controlled, cross-over trial. *Br J Nutr*. 2017;118:368-374.

Folic Acid vs. 5-Methyltetrahyrofolate (5-MTHF)

Thirty-nine healthy volunteers (mean age, 56 years) were randomly assigned to receive, in double-blind fashion, 400 µg per day of folic acid or an equimolar amount of 5-methyltetrahydrofolate (5-MTHF; 416 µg/day) in two divided doses per day for four weeks. The mean increase in the serum folate level from baseline was significantly greater in the folic acid group than in the 5-MTHF group (66.5 vs. 41.8 nmol/L; p < 0.04). The mean serum homocysteine concentration decreased to a nonsignificantly greater extent in the folic acid group than in the 5-MTHF group (13.4% vs. 7.8%; p = 0.24). There were too few participants homozygous for the MTHFR 677C→T genotype (2 in each group) to evaluate that subgroup separately.

Comment: A number of practitioners and supplement companies have argued, largely on theoretical grounds, that 5-MTHF is preferable to folic acid as a nutritional supplement. Some manufacturers have replaced folic acid with 5-MTHF in their multivitamin products, and some practitioners are of the opinion that products containing folic acid should not be used. I have previously reviewed this controversy[5] and concluded that the evidence is not sufficient to justify routinely switching from folic acid to 5-MTHF. Specifically, folic acid appears to be at least as effective as, and may be more effective than, 5-MTHF for lowering homocysteine levels and for treating depression, including among people homozygous for the MTHFR 677C→T genotype.[5] The results of the new study support previous research regarding homocysteine-lowering and also suggest that folic acid is more effective than 5-MTHF for raising serum folate levels.

Sicinska E, et al. Supplementation with [6S]-5-methyltetrahydrofolate or folic acid equally reduces serum homocysteine concentrations in older adults. *Int J Food Sci Nutr*. 2018;69:64-73.

High-Dose Multivitamins and Minerals Effective for Heart Patients

Some 1,708 patients aged 50 years or older (median age, 65 years) who had had a myocardial infarction at least six weeks (median, 4.6 years) previously were randomly assigned to receive, in double-blind fashion, in a 2 x 2 factorial design, a high-dose 28-component multivitamin-multimineral supplement (vitamins), EDTA chelation therapy, both treatments, or placebo. The vitamins were taken in two divided doses per day, and included (daily doses) 100 mg thiamine, 200 mg niacin/niacinamide, 50 mg pyridoxine, 800 µg folic acid, 100 µg cyanocobalamin, 400 mg pantothenic acid, 1,200 mg vitamin C, 400 IU alpha-tocopherol, 60 µg vitamin K1, 100 mg citrus bioflavonoids, 500 mg calcium, 500 mg magnesium, 20 mg zinc, 2 mg copper, 20 mg manganese, 150 µg iodine, 200 µg selenium, 200 µg chromium, and other nutrients. Intravenous treatment consisted of 40 infusions of disodium EDTA-based chelation therapy or placebo (normal saline).

The primary outcome measure was the time to first occurrence of any component of the composite endpoint of all-cause mortality, myocardial infarction, stroke, coronary revascularization, or hospitalization for angina. The results of the EDTA chelation component of the trial have been reported previously.[6] With respect to the vitamins component of the trial, in intent-to-treat analysis, the incidence of the primary endpoint was nonsignificantly lower by 10% in the vitamins group than in the placebo group (27% vs. 30%; p = 0.21).[7] In a pre-specified

➤

➤

subgroup analysis of the 27% of patients who were not taking statins at baseline, the incidence of the primary endpoint was significantly lower by 37.5% in the vitamins group than in the placebo group (22.76% vs. 36.44%; p = 0.006). The incidence of the secondary endpoint of a combination of cardiovascular mortality, stroke, or recurrent myocardial infarction was 54% lower in the vitamins group than in the placebo group (p = 0.002).

Comment: In this study, administration of a high-dose multivitamin-multimineral supplement substantially decreased cardiovascular disease-related morbidity and mortality in patients with a history of a myocardial infarction who were not taking a statin drug. The compliance rate was relatively low in this study, but all patients who were enrolled were included in the analysis, regardless of whether they adhered to the treatment recommendations. The results may have been even better if only the compliant patients were included in the analysis. The benefits of this multivitamin-multimineral supplement are similar to those reported in randomized controlled trials of statin drugs. However, that finding does not prove that vitamins and minerals can be used as an effective alternative to statin drugs. A randomized controlled trial that compares these two treatments would be needed to investigate that possibility.

Issa OM, et al. Effect of high-dose oral multivitamins and minerals in participants not treated with statins in the randomized Trial to Assess Chelation Therapy (TACT). *Am Heart J*. 2018;195:70-77.

Magnesium for Depression

One hundred twenty-six adults (mean age, 52 years) living in Vermont with mild-to-moderate depression were randomly assigned to receive, in open-label fashion, 248 mg per day of magnesium (from 500 mg of magnesium chloride) or no treatment (control) for six weeks, and then the alternate treatment assignment for an additional six weeks. Compared with no treatment, magnesium supplementation was associated with significant improvements in measures of both depression and anxiety (p < 0.001 for each). The mean degree of improvement relative to the control period was approximately 40% for depression. Similar effects were observed regardless of age, gender, baseline severity of depression, baseline magnesium level, or use of antidepressants. Effects were observed within two weeks.

Comment: Depression is one of the known manifestations of magnesium deficiency. A previous double-blind trial found that magnesium supplementation can improve symptoms of depression in people with a low serum magnesium level.[8] The results of the present study suggest that the beneficial effect of magnesium is not limited to people with hypomagnesemia. Serum magnesium is an unreliable indicator of magnesium nutritional status. Therefore, some people with normal serum magnesium might have depression as a result of intracellular magnesium depletion. It is also possible that magnesium improves depression through a pharmacological effect. Because magnesium is safe and inexpensive, it should be considered for adjunctive treatment of depression. In some cases, magnesium supplementation might obviate the need for antidepressant medication.

Tarleton EK, et al. Role of magnesium supplementation in the treatment of depression: A randomized clinical trial. *PLoS One*. 2017;12:e0180067.

Intermittent High-Dose Vitamin D Dosing Not Recommended

One hundred seven elderly individuals (mean age, 81 years) living in a long-term care facility in Colorado were randomly assigned to receive, in double-blind fashion, high-dose vitamin D3 (100,000 once a month; equivalent to about 3,300 IU per day) or standard-dose vitamin D3 (monthly placebo for those taking 400-1,000 IU per day as part of usual care, or 12,000 IU once a month for those taking less than 400 IU per day as part of usual care; thus, equivalent to approximately 400-1,000 IU per day for the standard dose) for one year. The mean serum 25-hydroxyvitamin D level at baseline was 23 ng/ml. The incidence of acute respiratory infections was significantly lower by 40% in the high-dose group than in the standard-dose group (0.67 vs. 1.11 per person-year; p = 0.02). The incidence of falls was significantly higher by 133% in the high-dose group than in the standard-dose group (1.47 vs. 0.63 per person-year; p < 0.001).

Comment: In this study, monthly high-dose vitamin D3 supplementation reduced the incidence of acute respiratory infections but increased the incidence of falls in elderly long-term care residents. At baseline, the mean vitamin D supplement dose was 229 IU per day, which suggests that many participants were consuming less than Recommended Dietary Allowance for their age group (800 IU per day). Previous studies have found that vitamin D in doses of 800 IU per day can decrease the risk of falls. In several studies, however, intermittent administration of large bolus doses of vitamin D3 significantly increased the incidence of falls. In a study in which participants received 500,000 IU as a single dose once a year for three to five years (equivalent to 1,370 IU per day) the excess falls occurred mainly in the three months after the annual vitamin D doses.[9] That finding supports the hypothesis that subtle toxicity occurs transiently after large bolus doses of vitamin D, and results in impaired strength or balance.

Based on the available evidence, more frequent administration of lower vitamin D doses seems preferable to less frequent administration of higher doses. There is no obvious reason to expect that more frequent vitamin D dosing would attenuate the protective effect against infections that was observed in the present study.

Ginde AA, et al. High-dose monthly vitamin D for prevention of acute respiratory infection in older long-term care residents: a randomized clinical trial. *J Am Geriatr Soc*. 2017;65:496-503.

References

1. Cogswell ME, et al. Sodium and potassium intakes among US adults: NHANES 2003-2008. *Am J Clin Nutr*. 2012;96:647-657.
2. Jarman PR, et al. Hyperkalaemia and apple juice. *Lancet*. 2001;358:841.
3. de Jager J, et al. Long term treatment with metformin in patients with type 2 diabetes and risk of vitamin B-12 deficiency: randomised placebo controlled trial. *BMJ*. 2010;340:c2181.
4. Gaby AR. Cardiovascular risk factors: platelet aggregation. In Gaby AR. *Nutritional Medicine*, 2nd Edition. Concord, NH, 2017, www.doctorgaby.com. Chapter 81.
5. Gaby AR. Which supplement should we use: folic acid or methylfolate? Available at www.doctorgaby.com under "Articles."
6. Lamas GA, et al. Effect of disodium EDTA chelation regimen on cardiovascular events in patients with previous myocardial infarction: the TACT randomized trial. *JAMA*. 2013;309:1241-1250.
7. Lamas GA, et al. Oral high-dose multivitamins and minerals after myocardial infarction: a randomized trial. *Ann Intern Med*. 2013;159:797-804.
8. Rajizadeh A, et al. Effect of magnesium supplementation on depression status in depressed patients with magnesium deficiency: A randomized, double-blind, placebo-controlled trial. *Nutrition*. 2017;35:56-60.
9. Sanders KM, et al. Annual high-dose oral vitamin D and falls and fractures in older women: a randomized controlled trial. *JAMA*. 2010;303:1815-1822.

◆

Still the Best

A Must Have for Kidney Function Support!

CORDIMMUNE ™

The only cordyceps product that is standardized for and declares its cordycepin content

- Supports mitochondrial function and ATP production
- Modulates immune system
- Enhances athletic performance safely
- An excellent adaptogen and adrenal support
- Supports hematopoiesis
- 0.2% Cordycepin (worth over $100 per bottle)
- 0.3% Adenosine • 22% Polysaccharides

Immune Support Beyond Just Polysaccharides!

CORIO PSP ™

The most clinically researched mushroom in Japan and China

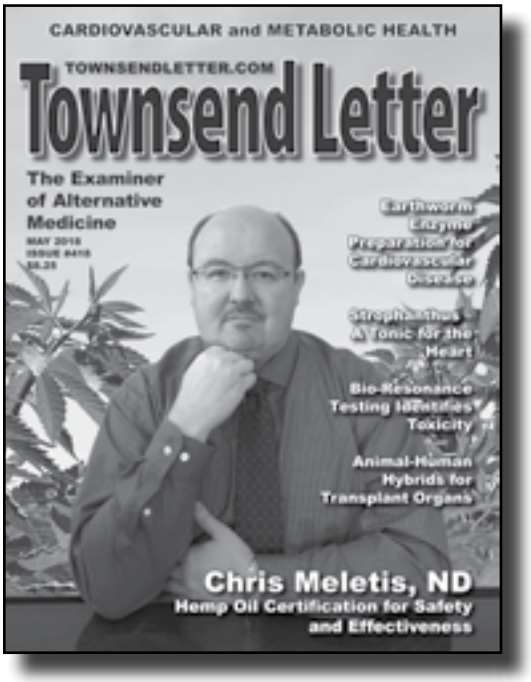
- Unmatched 38% polysaccharides
- Lessens the side effects of toxic treatments
- Raises the quality of life
- Raises the activities of NK cells and macrophages
- Increases thymus weight

The statements herein have not been evaluated by the FDA. This product is not intended to diagnose, treat, or prevent any disease.

CRNA

CANADA RNA BIOCHEMICAL INC.
Tel: (604) 273-2233 • **www.canadaRNA.com**

1-866-287-4986



On the cover

New Certification Program for Hemp Oil Benefits Manufacturers, Healthcare Practitioners, and Consumers, Part 1

by Chris D. Meletis, ND

Cannabinoid-rich hemp oil has emerged as a promising botanical therapeutic with both clinical experience and published studies to support its use. The Stanley brothers are largely credited for first awakening the public to its benefits. The six Colorado siblings developed a hemp extract low in Δ^{9}-Tetrahydrocannabinol (THC), the psychoactive component in marijuana, and high in cannabidiol (CBD), a phytocannabinoid that is not associated with the intoxicating effects of the plant. That hemp extract came to be known as Charlotte's Web after the parents of a little girl named Charlotte Figi convinced the brothers to provide their daughter with CBD-rich hemp oil.[1] Charlotte suffered from a severe type of medication-resistant epilepsy known as Dravet syndrome. She was having 300 seizures per week and her heart frequently stopped. After consuming three to four milligrams of the hemp oil per pound of body weight, Charlotte's seizures disappeared. The case received a lot of publicity in major media outlets such as CNN.[1]

Since then the demand for hemp as a medicinal has skyrocketed and so too has the number of companies producing it and doctors prescribing it. Its benefits have been demonstrated both clinically and in the scientific literature. Based on that scientific research and clinical observations, I employ hemp oil in clinical practice to support the health of patients with epilepsy, anxiety, depression, post-traumatic stress disorder, schizophrenia, inflammation, and pain among other applications. Upcoming articles in *Townsend Letter* will discuss its clinical applications and the evidence in the medical literature. In this article, I will discuss a new cannabinoid certification program for both manufacturers and healthcare practitioners.

Why Manufacturers and Practitioners Need a Certification Program

When new segments of most fields of commercial enterprise enter the marketplace, there are the initial well-intentioned pioneers. This is also true in the hemp oil marketplace. However, like the dietary supplement industry in its early years, the hemp oil marketplace is a Wild Wild West. Up until now, no entity was ensuring the consumer that optimal quantities of the beneficial cannabinoids found in hemp oil were actually contained in the purchased product. As a manufacturer, in order to maintain a respectable reputation and avoid legal complications, it's important to ensure that the hemp oil you're producing lives up to its label specifications. A 2017 article in *JAMA* tested 84 CBD/hemp oil extracts purchased online and found that although CBD oil labeling had the highest degree of accuracy compared to other products tested, 55% of the CBD oil products tested were either underlabeled (more CBD was detected in the product than claimed on the label) or overlabeled (CBD content that was negligible or less than 1% of the amount on the label).[2] In this study, the overlabeled CBD products contained insufficient levels similar to concentrations that resulted in Food and Drug Administration (FDA) warning letters sent to 14 businesses in 2015-2016. Some of the products also contained more THC than noted on the label. In the United States, only cannabinoid-rich hemp oil brands that contain less than 0.3% of the psychoactive cannabinoid THC are legal. Therefore, certainty surrounding the THC content of a particular brand is essential.

The International Center for Cannabis Therapy (ICCT) found similar inaccuracies when its scientists tested hemp oil products sold mainly in online shops in Europe. Not one

of the products tested was legally compliant as European legislation requires zero THC in hemp oil. Furthermore, the vast majority of products contained very little CBD and/or high concentrations of heavy metals and pesticides.

Another challenge that has arisen with the availability of hemp oil is that up until now, healthcare practitioners could not tap into a centralized knowledge base where they could have their cannabis questions answered. Because of hemp oil's relative newness in the dietary supplement arena, there are many healthcare practitioners who are unclear of the proper dosage. Some of them have employed hemp products in their practice with little success not realizing that the product may have contained insufficient CBD. I have also encountered uncertainty among practitioners about the best way to incorporate hemp oil into already-prescribed supplement regimens, whether there are any contraindications to its use, and how its effects differ from marijuana. In interacting with attendees of lectures I have conducted on the endocannabinoid system, it became clear to me that a number of healthcare practitioners have many questions and concerns about the prescribing of hemp oil as well as the endocannabinoid system on which it acts.

"It is essential that health professionals know what the cannabinoid content of a product is because depending on the illness being treated, too much or too little CBD can affect the outcome," said Petr Kastanek, PhD the director of the ICCT. "A Dravet syndrome patient for example will get strong relief from seizures using CBD, but too much CBD can actually trigger a seizure."

This echoes my clinical experience that as functional medicine providers we must always remember that all receptors throughout the body have an optimal tolerance – not only receptors for CBD – and there is such a thing as too much. This is particularly the case when there is an endogenous pathway which is being augmented, such as the endocannabinoid system. After all, achieving and sustaining homeostasis is the goal.

The ICCT's certification program will instruct practitioners (based on proven protocols) on the ideal amount of hemp oil. "Due to its non-toxic nature, a healthy patient won't suffer side effects, but flooding the CB1 and CB2 receptors with cannabinoids is not necessary or advised," said Petr Kastanek. "Micro dosing cannabinoids to activate the receptors creates a potent medical benefit in ICCT's experience."

Clearly, standards are needed both for all cannabis products *and* for practitioners prescribing them.

The International Center for Cannabis Therapy (ICCT)

The ICCT recognized the need for standards in the cannabis industry and consequently introduced three new certification programs: product certification, manufacturing facility certification, and medical certification for practitioners prescribing CBD and other active constituents of hemp. The ICCT is a Czech-based partnership of qualified doctors and scientists who specialize in the medical application of all forms of cannabis. ICCT scientists have spent decades conducting extensive research on the health benefits of medical cannabis as well as product development and medical treatment with an emphasis on enhancing the patients' quality of life.

The organization's certification programs are based on a decade of research conducted by more than 70 ICCT scientists from the Czech Republic and Israel. I recently became aware of the impressive ICCT's mission, clinical work, and the high-caliber of people associated with it. In addition to maintaining my naturopathic practice in Oregon, I accepted the role of Chief Medical Officer–USA of the ICCT.

ICCT Certification for Hemp Oil Manufacturers

The ICCT certification will standardize CBD-rich products and raw materials for human consumption. It uses metabolomic fingerprinting technology to construct a metabolic profile of the cannabinoid product through the pairing of data-rich analytic techniques with multivariate data analysis. The product will be analyzed for cannabinoid profile, pesticides, and contaminants. Manufacturers also have the option to obtain certification for their manufacturing facility similar to cGMP or NSF certification. The ICCT certification ensures that the manufacturer is compliant with local and state regulations. It also tests the quality and consistency of raw materials and provides staff training, product formulation, and compliant labeling. Annual randomized facility inspection is also a component of the manufacturing facility certification.

American Nutritional Products was the first hemp oil manufacturer to become certified by ICCT. "It is because of my 28 years in the supplement industry that I first realized what challenges were going to lie ahead for cannabis and hemp," said Maria Watson, president and CEO of American Nutritional Products, Inc. and former co-owner of Vitamin Research Products (VRP). "The supplement world started out with no known certification body and little control on quality. When we owned VRP, as an industry leader, we drove the movement to clean up our industry – that now needs to happen in the cannabis space."

The ICCT Medical Certification

Medical certification from ICCT for healthcare practitioners involves eight online webinar modules, plus one bonus lecture on marketing your certification to the community and to prospective patients. Conducted by myself and other experts, the webinar modules are based on ICCT research by a team of 70 scientists, the evidence-based peer-review literature, my experience in clinical practice, and proven protocols based on clinical studies. Practitioners enrolled in the certification course will also learn vital information that ensures patients do not overdose on CBD. Additionally, the modules will address other topics crucial to the proper prescribing of hemp oil as described below.

The Entourage Effect of Hemp Oil. The entourage effect is a concept originally proposed by Doctors Mechoulam and Ben-Shabat two decades ago. It originally referred to the ability of certain endocannabinoid system components to enhance the beneficial effects of the two most important actors in this system: anandamide and 2-arachidonylglycerol.[3,4] Since

➤

➤

then, the definition of the entourage effect evolved. It now can refer to the fact that components of cannabis or hemp oil other than THC and CBD – such as phytocannabinoids and terpenes – can actually act synergistically to THC, CBD, or each other. The ICCT certification online course will explain why the entourage effect is important in clinical practice.

CBD Receptors and Pain Perception. Hemp oil may be the answer to today's opioid and pain crisis. Opioid overdose is associated with more than 115 deaths per day in the United States.[5] Finding an alternative to their use is therefore critical.

The endocannabinoid system is closely associated with pain management. The receptors in this system including CB_1 and CB_2 are activated by endogenous endocannabinoids. However, CBD as a phytocannabinoid and other phytocannabinoids in hemp oil also affect receptors in this system as does THC, the psychoactive component of cannabis.[6,7]

The certification course will include an in-depth discussion of endocannabinoid receptors and their role in pain management.

Hemp Oil and Neurodegenerative Conditions and Mood Disorders. An abundance of evidence indicates hemp oil impacts the pathophysiology, progression, cause, and ecology of neurodegenerative conditions, mood disorders, and epilepsy. The certification program will help the busy healthcare provider digest this research and discover how it can be applied in clinical practice.

The Gut-Brain Axis and Cannabinoids. An increasing amount of evidence points to an interplay between intestinal and neurological systems and that this connection is modulated by the gut microbiota, the population of microorganisms found in the intestinal tract. This link between neurological and intestinal systems has become known as the gut-brain axis. Intriguing evidence has emerged that the endocannabinoid system is involved in this interaction.[8,9] The certification program will delve deeply into the role of the endocannabinoid system in the gut-brain axis and how this knowledge can be used to reduce inflammation and support the health of patients with anxiety and depression.

Legal Considerations of Prescribing Hemp Oil. Based on the expertise of a leading attorney in this field of practice, practitioners who receive their cannabinoid certification will move forward with confidence and reassurance on the clinical application of hemp thanks to information presented in a comfortable and simple manner. A number of questions about the legality of hemp oil often arise. These include: 1) What is the difference between federal and state law and the issues of intrastate commerce? 2) Is it true that hemp oil is legal in all 50 states? 3) Is it likely for a person who tests positive to THC, that it could be from hemp oil use alone? 4) Do I need to have special charting or record keeping if I sell hemp oil to patients? 5) If a product that I sell as hemp contains THC beyond the "Legal Limit" to be considered hemp, what is my risk? Hoban Law Group, the leading cannabis business law firm which has presented on behalf of the industry in front of the 9th circuit court, will answer these questions and discuss legal considerations of implementation of hemp oil therapy in practice.

"If you are carrying a hemp product or selling a product with more than 0.3 percent THC then you are dispensing marijuana," said Jason Searns counsel to Hoban Law Group. "It is legally essential to know without question what you are dispensing. With the legal system and U.S. government delineating the role of hemp oil, it is important for clinicians to adhere to a high standard of education as offered by organizations such as the international research and educational organization ICCT."

The Endocannabinoid System and Immunity, Cancer, Senescence, and Healthy Aging. The endocannabinoid system has been found to play an important role in diverse aspects of health. Hemp oil, through its modulation of this system, is a likely option for many health challenges faced by our patients. For example, endocannabinoids are synthesized by most immune cells and upregulate or downregulate a number of immune functions.[10] The CB2 receptor is also involved in reducing oxidative stress associated with cellular senescence, indicating the endocannabinoid system is involved in healthy aging.[11] The certification program will help practitioners understand the myriad ways in which the endocannabinoid system is involved in health and how modulating that system through hemp oil can achieve beneficial results.

Essential Facts Practitioners Must Know About Employing Hemp Oil in Clinical Practice. The different delivery mechanisms of cannabis can influence how it affects the body. The certification program will allow healthcare providers to become proficient in understanding these delivery systems. For example, there is a next generation of CBD products moving into the American market. These products have efficient, transdermal properties so they bring the active substances deep into the tissue. It is also important when using hemp oil not to unduly disturb the endocannabinoid system and overwhelm natural production of the endocannabinoids or alter receptor activity. The certification program will help practitioners understand how to achieve the benefits of hemp oil without causing this undesirable effect. Processing and extraction processes commonly used and pharmacokinetics, pharmacodynamics will also be discussed.

Dr. Chris D. Meletis is an educator, international author, and lecturer. His personal mission is "Changing America's Health One Person at a Time." He believes that when people become educated about their bodies, that is the moment when true change and wellness begins. Dr. Meletis served as dean of naturopathic medicine and chief medical officer for 7 years at National College of Natural Medicine (NCNM) and was awarded the 2003 Physician of the Year award by the American Association of Naturopathic Physicians.

www.DrMeletis.com

Anti-Inflammatory Properties. CBD and other phytocannabinoids and constituents of hemp oil modulate inflammatory pathways. CBD reduces the inflammatory mediators interleukin-6 (IL-6) and TNF-α in rodent models.[12-14] The certification program will discuss in detail hemp oil's role in influencing inflammatory pathways in various disease states.

Other Benefits of Certification. ICCT's certification includes a marketing module conducted by Marketing Unlimited, a firm with 28 years' experience in the natural products industry. This lecture will provide recommendations for marketing the ICCT certification to patients and prospective patients in order to help build clinicians' practice.

Raising the Bar on Hemp Oil Manufacturing and Prescribing

ICCT's ultimate mission in offering its certification programs is to bring European regulatory standards into the US cannabis market. The only type of products carrying ICCT certification will be those that incorporate the efficient use of cannabinoids in well-constructed products to maximize the medical benefit for patients. The ICCT anticipates that consumers will actually seek out doctors who have obtained its certification in cannabinoid therapy and products that have obtained ICCT's blessing as an assurance of quality and safety.

For more information about the ICCT certification programs, visit www.icctcertification.com and join the ICCT mission of education and empowerment.

References

1. Young S. Marijuana Stops Child's Severe Seizures. *CNN*. August 7, 2013. https://www.cnn.com/2013/08/07/health/charlotte-child-medical-marijuana/index.html Accessed February 3, 2018.
2. Bonn-Miller MO, et al. Labeling Accuracy of Cannabidiol Extracts Sold Online. *JAMA*. 2017 Nov 7;318(17):1708-9.
3. Piomelli D, Russo EB. The *Cannabis sativa* Versus *Cannabis indica* Debate: An Interview with Ethan Russo, MD. *Cannabis Cannabinoid Res*. 2016;1(1):44-6.
4. Ben-Shabat S, et al. An entourage effect: inactive endogenous fatty acid glycerol esters enhance 2-arachidonoyl-glycerol cannabinoid activity. *Eur J Pharmacol*. 1998 Jul 17;353(1):23-31.
5. National Institute on Drug Abuse. Opioid Overdose Crisis. February 2018. https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis Accessed February 3, 2018.
6. Miller RJ, Miller RE. Is cannabis an effective treatment for joint pain? *Clin Exp Rheumatol*. 2017 Sep-Oct;35 Suppl 107(5):59-67.
7. Morales P, Hurst DP, Reggio PH. Molecular Targets of the Phytocannabinoids: A Complex Picture. *Prog Chem Org Nat Prod*. 2017;103:103-31.
8. DiPatrizio N. Endocannabinoids in the Gut. *Cannabis Cannabinoid Res*. 2016 Feb;1(1):67-77.
9. Storr MA, Sharkey KA. The endocannabinoid system and gut-brain signalling. *Curr Opin Pharmacol*. 2007 Dec;7(6):575-82.
10. Chiurchiù V. Endocannabinoids and Immunity. *Cannabis Cannabinoid Res*. 2016 Feb 1;1(1):59-66.
11. Hu Y, et al. N-stearoyl-l-Tyrosine inhibits the cell senescence and apoptosis induced by H2O2 in HEK293/Tau cells via the CB2 receptor. *Chem Biol Interact*. 2017 Jun 25;272:135-44.
12. Durst R, et al. Cannabidiol, a nonpsychoactive Cannabis constituent, protects against myocardial ischemic reperfusion injury. *Am J Physiol Heart Circ Physiol*. 2007 Dec;293(6):H3602-7.
13. Barichello T, et al. Cannabidiol reduces host immune response and prevents cognitive impairments in Wistar rats submitted to pneumococcal meningitis. *Eur J Pharmacol*. 2012 Dec 15;697(1-3):158-64.
14. Li K, et al. Anti-inflammatory role of cannabidiol and O-1602 in cerulein-induced acute pancreatitis in mice. Pancreas. 2013 Jan;42(1):123-9.

◆

Hypertension Becomes a Much Bigger Threat

by L. Terry Chappell, MD

On November 13, 2017, everything having to do with adult blood pressure changed. Instantaneously, according to the major cardiology associations in the US, thirty million more Americans no longer could claim to have normal blood pressure. The number of adults now classified as having Stage 1 hypertension rose from 32 to 46%, and another 12% of the population are now determined to have elevated blood pressure. The new normal for BP is 130/80 mmHg for almost everyone, instead of the previous goal of 140/90. All of the newly labeled patients are now expected to be treated primarily with aggressive lifestyle changes.

The New Guidelines

The American Heart Association (AHA) and the American College of Cardiology (ACC), along with nine other health professional organizations presented new guidelines at the AHA's fall Scientific Sessions in Anaheim.[1] The previous guidelines began with the category of prehypertension. No longer is there prehypertension, but now BP is considered elevated if systolic levels are between 120 and 129 mm Hg *and* diastolic levels are less than 80. Previously, Stage 1 hypertension began at 140/90. The new guideline reclassifies Stage 1 hypertension as whenever the systolic BP is 130-139 *or* the diastolic is between 80-89. Stage 2 hypertension now begins when the systolic BP is at least 140 *or* the diastolic BP is at least 90 mmHg. Thus Stage 1 HBP is lowered from 140/90 to 130/80, and this applies to either systolic or diastolic readings.

Approximately 35% of current hypertensive patients are not adequately controlled. With the new guidelines, it is estimated that 53% of patients whose treated BP is currently considered well-controlled will no longer meet that standard. They require additional treatment.

Lifestyle changes are the primary treatments for those with elevated BP and Stage 1 hypertension. Those in both categories will try to prevent disease progression by maintaining the BP between 120/70 and 130/80. The systolic BP guidelines for the elderly had changed from 140 mmHg to 150 mmHg two years ago. But now the upper limit of a normal systolic BP has plunged twenty points to 130/80 for those over 60 years of age, as with the rest of the adult population. The current guidelines are a major attempt to switch the emphasis of treatment to prevention. There are 106 recommendations and 481 pages in the new guidelines. The plan is for every person in these redefined categories to get a comprehensive package of interventions.

Soon after the AHA/ACC guidelines were issued, the American Academy of Family Physicians (AAFP), which did not participate in the AHA/ACC review, rejected them. They insisted that Stage 1 hypertension does not begin until the BP reaches 140/90. Patients with kidney disease or diabetes previously had a lower acceptable limit of 130/80, and that continues. We now have two definitions of hypertension, those from cardiologists vs. those from family docs.

An important caveat in the 2017 AHA/ACC guidelines is that additional medications should be prescribed for patients with Stage 1 hypertension only if increased risk is also present. Unfortunately, plenty of increased risk occurs. Additional risk includes previous myocardial infarction, dementia, stroke, peripheral vascular disease, aneurysms, heart failure, high lipids (according to the AHA 10-year risk calculation), diabetes, and kidney disease. Furthermore, socioeconomic status and psychosocial stress are new risk factors that should be considered.

