

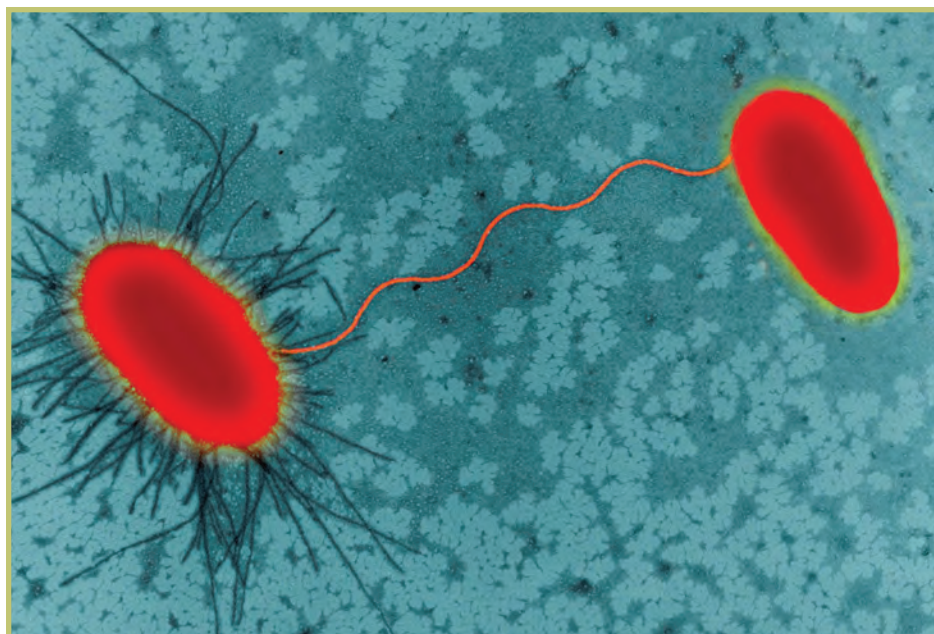
Holistic Primary Care

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COLOURED TRANSMISSION ELECTRON MICROGRAPH (TEM) OF *E. COLI* UNDERGOING CONJUGATION VIA A PILUS. RESEARCHERS AT THE UNIVERSITY OF CALIFORNIA – DAVIS IDENTIFIED LIPOPOLYSACCHARIDES AND PILI PROTEINS SPECIFIC TO *E. COLI* AT HIGH CONCENTRATIONS IN BRAIN TISSUE FROM PEOPLE DIAGNOSED WITH ALZHEIMER'S DISEASE. THE FINDINGS SUGGEST THAT BACTERIAL INFECTIONS MAY PLAY AN ETIOLOGICAL ROLE IN THIS AND OTHER FORMS OF DEMENTIA.

Image courtesy of Dennis Kunkel Microscopy/Science Photo Library

HEALTHY AGING

Does Alzheimer's Disease Have a Bacterial Trigger?

BY KRISTEN SCHEPKER
Assistant Editor

Last fall, researchers at the University of California, Davis MIND Institute made a surprising discovery: brain samples from late-onset Alzheimer's patients contained high levels of Gram-negative bacterial molecules.

Previous research has linked certain infections to a heightened risk of dementia, but the UC Davis team's findings are the first to conclusively show elevated amounts of bacterial antigens in the brains of patients with Alzheimer's disease.

A host of Gram-negative bacteria, including *Escherichia coli*, *Helicobacter pylori*, *Chlamydia pneumoniae*, *Salmonella* and *Shigella*, are pathogenic in various parts of the body. The UC Davis study, published in the journal *Neurology*, adds an important piece to the growing evidence that these disease-causing bacteria may play a role in triggering Alzheimer's.

Zinhua Zhan and colleagues at the UC Davis Department of Neurology, looked at samples of gray and white matter from 24 people with clinically documented Alzheimer's disease, and 18 age-matched controls.

Specifically, they screened the brain samples for two key bacterial components—Lipopolysaccharide (LPS) and *E. coli* K99 pili protein. These were measured using Western blots and immunocytochemistry. They

also analyzed the brain tissue for DNA signatures specific to *E. coli*.

Two Key Indicators

The results were striking. Zhan's group found consistently higher levels of both LPS and *E. coli* K99 pili protein, in the gray and white matter taken from the Alzheimer's patients, as compared to the controls (Zhan X, et al. *Neurol.* 2016; 87(22): 2324–2332).

E. coli K99 pili protein was more common and also present in higher amounts in the brains of Alzheimer's patients, appearing in nine of 13 Alzheimer's gray matter samples versus just one out of 10 samples from healthy controls.

The researchers also identified higher levels of K99 in the white matter samples from Alzheimer's disease patients.

LPS is a characteristic component of the outer cell membranes of Gram-negative bacteria. It was identified in all of the Alzheimer's brain samples, but not in the controls. It's noteworthy that LPS co-localized with the neurotoxic peptide, amyloid, in the plaques and blood vessels of Alzheimer's brains. Amyloid plaques are the distinctive neuropathological hallmark of Alzheimer's and a strong indicator of disease progression.

E. coli-related DNA sequences were detected in a majority of brain samples from control individuals as well as Alzheimer's patients, underscoring the fact that *E. coli*

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VITAMINS & SUPPLEMENTS

FTC's Crackdown Blows Chilly Wind Down "Memory Lane"

BY KRISTEN SCHEPKER
Assistant Editor

In January, the Federal Trade Commission—along with New York Attorney General Eric Schneiderman—filed a lawsuit against Quincy Bioscience, producers of Prevagen, a popular memory enhancement supplement, charging the company with false advertising, deceptive marketing, and unproven brain health claims that unfairly target vulnerable elders.

It is the latest in an ongoing series of regulatory actions targeting companies that market products or services in the rapidly growing cognitive health sphere.

Prevagen made a splash long before this new FTC action. The supplement contains an unlikely ingredient: apoaequorin, a calcium-binding protein derived from a bioluminescent species of jellyfish called *Aequorea victoria*. According to product descriptions, this protein, first identified and utilized by Quincy Bioscience, "has proven to uniquely support critical brain functions."

The company advertised Prevagen as a tool to promote improved memory, word recall, and learning for people concerned with the cognitive challenges associated with normal aging.

But the FTC and the state of New York argue otherwise.

Accusation of Fraud

"The marketing for Prevagen is a clear-cut fraud, from the label on the bottle to the ads airing across the country," said AG Schneiderman in a press release issued the day the

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NEWS & POLICY

Vaccine Debate Rages Over Trump, Kennedy & the Cleveland Clinic

BY KRISTEN SCHEPKER
Assistant Editor

The nation got a double-dose of vaccine controversy this winter, following two surprising events that stunned members of the medical community and the public alike.

Early in January, Daniel Neides, MD, medical director of the esteemed Cleveland Clinic Wellness Institute, published a highly controversial blog on a regional news site raising the possibility of safety risks associated with vaccinations.

The article, titled *Make 2017 the Year to Avoid Toxins (Good Luck) and Master Your Domain* describes the dangers of toxic exposures and the overburdening of the body's

immune and detox systems with harmful agents.

Neides drew a connection between the presence of preservatives and adjuvants in vaccines to the increasing rates of neurologic diseases like autism spectrum disorder (ASD) and ADHD. Pointing out the rapid increase in autism rates over the past few decades, he encouraged readers to discuss the risks and optimal timing of vaccinations with their doctors.

His post, which was not an official Cleveland Clinic communication, but did include the clinic's widely-recognized logo next to Neides' byline, spread quickly, causing an uproar within medical circles and alarming health professionals who were shocked that a well-respected fellow physician would dare

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Image: Courtesy NHS/Horphag

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Holistic Medicine in the Trump Era: What to Expect?

BY ERIK GOLDMAN
Editor in Chief

How will holistic medicine fare under the Trump administration?

It's a big question with no obvious answer. A lot depends on what the new administration does with healthcare at large. And that is still full of unknowns.

With a Republican majority in Congress, a voter base likely to demand action, and a new head of Health & Human Services who loathes the Affordable Care Act, the 45th president certainly has the legislative clout to drive big changes in how healthcare is financed, and possibly how it is practiced.

But the Trumpcare juggernaut must reckon with the rocks of political and economic reality, as it discovers "repeal and replace" is easier said than done.

First, many parts of the ACA—like protections for preexisting conditions—are popular with Republican voters. Millions of poor and working-class Trump supporters could find themselves uninsured if the administration goes with the more extreme Republican repeal proposals.

Second, short of a complete dictatorial overthrow of checks and balances, it is actually quite difficult to unmake a US law once it's on the books. And that's a good thing. If rewriting laws were easy, we'd be living in a different country every time there was an administration change.

A massive law like ACA, which affects multiple branches of government, several of the largest private sector industries, 17% of the GDP, and hundreds of millions of people is not something you change with a single pen stroke.

"Nothing Is Clear"

Assuming the administration will ultimately adhere to the fundamentals of legislative process, a Trump healthcare remake will face the same complex congressional wrangling as any law ever proposed—even with a Senate and House majority.

Whatever changes are coming, they won't be fast or simple.

"There's no way we can pretend the law (the ACA) doesn't exist, or that it can be easily repealed and replaced. There's wide disagreement even among Republicans about what the 'repeals' and 'replaces' should be," said Michael Leavitt, former head of Health & Human Services under George W. Bush, and a three-time governor of Utah.

Speaking last December at the Population Health Colloquium—a conference of healthcare administrators—Leavitt says he does expect action on healthcare in the coming year, but the direction is unknown.

"The only thing certain is that the new legislation will be called 'repeal and replace.' But nothing is clear."

Leavitt added that while November 8 was a victory day for Republicans, the GOP has only a 2-vote margin in the Senate that could be easily lost come 2018. "Much of what will

be proposed for repeal and replace will need 60 votes. Republicans don't have that margin in the Senate."

Is the Price Right?

Dr. Tom Price, the new Secretary of Health & Human Services, is the Republicans' choice to perform their Obamacare amputation. Price is an avowed opponent of the ACA, and no fan of government-funded healthcare in general, though he has benefitted from it.

An Atlanta orthopedic surgeon with a net worth upward of \$13 million, and investment ties to biomedical device companies, he is a political and cultural conservative with strong positions against abortion, gun control, environmental regulations, Planned Parenthood, National Public Radio, emergency mortgage relief, and increased tobacco regulation.

He is also an outspoken voice for physician independence, direct-pay practice, health savings accounts, malpractice reform, and health insurance tax credits.

In 2015, while in Congress, Price floated a repeal bill called the *Empowering Patients First Act*. Among other things, it proposed: nullifying all Obamacare mandates; tax credits of up to \$3000 on private insurance; allowing insurers to set surcharges based on health status (thus dashing protection for pre-existing conditions); expanding HSAs; blocking Medicaid expansion; and cutting constraints on private contracting between physicians and Medicare patients.

Price was lauded by the American Medical Association. Other physicians groups, like the new 6,400-member Clinician Action Network oppose him and his repeal and replace plans that "threaten to harm our most vulnerable patients and limit their access to healthcare."

According to a recent survey of 426 primary care physicians in the *New England Journal of Medicine*, only 15% say they support full repeal of Obamacare. None of the self-identified Democrats, and only 32% of Republicans support repeal. Even among the Trump voters, only 38% want the administration to kill ACA. Almost all (95%) support protections for people with pre-existing conditions.

"R 'n' R" Hoochie-Koo

As this article goes to press, the White House has yet to give details about its "R 'n' R" plan, and how far it is really willing to go.

But in January, House Speaker Paul Ryan updated his policy paper called *A Better Way: Our Vision for a Confident America*, which could become a blueprint for Trump's healthcare remix. It incorporates features from Price's bill, but retains protections for pre-existing conditions.

Key features of Ryan's "Better Way" include:

- **Repeal ACA** mandates, private market rules, standards for minimum benefits and maximum cost sharing, and premium subsidies.
- **Retain some private market rules**, including requirement to extend dependent coverage to age 26 and prohibition on pre-existing condition exclusions.
- **Provide refundable tax credits** based on age (unspecified), to individuals to purchase private insurance.
- **Provide for one-time Open Enrollment (OE)**. Individuals could obtain coverage at other times, but failure to sign up during OE forfeits continuous coverage and triggers higher premiums.
- **Require insurers to offer portability protections**
- **Implement state high-risk pools** with \$25 billion in federal grants.
- **Permit sale of insurance across state lines.**
- **Encourage use of Health Savings Accounts.**
- **Convert federal Medicaid funding to a per capita allotment or state level block grants.**
- **Raise Medicare eligibility age to 67** and combine all Medicare Savings Programs into one program with a unified asset test.
- **Create a personalized care demonstration** allowing physicians to enter into private contracts with Medicare beneficiaries.

It remains to be seen whether the Republicans will go with Price's hard-line repeal, Ryan's modified plan, or something yet to be revealed.

However, they frame it, pre-existing conditions could be their Waterloo.

Any plan that blocks insurers from cherry-picking based on health status while simultaneously nixing the ACA mandates that push healthier people to buy coverage would threaten insurance company solvency. In trying to keep the parts of Obamacare that Republican voters like while scrapping the rest, the GOP could end up pitting the demands of the insurance lobby against the needs of Trump's much-vaunted "base."

Even with ACA's mandates, the cost of chronic illness is imploding individual insurance markets in some areas. Insurers are simply abandoning states where the game is not profitable. "Roughly 20% of all Americans live in regions with only one insurer," noted Doug Badger, a senior fellow at the Galen Institute, and former healthcare advisor to George W. Bush.

"Before 'Repeal and Replace,' the administration is going to need to deal with Rescue," Badger says. "My reality-check for the President and Congress is, 'You've got a grease fire. You've got to extinguish it.'"

HSA! HSA! HSA!

GOP emphasis on HSAs appeals to many in the holistic field.

Speaking on behalf of the American Academy of Anti-Aging Medicine (A4M), Dr. Pamela Smith said she believes a Trump expansion of HSAs will be a boon for practitioners of personalized holistic care.

Smith, who heads an anti-aging practice in Traverse City, MI, says expanded HSAs will make it possible for more people to pay for time-intensive personalized care, functional tests, supplements and other things not covered by insurers.

She supports Price as HHS secretary. "It will be great to have a doctor in that job. He understands patients, and being healthy. Any administration that tries to change healthcare, but doesn't have enough involvement of physicians, nurses, exercise experts, pharmacists, and patients will run into problems. That's what's been lacking all along, regardless of administration."

Tom Blue, the Institute for Functional Medicine's Director of Strategic Development, is also hopeful about expanded HSAs, which are vital in many IFM members' practices. He acknowledged, however, that HSAs do little to improve healthcare for poor people or low-wage workers who earn too much to qualify for Medicaid but not enough to afford private insurance.

Blue sees both Trump and Price as supportive of the direct-pay models many functional practitioners favor. He also believes community-based cost-sharing plans like Liberty HealthShare, will see a boost under Republicans. This, he says, is a sunny prospect for functional medicine.

Run by Christian ministries, these non-profit plans allow people to pool healthcare dollars to cover each other's expenses. These plans cover preventive care, supplements, and other aspects of functional medicine. Monthly contributions are generally lower than conventional insurance. Programs require members to affirm "shared beliefs" and abstinence from tobacco, alcohol, drugs, and junk food.

Blue says growth of these plans has been robust. "In open enrollment, people are flocking to them. As a health conscious person, if you can find one that fits your beliefs, it's a no brainer." He expects enrollment to reach into the millions by the end of open enrollment this year.

He predicted that Trump's healthcare changes would ultimately be more subtle than substantive. "If you accept the basic premise that we want the majority of Americans to have some basic coverage, then you need certain things in place to make it viable. You're not going to win elections if you screw everyone with a pre-existing condition."

