Holistic Primary Care

Heal Thy Practice 2015 Sneak Peek INSIDE!

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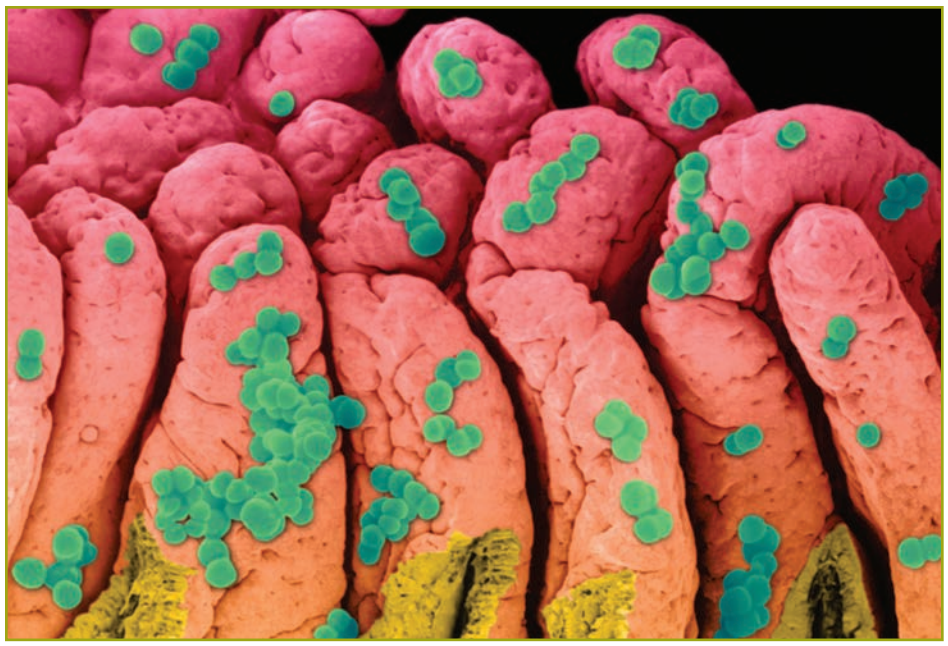

STAPHYLOCOCCUS AUREUS ON THE SURFACE OF THE SMALL INTESTINAL MUCOSA. THE GUT MICROBIOME IS AN EXTREMELY COMPLEX ECOSYSTEM AFFECTING MANY ASPECTS OF HUMAN PHYSIOLOGY. THE INFLUENCE OF ANY ONE MICROORGANISM DEPENDS HIGHLY ON ITS RELATIONSHIP TO OTHER SPECIES AND ON WHERE IT IS IN THE GI TRACT. A HARMLESS BUG AT ONE ANATOMIC SITE MAY PROVE PROBLEMATIC IN OTHER SITES.

Image courtesy of Dennis Kunkel Microscopy / Corbis

NEWS & POLICY

AG Action Triggers New Wave of Supplement Scrutiny

BY AUGUST WEST
Contributing Writer

New York Attorney General Eric Schneiderman's crusade against herbal products earlier this year has triggered a number of state and federal moves that could significantly change the way dietary supplements are regulated.

The supplement industry has come under increasing scrutiny at both the state and federal levels since February, when Schneiderman's office ordered four major retailers—Walmart, Walgreen's, Target, and GNC—to stop selling what the AG deemed fraudulent store-brand herbal products.

The move set off a firestorm of scientific controversy over the validity of DNA barcoding for identifying herbal extracts. (visit www.holisticprimarycare.net and read "NY Attorney General Assails Herbal Medicine") In the policy arena, it sparked a spate of local and national calls for overhaul of regulations now governing supplements.

Thought leaders in the supplement industry and in natural medicine say the entire field is coming under increased regulatory oversight, and most believe the pressure will only increase in the coming months.