Despite the expressed intent to shift treatment toward lifestyle changes and avoid increases in medication use, it appears likely that more medications will be prescribed as well. The Stanford Prevention Research Center predicts that 29 million currently treated patients will

Table 1. Key Lifestyle Improvements

Guideline	AHA/ACC Guidelines	Integrative Medicine
Stop smoking	X	X
Reduce obesity	X	X
5 servings of fruits & veggies	X	X
Exercise 2.5 hrs/week	X	X
Limited alcohol	X	X
Low salt routinely	X	
10 year cholesterol risk	X	
Potassium supplements	X	option
Following DASH diet	X	option
Chelation of heavy metals		X
Allergy desensitization		X
Candida treatment		X
Fiber and flax seed oil		X
Stress reduction techniques		X
Pain relief		X
Nutritional supplements		X
Herbals, homeopathics		X

now require additional medications to achieve BP control.[2]

There are six primary lifestyle goals that are specified by the new guidelines: weight loss, reducing sodium, enhancing potassium, 90-150 minutes per week of physical activity, limited alcohol intake, and following the DASH (Dietary Approaches to Stop Hypertension) diet, which emphasizes reduced solid fats and moderate sugar. For many years, integrative physicians have prescribed a much more comprehensive lifestyle program to achieve positive health improvements for their patients. These differing approaches are summarized in Table 1.

It is the purpose of this article to embrace the new guidelines and to suggest a more vigorous drug-free lifestyle program that will be acceptable to the patient, affordable, and effective in preventing vascular disease. Such a program might even enable a patient to discontinue BP medications that he/she is currently taking, which is often a goal that a patient has, perhaps separately from the physician. Integrative medicine has arrived. It is time to show what can be accomplished.

Accurate Measurement of Blood Pressure

According to a quality improvement project coordinated by Brent Egan in South Carolina involving 16 primary care clinics, which followed NIH recommendations, blood pressure readings should include the following for office assessment: Patient arrives without a recent stressful incident and no urgency to visit the rest room. In the previous 30 minutes, no alcohol, food, cigarettes or caffeine, and no exercise are allowed. He or she should be wearing loose clothing. The patient sits in a quiet room, preferably designated for measuring BP, without talking to anyone for three to five minutes. A proper-sized cuff is applied snugly around the upper arm. Both feet are flat on the floor. Three automated readings of BP are taken. An average of the three readings is the BP recorded for that visit.

At some point, the patient should purchase a BP unit to take his or her own BP at home. At least one reading a day should be taken at varying times of the day. The readings should be averaged over a two-to-four-week interval, with one or two outliers discarded if needed.

A BP reading taken soon after the patient arrives at the office or immediately upon the nurse coming into the exam room is not very accurate. One study showed an average reading eight points higher with the usual procedure as compared to a reading following the optimal protocol.

The SPRINT study (Systolic Blood Pressure Intervention Trial) at Kaiser Permanente of Northern California also gave a report at the AHA fall conference.[3] SPRINT used the optimal protocol for recording office blood pressures. They found that blood pressure targets of 120-125 mmHg achieved results with a 70% reduction in increased risk for cardiac events and a 28% reduction in all-cause mortality. This correlated with a systolic BP of 130-132 the way most doctors and nurses take BP. However, SPRINT also found that when systolic BP was over-corrected to 115-125, there was an increased risk of 9% for cardiac events, especially heart failure and cardiovascular death. More kidney failure occurred, and there was a 51% increase in visits to the ER due to hypotension and electrolyte abnormalities. Thus, the best BP target appears to be 120/70 to 130/80 with lifestyle factors the primary treatment.

Tests to Uncover Risk Factors That Interact with Hypertension

Blood tests that might affect blood pressure include a serum creatinine, glucose, CBC, total cholesterol, HDL, LDL, triglycerides, chol/HDL ratio, and hepatic panel (all of which might be included in a routine comprehensive metabolic panel). Additional tests that could be helpful include a TSH, T4, Free T3, the small dense LDL, Lp(a), vitamin D3, fibrinogen, CRPsens, homocysteine, ferritin, serum insulin, HBA1C, and a toxic metals challenge test. Serial CRPsens and HBA1C testing might join BP readings as simple ways to monitor the effects of lifestyle factors.

Hypothyroidism can cause either high or low blood pressure. Correction of hypertension in affected patients can occur with treatment of the thyroid disorder.

Circulation tests for the early detection of cardiovascular disease include cardio risk (ultrasound of carotids), calcium score of coronary arteries with CT scan, stress EKG, and echocardiogram. Family history is an important risk factor. Genetic tests such as MTHFR and ApoE might be useful for selected patients.

Each physician must establish a database of tests that should be accomplished for each patient. That could include the above listed tests. Some tests could be omitted and others added, as the doctor prioritizes.


Sue Visser

Lifestyle recommendations are preferable to drugs in controlling hypertension.

What must be kept in mind is that the most powerful risk factor for vascular disease is hypertension, more powerful than smoking, hyperlipidemia, or inactivity. Increased risk begins with an accurate reading of 120/70. If any of these tests are positive, BP control becomes even more important! If possible, the goal is to achieve BP control without the use of medications, which have potential side effects that create new risks and lessen the benefit of the therapy. Many factors contribute to cardiovascular risk but not to the degree that hypertension does. Since hypertension is the primary factor, it should be treated as such.

Making Blood Pressure a Priority

Hypertension is known as the "silent killer" because the symptoms often do not occur until the damage is advanced. Most doctors are interested in preventive medicine, but effective action does not always occur. If there is concern that blood pressure could be a problem, the patient should have home monitoring records to review. If there is a discrepancy between home and office readings, the patient's cuff should be compared to the office cuff. Both high and low blood pressure need to be addressed. Adrenal stress, anemia,

➤

➤

and low thyroid function contribute to hypotension.

Factors such as diet, exercise, stress, and the use of supplements should be discussed and put into the record. Compliance with and side effects from prescribed medications are reviewed. Risk factors that interact with hypertension and have been identified for each patient should be discussed.

Especially since the AHA/ACC guidelines state that lifestyle improvements rather than increased medications should be utilized to lower Stage 1 hypertension to normal levels, a more aggressive attention to lifestyle is now required. Setting goals, journaling, and increased monitoring with office visits or phone consultations by nurses, PAs, NPs, and physicians are often required for success. Team care is essential. Patients with Stage 1 hypertension should be seen monthly and those with Stage 2 every two weeks. Patient-shared decision making is a concept that is crucial for each patient to accept a treatment plan involving lifestyle changes that pertain directly to him or her. All staff members must buy into the benefits of lifestyle improvements and give positive reinforcement as much as possible. Hopefully, third parties will be more likely now to help pay for the extra time required to implement effective lifestyle changes.

Hypertension is both a disease and risk factor. It can cause coronary artery, cerebral artery, peripheral artery disease, and aneurysms. It can lead to kidney disease, macular degeneration, and intestinal infarctions. Poor BP control contributes to 68,000 preventable deaths yearly. Hypertension accounts for 54% of all strokes and 47% of all coronary artery disease. When combined with diabetes, multiple complications can result. The guidelines did not address isolated systolic hypertension or the additional risk for CAD and kidney disease created by lowering the diastolic BP below 60 mmHg in diabetic patients. These should be included.

Many patients resist treatment for hypertension. Some experience side effects from multiple medications prescribed. The cost of drugs can be a financial burden. Generics should be prescribed whenever possible. Some patients resist the pharmaceutical emphasis of conventional medicine. For those, the AHA/ACC guidelines emphasizing lifestyles should be welcome.

Modifiable Lifestyle Factors for a Suitable Treatment Plan

Certainly, smoking cessation, for well-established reasons, is a high priority. Air pollution is a risk that might be hard to avoid. Assessment and treatment for toxic metals, especially lead, mercury, cadmium, arsenic, and aluminum is major factor. Accumulations of lead and cadmium have been strongly linked to vascular disease.[4] High levels of toxic metals have been detected in many US cities. Lead is a common pollutant in the environment. Cadmium is found in cigarettes and batteries. Gadolinium dye used for MRI testing is an emerging risk factor. Not only is it toxic but as with other metals, it also stays in the body much longer than most doctors realize. Typically, toxic metals reside in the bloodstream for no more than two weeks. Then they are stored in the bone, brain, and fats. Blood tests might not detect accumulated metals. A challenge test with a chelating agent is suggested to assess the body burden of toxic metals and the risk that results. A series of intravenous EDTA chelation treatments is generally the best way to reduce such metals to a safe level.

The Trial to Assess Chelation Therapy (TACT) headed by Gervasio Lamas[5] showed that treatment with 40 IV infusions of EDTA significantly reduced future cardiac events in patients with established coronary artery disease. Toxic metals appeared to be the primary mechanism of action. Sometimes hyperbaric oxygen alone or with chelation can be used to treat resistant cases of hypertension.

Desensitization for airborne, mold, food, and harmful chemicals can lower hypertension as well as improve quality of life. Sensitivities of this type are extremely common. Low-dose antigen (LDA) therapy has been particularly effective in treating these problems. Simply identifying food allergies and avoiding those foods can be helpful. NSAIDs should only be used with extreme caution to control pain. They are known to raise BP and increase mortality.

Obesity, overweight, and the metabolic syndrome are identified by history, physical exam, and BMI measurements. Ideally, a BMI of 25 is a suitable goal. Each physician's office should have a program for weight loss and a list of healthy foods recommended for most patients. Even ten pounds of weight loss can lower blood pressure by several points. A baseline diet for weight loss and blood pressure control might be Trowbridge's anti-yeast low carbohydrate diet, a Mediterranean diet, the DASH diet, or a vegetarian diet. The most important aspect of any diet is the maintenance phase. The amount of improvement in BP control with weight loss has been reported to be comparable to treatment with metoprolol. If a patient has cravings, either for food or cigarettes, a simple supplement called Crave Arrest can be very helpful. If candida imbalance is suspected from a symptom questionnaire or from stool testing, probiotics and anti-fungal agents will probably be required. Otherwise, the toxins produced by yeast will contribute to hypertension.

Dietary factors that have been shown to reduce hypertension at least for some patients include raw foods, onion, garlic, whole oats, soy, olive and sesame oil, dark chocolate, pomegranate juice, fish, and reduction of excessive of salt intake. Five servings of fresh fruits and vegetables daily can reduce elevated blood pressure.[6]

Alcohol consumption is discouraged because it can raise blood pressure and contribute to kidney and liver damage. However, small amounts of red wine (<300ml per day) can have a positive effect on mortality. Multiple studies have shown that supplemented intake of dietary fiber (30 grams per day) can lower both systolic and diastolic blood pressure. Similar amounts of flax seed can also be of benefit. A cup or two of coffee has a relaxing effect for some patients, but excessive caffeine and sugar can raise blood pressure. Green tea is a good alternative.

Approximately two and a half hours of exercise per week is generally recommended. The type of exercise depends of the capabilities of the patient. A pedometer reading of 10,000 steps per day can be recommended for motivated patients. Interval training with three twenty-second bursts of almost all-out effort three times a week plus warm-up might often achieve fitness with a total of 10 minutes per week! Especially for those who have difficulty performing vigorous exercise, a vibration machine such as the Vibabody, will accomplish a mild workout in ten minutes. A sit-down trampoline has similar benefits. Either one can be purchased for $200-300.

The effects of stress are sometimes more difficult to identify and measure but can be a very important factor.[7] Heart rate variability testing, salivary adrenal measurements, serial urine neurotransmitter assessments, and brain wave testing are four ways to objectively document dysfunction due to stress. Once an abnormality is identified, there are specified ways to improve the response of the body to stress. Herbal preparations and homeopathics can reduce anxiety and improve autonomic dysfunction. Adrenal supplements can improve adrenal exhaustion. Neurotransmitters can be balanced with specific amino acids. Neurofeedback, a form of biofeedback, can improve brain wave function. Other techniques not specifically linked to testing include meditation, yoga, and tapping techniques such as NAET and the Emotional Freedom Technique (EFT). Various devices, including portable sauna and biomat, can generate far infrared waves, which are particularly effective in reducing stress. The price of the far infrared devices is in the range of $600-1400. Qi Gong, Yoga, Tai Chi, Heart Math, Transendental Meditation, and the Relaxation Response are all techniques that can reduce the effects of stress, if practiced regularly. Acupuncture and manipulation by chiropractors and osteopaths might also be helpful.

Special workshops like those presented by Steve Kaufman for Pain Neutralization, Dietrich Klinghardt for Neural Therapy, William Schrader for LDA and IV nutrient therapy, and Frank Shallenberger and Robert Rowen for Ultraviolet Blood Irradiation teach skills that are applicable for lowering blood pressure without drugs.

Medications and Supplements

There are five major drug categories for blood pressure treatment. They include the following with the most common side effects listed: thiazide diuretics (low potassium leading to fatigue), ACE inhibitors (high potassium causing arrhythmias and cough), calcium channel blockers (constipation, swelling, headaches), beta-blockers (dizziness, fatigue), and angiotension receptor blockers (dizziness). For Caucasian patients with BP exceeding 140/90 mmHg, an ACE inhibitor or ARB is usually the initial prescription, followed by a calcium channel blocker. For blacks, the calcium channel blocker is first line. A diuretic is next for whites and blacks, and then spironolactone as a fourth drug. Lower doses from multiple categories are preferred in an attempt to minimize side effects. Several drugs from other categories, such as clonidine, alpha ➤

➤

blockers, and hydralazine, are occasionally called upon for resistant cases.

Nutritional supplements could be considered a sixth category.[8] Most effective in that category might be garlic and magnesium. The latter is commonly deficient. One way to find the most effective dose of magnesium is to gradually increase the dose until the patient gets diarrhea. Then reduce the dose to the highest level tolerated by the patient.

Other nutritional supplements that might help lower high blood pressure include vitamin C with lysine (as recommended by Linus Pauling), fish oil, calcium (balanced with at least half as much magnesium), potassium, thiamine, l-arginine to increase nitric oxide, folic acid, vitamin B6, and a tomato extract containing lycopene. Vitamin D3 deficiency is common. If detected with a blood test, vitamin D supplementation might significantly lower blood pressure. The vitamin D effect can be enhanced with ultraviolet blood irradiation. Coenzyme Q10 lowers blood pressure independently with doses of 200-400 mg a day and is particularly important to replace if a patient is taking a statin drug, which can reduce the body's production of endogenous CoQ10 by 40%. Vitamin B12 shots can be self-administered at home several times per week to reduce stress and increase energy. The shots either work well within a month or there is no effect. Jonathan Wright has been a proponent of B12 injections for many years. He has taught many physicians about the effective use of many nutritional supplements and the frequent need for hydrochloric acid for proper digestion.

Herbal preparations and homeopathics can be helpful to treat anxiety and depression, which in turn might benefit patients who have hypertension. Examples of herbs for anxiety are kava, valerian, and passiflora for anxiety and St. John's wort, l-tryptophan, and SAMe for depression. CBD and hemp oils have a nice relaxing effect.

In order for optimal results, several lifestyle changes must be addressed, and long-term maintenance must be practiced. Medications for hypertension, anxiety, and depression can be prescribed, but often have side effects. Natural supplements are usually safer and can be quite effective. Each physician must choose which modalities she wants to utilize in her practice. Additional training might be required. Enough team care support must be provided for each intervention to be successful. A great deal more can be done to improve hypertension with lifestyle interventions than the six measures recommended in the AHA/ACC guidelines.

Two textbooks that contain further information on detecting and treating hypertension with integrative medicine are *Nutritional Medicine* by Alan Gaby and *Integrative Medicine* by David Rakel. Some of the organizations that teach techniques mentioned in this article include the International College of Integrative Medicine (ICIM), the American College for Advancement in Medicine (ACAM), the American Academy of Environmental Medicine (AAEM), the Academy of Integrative Health and Medicine (AIHM), and the Institute for Functional Medicine (IFM).

After graduating from the University of Michigan Medical School, Dr. Chappell became certified by the American Board of Family Medicine and later by the National Board of Physicians and Surgeons. He is the author of *Questions from the Heart* and has published many articles in the *Townsend Letter* and in other journals showing the effectiveness of chelation therapy for vascular disease.

Conclusions

The AHA/ACC has given us a new paradigm for detecting and treating hypertension, our number one cardiovascular risk factor. We should embrace it, improve it, and work together to achieve the best results possible. First, we must be certain that we have a consistent protocol for measuring blood pressure and treating it effectively. We should have three to five minutes of silent relaxation prior to taking the readings, both at home and in the office. Home readings usually have precedence over office readings. Second, the AHA/ACC guidelines are preferable over the older guidelines reaffirmed by the AAFP, because they save added lives and reduce complications from the disease. Effective lifestyle changes and a more natural treatment are strongly preferred to reduce BP to acceptable levels with an upper limit of 130/80 mmHg. Third, additional medications are to be avoided whenever possible to control Stage 1 hypertension. In fact, fewer medications than currently used are preferable. The lifestyle recommendations in the AHA/ACC guidelines are a good start, but we can do far better with the suggestions that have been offered by integrative physicians for many years. Fourth, more testing, office visits, phone call follow-ups, procedures, supplements, and devices will be required for lifestyle improvements to succeed. A team care approach is usually necessary. This will increase the cost of care somewhat in the short run, but in the long run, better BP will result in improved health and reduced costs for individual patients and society at large.

References

1. Whelton PK, chairman. Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension*. November 13, 2017 (Epub ahead of print).
2. Ioannidis, JP. Diagnosis and treatment of hypertension in the 2017 ACC/AHA guidelines and in the real world. *JAMA*. 2018;319:115-116.
3. Go A. Systolic blood pressure intervention trial (SPRINT). *N Engl J Med*. 2015; 373: 2103-2016.
4. Solenkova NV, et.al. Metal pollutants and cardiovascular disease: mechanisms and consequences of exposure. *Am Heart J*. 2014; 168:812-822.
5. Lamas GA, et.al. Effect of disodium EDTA chelation regimen on cardiovascular events in patients with previous myocardial infarction: the TACT randomized trial. *JAMA*. 2013; 309: 1241-1250.
6. Hypertension. In: Gaby AR, ed. *Nutritional Medicine*. Concord, NH: Fritz Perlberg Publishing; 2011: 323-335.
7. Dickinson HO, et.al. Lifestyle interventions to reduce raised blood pressure: a systematic review of randomized controlled trials. *J Hypertens.* 2006; 24:215-233.
8. Plotnikoff, GA, Dusek J. Hypertension. In Rakel D, ed. *Integrative Medicine*, 4th edition. Philadelphia: Elsevier; 2012: 230-241.

◆

Testosterone's Role in Cardiovascular Health:

A Review of the Literature

by Gary Huber, DO, AOBEM, and Andrew Comb, RPh

The practice of medicine in America is such an interesting beast. Much like the current political environment where there is such deep divide, we find similar camps in medicine where instead of a united review and discussion of the literature we either fall far left or far right on given issues. If we look back in history at the treatment of heart disease in this country, we see a once absolute belief that LDL cholesterol is "bad" and credited as the lone cause of heart disease, acquired from eating too much fat. Then the science catches up and disproves this belief more than 20 years ago; and yet still to this day, a majority of clinicians and even cardiologists still cling to this outdated paradigm. I detail this in an article published in March 2016, and you can review this in full detail in my library at www.huberpm.com.

And so it seems that testosterone has fallen to a similar fate. I published an article in February 2017 (www.huberpm.com) detailing the history of testosterone over time and the current societal lifestyle trends that cause its erosion in modern populations. This has become a hot issue as greater numbers of men are suffering from an escalating rate of hypogonadism at the same time that the FDA is trying to limit testosterone use and availability. The overwhelming evidence that proper testosterone levels are key to good cardiovascular health is being lost due to a few poorly constructed and executed studies that have received undue notoriety. It is my hope here to explore the current science and put to rest any unease that testosterone could in any way contribute to greater cardiovascular risk. Let's move beyond myth and engage our love of science to drive intelligent decision making.

Interesting to note that more than one study has explored the idea that a proven scientific fact can take 10 to 20 years before it becomes common knowledge in the medical community. The Morris study[1] in 2011 reported that it takes 17 years post publication to alter a previously set medical paradigm. Testosterone has a tainted history. Huggins' research in the 1960s proclaimed that testosterone was the cause of prostate cancer. This has since been disproved, and we generally accepted that testosterone is not a causative factor; but it took more than 40 years to erase that error. Methyl-Testosterone use back in 1935 created increased occurrence of liver cancer which even today leaves some uninformed clinicians with suspicion regarding the safety of modern bioidentical testosterone. Making matters worse is the fact that both medical school and pharmacy school training is seriously devoid of any detailed education in the proper physiology and proper use of bioidentical hormones. Many physicians still confuse drugs with hormones despite holding polar differences in effect.

Many physicians take on the task of using bioidentical hormones armed only with the information provided by the pharmaceutical companies. This invites another problem as the pharmaceutical companies have never studied the absorptive path of topical testosterone. None of the current topical testosterone manufacturers have any literature to demonstrate testosterone's absorptive rate, yet they have all made claims that it absorbs at a standard 10% rate. No company anywhere at any time has ever published literature demonstrating that they tested tissue levels after applying their product. These companies have no idea how their product moves through human physiology nor how it impacts metabolic byproducts such as dihydrotestosterone or estradiol; yet these same companies are the ones instructing uninitiated doctors on the use of this powerful endocrine agent. The Basaria study,[2] published in the *New England Journal of Medicine*, is a great example of this. Subjects were given 100 mg of topical testosterone as a starting point and then doses were increased from there. The human body on average only makes 10 mg of testosterone per day, so why were these men being given supra-physiological doses, ten times the normal daily production?

A look at the literature should provide a clue as to the absorptive rates of testosterone despite it having never been actually tested. In the Chang[3] study, women scheduled for lumpectomy were given one of four treatments: placebo, progesterone, estradiol, or progesterone plus estradiol topically for 11 to 13 days prior to procedure. The procedure was intentionally scheduled to be done prior to ovulation on day 11-13 of the menstrual cycle when progesterone would be at its lowest level. On the day of the surgical procedure, serum level for progesterone and estradiol were measured and compared to actual biopsied tissue levels. The plasma levels of progesterone were <1 ng/dl in all of the patient groups. Tissue levels however showed quite a different result. In patients receiving placebo or estradiol the progesterone level ranged between 0.6 to 2.1 ng/gram. But in the patients receiving progesterone, the

➤

➤

average level of progesterone found in the tissue was 53.5 ng/gram. That's roughly a 50-fold difference while the serum showed no elevation of any kind. This clearly demonstrates that progesterone is moving through the body by lymph flow, diffusion, and arterial spread but is not being reflected in the venous return. Therefore, we cannot use serum measures to assess topical steroid use.

This finding is confirmed with a look at the Du[4] study, which gave topical progesterone to women and tracked levels in the serum, saliva, and capillary blood over 24 hours. Again, we saw that whole blood and serum levels remain relatively unchanged while spikes were seen in both the saliva and capillary blood specimens. It would seem apparent that hormone movement through the body is being facilitated by lymphatic and arterial spread that is being metabolized by the cells into metabolites other than the parent compound and thus not being detected in the venous sample.

Yes, these are studies of progesterone not testosterone, but testosterone is a slightly smaller molecule than progesterone, is lipophilic like all of the steroid hormones and would be expected to move in identical fashion to progesterone. Given this knowledge how can we expect serum measures such as those used in the Basaria study to accurately reflect true physiology?

Topical hormones are absorbed, distributed, and metabolized differently than our endogenous hormones. There is a peak and trough effect that is not like our endogenous hormones. There is metabolism of parent compounds into metabolites, yet we are searching for the parent compound in venous blood and ignoring its metabolite.

If you were to follow the estradiol, DHT and testosterone metabolite levels in the venous blood of patients receiving the high dose topical testosterone given by the Basaria[2] study, you would see dramatic elevations; but these were not tested. It needs to be considered that this supra-physiologic dosing of testosterone may in fact cause tachyphylaxis, which may lead to adverse events. Bottom line, there is no evidence to support the notion that testosterone absorbs at a 10% rate, and then to assume we can track its movement through venous sampling is to ignore multiple physiologic principles.

The treatment of women with bioidentical hormones has typically engaged levels of hormone replacement that are on par with physiologic hormone production. A woman makes roughly 380 mcg of estradiol mid-cycle and about 250 mcg in the mid-luteal phase. Typical treatment doses of estradiol deliver 250 to 500 mcg of estradiol per day, which is close to and consistent with physiologic levels. Progesterone production in a cycling female ranges from 1 to 25 mg depending on the luteal timing, and we typically replace progesterone at a dose of 20 to 40 mg, so once again nearly consistent with physiologic production. The results of these treatments show obvious physiologic and clinical benefit for these women as studies have shown clear reduction in cardiovascular events, better bone density, and improvements in cognitive and neurologic function. So why is it that when we go to treat men we abandon the lessons learned about physiologic hormone replacement and hormone movement in tissue and insist upon using 10 times the physiologic dose of testosterone? There is no science to support such high dosing and absolutely no studies done to demonstrate tissue levels of testosterone when exposed to such high doses.

The Literature

As we look to explore the history of testosterone's relationship with heart disease in the literature, we can see that epidemiologic studies from 20 years ago have consistently shown an inverse correlation between the endogenous testosterone level and major risk factors of atherosclerosis, as well as the presence and extent of coronary artery disease.[5-7] Despite this history, a prior study by Gluud[8] in 1986 set a truly bad example by using an extremely high dose of a non-approved oral micronized testosterone that led to serum levels ranging from 4,000 to 21,000 ng/dl, a value 20 times the upper range of normal. The study included 221 men with cirrhosis who were treated with 600 mg of oral testosterone. Despite this toxic dose of testosterone in an ill group of men, there was only one myocardial infarction reported. The authors chose to label any bleeding event as a cardiovascular event. The most frequently observed cause of death in this study was bleeding from esophageal varices, which is not surprising given that this was a group of cirrhotic patients. Despite this poorly constructed study, it is cited as one of the examples of the dangers of testosterone by later studies such as the metanalysis by Xu[9].

The meta-analysis by Xu[9] in 2013 gives the impression to the medical community that it is a consensus statement as it claims to offer review of 27 studies. The authors of this meta-analysis specifically included only studies in which one or more cardiovascular (CV) events were reported, so any study without a reported CV event was excluded. Obviously, this selection process exaggerates the apparent rate of events, and misrepresents differences in event rates between groups. In addition, 2 out of the 27 studies contributed nearly 35% of all CV events in the testosterone arm. These two studies were the Basaria study and the 1986 Copenhagen (Gluud) study[8], both of which have already been cited as poorly designed and poorly executed studies.

The Basaria[2] study received a lot of notoriety as it appeared in the *NEJM*, but the study design was seriously flawed. When changing the hormonal milieu of the body, the cellular physiology may take as long as 12 weeks to fully reach steady state as binding proteins and hormones go through homeostatic adjustments. Despite this, the design of the Basaria study chose to test patients a mere two weeks after the introduction of topical testosterone. They also elected to start the original dosing of testosterone at 100 mg daily which represents 10 times physiologic dosing. They only measured serum levels which has already been discussed above; and if serum levels did not reach their desired level of >500 mg/dl then the dose was further increased to 150 mg daily. They did not elect to monitor any testosterone metabolites such as DHT or estradiol, which would one might expect to be abnormally high given the use of supra-physiologic doses of testosterone.

A total of 209 men (mean age, 74 years) completed the Basaria study. Baseline measures showed a high prevalence of hypertension, diabetes, hyperlipidemia, and obesity among the participants. This group of men had poor mobility and significant

levels of chronic disease such that risk for CV events was already high at the onset. The authors make the claim that during the course of the study, the testosterone group had higher rates of cardiac, respiratory, and dermatologic events than did the placebo group. A total of 23 subjects in the testosterone group, as compared with five in the placebo group, had what the authors report as "cardiovascular-related adverse events."

This study had several flaws in addition to its lack of power with only 209 participants:

- Men in the testosterone group had higher baseline risk compared to the control group (more hypertensive patients, more patients with hyperlipidemia) for cardiovascular events.
  - A greater percentage of the testosterone group was on statin therapy.
- Cardiovascular-related events were reported in patients receiving higher doses of testosterone with abnormally high serum levels:
  - Four subjects with testosterone levels higher than 1000 ng per deciliter,
  - Five subjects with testosterone levels of 500 to 1000 ng per deciliter.
- Cardiovascular events were not a planned primary or secondary outcome, so there was no structured evaluation of cardiovascular events.
  - In fact, there was only one myocardial infarction reported for the entire study.
- Clinical characteristics of the study population differ from those of most populations being considered for testosterone therapy:
  - Men who were younger than 65 years of age and men with severe hypogonadism were excluded from the trial.
- Participants had substantial limitations in mobility and a high prevalence of chronic conditions, including preexisting heart disease, obesity, diabetes, and hypertension.
  - Frail, elderly men with limitations in mobility are more likely to have clinical and subclinical cardiovascular disease.
- The testosterone doses in this trial were higher than those that are typically used in clinical practice.
- The lack of a consistent pattern in the cardiovascular events and the small number of overall events suggest the possibility that the differences detected between the two trial groups may have been due to chance alone.
- What was not highlighted was that the men in the testosterone group reported dramatic improvement in strength, stair climbing ability, and stamina.

A broadly discussed study from 2013 was the Vigen[10] study which has received broad criticism from many professional organizations for its inaccuracy in statistical analysis. This study was a retrospective cohort study of 8709 men in the Veterans Affairs system who underwent angiography over a six-year period and were then followed for any occurrence of myocardial infarction, stroke or death. To qualify for the study these men had to have demonstrated a low testosterone level below 300 ng/dl. Testosterone replacement was not a therapeutic treatment in the study design, but 1223 of the participants received some form of testosterone treatment from their physicians simply by chance. After the first prescription for testosterone was received, this study assumed that it was continued throughout the entire study period. However, 17.6% of the patients received only one prescription for testosterone. The authors reported an increased rate of heart attacks, strokes, and deaths in men receiving testosterone compared to those who did not. The overall event curves showed a 29% increase in CV events among men on testosterone according to the authors. These reported facts were not truly reflected in the analysis but were a misrepresentation obtained through statistical manipulation.

The actual event occurrence simply looking at the raw data are as follows:

Event	7486 Patients No testosterone exposure	1223 Patients Received testosterone
Myocardial Infarction	420 (5.6%)	23 (1.9%)
Cerebrovascular accident	486 (6.5%	33 (2.7%)
Death	681 (9.1%)	67 (5.5%)

Obviously, the group receiving testosterone therapy had a much better prognosis, which is exactly the polar opposite of what was reported by the authors of this study.

Literature in Support of Testosterone Use

Let's now turn our attention to the ample literature that show testosterone's physiologic impact on cardiovascular and related function.