Unique Challenge for Naturopathy

For the naturopaths, ACA repeal presents a conundrum.

Mike Jawer, Government & Public Affairs Director for the American Association of Naturopathic Physicians (AANP), also sees

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exposure is quite common, though not always pathogenic.

Other research from Dr. Zhan's lab shows clearly that the presence of *E. coli* in the brain can very definitely cause problems.

This current paper follows prior work demonstrating that *E. coli*-derived LPS promoted the formation of amyloid-like plaques in rodent models.

In a 2015 report, Zhan's group showed that bacterial LPS plus ischemia/hypoxia can increase amyloid β production resulting in amyloid plaque-like aggregates in rat brains.

"Gram-negative bacteria like *Escherichia coli* can deposit amyloid," Dr. Zhan stated in the new paper.

Broadening the Options

To date, conventional Alzheimer's therapies have been focused on amyloid plaque reduction. By and large, this strategy has given very modest results.

This new line of research suggesting that infectious agents may be Alzheimer's triggers could broaden the treatment options to include targeting bacterial components.

One area receiving increased research attention is the influence of systemic inflammation in the pathogenesis of Alzheimer's disease.

An overgrowth of Gram-negative bacteria anywhere in the body can cause systemic inflammation. The implication here is that treating infections linked to Alzheimer's could pose a novel strategy for modifying dementia risk (Pussinen P, et al. *Arterio Throm & Vasc Biol.* 2007; 27(6): 1433–1439; Kamer A, et al. *Alz & Dem.* 2008; 4(4): 242–250).

Though age is the primary risk factor for late-onset, sporadic Alzheimer's disease, Dr. Zhan points out that serious infections by a variety of different pathogens can double the five-year odds of developing the disease.

Statistically, vaccines against diphtheria, tetanus, polio and influenza are associated with lower risk of Alzheimer's (Verreault R, et al. *CMAJ.* 2001; 165: 11).

Zhan's team at UC Davis is not the only research group suggesting an association between Alzheimer's disease and bacterial infections. A French team has identified *H. pylori*—the once controversial but today widely recognized cause of peptic ulcers—as a possible culprit in the etiology of dementia. Alzheimer's patients infected by *H. pylori* tended to be more cognitively impaired than those without infection (Roubaud-Baudron C, et al. *Neurobiol Aging.* 2012; 33(5): 1009.e11–9).

There's also evidence that the Herpes simplex virus (HSV) may also influence the course of Alzheimer's disease.

The presence of anti-HSV IgG antibodies in plasma increases the odds ratio for an Alzheimer's diagnosis by 2.25, and it was predictive of onset of the disease 6.5 years before the diagnosis is made. The HSV-associated risk appeared to be especially increased both among women and those over 60 years of age at time of plasma sampling. These findings confirm previous indicators that HSV infection could play a role in the early development of Alzheimer's (Lövhem H, et al. *Alz & Dem.* 2015; 11(6): 587–592).

It is interesting to note that HSV type 1 is frequently identified in brain tissue of carriers of the type 4 allele of the apolipoprotein E gene (APOE)—the so-called "Alzheimer's gene" (Itzhaki R. *Front Aging Neurosci.* 2014; 6: 202. doi: 10.3389/fnagi.2014.00202).

In a 2011 article published in *Holistic Primary Care*, neurologist David Perlmutter, author of *The Better Brain Book* and *Grain Brain*, proposed the idea that beta-amyloid formation in the brain may actually be a protective mechanism triggered by the presence of bacterial or viral pathogens.

Though amyloid plaque is clearly connected with neurodegeneration and loss of

cognitive function, in essence it may not be truly causal. If that is true, then attempts to eliminate or block amyloid may be a fool's errand.

The UC Davis study authors write that further research is needed to determine whether the Gram-negative bacteria are a true cause of dementia. Another major ques-

tion is how exactly Gram-negative bacterial LPS, proteins, and DNA enter into the brain.

Zhan's group did not screen for the presence of live bacteria in brain tissue, but others have published data suggesting that live bacteria can, in fact, be found in human brain tissue in some cases. "Studies of brain biopsies obtained during life would help

address the possibility of contamination during autopsy."

As scientists develop a greater understanding of the pathways and impacts of infectious agents on Alzheimer's disease etiology, their discoveries may open doors to new Alzheimer's treatment and prevention options. ☺

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FTC Crackdown

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complaint was filed. Schneiderman stated that it is unacceptable that Quincy targeted seniors with advertising for a supplement costing "more than a week's groceries," and charged the company with pushing a product that "provides none of the health benefits that it claims."

Sold at major pharmacies across the country, a month's supply of Prevagen costs between \$24 and \$68. Sales of the supplement have topped \$165 million.

The complaint further states that Prevagen's marketers have violated both the FTC Act and New York state laws requiring that advertisements be truthful.

In issuing the complaint, filed in the US District Court for Southern New York, the two government agencies intend to ban future false claims about Prevagen, impose civil

penalties upon its makers, and obtain refunds for consumers who purchased it.

In response to the lawsuit, Quincy Bioscience released a statement describing the charges as "unfounded and inaccurate."

The company says it has "amassed a large body of evidence that Prevagen improves memory and supports healthy brain function," referencing results from a randomized, double-blind, placebo-controlled study it sponsored and completed in 2011.

In that study, 211 participants ages 40–91 with self-reported cognitive difficulties received either a 10 mg capsule of Prevagen or a rice flour-based placebo daily for three months. Using several different screening tools, researchers measured participants' cognitive functioning across a variety of domains, including memory, working memory, verbal and visual learning, executive and psychomotor function, and attention.

The data indicate that the Prevagen group experienced statistically significant improvements in some select brain health

categories. Based on these findings, Quincy Bioscience concluded that Prevagen "supports cognitive function in healthy, non-demented individuals."

The FTC has a very different interpretation. The lawsuit asserts that the company's study, "failed to show a statistically significant improvement in the treatment group over the placebo group" and that its "few positive findings on isolated tasks for small subgroups of the study population do not provide reliable evidence of a treatment effect."

The regulators are not the first to point out the shortcomings of this study. A 2015 column in *Pharmacy Today*, questioned veracity of the tests used to measure executive functioning. The Groton Maze Learning and the Groton Maze Recall tasks, among others, "are not validated tests like the Trail Making Test Part B," writes the column's author, Anne L. Hume, PharmD, FCCP, BCPS. Hume also points out that Prevagen's key ingredient, apoaequorin, is "unlikely to be absorbed to a significant degree" in the body; "instead it degrades into amino acids" like other proteins.

Protection or Over-Reach?

According to Quincy Bioscience, the backlash from federal authorities against Prevagen is just, "another example of government over-reach and regulators extinguishing innovation by imposing arbitrary new rules on small businesses like ours."

The new lawsuit is not Quincy's first tangle with regulators. In 2012, the Food and Drug Administration (FDA) sent a warning letter to the company questioning its marketing tactics and stating that its line of Prevagen supplements was, "being promoted for conditions that cause these products to be drugs," rather than supplements.

"The therapeutic claims on your websites...establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease," the letter stated. As reported by CBS, the FDA continues to question Quincy's marketing strategies today. In October and November, the Administration conducted inspections at two locations owned by Quincy's parent company. The agency declined to provide further comment, stating that "the matter remains open."

Additionally, in 2015, Quincy Bioscience was the subject of a class-action lawsuit accusing the company of false advertising. The complaint states that Prevagen's "brain function and memory representations are false, misleading, and reasonably likely to deceive the public."

There's little doubt that Quincy's marketing campaigns crossed a regulatory line for dietary supplements, and it is not surprising that the company has incurred the wrath of the FTC, the FDA, and a state AG with a strong record of action against the supplement industry.

But the move against Prevagen is not an isolated incident. Over the past few years regulators have been vigorous in clamping down on products and services marketed for cognitive improvement, brain health, or prevention of dementia.

In 2014, the FTC filed a complaint against i-Health and Martek Biosciences Corporation (now a division of DSM), makers of the BrainStrong Adult dietary supplement, which contains the omega-3 fatty acid DHA. The agency charged the companies with falsely claiming they had clinical proof that BrainStrong could improve memory and prevent cognitive decline. In 2014, the companies agreed to settle the charges.

More recently, the FTC squelched Lumos Labs—the San Francisco company that markets the popular Lumosity cognitive fitness system—charging that Lumos had made false and misleading claims about the system's ability to improve IQ, stave off age-related cognitive decline, and restore brain function following stroke.

At peak in 2015, Lumosity had engaged roughly 70 million people, many of whom were paying \$15 per month for access to the system's array of games to stimulate and strengthen various cognitive skills.

Last year, the company settled for \$2 million, which will be used to refund more than 13,000 customer grievances.

Lumosity has actually been tested in a number of studies. While outcomes are mixed and there is no definitive evidence that this or any other brain training system can "prevent" Alzheimer's, there are several trials showing that Lumosity training increased alertness, enhanced neurocognitive plasticity, strengthened visual attention, and improved function across several cognitive parameters.

Neurocore Raises Questions

Another brain-training company—Neurocore Brain Performance Centers—has also come under scrutiny, not only for its marketing claims, but also for its ties to Betsy DeVos, the Trump administration's new secretary of the Department of Education.

At its eight centers in Michigan and Florida (with plans for broader expansion), Neurocore claims to provide effective treatment for memory impairment, ADHD, depression, migraines, sleep problems and other neurological problems, using a combination of biofeedback, heart rate variability monitoring, and attention-conditioning exercises.

Neurocore's pitch states: "Your brain isn't hard-wired; it can change," and promises to "look past the label you've been given to scientifically diagnose the root of your issue," Neurocore says it can offer patients "a data-centric, drug-free brain exercise program that optimizes your brain for a better life."

In a recent *New York Times* article, a number of prominent physicians and neuroscientists question Neurocore's claims, as well as its science—much of which is unpublished.

A group of Democratic senators have raised questions about potential conflicts of interest arising from Mrs. DeVos' ownership stake in Neurocore. She and her husband are primary investors in the company, with holdings estimated to be worth between \$5 million and \$25 million, according to the Office of Government Ethics.

Children with ADHD, autism, anxiety, and other neurological conditions make up a large portion of Neurocore's clients, and the company has a history of marketing its services in Michigan schools—especially Christian schools—as a drug-free way of managing attention or behavioral disorders and improving academic performance.

The Neurocore system was developed by psychologist and theologian Timothy Royer, who ran the pediatric psychiatry department at Helen DeVos Children's Hospital in Grand Rapids. The hospital is named for Betsy DeVos' mother-in-law, the wife of Richard M. DeVos, Sr., co-founder of Amway, and a major Republican donor.

Prior to her confirmation as Secretary of Education, DeVos said she was leaving Neurocore's board of directors but will maintain her investment in the company, though she plans to divest from many other companies in her family's portfolio.

The rising regulatory oversight of products and services marketed for neurological or cognitive health is blowing a chilly wind through a rapidly growing sector of the natural products industry. It serves as an important reminder that contrary to the common assertion that the industry is "unregulated"—there are in fact very clear federal truth-in-advertising rules. Moreover, there are federal and state agencies capable of enforcing them, though with the change in administration the future of the regulations and the agencies is in question.

The recent moves will likely prompt marketers to think very carefully about making memory or cognitive function claims.

But given that mainstream medicine has essentially nothing to offer to patients at risk of dementia, and little in the way of truly effective therapy for ADHD and autism, the targeting of brain health products seems a bit heavy-handed, and some observers question whether the FTC and the New York AG have moved from legitimate consumer protection to regulatory over-reach.

The FTC states that it "looks especially closely at advertising claims that can affect consumers' health or their pocketbooks." For the moment, it is very clear that the agency considers memory improvement and brain health to be just such an issue. ☺

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Pycnogenol a “No Brainer” for Improving Cognitive Function

BY DONNA AUBINOE
Contributing Writer

An extract from French maritime pine bark (*Pinus pinaster*) may provide restorative benefits to the aging brain.

To date, four clinical trials have shown that supplementation with Pycnogenol, a patented, standardized extract of condensed pine bark flavonoids, can improve cognitive function. The data suggest that this botanical medicine could be a valuable tool in helping to reduce the staggering burden of cognitive dysfunction.

A research team at the Cheiti-Pescara University in Italy studied Pycnogenol in a cohort of 77 “baby boom” subjects, aged 55–70.

All participants were deemed healthy, but had high levels of oxidative stress, as determined by plasma free radical levels. Half the participants supplemented with 50 mg of Pycnogenol twice a day, and the other half did not.

All participants followed a healthy protocol that included adequate sleep, regular exercise, and reduced caffeine, salt and sugar intake. They were followed for 12 months. The researchers used the Informant Questionnaire on Cognitive Decline in the Elderly, and Short Blessed Tests to evaluate cognitive function.

They were specifically interested in assessing the participants’ ease in engagement with twelve daily tasks, such as shopping, decision-making, exercising, dealing with money, eating and sleeping.

The changes observed in the Pycnogenol users were very promising:

- A 72% improvement in daily decision-making scores, compared to a –5% in the control group
- A 57% improvement in social interaction skills, compared with a –5% in the control group
- A 41% improvement in attention span, compared with a 2% in the control group
- A 37% improvement in memory, compared with a 10% in the control group
- A 32% improvement in the ability to manage finances compared with a –12% change in the control group
- A 28% decrease in oxidative stress, compared with no measurable change in the control group (Belcaro G, et al. *J Neurosurg Sci.* 2015; 59(4): 437–446)

According to Frank Schonlau, PhD, Director of Scientific Communication at Horphag Research, the exclusive worldwide supplier of Pycnogenol, the supplement’s unique metabolites are the key to its biological effects.

Microbiome-Mediated Metabolites

The gut microbiome interacts with the bioflavonoids in Pycnogenol, generating and releasing bioactive metabolites that travel from the gut via the GLUT1 transporter and distribute throughout the body’s tissues. These compounds are able to pass through the blood-brain-barrier, where they exert an antioxidant neuroprotective effect.

Pycnogenol-derived metabolites also positively affect the endothelium, enhancing nitric oxide production. This promotes greater vasodilatation, sending more oxygen-rich blood to the brain.

Cerebral hypoxia is a major causal factor in serious brain damage, leading to neuronal cell death, mental deterioration, and ultimately, the development of dementia and Alzheimer’s disease. Pycnogenol metabolites could play a role in preventing this, at least in part, by improving cerebrovascular blood flow.

An earlier study by Belcaro’s group, focused on a slightly younger demographic. Sixty volunteers, aged 35–55, who were identified as otherwise healthy except for elevated oxidative stress biomarkers, participated in a twelve-week protocol. Again, diet, lifestyle and exercise patterns were controlled for both groups. Half of the participants took Pycnogenol, 50 mg, thrice daily, while the other half did not. All subjects refrained from using any other drugs or supplements during the 12-week study period.

In addition to assessing attention, memory, executive function, and mood parameters, the researchers also measured thyroid hormone levels and oxidative stress.

By the end of the 12 weeks, both groups showed improvement in cognitive function. However, the Pycnogenol volunteers showed a much more significant improvement than the controls. Attention levels rose 13.4% versus 3%. Mood improved as well, with measures of contentedness reaching 49.7% compared to the control group at 12.9%.

Most impressive, however, was the 30.4% drop in oxidative stress among the people taking Pycnogenol. The control group showed a +0.9% increase in plasma biomarkers. (Belcaro G, et al. *J Neurosurg Sci.* 2014; 58: 239–248).

Inhibiting Apoptosis

The notion that Pycnogenol had neuroprotective effects began to emerge more than a decade ago.

In 2000, investigators first showed that Pycnogenol could inhibit beta-amyloid related apoptosis of neurons and vascular cells, which are pathological features of Alzheimer’s Disease (Liu F. *Biological and Pharmaceutical Bulletin.* 2000; 23(6): 735–737; Peng QL. *Molecular Brain Research.* 2002; 104(1–2): 55–65).