Among the significant developments since February 2:

- **GNC Reaches Agreement with AG's Office:** On March 25, GNC agreed to provide Schneiderman's office with twice-yearly DNA barcode data on all botanical raw materials in its HerbalPlus line for a 36-month period, effective Fall 2016. The company also agreed to test for the 8 most common food allergens defined by the FDA, and to deploy in-store signage explaining the difference between whole plants and plant extracts.

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INSIDE

DIGESTIVE HEALTH

Making Clinical Sense of the Microbiome

BY ERIK GOLDMAN
Editor in Chief

It's "the greatest turnaround in science and medicine in the last 150 years," says Raphael Kellman, MD, of the current microbiome revolution.

The recent shift from a view that bacteria are our worst enemies to one that sees microbes as our most important allies in health "is opening a new chapter in medicine," says Dr. Kellman, an internist and functional medicine practitioner in New York City.

Of course, the core concepts in this "new" chapter are not really all that new!

Hearken back to 1907, when Benedict Lust—widely recognized as the father of naturopathic medicine—said the following: "We believe that germs and microbes should be looked upon as beneficent workers instead of enemies to human health."

What *is* new is our ability to plumb the mysteries of the microbiome with sophisticated scientific tools, and to discover the myriad ways in which prokaryotic organisms influence and regulate (dare we say control?) human physiology and behavior.

The microbiome is no longer a fringe concern. It's gone mainstream. Last year, an article in the *Mayo Clinic Proceedings* predicted that "In a short time understanding the basic concepts about the interactions between humans and their microbiomes will be as important to clinicians as understanding concepts of genetics or germ theory" (Khanna S, et al. *Mayo Clin Proceed.* 2014; 89(1): 107–114).

When Zeal Overtakes Reason

New microbiome information is emerging at such a rapid clip that few can keep up. Ninety percent of the roughly 4,000 microbiome articles now on PubMed were only published within the last 5 years!

As in all revolutions, zeal sometimes overtakes reason. Over-simplification of the complex relationships between man and microbes is leading many clinicians and patients to intervene in ways that far exceed our actual scientific understanding.

Wanton use of probiotics is one example. Many people are using probiotic supplements indiscriminately. That, says Dr. Kellman, isn't such a good idea.

He stressed that probiotics are an important piece of the gut health equation. But in the absence of a comprehensive approach aimed at eliminating unfriendly organisms, improving diet and lifestyle, rebuilding damaged GI mucosa, and eliminating food triggers, they are unlikely to be effective.

The challenge for clinicians today is how to synthesize the wealth of new microbiome information into truly effective therapeutic strategies.

see ***Microbiome*** p. 9

HERBAL MEDICINE

NIH Center to Confront Fears of Herb–Drug Interactions

BY JANET GULLAND
Editor in Chief

Misplaced fear about herb–drug interactions is keeping many practitioners from recommending potentially beneficial botanical medicines, said Josephine Briggs, MD, director of the NIH's National Center for Complementary and Integrative Health (NCCIH).

Speaking at the annual meeting of the American Herbal Products Association earlier this year, Dr. Briggs said NCCIH (formerly known as the National Center for Complementary & Alternative Medicine) is launching a major initiative to re-evaluate herb–drug interactions. The new center will develop "rigorous standards for herb–drug interaction testing."

Clinicians' apprehensions are largely unfounded, she said. "Most interactions identified in current resources are hypothetical, inferred from animal studies, cellular assays or other indirect means. Concern is often poorly founded, not based on rigorous studies."

The new project will begin by studying test cases of five widely used herbal products and their interaction with five common meds, and then to begin to establish clinically validated criteria for identifying and quantifying interactions.

Dr. Briggs, a nephrologist, believes clinical judgment about herbs is clouded by significant, unexamined biases.

Unexamined Biases

"There are 11 major drug interactions with coffee, yet doctors don't tell patients not to drink coffee based on possible interactions! A lot of the fears about herbs are not founded

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Scrutiny

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On reaching the agreement, the AG's office permitted GNC to resume selling the products held back by the initial cease-and-desist—a move indicating that there was never anything fraudulent about these products in the first place.