The 2015 meta-analysis by Corona[11] compared five different meta-analysis studies (Calof et al,[12] Haddad et al,[13] Fernández-Balsells et al,[14] Xu et al,[9] Corona et al[15]). Of the five available meta-analyses, four of them did not find any effect of testosterone therapy on CV events, positive or negative. Xu[9] was the only study to show any effect on CV events and this has already been discussed above. The Corona study concludes that there is little evidence to support any causal relationship between testosterone replacement therapy and adverse cardiovascular events. This meta-analysis concluded that testosterone therapy could be a new strategy in managing and improving blood glucose and cholesterol, as well as reducing body fat and increasing lean muscle mass. All of which are factors that reduce heart disease risk. In addition, for patients with type 2 diabetes or metabolic syndrome, there was a protective effect of testosterone therapy against major adverse cardiovascular events (MACE).

The paradigm of testosterone increasing CV risk is not only false but dangerous as testosterone is in fact one of the keys to reducing cellular inflammation, guarding against elevated glucose, dilating coronary vessels, and protecting the heart against the progression of atherosclerotic disease.

In 2000, English et al[16] conducted a double-blind randomized control trial in an effort to define the effects of low-dose transdermal testosterone therapy on men with chronic stable angina. Men were given transdermal testosterone patch that delivered 5 mg per day. This study concluded that low-dose testosterone therapy has a positive impact on angina threshold, as well as reducing exercise-induced myocardial ischemia in these men. This was one of the first of many studies in the early 21st century to define the positive impacts of testosterone therapy.

Due to the myths about testosterone having a negative impact on cardiovascular health, numerous studies were conducted in the early 2000s on testosterone use in patients with heart failure. A double-blind randomized placebo-controlled trial was

➤

Testosterone's Role

➤

done by Malkin[17] in 2006, looking at patients with moderate heart failure. Again, we see the use of a transdermal patch of testosterone to deliver daily physiologic dose of 5 mg. This study found that testosterone therapy had little consequence in terms of cardiovascular risk but provided an improvement in functional capacity and heart failure symptoms in men treated with testosterone. Later on, in 2009, the Caminiti[18] study found that long-acting testosterone therapies (undecanoate) had a plethora of positive outcomes in men with moderately severe CHF, including improved exercise capacity, muscle strength, glucose metabolism, and baroreflex sensitivity (BRS). They employed an IM injection of 1000 mg every six weeks, yielding roughly 20-24 mg per day.

The next few years yielded studies that delved into the use of testosterone therapy in men who were deficient in testosterone. This is likely due to the uptick in commercial advertisements for "Low T" during this time period. In 2012, the Shores[19] study concluded that men with low testosterone levels treated with testosterone therapy had a dramatic overall decrease in mortality compared with men who received no testosterone therapy at all. The patients given testosterone therapy (IM testosterone) had a mortality rate of 10.3% compared with 20.7% in untreated men over the length of the study. These men had a high degree of chronic medical morbidity with an average of seven pharmacologically treated medical conditions. They had a 21% prevalence of coronary heart disease and a 38% prevalence of diabetes. This study demonstrates the broad impact appropriate testosterone therapy can have on chronic degenerative disease states.

A study done by Muraleedharan et al.[20] in 2013, found that testosterone therapy could improve survival in hypogonadal men with type 2 diabetes. This study was further supported by the Cai[21] study which established that testosterone therapy can improve glycemic control and decrease triglyceride levels of hypogonadal men with type 2 diabetes.

One of the most recent studies from 2016 by Haider[22] showed impressive impact across many physiologic parameters using sensible testosterone therapy. They treated 77 men with low testosterone levels below 300 ng/dl, using slow release undecanoate testosterone injections every three months. They elevated the testosterone level to an average between 420 to 680 ng/dl. These men were followed over the course of eight years and showed yearly progressive improvements in weight reduction, blood pressure, and HgbA1c measures. There was improvement in all of the cardiometabolic risk factors. The authors concluded that testosterone therapy could be an effective add-on therapy in secondary prevention of cardiovascular events in hypogonadal men with a history of CVD.

For more than 20 years now, we have come to realize that LDL is not the cause of heart disease but rather its oxidation that drives the atherosclerotic process. Oxidized LDL is taken up by macrophages thus driving foam cell formation. This oxidized LDL within plaque is highly immunogenic and creates autoantibodies thus further driving this inflammatory immune process, accelerating the accumulation of LDL and plaque.[23-26] Rising autoantibodies to oxidized LDL is predictive for carotid atherosclerosis progression and myocardial infarction. These antibodies are a very reliable predictor of coronary vessel involvement.[27]

The Barud study[28] looked at a host of clinical characteristics and biometric measures and found that testosterone had a consistent inverse correlation with the level of LDL autoantibodies and showed more reliable correlation than lipid levels, age, body weight, or smoking history. Testosterone as an immune modulator is key to reducing coronary risk via its impact as an anti-inflammatory and immune modulating agent.

Direct-to-consumer advertisements by the pharmaceutical industry prompting men to seek treatment for reduced sex drive, decreased energy, and mood changes has led to a dramatic increase in testosterone prescriptions. Unfortunately, the FDA is looking at old literature and maintaining a stance that testosterone may be dangerous for cardiovascular patients. The FDA put out a statement that men should only receive

Dr. Gary Huber is president of the LaValle Metabolic Institute. He spent 20 years as an emergency medicine physician before joining Jim LaValle in the practice of integrative medicine at LMI. Dr. Huber is an adjunct professor teaching integrative medicine practice at the University of Cincinnati College of Pharmacy as well as a clinical preceptor for pharmacy students. Dr. Huber also lectures on hormone replacement therapies and integrative care for the American Academy of Anti-Aging Medicine for the University of South Florida. He has developed the Metabolic Code Professional Weight Loss Program that has proved very beneficial in reversing metabolic syndrome issues. Dr. Huber has a long-held interest in nutrition and human physiology as they relate to wellness and longevity. He has served as medical director for the Flying Pig Marathon and is presently on the board of directors for Loveland's Amazing Race, a local charity event.

testosterone therapy if they have documented hypogonadism. This recommendation makes sense and seems prudent, but I would add that as clinicians interested in disease reversal and prevention we need to take a more proactive stance and screen for hypogonadism given the inexpensive and valuable nature of replacement therapy. The time of fearing the boogie man has passed. Science has shown that we needn't fear unproven risks. Testosterone has proven itself to be a most valuable therapy when applied in a sensible manner.

References

1. Morris, Wooding, Grant. The answer is 17 years, what is the question: understanding time lags in translational research. *J R Soc Med*. 2011: 104: 510–520.
2. Basaria S, et al. Effects of testosterone administration for 3 years on subclinical atherosclerosis progression in older men with low or low-normal testosterone levels: a randomized clinical trial. *JAMA*. 2015;314(6): 570-581.
3. Chang KJ, et al. Influences of percutaneous administration of estradiol and progesterone on human breast epithelial cell cycle in vivo. *Fertility and Sterility*. 1995;*63*(4):785-791.
4. Du, Sanchez K, et al. Percutaneous progesterone delivery via cream or gel application in postmenopausal women: a randomized cross-over study of progesterone levels in serum, whole blood, saliva, and capillary blood. *Menopause: The Journal of The North American Menopause Society*. 2013; 20 (11).
5. Zhao SP, Li XP. The association of low plasma testosterone level with coronary artery disease in Chinese men. *Int J Cardiol*. 1998;63:161.
6. Simon D, et al. Association between plasma total testosterone and cardiovascular risk factors in healthy adult men: the Telecom Study. *J Clin Endocrinol Metab*. 1997;82:682.
7. English KM, et al. Men with coronary artery disease have lower levels of androgens than men with normal coronary angiograms. *Eur Heart J*. 2000;21:890.
8. Gluud, C. Testosterone treatment of men with alcoholic cirrhosis: A double-blind study. *Hepatology*. 1986; 6(5), 807-813.
9. Xu L, et al. Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. *BMC Med.* 2013;11:108.
10. Vigen R, et al. Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels. *JAMA*. 2013; 310: 1829–36.
11. Corona G, et al. Testosterone replacement therapy and cardiovascular risk: a review. *World J Men's Health*. 2015; 33(3):130-142.
12. Calof OM, et al. Adverse events associated with testosterone replacement in middle-aged and older men: a meta- analysis of randomized, placebo-controlled trials. *J Gerontol A Biol Sci Med Sci*. 2005;60:1451-7.
13. Haddad RM, et al. Testosterone and cardiovascular risk in men: a systematic review and meta-analysis of randomized placebo-controlled trials. *Mayo Clin Proc*. 2007;82:29-39.
14. Fernández-Balsells MM, et al. Clinical review 1: adverse effects of testosterone therapy in adult men: a systematic review and meta-analysis. *J Clin Endocrinol Metab*. 2010;95:2560-75.
15. Corona G, et al. Cardiovascular risk associated with testosterone-boosting medications: a systematic review and meta-analysis. *Expert Opin Drug Saf*. 2014;13:1327-51.
16. English KM, et al. Low-dose transdermal testosterone therapy improves angina threshold in men with chronic stable angina: a randomized, double-blind, placebo-controlled study. *Circulation.* 2000; 102: 1906–11.
17. Malkin CJ, et al. Testosterone therapy in men with moderate severity heart failure: a double-blind randomized placebo controlled trial. *Eur Heart J*. 2006; 27: 57–64.
18. Caminiti G, et al. Effect of long-acting testosterone treatment on functional exercise capacity, skeletal muscle performance, insulin resistance, and baroreflex sensitivity in elderly patients with chronic heart failure a double-blind, placebo-controlled, randomized study. *J Am Coll Cardiol.* 2009; 54: 919–27.
19. Shores MM, et al. Testosterone treatment and mortality in men with low testosterone levels. *J Clin Endocrinol Metab*. 2012;97:2050–8.
20. Muraleedharan V, et al. Testosterone deficiency is associated with increased risk of mortality and testosterone replacement improves survival in men with type 2 diabetes. *Eur J Endocrinol.* 2013; 169: 725–33.
21. Cai X, et al. Metabolic effects of testosterone replacement therapy on hypogonadal men with type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials. *Asian J of Andrology*. 2014;16(1): 146.
22. Haider A, et al. Men with testosterone deficiency and a history of cardiovascular diseases benefit from long-term testosterone therapy: observational, real-life data from a registry study. *Vascular Health and Risk Management*. 2016;12: 251.
23. Esterbauer H, Wag G, Puhl H. Lipid peroxidation and its role in atherosclerosis. *Br Med Bull*. 1993;49:566.
24. Kodama T, et al. Type I macrophage scavenger receptor contains alpha-helical and collagen-like coiled coils. *Nature*. 1990;343:531.
25. Witztum JL. Immunological response to oxidized LDL. *Atherosclerosis*. 1997;131:S9.
26. Lopes-Virella MF, et al. The uptake of LDL-IC by human macrophages: predominant involvement of the Fc gamma RI receptor. *Atherosclerosis*. 1997;135:161.
27. Puurunen M, et al. Anibody against oxidized low-density lipoprotein predicting myocardial infarction. *Arch Intern Med.* 1994;154:2605.
28. Barud W, et al. Inverse relationship between total testosterone and anti-oxidized low density lipoprotein antibody levels in ageing males. *Atherosclerosis*. 2002;164 (2):283-288.

◆

Lumbrokinase – An Enzyme for More Than Just Circulatory Health!

by Martin Kwok, BSc, MSAOM, ND

Heart attack and stroke are the two most devastating and common circulatory issues we face in our time. Heart attacks are due to blockage of coronary arteries, and majority of stroke cases are due to thromboembolism. Currently there are three main categories of pharmaceutical agents used to treat or prevent ischemia issues: thrombolytics, antiplatelets, and anticoagulants. Thrombolytics can be a life-saver in acute situations when used appropriately but have a few drawbacks: short window of opportunity for its application, the risk of intra-cranial bleeding, and the fact that they have to be administered via intravenous infusion. Antiplatelets and anticoagulants may be used acutely or as a secondary prevention. They work by interfering with the coagulation system thus limiting the spread or worsening of the ischemia; they do not resolve the existing thrombus or embolus. It is still up to the body's own fibrinolytic system to resolve the blockage, which may or may not happen. Like thrombolytics, antiplatelets and anticoagulants also carry the risks of causing unforeseen bleeding in spite of due care or testing. Is there not a safer and also effective natural option for helping patients besides the above categories of pharmaceuticals? The answer is "YES," and the agent is called LUMBROKINASE!

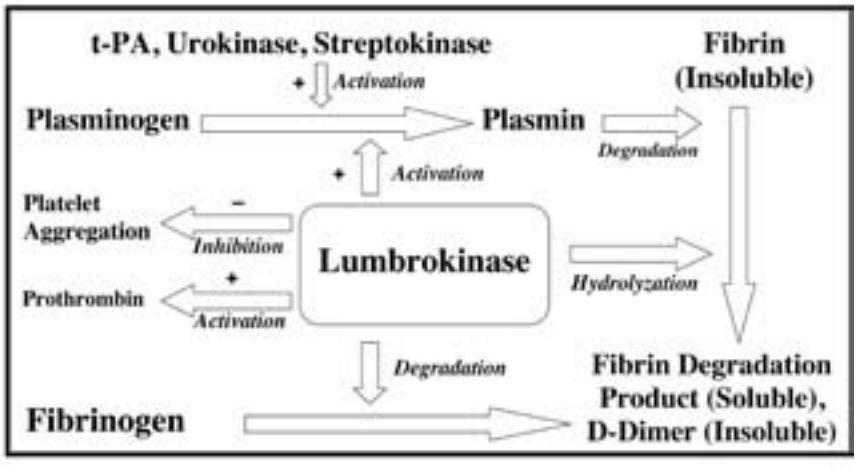
What Is Lumbrokinase?

Lumbrokinase is a complex enzyme preparation extracted from earthworms. Lumbrokinase can also be referred to as earthworm powder enzymes (EPE) or earthworm fibrinolytic enzymes (e-PPA). Earthworms have been used in traditional Eastern medicine for thousands of years in countries such as China, Japan, Korea, and others. According to the ancient Chinese medical publication *Ben Cao Gang Mu* (Compendium of Chinese Botanical and Animal Products), earthworms or "Earth Dragons" possess the properties to "*invigorate blood, resolve stasis, and unblock the body's meridians and channels*." As a result, earthworms are commonly included in traditional herbal formulae that treat ischemic or thromboembolic conditions.

Inspired by the empirical wisdom of traditional Eastern medicine, modern Japanese researchers started searching for active ingredients that could account for the observed properties of earthworms. Finally, in 1983 Dr. Hisashi Mihara succeeded in extracting powerful fibrin-dissolving enzymes from earthworms, and he named this group of enzymes lumbrokinase.[1] Since then, Korean and Chinese researchers have compiled extensive in vitro, animal, and clinical data on the safety and potential applications of lumbrokinase over the past 30 years.

As of February 18, 2018, a simple PubMed keyword search of "lumbrokinase" generated 65 results, with papers dating as far back as 1991 and as recent as February 2018. However, performing the same keyword search in one of the largest Chinese digital periodicals database (www.cnki.net) generated over 650 publications! This article is by no means an attempt to summarize all of the available clinical research on lumbrokinase, but merely to point out some of the clinically relevant highlights. Still, what is presented here is barely scratching the surface.

Diagram 1: Lumbrokinase Mechanism



M. Kwok

Mechanisms of Lumbrokinase

Over the years various researchers have extracted lumbrokinase from different earthworm species by different methods and also studied its physiological properties in animal models. Most research indicated that

lumbrokinase is primarily a fibrinolytic enzyme and it possesses both direct and indirect fibrinolytic effects.[2,3] It can activate the innate plasminogen system and also can achieve direct fibrinolysis independent of the plasminogen system (see Diagram 1). In 2004, Zhang el al discovered that lumbrokinase also inhibits PAI-1 activity and enhances t-PA activity.[4] In addition to being a strong fibrinolytic agent, lumbrokinase may indirectly achieve anticoagulation by inhibiting platelet functions. Jiang et al. were among the first researchers to report on such a property.[5] Interestingly, many people are not aware that lumbrokinase contains an enzyme that has opposing actions on the coagulation system. In a paper published in 2007, Zhao et al. demonstrated that lumbrokinase not only promotes fibrinolysis but also prothrombin activation (thus fibrinogenesis).[6] It appears that Nature has intended lumbrokinase to have a bi-directional rather than a uni-directional property. This built-in "balancing" mechanism may have contributed to the excellent safety record of lumbrokinase as explained later in the article.

Potential Clinical Applications

As an oral enzyme supplement, lumbrokinase is not allowed or approved to make any therapeutic claims in North America. However, by looking into available animal and human research, it is not too hard for anyone to see the following potential applications:

Ischemic Stroke. To further explore the traditional medical uses of earthworms in stroke, naturally one of the most intensely researched areas has been in the prevention and treatment of ischemic stroke patients. Lumbrokinase has been shown to be safe and effective for treating acute ischemic stroke by lowering blood viscosity, preventing re-perfusion damage, and reducing neural deficits.[7-9] It was also shown to improve the efficacy of aspirin as a secondary prevention of stroke.[10,11] In fact, for people who are resistant to aspirin (thus does not benefit from taking aspirin as a prevention), lumbrokinase appears to negate aspirin resistance and potentially help achieve the goal of cardiovascular disease prevention.[12]

Coronary Artery Disease. Lumbrokinase is equally impressive in the treatment of coronary arterial diseases, including patients with unstable angina. Besides lowering whole blood viscosity, plasma viscosity, fibrinogen, and ESR, research data indicated that lumbrokinase was able to minimize angina attack frequency, minimize the need for nitroglycerine, and improve ST segment elevation on the EKG.[13-16] Other potential applications of lumbrokinase in circulatory conditions include deep venous thrombosis,[17] essential hypertension,[18] vascular dementia,[19] etc.

Oncology. It is a well-known fact that most cancer patients (especially late stage) are hypercoagulable and prone to develop venous thromboembolism.[20-22] Thus, it is quite reasonable to use lumbrokinase in the prevention or treatment of cancer-associated thromboembolism. In recent years lumbrokinase has also been investigated as a potential anti-tumor and anti-metastatic agent. There is various in vitro and clinical evidence pointing towards the involvement of hypercoagulation in stimulating tumor growth and metastasis.[23,24] There are also evidence showing the potential use of anti-coagulants in limiting cancer growth and metastasis.[25-27] Thus, it is quite reasonable to investigate if lumbrokinase can be beneficial in the overall treatment of oncology patients. Though still early in the research stage, lumbrokinase has been shown to inhibit stomach cancer cell growth and liver cancer cell metastasis in vitro and in animal models.[28-30] Human studies are surely to follow in the near future.

➤

Enzymatic Activity Comparison of Common Fibrinolytic Enzymes

Product	t-PA Activity/cap	t-PA Activity/mg	Relative Strength to Lumbrokinase
Lumbrokinase 20 mg/cap, 300,000 u/cap Lot#041210	2,597,000 u	129,800 u	1
AH Nattokinase 100 mg/cap, 20,000 FU/g Lot#070403	360,000 u	3,600 u	1/36
OH Serrapeptidase 20 mg/cap, 40,000 iu/cap Lot#B39275006	8,832 u	441 u	1/294
DH PLA Bacillopeptidase F 250 mg/cap Lot#402935	2,906 u	11 u	1/12,900

M.Kwok

Note 1: Boluoke® was the lumbrokinase standard used for comparison

Note 2: All Samples were blinded. t-PA chromogenic assays were performed by Hemostasis Reference Laboratory Inc., Hamilton, Ontario, Canada (Feb. 2011)

Note 3: When comparing the enzymatic strength between various products, it is important to know the enzymatic activity per unit and the total enzymatic activity per capsule. However, the enzymatic activity per milligram may be MORE important than the total enzymatic activity per capsule. If two products have the same total enzymatic activities per capsule, taking the weaker enzyme may not give you the same benefits as taking the stronger one. For example, if Product A & B both contain 100,000 units of a particular enzymatic activity per capsule, but Product A contains 10mg active enzyme and Product B contains 200mg active enzyme per capsule. Clinically, you will likely see a better response from taking Product A because it contains a stronger enzyme.

➤

Chronic Biofilm-Associated Infections. Biofilm-associated chronic infection has become a popular topic in recent years. Thus, it is worth mentioning that lumbrokinase has been shown to break down biofilm and improve the effectiveness of antibiotics in vitro, though it still lacks human studies at this point. However, since chronic infection and chronic inflammation tend to create a hypercoagulable blood state,[31,32] some clinicians may feel that lumbrokinase's true benefit is in reducing hypercoagulation-associated complications.

Other note-worthy areas of lumbrokinase research: It may improve diabetic nephropathy[33] and diabetic neuropathy.[34] It may prevent the damage to heart cells from second-hand smoke.[35] It may also play a role in promoting bone repair and regeneration.[36,37]

Safety Record of Lumbrokinase

The discovery of lumbrokinase in earthworms is not by accident but rather a targeted investigation into understanding traditional medical practices in Asian cultures. Earthworms have been used for many centuries (including present days) in traditional Asian medicine and are considered as a safe ingredient according to all ancient and modern medical writings and cumulative experiences.

Even though earthworms appear to be very safe, what about enzymes extracted from earthworms? Past experiences with the development of pharmaceuticals have taught us to be vigilant about the risk of bleeding with any agent that affects the coagulation system. Thus, bleeding risk is one of the most watched for side-effect in the early research and trials involving lumbrokinase. To date, virtually all of the researchers who have ever studied or published on lumbrokinase concluded that it is a well-tolerated and very safe fibrinolytic enzyme preparation.

The review paper by Wang et al estimated the overall adverse reaction rate to be about 3% with symptoms like mild headache, dizziness, constipation, and nausea; all the symptoms resolved spontaneously after stoppage of medicine and required no special treatment.[38] Another review paper by Tang et al reached an even lower rate of adverse reactions – 0.7% – though the authors believed this number to be an under-estimation.[39] The types of adverse reaction include nausea, vomiting, rash, skin itch, and dizziness; there are no bleeding issues nor damage to liver or kidney functions.

Experiences in pharmaceutical drug development have taught researchers that clinical trials are simply simulations, no matter how perfect the study designs are. Adverse reaction profile of any drug can only be truly realized, in time, after it has been put on the market and used in real life conditions. Currently there are many lumbrokinase-containing products on the market, with most of them being sold in Asian countries. Some of these products are considered as nutritional supplements, some as Traditional Chinese Medicine, and some as pharmaceutical products. Over the past 30 years, lumbrokinase and earthworm-derived products have maintained an excellent safety record with little to none adverse reaction reported.

Differences Between Lumbrokinase Products and Other Enzymes

Not all lumbrokinase products are made the same. Lumbrokinase is a mixture of enzymes from earthworms, thus products manufactured by different companies will have slightly different properties due to the differences in earthworm species used, extraction methods, and purification processes. As a result, some lumbrokinase products may affect lab tests like INR or aPTT and some may not. They may also differ in the type of capsules used, fillers, and the quality control processes. Despite the differences, good quality lumbrokinase products should provide similar clinical benefits when used properly. In addition to products with standardized enzymatic activities, there are also products that use ground-up earthworms or crudely extracted earthworm proteins, which may contain lumbrokinase but without having the enzymatic strength and total enzymatic activities assayed.

Then how does lumbrokinase compare to other proteolytic enzymes? There are many oral proteolytic enzymes currently on the market, including bromelain, pancreatic enzymes, serrapeptase, nattokinase, etc. In terms of safety, by nature of being a protein, oral proteolytic enzymes are considered very safe. In terms of enzymatic activity, many proteolytic enzymes have broad-spectrum enzyme activities that are not specific towards fibrin. Presently only serrapeptase and nattokinase are being promoted as possessing fibrinolytic activities, thus more similar and comparable to lumbrokinase.

Serrapeptase is an enzyme extracted from silkworms and has been shown to be an effective anti-inflammatory enzyme for pain and swelling reduction.[40] However, it still lacks clinical research supporting its use in thromboembolic conditions. On a milligram to milligram basis, the fibrinolytic strength of lumbrokinase is about 300-fold stronger than serrapeptase (see Table 1).

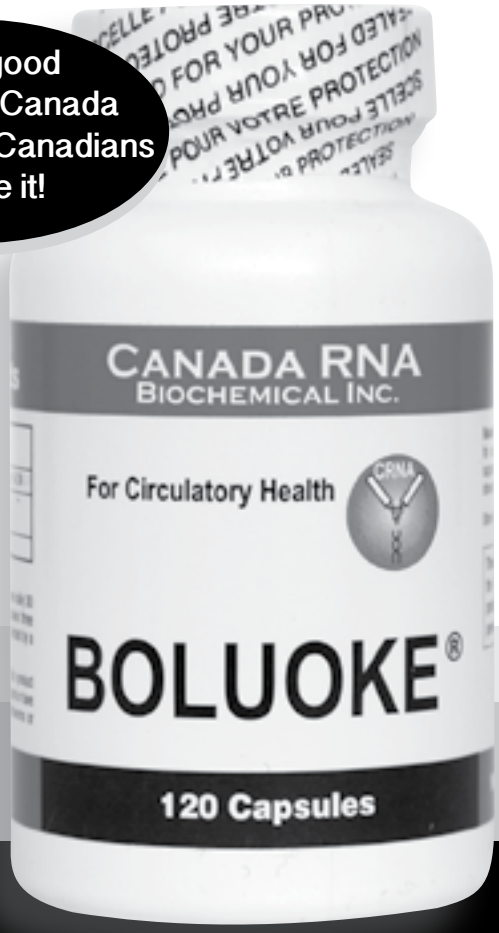
Nattokinase is an enzyme extracted from traditional Japanese fermented soybeans and has been shown to an effective enzyme in improving various hypercoagulation-associated parameters; it looks very promising as an oral enzyme in the treatment and prevention of cardiovascular diseases. However, the use of nattokinase in human clinical trials involving thromboembolic conditions is still limited.[41] On a milligram to milligram basis, the fibrinolytic strength of lumbrokinase is about 30-fold stronger than nattokinase (see Table 1).

Therefore, serrapeptase is not considered a strong fibrinolytic enzyme and should primarily be used for inflammation and pain association with oral/facial surgeries, sinus infection, arthritis, or chronic airway diseases. Respectively, nattokinase and lumbrokinase would be more suited for patients with mild and severe hypercoagulation or for patients with low and high cardiovascular risks.

continued on page 56 ➤

HYPERCOAGULATION

It's so good that Health Canada doesn't want Canadians to have it!



A central issue in:

- conditions with a poor circulation
- growth and spread of malignant cells
- chronic infections with biofilm
- poor tissue healing due to hypoxia

Boluoke® (lumbrokinase), simply the best in:

- Enzymatic strength
- Research data
- Quality, safety, and efficacy

Your Patients. Your Reputation.

TRUST NOTHING LESS!

Boluoke® is also available through

Researched Nutritionals® solutions for life

BIORESOURCE INC

antiaging-systems.com

return 2 health

MP Mountain States Health Products, Inc.

Pro Health Network

Dragon's www.dragonsmedicalbulletin.com
Medical Bulletin
Your Quick Stop for Integrated Clinical Research Updates

CRNA

1-866-287-4986

www.canadaRNA.com

Lumbrokinase

➤ *continued from page 54*

Current and Future Challenges for Lumbrokinase

The use of earthworms to achieve circulatory health in traditional medicine has come a long way. First there were dried earthworms used in traditional oriental herbal decoctions, and then there were ground-up earthworm powders. Later came crude extracts of earthworms, and now there is lumbrokinase -- a purified multiple-enzyme preparation extracted from earthworms. Just like omega-3 molecules from fish oil, polyphenols from green tea, and curcumin from turmeric root, in time lumbrokinase shall be known as the most valuable therapeutic ingredient from the humble earthworms.

Even though lumbrokinase is a well-researched and clinically proven enzyme preparation, outside of Asia it is still relatively unknown to most practitioners and consumers. This is likely due to three main factors: first, most of the available clinical data on lumbrokinase is in Chinese and not readily accessible or understood by non-Chinese clinicians or researchers; second, pharmaceutical grade lumbrokinase is expensive and hard to come by (primarily from China), thus only a few companies are selling and promoting its clinical benefits; third, major pharmaceutical companies (with their massive influence on the media) have not found a way to profit from this enzyme yet. However, works have begun in further selecting and isolating one single enzyme from lumbrokinase for the eventual patenting and manufacturing of that specific enzyme via recombinant DNA technology.[42] Will a singular lumbrokinase, without the synergistic and balancing actions of other lumbrokinase sub-enzymes, still be as safe and effective as the whole lumbrokinase enzyme group? Only time can tell.