Pycnogenol was also deemed beneficial in inhibiting glutamate-induced cytotoxicity in HT-4 neuronal cells, a principle source of reactive oxygen species in the brain (Kobayahi M. *Free Radical Research.* 2000; 32(2): 115–124).

In a double-blind placebo controlled study, Australian researchers looked at the effect of Pycnogenol in 101 people aged 60–85 years. The participants were randomized to 150 mg Pycnogenol or placebo for a period of three months. At the close of the study, those in the Pycnogenol group showed significant improvements in the quality of working memory. They also showed marked decreases in concentrations of F2 isoprostanes—markers of oxidative stress—relative to the control group (Ryan J. *Journal of Psychopharmacology.* 2008; 22(5): 553–562).

Investigators Down Under are planning one of the largest and most comprehensive clinical studies of botanical extracts in the context of age-associated cognitive decline.

This three-arm study involves 465 participants between 60–75 years of age, and will examine the effects of both Pycnogenol and *Bacopa monnieri*, an herbal extract used in traditional Ayurvedic medicine for memory decline.

Over the course of 12 months, 155 participants will take 150 mg of Pycnogenol daily; another 155 people will take 300 mg of *Bacopa monnieri*; and 155 will get a placebo. The objective is to examine the effects of these supplements on cognitive performance and the biochemical mechanisms behind cognitive enhancement. The assessment will also include full cardiovascular, neuropsychological, cognitive, and biochemical evaluations.

Given the aging of the population in the US and in most other industrialized countries, the issue of cognitive decline and corresponding dementia is imminent. Conventional medicine has little to offer those suffering from dementia, and even less for those hoping to prevent it.

Pycnogenol is a natural supplement that has been widely studied for the past 40 years. It has been the subject of over 340 published studies and review articles, none of which indicate any negative side effects or health risks.

What the research does tell us is that Pycnogenol appears to have anti-inflammatory, anti-oxidative and anti-edema effects, all of which can contribute to improved cognitive function, and potentially, to preventing age-associated cognitive decline.

Based on the available data, supplementation with Pycnogenol is a “No Brainer” for those concerned about dementia. ☺

Donna Aubinoe is a graduate student at Maryland University of Integrative Health. She is currently a clinical intern practicing Integrative Nutrition at the Natural Care Center at MUIH.

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A Role for N-Acetyl Cysteine in Parkinson's Disease

BY MADIHA SAEED, MD
Contributing Writer

People with Parkinson's disease may benefit from supplementation with N-acetyl cysteine (NAC), a powerful antioxidant that may also enable damaged dopaminergic neurons to recover some function.

Researchers at Thomas Jefferson University recently published a pilot study showing that Parkinson's patients who took NAC daily for three months showed significant improvements on clinical evaluations of mental and physical abilities, as well as beneficial changes on brain imaging studies that tracked levels of dopamine.

The study, recently published on *PLOS ONE*, suggests that NAC has direct effects on the dopamine system in Parkinson's patients.

Consistent Protective Effect

Daniel Monti and colleagues at TJU studied a small cohort of 23 Parkinson's patients, all of whom were living independently, and already on standard drug therapies, which they continued throughout the course of the three-month trial.

The patients were randomized into two groups, with the first group receiving a combination of oral NAC, 600 mg twice daily, plus weekly intravenous infusions of NAC (50 mg/kg). The second group received no NAC, but remained on standard Parkinson's drug therapy. The researchers made comprehensive evaluations at baseline and again after three months, using standard clinical measures like the unified Parkinson's Disease Rating Scale (UPDRS), and a DaTscan SPECT brain scan, to measure the amount of dopamine transporter in the basal ganglia.

The data showed that NAC exerted a consistent, protective effect.

Compared to the controls, the patients that received the oral/intravenous NAC had

improvements of 4–9% in dopamine transporter binding in the caudate and putamen regions of the brain ($p < 0.05$ for all values), and 13% improvements in their UPDRS scores ($p = 0.01$). The mean UPDRS score dropped from 25.6 to 22.3 in the NAC-treated group (Monti DA, et al. *PLOS ONE*. 2016).

The authors note "a significant correlation between the change in UPDRS scores and the change in dopamine transporter binding in the caudate and putamen." They also point out a significant change in midbrain serotonin transporter binding in the NAC group, though not in the control cohort.

Oxidative Stress in PD

There is a growing body of data suggesting that oxidative stress is an important factor in the pathophysiology of Parkinson's. Brain tissue samples from people with the disease show evidence of increased in lipid peroxidation, protein oxidation, and DNA oxidation (Chinta SJ, Andersen JK. *Biochimica et Biophysica Acta*. 2008; 1780: 1362–1367).

Monti and colleagues point out that, "reactive oxygen species (ROS) are derived from dopamine itself, which is chemically unstable and undergoes auto-oxidation to form dopamine quinones (DAQs) and superoxide anion radicals. The DAQs can further act as oxidants thus supporting ROS formation. Auto-oxidation of dopamine may be increased in the early stages of PD when dopamine turnover is increased to compensate for dying dopaminergic neurons."

Further, Parkinson's brains tend to show decreased levels of glutathione, arguably the body's most important antioxidant. The degree of neuronal glutathione depletion tracks closely with the severity of disease symptoms, and is the earliest known indicator of nigral degeneration.

Dr. Monti's current clinical study was based on earlier cell culture work showing that NAC can prevent oxidative damage and neuronal

cell death *in vitro*. A series of rodent studies suggested that NAC could increase glutathione levels, neutralize hydrogen peroxide radicals as well as toxic dopamine-related quinones, and prevent neuronal death.

Acknowledging the limitations inherent in a non-blinded pilot trial involving a small number of patients, the authors none the less believe that "NAC might positively impact dopamine function and potentially, clinical symptoms." They contend that this subject is worthy of a large, randomized, blinded study.

Addressing Oxidative Stress

Toxins are everywhere in our environments these days, and oxidative stress is widely prevalent. A high burden of toxins can directly damage cells down to the mitochondria. Oxidative stress can lower immunity, increasing the vulnerability to autoimmunity, cancer, preventing weight loss and blood sugar issues.

It is increasingly obvious that toxins and oxidative stress play a role in the etiology of most common chronic diseases including insulin resistance and diabetes, heart disease, and strokes. Gut inflammation, leading to leaky gut, only amplifies the problem.

With so much at stake, we as clinicians need to pay much more attention to oxidative stress and toxin burdens in the patients we serve. Fortunately, we have some good nutraceutical tools, in the form of glutathione and NAC.

Glutathione is found in every cell of the body but has its highest concentration in the liver. Glutathione helps to mop up heavy metals, free radicals, and just about anything that can damage cells. Glutathione also helps with DNA protection, mitochondrial and immune support, protects against heart disease, cancer, dementia and other chronic illnesses.

Most diseases involve a glutathione deficiency leading to DNA damage and unhealthy cells.

Optimize thyroid hormone levels: This is critical for both men and women, and it is important to look at both ends of the thyroid spectrum, because there are data showing that in terms of diabetes risk, both hyper- and hypo-thyroid states can be problematic (Iwen KA, et al. *Eur Thyroid J*. 2013 Jun; 2(2): 83–92).

Optimize testosterone levels: In men, low testosterone increases metabolic syndrome. Paradoxically, in women elevated testosterone will cause the same problem. This is seen in polycystic ovary syndrome (PCOS), and can also be seen with excessively high doses of testosterone replacement therapy.

In men, the so-called "normal range" for testosterone levels will miss a very large percentage of those who would benefit from bio-identical testosterone replacement. Over 50% of diabetic men have low testosterone, and optimizing testosterone can be very helpful.

In one study, giving testosterone to men who were deficient produced a mean 12.9 kg weight reduction, from an average of 106.6 to 93.7 kg. Simultaneously, blood pressure dropped from 155/94 to 140/80.8 mm Hg. Serum cholesterol dropped from 297.7 to 194.5 mg/dL. There was also a significant decrease in liver enzymes.

Mean plasma glucose levels declined from 105.8 to 97.0 mg/dL, over the 4-year period (*International Diabetes Federation (IDF) World Diabetes Congress 2011. Abstract O-0535. Presented December 7, 2011*).

Nutritional & Herbal Support

Magnesium: This mineral is needed for metabolism of insulin and glucose. A meta-analysis of six studies has shown that people with the highest magnesium intakes have a 31% lower risk of metabolic syndrome than those with the lowest intakes (He K, et al. *J Cardiometaab Syndr*. 2008; 1(5): 351–355).

I recommend that metabolic syndrome patients take 200 mg of magnesium daily, though I am much more cautious and use lower doses if someone is showing compromised kidney function.

I typically recommend the Daily Energy Enfusion vitamin and mineral powder by Integrative Therapeutics to all of my patients. It supplies the needed amount of magnesium, as well as 1000 units of vitamin D, and many other critical nutrients in one simple daily drink, sparing patients the need to take handfuls of pills.

NAC is a precursor to glutathione, and supplementation can restore intracellular levels of glutathione. As this new study suggests, it may also help to reduce oxidative damage in the brain, by increasing neuronal glutathione.

To optimize detoxification and improve our immune systems, we can help our bodies make glutathione simply by eating plenty of garlic, onions, cilantro, and cruciferous veggies like broccoli, kale, cauliflower and cabbage.

For those with a high toxic load, and—as the Monti paper suggests, for those at risk of Parkinson's—NAC supplementation makes good sense.

The world around us can be a scary place. It seems our bodies are being bombarded in all directions with pesticides, heavy metals, pharmaceutical metabolites, estrogen-mimicking compounds, radiation, and other toxins.

All the research on glutathione and NAC suggest that these supplements can optimize our detoxification capacities, reducing the overall negative effects of oxidative stress, and improving our resilience.

Rather than putting up fences, let's protect ourselves from a toxic environment with love, friendships, and "superhero" antioxidants like glutathione and NAC! ☺

Madiha Saeed, MD is a holistic family physician in Naperville, IL. She trained at National University of Science and Technology and completed her residency in 2010 at St. Joseph Regional Medical Center. She is board certified in both Family Medicine and Integrative Holistic Medicine, and has a particular passion for women's health and family health issues. A busy mother of four young boys, Dr. Saeed shares her "walk the talk" nutrition & lifestyle tips and her lively "bring it on" spirit with families worldwide via her *HolisticMomMD* website, and her forthcoming book, *The Holistic Rx: Every Patient's Guide to Healing and Preventing Chronic Disease*.

Metabolic Syndrome—Simplified!

BY JACOB TEITELBAUM, MD
Contributing Writer

It may surprise you to realize that diabetes used to be extremely rare.

Although recognized for over 1000 years, it was a very unusual condition for much of recorded history (H. C. Trowell, ed., *Western Diseases: Their Emergence and Prevention*. Cambridge, MA: Harvard University Press, 1981).

Today, metabolic syndrome—the precursor to diabetes—affects approximately 35% of the adult population, and the prevalence has increased by 6% in the last decade alone. Current estimates are that half of adult Americans will eventually become diabetic.

Why the current epidemic?

Insulin resistance skyrocketed with the introduction of the Western high sugar and low fiber diet. The average American on the so-called "standard American diet" consumes approximately 140 pounds of added sugar from processed foods—an obscene 18% of our calories.

Other major factors driving insulin resistance include:

- The misguided advice to avoid sunshine (which leads to vitamin D deficiency)
- Lack of exercise and physical activity
- Hormonal deficiencies, including inadequate testosterone levels (in males) and hypothyroidism—likely due in part to endocrine-disrupting chemicals in the environment.

A Larger Disaster

The standard medical approach has been to prescribe medications that, except for certain blood pressure drugs, have been more toxic than helpful.

For example, use of statins to simply treat elevated cholesterol in the absence of known heart disease (so-called "primary prevention") has had a minimal effect on decreasing heart attack deaths. This data has, in my opinion, largely been ignored or "spun" to help maintain a \$29 billion per year market.

Diabetes medications have been a larger disaster. Although insulin is life-saving in Type 1 childhood diabetes—where insulin levels are low because of autoimmune destruction of the insulin-producing beta cells—it is much less helpful for adult onset type II diabetes, where the body is making much more

insulin than normal. The problem is one of insulin resistance not absence of insulin.

Although insulin treatment will temporarily lower blood sugar surges, it results in dramatic fat deposition and obesity, worsening the diabetes in the long run.

Meanwhile, most other diabetes drugs—but for the notable exception of Metformin—have actually been shown to increase mortality, though these findings generally arise after the patents on the drugs expire.

It's time to take another approach.

We need to think about strategies to increase insulin sensitivity in any person showing elevated cholesterol, hypertension, and abdominal fat deposition—the so-called "spare tire"—even if overt diabetes has not yet begun to show itself.

A fasting insulin measurement over 10 mIU/L also suggests the need, as does a glycosylated hemoglobin of 5.7% or higher.

Here is a highly effective integrative clinical approach to improving insulin sensitivity:

Lifestyle Changes

Manage sugar addiction: There are four main types of sugar addiction: Chronically exhausted but hooked on caffeine; Extreme adrenal depletion; Yeast/candida overgrowth; and Hormonally-mediated cravings (perimenstrual, menopausal, andropausal).

Recognizing and treating each of the underlying types will make the cravings go away—while leaving the person feeling dramatically better. Several years ago, I published a book, *The Complete Guide to Beating Sugar Addiction*, to help patients do this easily.

Increase exercise: Physical activity is essential—especially outdoors in the sunshine. Vitamin D deficiency is strongly associated with metabolic syndrome.

Lose weight: This is, admittedly, difficult for somebody with elevated insulin levels, until the levels are brought down. Once insulin sensitivity increases, it becomes easier.

Minimize excessive stress: Occasional, self-limiting stressors are a necessary part of life. Excessive chronic stress is not, and it can be extremely detrimental because it raises cortisol levels and metabolic syndrome risk (Chandola T, et al. *BMJ*. 2006; 332: 521–525).

Hintonia latiflora: Hintonia (also known as Copalchi) is a desert plant native to Central America, the bark of which contains a substance called coutareagenin that can lower blood glucose levels. This has been shown in animal studies as well as human clinical studies (Koreca R, et al. *Arzneimittelforschung Drug Research*. 2000; 50(2): 122–128).

In a 2014 multicenter study, an extract of *H. latiflora* was given to 178 people with type 2 diabetes or pre-diabetes for a period of eight months. HbA1c values improved by 10% over the course of the study, from 7.2 % at baseline to 6.4% ($p < 0.0001$). The sum score of the accompanying diabetic symptoms improved from 4.8 points to 1.3 points.

The treated patients also showed reductions in blood pressure, blood fats, and liver enzyme values. The herb showed excellent tolerance with no significant side effects (Schmidt M, Hladikova MM. *Naturheilpraxis*. 2014).

Hintonia was recently introduced into the US by EuroMedica, as a product called Sucontral D. Each once-daily tablet provides 20 mg of polyphenols extracted from *H. latiflora* bark, as well as vitamin C, vitamin E, the B vitamins, chromium, zinc, and biotin.

Berberine: Berberine is a bioactive alkaloid produced by a number of different medicinal plants including Goldenseal (*Hydrastis canadensis*), Oregon Grape (*Berberis aquifolium*) and Barberry (*Berberis vulgaris*). Berberine-containing herbs have been used for centuries in both Asian and European traditional medicine systems.

The compound has multiple physiological effects in humans, including reduction of inflammation, stimulation of bile secretion and bilirubin discharge, and antimicrobial actions against a variety of bacteria, fungi, protozoa, and helminths.