- **14 State AGs Call on Congress to Increase FDA Oversight:** On April 2, AGs in 12 other states (CT, DC, HI, ID, IN, IA, KY, MA, MS, NH, PA, RI) plus the Mariana Islands joined the New York AG in signing a joint letter to 4 US Congressional committees urging legislators to give the FDA more oversight authority over herbs, and by extension, all supplements.

  The AGs called on congress to review the adequacy of existing quality assurance measures, the measures used for verifying identity and purity, the degree to which marketers are using terms like "natural" and "herbal" in a misleading manner, the need for further federal mandates on dietary supplement quality, and the need to develop new raw materials management requirements.
- **Senate Democrats Urge FTC to Investigate BMPEA:** Also in April, Senators Richard Blumenthal (D-CT) and Dick Durbin (D-IL) pushed the Federal Trade Commission to investigate products marketed as herbal supplements for weight loss that contain β-Methylphenethylamine (BMPEA), a synthetic stimulant. According to a recent FDA report, 52% of retail products labeled as containing *Acacia rigidula* (an adrenergic herb) are spiked with BMPEA. Sens. Durbin and Blumenthal claim that some supplement makers are deliberately mislabeling these products and using deceptive advertising to sell them.
- **Class Action Attorneys Meet to Develop Strategies:** A host of individual class action lawsuits emerged in district courts within weeks of Schneiderman's initial action. On May 27, hundreds of plaintiffs attorneys from across the country met in Minneapolis for a law conference devoted specifically to strategies for mounting class actions based on the New York AG's precedent.
- **FDA Rethinks Homeopathy Regulations:** At the end of April, FDA's Center for Drug Evaluation & Research held a two-day "information-seeking" hearing on the use of homeopathic products, in preparation for a re-think of the regulatory framework governing the manufacture and marketing of these increasingly popular remedies. Though officials have been mum on what potential revisions may be considered, this is the first time the agency has looked at homeopathy in nearly 30 years.
- **Top FDA Official Nods Consent to AG Actions:** "GMP standards are minimal standards. Anything over and above what industry might want to set up, or the states might want to undertake, if it strengthens the industry we are all for that," said Cara Welch, director of the FDA's Division of Dietary Supplements. Speaking at the recent International Conference on the Science of Botanicals, Welch indicated that FDA does not see Schneiderman's actions as an overstep of authority or a breach of FDA jurisdiction.

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So far, all of the regulatory attention and negative media have been trained on botanical supplements sold in retail channels, though the language of both the consumer media coverage and the state and federal demands for greater regulation are clearly inclusive of supplements in general.

While practitioner-focused brands have not been implicated so far, there's no reason to believe practitioner lines will avoid scrutiny indefinitely.

A Chaotic Patchwork

Jeff Bland, PhD, a founder of the *Institute for Functional Medicine,* as well as one of the original founders of nutraceutical giant Metagenics, said he is particularly concerned about precedents set by Schneiderman's action.

Though scientific questions about DNA barcoding in the context of herbal medicine remain wide open, and though the AG's office ultimately agreed that GNC's products were not fraudulent, Dr. Bland says the allegations and the subsequent GNC agreement, "set up *de facto* standard for all types of class action suits for hungry lawyers to bring all kinds of lawsuits against the industry."

Other industry-watchers say the individual actions of various state AGs could result in a chaotic patchwork of state-by-state regulations and analytic standards that would make it extremely difficult for supplement makers to comply.

According to Mark Blumenthal, of the American Botanical Council, there is a grave danger in allowing state attorneys general to set standards for something like analytical methodologies. These, he says, are scientific questions, not political or legal ones.

"Is the AG trying to dictate authentication methods? A single state stipulating issues that could lead to a patchwork quilt of regulatory standards . . . is not in the interest of industry or consumers."

Loren Israelsen, President of the United Natural Products Alliance, an industry group, agreed.