References

1. Mihara H, et al. A novel fibrinolytic enzyme extracted from the earthworm, *Lumbricus rubellus*. *Japanese Journal of Physiology*. 1991;41(3):461–472.
2. Ma EL, et al. Effects of Rongshuan No 1 (F-1) on the antithrombotic and antiplatelet aggregation. *Journal of Shenyang Pharmaceutical University.* 2001;18(5):370-372.
3. He ZZ, et al. Separation and purification of earthworm fibrinolytic enzyme and the study of anti-thrombosis activity. *Chinese Journal of Biochemical Pharmaceutics*. 2001;22(6):284-286.
4. Zhang J, et al. Experimental study on the effect of lumbrokinase on fibrinolysis in rats. *Chinese Journal of Pathophysiology*. 2004;20(5):891-892.
5. Jiang DS, et al. Inhibition of platelet aggregation in hamsters by lumbrokinase extracted from Eisenia fetida. *Journal of Capital Medical University*. 1994;15(4):291-294.
6. Zhao J, et al. *Eisenia fetida* Protease-III-1 Functions in Both Fibrinolysis and Fibrogenesis. *J Biomed Biotechnol*. 2007;2007(5):97654.
7. Yang M, et al. Eisenia fetida lumbrokinase research VI – thrombolytic effect in rabbits and protective effects in experimental stroke model in hamsters. *Biotechnology*. 1995;5(3):9-11.
8. Li WY, et al. Observation of treating twenty-seven cases of ischemic stroke patients with lumbrokinase. *New Chinese Medicine*. 2003;34(4):63-64.
9. Zhang HY. Observation of treating acute ischemic stroke with lumbrokinase. *Capital Medicine*. 2000;7(3):45-46.
10. Zhang DJ, et al. Prevention of ischemic stroke recurrence using lumbrokinase. *Capital Medicine*. 2003;5(10):47-48.
11. Cao YJ, et al. Oral fibrinogen-depleting agent lumbrokinase for secondary ischemic stroke prevention: results from a multicenter, randomized, parallel-group and controlled clinical trial. *Chin Med J* (Engl). 2013 Nov;126(21):4060-5.
12. Sun MY, et al. Clinical Observations of Lumbrokinase Intervention in 60 Coronary Heart Disease Patients with Aspirin Resistance. *Chinese Journal of Gerontology*. 2009; 29: 760-761.
13. Liu HS. Clinical observation of treating 60 angina patients with lumbrokinase. *Tianjin Pharmacy*. 2002;14(2):45-46.
14. Yi XF, et al. Efficacy of treating unstable angina seniors with lumbrokinase. *Capital Medicine*. 2002;9(9):57-58.
15. Zhou HS, et al. Clinical observation of treating unstable angina seniors with lumbrokinase capsules. *Central Plains Medical Journal*. 2001;28(9):2-3.
16. Kasim M, et al. Improved myocardial perfusion in stable angina pectoris by oral lumbrokinase: a pilot study. *J Altern Complement Med*. 2009 May;15(5):539-44.
17. Song JS, et al. Clinical analysis of treating 17 cases of deep venous thrombosis with lumbrokinase. *Occupation and Health*. 2001;17(4):111-115.
18. Ye SZ, et al. Observation of treating 51 cases of essential hypertension with lumbrokinase. *Clinical Medicine*. 2007;27(9):59.
19. Gao Y, et al. Efficacy of combining lumbrokinase with nimodipine in the treatment of vascular dementia. *Journal of Liaoning University of Traditional Chinese Medicine*. 2008;10(11):5-7.
20. De Cicco M. The prothrombotic state in cancer: pathogenic mechanisms. *Crit Rev Oncol Hematol*. 2004 Jun;50(3):187-96.
21. Molnar S, et al. Procoagulant factors in patients with cancer. *Hematology*. 2007 Dec;12(6):555-9.
22. Falanga A, et al. Hypercoagulability and tissue factor gene upregulation in hematologic malignancies. *Semin Thromb Hemost*. 2008 Mar;34(2):204-10.
23. Francis JL, et al. Effect of antihemostatic agents on experimental tumor dissemination. *Thrombosis and Hemostasis*. 2002; 28: 29-38.
24. Caine GJ, et al. The hypercoagulable state of malignancy: pathogenesis and current debate. *Neoplasia*. 2002 Nov-Dec;4(6):465-73.
25. Clerk CP, et al. The effect of low molecular weight heparin on survival in patients with advanced malignancy. *J Clin Oncol*. 2005 Apr 1;23(10):2130-5.
26. Kakkar AK, et al. Low molecular weight heparin, therapy with dalteparin, and survival in advanced cancer: the fragmin advanced malignancy outcome study (FAMOUS). *J Clin Oncol*. 2004 May 15;22(10):1944-8.
27. DeFeo K, et al. Use of dabigatran etexilate to reduce breast cancer progression. *Cancer Biol Ther*. 2010 Nov 15;10(10):1001-8.
28. Li HY, et al. Antitumor activity of earthworm fibrinolytic enzyme. *Chinese Pharmacological Bulletin*. 2004;20(8):908-910.
29. Chen H, et al. Effect of earthworm fibrinolytic enzyme on the inhibition of invasion and metastasis in hepatocellular carcinoma cell. *Jiangsu Medical Journal*. 2008;34(4):383-385.
30. Chang CX, et al. Anti-metastatic activity of earthworm fibrinolytic enzyme on hepatoma cell in vivo. *Traditional Chinese Drug Research & Clinical Pharmacology*. 2009;20(6):520-524.
31. Levi M, et al. Infection and inflammation and the coagulation system. *Cardiovasc Res*. 2003 Oct 15;60(1):26-39.
32. Kitchens CS. Concept of hypercoagulability: a review of its development, clinical application, and recent progress. *Semin Thromb Hemost*. 1985 Jul;11(3):293-315.
33. Song WG, et al. Clinical observation of Boluoke with Lotensin, a new therapy for early stage diabetic nephropathy. *Jiangxi Medical Journal*. 2010 July; 45(7): 667-668.
34. Gu XL, et al. Observation of the effectiveness of treating diabetic peripheral neuropathy by lumbrokinase. *Chinese Journal of Primary Medicine and Pharmacy*. 2003 July; 10(7): 665.
35. Liao HE, et al. Cardio Protective Effects of Lumbrokinase and Dilong on Second-Hand Smoke-Induced Apoptotic Signaling in the Heart of a Rat Model. *Chin J Physiol.* 2015 Jun 30;58(3):188-96.
36. Fu YT, et al. Porous gelatin/tricalcium phosphate/genipin composites containing lumbrokinase for bone repair. *Bone*. 2015 Sep;78:15-22.
37. Fu YT, et al. Earthworm (Pheretima aspergillum) extract stimulates osteoblast activity and inhibits osteoclast differentiation. *BMC Complement Altern Med*. 2014 Nov 11;14:440.
38. Wang CL, et al. Progress in lumbrokinase. *Progress in Veterinary Medicine*. 2009;30(11):86-90.
39. Tang YJ, et al. Lumbrokinase: A review of domestic research literatures. *Capital Medicine*. 2011;18(6):39-42.
40. Serrapeptase Monograph, Natural Health Products Ingredients Database, Health Canada. 2014 February 7. http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=serrapeptase&lang=eng
41. Weng YQ, et al. Nattokinase: An Oral Antithrombotic Agent for the Prevention of Cardiovascular Disease. *Int J Mol Sci*. 2017 Mar; 18(3): 523.
42. Wang KY, et al. Recombinant protein production of earthworm lumbrokinase for potential antithrombotic application. *Evid Based Complement Alternat Med*. 2013;2013:783971.

◆

Dr. Martin Kwok completed his Bachelor of Science degree from the University of British Columbia, BC, Canada. Then he went on to receive his Doctor of Naturopathic Medicine and Master of Science in Acupuncture & Oriental Medicine from Bastyr University in Washington State.

Dr. Kwok is dual-licensed as a naturopathic physician and a doctor of traditional Chinese medicine in BC, Canada, and has had an active practice at the Richmond Alternative Medical Clinic, Inc. (Richmond, BC, Canada) for over 20 years. Dr. Kwok has a general practice with focuses on cardiovascular conditions, cancer supportive care, and hyperthyroid issues.

Dr. Kwok currently holds positions as a board member at National Traditional Chinese Medicine Association of Canada, as the Editor-in-Chief at *Dragon's Medical Bulletin* (an e-newsletter for health care professionals), as the Vice-President at Canada RNA Biochemical Inc., and as an advisor for Vita Aid Professional Products.

Dr. Kwok can be contacted by email at drmartinkwok@yahoo.ca or via his website at www.DrMartinKwok.com.

Strophanthus: The Insulin of the Heart

by Thomas Cowan, MD

In 2003 the Mayo Clinic published a major review article whose intention was to understand the risks and benefits of coronary artery bypass surgery. It came to the following conclusions:

a) Bypass surgery can effectively relieve symptoms.
b) Bypass surgery does not prevent further heart attacks.
c) Only high-risk patients benefit from bypass surgery with regard to better chances of survival.[1]

In other words, having a bypass operation with its attendant mortality risk is effective only at relieving symptoms in the vast majority of the patients who undergo this procedure. There is no evidence of prevention of future heart attacks (MI), nor of extending life.[2,3]

Similar results have been found for the more common procedure of stent placement. Instead of surgery to place new grafts in the heart, the blockages are mechanically opened, and stents are placed in the coronary arteries to keep the vessels open. Again, while this procedure is effective for symptom relief, it does not reduce the likelihood of a future heart attack nor confer a longer life to the patient.[4]

One would think that cardiologists and internists armed with this information would doggedly pursue other avenues for treatment, avenues that would help prevent heart attacks and increase functional lifespan. However, sadly, since these results were published, the numbers of these procedures have increased rather than decreased, reaching a peak of 4.5 million worldwide in 2016.[5] Something is seriously amiss in the halls of our modern cardiology wards.

One clue to understanding why bypass grafting and stent placement have not delivered on their promised results comes from the work of Italian pathologist Giorgio Baroldi. In his groundbreaking book *The Etiopathogenesis of Coronary Heart Disease: A Heretical Theory Based on Morphology,*[6] he concluded that after doing autopsies for 40 years on patients who died of heart attacks, only 41 percent of these patients had a significant stenosis (plaque build-up) in the artery leading to the area of the heart affected by the heart attack. And 50 percent of these stenoses came AFTER the heart attack occurred, not before, as one would commonly assume. These results suggest that approximately 80 percent of heart attacks have some other cause than simply a "blocked" or stenosed artery. Given this information, it is no wonder that, in the majority of cases, unblocking arteries — no matter how thoroughly or carefully done — will never be the solution for our nation's epidemic of heart disease.

In my book *Human Heart, Cosmic Heart*,[7] I reviewed the existing literature on the controversy about the cause of heart attacks and suggested three other causes of heart attacks. I assert that these possible causes must be addressed if we are to have a thorough approach to the prevention and treatment of angina, unstable angina and heart attacks. Briefly, these three other causes are autonomic nervous system imbalance, microcirculation, and metabolic acidosis.

Autonomic Nervous System Imbalance

With the advent of heart-rate variability testing, a sensitive and accurate way to assess the autonomic nervous system activity, we now know that a large percentage of patients who go on to have an MI have decreased parasympathetic activity in the days, weeks, and months leading up to the MI. Baroldi suggests that the majority of MIs are caused by the combination of chronically low parasympathetic activity and a temporary stressful event, which furthers this imbalance.

The important point here is that although they are similar, decreased parasympathetic tone is not the same as excessive sympathetic activity. Decreased parasympathetic tone is a consequence of chronic stress, diabetes, hypertension, smoking, and lack of physical activity. Increased sympathetic activity, which conventional cardiology focuses on with its use of beta-blockers, is more of a short-term imbalance and doesn't have the same predictive value in determining whether an MI will occur. Cardiology is in need of a strategy that will support the patient's parasympathetic nervous system while he or she implements long-term strategies to transform the causes of parasympathetic dysfunction.

Microcirculation

Typical anatomical drawings of the heart suggest that all of the blood flow to the myocardium goes through the three major coronary arteries. Although these arteries are certainly important, it turns out that, even from a young age, the heart is endowed with a rich

➤

➤

supply of blood vessels that make up the microcirculation of the heart. If you go to Figure 1 in the FAQ section of the heartattacknew.com website, under the heading "The Riddle's Solution," you can see a perfectly illustrated depiction of the normal cardiac microcirculation.

Again, as Baroldi points out, the normal heart is perfectly well suited to do its own bypass in the event of a chronic disruption of flow through one or more of the coronary arteries. This ability is why thousands, maybe millions, of Americans are walking around with arteries greater than 90 percent occluded, yet with no symptoms whatsoever. The body, using its robust capillary network, has done its own bypass, and the heart is protected. It is only in the case of chronic disease, in particular, diabetes, with its well-known microcirculatory pathology, that MIs start to show up. Clearly, stents and bypasses confer no benefit to those with microcirculatory disease. Modern cardiology is clearly aware of this issue, as this is the rationale for the use of Plavix and aspirin in cardiac patients. Both affect the microcirculation and increase blood flow therein. Both, of course, have their own toxicity, which limits their use and the ability of patients to tolerate these drugs.

Metabolic Acidosis

This situation is perhaps the most important and most overlooked reason that people suffer from angina, unstable angina and MIs. The production and build-up of lactic acid in the myocardial tissues is the final common pathway in all cases of angina, unstable angina and MI. What happens is that, because of parasympathetic disease, coupled with micro-circulatory problems, the heart finds itself in a stressful situation, one in which it is forced to undergo what is called a glycolytic shift. This shift means that the heart is unable to generate energy in the usual manner, which is through mitochondrial-based respiration, and instead begins to ferment sugars to obtain fuel. A similar shift is thought to underlie the cancer process and is becoming well known as an important etiology in chronic disease. Once this glycolytic shift happens, the cells start to build up lactic acid in the surrounding tissues. The same process happens in your leg muscles as the result of over-exercising. However, in contrast to leg muscles, the heart muscle can't relax, so the lactic acid continues to build up. It is at this point that the familiar feeling of angina or chest pain begins to occur.

As the process continues, the lactic acid continues to accumulate, which then causes a localized metabolic acidosis (lowered pH) to occur. The lowered pH prevents the influx of calcium into the myocardial cells, essentially preventing the contraction of the heart muscle fibers. This result can be seen on the stress echo or nuclear-perfusion tests used to diagnose heart disease in modern cardiology. As the process continues and the lactic acid continues to accumulate, eventually there is a necrosis of the surrounding tissue, which is what we call a MI.

Along with the destruction of the myocardial tissue, the dyskinetic or akinetic areas of the heart create shear pressure on the embedded arteries, which results in clots forming after the MI occurs. This sequence of events perfectly describes the events that occur as the MI is progressing. Modern cardiology has no tools in which to address this central pathology of the build-up of lactic acid in the myocardial cells.

Strophanthus: The Insulin of the Heart

An effective treatment for angina, unstable angina and heart attack prevention must address each of these three areas to be truly successful. Luckily, such a medicine already exists and has been both widely used and sorely overlooked during the past century.

An African perennial vine called strophanthus makes seeds that contain the active ingredient referred to as g-strophanthin in Europe and ouabain in the US. Ouabain is a copy of a hormone made by our own adrenal cortex, and it has many functions that are useful in treating patients with heart disease. Used as the main treatment for the prevention of MIs in Germany for many decades, ouabain has been shown to support the parasympathetic nervous system, improve the micro-circulation and, crucially, convert the lactic acid in the myocardial tissue into pyruvate, which is the preferential fuel of the heart.[8,9] With the conversion of lactic acid into a nutrient for the heart cells, the cycle of pain and subsequent necrosis of the myocardial tissue is broken. In the majority of cases, the patients will experience relief from their angina as well as improvement in heart function.

During the past decade, I have treated heart patients with either g-strophanthin capsules or, more recently, an extract of the strophanthus seed extract with positive effects on their overall sense of well-being, and, specifically, on their heart function. Since the book was published, we have started a program to make strophanthus extract available to all heart patients who wish to use it. We ask each patient to find a health-care practitioner who will order the medicine from us and supervise its use. By doing this, we hope to develop a network of practitioners who are well versed in its use. The results from practitioners are beginning to come in, some of which are showing remarkable benefit. Below are some of those cases (either written by the practitioner or the patient him or herself).

If you are interested in learning more about the use of strophanthus for heart disease, please contact our office at (415) 334-1010 to schedule a free, 15-minute phone consultation on the use of strophanthus and how to order it.

Case Studies

Case 1. From a Physician in Kentucky. Bruce, a 60-year-old male, suffers from atrial fibrillation and severe heart failure. Left ventricular hypertrophy and cardiomyopathy had developed from substantial untreated hypertension. His heart ejection fraction fell to <20%. His main measure of heart failure — BNP — rose to 3000. I had treated him with every supplement that I could contemplate, including ones that

normally are very helpful for the heart from L-carnitine, 400mg ubiquinol, d-ribose, cordyceps, hawthorn, and other anabolic botanicals — literally 40 supplements due to his severe situation, along with natural blood thinners. Despite these he was on Lasix 40 mg daily; an ARB produced a highly annoying persistent cough and had to be stopped.

With the aggressive supplementation, he did improve. However, BNP was still 1316, Bilirubin – 5.3, Alkaline Phosphatase 248, C-reactive protein 29, and d-dimer 2.8; these had all proven to be indicators of his heart failure in the previous two years. But he still was very limited as to physical activity.

Then I read Dr. Cowan's report about strophanthus. Out of desperation – all options had been exhausted – it was ordered. Over three weeks he titrated up to 10 drops twice a day. BNP dropped to 1244, CRP to 23.2, Bili to 3.5, Alk phase to 219, and d-dimer to 1.73. He was told to continue to titrate up on the strophanthus until reaching 15 drops twice a day.

We didn't hear from Bruce for many months afterwards but heard indirectly that he was doing better. When he did come in six months after the previous visit, he reported only minor physical limitations. His BNP had dropped to 492, CRP to 12.6, Bili to 1.9, Alk phos to 181 and d-dimer to 0.67. His blood pressure that typically was 100 diastolic, and as high as 178 systolic, was essentially normal for the first time at 132/80.

He reports no side effects from strophanthus (though he does note the taste and smell). After having blood drawn almost monthly for two years with constant adjustment in his regimen, and hobbled from physical activity, Bruce now has his life back with optimism about the future. Strophanthus has proved miraculous in Bruce's improvement at a time when he had nearly lost hope.

Case 2. Patient Report. My father had his first heart attack at age 45 and a second one at age 60 while undergoing bypass surgery. He died on the table. So, I have been careful to watch my diet and lifestyle. About a year ago, I began having left-sided chest and arm pain — only at night, in bed. A recent ECG had a "dip" that the doctor stated may be a sign of having had a heart attack at some point. I didn't want to overreact. I also didn't want to go down the same path as my father. I wasn't going to go "traditional" on this one!

(My naturopathic doctor) suggested I start taking strophanthus drops twice a day. After two months of using it, my chest pain is completely gone! Additionally, I have a very strong sense of peace in my physical body. Not sure how to describe it.

Case 3. Patient Report. I suffered from cardiac cephalgia angina attacks —35 to 45 per month, even though I was taking 30 mg of isosorbide mononitrate daily and using 0.4 mg nitroglycerin transdermal patches. After taking strophanthus seed extract, I'm down to around five angina attacks per month.

Case 4. Patient Report. I've been diagnosed with a-fib in November last year. After the diagnosis, the additional symptoms were tingling in hands and feet and chest pain and pressure on continuous basis. Everything else was healthy with my heart.

Luckily Dr. Cowan is my doctor. He prescribed strophanthus with vitamin E and beet juice. This is the month of June. My a-fib symptoms are almost gone. Tingling is slowly going away, and chest pain and pressure are gradually vanishing.

Case 5. Patient Report. I had two CT chest scans. The one in October of 2016 had a calcium score of 40. I started the strophanthus in November 2016. The second CT scan in May 2017 had a calcium score of 12.

Strophanthus

Case 6. From a Chinese-Medicine Physician in Colorado. On February 7, 68-year-old male was hospitalized with heart failure due to left ventricle damage, rigidity. After stent installed, the ejection fraction was 18 percent. I started him six weeks ago on strophanthus 3 drops bid, and then three weeks later increased to 6, bid. (I also used ubiquinol, magnesium orotate, proteolytic enzymes, activated B vitamins). Checkup ECG yesterday, ejection fraction now at 47 percent. The technician commented that in 15 years he never saw this kind of recovery. Patient feels excellent and says, "I felt my heart moving differently" shortly after starting the strophanthus. I guess so!

References

1. Rihal CS, et al. Indications for coronary artery bypass surgery and percutaneous coronary intervention in chronic stable angina. *Circulation.* 2003;108:2439-2445.
2. European Coronary Surgery Study Group: Long-Term Results of Prospective Randomised Study of Coronary Artery Bypass Surgery in Stable Angina Pectoris. *Lancet*. 1982; ii:1173-1180.
3. Alderman EL, et al. Ten-Year Follow-up of Survival and Myocardial Infarction in the Randomized Coronary Artery Surgery Study. Circulation. 1990;82:1629-1646.
4. Rihal CS, et al. Indications for coronary artery bypass surgery and percutaneous coronary intervention in chronic stable angina. *Circulation*. 2003;108:2439-2445.
5. MedMarket Diligence, LLC; "Global Dynamics of Surgical and Interventional Cardiovascular Procedures, 2015-2022," (*Report #C500*).
6. Found under "Print Version" tab on heartattacknew.com.
7. Available at humanheartcosmicheart.com.
8. Fürstenwerth H. Ouabain – The Insulin of the Heart. *Int J Clin Prac.* Nov 2010. Under "News" on the humanheartcosmicheart.com website.
9. "The Story of Ouabain," found under "News" on the humanheartcosmicheart.com website.

◆

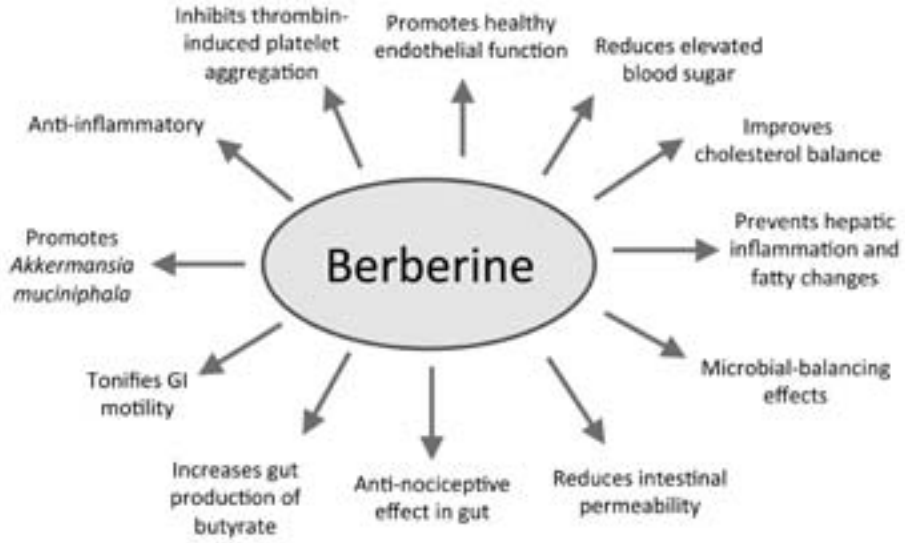
Thomas Cowan, MD, has studied and written about many subjects in medicine including nutrition, anthroposophical medicine, and herbal medicine. He is the author of *Human Heart, Cosmic Heart*, the principal author of *The Fourfold Path to Healing,* and co-author (with Sally Fallon) of *The Nourishing Traditions Book of Baby* and *Child Care*. Dr. Cowan has served as vice president of the Physicians Association for Anthroposophic Medicine and is a founding board member of the Weston A. Price Foundation®. He also writes the "Ask the Doctor" column in *Wise Traditions in Food, Farming, and the Healing Arts* (the Weston A. Price Foundation's quarterly magazine) and has lectured throughout the United States and Canada. In 2016, he and his family launched Dr. Cowan's Garden, a company that makes and sells organic vegetable powders to help people diversify their vegetable consumption. He has three grown children and lives and practices medicine in San Francisco.

Berberine: New Research on Mechanisms Via Which This Alkaloid May Impact Metabolic and Cardiovascular Health

by Carrie Decker, ND

Berberine, an orangish-yellow alkaloid found at high levels in the bark and root structures of plants including Oregon grape (*Mahonia aquifolium*), goldenseal (*Hydrastis canadensis*), barberry (*Berberis vulgaris*), and Chinese goldthread (*Coptis chinensis*), has a broad and wide history of use. Oregon grape, a North American source of this alkaloid, was used by the native inhabitants and European colonists in the Pacific Northwest as a blood toner, an antimicrobial, and to ease digestive distress.[1] As a bitter tonic, the extract from the roots and bark of these herbs was used to stimulate digestion, while its antimicrobial properties were taken advantage of both topically and internally.[2] Chinese goldthread, known as *duǎn è huánglián*, is one of the 50 fundamental herbs in traditional Chinese medicine,[3] where its bitter and cold properties are used to influence conditions of the Heart, Large Intestine, Liver, and Stomach.

In the digestive system, berberine exerts a multitude of actions. Berberine acts as an antimicrobial, having both a direct bactericidal effect as well as decreasing bacterial adherence to mucosal epithelial surfaces.[4,5] Berberine also directly influences intestinal permeability, improving tight junction integrity.[6,7] Berberine has evidence of exerting a tonifying effect on gastrointestinal motility – increasing motility and contractility in states of hypofunction, and relaxing the system when it is in an excessively contractile state.[8] Berberine has an antinociceptive effect, which may be in part due to its impact on contractility, or mediated via its interactions with the endogenous opioid system,[9] or via nitric oxide synthesis.[10] Berberine increases the gut production of short chain fatty acids (SCFAs), in particular butyrate.[11] Butyrate has an anti-inflammatory effect in the colon, which may play a role not only in digestive disorders, but neurological and metabolic conditions as well.[12]



Because of its low bioavailability in its non-transformed state,[13] much of the research surrounding berberine has looked at the impact on the gut. The gut microbiota also plays a significant role in the absorption of berberine, as it transforms it to dihydroberberine, which has a five-fold increase in absorption over that of berberine.[14] Dihydroberberine then oxidizes back to berberine in the intestinal tissue and enters the blood. One cautionary note which must be remembered in practice is that berberine, at commonly used doses, moderately inhibits cytochrome P450 3A4 (CYP3A4), CYP2D6, and CYP2C9,[15,16] which may lead to increased levels of commonly used medications including lovastatin, clarithromycin, sildenafil, losartan, venlafaxine, and metoprolol, as well as many others.

Metabolic Balance and Healthy Cardiovascular Function: An *Akkermansia* Effect?

One type of bacteria in the gut that has been shown to impact metabolic balance and cardiovascular health is

*Akkermansia muciniphila.*This gram-negative bacteria feeds on mucin, as well as certain sugars including N-acetylglucosamine, N-acetylgalactosamine, and glucose.[17] Although *A. muciniphila* represents only a small fraction (3 to 5 percent) of the bacteria in the gut, the impact it may have on metabolism is significant. Reduced levels of *A. muciniphila* have been observed in patients with impaired glucose metabolism and obesity,[18,19] while higher levels of the genus *Akkermansia* have been found in athletes and individuals with a low body mass index (BMI).[20]

In mice, supplementation with *A. muciniphila* reduced weight gain and fat mass, and improved glucose tolerance and insulin sensitivity.[21] In one mouse study, excess weight due to high fat diet (HFD) feeding was reduced by more than half when supplemented with this bacterium. *A. muciniphila* may have this impact on metabolism by the reduction of chronic low-grade inflammation, as these changes were observed in conjunction with decreased lipopolysaccharide (LPS) signalling and increased anti-inflammatory factors such as α-tocopherol and β-sitosterol. Administration of *A. muciniphila* also has been shown to increase the intestinal levels of endocannabinoids, the endogenous cannabinoids produced by the body, which play a role in controlling inflammation, the gut barrier, and gut peptide secretion.[22]*A. muciniphila* also was shown to reduce the development of atherosclerosis, improving gut tight junction integrity, and attenuating LPS-induced inflammation.[23]

Both metformin and berberine have been shown to increase levels of *Akkermansia* spp., with both treatments increasing the number of mucin-producing goblet cells that produce the substrate (mucin) that serves as food for this bacterium.[24,25]Along with this finding, berberine was shown to improve HFD-induced atherosclerosis in the standard mouse model where development of atherosclerotic disease is inevitable, reducing inflammation systemically and in the atherosclerotic lesions.

Berberine and Blood Vessel Function

Endothelial dysfunction is one contributing factor that leads to increased blood pressure and cardiovascular disease. There are many different facets of dysfunction which include diminished vasodilation in response to stimulation, increased leukocyte (white blood cell) adhesion, and frequently, increased platelet activation.[26] Collectively, these factors contribute to atherosclerosis and cardiovascular disease in addition to an increase in blood pressure. Endothelial dysfunction has also been observed in polycystic ovarian syndrome, migraines, and the vascular complications associated with diabetes.[27-29] Increased proinflammatory cytokines and decreased adiponectin (a hormone produced by adipose tissue) levels both contribute to altered endothelial homeostasis.[30]

Berberine increases activation of adenosine monophosphate–activated protein kinase (AMPK), a fuel-sensing enzyme that is present in all mammalian cells. When activated, AMPK stimulates energy-generating processes within the cell such as glucose uptake and decreases energy consuming processes such as lipid synthesis, reducing blood sugar and cholesterol production.[31,32] AMPK is also present in the endothelial cells of the blood vessels, and promotes normal function via anticontractile, anti-inflammatory, and antiatherogenic actions.[33] Consumption of a HFD contributes to endothelial dysfunction in part via downregulation of the AMPK pathway.[34]

Although hyperglycemia leads to endothelial dysfunction, berberine has been observed to alleviate this negative effect and promote normal vasodilation via the AMPK pathway.[35] Via activation of AMPK, berberine reduces the pro-inflammatory response of macrophage foam cells, a cellular responder of the immune system which plays a role in the development of atherosclerotic plaques, to stimuli including hydrogen peroxide and LPS.[36] Berberine also inhibits the release of platelet-derived growth factor (PDGF) from vascular smooth muscle cells as well as smooth muscle hypertrophy via activation of the AMPK pathway. By doing so, berberine promotes normal endothelial function and the reduction of stenosis, that is, the narrowing of blood vessels.[37]

Berberine also induces vaso-relaxation via endothelial-independent mechanisms similar to a calcium-channel blocker, decreasing mean blood pressure and pulse pressure in the mouse model of atherosclerotic disease.[38] Endothelium-dependent relaxation has also been observed with berberine treatment, mediated by the endothelial release of nitric oxide.[39]

One additional mechanism via which berberine may improve cardiovascular system function and hemodynamics is via the inhibition of clot formation. In platelet aggregation assays, berberine was observed to inhibit thrombin-induced platelet aggregation.[40] Thrombin is a key enzyme in the blood coagulation cascade that converts fibrinogen to fibrin during blood coagulation. Berberine has been shown to have neuroprotective effects in animal models of stroke;[41] this may be one mechanism by which these benefits are seen.

Berberine and Dyslipidemia

In addition to improving lipid dysregulation via activation of AMPK,[42] there are several additional mechanisms via which berberine acts to restore cholesterol balance.[43] Berberine inhibits cholesterol absorption and promotes its excretion via the bile.[44,45] Berberine increases the expression of LDL receptors in the liver, which promotes bile formation and secretion.[46] In animals, oral supplementation with berberine was observed to reduce total cholesterol and non-HDL cholesterol levels by 29 to 33 percent and 31 to 41 percent respectfully, also reducing the absorption of dietary cholesterol by 40 to 51 percent.[47]

Berberine also alters the expression of genes related to cholesterol metabolism via interaction with the bile acid farnesoid X receptor (FXR) in the intestinal epithelial cells.[48] Interaction with FXR increases excretion of conjugated bile acids in the feces and reduces the accumulation of hepatic

➤

➤

triglycerides and the development of HFD-associated obesity. Although the inhibition of HMG-CoA reductase is not the primary mechanism via which berberine reduces cholesterol, in the setting of hyperhomocysteinemia (common in cardiovascular disease, also contributing to increased hepatic cholesterol synthesis and lipid accumulation), berberine was observed to inhibit HMG-CoA reductase activity and reduce hepatic cholesterol content.[49]

Clearly, berberine has a broad range of effects on metabolism and the function of many systems of the body, some of which may be mediated via interactions with the microbes in the gut, and others which occur at a cellular and genetic level. Research continues to elucidate the mechanisms via which this botanical has such a broad impact on physiology. For our many predecessors and the pioneers of herbal medicine, this only serves to reinforce that which they already observed.