It also has glucose-regulating effects. In a pilot study of 36 adults with newly-diagnosed type 2 diabetes, a thrice-daily dose of 0.5 g berberine, taken at the start of each meal, was shown to be as effective as Metformin for decreasing blood sugars (Yin J, et al. *Metabolism*. 2008; 57(5): 712–717). The herbal extract also lowers cholesterol.

For people with metabolic syndrome, I generally recommend 300 to 500 mg three times per day. Use less if it causes GI symptoms.

A side benefit? They will feel dramatically better! ☺

Jacob Teitelbaum, MD is author of *The Complete Guide to Beating Sugar Addiction and From Fatigued to Fantastic!*

Supplements & Liver Damage: Big Indictment, Tiny Numbers

BY ERIK GOLDMAN

Editor in Chief

The numbers are small, but the headlines linking dietary supplements to liver damage are big—big enough to generate yet another round of hand-wringing about the problem of “uncontrolled” supplements.

The study in question, headed by Victor Navarro, MD, of the Einstein Medical Center, Philadelphia, and published in late September in the journal *Hepatology*, claims that 20% of all cases of chemical-induced hepatotoxicity—that’s one in five—are traceable to herbal products and dietary supplements.

That’s up from 10% of all cases a decade ago. Drawing from a national registry of drug-induced liver injuries, Dr. Navarro and colleagues identified 130 cases with a clear link to supplements over a period of eight years. That’s roughly 16 cases per year.

One third of these were due to anabolic steroids in muscle-building or performance-enhancing “supplements.” Steroids are known to cause cholestatic liver damage, though in most cases this is reversible.

Naming Names

The remaining 85 cases were tied to a wide range of herbal and nutraceutical products. The investigators named six products from a company called Slimquick, four from Herbalife, four from Hydroxycut, and two each from MoveFree and Airborne.

But they note that many of the products in question contain multiple ingredients, and might also contain undisclosed compounds or contaminants, making it difficult in most cases to peg the liver problems to any specific vitamins, minerals or bioactive substances.

One specific ingredient did stand out in several cases: green tea extract, which can cause acute hepatitis-like damage in some rare cases. The authors claim that Chinese, Korean and Indian/Ayurvedic multi-herb formulations are particularly problematic.

Dr. Navarro believes supplement-related hepatotoxicity is greatly under-reported. This is because: (A) the onset is slow and non-dramatic, often taking months or years to develop; (B) people seldom report adverse reactions on their own and they’re not always forthright with healthcare practitioners (or do not have time during standard office visits); and (C) busy practitioners fail to ask about supplements or fail to report adverse events.

That said, the authors acknowledge that fortunately, “liver injury from supplements is rare.” And indeed, it is.

Under-Reported, Over-Inflated

There are approximately 324 million adults in the US. According to a recent federal estimate just published in the *Journal of the American Medical Association*, 52% take supplements, meaning there are about 166 million supplement users in the country.

Taking that figure as the denominator and Dr. Navarro’s 16 hepatotoxicity cases as the numerator, the incidence of supplement induced hepatotoxicity would calculate out to roughly 0.000009% per year.

Let’s assume Navarro is correct and the problem is grossly under-reported. Even if it were a thousand times more common than these current data indicate, the incidence would still be 0.009%!

But that didn’t stop *Hepatology*, a major gastroenterology journal, from spotlighting the study. Nor did it stop *Reuters* newswire service from running a generalized and alarmist headline stating, “Herbal and Dietary Supplements Tied to Liver Damage.”

There’s no question that there are holes in the regulatory process, or that some supplement products get to market containing potentially hazardous compounds. Adverse effects can and do occur, and they likely go unreported.

But studies like this, and the news reports that follow—which make sweeping judgments based on very small numbers—smell more of sensationalism than science. ☺

CBD Reduces Seizures in Treatment-Resistant Epilepsy

BY KRISTEN SCHEPKER

Assistant Editor

Cannabidiol (CBD)—a compound found in marijuana—can lower the frequency of seizures in young patients with treatment-resistant epilepsy, according to research published in *The Lancet Neurology*.

This publication is just a single example of numerous recent studies showing meaningful therapeutic benefits of cannabis and cannabis-derived products.

The marijuana plant contains over 80 distinct cannabinoids, several of which are used medicinally to treat a broad assortment of health conditions. Cannabidiol (CBD) is among the most-researched cannabinoids.

Unlike tetrahydrocannabinol (THC)—the major psychoactive cannabinoid well-known for inducing anxiety and other psychological symptoms—CBD is non-psychoactive. It confers its sedative and anti-anxiety effects without causing the THC-induced “high” associated with marijuana.

There is evidence that CBD also possesses anti-convulsive, hypnotic, anti-psychoactive, anti-nausea, antioxidant, and anti-inflammatory properties.

In one study, researchers used the compound to successfully treat collagen-induced arthritis, noting its “potent anti-arthritis effect” (Malfait A, et al. *Proceed Nat Acad Sciences USA*. 2000; 97(17): 9561–9566).

Others have demonstrated that CBD can alleviate psychotic symptoms associated with severe brain disorders, and it may have potential as an “effective, safe and well-tolerated alternative treatment for schizophrenic patients” (Zuardi A, et al. *Braz J Med & Biol Res*. 2006; 39: 421–429).

Anti-Convulsive Actions

There are many CBD studies highlighting the compound’s efficacy in treating various neurological disorders. This makes some mechanistic sense, since the brain and spinal cord contain cannabinoid receptors (Consroe, P. *Neurobiol Dis*. 1998; 5(6): 534–551).

CBD’s anti-convulsive actions in particular have garnered it a good deal of attention in the field of epilepsy research.

In the new study, investigators looked at CBD in children and young adults with treatment-resistant epilepsy. This was an open-label trial including 214 patients whose presentations included Dravet syndrome and Lennox-Gastaut syndrome, both of which are severe, often drug-resistant forms of epilepsy.

Recruited from 11 centers across the US, participants ranged from one to 30 years. All had been on stable doses of anti-epileptic medications.

During the trial, the patients took a pharmaceutical form of oral CBD called Epidiolex (GW Pharma) at 2 to 5 mg/kg per day, adjusted until intolerance or until a maximum dose of 25 mg/kg or 50 mg/kg per day (depending on study site allowances). The researchers’ primary aim was to establish CBD safety and tolerability.

Seizures Down by One-Third

Over the course of a 12-week study period, the frequency of motor seizures fell by a median 36.5%, from an average of 30 per month at baseline to 15.8 (Devinsky O, et al. *Lancet Neurology*. 2016; 15(3): 270–278).

CBD had a very favorable safety profile. It was well-tolerated by patients, with few subjects reporting adverse events such as drowsiness (25% of subjects), decreased appetite (19%), diarrhea (19%), fatigue, (13%), and convulsion (11%).

The authors contend that CBD holds great promise for safely and effectively reducing seizure frequency in children and young adults with few other therapeutic options.

That said, lead author, Orrin Devinsky, MD, a neurologist at New York University’s Langone Medical Center, is critical of parents who take it upon themselves to treat their epileptic children with marijuana.

Devinsky stated that he “empathize[s] with parents who are looking for answers and will try anything to help their children suffering the devastating effects of intractable epilepsy.” He cautions, however, that, “We must let the science, and not anecdotal success stories and high media interest” lead our conversations on medical cannabis.

“Taking CBD in a controlled medical setting is vastly different from going to a state where medical marijuana is legal and experimenting.” ☺



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Telomeres, Mitochondria, and The New Age of Aging

ISAAC ELIAZ, MD, MS, LAC
Contributing Writer

Though it may seem implausible, some researchers claim we'll soon have the capacity to extend human life well beyond 120 years.

While many of the emerging technologies proposed to slow aging are still a long way from becoming accessible, the findings in areas of gene expression, mitochondrial function and the role of specific biomarkers, are leading to practical solutions we can apply today to increase longevity, vitality and overall health.

Simply living longer isn't really the ideal. Yes, we want longevity, but if we're going to thrive in advanced age, we need to maintain good cardiovascular function, mental acuity, immune resilience and more.

Cutting-edge research continues to elucidate the complex biological cascades and pathways involved in the aging process, offering us roadmaps to help develop protocols that can support healthy aging and vitality.

Discoveries in the field of epigenetics are revealing how gene activity can be altered depending on diet, exercise, toxin exposure, even mental processes. Of course, epigenetics is not a new field. About 20 years ago, researchers noticed that turning certain genes on or off in *Caenorhabditis elegans* roundworms could extend their lifespan and make them healthy.

We humans share many of those genes with *C. elegans*, though controlling them in real people is, admittedly, a bit more difficult than it is in helminth experiments.

Researchers have found that caloric restriction can help organisms live longer and healthier. Caloric restriction in humans is difficult, especially when there are other health challenges, but there may be some alternatives with similar effects.

One of the genes associated with aging is SIRT1, and caloric restriction appears to favorably modulate its activity to protect the body during times when food is scarce. The compound resveratrol is also shown to interact with SIRT1 to delay some of the degenerative processes of aging (Sin TK, et al. *Acta Diabetol.* 2015 Dec; 52(6): 1063–1075).

Melatonin is also shown to activate SIRT1, and research shows the two may work syner-

gistically together (Ramis MR, et al. *Mech Ageing Dev.* 2015 Mar; 146–148: 28–41).

The Great Telomere Debate

Research into telomere function has also added to our understanding of the aging process. Telomeres are short DNA sequences found at the ends of each chromosome, which help protect our genetic material. However, with each cell division telomeres get shorter, reducing their ability to preserve chromosomes. In time, telomeres fail, chromosomes degrade, and cells can no longer divide, leading to cell death.

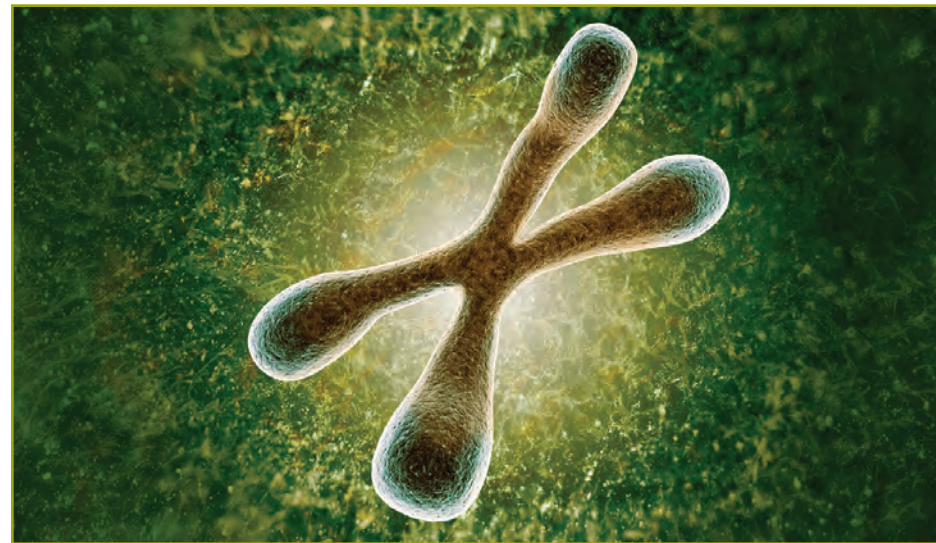


Photo Credit: Vitaly Smolygin / Dreamstime.com

Telomeres provide interesting insights into aging. Some researchers and clinicians believe that if we can preserve telomeres, we could extend longevity and improve health. An enzyme called telomerase rebuilds telomeres, so there's a lot of interest in compounds that naturally activate telomerase.

However, the jury is still out. Some researchers are concerned telomerase might also boost cancer growth. New data show that cancer can hijack DNA repair pathways and cause telomeres to lengthen instead of shorten, allowing tumors to grow and spread (Garcia-Exposito L, et al. *Cell Reports.* 2016; 17(7): 1858). These findings are leading some researchers to investigate telomerase inhibitors as anticancer adjuncts.

On the other hand, there are some studies suggesting that protecting telomere function does provide significant health and longevity benefits.

There's some fascinating research showing that regular meditation practice is linked to healthier telomeres (Schutte NS, Malouff JM. *Psychoneuroendocrinology.* 2014 Apr; 42: 45–48). Other studies show that eating nutrient-dense whole foods can support healthy telomeres.

There is also evidence that curcumin, resveratrol and other botanical compounds may selectively support healthy telomere behavior. One interesting theory suggests that

these and other compounds are beneficial in part because they fight cancer by regulating the telomere activity of malignant cells (Fuggetta MP, et al. *J Exp Clin Cancer Res.* 2006 Jun; 25(2): 189–193. Mukherjee N, et al. *Mol Cell Biochem.* 2007 Mar; 297(1–2): 31–39).

Conversely, emotional stress, certain processed foods, and high body burden of environmental toxins have all been linked to shorter telomeres and premature aging.

The Guardian of the Genome

One of the most important anti-cancer genes, called p53, is known as "the guardian of the genome" because it regulates the cell reproductive cycle and functions as a tumor suppressor.

The p53 gene codes for proteins that govern the cell cycle and correct errors in DNA replication. If the errors can't be fixed, p53 promotes apoptosis. One theory is that, in response to shortened telomeres, aged cells produce more p53, which in turn puts more oxidative stress on mitochondria.

There are a number of natural ways to boost mitochondrial function and support vitality and cellular health as we age.

Certain nutrients and botanical agents can promote healthy mitochondrial activity. For example, Coenzyme Q10 helps mitochondria make ATP. Pyrroloquinolone (PQQ), a molecule that is similar to CoQ10 is another nutrient that can increase mitochondrial ATP production, while also increasing the number of mitochondria.

PQQ is available as a supplement, and found in significant quantity in foods such as natto, parsley and green tea.

Certain medicinal mushrooms, particularly Cordyceps and Reishi, are also excellent for mitochondrial health. Aerobic interval exercise supports mitochondria, as does a nutrient-dense, low glycemic diet.

Galectin-3: New Aging Biomarker

A rapidly expanding body of data points to elevated circulating galectin-3 (Gal-3) as a chief culprit in the advancement of life-threatening illnesses, from heart disease, to diabetes, to the formation, proliferation and metastasis of cancer.

A ten-year Gal-3 all-cause mortality study involving almost 8,000 people showed that elevated serum Gal-3 was associated with a three-fold increase in all-cause mortality in the general population (deFilippi CR, Felker GM. *U.S. Cardiology.* 2010; 7(1): 3–6).

A 2016 cohort study showed that lower levels of Gal-3 are associated with healthy aging (Sanchis-Gomar F, et al. *Clin Chem Lab Med.* 2016 Apr 1; 54(5): 873–877).

The reason elevated Gal-3 is a chief culprit in the progression of life-threatening illnesses, is because it fuels chronic inflammation and fibrosis in organs and tissues.

It also plays significant roles in the formation, proliferation, and metastasis of cancer, acting as a sticky surface molecule which allows cancer cells to aggregate, disseminate throughout the circulatory system, evade immune surveillance, and establish themselves at distant sites. Gal-3 is also involved in angiogenesis (Newlaczy AU, Yu LG. *Cancer Lett.* 2011 Dec 27; 313(2): 123–128. Yu LG. *World J Gastrointest Oncol.* 2010 Apr 15; 2(4): 177–180. Nangia-Makker P, et al. *Am J Pathol.* 2000; 156: 899–909. Yu LG, et al. *J Biol Chem.* 2007; 282(1): 773–781. Zhao Q, et al. *Cancer Res.* 2009; 69: 17: 6799–6806).

Gal-3 is now recognized as a predictive biomarker and therapeutic target for heart disease. It is easily measured with a serum assay, and covered by most insurance for cardiovascular screening. Some practitioners are also using this test to assess cancer risk and progression.

Researchers have shown that Modified Citrus Pectin (MCP) binds to Gal-3 to block and reverse inflammatory and fibrotic damage to the heart, kidneys, liver, nervous system, and other tissues (Calvier L, et al. *Arterioscler Thromb Vasc Biol.* 2013; 33(1): 67–75. Kolatsi-Joannou M, et al. *PLOS ONE.* 2011; 6(4): e18683. Nangia-Makker P, et al. *J Natl Cancer Ins.* 2002; 94: 1854–1862).

MCP is a highly absorbable and bioactive form of citrus pectin recognized as the only available Gal-3 inhibitor, with extensive data showing its ability to prevent and reverse the degenerative effects of elevated Gal-3 throughout the body.

In order for the MCP to be effective against elevated galectin-3, it must have a molecular weight between 5–15 kDa, and low degree of esterification.

A Foundation for Healthy Aging

It is possible to foster healthy aging by keeping Gal-3 levels within a healthy range, promoting mitochondrial health, and encouraging favorable genetic expression.

Detoxification is critical, starting with diet. For patients with high body burden of toxic metals, I recommend a formula of MCP and sodium alginate. This combination can remove heavy metals such as lead, mercury and arsenic, by trapping them in circulation and excreting them through the urinary and GI tracts (Eliaz I, Weil E, Wilk B. *Forsch Komplementmed.* 2007 Dec; 14(6): 358–364).

Mindful meditation and other mind-body practices like yoga, Tai Chi and Qi Gong are also important. In addition to the tangible results on our mental and physical health. Any form of healthy stress relief will help prevent the inflammatory cascade that leads to degenerative aging. ☺

Isaac Eliaz, MD is an integrative medical doctor, licensed acupuncturist, researcher, product formulator and frequent lecturer. He has been a pioneer in holistic medicine since the early 1980s, and has published numerous peer-reviewed research papers. He is founder and medical director of the Amitabha Medical Clinic in Santa Rosa, CA, an integrative center specializing in cancer, Lyme disease, and other chronic conditions. He is also the founder and chief formulator of Clinical Synergy, a company providing targeted, research based, physician-formulated nutraceuticals.

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New Botanical Combo Promotes Fat Loss, Weight Management

BY KRISTEN SCHEPKER
Assistant Editor

A novel botanical combination that includes extracts of *Coleus forskohlii*, *Salacia reticulata*, and sesame, can limit the absorption of excess dietary fats, according to the results of a study published in the *Journal of Functional Foods*.

Researchers suggest that this unique blend of tropical Asian herbs holds potential to prevent obesity, overweight, and associated comorbid conditions like insulin sensitivity, diabetes, metabolic syndrome, and chronic degenerative disease.

It offers an alternative to prescription obesity-fighting drugs like Orlistat (tetrahydrolipstatin), which, while generally considered safe, causes unpleasant gastrointestinal side effects and has, in rare cases, been linked to severe liver injury.

With support from National Taiwan University and the National Science Council of Taiwan, a group of investigators conducted a six-week, placebo controlled study of this formula containing three botanical actives, *Coleus forskohlii*, *Salacia reticulata*, and *Sesamum indicum*, standardized for forskolin, salacinol, and sesamin, respectively.

Lipase Inhibition

They also evaluated each of the three components individually for their respective abilities to inhibit the activity of pancreatic lipase, a digestive enzyme that plays a key role in the absorption of dietary fats (Badmaev V, et al. *J Func Foods*. 2015; 15: 44–51).

While each of the three extracts showed measurable degrees of pancreatic lipase inhibition, the trifecta of the herbs in combination was by far more effective than any one of them by itself.

During the course of the study, participants took 1000 mg per day of the herbal formulation or a placebo, split into four 250 mg gel capsule doses. Subjects included 14 male and female participants with a BMI between 25 and 30. They were not asked to modify their diets or lifestyles in any other way.

The herbal blend used in the study was obtained from Bio Actives Inc., a botanical ingredient company headquartered in Tokyo. Bio Actives offers the formula as its FB3® Fusion Ingredient product. The company describes the product as the “first ‘smart’ ingredient formulation assisting healthy weight management by addressing dietary fat absorption.”

The product was introduced into the US by Dr. Vladimir Badmaev, the study's author, and a long-time pioneer in the integration of Asian, European and American herbal medicine.

Long Therapeutic Legacies

The three primary ingredients in FB3 have extensive individual histories of use as herbal medicines.

Native to India and rich in alkaloids, *C. forskohlii* is a plant that has long been used as an Ayurvedic remedy to treat various disorders of the cardiovascular, respiratory, gastrointestinal, and central nervous systems (Henderson S, et al. *J Int Soc Sports Nutr*. 2005; 2(2): 54–62).

S. reticulata possesses antidiabetic, antiviral, and antioxidant properties and comes

from a larger family of plants widely used in traditional Asian medicine to treat diabetes, cancer, and immunosuppression (Romero-Pérez G. *Front Immunol*. 2016; 7: 115).

The study's authors point to the ability of *S. reticulata* to inhibit alpha-glucosidase, an enzyme that regulates the gastrointestinal absorption of dietary carbohydrates.

Sesamum indicum—the common but powerful sesame seed—is one of the world's oldest oilseed crops and is cultivated in tropical and subtropical regions of Asia, Africa and South America with a multitude of uses in both food and medicine.

Study participants receiving the three-herb FB3 blend showed a greater reduction of total body fat than the placebo group.

These positive benefits came with an absence of unintended adverse effects; none of the study subjects reported any objective and/or subjective side effects in connection with the herbal formula.

The researchers postulate that when taken in combination, the three herbal extracts act in a synergistic and complementary manner to prevent the gastrointestinal absorption and accumulation of excess dietary fat. They found that *C. forskohlii* and *S. reticulata* together inhibited fat absorption by 20.7%—almost double the sum of the fat-blocking activity generated by each of the two components alone.

The synergy between these two compounds is potentially important because the efficacy of *C. forskohlii* appears to be somewhat age- and gender-dependent. Males are less responsive to *C. forskohlii* than females, and that the overall efficacy tends to decline with age in both genders.

Gender-Dependent Effects

Badmaev and colleagues suggest that *C. forskohlii* and *S. reticulata* work together to prevent any age- or gender-dependent *C. forskohlii* “resistance.”

Extracts of sesame, taken alone, have differential abilities to inhibit pancreatic lipase depending on dosage. In a low dose range (0.1 and 1 µg/mL), sesame outperforms *C. forskohlii* and *S. reticulata* in reducing pancreatic lipase activity.

However, at an increased dose (10 and 100 µg/mL), *S. indicum* gradually becomes less effective at inhibiting the enzyme, compared to the equivalent independent doses of *C. forskohlii* or *S. reticulata* alone.

When added to the herbal blend, *S. indicum* may be providing a sort of safety mechanism by preventing any potential side effects that may result from excessive inhibition of pancreatic lipase.

The Badmaev study also turned up the significant finding that *C. forskohlii* markedly decreased participants' appetites and caloric intake. This quality distinguishes the FB3 combination from the drug, tetrahydrolipstatin, whose shortfalls include increased appetite.

When combined with a healthy diet and active lifestyle, the new herbal supplement holds promise as a safe and effective tool for body fat reduction and weight loss promotion. 🍌

“When taken in combination, the three herbal extracts act in a synergistic manner to prevent absorption and accumulation of excess dietary fat.”

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Vaccine Debate

cont'd from page 1

assail what a majority considers to be one of the most significant life-saving advancements in biomedical history.

Cleveland Clinic leadership responded swiftly and predictably to Neides' commentary, emphasizing that the Clinic "is fully committed to evidence-based medicine," that "Harmful myths and untruths about vaccinations have been scientifically debunked in rigorous ways," and that "appropriate disciplinary action will be taken" against Neides, whose views on vaccines "do not reflect the position of [the] Clinic."

A Cleveland Clinic communications officer responsible for posting Neides' articles to the non-affiliated Cleveland.com site succeeded in unpublishing it shortly after it was initially posted. The site, which is owned by the *Plain Dealer* newspaper, cried foul, promptly restored the original article, and reportedly revoked Cleveland Clinic's ability to access the site's back-end.

Feverish Reaction

Neides' post triggered a feverish reaction from physicians across specialties, with some vilifying him as "downright dangerous," "irresponsible," "anti-science," and a representative of "the new world order." Some called for his termination from the renowned clinic.

Others applauded Neides for his willingness to raise what they see as legitimate concerns not only about vaccines but about environmental toxins in general—an issue the medical community tends to overlook.

As an institution, Cleveland Clinic made it clear that certain modalities—like vaccines—are beyond critique, and that physicians employed there should think twice before publicly sharing a personal view especially one considered "fringe."

The Neides incident prompted Cleveland Clinic's CEO, Delos "Toby" Cosgrove, to issue a statement reminding employees that, "Whether we realize it or not, every caregiver is a representative of Cleveland Clinic. How we engage in our lives outside of work can be linked back to our health system."

He closed with an admonition in the form of a request: "Our good name is among Cleveland Clinic's greatest assets. Please help us protect it."

Neides consistently earns very high patient satisfaction ratings, and received an outpouring of public support from citizens who share his concerns about vaccines. This included a petition with more than 2,700 signatures urging the Cleveland Clinic not to punish the doctor for his views.

In a formal—and probably coerced—statement, Neides wrote: "I apologize and regret publishing a blog that has caused so much concern and confusion for the public and medical community. I fully support vaccinations and my concern was meant to be positive around the safety of them."

Trump-Kennedy Bromance

Just two days after "vaccinitis" broke out in Cleveland, President Donald Trump loudly reiterated his belief that vaccines not only cause autism, but are responsible for the current epidemic of autism spectrum disorders. Trump initially voiced this view in a widely shared March 2014 tweet: "Healthy young child goes to doctor, gets pumped with massive shot of many vaccines, doesn't feel good and changes—AUTISM. Many such cases!"

Trump took a further step in calling for creation of a new federal committee on vaccine safety with the goal of ensuring "scientific integrity" in the "vaccine process." To the shock of Democrats and Republicans alike, he asked Robert F. Kennedy, Jr.—a longstanding vaccine critic, environmental activist, and son of liberal icon Sen. Robert "Bobby" Kennedy—to be the chairman.

Kennedy insists that he is not categorically "anti-vaccine," any more than he is categorically "anti-fish" because he has been vocal about the risks of mercury contamination in seafood. But he shares Trump's view that there is a link between vaccines and autism.

Among his many controversial publications, Kennedy edited a 2014 book called *Thimerosal: Let The Science Speak*, which "exposes the dangerous—and wholly unnecessary—use of the mercury-based preservative thimerosal in vaccines being given to millions of children and pregnant women here and around the world."

While many in the autism community believe there is a link with vaccines, others were quick to distance themselves from Trump and Kennedy.

As reported by CNN, Autism Science Foundation president Alison Singer said after Trump's meeting with Kennedy that, "the scientific research has been done and the results are clear—vaccines do not cause autism." Singer also argued that some people may choose not to believe the facts, but perpetuating a myth from the very highest levels poses a dangerous threat to public health."

It is difficult to imagine that the budding "bromance" between Trump and Kennedy will extend beyond vaccines. Kennedy is an outspoken environmental activist who stood with protesters at Standing Rock to stop the Dakota Access Pipeline.

His views on the environment won't likely make Kennedy popular with Trump's petro-friendly cabinet, and a cynic might wonder whether this vaccine commission is really just an attempt to demonstrate "bipartisanship" while simultaneously pre-empting a high-profile environmental adversary.

When Emotion Trumps Reason

Few healthcare issues arouse as much passion, rancor and hyperbole as childhood vaccines. Its current positioning on the national stage has fueled massive concerns about the potential implications of widespread anti-vaccine rhetoric on future public health.

Many view Trump's vaccine statements as simply one more example of his willingness to adopt anti-authoritarian, iconoclastic stances—though this one has huge potential consequences. As the *New Yorker's* Michael Specter wrote, "the Trump vaccine commission is not simply a bad idea—it is a deadly one."

If Trump's assertions about vaccines rings like a defiant call to arms for the so-called "anti-vaxer" movement, statements like Specter's reflect an equally emotional and unquestioning faith in the absolute beneficence of vaccines.

Lost in the polemics are more nuanced questions around vaccine safety—questions that, in a fiercely pro-vaccination medical world, cannot easily be raised without retaliation.

It may be possible that for the vast majority of children vaccines are safe and without consequence, while for certain subgroups with specific genetic predispositions, those same shots become problematic.

In the book *Vaccines & Autoimmunity* (Wiley Blackwell 2015) authors Yehuda Shoenfeld, Nancy Agmon-Levin, and Lucija Tomljenovic, cite a number of studies showing that variants of the HLA (human leukocyte antigen) gene family are strongly associated with vaccine-induced autoimmune reactions.

Is a researcher or clinician inherently "anti-science" or "irresponsible" if she or he publicly raises these data and suggests that they may have clinical implications? Does raising a question about vaccine safety automatically mean that someone is advocating the ban of all vaccines?

Consensus or Group-Think?

While the Kennedy-Trump announcement is arguably the bigger story, the unfolding drama surrounding Dr. Neides and the Cleveland Clinic may be the more important one—at least for clinicians who hold unorthodox views.

Undoubtedly, many integrative health professionals have, like Neides, wrestled with dif-

icult clinical and policy questions they believe should be raised openly—but which also run counter to prevailing medical wisdom.

Leaving aside specific questions about vaccine science, the Cleveland Clinic situation raises profound questions about physicians' freedom of thought and speech.

The tremendous publicity Neides' blog generated was viewed by some as an embarrassment to one of the world's most respected medical centers. It prompted the clinic's CEO—who several years ago spearheaded a pioneering Functional Medicine center—to politely but forcefully pressure the clinic's physicians toward what amounts to a subtle form of group-think.

The Cleveland Clinic has already stated that the vaccine fallout has prompted a thorough review of the types of services, clinical advice, and health products provided at the Wellness Institute run by Dr. Neides.

In a sense, all other holistic modalities have become guilty by association owing to this physician's view on vaccines.

If Neides does, in fact, receive the "disciplining" promised in the Clinic's public statements, it will likely discourage other integrative physicians from voicing opinions that run counter to or are critical of mainstream medicine.

That, in the long run, could be detrimental to the entire field. An atmosphere in which clinicians do not feel free to raise questions, publish observations, or explore alternative viewpoints, is one that will kill innovation.

Understandably, Neides' post and the specter of a Trump-Kennedy vaccination committee have raised fears about a backlash against some hard-won public health victories. Most experts agree that there are enormous individual and public health benefits obtained from vaccines.

In that light, one has to ask: are vaccine science and public health policy so fragile that defending them warrants a muzzling of physicians' freedom of inquiry and freedom of speech?

The vaccine issue strikes deep chords in practitioners and ordinary citizens alike.

"Are vaccine science and public health so fragile that defending them warrants a muzzling of physicians' freedom of speech?"

Red Yeast Rice: A Regulatory Quagmire

BY ERIK GOLDMAN

Editor in Chief

If you're recommending Red Yeast Rice supplements to patients as a natural alternative for reducing CVD risk, you may be unwittingly guiding them to ineffective products, and simultaneously compromising your clinical credibility.

This is all thanks to a regulatory gray zone that permits companies to market Red Yeast Rice (RYR) products as dietary supplements so long as they do not contain levels of monacolin K—the main lipid-lowering component—in excess of what is found in traditional fermented foods.

Monacolin K is a byproduct of the fermentation of rice by *Monascus purpureus*, a reddish mold that can grow on grain, and some forms of tea (e.g., Pu'er). It is also naturally produced—in small amounts—by various types of mushrooms including *Pleurotus ostreatus*, known to chefs and foodies as oyster mushrooms.

This compound is better known to physicians as Lovastatin, though the monacolin K in the prescription drug is derived from *Aspergillus* rather than *Monascus* fermentation.