References

1. Matthews HB, Lucier GW, Fisher KD. Medicinal herbs in the United States: research needs. *Environ Health Perspect*. 1999 Oct;107(10):773-8.
2. Dattner AM. From medical herbalism to phytotherapy in dermatology: back to the future. *Dermatol Ther*. 2003;16(2):106-13.
3. Wong M. *La médecine chinoise par les plantes*. Paris: Editions Tchou; 1976.
4. Jin JL, et al. Antibacterial mechanisms of berberine and reasons for little resistance of bacteria. *Chin Herb Med*. 2010;3:27-35.
5. Sun D, et al. Influence of berberine sulfate on synthesis and expression of Pap fimbrial adhesin in uropathogenic Escherichia coli. *Antimicrob Agents Chemother*. 1988 Aug;32(8):1274-7.
6. Gu L, et al. Berberine ameliorates intestinal epithelial tight-junction damage and down-regulates myosin light chain kinase pathways in a mouse model of endotoxinemia. *J Infect Dis*. 2011 Jun 1;203(11):1602-12.
7. Li N, et al. Berberine attenuates pro-inflammatory cytokine-induced tight junction disruption in an in vitro model of intestinal epithelial cells. *Eur J Pharm Sci*. 2010 Apr 16;40(1):1-8.
8. Chen DP, et al. Effects of berberine on rat jejunal motility. *J Pharm Pharmacol*. 2013 May;65(5):734-44.
9. Feng Y, et al. Inhibiting roles of berberine in gut movement of rodents are related to activation of the endogenous opioid system. *Phytother Res*. 2013 Oct;27(10):1564-71.
10. Tang QL, et al. Antinociceptive effect of berberine on visceral hypersensitivity in rats. *World J Gastroenterol*. 2013 Jul 28;19(28):4582-9.
11. Wang Y, et al. Berberine-induced bioactive metabolites of the gut microbiota improve energy metabolism. *Metabolism*. 2017 May;70:72-84.
12. Stilling RM, et al. The neuropharmacology of butyrate: The bread and butter of the microbiota-gut-brain axis? *Neurochem Int*. 2016 Oct;99:110-132.
13. Pan GY, et al. The involvement of P-glycoprotein in berberine absorption. *Pharmacol Toxicol*. 2002 Oct;91(4):193-7.
14. Feng R, et al. Transforming berberine into its intestine-absorbable form by the gut microbiota. *Sci Rep*. 2015 Jul 15;5:12155.
15. Wu X, et al. Effects of berberine on the blood concentration of cyclosporin A in renal transplanted recipients: clinical and pharmacokinetic study. *Eur J Clin Pharmacol*. 2005 Sep;61(8):567-72.
16. Guo Y, et al. Repeated administration of berberine inhibits cytochromes P450 in humans. *Eur J Clin Pharmacol*. 2012 Feb;68(2):213-7.
17. Derrien M, et al. Akkermansia muciniphila gen. nov., sp. nov., a human intestinal mucin-degrading bacterium. *Int J Syst Evol Microbiol*. 2004 Sep;54(Pt 5):1469-76.
18. Escobar JS, et al. The gut microbiota of Colombians differs from that of Americans, Europeans and Asians. *BMC Microbiol*. 2014 Dec 14;14:311.
19. Dao MC, et al. Akkermansia muciniphila and improved metabolic health during a dietary intervention in obesity: relationship with gut microbiome richness and ecology. *Gut*. 2016 Mar;65(3):426-36.
20. Clarke SF, et al. Exercise and associated dietary extremes impact on gut microbial diversity. *Gut*. 2014 Dec;63(12):1913-20.
21. Zhao S, et al. Akkermansia muciniphila improves metabolic profiles by reducing inflammation in chow diet-fed mice. *J Mol Endocrinol*. 2017 Jan;58(1):1-14.
22. Everard A, et al. Cross-talk between Akkermansia muciniphila and intestinal epithelium controls diet-induced obesity. *Proc Natl Acad Sci U S A*. 2013 May 28;110(22):9066-71.
23. Li J, et al. Akkermansia muciniphila protects against atherosclerosis by preventing metabolic endotoxemia-induced inflammation in Apoe-/-mice. *Circulation*. 2016;133:2434-2446.
24. Shin NR, et al. An increase in the Akkermansia spp. population induced by metformin treatment improves glucose homeostasis in diet-induced obese mice. *Gut*. 2014 May;63(5):727-35.
25. Zhu L, et al. Berberine treatment increases Akkermansia in the gut and improves high-fat diet-induced atherosclerosis in Apoe-/- mice. *Atherosclerosis*. 2018 Jan;268:117-126.
26. Anderson TJ. Assessment and treatment of endothelial dysfunction in humans. *J Am Coll Cardiol*. 1999 Sep;34(3):631-8.
27. Paradisi G, et al. Polycystic ovary syndrome is associated with endothelial dysfunction. *Circulation*. 2001 Mar 13;103(10):1410-5.
28. Tietjen GE, et al. Migraine and biomarkers of endothelial activation in young women. *Stroke*. 2009 Sep;40(9):2977-82.
29. Schalkwijk CG, Stehouwer CD. Vascular complications in diabetes mellitus: the role of endothelial dysfunction. *Clin Sci* (Lond). 2005 Aug;109(2):143-59.
30. Shimabukuro M, et al. Hypoadiponectinemia is closely linked to endothelial dysfunction in man. *J Clin Endocrinol Metab*. 2003 Jul;88(7):3236-40.
31. Viollet B, et al. Targeting AMP-activated protein kinase as a novel therapeutic approach for the treatment of metabolic disorders. *Diabetes Metab*. 2007 Dec;33(6):395-402.
32. Brusq JM, et al. Inhibition of lipid synthesis through activation of AMP kinase: an additional mechanism for the hypolipidemic effects of berberine. *J Lipid Res*. 2006 Jun;47(6):1281-8.
33. Salt IP, et al. AMP-Activated Protein Kinase: An Ubiquitous Signaling Pathway With Key Roles in the Cardiovascular System. *Circ Res*. 2017 May 26;120(11):1825-1841.
34. García-Prieto CF, et al. High-fat diet induces endothelial dysfunction through a down-regulation of the endothelial AMPK-PI3K-Akt-eNOS pathway. *Mol Nutr Food Res*. 2015 Mar;59(3):520-32.
35. Wang Y, et al. Berberine prevents hyperglycemia-induced endothelial injury and enhances vasodilatation via adenosine monophosphate-activated protein kinase and endothelial nitric oxide synthase. *Cardiovasc Res*. 2009 Jun 1;82(3):484-92.
36. Jeong HW, et al. Berberine suppresses proinflammatory responses through AMPK activation in macrophages. *Am J Physiol Endocrinol Metab*. 2009 Apr;296(4):E955-64.
37. Liang KW, et al. Berberine inhibits platelet-derived growth factor-induced growth and migration partly through an AMPK-dependent pathway in vascular smooth muscle cells. *Eur J Pharmacol*. 2008 Aug 20;590(1-3):343-54.
38. Wang J, et al. Berberine via suppression of transient receptor potential vanilloid 4 channel improves vascular stiffness in mice. *J Cell Mol Med*. 2015 Nov;19(11):2607-16.
39. Ko WH, et al. Vasorelaxant and antiproliferative effects of berberine. *Eur J Pharmacol*. 2000 Jul 7;399(2-3):187-96.
40. Wang X, et al. Identification of berberine as a direct thrombin inhibitor from traditional Chinese medicine through structural, functional and binding studies. *Sci Rep*. 2017 Mar 9;7:44040.
41. Zhou XQ, et al. Neuroprotective effects of berberine on stroke models in vitro and in vivo. *Neurosci Lett*. 2008 Dec 5;447(1):31-6.
42. Kim WS, et al. Berberine improves lipid dysregulation in obesity by controlling central and peripheral AMPK activity. *Am J Physiol Endocrinol Metab*. 2009 Apr;296(4):E812-9.
43. Zhang Y, et al. Treatment of type 2 diabetes and dyslipidemia with the natural plant alkaloid berberine. *J Clin Endocrinol Metab*. 2008 Jul;93(7):2559-65.
44. Li XY, et al. Effect of berberine on promoting the excretion of cholesterol in high-fat diet-induced hyperlipidemic hamsters. *J Transl Med*. 2015;13:278.
45. Wang Y, et al. Berberine and plant stanols synergistically inhibit cholesterol absorption in hamsters. *Atherosclerosis*. 2010;209:111–7.
46. Briand F, et al. Upregulating reverse cholesterol transport with cholesteryl ester transfer protein inhibition requires combination with the LDL-lowering drug berberine in dyslipidemic hamsters. *Arterioscler Thromb Vasc Biol*. 2013 Jan;33(1):13-23.
47. Wang Y, et al. Berberine decreases cholesterol levels in rats through multiple mechanisms, including inhibition of cholesterol absorption. *Metabolism*. 2014 Sep;63(9):1167-77.
48. Sun R, et al. Orally Administered Berberine Modulates Hepatic Lipid Metabolism by Altering Microbial Bile Acid Metabolism and the Intestinal FXR Signaling Pathway. *Mol Pharmacol*. 2017 Feb;91(2):110-122.
49. Wu N, et al. Regulation of hepatic cholesterol biosynthesis by berberine during hyperhomocysteinemia. *Am J Physiol Regul Integr Comp Physiol*. 2011 Mar;300(3):R635-43.

◆

Dr. Carrie Decker, ND, graduated with honors from the National College of Natural Medicine (now the National University of Natural Medicine) in Portland, Oregon. Dr. Decker sees patients at her office in Portland, Oregon, as well as remotely, with a focus on gastrointestinal disease, mood imbalances, eating disorders, autoimmune disease, and chronic fatigue. Prior to becoming a naturopathic physician, Dr. Decker was an engineer, and obtained graduate degrees in biomedical and mechanical engineering from the University of Wisconsin-Madison and University of Illinois at Urbana-Champaign respectively. Dr. Decker continues to enjoy academic research and writing and uses these skills to support integrative medicine education as a writer and contributor to various resources. Dr. Decker supports Allergy Research Group as a member of their education and product development team. BlessedThistleND@gmail.com

Management of the Allergic Patient: The Role of a Changing Environment

by Diego Saporta, MD, and David Hurst, MD, PhD

Observations of Changes in Skin Reactivity

In late 2012, one of the authors (DS) started to observe unexpected results when testing patients for inhalant allergens with the Intradermal Dilutional Test (IDT) even though no changes in testing protocols or personnel had occurred. At the same time the management of these patients became more challenging.

New Jersey, where the practice is located, was affected by two severe hurricanes. The first one in 2011 (Irene) and the second one in 2012 (Sandy). Perhaps these storms changed the environment in such a way that patients became more reactive.

The changes in skin reactivity during Intradermal Dilutional Test (IDT) from before and after the hurricanes above described were studied, and the results published in two reports: the first one for dust, dander and pollen, published in 2015,[1] and the second one for molds, published in 2017.[2] The findings included the following:

• *Larger than usual wheals during testing*. A positive (reactive) wheal usually measures 7-11 mm. In late 2012, abnormal wheals with diameters of 15-20 mm and more were observed with increased frequency during usual testing sessions for dust, dander, and pollen allergens but not so frequently for mold allergens.

• *Skin reactivity to very diluted allergen concentration.* According to the allergenic concentration required to elicit a skin response, a patient (or allergen being tested) can be classified as a high reactor or as a low reactor. A high reactor requires a weak-diluted concentration of allergen to elicit a positive response in the allergy test (dilutions #4, #5 or #6). A low reactor requires a strong concentration of allergen to elicit a skin response (dilutions #3, #2 or #1). For allergen extracts that are available as 1:20 wt/vol, the six dilutions contain an allergenic concentration of: 1:100 for dilution #1; 1:500 for dilution #2; 1:2500 for dilution #3; 1:12,500 for dilution #4; 1:62,500 for dilution #5 and 1:312,000 for dilution #6.[3]

It is not unusual to find tests with a combination of results where the patient exhibits reactivity to some allergens that require a weak concentration of allergen and to some allergens that require a strong concentration of the allergen. Positive test results during an IDT more frequently occur with strong allergenic concentrations (dilutions #3, #2 or #1).

According to traditional teaching it is rare to find an allergen that reacts to dilution #6.[4] In agreement with that statement, prior to 2012 it was rare to find a patient that showed reactivity to the 6th dilution during skin testing. Since late 2012, it became increasingly frequent to find patients that exhibited positive skin responses to very weak allergenic concentration, like the 5th and even to the 6th dilutions.

• *Many positive results.* It would have been rare before 2012 to find a patient that reacted to most of the allergens in the tested panel. Since that time, it was not uncommon to find patients that react to many or even all tested allergens.

Skin Reactivity and General Health in the Post-Hurricane Population

The findings in the two reports mentioned above[1,2] suggested not only that post-hurricane patients were more reactive (skin tests had a larger number of positive results, with more tests being reactive to very diluted allergen) but also that the general population after the hurricanes was more affected with earlier onset of symptoms and with more severe symptoms as suggested by a lower age average: more patients younger than 18 years of age and more patients with asthma or lower respiratory symptoms (LRS).

The patient charts were randomly selected and were not necessarily the same for both reviews. Yet, both reviews showed similar results, which again suggests a change in the health of the local population.

Mold Skin Reactivity During Skin Testing

Molds allergens are characteristically not as reactive in the skin as pollen allergens, for example. It was not unusual prior to the hurricanes to use the 3rd or even 2nd dilutions (carrying strong allergenic concentration) as the first injection when testing molds with IDT in healthy patients. After 2012, molds became more reactive. Many

➤

➤

more molds were positive in the allergy test, and results occurred at much weaker allergenic concentration (4th, 5th or even 6th dilutions). Molds did not elicit large wheals as it was observed for the other allergens.[1] The overall number of positive mold skin test results before the hurricanes was 285 versus 987 after the hurricanes. [2]

Before the hurricanes, 97% of the positive results required a strong allergenic concentration (dilutions #3, #2 or #1). After the hurricanes, only 75% of the results did so ($p<0.0001$). The decrease in the percentage value occurred despite the overall increase in the number of positive results because of the large increase in the number of positive reactions occurring with weak allergenic concentration after the hurricanes.

Of note is that many of the 97% of the positive results before the hurricanes or the 75% of the positive results after the hurricanes that required strong allergenic concentration would have been missed if only a 1:1000 wt/vol dilution of the mold allergens was used.[5]

With the Intradermal Dilutional Test, dilution #2 has an allergenic concentration of 1:500 wt/vol and dilution #3 a concentration of 1:2500 wt/vol. A single injection of allergen with a concentration of 1:1000 wt/vol as advised by the guidelines of the main allergy society is an intermediate concentration between the second and third dilutions of the IDT, and it would miss many of the positive results obtained by the IDT. This can explain the perception in main allergy communities that the role of mold in allergic disease is negligible.[5,6]

This perception is understandable as molds are usually missed by skin prick tests (SPT), and they can frequently be missed by an intradermal test with a 1:1000 wt/vol dilution.[3] The IDT can demonstrate reactivity to allergens that appear to be not reactive with the SPT[7] or with an intradermal injection of a fixed allergenic dose. This is more important when considering mold allergens because they are, as explained above, not very reactive in the skin.

The increase in the number of positive results with weak allergenic concentration after the hurricanes ($p<0.0001$) strongly suggests that the skin reactivity for mold allergens has greatly increased in our patients after the hurricanes. This is further suggested by the following findings:

a) Before the hurricanes, 38% of the charts showed no reactivity to any of the 18 molds sampled. After the hurricanes, this occurred only in 5% of the cases.
b) Before the hurricanes, no chart was found where the patient reacted to all of the 18 tested molds. After the hurricanes, this happened in 17% of the sample.

Relevance of Lower Respiratory Symptoms

In a chart review done to validate the use of a Peak Flow Meter (PFM) device as an adjuvant for the management of allergy patients,[8] it was observed that a large majority of the patients that denied having asthma had symptoms pertaining to the lower airway like shortness of breath, exercise-triggered symptoms, history of inhaler use, or abnormal spirometries.

In that paper it was established that the PFM was a useful device in the management of allergic patients, as the peak flow value improved if immunotherapy was successful (predictor value of 91%), but it also suggested that simply asking "Do you have asthma?" is not enough to determine if a patient has potential lower airway reactivity. It became obvious that patients with symptoms pertaining to the lower airway could be more reactive than patients without symptoms suggestive of inflammation of the lower airway. Taking this into consideration can help decrease the chances of triggering a reaction during testing or treatment. It is our opinion that a patient with lower respiratory symptoms (LRS) should be on an inhaled corticosteroid during the time that testing is being done and probably for the first few months of immunotherapy.

About Flooded and Damp Environments

Floods after hurricanes provide a propitious environment for mold growth. Buildings that remain wet for 48–72 hours following hurricanes or floods frequently develop visible and extensive mold growth.[9]

We have often observed that patients reported becoming allergic or experiencing a worsening of their preexistent allergies after their homes flooded during those hurricanes. Home water damage can also occur after leakage from water or sewage pipes, but these water intrusions do not affect a massive segment of the general population as it happens with hurricanes or floods. The flooding that followed hurricanes Irene and Sandy was significant. It makes logical clinical sense to infer that the environmental changes following those storms affected the local population.

A unique aspect of our studies is that because we had access to both pre- and post-hurricane charts, the comparison included the same local population both before and after the climatic events.

Impact of These Findings for Patient Management

Changing testing protocol. The concept of the IDT is based on starting the test with a weak dilution of the allergen, considered safe to inject in the patient being tested.[10] If this dilution is non-reactive, the test continues by injecting a more powerful dilution; and this process continues until determining reactivity to the allergen being tested (or lack of).

In the years before the hurricanes, it was so rare to see a patient reacting at the 6th dilution, that unless the patient was asthmatic, testing usually started for most allergens with the 4th dilution.[4]

Since the hurricanes, most tests are now started with the weakest 6th dilution. Even with this precaution, some reactions have been encountered upon injecting the 6th dilution as the initial dose. This had never occurred before 2012.

Use of inhaled cortico-steroids. The number of patients with asthma or with LRS has markedly increased since the hurricanes. These patients have lower

airway inflammation. A frequently encountered example is shortness of breath with exertion. Often these LRS have developed no more than a few years before consultation. Even though many patients explain that the problem is related to their lack of exercise, their smoking, or their being overweight, it is a common finding that the symptoms improve after two to three weeks of administering an inhaled cortico-steroid (ICS). Administering ICS to patients with LRS, starting two to three weeks before testing date, probably helps decrease the chance of triggering a reaction involving the lower airway during testing. A good history is now more important than ever to decide if and when to test an allergic patient with LRS.

Number of allergens tested in one session. Instead of testing all allergens in one session, we now divide the IDT panel in smaller sub-panels for patients with LRS. Having a smaller number of injections per session decreases the chance of triggering a reaction during testing.

Co-seasonal testing. Before the storms, it was not unusual to test well-controlled asthmatic patients in season (such as ragweed in July-August). Since the hurricanes, in season testing of patients with LRS is avoided. -

Conclusions

The general patient population in our geographical area has been found, from the clinical point of view, to be more reactive since exposure to the hurricanes of 2011 and 2012.

This is suggested by the larger number of patients presenting with symptoms suggestive of lower airway inflammation and larger number of younger patients presenting with allergic symptoms and was confirmed by the overall increased sensitivity with increased reactivity during testing.

Extra precautions have been incorporated in clinical practice to manage these patients.

Discussion

After the hurricanes many patients developed allergies, with or without asthma, or experienced worsening of preexistent allergies with or without asthma. Some patients reported having had asthma during childhood and having been well controlled until after the hurricanes. Home water intrusion after the hurricanes has been described. Without addressing the significance of home remediation or the lack of awareness in the general population of the significance of a damp environment, it is clear that a change in the general population of the affected geographical area has occurred.

There has been flooding after hurricanes in other geographical areas. The better studied example is, perhaps, the effects of Hurricane Katrina over the New Orleans area. Published reports show confusing results that prevent clear conclusions. For example, it was reported that symptoms were significantly higher in children exposed to below-median levels of indoor airborne mold, that no relationships were observed between skin sensitivity and indoor or outdoor allergen concentrations, and that asthma symptoms were not influenced by allergen concentration/sensitivity,[11] or that while upper and lower respiratory symptoms were higher after the hurricane, mold growth at home was associated with lower respiratory symptoms.[12]

It has been proposed that the difficulty interpreting the studies on health effects of indoor mold exposure is related to the perception that mold is associated with few serious adverse effects in healthy people, that relocation of affected individuals led to avoidance of exposure to mold, and that the lack of access to health centers prevented cases from being recorded.[13]

The potential role of mold in the development and exacerbation of respiratory disease is still not part of basic accepted medical knowledge, even though it has been found that exposure to damp-moldy indoor spaces is associated with cough, wheezing, and lower respiratory illness.[14]

Below are examples of how data can become confusing:

- A report described that the respiratory symptoms with dry cough called "Katrina cough" were believed to be caused by reactions to mold and dust left after the storm.[15] The same report concluded that the respiratory conditions were not severe enough and that the consultations at emergency rooms in New Orleans were similar to the national data.[15]
- A study claimed that dust and sediment from Hurricane Katrina did not cause an increase in severe respiratory problems for people living in the Greater New Orleans area.[16] It further stated that the rates of respiratory illness were not different from the rates of these illnesses occurring in other parts of the state and the country and also that "there is no such thing as a single condition such as 'Katrina Cough' that would be different from the bacterial and viral respiratory conditions we would expect to see at that time of year."[16]
- Another study concluded that there was no increased incidence of upper or lower respiratory tract symptoms from before and after Katrina.[17] In this particular study the subjects were recruited from an area of the city that did not flood; the majority of homes had minor or no water damage, and from those that did, half of them had been repaired before the study began. The negative findings of this study are not surprising.
- A group of people was evaluated after their homes were damaged by Hurricane Katrina.[6] Despite significant home damage and evidence of extensive exposure to dampness and mold, no relationship between that exposure and sensitivity to mold allergens was encountered. The authors concluded that, in agreement with previous literature, there was no excess risk of respiratory symptoms. The subjects in this[6] and other studies[11] were tested with SPTs. When considering that SPTs are not sensitive[18] and that only the IDT is able to diagnose patients that exhibit reactivity to strong allergenic concentration,[3] the reported results and subsequent conclusions are not unexpected.

In the 12 years prior to Katrina, children from the local population ➤

➤

had a sensitization rate to fungi of 59% to 66%[19] which increased to 75% after the Hurricane.[20] This is, at best, a modest increase. It appears that a large percentage of the children of the area affected by Katrina were already reactive to mold. This could be an underlying problem: The area that was eventually affected by Hurricane Katrina is known to have an endemic rate of asthma that reaches epidemic proportions,[21] so the influence of a natural disaster perhaps did not become clear as this was already a heavily affected area with a high prevalence of sensitization to mold and to other allergens.

Planning an epidemiological study is at best extremely difficult and complicated. Relying on tests that are not accurate will obviously lead to wrong conclusions. Evaluating the population itself might be more revealing than evaluating test results or dust samples. A sick person is a sick person even if the air samples do not show what is usually assumed to be a dangerous level of particulate matter. A survey where patients are asked how their health is at the time of the survey compared to before the natural disaster might perhaps be more helpful in establishing a change in the health of the general population. More important than measuring how much dust is in a home or what is the concentration of specific allergens or other toxic substances, it is to determine if the inhabitants from that home are symptomatic or not. A sensitive individual will react to a lower allergenic concentration. The fact that it has been "proven" that a certain population did not develop asthma with a certain allergen concentration in a prior study does not mean that another population will not be affected by that supposedly low level of allergen, so measuring allergen concentration rather than evaluating the health of the local population may lead into erroneous conclusions.

Are the observations discussed in this report also occurring in other areas of the country affected by flooding or hurricanes, and if they are, how are those patients handled? The answer to this obvious question is difficult.

Because most patients are studied with tests of poor diagnostic power, it is not surprising that many people live their lives affected with symptoms, frequently severe enough to impact on their quality of life. Reactivity to mold or to other inhalant allergens is frequently not demonstrated or incompletely demonstrated. Adding to this fact, the usual lack of awareness of the potential adverse effects on health due to mold exposure helps to explain why intervention is usually not implemented.

Well-referenced information about the real implications of a natural disaster is available.[22] That information helps to explain why the published reports offer confusing information. The fact that mold develops after a flood (and toxins and other irritants accumulate) becomes easy to understand. It is logical to assume that similar problems will develop in other similarly affected areas.[22] Compared with the real consequences of mold exposure,[22, 23] our report is just like "the tip of the iceberg": we learned that the skin reactivity has changed and that patients appear to be sicker. People exposed to mold from floods or other forms of water intrusion, indeed, become extremely sick with a much more significant array of problems than allergies.

Dr. Saporta completed his training in 1990 at Columbia Presbyterian Hospital in New York City. He is board certified in otolaryngology and has been a fellow of the American Academy of Otolaryngic Allergy (AAOA) since 2001. His private practice in Elizabeth, New Jersey, is heavily oriented to the management of allergic conditions. Interested in the use of oral vaccines since early in his practice, Dr. Saporta presented a protocol for sublingual immunotherapy at the 64th annual meeting of the AAOA that since then has been successfully used for the management of allergic rhinitis with or without asthma.

David Hurst, MD, PhD is a clinical instructor in otolaryngology at Tufts University in Gorham, Maine.

References

1. Saporta D. Changes in Skin Allergy Testing Reactivity observed after a Hurricane. Is the Environment Responsible? *SOJ Immunol*. 2015;3(3): 1-6.
2. Saporta D, Hurst D. Increased Sensitization to Mold Allergens Measured by Intradermal Skin Testing following Hurricanes. *Journal of Environmental and Public Health*. 2017. Article ID 2793820.
3. Saporta D, Hurst D. Management of the allergic patient. The role of different diagnostic tests. *Townsend Letter*. April 2018;52-55.
4. Fornadley JA. "Skin testing in the diagnosis of inhalant allergy," in *Allergy and Immunology, an Otolaryngic Approach*. J. H. Krouse, et al, Eds. Philadelphia, PA; Lippincott Williams & Wilkins: 2002; 114–123.
5. Bernstein L, et al. Allergy Diagnostic Testing: An Updated Practice Parameter. *Annals of Allergy, Asthma, & Immunology.* 2008;100(3): S3.
6. Rabito FA, et al. The Relationship between Mold Exposure and Allergic Response in Post-Katrina New Orleans. *J Allergy* (Cairo). 2010; pii: 510380.
7. Simons JP, et al. Comparison of Multi-Test II skin prick testing to intradermal dilutional testing. *Otolaryngol Head Neck Surg*. 2004;130(5):536-544.
8. Saporta D. Changes in Peak Flow Meter Values During Immunotherapy Administration. *Journal of Environmental and Public Health*. Volume 2012, Article ID 212867.
9. Brandt M, et al. Mold prevention strategies and possible health effects in the aftermath of hurricanes and major floods. MMWR. Recommendations and Reports. 2006;55(RR-8): 1–27.
10. King HC, Mabry RL, Mabry CS. *Allergy in ENT Practice*. New York: Thieme; 1998: p. 118.
11. Grimsley LF, et al., Few Associations Found Between Mold and Other Allergen Concentrations in the Home versus Skin Sensitivity from Children with Asthma after Hurricane Katrina in the Head-Off Environmental Asthma in Louisiana Study. *International Journal of Pediatrics*. 2012;Article ID 427358.
12. Rath B, et al. Adverse Respiratory Symptoms and Environmental Exposures Among Children and Adolescents Following Hurricane Katrina. *Public Health Rep*. 2011 Nov-Dec; 126(6): 853–860.
13. Barbeau DN, et al. Mold exposure and health effects following hurricanes Katrina and Rita. *Annual Review of Public Health*. 2010;31(1):165–178.
14. Inst. Med. Comm. Damp Indoor Spaces Health. 2004. Damp Indoor Spaces and Health. Washington, DC: Natl. Acad. Sci.
15. http://new.dhh.louisiana.gov/assets/oph/Center-PHCH/Center-CH/stepi/specialstudies/KatrinaCoughReport.pdf
16. http://dhh.louisiana.gov/index.cfm/newsroom/detail/716
17. Rabito FA, et al. Children's respiratory health and mold levels in New Orleans after Katrina: a preliminary look. *J. Allergy Clin. Immunol*. 2008;121:622–25.
18. www.worldallergy.org/UserFiles/file/WhiteBook2-2013-v8.pdf. (page 111)
19. Kim LR, El-Dahr JM. Skin test reactivity in children with asthma and rhinitis in New Orleans prior to Hurricane Katrina. *J Allergy Clin Immunol*. 2006;117(2):S6.
20. El-Dahr JM, et al. HEAL-ing New Orleans: the post-Katrina pediatric asthma study (abstract). *J Allergy Clin Immunol*. 2008;121:S232.
21. Salvaggio J, Seabury J, Schoenhardt EA. New Orleans asthma v. Relationship between Charity Hospital asthma admission rates, semiquantitative pollen and fungal spore counts, and total particulate aerometric sampling data. *J Allergy Clin Immunol*. 1971;48(2):96-114.
22. *MOLD: The War Within* by Kurt and Lee Ann Billings. Kodak, Tennessee; Partners Publishing LLC. 2013.
23. *Surviving Mold: Life in the Era of Dangerous Buildings* by Ritchie C. Shoemaker. Baltimore, Maryland; Otter Bay Books. 2010.

◆

The Nature of Information and the Metaphysics of Science

by Kenneth Smith

Abstract

There is a scientific debate occurring about the nature of information: is it solely physical without meaning or is it *everything*? This article explores the debate, presenting scientific and philosophical – materialistic and pantheistic – considerations of consciousness and cognition as these pertain directly to the nature of information. In so doing, this article reveals scientific findings pertaining to neural and extracellular communication systems of the body as well as to transphysical phenomena such as mystical, out-of-body, and near-death experiences. The article also covers how each of these may influence health and the practice of medicine, concluding that information is everything.

Introduction

There's a storm brewing, and it's a whopper. It has taken form as a scientific debate and, like any major storm, when it fully develops it has the potential to change the landscape. This storm has already been named "Information," and it stands to reveal intricate processes of science and consciousness. As a result, the outcome of the debate carries wide-ranging ramifications from how we view life to how we conduct medical care.

The information age has grown from being related to storage and utilization capacities of computers to information being considered the bedrock of reality.[1] It can be a process, state, or disposition.[2] However, the essence of the debate centers on whether information exists without having meaning and is exclusively physical, or rather is information *everything*?[3, 4] That information can exist without meaning is not the central issue, that it needs to be physical is.

There are staunch advocates on both ends of the spectrum, each hurling lightning bolts at the other in trying to claim the throne of Zeus. A search Google or YouTube proves the point. It turns out, though, that one side may have the higher ground. In exploring this, we're not going to run through the competing forces of personalities. Instead, as this goes straight to the heart of the philosophy of science, let's look at some of the ins and outs of information to gain a sense of the nature of it.

My interest in this debate first took root when I heard scientists and engineers talk about carrier waves and the embedded information. These people made a case that the carrier wave was simply along for the ride, or rather it is what gave information a ride, and that in and of itself it is discounted. This didn't sit well in my imagination.

Summoning memories of my days in military communications, I knew that carrier waves are loaded with information. The frequency of a carrier determines what type of gear is needed to send and receive transmissions. Each type of carrier and its corresponding equipment operate within a particular bandwidth with specific characteristics. Amplitude modulated (AM) signals, for example, can travel further with less power than frequency, or phase, modulated (FM) signals, while FM grants better fidelity. So there's information on top of information. This started the investigation.