Many see it in clear-cut black or white terms: One is either "pro-vax" or "anti-vax," and people feel they must take a stance. In healthcare institutions the pressure is almost exclusively on the "pro-vax" side.

Beyond Black & White

The holistic medical community appears split on vaccine issue. Many clinicians hold the view that vaccines are unquestionably safe while others, like Neides, believe that while they are "helpful when used properly," adjustments in vaccination timing and a clear understanding of individual epigenetics could lead to safer use.

Still others claim they are inherently dangerous.

Medical organizations are definitely feeling pressure to take a firm stance on vaccination.

The Institute for Functional Medicine (IFM), whose chairman—Dr. Mark Hyman—is a founding director of the Cleveland Clinic's Center for Functional Medicine, has issued an official statement.

"IFM's medical education supports the use of vaccinations," the Institute says. "Vaccinations against a variety of diseases have been a critically important step forward in medical science. Vaccines have been studied extensively, and while continued critical evaluation and discussion about all medical treatments is the way science moves forward, vaccination administration is an important standard of care that is supported by IFM."

Michael Jawer, Director of Government and Public Affairs for the American Academy of Naturopathic Physicians (AANP) says his organization is evaluating its official position with the goal of issuing a formal statement this summer.

Vaccines live at the intersection of many contentious societal issues: childhood health; the balance between personal autonomy and public good; the rightful extent of government authority; the influence of corporate interests on public health policy. The fever pitch that characterizes public discussion of vaccines likely has more to do with these issues than with vaccine science itself.

As the debate continues to unfold both on the largest public stage and in the day-to-day lives of the public, it will be increasingly important to discern between actual scientific and clinical questions about vaccines, and the deeper social and political issues that hide beneath this seemingly cut-and-dried topic. 🍌

Since monacolin K does arise naturally—at sub-clinical concentrations—in various food sources, the FDA permits companies to market these foods and supplements derived from them provided they do not contain pharmaceutical levels of the compound.

And that's where the gray area begins.

There are no formal guidelines defining the "naturally-occurring" level of monacolin K in a food or supplement. From a practical point of view the FDA has considered products containing greater than 0.4% monacolin K to be either unapproved drugs—or adulterated products.

No Guidelines

Simply put, if a food or supplement contains levels of monacolin K higher than what would naturally result from traditional Asian culinary fermentation, the FDA views it as an unapproved statin drug.

As a result, most companies selling RYR products in the US are simply side-stepping the issue by either not testing monacolin K levels in their products or not disclosing the information about monacolin K concentration on their labels.

In Cannabis-Friendly States Opioid Overdoses Decline

BY KRISTEN SCHEPKER
Assistant Editor

Could cannabis be the solution to America's opioid overdose epidemic?

Mounting evidence indicates that medical marijuana may help save lives by reducing prescription painkiller misuse.

With opioids under intense scrutiny, and the hazards of long-term NSAID use becoming more apparent, patients and clinicians alike are finding themselves with a dwindling set of tools for managing chronic pain.

But a budding trend suggests that cannabis and its derivatives can be effective analgesics. Pain associated with inflammation, headaches, neuropathy, muscle damage, spinal injury, and fibromyalgia are among the most common reasons for cannabis prescriptions in states that have legalized medical marijuana.

As of the November 2016 election, 28 states and the District of Columbia have done so. Yet marijuana legalization remains one of the most controversial policy issues brought forward in recent decades.

The controversy stems in part from the fact that despite regulatory changes in more than half the country, the federal government still classifies it as an illegal substance.

The Drug Enforcement Administration still lists cannabis as a Schedule I substance, placing it in the most restrictive drug category. Schedule I drugs—which also include heroin, LSD, and ecstasy—are characterized by their high potential for abuse, lack of accepted medical applications, and safety concerns even when used under medical supervision.

Compared with cannabis, many legal painkilling drugs have a far greater potential to cause harm and to engender abuse.

Prescription opioid use—and abuse—is at an all-time high in the US. Sales of these drugs have quadrupled since 1999, according to the Centers for Disease Control and Prevention (CDC). Analgesics now rank as the second most prescribed class of medications nationwide.

Nutritionist and supplement industry expert Tom Guilliams, PhD, says regulators do not require disclosure of monacolin K on supplement products, and in fact, the way the law is written, companies have a strong disincentive to post any such information.

Guilliams, who heads the Point Institute—an independent educational organization focused on natural therapeutics—and who serves as vice-president of regulatory affairs for Ortho Molecular Products—says the situation creates a potentially dangerous Catch-22 for practitioners and their patients.

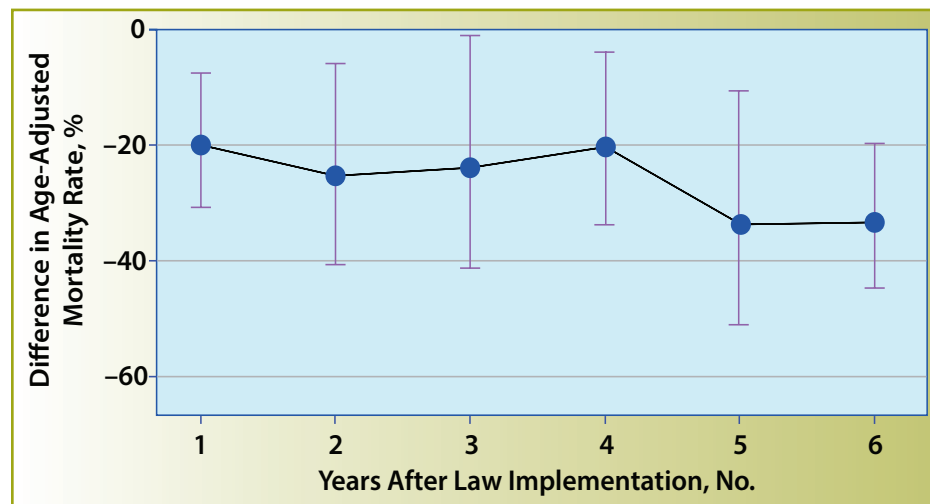
If a RYR product does contain therapeutically active levels of monacolin K, but the precise concentrations are not disclosed, there is no way to accurately and safely control dosing.

If a product does not contain high levels of the compound, it will not likely work to lower LDL and modulate cardiovascular risk. This means the patient has wasted money, and the practitioner has failed in the duty to mitigate risk and improve health.

Gambling in the Dark

Either way, both practitioner and patient are in the dark. Without meaningful disclosure of monacolin K content, it is not possible to know how much is too much.

Paralleling the upsurge in sales, are soaring rates of overdose deaths. Opioids—including both prescription pain relievers and heroin—killed over 28,000 Americans in 2014, more than any other year on record. Emergency department visits involving the misuse or abuse of prescription opioids jumped a massive 153% between 2004 and 2011 (Compton W, et al. *N Engl J Med*. 2016; 374(2): 154–163).



Association Between Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in Each Year After Implementation of Laws in the US. The points indicate the mean difference in opioid analgesic overdose mortality rate in states with medical cannabis laws compared with states without such laws. (*JAMA Intern Med*. 2014; 174(10): 1668–73)

The CDC estimates that today, at least half of all opioid overdose deaths involve a prescription analgesic.

In contrast, the likelihood of a marijuana overdose is extremely low. While occasionally listed as a secondary cause contributing to patient fatalities, cannabis overdose alone has never once been implicated as the primary cause of death.

Cannabis Laws Reduce Opioid Use

Several studies over the last few years indicate that in states where medical marijuana has been legalized, painkiller prescriptions—and opiate overdose rates—have fallen substantially.

Guilliams believes use of RYR is a very dicey gamble, one that too many clinicians are taking simply because they do not understand the regulatory situation.

In a recent White Paper, he recommends that practitioners discontinue dispensing or recommending RYR until all regulatory and quality control issues are sorted out, and there are no longer any gray areas.

He adds that while it seems reasonable to petition FDA to specify a clear permissible upper limit for monacolin K in each dose of RYR (perhaps 5 mg), the legal precedent this would set is likely to prevent such a ruling.

In the past, the FDA has rejected several attempts to establish low-dose statins as OTC medications. The agency is unlikely to change its stance, though in the wake of the Trump election, anything and everything having to do with federal agencies and their jurisdictions is in question.

Guilliams stresses that there are many effective ways to reduce risk for chronic cardiovascular events. Reliance upon low-dose statin therapy via RYR supplements that do not disclose any information about concentration of active compounds is probably not the most intelligent or effective option. ☺

To access Dr. Guilliams' new White Paper exploring the Red Yeast Rice issue, visit www.pointinstitute.org/white-papers

A 2014 report in *JAMA Internal Medicine* showed a strong association between legalization of medical cannabis and lower state-level opioid overdose deaths. Data collected between 1999 and 2010, when only 13 states had legalized, showed that cannabis-friendly states had a 24.8% lower mean annual overdose mortality rate compared to states where marijuana wasn't legal (95% CI, 7.7% to 41.9%; p = .003).

The association between legalization of cannabis and lower overdose mortality generally strengthened over time. The longer a state's medical cannabis laws had been in effect, the larger the drop in opioid-related deaths (Bachhuber M, et al. *JAMA Intern Med*. 2014; 174(10): 1668–1673).

Another more recent study, published earlier this year in *Health Affairs*, showed similar findings.

Challenging a common argument that only young people are interested in marijuana, investigators looked at data from all prescriptions filled by Medicare Part D enrollees to treat nine different clinical conditions between 2010 and 2013.

In states with medical cannabis laws, the use of pharmaceuticals for which marijuana could serve as an alternative fell significantly. The only exceptions were for spasticity- and glaucoma-related drugs, which continued to be prescribed at similar rates before and after medicinal cannabis legalization.

"Our findings and existing clinical literature imply that patients respond to medical marijuana legislation as if there are clinical benefits to the drug," the researchers write, arguing that their data provide not only key insights on the positive state-level impact of cannabis reform, but also important evidence of marijuana's outdated status as a Schedule I substance (Bradford A, Bradford W. *Health Aff*. 2016; 35(7): 1230–1236).

The Bradford team notes that in addition to its clinical merits, medical cannabis legalization may offer economic benefits to the states.

Nationally, Medicare and its enrollees spent an estimated \$165.2 million less in 2013, as a result of the changed prescribing patterns associated with medical cannabis legalization.

Which Is the Real Gateway Drug?

Cannabis critics have been quick to condemn the dangers of unregulated cannabis use in states that have legalized.

A widely publicized case report documenting the death of a teenager in Colorado who fell from a balcony after eating an edible marijuana product led to concerns about over-consumption and endangerment. Impaired driving ability is another common critique.

National studies provide conflicting evidence on the impact of marijuana use on traffic fatalities. The data are equivocal, and it is still an open question whether states with medical marijuana laws really do have more traffic fatalities (Ghosh T, et al. *N Engl J Med*. 2015; 372(11): 991–993).

For decades, marijuana has been vilified as a "gateway drug," leading users down a path towards more dangerous substances. The same criticism, however, can also be made for prescription painkillers.

The reality is, pharmaceutical opioid abuse can—and often does—open the door to future heroin use. The National Institute on Drug Abuse reports that nearly half of young heroin users surveyed in three recent studies had abused prescription opioids before starting to use heroin. Some reported switching to heroin because it is less expensive and easier to obtain than pharmaceuticals.

Cannabis, on the other hand, may reduce consumption of opioids.

Researchers examined cannabis consumption among 653 injection drug users in Los Angeles and San Francisco, and found a statistical association between recent cannabis use and lower use of nonmedical opioids. The mean and median number of times individuals used opioids in the previous 30 days were significantly lower among those who used cannabis than those who had not (Kral A, et al. *Drug Alcohol Depend*. 2015; 153: 236–241).

Further research on cannabis as an analgesic is clearly warranted. But the reality is, advocates for this green movement are not waiting for definitive data. Neither are the hundreds of thousands of people using cannabis and its derivatives like cannabidiol (CBD) for medical purposes.



The favorable results from studies so far suggest marijuana is a pain treatment option worth exploring. Its potent analgesic properties, limited side effects, and the near impossibility of overdose merit consideration.

To be sure, there are important questions still to be answered about dose standardization, the risks and benefits of combining cannabis with opioids, and the best ways for practitioners and patients to communicate about cannabis and other controlled substances.

According to the authors of a recent paper published by the Mayo Clinic, "these are all issues that deserve attention as we better understand the role of medical marijuana in the treatment of patients with chronic pain" (Becker W, Tetraault J. *Mayo Clin Proc*. 2016; 91(7): 830–832). ☺

How to “Beet” Hypertension

BY ELIZABETH HERBERT
Contributing Writer

Drinking one cup of raw beet juice daily can markedly reduce blood pressure, while simultaneously quelling systemic inflammation and improving lipid profiles in people with hypertension.

Dr. Sedigh Asgary and colleagues at the Isfahan Cardiovascular Research Center, Iran, assessed the BP modulating potential of freshly pressed beet juice, as well as that of cooked beets, in 24 hypertensive women and men not currently taking anti-hypertensive drugs.

The patients were instructed to drink either 250 ml of raw beet juice (approximately 1.06 cups) or 250 ml of cooked beet juice every day for two weeks. The groups then switched from raw to cooked juice, or vice versa, for an additional two weeks.

The results, published in December 2016 in the *Journal of Human Hypertension*, were pretty rosy . . . er . . . make that magenta.

Daily consumption of raw beet juice lowered mean systolic blood pressure by roughly 7 mmHg, from a baseline average of 133.9 mmHg to 127.3 mmHg. Diastolic pressure went from a baseline of 82.7 to 78.1 mmHg.

The cooked beet juice was not quite as effective, but still exerted a measurable BP lowering effect, with systolic pressure declining by 5 mmHg, and diastolic dropping by approximately 3 mmHg on average.

Daily beet consumption—particularly the raw beet juice—also attenuated a myriad of cardiovascular risk factors. High-sensitivity CRP level dropped from a mean of 1.1 to 0.7 ng/ml. Interleukin (IL)-6 went from 2.2 to 1.6 ng/ml, and TNF-alpha went from a mean 4.19 to 3.18 ng/ml. All of these are reliable markers

of systemic inflammation, suggesting that the humble beetroot contains potent anti-inflammatory compounds.

Go Raw

Indicators of vessel dilation showed marked improvements: mean ICAM levels went from 143.9 ng/ml at baseline to 119.6 after two weeks of raw beet juice, and VCAM dropped from a mean of 657.5 to 515 ng/ml.

The raw beet juice—though not the heated juice—also lowered total cholesterol

from a baseline of 189.9 to 169.9 ng/dl. LDL went from 117.7 to 103 (Asgary S, et al. *J Human Hyperten*. 2016; 30: 627–632).

Beets, from the family Chenopodiaceae, are high in folate, fiber, manganese and potassium. They're known to be anti-carcinogenic due to their betacyanin levels, a pigment which gives them their rich red color.

They are also a dietary source of nitrates, which are used to make nitric oxide (NO), a strong vasodilator important in regulating blood pressure.

The anti-inflammatory effect observed in the Asgary study is likely due to the betaine content in these widely available and inex-

ginseng studies have been a bit more variable than those of beetroot.

A recent meta-analysis of 17 studies (12 for Asian ginseng, 5 for American ginseng) looking at the impact of this root on systolic, diastolic and mean arterial pressure in a wide range of human subjects (healthy adults, adults with hypertension, and adults with diabetes, obesity or metabolic syndrome) led to the conclusion that neither the Asian nor the American species had a clinically or statistically significant overall impact on blood pressure (Kommishon AM, et al. *J Human Hypertens*. 2016; 30: 619–626).