I also knew that there are a host of environmental influences such as Schumann Resonances, circadian rhythms, and biomagnetism that inform and influence the body.[5] Plus, other types of biological information are transmitted through a lock-and-key mechanism where the physical structure of a molecule docks with a receptor, just like a space pod connects with the space station, which can only be done by matching physical conformations of molecules with receptors.[6] When connected, a cascade of processes pertaining to signal transduction kicks in. In turn, there are biological energy receptors where an energetic signal places events in motion.[7] All of these examples are physical and ultimately can exist without meaning as they just *are*. After all, meaning is a representation of pure form, not the actual thing itself. Very Zen-like.

But something else occurs when it is revealed how these signaling processes affect the body; specifically, meaning is generated in the form of modeling – modulated, if you will – the physiological activity induced by the signals. However informative the modeling may be, in and of itself it is not considered to be information, as interpretation affects how something in a pure state is viewed.

There are also representational forms of information such as languages and road signs that, according to the physicalists, don't technically count as being information, a point we'll return to shortly. The existence of something without a cognitive value, without an overlay of interpretation, is unstained

➤

➤

and unfettered. The argument that perception devoid of meaning is the basis of objective measurement has merit since there is a universal starting point. One must then consider, however, whether information can actually be devoid of meaning or whether meaning itself is another form of information. In answering this, we must consider that modeling is also representational – including the conceptualization that information is solely physical. Herein lays the sticking point with the physicalist point of view.

It turns out that a central dynamic in the information debate is also evident here. On one side are materialists who view consciousness as an emergent property relegated to the brain and cognition as being solely mental, generated by neural activity.[10] Mind is equated with cognition. The opposing side takes the posture that cognition stems from many environmental influences and serves to process information from a consciousness in which all things, including information beyond the physical, already exist and are connected. This is a pantheistic view.[11] Both of these lenses filter the perception and use of information.

… the hypothesis that consciousness is neurological remains an assumption – especially considering that psychophysiological data of extreme phenomena contrasts with a production or generation model of the brain-mind relationship.

Consciousness and Cognition

To help shed light on the information debate, it turns out that another scientific argument, one focused on consciousness and cognition, provides useful reference as we again find ourselves in a physical basis of reality versus an expanded view. After all, how cognition is viewed generates the lens that brings information into focus, and on the flip side, how information is viewed affects the lens of cognition.

In general, consciousness is thought to relate to being aware of one's body, the environment, and oneself in relation to the environment. Elements of consciousness include sensation and conception.[8] Sensation is basic perception devoid of meaning which correlates with information not having meaning. Conception is when basic information is cognitively modulated or modeled – given meaning – in order to gain utility of sensation. A basic perception, for example, might be simply seeing the shape of a door whereas conception rests on assigning purpose for the door. And therefore, cognition pertains to various forms of awareness and the utilization of that awareness such as with perception, memory, thinking, and learning.[9]

Counterpoints to begin prying away physicalist thinking are plainly evident in modern science. Findings of neuroplasticity changed the way we look at brain and ushered in new models. So did multiverse and alternative realities theories. While these still pertain to a physical world, it is just a matter of applying these changes in thinking to consciousness, cognition, information, and even an underpinning of science that reality is physical. In other words, what was once considered to be static or concrete becomes fluid and dynamic.

A result of expanding perception beyond the material is the consideration that neural correlates do not equal causation.[12] That is to say, it is an awkward jump to rigidly hold that cognition is generated by physical processes alone simply because there is brain activity associated with it. With a sweeping hand, some say that we need to separate the findings of scientific inquiry from a worldview formed by extrapolating those findings. By equating materialistic findings with worldview, a powerful learning tool known as the scientific method broaches what is considered to be scientism. Advocates of pantheistic philosophy would add that we can't ignore extreme, or transphysical, phenomena when using a scientific lens.

Transphysical Phenomena

A pantheistic view allows a spectrum of phenomena and corresponding information to exist. For those open to this prospect, the hypothesis that consciousness is neurological remains an assumption – especially considering that psychophysiological data of extreme phenomena contrasts with a production or generation model of the brain-mind relationship.[11] For instance, transphysical phenomena such as out-of-body experience (OBE), near-death experience (NDE), and mystical experience (ME) are considered to provide sources of out-of-this-physical-world types of information.

Each of these phenomena relates to innate abilities to apprehend and decode layers of information. Each is non-physical but carries weight, perhaps more so in some instances than physical experience. And there's a growing body of evidence that each influences cognition and physiology just as biological signaling mechanisms affect the body. The following examples not only support the validity of the phenomena but also demonstrate that non-physical information is as real as its physical counterpart. In and of itself, experience is informative.[13]

Out-of-Body Experience

Key elements of OBE include exteriorization of consciousness, the capacity for locomotion, a distinct form, and emotional content. Exteriorization pertains to a projection and focus of consciousness beyond the physical body. Locomotion takes on a range of abilities from crawling along a ceiling to teleportation-like travel within and among different dimensions. One's form during an OBE may vary. Due to habit, it is often humanoid or for those with a shamanic bent may take the form of an animal. The form may also

change depending on duration of an OBE or frequency of OBEs. This form carries emotional sensing as opposed to remote viewing which may be a drier, mental perception.

An OBE can shift one's relation to the world. In one study, researchers found that 95 percent of cultures worldwide report OBEs, with an incidence ranging from 10 percent of population to virtually all depending on cultural conditioning or values. Eighty-nine percent of those interviewed wanted another OBE while 78 percent found lasting benefit, with only 2 percent regarding the experience as mentally harmful. Twenty percent of Western university students reported having had an OBE without having taken drugs while fever, accident, drugs were on the lower scale of correlations. Indicating the normalcy of OBEs, pervasive relaxation was the single principle element associated with having an OBE.[14]

OBEs are often discounted by scientists as illusory by relating them to temporal lobe seizures or otherwise abnormal neural activity. One researcher claimed to produce OBEs by cortical stimulation but the reported experiences didn't resemble OBEs.[15] Therefore, a concern of transphysical proponents is that data are forced to comply with existing models.

In addition, neuroimaging finds impaired integration of body location associated with temporal and parietal cortex.[16] Yet wouldn't one expect unusual neural activity to be associated with extreme or unusual phenomena? As for abnormal neural activity associated with an OBE, wouldn't one expect different neural patterns resulting from out-of-the-ordinary experience? Wouldn't a different localization of awareness produce different readings pertaining to body location? And since there will be specific neural activity that occurs by walking down a street, by the same rules shouldn't this common behavior be considered illusory?

Near-Death Experience

Similar dynamics occur with NDEs. For example, they are discounted by relating them to temporal lobe abnormalities such as seizures, yet there is little correlation of temporal lobe seizures to NDE accounts. NDEs are also debunked by relating them to the effects of a dying brain. However, NDEs do not necessarily occur near death.[12] Universally there is a shift from normal waking consciousness to extrasomatic refocus of attention.[11] And not only hasn't this been mapped, it is automatically rendered illusory by overly focusing on what is meant by living in a world deemed to be exclusively physical.

There is a variety of NDE characteristics. Sometimes a person has an OBE. There is often a tunnel leading to white light. Many times, one has encounters with the deceased and it is normal to receive some type of revelation.[12] Not all elements need to be apparent for an NDE, just awareness of the overall configuration. I had one at eight years of age where, when almost drowning, a cloaked shape with a faceless, deep darkness under the cowl glided toward me – an archetypical form of death. I had another by traveling through a tunnel to white light. The ensuing revelation was that an infinite number of physical Earths exist, each different than the others – a concept later to be put forward in scientific thinking.

Within the NDE constellation, a person's expectation formed by cultural and educational conditioning plays a role in the forming experience.[12] As a result, a devout Christian stands to connect with Jesus whereas a practicing Buddhist may have an experience of meeting Buddha. Overall, the odds are that having an NDE will recast how one views life and death, influencing cognitive qualities of perception, memory, thinking, and learning.

Related to NDE is reincarnational-like survival. Investigators at The University of Virginia's Division of Perceptual Studies (DOPS) are carrying forward the work of Professor Ian Stevenson who ushered in a discipline of examining health conditions relating to reincarnation. In what may be a transdimensional effect, he documented birth defects correlating with manner of death in a previous life. He was rigorous in the use of medical records and screening personal reports against subjects having a common means of knowledge.[17] Focusing on children, DOPS researcher Jim Tucker has also published on this phenomenon.[18] In addition, Brian Weiss, Chairman Emeritus of Psychiatry at the Mount Sinai Medical Center in Miami, has successfully employed past-life therapy to address a range of health conditions.[19]

Mystical Experience

Mystical experience, simply put, is direct participation with a transphysical, extended environment. It provides a person a deepened connection with reality and can be life changing. The physical world may be seen as limiting.[11] Among its features are transiency or short-lived experience, ineffable or difficulty rendering events into mental constructs, gnosis or direct somatic awareness outside of mental considerations, objectivity or clarity, and a sense of oneness or awareness that all things are connected.[20, 21]

Based on talks with Edgar Mitchell, the sixth astronaut to walk on the moon, a ME differs from an epiphany. Both can be profound, but a mystical experience is grander in scope, feeling, experience, and the robustness of resulting awareness. There is often an intense sense of being connected with all life, for instance. It can be emotionally consuming with little mental reference. Mitchell said that his deep-space epiphany, where his realization of the interconnectedness of life which led to his founding The Institute for Noetic Sciences, was less intense that a full-blown ME.[22]

An ME stimulates and affects multiple areas of the brain. In one study, physiological changes during meditation

➤

➤

correlated with five frequent elements of ME: intensity, unity, transformation, clarity, and surrender. Researchers also found increased blood flow to the frontal lobe (planning), parietal lobe (sense of self), and limbic system (emotions).[23]

As with OBE and NDE, investigators attempting to discredit ME associate it with temporal lobe epilepsy, yet there has been no credible evidence to support the connections. There is, however, abundant research showing that, on average, people having mystical experiences are well-adjusted, healthy, educated, and creative. Therefore, some investigators consider this to be just another instance of conflating ordinary phenomena with the extreme.[12]

Common features among OBE, NDE, and ME are characteristic of pantheism, a centuries-old perspective of an interconnected, conscious reality. Cognition, in this model, is more expansive than mental activity alone as it forms from a variety of influences. Likewise, "mind" is all-pervasive, not to be boxed in as being exclusively mental activity. In short, pantheism represents integrated information.[11] It is a philosophy that supports the validity, the realness, of extreme phenomena.

The Body Knows

Reflected in neural and extracellular matrix systems in the body, there are conscious and unconscious forms of information.[24] The neural system gives rise to conscious awareness such as decision making, whereas the matrix system deals with unconscious processes and provides more analysis of athletic movement, martial arts, kinesiology, and therapeutic encounters. The matrix system relates to intuitive, somatic decision making, thereby challenging a definition that cognition is solely mental and generated by neural activity.[7]

This also relates to how information is carried throughout the body. Many living processes, for instance, occur too rapidly to be explained by nerve conduction. Instead, there are sensors that consist of ordered arrays of molecules found in tissues. As a result, organisms are poised to respond to whispers of environmental electromagnetic information.[7]

Studies at Heartmath Institute found that different perceptions of spacetime become evident in an all-connected scheme of consciousness.[25] This led to considerations that the ability to process information of distant events is a property of all biological organization, including the ability to scan for and perceive future events.[26]

Reflected in neural and extracellular matrix systems in the body, there are conscious and unconscious forms of information.

These researchers also found that the heart processes and decodes intuitive information. In another study, they found that the heart and brain together receive, process, and decode intuitive information with intuition being system-wide, possibly including bodily systems in addition to the heart and brain.[25]

Cognition being generated neurally or as a whole-body processor of multiple influences has real-world implications. The resulting modeling of either viewpoint, and therefore the resulting behavior, impacts subjects such as memory and its location, native forms of intelligence, styles of learning, and therefore how to better educate and psychologically treat people. It also concerns physical health.

Information and Health

The placebo response has become an accepted psychophysiological influence.[11] As with transphysical experiences, expectation and conditioning are the two main drivers.[27] Demonstrating their physical effects, in pain studies they have been shown to stimulate different opioid pathways.[28]

Expectation and conditioning are learned behaviors and so carry meaning.[29] As a form of information, meaning acts like a physical force producing physical effects. Blue pills, for example, work better as tranquilizers than red pills, except for Italian men as blue is associated with their national soccer team and so they get revved up rather than relaxed.[30]

A medical clinician is a source of information influencing patient outcomes, and models of health inform the practitioner.[31] The information then imparted to a patient can produce a positive or a negative, nocebo response. Moreover, incorrect diagnoses might occur. A person reporting an OBE might be thought to have a temporal lobe abnormality when, in reality, the person might be the picture of health and normalcy. In general, the fullness of a patient's experiences and reporting needs to be allowed, freely expressed, and to be appreciated at face value in order to achieve a comprehensive, accurate evaluation. The current research and responses surrounding transphysical phenomena aptly illustrate this need.

In like manner, group norms – such as those held by contingents of like-minded scientists – can produce perceptual entrainment, or groupthink, which is fostered by expectation based on professional conditioning, then becomes a determinant of worldview and state of mind. As a result, valuable information pertaining to one's health may be overlooked by a clinician or may even be considered prejudicial, worthy of condemnation, and therefore negatively impact the patient. It would therefore behoove the professional to be acquainted with different views of reality and, perhaps more so, to allow for possibilities beyond consensus thinking.

All of the physical and transphysical influences listed above carry effects whether or not they are modeled. Schumann Resonances and circadian

rhythms act within the body without having to be described and interpreted. Molecules continue to dock with cellular receptors even without the need for articulating their presence. Transphysical experiences impact the body and consciousness even if one doesn't know what they may represent. Meaning, as illustrated by placebo studies, can significantly influence physiology regardless of how conscious one might be of the process.

Furthermore, this dynamic stretches across all considerations of health. Homeodynamics, the body's innate regulation, is an orchestration of the entire body in concert with a multi-faceted environment.[5] Therefore, a more accurate modeling of homeodynamics would include neural and matrix systems, somatic intelligence, and a redefinition of cognition and information to include transphysical elements. Such articulation would then lead to other models, new therapies, and a more enhanced knowledge of health and healing.

I am physical; therefore I am … or am I?

Like the circular pattern of a hurricane, the physicalist argument maintains an exclusive, self-fulfilling prophecy. The baseline of modern science centers on examining a physical world. A plethora of findings then form a worldview of reality being physical, and the physicalist definition of information naturally follows – and the definition reinforces the worldview. Deviations from the definition are deemed errant. Transphysicalists, on the other hand, are more like a weather front sweeping through a region as they apply steady pressure hoping to push aside another system. Both are forms of nature.

The essential problem of the physicalist argument, however, is actually pretty simple. Defining information as "physical" is giving it meaning, as that is the definition of definition. But this is contrary to the physicalist definition of information not having meaning. In other words, "physical" is given meaning by defining it but then it is reduced to having none in order to define information. Perceiving something without layering it with meaning is a step toward objectivity as it reflects an understanding of how conceptualization distorts pure sensation. Physicalists thereby offer the essence of objectivity by attempting to have a fixed, standard reference. But relegating information solely to the physical indicates the process has gone awry.

Moreover, the same Zen-like approach of perceiving something without instilling meaning can be applied to any phenomena. Each of the transphysical phenomena mentioned herein can exist as information without conceptualization. One can perceive only the raw, undistilled extreme experience and try not to interpret or make sense of it, thereby fulfilling a physicalist requirement concerning meaning. We therefore have a layer of objective reference. But these phenomena also exist beyond the definition of being physical, and this throws a weather-wrench into the mix.

In principle, this is no different than the carrier wave and transmitted information illustration. There is the basic experience itself and then the meaning or utility relating to it. In and of themselves, carrier waves are both material and meaningless. Likewise, roads signs exist without interpretation. They just are…until the instructions of what they represent have been communicated. In the same manner, transphysical phenomena occur and are perceived, and carry information whether or not one interprets the experiences. From here, it is a short leap to realize that the entirety of existence is information. At any given turn, basic level sensation is modulated or formed into conceptualization and, in so doing, establishes meaning which becomes another level of information.

The Metaphysics of Science

As put forward above, non-interpretation of basic perception can be applied to anything, and so to any form of information. Again, the problem is defining information as having to be physical. This reflects the baseline starting point – the point of initial conditions – that reality is solely physical, rather than material existence being a reference for a certain line of inquiry. As such, the information debate brings more clarity to the philosophy of science.

In a classical sense, philosophy is a means to acquire knowledge. As a branch of philosophy, metaphysics deals with underlying structures and processes concerning the nature of reality, and that's what we're dealing with here. Dismissing the transphysical in order to maintain a "physical-only" reality does not add to awareness and knowledge. It is prejudicial groupthink, if not scientifically unjustified.

While the physical is a valuable focus of research, it also represents learning to the exclusion of other awareness and knowledge. It stands

➤

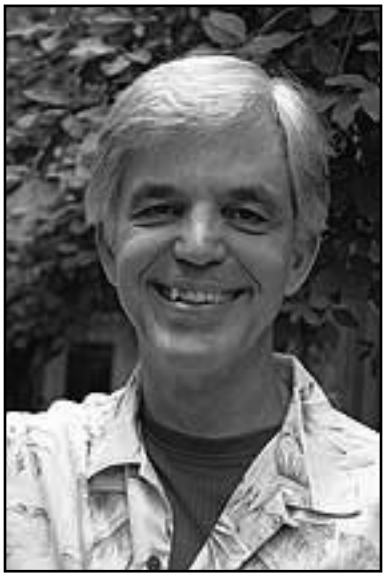
➤

to reason that people who develop their world, including livelihood, based on mental constructs ascribe cognition and consciousness as being materially based. This, however, becomes a matter of professional projection; and, scientifically speaking, in order to investigate something scientifically it must first be allowed to exist.

Information, cognition, and consciousness are intertwined, each affecting the others. From developing research models to understanding life, confining any of them produces significant effects. The debates about information as well as cognition reflect a much larger dispute concerning a philosophy of materialism, and whether this view overly emphasizes the physical thereby stultifying research rather than stimulating open-ended inquiry.

As a counterpoint, pantheistic philosophy supports transphysical experiences just as the philosophy of science supports and details physical phenomena. At the same time, pantheism can hold science but not vice versa. Should not physicalists then give way? Doing so would not obviate scientific findings of the physical world but would render the physical as a reference point of life rather than the only condition of it. Expanding the reference would only enhance the capacity of scientific research, provide new avenues of inquiry, expand the scope of meaning of reality, and offer substantial perspectives on homeodynamics, health, and healing.

Expectation and conditioning create models that filter perception and determine behavior. This applies to any endeavor, including those of physicalists and pantheists. This process provides for education to accelerate learning until the conditioning becomes locked in stone and thereby shunts awareness. A more complete picture of life is that the physical world is only part of discoverable order, and that a multi-dimensional environment enriches our lives. By reviewing the nature of information, the emergent fact is that both sides of the debate could allow a warm steady breeze to usher in new worldviews, technologies, and ways to approach life. Both camps have something to offer. Realness, after all, is in the eye of the beholder and so, of one kind or another, *everything* is information. It then becomes a matter of what you do with it.



Kenneth Smith serves as the communications director of Beech Tree Labs, Inc. (www.beechtreelabs.com), a discovery and early-stage development biopharmaceutical company, and as the executive director of Beech Tree's sister company, The Institute for Therapeutic Discovery (www.tiftd.org), a non-profit organization focused on bridging biochemistry and biophysics. He is the author of *Shamanism for the Age of Science*.

References

1. Ananthaswamy A. Essence of Reality: Hunting the universe's most basic ingredient. *New Scientist*. 1 February 2017.
2. Stanford University on-line library: https://plato.stanford.edu/entries/information/#HisDevMeaTerInf, accessed 11/15/17.
3. Kelly K. Why the Basis of the Universe Isn't Matter or Energy – It's Data. *Wired*. February 28, 2011.
4. Oxford University Physicist Vlatko Vedral, https://www.youtube.com/watch?v=QfQ2r0zvyoA, accessed 11/02/17.
5. Smith K. The Temporal Architecture of Life: A Survey of Environmental Dynamics in Human Health. *EdgeScience.* June 2016:14-20.
6. Gleick J. *The Information: A History, A Theory, A Flood*. New York: Pantheon Books; 2011:292.
7. Oschman JL. *Energy Medicine: The Scientific Basis*, Second Edition. Edinburgh, Scot. Churchill Livingston, 2016.
8. Zelazo PD, Moscovitch, M, Thompson, E, eds. *The Cambridge Handbook of Consciousness*. New York: Cambridge University Press; 2007.
9. Stillings NA, et al. *Cognitive Science: An Introduction. 2nd edition*. Cambridge, Mass.: The MIT Press; 1995:15.
10. Kandel ER, Schwartz JH, Jessell TM, eds. *Principles of Neural Science, Fourth Edition*. New York: McGraw-Hill; 2000.
11. Kelly EF, Crabtree A, Marshal P, eds. *Beyond Physicalism: Toward a Reconciliation of Science and Spirituality*. Lanham, MD: Rowman & Littlefield; 2015:31.
12. Kelly EF, et al. *Irreducible Mind: Toward a Psychology for the 21st Century*. Lanham, MD: Rowman & Littlefield Publishers; 2007:117.
13. Tonini G. Integrated information theory of consciousness: an updated account. *Archives Italiennes de Biologie*. 2012;150:290-326.
14. Gabbard GO, Twemlow S. *With the Eyes of the Mind: An Empirical Analysis of Out-of-Body States*. New York: Praeger;1984:27-39.
15. Penfield W. The Role of the Temporal Cortex in Certain Psychical Phenomena, *The Journal of Mental Science*. July 1955; 101(424):451-465; and Penfield W, Perot P. The Brain's Record of Auditory and Visual Experience. *Brain.* 1963; 86:595-696.
16. Blanke O, et al. Out of body experience and autoscopy of neurological origin. *Brain*. 127, 2004:243-258.
17. Stevenson I. *Where Reincarnation and Biology Intersect*, Westport, Conn.: Praeger, 1997.
18. Tucker JB. *Return to Life: Extraordinary Cases of Children Who Remember Past Lives*, New York: St. Martin's Griffin, 2013.
19. Weiss BL. *Many Lives, Many Masters*, New York: Touchstone, 2012.
20. James W. *Varieties of Religious Experience*, New York: Macmillan, 1961 (original publication 1902).
21. Stace WT. *Mysticism and Philosophy*, New York: Oxford University Press, 1987 (original publication 1960).
22. Author communication with Edgar Mitchell during 2006-07.
23. Dimitropoulos S. Trying to Lose My Religion. *Discover*. September 2017:26-27.
24. Oschman JL, Pressman MD. An Anatomical, Biochemical, Biophysical and Quantum Basis for the Unconscious Mind. *International Journal of Transpersonal Studies.* 2014: 33(1):77-96.
25. McCraty R, et al. Electrophysiological Evidence of Intuition: Part 2. A System-Wide Process? *The Journal of Alternative and Complementary Medicine*. 2004: 10(2):325-336.
26. McCraty R, et al. Electrophysiological Evidence of Intuition: Part 1. The Surprising Role of the Heart. *The Journal of Alternative and Complementary Medicine*. 2004; 10(1):133-143.
27. Colloca L, Benedetti F. Placebos and painkillers: is mind as real as matter? *Nature Reviews Neuroscience*. July 2005;6:545-552.
28. Price DD, et al. A Comprehensive Review of the Placebo Effect: Recent Advances and Current Thought. *Annual Review of Psychology*. January 2008:565-590.
29. Walach H. Placebo and placebo effects – a concise review. *Focus on Alternative and Complementary Therapies*, June 2003: 8(2):178-187.
30. Silberman S. Placebos Are Getting More Effective. Drugmakers Are Desperate to Know Why. *Wired Magazine*. August 24, 2009.
31. Smith K. The Mind of Placebo: In Search of the Perfect Medicine. *EdgeScience*. January-March 2011;6:9-13.

◆

Alien Species... On the Threshold of a Brave New World

by Katherine A. Carroll, NTP

Executive Director, National Health Federation

The European Union has highlighted the lack of organs for transplant and the increasing number of patients on waiting lists worldwide. While the United States operates with an opt-in system for organ donation, Spain, the undisputed world's transplant leader, has an opt-out system as does Belgium, which France also adopted in 2017. The Netherlands passed a law February 2018, with two years to implement, that **makes all adults organ donors by default, unless they specifically opt out**. China handles organ shortages differently; the Chinese government has been exposed in forced organ harvesting of living prisoners. Organs are Big Money. Science and market-greed progress while ethics lag, the victim of a myriad of undecided questions. Shoot first; ask questions later about actions that play Russian roulette with our lives as we have known them.

Ethical Organ-Shortage Solutions

Safe, clean food and nutritional supplements with therapeutic strengths are among the most obvious solutions for preventing disease that leads to organ transplants in the first place. Heart disease alone claims over 600,000 American lives a year, yet only 5,000 heart transplants are performed worldwide. With 116,000 people on national waiting lists for transplant organs as of August 2017 and only 34,000 transplants performed in 2016, ill people and the market are poised for a solution. While we wait for the first successful organ 3D/4D bio-printing, medicine's next big frontier,[1] the controversial chimera appears a viable solution for those who have irresponsibly failed their own organs or their organs have genetically failed them or succumbed to environmental manipulations. *Along with preventive lifestyles, the ethical solution, however, is 3D or 4D organ printing that is based not on aborted fetal cells but the body's own cells.*

Traversing millennia, chimera (animal-human hybrids) now thrive in United States, UK, and other research labs growing tissue that may yield liver, kidney, heart, or other transplanted organs, eliminating the wait for a human donor and reducing the risk of organ rejection. Despite ocular, neurodegenerative, and other applications, fiery controversy surrounds chimera and rightfully so. Humans and animals have mixed throughout the ages in various ways. Beyond an initial repulsion, what makes a chimera, not the mythical Greek fire-breathing union of human and animal, but a living being composed of cells coalesced from two different organisms, either from the same or different species, so hotly debated? Foundations matter. Arguments begin with taking one life to provide another's; an entire emerging industry based upon aborted human fetuses is suspect particularly when Planned Parenthood staff reveal financial incentivization for meeting monthly corporate abortion quotas.[2] Dead babies are big business and an integral part of emerging tech where chimeras are concerned. But there are other concerns as well.

How it Works

Scientists research chimera in the form of *humanized mice* to study inflammatory disease, cancer, infectious disease, and hematopoiesis. For transplant hopefuls, the big news out of Juan Carlos Izpisua Belmonte's Salk Institute Lab was the creation of human-pig chimeras,[3] fetal pigs with human cells mixed in. Yet "even with complementation (where for example a pig chimera would ideally only have human cells contributing to one organ such as a kidney or pancreas**),** one of the ethical dilemmas is that the chimeras would have to be taken to term in order to get a usable human pancreas. It is unclear if taking a human-animal chimera to term could be ethically permissible."[3] Hopefully, bioethical issues will be decided by the time technical problems are solved, such as increasing the percentage of human cells in pigs by using the CRISPR gene technique. For a viable transplant, at least one percent of the embryo's cells must be human. Until then, organ growth is a long way off, so 3D/4D printing still stands a chance.

In 2012, in my book review of Michio Kaku's *Physics of the Future,*[4] I asked how the health-freedom community (which the National Health Federation began

➤

➤

in 1955) would protect humans against runaway technology. Kaku cited radical futuristic changes, advancements in technology, robotics, and the amalgamation of species including AI-enhanced humans. I cited the need for a Bill of Rights for the Race of Mankind, fresh guidance, and intervention in a Brave New World, much the same as our founding fathers like Jefferson and Adams saw the need for a new set of standards and guidelines in the New World. In our day, we need not merely the recommendations or proposals that Ethics Committees provide, which may or may not be adhered to, but a global standard and commitment to respect and protect the sanctity of life. This is a war on humanity – on what it means to be human.

The Weaponization of Scientific Research.

Novel-lifeform creation management is comparable in magnitude to the need for international nuclear warfare restraint. Driving the international conversation is a need for China, North Korea, and Russia in particular to cooperate versus compete. Russian President Vladimir Putin stated in 2017 that the control of artificial intelligence will be crucial to global power noting that it would be strongly undesirable if someone wins a monopolist position. The same can be said for the potential dangers of weaponized chimera. For instance, concerning Russia's dominance in cyber-warfare, one could easily imagine one of their bot groups taking control of an on-going chimera lab and wreaking unimaginable havoc. If new lifeforms with a strong resemblance to human beings, either emotionally or physically, begin to appear and even populate on Earth, life will be forever changed. We are fast sailing into uncharted territory without a safe harbor in sight.

Based on stem-cell biology and gene-editing technology, scientists alter DNA in sheep or pig embryos to circumvent tissue development in favor of the organ they wish to grow. When human stem cells are introduced into the animal, it is hoped that the human cells will assume formation of the missing organ, thus creating a human liver, kidney, heart, or other organ for harvest from the animal for use in a transplant operation. In late 2015, at the same time I was researching material for my first article on this subject (which published in 2016),[5] scientists had been gathering preliminary information, observing cell growth and cell fate, deducing how great the contribution of human cells is to the animals' bodies, and then presumably destroying research samples in 28 days. Scientific progress has since been rapid but fails to keep pace with ethical decision-making on a global level.

Chimera researchers and scientists began inserting human cells into early sheep and pig embryos in 2014. *MIT Technology Review* stated that 20 pregnancies of pig-human or sheep-human chimeras were established during 2016 in the U.S. alone.[6] Another three dozen pig transfers have taken place outside the US. *Yet, biological humanization balances tenuously against the risk of moral humanization; the great fear being creation of a novel sentient being with human qualities.*

Thinking Pigs and Standing Sheep

Stanford University stem-cell biologist Hiromitsu Nakauchi experiments with human-sheep chimeras. Offering a disturbing analysis of potential outcomes, Nakauchi noted current contributions by human cells to the animals' bodies appear to be relatively small. "If the extent of human cells is 0.5 percent, it's very unlikely to get thinking pigs or standing sheep," he says. *"But if it's large, like 40 percent, then we'd have to do something about that."*[6] (*emphasis added)* "Desperately ill people on organ waiting lists might someday order a chimera and wait less than a year for their own custom organ to be ready. I really don't see much risk to society," Nakauchi says.