Beets (*Beta vulgaris*). Credit: Kuhar / Dreamstime.com



Ginseng. Credit: Mingwei Chan / Dreamstime.com

Restorative Sleep—It's a Choice!

BY RUSSELL JAFFE, MD
Contributing Writer

Much has been said about sleep. It's a key part of a healthy lifestyle that can benefit the heart, weight, mind, skin and so much more. Unfortunately, insufficient and improper sleep is an epidemic.

Nearly 8 in 10 Americans admit they would feel better if they had just one extra hour of sleep, according to a 2014 survey by the Better Sleep Council.

Sleep may seem like one of the most repetitive, mundane and boring aspects of our physiology. But falling asleep actually requires a huge degree of orchestration of various organ systems, hormones, and biochemical reactions.

From the priming of the body to feel sleepy, to falling asleep, to sustaining that state till the morning and last but not least waking up rested and refreshed—the entire process is nothing short of miraculous.

To sleep healthfully, two vital and fundamental things need to happen in the sleep center of the brain: adrenalin and cortisol have to fall and melatonin has to rise.

For the necessary rise and fall of adrenalin, there needs to be enough of the amino acid, tyrosine. If tyrosine is deficient, the individual will typically feel exhaustion and the need to sleep, but sleep evades the person.

Tryptophan—another amino acid that is essential for serotonin and later melatonin production—can be diverted into the quinolone pathway in people with high oxidative states, especially when there is a lack of essential antioxidants and a chronic state of acidosis.

This negatively affects the rising and dipping of serotonin, and later melatonin, during the night—often leading to the very common problem of waking up too early and not being able to go back to sleep. So many people face the unpleasant state of “I am awake but I don't want to be, and I am definitely not rested” every single night.

With the pressures of work, family, environment, and health stressors, sleep is elusive for so many of our patients.

The good news is that for most people, it is well within their power to create the physiological and environmental conditions that nurture restful and restorative sleep—and to do so without potentially harmful medications.

Insomnia and sleep disturbances need not be inevitable—even in the context of a busy life. To a large degree, healthy sleep is a choice or, to put it more accurately, a combination of choices.

I have outlined a few basic actions and habits that I've found very effective for promoting healthier, more restful sleep:

- Incorporate relaxing rituals.
- A 20-minute salt and soda bath. This requires ½ cup of Epsom salts and baking soda in a tub of warm water (with calming essential oils if desired); towel off when done.
- 5 minutes of abdominal breathing before laying down to sleep.
- 15 minutes of active meditation.
- Dichromatic green lights before bed to improve galvanic skin responses.
- Keep all electronic devices like phones, computers and tablets out of the bedroom. They increase electromagnetic fields that can disrupt sleep. Some people sleep better after clearing their bedroom of clocks and even books.
- Tryptophan, with B6 and zinc for enhanced uptake, to fuel healthy serotonin and melatonin production. Magnesium is a valuable calming mineral, and can be vital for relaxing the nerves and muscles.
- Avoid caffeinated drinks after lunch. Water and other alkalizing beverages like herbal teas are much better choices.
- Do not eat too close to bedtime. Try to maintain at least 2–3 hours' gap between eating and sleeping. Create evening meals around foods that can be easily digested and assimilated, without triggering the immune system.

Happiness is sleeping undisturbed till you wake up naturally! The aforementioned suggestions can go a long way in helping more people realize that ideal. ☺

pensive root vegetables. Betaine helps protect cells and organs from stress, calms inflammation and also reduces risk of vascular disease.

Murray and colleagues have suggested that the anti-inflammatory properties of compounds contained in beets may also assist with the anti-hypertensive effect (Murray MT, Pizzorno JE, Pizzorno L. *The Encyclopedia of Healing Foods*. 2015; Simon and Schuster).

Beeturia—the red or pink coloration of urine—is the main consequence of consuming high quantities of beets or beet juice. While it may be frightening for people experiencing it for the first time, it is perfectly harmless, and results from pigments contained in the beets.

The only true caveat about beets is their high oxalate content. People with a history of oxalate kidney stones should probably not use beet juice to lower blood pressure.

These roots have a strong flavor, so someone new to beet juice, should try mixing it with carrot juice or another vegetable juice at first.

Drug-Free Options?

Despite the vast quantities of drugs that the medical industry has hurled at hypertension, the problem has not gone away.

The Centers for Disease Control and Prevention estimate that 75 million Americans, or 1 in 3 adults, has hypertension, as defined by a blood pressure of 140/90 mmHg or higher. This leads to around 9 million deaths annually, with 50% due to stroke. The numbers continue to rise despite widespread prescription of ACE inhibitors and beta-blockers.

These drugs, though generally safe, are not without adverse effects. They can also be costly, leading many hypertensive people to seek natural alternatives.

Beets, which sell for between \$1–2 per pound in most supermarkets, seem like a pretty good option.

Asgary and colleagues suggest that future studies should look at whether beetroot juice would have clinical efficacy as a long term “therapy” for hypertension and cardiovascular disease.

A Role for Ginseng?

Ginseng is another natural option for managing high blood pressure, though the results of

That said, the authors—a team representing major Canadian universities—note that ginseng does have favorable effects on systolic pressure in people with diabetes, metabolic syndrome, or obesity. Differences in response to ginseng were related to body mass index.

Herbs often have different effects in different people based on their physiology. The Canadian data, though not definitive, suggest that ginseng may offer the greatest benefit for those who need it the most—those with significant co-morbidities and high CVD risk profiles.

It is important to note that the authors did not specify which type of ginseng was the most favorable overall. This may be important because American and Asian ginseng appear to have different physiological effects.

While American ginseng calms the central nervous system and helps the body deal more effectively with stress and inflammation, Asian ginseng may offer protection for neurodegenerative disease and be more beneficial for reducing risk of CVD and hypertension (Mercola J, MD. 2015 June 22; *The Many Health Benefits of Ginseng*).

Future metanalyses should differentiate between the two types of ginseng.

Ginseng does need to be used carefully. Pregnant or breastfeeding women should be particularly cautious. This is probably not a good option for people already taking diabetes drugs, warfarin or other anti-coagulants, monoamine oxidase inhibitors (MAOIs), antipsychotics, or morphine.

If using ginseng in whole form, it is best not to peel the roots, as the peel contains many important bioactive compounds.

There's no question chronic diseases like hypertension are definitely making headlines—and affecting bottom lines.

Many patients facing a strict drug regimen for the rest of their lives are looking for safer, more natural ways to reduce their risk and help them on their road to health. The good news from these two recent papers is that both ginseng and beets show promise as contenders for treating hypertension naturally. ☺

Elizabeth Herbert is a graduate student and clinical intern in the clinical nutrition program at The Maryland University of Integrative Health. Upon graduation this Spring, she plans to sit for the certified nutrition specialist (CNS) board exam before beginning clinical practice in PA.

Why Probiotics Should Be a Routine Part of Pregnancy Care

BY BELINDA REYNOLDS
Contributing Writer

In recent years, microbiome researchers have uncovered a wealth of new information about how beneficial microbes promote fertility, pregnancy, and postnatal health, all of which suggests that probiotics should become a routine part of prenatal healthcare.

Friendly microorganisms provide support for a healthy immune system and genitourinary tract. They can also help to relieve symptoms of infectious lactational mastitis and pregnancy-associated gastrointestinal disturbances, while modulating the infant immune system to improve defense mechanisms and decrease the risk of infant atopic dermatitis and eczema.

The effects can be profound for both mother and child.

In one study, maternal probiotic use during pregnancy reduced the risk of childhood allergic disease by half!

Probiotics exert a plethora of local and systemic health benefits. They positively influence digestive health, synthesize health-promoting short chain fatty acids (SCFAs), improve microbial balance, maintain intestinal integrity, and enhance sIgA release. Their immune-regulatory influence supports healthy immune responses while dampening inflammatory and allergic responses.

Researchers have long known that organisms living in the vaginal tract, and in breast milk influence an infant's gut microbiome. Absence of exposure to these organisms is one reason why infants born via C-section, and those who are not breastfed, are often predisposed to colic and other GI disturbances.

A recent wave of research is showing just how important breast milk is in establishing a baby's microbiome.

Entero-Mammary Transfer

There is a direct connection between the organisms in a mother's gut and those in her milk. An ongoing process of systemic translocation occurs, where intestinally derived components (including probiotics and their DNA signatures) are carried by monocytes to other areas of the body. Transport from the GI tract to the lactating breast is known as the "entero-mammary pathway."

In other words, beneficial microbes are actively transported from a woman's GI tract to her breasts, and then into her child's GI tract via the milk. The entero-mammary transport process is upregulated by the hormone cascades associated with pregnancy and lactation.

Organisms in breastmilk contribute greatly to the establishment of infant commensal communities and maturation of infant immune systems.

Translocation is not limited to the GI tract and lactation glands. Further findings that defy our past beliefs include the discovery of probiotic organisms within amniotic fluid, the placenta and meconium (first stool) of neonates.

This is an incredible revelation, one that runs counter to past literature describing the infant GI tract as sterile prior to delivery. These findings have huge implications for the use of probiotics throughout pregnancy.

Most recently, researchers have found that that these transported probiotics trigger the process of fetal immune system maturation much earlier than previously thought. A trial of *Lactobacillus rhamnosus* and *Bifidobacterium lactis* given to pregnant women illustrated this. The probiotic treatment significantly modulated factors related to innate immunity (e.g., the expression of TLR-related genes), both in the placenta and in the fetal gut.

Probiotic intake during pregnancy and lactation has the potential to positively influence a child's immune system. The potential health benefits can be profound.

Quelling Atopic Dermatitis

Probiotics during pregnancy and lactation (for up to six months), markedly decrease the incidence of atopic dermatitis and eczema in

the first (two-seven) years of children's lives. The key strains studied here include *L. rhamnosus* and *B. lactis*.

Atopic dermatitis is very common among infants and small children. It causes significant discomfort, compromised sleep patterns (for children and parents alike) and interferes with other aspects of life. Given that roughly 40% of all atopic children will develop asthma, this clearly is an issue to be taken seriously.

Stool samples from infants and children with atopic eczema have significantly less lactobacilli and bifidobacteria than samples from healthy kids. Increasing the presence of these microbes reduces the risk of AE via various mechanisms.

Lactic acid-producing bacteria improve intestinal integrity, reducing the leakage of allergens from the intestine. As discussed, probiotics also modulate immune responses to allergens. They do this by increasing regulatory T cell

release, thus reducing Th2 cytokines and resultant IgE levels. This influences phagocytosis, secretion of sIgA, and suppression of pro-inflammatory cytokines.

It is important to note that infants are naturally born in a Th2-dominant state, and they produce a lot of IgE. Thus they are innately predisposed to allergic reactions via mast cell activation. Early exposure to organisms like *L. rhamnosus* and various species of Bifidobacteria will reverse this Th2 bias, and promote IgA production which promotes allergen exclusion and reduces exposure of the baby's immune system to antigens.

During pregnancy, there is an increased risk of certain conditions such as urinary tract infections, digestive disturbances, and thrush. Each of these conditions is associated with local dysbiosis and compromised mucosal immunity.

Probiotic therapy with lactobacilli can improve urogenital health via immune modulation, pathogen displacement, and creation of an environment less conducive to proliferation of pathogens.

Reversing Mastitis

Given what we know about the importance of breastfeeding, it is essential that we do all we can to help new mothers avoid complications, such as mastitis, which may compromise their ability, or desire, to breastfeed.

Mastitis affects up to 33% of lactating mothers, and represents a significant cause of early weaning. Lactational mastitis is an inflammation of the lobules in the mammary gland. It usually has an infectious origin, but additional factors such as insufficient draining of the breast and poor attachment will also contribute.

Staphylococcus aureus and *S. epidermidis* are considered the main culprits in acute and chronic mastitis respectively. Each exhibits multi-drug resistance, making these infections difficult to treat. This has motivated researchers to seek alternative methods to prevent and provide symptomatic relief of mastitis.

Spanish scientists isolated two probiotic strains present in breast milk of healthy mothers: *L. salivarius* and *L. gasseri*. In women with lactational mastitis these two species are almost undetectable, while levels of pathogenic staphylococcal species are usually very high.

In short, lactational mastitis seems to correlate with dysbiosis. In general, loss of GI microbial diversity increases the risk of overgrowth of group B streptococci.

What if we could correct this imbalance? A small cohort of 20 breastfeeding women with mastitis were divided into two groups: a probiotic treatment group (receiving a combination of *L. salivarius* and *L. gasseri*) and a control group. All had previously tried prescription antibiotics with no relief.

After a period of 14 days, the probiotic treatment group showed no signs of lactational mastitis, whereas the condition persisted in those of the control group. These results showed probiotic therapy to be effective where antibiotics had failed.

In a larger study involving 352 women with lactational mastitis, treatment with *L. salivarius* or *L. fermentum* (also found in the breast milk of healthy women), produced greater symptom improvement when compared to standard therapy, and a lower recurrence of mastitis.

Probiotics & Fertility

Simply put, dysbiosis—the overgrowth of unfriendly gut organisms—compromises fertility in women. One reason for this is that dysbiosis and leaky gut lead to chronic systemic inflammation, which raises aromatase activity. Systemic inflammation also compromises luteinizing hormone (LH) and follicle-stimulating hormone (FSH). The net result is widespread hormone dysregulation and reduced fertility.

It is notable that irritable bowel syndrome—a condition clearly associated with dysregulation of the gut microbiome—is associated with increased risk of miscarriage and ectopic pregnancy.

Long-term use of oral contraceptives—especially hormonal combinations—substantially alter the vaginal microbiome, and this can compromise fertility long after a woman has stopped using the contraceptive.

While there are no definitive trials showing that probiotics can improve fertility or reverse infertility, it is certainly worth considering. At the very least, women who are discontinuing oral contraceptives and who want to become pregnant should consider taking a broad-spectrum, multi-strain probiotic for a few months.

The health benefits of probiotics—especially those rich in Lactobacillus species—for reproductive-age women are many. They can be effective in preventing genitourinary infections, which in turn would reduce the risk of pre-term labor. They can attenuate the risk of diabetes and obesity in both mother and child, and they also reduce risk of depression and mood disorders for both mother and child.

Pregnant women who take probiotics regularly are less likely to experience constipation—a common, unhealthy, and extremely uncomfortable condition.

For all these reasons, probiotics should be carefully considered for most, if not all women during pregnancy and lactation. The research is strong; it simply needs to be implemented.

Complete references are available in the online version of this article at www.holisticprimarycare.net

For more health articles, go to www.bioceuticals.com.au/education/articles.

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"Beneficial microbes are actively transported from a woman's GI tract to her breasts and then into her child's GI tract via the milk."

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Anthroposophy, Quantum Physics & Holistic Medicine's Epistemology Crisis

BY WALTER ALEXANDER
Contributing Writer

Book Review: Peter Heusser, MD. *Anthroposophy and Science (An Introduction)*, Peter Lang GmbH, 2016 English edition, transl. Lynda Hepburn.

Why would someone with a busy holistic practice pause to read a book with an arcane title such as *Anthroposophy and Science*, and pages overflowing with—get ready—epistemology?

You'd first have to recognize that holistic medicine has an epistemology problem. Which it does. And this not an academic matter—it has very real, practical implications for practitioners and patients alike.

In its simplest definition, epistemology is concerned with the origins, nature, and limitations of knowledge. In short, it's about how we know what we think we know. When it comes to many facets of holistic medicine, this is not such a simple question.

The epistemology crisis came to light last November, when the Federal Trade Commission (FTC) announced plans to hold homeopathic products to the same standards of scientific evidence as other products (ie. pharmaceuticals) making similar claims.

The FTC contends that for the vast majority of OTC homeopathics, "the case for efficacy is based solely on traditional homeopathic theories [from the 1700s] and there are no valid studies using current scientific methods showing the product's efficacy."

The latter clause echoes a statement on the National Center for Complementary and Integrative Health (NCCIH) website saying that there is little evidence to support homeopathy as an effective treatment for any specific condition.

Neither the FTC nor the NCCIH mentions the 2011 Swiss Health Technology Assessment (HTA) report outlining 20 of 22 systematic reviews favoring homeopathy, and the 24 out of 29 studies showing strong evidence for effectiveness in treatment of upper respiratory tract infection and allergic reactions.

The Swiss HTA report specifically discredited an earlier disparaging report in *The Lancet* (Shang A, et al. *Lancet*. 2005; 366(9487): 726–732), and concluded that homeopathy as practiced in Switzerland is effective, safe and cost-effective, and led the Swiss government to include homeopathy on the list of services covered by the Swiss statutory health insurance scheme after a five-year trial period that began in 2012.

If the NCCIH takes a dim view on homeopathy, it is only slightly more accepting of Ayurveda. The NCCIH's website includes the statement: "Do not use Ayurvedic medicine to replace conventional care." This might as well be generalized to most if all Asian medical systems and practices (Chinese medicine, acupuncture, osteopathy, chiropractic, yoga, tai chi, chi-gong, etc.).

These are the very things that NCCIH is supposed to study. Since these forms of medicine generally involve non-patentable products and procedures, few other entities outside government institutions have the incentive or resources to undertake meaningful studies.

An Unreimbursed Netherworld

But, given the high price tag for trials, the anemic funding for institutes like NCCIH, and a new administration that's not likely to prioritize research on unpatentable medical alternatives, these modalities will not likely get any serious research attention in the future, and will remain forever marginalized.

Practitioners of these modalities are then relegated to a weakly reimbursable netherworld at the margins of healthcare—tolerated but always at the whim of capricious, overzealous watchdogs.

Mainstream medicine has a particular animus toward homeopathy, largely because it's purported mechanism seems implausible to a reductionist science that demands that all explanations of biological life—and ultimately of psychic life—be reduced to chemical reactions found in inert matter.

Francis Crick, of double-helix fame, summed it up in 1994: "You . . . are in fact no more than the behaviors of a vast assembly of nerve cells and their associated molecules . . . you're nothing but a pack of neurons" (Francis Crick. *The Astonishing Hypothesis. The Scientific Search for the Soul*. Simon & Schuster Ltd., London).

This view is hardly "holistic"; it is instead "part-istic"—or as we call it, *reductionist*, a view of life as assembled from below up.

More and more, the reductionist model is being contradicted from many quarters, from quantum physics to open systems biology. Current physics tells us that the "building blocks" with extension in space (protons, neutrons) turn out to be made of sub-particles (up- and down-quarks) without extension in space.

An October 2015 article by John Markoff in the *The New York Times* underscored this shift. The piece detailed a Delft University experiment providing, "the strongest evidence yet" to support *the collapse of the wave function*, and

the notion that, "matter does not take form until it is observed [or measured]."

Markoff goes on to say that particles can "exist simultaneously in two or more places. Once measured, however, they snap into a more classical reality, existing in only one place."

An Emergent World

The kickers here are twofold: first, our Cartesian world of sense is precipitated from an interconnected world of greater but not yet manifest possibility, and second, the precipitant is our own consciousness.

This represents a 180-degree turn away from Crick's "pack of neurons" picture. It suggests a choice: we can continue to assert a science that holds human understanding and consciousness to be an essentially irrelevant froth, an exudate of invisible molecular processes, or we can embrace one that recognizes them together as an evolving sense organ integral to the actual progress of the cosmos.

This latter choice doesn't abnegate the molecular processes, but it does expand the frame of our thinking to allow that causation may be rooted in something beyond the molecules.

This is the threshold of holistic medicine's epistemological crisis, and it's where a seemingly esoteric book like Heusser's *Anthroposophy and Science* becomes relevant.

Heusser who is director of the Centre for Integrative Medicine at the University of Witten/Herdecke, Germany, is one of the world's leading scholars of anthroposophic medicine in its theoretical aspects as well as its clinical application.

In the book, Heusser clearly states that matter is not exactly "made up of parts." Rather, the things we see as parts, when chemically combined, become "sublated" or submerged into a *new whole*. From this viewpoint, water is an *emergent* phenomenon that is as *elementary as hydrogen or oxygen*.

While hydrogen and oxygen are conditionally necessary for water, they are not causal, and once combined as water, they lose the individual qualities of hydrogen and oxygen. Moreover, the qualities and behaviors of water cannot be predicted from the qualities of oxygen and hydrogen taken by themselves.

"For every quantum," Heusser writes, "there is a quale," a perceived quality that is as essential as any part that is mathematically quantifiable. This aspect of *emergence of new entities that are as primary as the components associated with their arising* applies upward from cell to tissue, from tissue to organ, from organ to organism and to individualized being. At each level "all of these have their laws," Dr. Heusser states.

A medical science that works with these laws, he recognizes, needs rigor and discipline every bit as much as a science that restricts itself to the mathematical and statistical.

Dr. Heusser explores in detail the problems inherent to clinical trials of integrative modalities such as homeopathy. Truly treating the whole patient, he asserts, calls for a still objective but "cognition-based medicine" that encompasses the realities and subtleties of the individual patient as well as the elements revealed through an "evidence-based medicine."

One of the unexpected and somewhat unwelcome children of post-quantum physics is the recognition that we, the world, and our cognition of it, are intimately and causally linked.

That is a lot to take in. In a sense it is a reversal of an intellectual and scientific movement that began in the 1600s with Francis Bacon's experimental inductive methods and the attempt to exclude subjectivity from science. This movement gained momentum with John Locke's emphasis on the primary sensory qualities of outer things. In short, the history of Western medical science has been governed by the belief that the quantitative is inherently more valid than the qualitative.

As Heusser clearly explains, modern physics is upending this longstanding invalidation of the qualitative. It urges medical science to take an evolutionary step and turn much more of its vast powers toward truly investigating "holism," the reality of organisms, their identities, and their interrelated systems as they affect health, illness and healing.

Anthroposophy and Science (An Introduction) surveys the development of western understanding of knowledge as it has informed science and medicine.

Rudolf Steiner (1861–1925), anthroposophy's founder, was trained as a scientist, and allowed only qualified MDs into his medical courses. Steiner asked always for disciplined observation and verification. On that foundation, he wished medical professionals to expand their understanding and perceptual capacities, and as clinicians to adopt a holistic and more nuanced view of factors affecting health, illness and healing.

Peter Heusser's narrative is thorough, clear, sometimes challenging, and often thrilling in its syntheses. As complementary/integrative practices step further out of the shadows, practitioners will be called upon increasingly to represent what they do in the face of both honest inquiry and fierce antagonism. *Anthroposophy and Science (An Introduction)* offers bedrock support. ☺

Trump Era

cont'd from page 2

HSA expansion as a good thing for the profession.

But a complete repeal would kill Section 2706—the much-praised "Non-Discrimination in Healthcare" provision that obliges insurers to reimburse all categories of licensed practitioners of a given service if that service is within a practitioner's legally-recognized scope.

Under the law insurers are supposed to reimburse licensed naturopaths for primary care. Though implementation of Section 2706 has been inconsistent, it has expanded ND reimbursement in some states. Most AANP members, Jawer says, would hate to lose it.

Despite its "liberal" public persona, the naturopathic profession is actually quite diverse politically, says Jawer. Though many NDs might disdain Trump's autocratic style, AANP hopes to tap the iconoclastic spirit that got Trump elected.

"Our profession is very much in synch with what seems to be a lesson from the campaign: people want non-conventional solutions. That's exactly what naturopaths are trained in—alternatives to Big Pharma and Big Medicine."

The Affordable Care Act—and its possible demise—is only one factor affecting American healthcare, albeit a big one. There are many other ways in which the new administration could affect the clinical landscape.

The Future of FDA & EPA: Given the GOP's extreme contempt for regulation, it is possible we'll see major alterations at the Food and

Drug Administration—which Trump demeans as, "the food police."

The White House has been short on specifics, but their top pick to head FDA is Jim O'Neill, a libertarian who runs Trump donor Peter Theil's Mithril Capital Management, and who advocates for Seasteading—the construction of ocean-based utopias beyond federal reach.

Lauded by many in the investment and biotech sectors, O'Neill detests FDA's status quo, believing that its burdensome rules block innovation and kill people.

O'Neill's a strong supporter of the "right to try," which would take FDA out of determining drug and device efficacy, and limit it to ensuring minimum safety. The free market, says O'Neill, is the best arbiter of efficacy.

Holistic medicine has had a long, contentious relationship with the FDA. No doubt many in the field won't mind seeing the agency castrated. Supplement industry executives are hoping for a less restrictive, more business-friendly atmosphere under Trump's FDA.

But deregulation could have serious blowback. In the void of a weakened FDA, state Attorneys General as well as plaintiffs lawyers could opt to pick up the slack, mirroring the industry in countless lawsuits. And the troubling flow of spiked, contaminated, poorly made products already tainting the market could become a torrent in a deregulated environment.

But people might not notice toxins in their supplements if the Trump administration gets its way and obliterates the Environmental Protection Agency. The amount of toxins in the air, water and food supply—already a major driver of chronic disease—will no doubt increase.

Vaccine Policy: Trump's assertions that vaccines can cause autism and his promise to create a review committee headed by liberal icon and vaccine critic Robert Kennedy, drew applause from many in holistic medicine. (See "Vaccine Debate Rages Over Trump, Kennedy & the Cleveland Clinic," front page.) They see it as an indicator of his willingness to challenge medical orthodoxy.

Others see it as anti-science, likening it to his climate change denial, his willingness to censor scientists, and his propensity for making up stats about everything from his inaugural audience to the incidence of terrorism.

It remains to be seen whether the president's anti-establishment stance on vaccines comes from genuine open-mindedness or ignorance.

Trump's Supplement Blunder: In 2009, Trump licensed his brand to Ideal Health, a multi-level vitamin company. With Trump himself fronting the launch, this new "Trump Network" usurped concepts from personalized medicine to sell "customized wellness" protocols guided by an unverified, proprietary urine test. More than 20,000 independent sellers paid to join the network and sell the kits.

As reported by STATNews, the company was initially successful with annual growth of 300% in the first years. But management got sloppy, stopped paying commission checks, and the network tanked. Trump's licensing agreement ended in 2011 and was not renewed.

Trump is not the only GOP heavyweight to dabble with supplements. Dr. Ben Carson, the nominee to head Housing & Urban Development, has been a paid speaker for Mannatech, one of the largest multi-level supplement companies.

Arkansas governor Mike Huckabee starred in infomercials promoting a "Diabetes Solution Kit" that promised to spare people from becoming, "loyal pill-popping, finger-pricking, insulin-shooting" customers of Big Pharma.

MACRA & MIPS Here to Stay: Physicians hoping that a Trump presidency means elimination of value-based payment systems will probably be disappointed, say DC healthcare insiders. Short of a GOP move to destroy Medicare and Medicaid—which no one has proposed so far—MACRA and MIPS will continue to roll out.

Both programs have broad bipartisan support. Republicans—even hardliners like Tom Price—have gotten behind value-based reimbursement, at least in principle. MIPS and MACRA are independent of the Affordable Care Act, and would not be directly affected even if the new administration does vanquish Obamacare.

The truth is, healthcare is as much of a political minefield for Republicans as it was for the Democrats. Beyond the name "Obamacare," what Trump supporters generally dislike are the individual mandates, the taxes, the limitations on choice of practitioners, the rising out of pocket costs, and the "surprise" medical bills. Nobody likes these things.

But they're not going to be easy to fix—from the Left or the Right—so long as we have an insurance-dominated system, an aging population, and staggering burdens of chronic disease.

As Thomas Miller, JD, senior healthcare analyst from The American Enterprise Institute, put it, "The Democrats have had 8 years to screw up healthcare, and now it is the Republicans' turn." ☺



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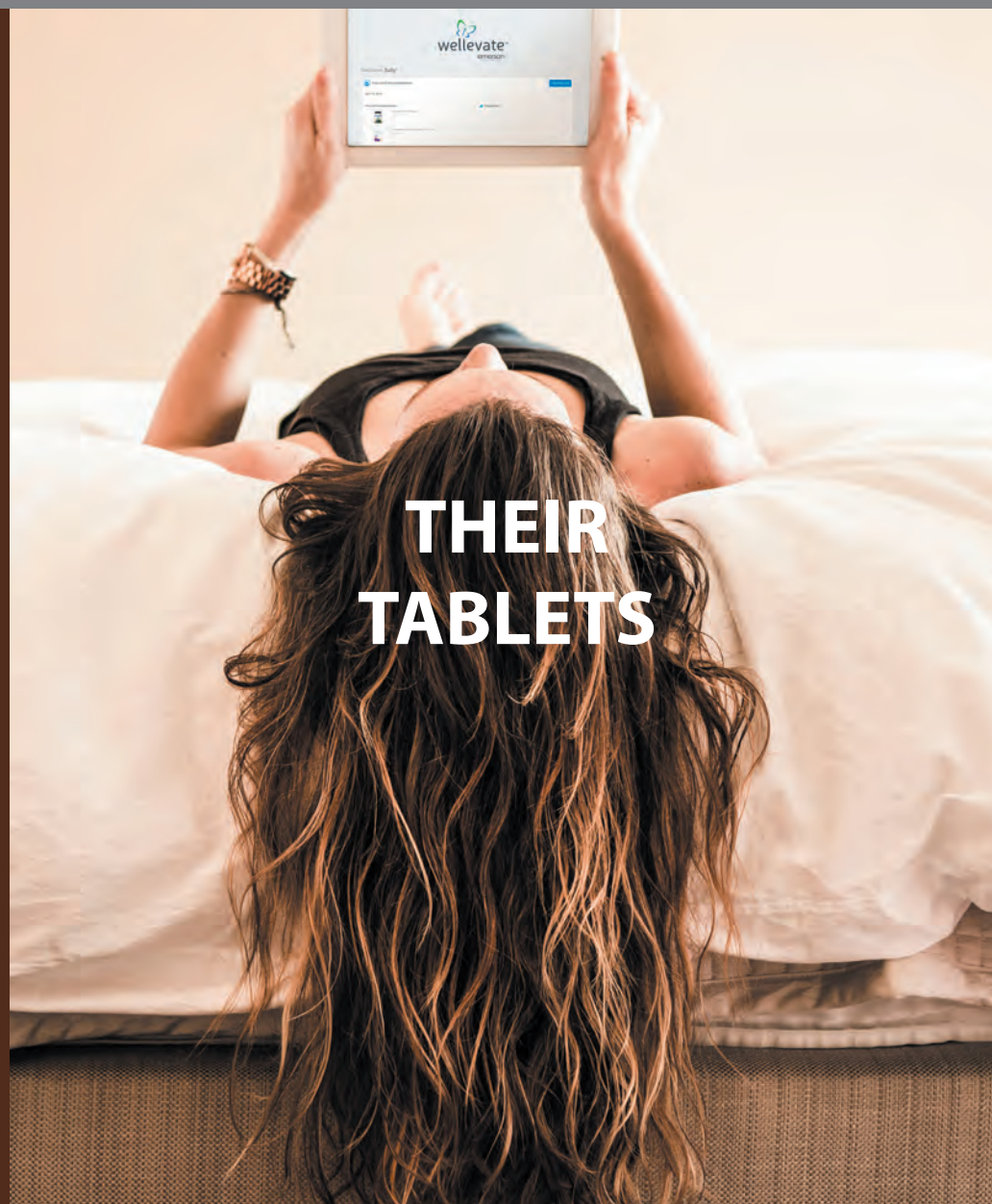
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