Michio Kaku notes, "Since we are drowning in an ocean of information, the most precious commodity in modern society is wisdom." This is never truer than for health-freedom advocates today. *We need an expanded definition of health freedom as prior delineations are obsolete in the face of novel life forms.* Stephen Hawking admits further progress in science and technology will create "new ways things can go wrong": "We are not going to stop making progress, or reverse it, so we have to recognize the dangers and control them. I'm an optimist, and I believe we can."[7]

But there are scientific and social implications to be considered; namely the humanization of animals. Chimerism concerns encompass crossing inviolable species borders.[8] These are real concerns leading to real questions, particularly if brought to term: do we put this new creation in a zoo or allow it to live among us? Our days of being fully human and being fully animal are numbered, the distinction forever blurred and now compounded with AI/human amalgamation. Elon Musk notes, "Humans must merge with machines or become irrelevant in AI age."[9]

Progress must find its balance. Stem-cell research was held up during the last Bush Administration due to fears it would encourage increased abortion rates. Criticism abounds, primed by that action, that the "religious right," which now includes Muslims due to the use of pigs in chimera research, will delay progress. *Yet science unchecked against the moorings of ethics, human dignity, and sanctity is unwise particularly in the face of the sheer magnitude of unknown variables versus known benefits.*

Playing with the Fire-Breathing Chimera

There are some who argue against chimeras by claiming that humanity would lose its dignity. However, according to Ethics Committee publications, the "retaining human dignity" argument is flawed. The human is not diminished by an animal becoming more human. Additional ethical challenges concern human-cell contribution to chimeric brains and any human contribution to germ cells. Safety measures mandate sterilization at a minimum. The great unknown is animals starting to possess human characteristics and features. Others suggest that such characteristics

as linguistic capacity, rationality, and a capacity for sufficiently social relationships are inherent only in human relationships. Animal sciences such as ethology, primatology, animal psychology, and behavioral ecology suggest otherwise.[10]

Pablo Ross, a veterinarian and developmental biologist at the University of California, Davis, advises, "We don't want to grow them to stages we don't need to, since that would be more controversial. … My view is that the contribution of human cells is going to be minimal, maybe 3 percent, maybe 5 percent. But what if they contributed to 100 percent of the brain? **What if the embryo that develops is mostly human? It's something that we don't expect, but no one has done this experiment, so we can't rule it out."**[10] (emphasis added) Embryo complementation is a concern because the human cells can multiply, specialize, and potentially contribute at will to any part of the developing animal's body.

Wolfgang Enard of Ludwig-Maximilians University Munich in Germany, showed that mice are better at learning if they have the human Foxp2 gene, which has been linked with human language development. Yet he asks the wise cautionary question, "If you make animals more human-like, where do you stop?" In the "smart mouse" model,[11] researcher Steve Goldman cites, "Within a year, the mouse glial cells had been completely usurped by the human interlopers. The 300,000 human cells each mouse received multiplied until they numbered 12 million, displacing the native cells. We could see the human cells taking over the whole space." Goldman continues, "It seemed like the mouse counterparts were fleeing to the margins." Otherwise said, the mice became measurably smarter. The team stopped short of putting human cells into monkeys and great apes due to ethical concerns.

A richer discourse is demanded surrounding the ethics of a novel-being creation. The 1997 book and its 2007 film adaptation *The Diving Bell and the Butterfly* (original French title*: Le Scaphandre et le Papillon*) is a memoir by journalist Jean-Dominique Bauby. After suffering a massive stroke that left him with "locked-in syndrome," he blinks his way through the alphabet with the help of a friend to write his experiences of being fully cognizant and unable to "get out." This is the great fear of the results of chimera research and is one reason why great apes have been excluded as candidates. How would we know? Helen Keller found a way out. Ethics demand a sufficient reason to pause.

Despite the fact that scientists from other countries such as Japan move to the US in order to conduct chimera research as it is allowed here (and in the UK with more stringent restrictions), the National Institutes of Health (NIH) – which controls the federal expenditures on medically-based research – wisely exercised caution, withdrawing funding until ethical and social considerations could be addressed even though NIH was hit with criticism for a fear-based decision, impeding progress. Hiromitsu Nakauchi himself admits, "What if the embryo that develops is mostly human? It's something that we don't expect, but no one has done this experiment, so we can't rule it out."

Ethics of Funding Chimera Research

Since the NIH denied funding, other funding sources including California's state stem-cell agency were sought and came through. The California Institute of Regenerative Medicine, a State agency instituted 10 years ago to bypass political interference from Washington, provided a $6 million grant for Nakauchi's work.

Government funding in and of itself is a major concern. But when the military gets involved we must ask "why"? Dr. Daniel Garry, a cardiologist heading a chimera project at the University of Minnesota was awarded a $1.4 million grant from the US Army to attempt growing human hearts in pigs. Dr. Garry was one of 11 who co-authored a letter in November 2015 criticizing the NIH for creating "a threat to progress" that "casts a shadow of negativity" on their work. Yet neither they, nor others, have weighed the ethics and come up with a universal agreement. Instead, the NIH might be commended for exercising wise caution until answers emerge regarding animals that could possess human consciousness and inadvertently be released into the wild or society.

The worry is that the animals might turn out to be a little too human for comfort, such as ending up with human reproductive cells, patches of people hair, or just higher intelligence. "We are not near the island of Dr. Moreau, but science moves fast," NIH ethicist David Resnik said during the NIH's meeting. "The specter of an intelligent mouse stuck in a laboratory somewhere screaming 'I want to get out' would be very troubling to people."[6]

The last thing we need is to turn over this vital and crucial decision-making process to government, the pharmaceutical sector, the medical sector, or the Pope. Research must progress but within ethical bounds. We need an expanded definition of health freedom as prior delineations, which apply to human-only models and

➤

➤

human-only post-embryonic stage, are obsolete in the face of novel life forms. The creation of an artificial embryo,[12] conceived without egg or sperm, raises more ethical implications. Will this novel life form the new foundation, bypassing aborted fetuses, to create a bank of donor cells to merge with animals to make chimera? Are they human, possessing a soul or useful only as organ-breeders? The questions fall into a seeming spiritual and intellectual vacuum as science marches on to slake the market's thirst for problem-solving innovation.

Old British Common Law and Emerging Biotechnology

Richard Maybury, in *World War I, The Rest of the Story and How It Affects You Today,* expounds on two legal principles making peace, liberty, and civilization possible. These two laws have been the basis of the old British Common Law and are inherent in all main religions. The first forms the basis of contract law: to do what you say you will. The second: to not encroach on humans or their property. The disregard of these laws undermines civilizations and starts wars.

Despite ethics committees disregard of the "human dignity" argument, the *sanctity of life* is sacrificed on the altar of scientific research and the creation of novel life forms wars against these basic foundational legal principles. There is too much risk in contract-law violations for simple trust that the chimera will indeed *be* destroyed in 28 days. In a theoretically lucrative and competitive climate or one fueled by the Deep State, the Military-Industrial Complex, Big Pharma, Big Medicine, Wall Street, greed, and basic human need for innovation, more reliable, firmly accountable boundaries need to be set with strict penalties for their disregard. This places a greater responsibility and agreement among nations regarding chimera development. The tenuous trust and shared vulnerability is too great to assume without firm boundaries should these two principles of law be violated; and if history serves, they will be.

We have crossed the threshold into yet another Brave New World populated by chimeras, cyborgs, artificial embryos, enhanced humans, and potential weaponized combinations of these. Technology sweeps over us like a tsunami and yet we are making judgments as we go along integrating new research, data, and applications with scarcely time to consider their long-term impact. Together, we must consider carefully in the creation of this New World and demand respect for health, health freedom, and the basic laws of civilization as new life forms challenge current models and boundaries. Critical thinking, of which I have written much in the past, must be applied here to prevent any disasters by government or business. Just as countries lose their unique flavor through mass immigration, so humans stand to lose their sanctity, sacredness, and distinctiveness through fusion for the sake of a science-driven market.

References

1. BIOLIFE4D – Build a Heart, Save a Life. https://www.youtube.com/watch?time_continue=211&v=yUY_S8SMAhY
2. Payton B. Whistleblowers: Planned Parenthood Had Dead Baby Quotas. *The Federalist.* February 8, 2017.
3. Knoepfler Stem Cell Lab. Perspectives on pig human chimera paper. *The Niche.* January 2017.
4. Carroll KA. Book Review: *Physics of the Future, How Science Will Shape Human Destiny and Our Daily Lives By The Year 2100*. https://www.thenhf.com/resources/blog/nhf-news/10book-review-by-katherine-a-carroll-ntp-physics-of-the-future-how-science-will-shape-human-destiny-and-our-daily-lives-by-the-year-2100-by-machio-kaku
5. Carroll KA. Alien Species; A Brave New World. *Health Freedom News.* Winter 2015;33(4).
6. Regalado A. Human-Animal Chimeras Are Gestating on U.S. Research Farms, A radical new approach to generating human organs is to grow them inside pigs or sheep," *MIT Technology Review*, January 6, 2016.
7. Shukman D. Hawking: Humans at risk of lethal 'own goal.' *BBC News, Science and Environment,* 19 January 2016.
8. ISSCR: Committee Forum. Ethical Standards for Human-to-Animal Chimera Experiments in Stem Cell Research. *ISSCR Cell Press.* http://www.isscr.org/docs/default-source/2015-am-stockholm/hyun-08-07.pdf?sfvrsn=2.
9. Kharpal A. Elon Musk: Humans must merge with machines or become irrelevant in AI age. CNBC.com. February 13, 2017.
10. Baylis F, Fenton A. Chimera research and stem cell therapies for human neurodegenerative disorders. *Cambridge Quarterly of Healthcare Ethics*. 2007;16:195-208.
11. Coghlan A. The smart mouse with the half-human brain. *New Scientist*. December 6, 2014.
12. Crew B. Scientists Have Grown the World's First Artificial Embryo, And It's Nuts. March 2017. www.sciencealert.com.

◆

Katherine A. Carroll is Executive Director of the National Health Federation and Foundation for Health Research and is Managing Editor of NHF's magazine, *Health Freedom News.* Katherine is on the Board of Directors of the National Health Federation Canada and the Advisory Board for GreenMedInfo.

Katherine received the NHF 2014 Health Freedom Hero award for her food-activist work as an NHF delegate at Codex Alimentarius since 2012. Certified in Nutritional Therapy, she also writes for several magazines and blogs as frequent contributor to several publications. Additionally, Katherine enjoys hosting international guests at Adytum Sanctuary, their Western Washington Pacific Northwest Retreat.

katacarroll@gmail.com
360-790-2011
www.thenhf.com
www.adytumsanctuary.com
www.medicalvisioncenter.com

Letter to the Editor

Consumer Reports Magazine Bias

The article in the March 2018 edition of *Consumer Reports* (CR) concerning naturopathic doctors (NDs) is filled with bias and inaccuracies.

I am a medical doctor who is a board-certified specialist in internal medicine, and I have been practicing primary care for over 40 years. As a faculty member of the University of Michigan Medical School, I have been teaching MD, DO, and ND students, as well as medical residents and physicians for that many years. I have been to three different naturopathic medical schools and have seen personally the rigors of their four-year medical post graduate training. Therefore, I can discuss these facts with knowledge and experience.

I have listened to some of the most brilliant lectures by and have shared complex cases with NDs. Of course, it would be prudent to check out the certification and payment structure of any physician that one chooses to see.

The author states that naturopaths have a lack of training. Accredited ND schools have four years of post-graduate education and much of their program is evidence based. We presently have physician assistants and nurse practitioners treating patients in primary care. Their years of education is also less than MD and DOs. Yet, many do an excellent job, provide superb care; and they have my utmost respect.

There are bad apples in all professions, including medicine. So why the author would focus on a particularly bad ND is confrontational and misleading. In fact, this type of comparison is poorly chosen and appalling reporting. It is inappropriate and insulting to lump together this bad apple with all well-meaning ND colleagues (there are bad and untruthful journalists as well). For example, just recently in Michigan an MD (Larry Nassar, MD) was charged with pedophilia and abusing girls and young women for decades. Also locally another MD, a board-certified oncologist (Farid Fata, MD) was charged and jailed for giving FDA-approved cancer drugs to patients without cancer. Yet, the author doesn't scare all people from seeing MDs!

Most practicing MDs pay only lip service to lifestyle changes and are quick to take out the prescription pad to write for medications that may be unnecessary or have side effects (including death). NDs usually do spend more time with their patients discussing preventive measures rather than the typical seven-minute office visit. Meanwhile, there are few lectures on nutrition in standard medical relative to naturopathic medical schools.

Meanwhile, as a self-confessed, medical-research nerd, there are plenty of peer reviewed articles supporting natural remedies, including herbal medicine, homeopathy and vitamin and mineral nutrients. As an MD, I believe that we are well trained and will continue to be an important part of our health care system (most people know me as the happiest doc around). Of course, any professional should know their limits and when to ask for help or a referral. NDs have nothing against MDs or appropriate medications or surgery. Let us all work together for the benefit of the patient.

Thumbs down and shame on *Consumer Reports* for publishing such an article filled with ignorance. It misrepresents a valuable medical profession that has and will continue to have a positive contribution to the health of many people. NDs may well become the cost-saving, preventive medicine, primary-care doctors of the future!

Edward(Lev) Linkner, MD, ABIHM

The Benefits of Low-Dose Naltrexone

review by Carol Petersen, RPh, CNP, Women's International Pharmacy,

The LDN Book, edited by Linda Elsegood
Chelsea Green Publishing, White River Junction, Vermont. www.chelseagreen.com
2016; 240 pp.; $27.99

Linda Elsegood's personal success story tells how using low-dose naltrexone (LDN) to treat her multiple sclerosis restored her quality of life and gave her hope for the future. Now she is a woman on a mission to help others learn about LDN and to promote further research into how it may be used to treat a variety of diseases. In *The LDN Book: How a Little-Known Generic Drug – Low Dose Naltrexone – Could Revolutionize Treatment for Autoimmune Diseases, Cancer, Autism, Depression, and More*, Elsegood has compiled chapters written by practitioners who have become experts in the use of LDN.

History

Pharmacist Stephen Dickson provides a comprehensive history of the opium poppy and the subsequent creation of synthetic drug compounds called opiates, which are all active at the opioid receptor sites. Opioid receptors are meant to be activated by hormones produced in the body called endorphins and enkephalins, which can relieve pain and contribute to wellbeing. However, these receptors can also be stimulated by opiates. Naltrexone was originally developed to block these receptor sites in order to assist people addicted to opiates. The developers of naltrexone reasoned that when opioid receptors were blocked, there would be no need to use or abuse opiate drugs. While a logical theory, in actual practice they had little success.

However, in low doses, naltrexone acts to temporarily block opioid receptors. The body responds by producing increased amounts of endorphins and enkephalins. The opioid receptors also increase in sensitivity and number.

Multiple Sclerosis and Lupus

Dr. Deanna Windham begins with a thorough explanation of multiple sclerosis and lupus. While she recognizes that we do not currently have drugs that treat the complexity of these diseases, LDN has been shown in a number of studies to stabilize and stop their progression. The use of LDN is a pillar in Dr. Windham's treatment plans, though she maintains that each patient must be treated individually for their toxic load, hormone imbalances, nutrient deficiencies, and sleep issues.

Inflammatory Bowel Diseases

Dr. Jill Smith was the first to publish a study on LDN and inflammatory bowel diseases. There are opioid receptors in the gut and on immune system cells. There are a number of different types of opioid receptors, and naltrexone may target different opioid receptors depending on the dose.

Dr. Smith provides case studies of remissions of inflammatory bowel diseases, Crohn's disease and ulcerative colitis with the use of LDN, both alone and with other commonly-used drugs. LDN blocks opioid receptors for about six hours, during which the body increases its endorphin and encephalin production. After about six hours, the LDN is removed from the opioid receptors by the body and the elevated endorphins and enkephalins can act at the receptor to block cell proliferation or reverse inflammation. LDN also sensitizes and increases the number of receptors. Remission may be confirmed with radiology showing healing of the intestinal tract.

Few of Dr. Smith's patients have experienced side effects. However, one possible side effect is sleep disturbances, which can be alleviated by changing to a morning dose or using a lower strength.

Thyroid

Dr. Kent Holtorf, president of the National Academy of Hypothyroidism, explores LDN treatment with thyroid disorders. He explains how LDN can be used effectively in both Grave's disease (hyperthyroidism) and Hashimoto's disease (hypothyroidism). He believes LDN can potentially improve abnormal inflammation and immune dysfunction seen with thyroid disorders, and thus, improve the reduced tissue T3 (active thyroid hormone) levels inside the cells that these conditions can cause. Normal thyroid tests cannot predict the activity of thyroid inside the cell, and so this can go unidentified and untreated.

Chronic Fatigue and Fibromyalgia

Dr. Holtorf also addresses chronic fatigue and fibromyalgia. He writes about phases of treatment with LDN:

1. Stabilize the patient. This stage is where pain and sleep disturbances are addressed.
2. Enhance mitochondrial energy production with nutrients.
3. Balance hormones as these patients typically have deficiencies.
4. Enhance the immune system function and treat the infectious components. LDN is often part of this stage of treatment.

5. Address issues like heavy metals, leaky gut, mold toxicity, and coagulation problems.
6. Maintain health and balance.

An integrative approach has shown success, with treatment plans adjusted to the individual needs of each patient.

Restless Leg Syndrome

Dr. Leonard Weinstock is a gastroenterologist and internist with a special interest in restless legs syndrome (RLS) and has identified an association between RLS and small intestine bacterial overgrowth (SIBO) and other inflammatory conditions in the gut. He used LDN to treat patients with and without antibiotics for infection. In each case he found some positive results and has used LDN for long-term remission.

Depression

Endorphins are very psychoactive and account for the warm feelings of falling in love, coping with stress, and bringing joy and contentment. Dr. Mark Shukhman describes the symptoms of endorphin deficiency as including:

- Discomfort with disturbances such as changes in sound, light, temperature, or touch;
- Immune system problems such as frequent infections, allergies, and autoimmune disease;
- Crying easily, and have difficulty with painful situations; and
- Craving chocolate, wine, marijuana, and alcohol.

LDN helps in these conditions by increasing the levels of endorphins. Many people who have turned to opiates describe that it is the first time that they have felt normal. Although his chapter focuses on depression, psychiatrist Dr. Shukhman has also used LDN in his practice for treatment of autism, post-traumatic stress disorder, multiple personality disorder, anxiety, obsessive compulsive disorder, psychosis, and even sexual dysfunctions.

Autism

Dr. Brian Udell has a special needs pediatric practice and has found a common theme with autism to be inflammation and gut disturbances. He cites Dr. Jacquelyn McCandless' work with children using LDN as a cream, rather than tablets, because of its bitter taste. He has seen LDN increase speech and communication, decrease aggression, and improve social development. Beta endorphin levels can be measured to confirm LDN activity.

continued on bottom of page 80 ➤

The Big Book Competition!

review by Jacob Schor, ND, FABNO

Natural Approach to Urology, 2nd edition by Eric Yarnell, ND.
Wild Brilliance Press, Inc.; wildbrillancepress.com
2017; 1143 pages; $199.95

We certainly do like to swim against the tide. While the rest of the world is metamorphosing into a virtual online existence, we naturopathic sorts are moving in the opposite direction, back in time to celebrate the preservation of the printed word in traditional books printed on paper. We naturopathic sorts seem to derive pleasure from not just books but big books; good, solid, big books, with lots of pages and tiny font, books that take on the big topics, books with heft! How else to describe Eric Yarnell's new text, *Natural Approach to Urology*, other than by saying, "This is a Big Book." Weighing in at 6 pounds 12-5/8 ounces, it's in the same league as Alan Gaby's second edition of *Nutritional Medicine,* though admittedly Yarnell's entry is a shade lighter weight. My copy of Gaby's book is a full 7 pounds 14-7/8 ounces, while Yarnell's, though of similar dimension (9 x 11.5 x 3 inches), weighs more than a pound less. Neither book is what you would describe as portable; they don't travel between office and home often. Both books will look good in close proximity on the same bookshelf, but reading either in bed could be hazardous. Yarnell's entry is printed on thicker, less dense paper and so contains a mere 1143 pages vs. Gaby's 1454 pages.

[Note: while comparing the size of things we should note that Dr. Yarnell has chosen to post the 495 pages of references cited in his book online rather than in print, while Dr. Gaby includes the reference in the printed text. Thus, if we were to include references in our comparisons, Yarnell's is longer.]

Yarnell chose a larger, easier to read font than Gaby did. I point out these differences right up front because in a way they point out the somewhat absurd task I volunteered for. Who among us will actually read Yarnell's book cover to cover? The first edition of *War and Peace* had 1,225 pages, AND it came with a plot to make reading easier. This is a textbook, a reference book, a book that contains the information you may someday want for day you need it.

The idea that any of us will peruse these new big books cover to cover harkens to a bygone era. Perhaps we should start a Society of Anachronistic Readers. We could sit in our reading chairs, put on our reading jackets and our reading glasses, and while away long evenings with these books. And slippers, I need to mention slippers. These big books could help us travel back to a forgotten era. I'm sure that our good friend Eric Yarnell could be a founding member of this imagined association. In so many ways, he himself is an anachronism, "a thing belonging or appropriate to a time period other than that in which it exists, especially a thing that is conspicuously old-fashioned." [from the Greek 'ana' (backwards) + 'khronos' (time)].

Eric is a Denver kid. We first met when he was still a Bastyr student who would sometimes act as preceptor at our office. The sort of geeky kid who used *Star Wars* metaphors in conversation and who quoted lines from the *Lord of the Rings* as easily as he could quote details from clinical trials, a

➤ *continued from page 79*

Cancer

Dr. Angus Dalgleish, an oncology practitioner in the UK, writes that, while there is very little in the published literature, LDN seems to be universally useful across all tumor types. He writes of his personal experience treating patients with metastases, achieving stability and long–term, disease-free status. He finds that LDN affects more receptor sites than just the opioid receptors. Naltrexone in large doses actually promotes tumor growth in the laboratory, so the best effects occur when it is used in low doses and used intermittently rather than continuously. Its anti-inflammatory action can be helpful in cancer. Dr. Dalgleish reports that the use of LDN also increases the production of natural killer cells. Finally, LDN can produce positive effects on mood that help in combatting the disease. He writes that failure with LDN may be linked to low vitamin D levels.

Conclusion

The LDN Book is just a part of Linda Elsegood's work. Under her direction, the LDN Research Trust has an incredible number of accomplishments, including organized conferences, LDN radio, and crowdfunded documentaries. This outreach has stimulated investigation into endocrine and immune system activity that was hardly known before. This book is a window into the large body of knowledge we have gained in the last ten years.

Resources

- Holtdorf K. The National Academy of Hypothyroidism. https://www.nahypothyroidism.org/.
- The LDN Research Trust. https://www.ldnresearchtrust.org.
- Udell BD. The Autism Doctor.com. http://www.theautismdoctor.com.

◆

kid who didn't miss Comic Con. I quickly learned that he was a preceptor I could take advantage of: when patients asked specific questions about supplements, I would pass them over to Eric to answer. Eric would open this kind of mental filing cabinet he had in his brain and start reciting details from specific studies. Year, lead author, journal, title study design. He had all the information in there ready to access. At a certain point, the patient would cry uncle.

I have had the pleasure of watching Dr. Yarnell's career blossom over the years since. We had hoped he would come back to Denver when he graduated from Bastyr University in 1996 and practice with us, but instead he spent two years as Silena Heron's resident in Sedona, Arizona. At one point we got as far as co-signing an office lease with him, only to discover the prospective landlord was a schmuck and went to court to break that lease; Eric managed to bail out of the courtroom proceedings and moved back to Arizona where he chaired the botanical medicine department at Southwest College of Naturopathic Medicine. From Arizona he returned to Seattle where he has been a full professor of botanical medicine ever since, I think 15 years now. Along the way he took over Silena's company and is among other things, president of Heron Herbs.

Over the years he's grown up a bit and, while he probably still knows the dates of the next Comic Con in Seattle, has a more diverse set of interests. He skipped the annual AANP conference recently to attend a 'camp' to learn to play the hammered dulcimer.

Dr. Yarnell has published hundreds of articles on urology and related fields. In addition to this current book, he is the co-author of *Clinical Botanical Medicine* and the sole author of the two-volume set, *Natural Approach to Gastroenterology*. I could say that his gastro book is longer than this urology book but that would be ignoring the fact that since publication of the urology text, it has been joined by a sister volume, *Natural Approach to Prostate Conditions* (2nd ed).[1] You might question, given the topics, whether it is appropriate to use the term 'sister' rather than 'brother volume.'[2]

In addition to writing these monster texts, Dr. Yarnell is chief medical officer at Northwest Naturopathic Urology, a staff physician at the Bastyr Integrative Oncology Research Center, a supervising physician at Bastyr's Center for Natural Health, a co-founder of Healing Mountain Publishing and, as mentioned, President of Heron Botanicals. The list of awards and honors on his resume is equally impressive, but most impressive to me, Dr Yarnell is a recipient of the AANP's Vis Award, perhaps in my humble opinion, the most deserving of all past recipients as his life closely mirrors that of John Bastyr, perhaps more so than any other past recipient. ➤

➤

Technically there should be an asterisk in the title of the book. Urology is defined as "the branch of medicine concerned with the function and disorders of the urinary system." The asterisk should lead to a disclaimer that this book is focused only on men's urology. Most of those familiar with Dr. Yarnell's work already knew this, but for those who don't, Dr. Yarnell's specialty has always been men's health. This book is only about male plumbing problems and how to fix them naturally.

This would make a perfect textbook for a men's urology course if our naturopathic colleges offered such courses. Assign a hundred pages to read every week and in 10 weeks you will have covered all there is to know from testicular torsion to circumcision, or what Dr Yarnell refers to as "male genital mutilation." One must admit that one of the things to love about Eric is that he is not hesitant to share his opinions.

The advantage of his tendency to share opinions shows up in his chapter sections regarding disease management. For example, in Chapter 27, which covers Peyronie's disease, the management section starts out:

> It is important to note that the degree of plaque formation correlates poorly to symptoms. The goals of treatment are cure (difficult), improvement or normalization in erection function (very possible), reduction or elimination of pain on erection (very possible), and usually least of all, reduction of curvature and plaque size (possible).

The parentheses are all Eric's.

It is this tendency to express well informed, intelligent opinions based on a combination of extensive clinical practice and a wide reading of the relevant scientific literature that makes Dr. Yarnell's book so interesting and readable. While I may save some of the specific disease/condition-related chapters to read for a specific patient, chapter sections such as "Men's emotional health and the toxicity of machismo" are particularly well written and fascinating summaries of paleo-archaeology, psychology, and Eric's own insight to the particular world view held by the male of our species.

Where appropriate, sections are divided into clinical summaries, epidemiology, etiology and pathogenesis, risk factors, diagnosis, therapeutics and prognosis. This makes the book eminently handy for those of us seeking a useful tool in clinical practice. Put simply, the book makes it easy to cram a lot of information into your brain on short notice just prior to a patient visit, allowing one to maintain a pretense of knowledgeable intelligence.

There are over a hundred pages on testicular cancer alone. Standard of care medical treatment for this cancer is highly successful so that many patients will have little need to look for further adjunctive treatment. Nevertheless Dr. Yarnell provides an extremely comprehensive review of what botanical agents and nutritional therapies may be useful as therapies for each specific treatment option. His review of which herbs researchers have suggested beneficial with specific chemotherapy drugs is among the most comprehensive that I have ever read. So, too, are the reviews of ginger to prevent nausea induced by chemotherapy or from anesthesia.

While the book covers testicular cancer in great depth, there is no mention of prostate cancer. "Why is that?" I ask Dr. Yarnell early in my reading. Well, it turns out there is an entire separate volume called *Natural Approach to Prostate Conditions* (2nd ed) that was originally meant to be part of this book. Including the additional 300+ pages about prostate cancer would have made it impossible to bind all the pages in the book together. So instead, Yarnell created a separate book, *Natural Approach to Prostate Conditions*, 2nd ed. A few of the chapters on herbs are included in both books so that they each are stand-alone references. I hate to be the one to tell you this, but if you see men in your practice, you should probably have both of these books on your office shelf. There just aren't any serious competitors.

Somewhere I should mention that Eric is an excellent writer. Early on in his career he admitted he tries to emulate Steve Austin's style. On a good day I would hope that my own writing imitates Eric's, even if it lacks some of the erudition and pure braininess.

About half of this urology text is pure herbal materia medica, a compendium of details on the specific botanicals essential for men's health that you will not find covered elsewhere in anything close to this depth. This is Eric Yarnell writing to his heart's content on the topic that has always interested him the most. Sure, he may at times provide more detail than you may actually need, or want, but this isn't school, and no one is going to test you on the minutiae. You can skip the parts that get boring. As I said, there isn't a plot and you won't miss anything crucial. For me it is a simple pleasure to see Eric doing what he does best, reviewing the science of botanical medicine and having a wonderful time doing it: Eric can turn a concise literature review into a thing of beauty and poetry.

NOTE: A review of Alan Gaby's book *Nutritional Medicine* (2nd ed) was published in a recent issue of *Townsend Letter* (October 2017). In that review, I made several statements that have proven inaccurate. In my initial perusal, I had been unable to locate Dr. Gaby's discussion on melatonin and cancer, but indeed he does discuss this use at depth starting on page 1310. I was also unable to locate an in-depth discussion of MTHFR polymorphisms. It turns out they are in the Folic Acid Chapter. I had looked for the discussion under folate supplements. The MTHFR polymorphisms are mentioned in numerous other chapters when relevant to specific diseases. While these discussions are not listed in the index, these topics are well covered in the text.

1. Well, as the word "volume" comes from the Latin 'volver' to roll (as in rolling a parchment scroll), and the Latin noun 'volumen' is considered gender neutral, technically you could flip a coin and refer to a volume by either gender you please.
2. http://wildbrilliancepress.com/production/natural_approach_to_prostate_conditions_2nd_ed

◆

Ask Dr. J

by Jim Cross, ND, LAc
thias1020@yahoo.com

The Truth Is Out There

I have a little mantra that I use in all aspects of my life: truth is no match for belief. We could spend hours linking this to politics, but I will use it here to relate to this *Townsend*'s monthly topic of cardiovascular health. Sometimes too much access to dubious medical knowledge can lead to misinformation or misinterpretation of medical studies. I find this continuously in my patients with regards to cardiovascular disease/CVD.

An excellent example is a 69-year-old woman who thinks that fat is the devil's medicine which she avoids like the plague. She eats non-fat yogurt, substitutes margarine for butter, etc. She is a psychologist and quite intelligent but only reads one aspect referencing heart health and diet and refuses to consider any other relevant data. From my observation, her body is a physical wreck. She can't walk up a slight slope and has multiple physical maladies. I feel she may have also progressed to moderate dementia, but she will not consider incorporating heart healthy fats into her diet. She is the perfect example of a patient where truth is no match for belief.

For my article this month, I am going to throw some nutritional heart trivia at you by asking fact or fiction and giving you what I consider to be the answers backed up by clinically relevant data.

Fact vs. Fiction #1: High Serum Cholesterol Causes Atherosclerosis

Many studies involving autopsies have found very weak and very inconsistent correlations between serum total cholesterol levels or LDL-cholesterol levels and the degree of atherosclerosis. The only correlation was in individuals with cholesterol levels greater than 350 mg/ml, and this correlation disappears below 350.[1]

Correlations also magically appear in white men but not black men,[2] in men in general but not in women in general,[3] and in the coronary arteries but not in the aorta in either the thoracic or abdominal cavities.[4] Cholesterol levels also do not correlate with the amount of atherosclerosis found on autopsy studies.[5] I'm ecstatic that I don't prescribe statins. I would have to place a flow chart on my wall to figure out whom to give them to and whom not to.

In addition, cholesterol does not correlate with the degree of coronary calcification. The degree of coronary calcification correlates strongly with total plaque volume and the amount of blockage in the coronary artery. Coronary calcification also is an extremely strong predictor of clinical outcome, but the degree of coronary calcification does not correlate with the amount of serum cholesterol.[6]

One last parameter to look at that is more reliable is exposure-response. If serum cholesterol is truly causing and worsening atherosclerosis, then we should see a decrease in amount of atherosclerotic growth when we lower serum cholesterol. Unfortunately, that does not appear to be the case. In three studies there was no correlation with a decrease in serum cholesterol.[7-9]

Fact vs. Fiction #2: Lowering Your Cholesterol Will Lengthen Your Life

There are so many places to start here, but I'll begin with a World Health Organization or WHO study that began in 1965. It was led by Professor Michael Oliver of the University of Edinburgh, Scotland, and tested the lipid-lowering drug clofibrate. The blood cholesterol of 30,000 healthy, middle-aged men from Edinburgh, Prague, and Budapest was analyzed for cholesterol levels. The researchers selected a total of 10,000 men from the sample who had the highest cholesterol levels. Half were treated with clofibrate and half with a placebo that was deemed ineffective.

After five years the drug appeared to be successful as 174 men who had taken the placebo suffered non-fatal heart attacks whereas only 131 did who had taken the drug.

There were a few small problems though. The number who had actually died from heart attacks was equal in both groups plus considerably more who had been treated with clofibrate had died from other diseases. In other words, only a total of 87 men had died in the control group versus 128 in the treatment group. These deaths were due to a wide variety of causes other than heart disease and remain unexplained.

Four to five years after the trial, the number of deaths in the treatment group significantly exceeded those in the high cholesterol group ($p < 0.05$). Amazingly clofibrate is still recommended in many countries as a useful drug![10]

Many meta-analyses on cholesterol-lowering trials have been published, but most of these analyses have excluded trials that didn't support the hypothesis. Uffe Ravnskov, MD, PhD, author of *The Cholesterol Myths*, decided to perform a meta-analysis that

➤

➤

included all randomized and controlled trials whose purpose was to lower cholesterol by either drug or diet or other intervention. What he found was quite intriguing.

There was a total of 50,000-60,000 people in the treatment and control groups. He looked at three parameters: nonfatal heart attacks, fatal heart attacks, and total number of deaths. 3.1% of the individuals in the control group suffered a nonfatal MI, whereas 2.8 percent of the treatment group did. This is where statistics can totally make or break your hypothesis. If you calculate relative risk, there was a 10.4% improvement which sounds impressive and which is also how drug companies massage so-so data into impressive-sounding data. The change in absolute risk was 0.3%. Now which set of data would encourage you to spend $200/month on a drug prescription?

In the second parameter, there were exactly 2.9% fatal MI's in both groups, a wash. The third parameter actually resulted in 5.8% total deaths in the control group versus 6.1% in the treatment group, a win for no cholesterol-lowering drug therapy.[11]

So, by my tally: a draw, a narrow win for cholesterol-lowering drug therapy, and a narrow win for no cholesterol-lowering drug therapy. I don't know, heads I win, tails you lose?

Fact vs. Fiction #3: Vascular Calcification Is Irreversible

Calcification of arteries has been demonstrated to be an independent risk factor of the development of atherosclerosis, MI, stroke, and renal disease.[12,13] Patients who present with arterial calcification will have a poorer prognosis in comparison with patients with none or mild calcification.[14,15] Therefore, altering the arterial calcification process should lead to improved patient outcomes.

Interestingly enough vitamin K2 appears to act similarly to a traffic cop by directing the absorbed calcium to the correct areas in our body and away from the inappropriate ones. Vitamin K2 inhibits tissue calcification and can stimulate regression of tissue calcification and promote restoration of arterial distensibility. K2 is the cofactor for an enzyme called vitamin K-dependent carboxylase, which alters the structure of osteocalcin and matrix gla protein/MGP. This process allows both of those proteins to bind calcium. Osteocalcin binds calcium and guides it into the appropriate places in our bodies, the bones and teeth. MGP sweeps calcium out of soft tissues and prevents buildup of calcium in many unwanted areas such as arterial walls.[16]

A study in the April 2009 European journal *Atherosclerosis* showed that high dietary K2 but not K1 was associated with reduced coronary calcification.[17] Another study in the journal *Blood* demonstrated that vascular calcification induced by warfarin in rats was preventable and even reversible by high vitamin K2 intake.[18] Now this study might have only been done on rats, but traditionally vascular calcification was thought to be a passive process that was irreversible. After reading that article, I'm feeling extremely lucky that I regularly drink red miso soup on a regular basis which is an exemplary source of vitamin K2!

Now I could keep going with fact versus fiction in multiple other directions, but that has already been done by various authors. One place to look is *The Great Cholesterol Con: The Truth About What Really Causes Heart Disease and How to Avoid It* by Malcolm Kendrick, a Scottish MD. A side note on Dr. Kendrick: his book *Doctoring Data* is a must read if you want to learn to sort real medical data from medical nonsense that passes for hard medical data in most medical journals.

The Cholesterol Myths: Exposing the Fallacy That Saturated Fat and Cholesterol Cause Heart Disease by the Danish MD Uffe Ravnskov is also a must read that absolutely shatters the myth of cholesterol levels and heart disease.

Basically, I think that the medical establishment is highly regarded by the public who rarely questions its edicts because they perceive that doctors are realistically attempting to improve the health of each and every human. If you have read Marcia Angell's *The Truth About Drug Companies: How They Deceive Us and What To Do About It*, it will come as no surprise that most studies of drugs and heart disease have been poorly designed and conducted, did not produce the results that have been claimed by them, have been quoted misleadingly, and whose results question or contradict the dietary fat/heart idea.

To this end, it really is up to us in the functional medicine field to bring these "alternative" facts to light and educate people/our patients about what is statistically real. We need to embrace the spirit of the great Fred Kummerow, who was a German-born biochemist and lifelong contrarian who died in 2017 at the ripe old age of 102 and whose nearly 50 years of advocacy led to a federal government ban on the use of trans fatty acids. Fred was one of the first scientists to suggest that the saturated fat in butter and meats did not contribute to atherosclerosis and was beneficial in moderate amounts. His own diet included red meat, whole milk, and eggs scrambled in butter. Dr. Kummerow was the true canary in a coal mine.

References

1. Sharrett AR. Serum cholesterol levels and atherosclerosis. *Coron Artery Dis.* 1993; 4:867–70
2. Oalmann MC, et al. Community pathology of atherosclerosis and coronary heart disease: post mortem serum cholesterol and extent of coronary atherosclerosis. *Am J Epidemiol*. 1981; 113:396–403.
3. Feinleib M, et al. The relation of antemortem characteristics to cardiovascular findings at necropsy. The Framingham Study. *Atherosclerosis*. 1979; 34:145–57.
4. Reed DM, et al. Serum lipids and lipoproteins as predictors of atherosclerosis. An autopsy study. *Arteriosclerosis*. 1989; 9:560-4
5. Ware WR. The mainstream hypothesis that LDL cholesterol drives atherosclerosis may have been falsified by non-invasive imaging of coronary artery plaque burden and progression. *Medical Hypotheses*. 73.4 (2009): 596-600
6. Hecht HS, Superko HR. Electron beam tomography and National Cholesterol Education Program guidelines in asymptomatic women. *J Am Coll Cardiol*. 2001; 37:1506–11.
7. Bruschke AVG, et al. The dynamics of progression of coronary atherosclerosis studied in 168 medically treated patients who underwent coronary arteriography three times. *Am Heart J*. 1989; 117:296–305.
8. Bemis CE, et al. Progression of coronary artery disease: a clinical arteriographic study. *Circulation*. 1973; 47:455–64.
9. Krauss RM, et al. Intermediate-density lipoproteins and progression of coronary artery disease in hypercholesterolaemic men. *Lancet.* 1987; 2:62–6.
10. A co-operative trial in the primary prevention of ischaemic heart disease using clofibrate. Report from the Committee of Principal Investigators. *Br Heart J*. 1978 Oct; 40(10): 1069–1118
11. Ravnskov U. Cholesterol-lowering trials in coronary heart disease: frequency of citation and outcome. *BMJ*. 1992;305:15-19.
12. Zieman SJ, Melenovsky V, Kass DA. Mechanisms, pathophysiology, and therapy of arterial stiffness. *Arterioscler Thromb Vasc Biol*. 2005; 25:932–943.
13. Doherty TM, et al. Calcification in atherosclerosis: bone biology and chronic inflammation at the arterial crossroads. *Proc Natl Acad Sci USA*. 2003; 100:11201–11206.
14. Rosenhek R, et al. Predictors of outcome in severe, asymptomatic aortic stenosis. *N Engl J Med*. 2000; 343:611–617.
15. Raggi P, et al. Prognostic value of coronary artery calcium screening in subjects with and without diabetes. *J Am Coll Cardiol*. 2004; 43:1663–1669
16. Rheaume-Bleue K. *Vitamin K2 and The Calcium Paradox*, 1st Ed. (Toronto, Ontario: Harper Collins Publishers Ltd: 2012;12-16.
17. Beulens JW, et al. High dietary menaquinone intake is associated with reduced coronary calcification. *Atherosclerosis*. 2009 April, 203(2);489-93.
18. Schurgers LJ, et al. Regression of warfarin-induced medial elastocalcinosis by high intake of vitamin k in rats. *Blood*. 2007;109:2823-2831.

◆

Calendar

Please submit an announcement of your event 90 days in advance.
Event publication must be limited to 25 words or less. Multiple event listings require paid advertising.
Contact calendar@townsendletter.com for details.

APRIL 26-29: 24th CLINICAL APPLICATIONS FOR AGE MANAGEMENT MEDICINE in Orlando, Florida. CONTACT: https://www.agemed.org

APRIL 27-29: ACUPUNCTURE MERIDIAN ASSESSMENT (AMA) TRAINING for Doctors, Dentists & Health Professionals: Detecting Chronic Diseases & Causes with Simon Yu, MD, in St. Louis, Missouri. **CONTACT:** http://www.preventionandhealing.com/

APRIL 27-29: 47th ANNUAL INTERNATIONAL ORTHOMOLECULAR MEDICINE TODAY CONFERENCE in Tokyo, Japan. CONTACT: https://www.isom.ca/omt/

APRIL 29: CONNECTICUT NATUROPATHIC PHYSICIANS ASSOCIATION 10th ANNUAL CONFERENCE in Cromwell, Connecticut. CONTACT: http://www.events.syncopatemeetings.com/cnpa/

MAY 3-JUNE 10: ORTHOMOLECULAR APPLICATIONS IN INTEGRATIVE PSYCHIATRY – SCHIZOPHRENIA & PSYCHOSIS. Online course presented by the Canadian Society for Orthomolecular Medicine. CONTACT: https://csom.ca/event/schizophrenia-psychosis/

MAY 3-5: 7th ANNUAL AMERICAN ACADEMY OF OZONOTHERAPY MEETING in Henderson, Nevada. CONTACT: 888-991-2268; admin@aaot.us; http://aaot.us/

MAY 4-5: FCT TRAINING SEMINAR – Its Major Breakthrough in Bio-Resonance Testing and Combining the Best in Medicine with Savely Yurkovsky, MD, in Chappaqua, New York. CONTACT: 914-861-9161; www.yurkovsky.com

MAY 4-6: KLINGHARDT ACADEMY LYME & LIGHT MASTERMINDS in Morristown, New Jersey. Energetic Detox-Brain Solutions. Also, **SEPTEMBER 14-23** in Kenmore, Washington with Neural Therapy-Autonomic Response. CONTACT: 908-899-1650; info@klinghardtacademy.com; http://www.kinghardtacademy.com

MAY 9-13: THE AMERICAN PROLOTHERAPY & REGENERATIVE MEDICINE CONFERENCE in Plano, Texas. CME credits available. CONTACT: http://prolotherapycollege.org/

MAY 10-12: BIOREGULATORY MEDICINE INSTITUTE CONFERENCE in Louisville, Kentucky. CONTACT: https://www.brmi.online/events

MAY 17-19: 16th ANNUAL INTEGRATIVE ONCOLOGY CONFERENCE – Cancer, Cannabis, & Keto Therapies in Orlando, Florida. Sponsored by Best Answer for Cancer Foundation. CONTACT: https://bestanswerforcancer.org/

MAY 18-20: 5th ANNUAL TRADITIONAL ROOTS HERBAL CONFERENCE @ National University of Natural Medicine in Portland, Oregon. CONTACT: http://traditionalroots.org/tradrootscon2018/

MAY 19: MNANP ANNUAL CONVENTION & MEETING – Integrative Chronic Infections Assessment and Treatment with Dr. Paul Anderson in St. Paul, Minnesota. 5 CEUs available. CONTACT: http://www.mnanp.org/conference

MAY 19-20: THE GREAT PLAINS LABORATORY, INC. presents GPL ACADEMY PRACTITIONER WORKSHOPS in Charlotte, North Carolina. This workshop will review organic acids testing, toxic chemical testing, and mycotoxin testing. CONTACT: http://www.GPLWorkshops.com

MAY 24-26: AUTISM ONE 2018 CONFERENCE in Chicago, Illinois. CMEs available. CONTACT: http://www.autismone.org/CUTTING-EDGE-AUTISM-CME-PROGRAM

MAY 31- JUNE 2: INSTITUTE FOR FUNCTIONAL MEDICINE ANNUAL INTERNATIONAL CONFERENCE – Solving the Puzzle of Autoimmunity: The Interplay of Gut, Genes, and Environment in Hollywood, Florida. CONTACT: 800-228-0622; https://www.ifm.org/

JUNE 1-3: ADVANCED APPLICATIONS IN MEDICAL PRACTICE SPRING EVENT in Scottsdale, Arizona. CONTACT: 954-540-1896; https://aampconferences.com/

➤

Please Support the Advertisers in this Issue

Calendar

➤

JUNE 1-4: MEDICINES FROM THE EARTH HERB SYMPOSIUM in Black Mountain, North Carolina. CE credits available. CONTACT: 541-482-3016; http://www.botanicalmedicine.org

JUNE 9-10: 5th ANNUAL SIBO SYMPOSIUM at National University of Natural Medicine in Portland, Oregon. Contact: nunm.edu/ce

JUNE 14-16: HOMEOPATHY RESEARCH INSTITUTE CONFERENCE in London, United Kingdom. CONTACT: https://www.hri-research.org/

JUNE 16-23: CLINICAL & COMPARATIVE MATERIA MEDICA with Dr. Subrata K. Banerjea at Allen College of Homeopathy in Chelmsford, Essex, United Kingdom. CONTACT: http://www.homeopathy-course.com/index.php/training-courses

JUNE 20-23: SOCIETY OF PROGRESSIVE MEDICAL EDUCATION (SOPMed) INTEGRATIVE THERAPY TRAINING AND ANNUAL CONVENTION in Colorado Springs, Colorado. Includes pre-conference events. CONTACT: 517-242-5813; https://sopmed.org/

JULY 6-8: 5th INTERNATIONAL CONGRESS ON NATUROPATHIC MEDICINE - Promoting Excellence in Natural Medicine in London, United Kingdom. CONTACT: + 44 (0)1745 828 400 Email: secretariat@icnmnaturopathy.eu; http://icnmnaturopathy.eu/en/

JULY 7: LDN 2018 CONFERENCE in Glascow, Scotland, UK. CONTACT: https://www.ldnresearchtrust.org/conference-2018/

JULY 12-14: INSTITUTE FOR FUNCTIONAL MEDICINE - HORMONE APM in Portland, Oregon. CONTACT: 800-228-0622; https://www.ifm.org/

JULY 12-14: AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS (AANP) ANNUAL CONVENTION AND EXPOSITION in San Diego, California. CONTACT: http://www.naturopathic.org/aanp2018

JULY 13-15: METHYLATION SUMMIT 2018 – Integrating Methylation into Clinical Treatment Plans in Chicago, Ilinois. CONTACT: 800-755-3402; https://www.researchednutritionals.com/Methylation-Summit/

JULY 15-17: INSTITUTE FOR FUNCTIONAL MEDICINE – ENERGY APM in Portland, Oregon. CONTACT: 800-228-0622; https://www.ifm.org/

AUGUST 4-5: THE GREAT PLAINS LABORATORY, INC. presents GPL ACADEMY PRACTITIONER WORKSHOPS in Denver, Colorado. This workshop will review organic acids testing, toxic chemical testing, and mycotoxin testing. CONTACT: http://www.GPLWorkshops.com

AUGUST 10-12: INTERNATIONAL HYPERBARIC MEDICINE CONFERENCE & EXPO – ADVANCING HYPERBARIC MEDICINE GLOBALLY in Denver, Colorado. CONTACT: https://www.hyperbaricmedicalassociation.org/conference-agenda

AUGUST 24-26: ACUPUNCTURE MERIDIAN ASSESSMENT (AMA) TRAINING For Doctors, Dentists & Health Professionals: Detecting Chronic Diseases & Causes with Simon Yu, MD, in St. Louis, Missouri. CONTACT: http://www.preventionandhealing.com/

SEPTEMBER 1-3: 46th ANNUAL CANCER CONVENTION in Glendale, California. CONTACT: 323-663-7801; http://cancercontrolsociety.org/

SEPTEMBER 6-9: 9th INTEGRATIVE MEDICINE FOR MENTAL HEALTH CONFERENCE (IMMH) in Dallas, Texas. Evidence-based diagnostic and treatment options to reduce symptoms of autism, ADHD, depression, anxiety, Alzheimer's, and more. CONTACT: http://www.IMMH2018.com

SEPTEMBER 14-15: CLINICAL MITOCHONDRIAL AND ENVIRONMENTAL MEDICINE in Heidelberg, Germany. Specialist lectures in English. CONTACT: info@mito-medizin.de; http://www.mito-medizin.de/

OCTOBER 17-22: INTERNATIONAL COLLEGE OF INTEGRATIVE MEDICINE – An Orthomolecular Approach to Cancer in Minneapolis, Minnesota. CONTACT: http://icimed.com/

OCTOBER 19-20: DERMVEDA INTEGRATIVE SKIN CARE SYMPOSIUM in Sacramento, California. CONTACT: http://2018.integrativeskinsymposium.com/

OCTOBER 19-21: AMERICAN INSTITUTE OF HOMEOPATHY ANNUAL CONFERENCE-TACKLING PATIENTS WITH SEVERE PATHOLOGY with Andre Saine, ND in Cleveland, Ohio. CONTACT: https://homeopathyusa.org/education/2018-conference.html

OCTOBER 25-27: INSTITUTE FOR FUNCTIONAL MEDICINE – GASTROINTESTINAL APM in Nashville, Tennessee. CONTACT: 800-228-0622; https://www.ifm.org/

FEBRUARY 15-17, 2019: 8th ANNUAL OncANP NATUROPATHIC ONCOLOGY CONFERENCE in San Diego, California. CONTACT: https://oncanp.org/

◆

Classified Advertising

BOISE IDAHO INTEGRATIVE MD has a thriving 19 year all-cash, turn-key practice for sale. Therapies offered include BHRT, prolozone, IV nutrition, and breast thermography. The 38 by 40 square foot clinic is included in the sale. Doctor willing to stay on short term to ease the transition. Contact: windyriverranch1@gmail.com.

Methylation Summit – Integrating Methylation into Clinical Treatment Plans

When: July 13-15, 2018
Where: Chicago, Illinois

Are your toughest-to-treat patients not improving even while following your standard successful treatment protocol?

- Do you wonder why some patients improve while others do not?
- Why do so many patients experience such difficult Herxheimer reactions?
- Why can some patients not overcome detoxification challenges?

Think Methylation. Dysfunctional methylation impairs the body's detoxification process, and it may be the answer to the aforementioned questions. Beyond methylation genetics, many otherwise "healthy" patients experience methylation issues. This widespread problem is a result of the environmental impact on our methylation pathways, and it impacts a significant number of your patients and the general population. Whatever the cause(s), understanding why it is happening AND how to fix it is essential. Effective treatment goes way beyond just adding methylated B vitamins.

Impaired methylation is research cited as playing a contributing role in many common diseases:

- Cardiovascular,
- Diabetes,
- Lyme,
- Chronic Fatigue,
- Insomnia,
- Anxiety,
- Autism,
- Fertility.

Our program combines the methylation science with case studies so that you can make a difference as soon as you return to your office.

Register Online: https://www.researchednutritionals.com/Methylation-Summit/
Questions?
800-755-3402, Ext. 1002
cbyrd@researchednutritionals.com

Sponsored by Researched Nutritionals

◆

Editorial | Editorial | Editorial | Editorial | Editorial

➤ *continued from page 88*

means that strontium had potentially deleterious effects on the endocrine system at dosages well below those used in clinical trials.

In the absence of systematic toxicity studies, it is difficult to determine the risk-benefit ratio for non-ranelate forms of strontium. High-dose strontium probably should not be given to patients who have or are at high risk of developing cardiovascular disease; and patients being treated with high-dose strontium should be monitored for the development of heart disease and thromboembolism.

Researchers should investigate the possibility that the beneficial effects of high-dose strontium could be duplicated at least in part by much lower "nutritional" doses, such as 2-6 mg per day. The improvement in bone quality that results from the incorporation of strontium into hydroxyapatite crystals likely occurs with small doses of strontium, since strontium is present in the hydroxyapatite crystals of people who do not take strontium supplements. The possibility that low-dose strontium is beneficial is supported by the results of one study, in which the reduction in fracture incidence was nonsignificantly greater with 170 mg per day of strontium than with 340 or 680 mg per day.[5] Whether doses less than 170 mg per day would influence bone mineral density or fracture risk has not been investigated.

Alan R. Gaby, MD

References

1. Schroeder HA, et al. Trace metals in man: strontium and barium. *J Chronic Dis*. 1972;25:491-517.
2. Meunier PJ, et al. The effects of strontium ranelate on the risk of vertebral fracture in women with postmenopausal osteoporosis. *N Engl J Med*. 2004;350:459-468.
3. Reginster JY, et al. Strontium ranelate reduces the risk of nonvertebral fractures in postmenopausal women with osteoporosis: Treatment of Peripheral Osteoporosis (TROPOS) study. *J Clin Endocrinol Metab*. 2005;90:2816-2822.
4. Reginster JY, et al. Effects of long-term strontium ranelate treatment on the risk of nonvertebral and vertebral fractures in postmenopausal osteoporosis. Results of a five-year, randomized, placebo-controlled trial. *Arthritis Rheum*. 2008;58:1687-1695.
5. Meunier PJ, et al. Strontium ranelate: dose-dependent effects in established postmenopausal vertebral osteoporosis - a 2-year randomized placebo controlled trial. *J Clin Endocrinol Metab*. 2002;87:2060-2066.
6. Bolland MJ, Grey A. A comparison of adverse event and fracture efficacy data for strontium ranelate in regulatory documents and the publication record. *BMJ Open*. 2014;4:e005787.
7. Donneau AF, Reginster JY. Cardiovascular safety of strontium ranelate: real-life assessment in clinical practice. *Osteoporos Int*. 2014;25:397-398.
8. Cacoub P, et al. Drug rash with eosinophilia and systemic symptoms (DRESS) in patients receiving strontium ranelate. *Osteoporos Int*. 2013;24:1751-1757.
9. Bolland MJ, Grey A. Cessation of strontium ranelate supply. *BMJ*. 2017;357:j2580.
10. Kroes R, et al. Short-term toxicity of strontium chloride in rats. *Toxicology*. 1977;7:11-21. Note: This estimate was based on a human diet providing 2,000 kcal/day, with 30% of energy from fat (i.e., 417 g/day of food, dry weight.

◆

Should We Stop Using High-Dose Strontium for Osteoporosis?

Strontium is a mineral that is present in small quantities in food and water (a few milligrams per day), as well as in the human body (primarily in bone and connective tissue). Strontium is incorporated in small amounts into the hydroxyapatite crystal lattice of bone, where it remains bound for years or decades and may improve bone quality.[1] When administered in pharmacological doses, strontium stimulates bone formation, inhibits bone resorption, and increases bone mineral density.

In several double-blind trials, treatment with strontium in doses of 170-680 mg per day (as strontium ranelate) for two to five years significantly increased bone mineral density of the hip and spine and significantly reduced the incidence of fractures by 16-49%, compared with placebo, in postmenopausal women with osteoporosis.[2-5] Because of these studies, high-dose strontium became popular for the prevention and treatment of osteoporosis. However, concern has been raised in recent years that the risks of high-dose strontium may be at least as great as the benefits. The doses of strontium used in clinical trials are in the range of 60-200 times the amount present in a typical diet. For perspective, long-term administration of other trace minerals (such as zinc, copper, or selenium) in amounts 60-200 times greater than typical dietary intake has been reported to cause serious adverse effects.

Several years ago, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee reviewed randomized controlled trials of strontium ranelate and concluded that it increases the risk of cardiovascular disease. A review of seven trials and five publicly available regulatory documents concluded that the number of fractures prevented by strontium ranelate was similar to the number of extra cases of venous thromboembolism, pulmonary embolism, and myocardial infarction caused by this compound.[6] Strontium ranelate is therefore contraindicated in patients with cardiovascular disease (i.e., ischemic heart disease, peripheral artery disease, and/or cerebrovascular disease) and in those with uncontrolled hypertension.[7] In addition, at least 47 cases of drug-induced hypersensitivity syndrome (DRESS syndrome), one of which was fatal, have been reported in patients taking strontium ranelate.[8] Other side effects of strontium ranelate include transient increases in creatine kinase levels and mild gastrointestinal, nervous system, and muscular disorders. Because of these adverse effects, the European Medicines Agency recommended that strontium ranelate be used only by patients who cannot be treated with other medicines approved for osteoporosis.

In August 2017, Servier (the manufacturer of strontium ranelate) withdrew this compound from the market worldwide.[9] The company stated that the decision to withdraw strontium ranelate was not related to a safety issue but, rather, to restricted indications and limitations on its use. Of course, those restrictions and limitations were imposed as a direct result of safety concerns.

Strontium ranelate was licensed as a prescription medicine in Europe, but it was never approved by the Food and Drug Administration for use in the United States. Other forms of strontium (mainly strontium citrate) have been available without a prescription in the US for the past decade or so. It is not known whether the reported adverse effects of strontium ranelate would also occur with other forms of strontium. While there have been no reports of DRESS syndrome or of an increased risk of cardiovascular disease in people taking non-ranelate forms of strontium, there have been no systematic toxicity studies of these compounds in humans. In rats, administration of strontium chloride resulted in an increase in thyroid weight and a decrease in pituitary weight. The "no-observed-adverse-effect level" in the rat studies was roughly equivalent to 41 mg of strontium per day for humans,[10] which

continued on page 87 ➤

Sovereign Laboratories

Win the War on Inflammation

Put the Fire Out with PRO Colostrum-LD™

Whether the diagnosis is allergies, arthritis, Crohn's, depression, diabetes, fibromyalgia, multiple sclerosis, or psoriasis, your patients experience **pain**. The underlying cause is chronic **inflammation** caused by an overreactive immune system responding to a leaky gut (intestinal hyperpermeability). Now **you** have the power to stop this vicious cycle and win the war on inflammation.

- Heal their leaky gut.
- Quell their internal fire.
- Put them on the path to better health and well-being.

Colostrum-LD® is the only substance clinically proven to heal and prevent leaky gut syndrome, a pervasive condition now recognized as a primary cause of allergies, autoimmune conditions, and chronic health problems.

For additional information about the key metabolic and inflammatory markers used to assess leaky gut and how PRO Colostrum-LD™ can help your patients, visit ColostrumTherapy.com and watch the War on Inflammation video.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Jarrow FORMULAS®

Clinically Tested & Patent Protected Strains of the Predominant Vaginal Microflora

1. *L. crispatus* LbV 88
2. *L. jensenii* LbV 116
3. *L. gasseri* LbV 150N
4. *L. rhamnosus* LbV 96

Unlike the intestinal flora, the predominant vaginal microbiome are confined to much fewer species. Accordingly, only a few such vaginal specific *Lactobacillus* strains have been clinically tested for their ability to support vaginal health.*

Jarro-Dophilus® Women contains the four predominant *Lactobacillus* strains of the healthy vaginal tract known as the "Astarte" strains. All four Astarte strains were originally isolated from the vaginal tracts of young, healthy women in their third month of pregnancy. The samples were enumerated for the predominant strains and then screened for efficacy. The Astarte strains have been clinically documented to promote vaginal microflora and urinary tract health.*

Clinical Study #1 (1999)

In a study of 319 women visiting three medical clinics, most women's normal vaginal bacterial residents included *L. crispatus* (32%), followed by *L. jensenii* (23%), *L.* 1086V (15%), *L. gasseri* (5%), *L. fermentum* (0.3%), *L. oris* (0.3%), *L. reuteri* (0.3%), *L. ruminis* (0.3%), and *L. vaginalis* (0.3%).*

Antonio MAD, *et al. Journal of Infectious Diseases* 1999;180:1950–6.

Clinical Study #2 (2007)

In another study involving 126 healthy pregnant women, *L. crispatus* and *L. gasseri* were the most dominant species found, followed by *L. jensenii* and *L. rhamnosus*.*

Kiss H, *et al. BJOG: An International Journal of Obstetrics & Gynaecology* 2007;114: 1402-1407.

Clinical Study #3 (2014)

In a double-blind, randomized placebo-controlled trial, 1-week of oral supplementation with the four Astarte strains significantly enriched *Lactobacilli* in the vaginal tract and reduced Nugent score in the neo-vagina of post-operative transsexual women, an environment typically resistant to colonization by *Lactobacilli.*

Kaufmann U, *et al. Eur J Obstet Gynecol Reprod Biol.* 2014 Jan;172:102-5.

Clinical Study #4 (2016)

In immunosuppressed pregnant women with herpes infection, oral supplementation with the four Astarte strains significantly reduced undesirable microbes in the intestines and vagina, and simultaneously increased vaginal *Lactobacilli* 3-fold compared to placebo.* This was accompanied by reduced incidence of placental insufficiency, pre-eclampsia and fetal distress in the probiotic supplemented women.

Anoshina TM, *et al. Perinatologiya I Pediatriya* 2016;4(68):22-25.

ASTARTE

Protected by U.S. Patent 8,846,027 and European Patent 2,509,610, which are owned by HSO Health Care GmbH, Vienna, Austria, and licensed in the U.S. to Jarrow Formulas, Inc. Other international patents pending. Sold worldwide as Astarte.

Health care practitioners, please find Jarrow Formulas' products at:

emerson ECOLOGICS delivering to improve health™ — **emersonecologics.com**

natural partners — **naturalpartners.com**

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Visit us at www.jarrow.com for more product information.