"AGs are the ranking law enforcement officer of the respective states. Their jobs are to enforce the law. They are now getting into the policy business. This letter (to Congress) is directly related to policy considerations. They discuss and agree among themselves what the policy should be, and then they will go and enforce the policy they set. Instead of having federally mandated policy coming from Congress to FDA or USDA or FTC, this is a completely new and different mandate coming from law enforcement agencies in the states."

Israelsen added that "Our sense is that congress has not responded favorably" to the letter issued by the 14 state AGs.

"Congress has other fish to fry, and that's good news for the moment. But as the AGs drive this further, other states may join on board, not wanting to buck the trend."

A Contentious Agreement

GNC took considerable flack from many in the industry for consenting to monitoring by the AG's office, and for accepting DNA barcoding as a valid method for confirming plant identity.

An attorney who worked closely with GNC on the agreement, stressed that the agreement to use DNA barcoding applies only to botanical raw materials, not to final extracts. In the context of raw materials analysis, DNA barcoding is one among a number of valid methods of identification.

He also stressed that the terms of the agreement are narrower than they might seem on first glance. "The agreement recognizes that some barcodes may not exist. If you read the agreement in its full context, you'll see there's no way to implement DNA barcoding unless there's a valid scientific method for doing so. For many herbs there is not."

GNC, a publicly traded company, was "situated very differently," than the three other retailers implicated by the New York AG.

Whereas the herbal issue is a very small part of business for Walmart and the others, for GNC it is significant. GNC also makes all of its own products. The other retailers use contract manufacturers. So GNC had to take this much more seriously. They were also more in position to pull together the relevant records."

So far, none of the other three retailers have come to any terms with Schneiderman's office.

By consenting to allow the products in question back on the shelves, the AGs office as much as admitted that its original allegations were not scientifically founded in the first place.

By agreeing to allow the products in question back on the shelves, the AG's office as much as admitted that its original allegations were not scientifically founded in the first place.

Supply Chain Integrity

Most thought leaders in the supplement industry recognize that there are gaps in quality control, particularly with regard to the raw materials supply chain. Under current regulations, finished product manufacturers must comply with the Dietary Supplement Health & Education Act (DSHEA) of 1994 and with the good manufacturing practices (GMPs) defined by the FDA.

The big issue, say many in the field, is that suppliers of raw materials are not required to comply with these existing regulations, meaning that it falls to manufacturers to police their suppliers.

Karen Howard, executive director of the newly formed Organic & Natural Health Association recently met with AG Schneiderman's staff to discuss a potential solution to this problem: a mandate to require that all dietary ingredient suppliers to comply with current GMPs, and to clarify the regulatory responsibilities of private label supplement distributors.

The non-partisan group, which represents consumers, practitioners and members of industry, recently filed a citizens petition to the FDA detailing this request.

Howard believes such a move is critical for strengthening the integrity of the supply chain and eliminating many of the quality gaps for which the supplement industry is routinely criticized.

"If you're a vertically integrated company, you control your supply from the source. If you are not, there is all sorts of room for breaches of integrity." She acknowledged that if raw materials were covered under existing laws it could add some cost to the production of supplement products. On the other hand, it would very likely drive out unethical, fly-by-night players and would raise the overall integrity of the industry.

Open Dialog

Many in the industry view the New York AG's actions as a purely political maneuver designed to generate a lot of media attention for Schneiderman—which it did.

After meeting with his staff, however, Ms. Howard came away believing there's more to it.

"I think they are genuine in their consumer protection intentions," she told *Holistic Primary Care*. "They are well schooled on our issues, and they are not being disingenuous. I think it behooves industry to be respectful, even in situations where we know we will disagree. It is always better to keep an open dialog in a situation where there's room for honest disagreement and an opportunity to educate. It may not mean you'll get your desired outcome. But you will surely not get anywhere by being in opposition."

Absence of Clinical Voices

Organizations representing holistic and natural medicine practitioners have been noticeably silent about the recent round of regulatory sword-rattling. Perhaps this is because so far no practitioner brands have been implicated in any of the allegations. But any major shift in regulation of supplements could affect practitioners who routinely dispense or recommend them as part of patient care.

Holistic Primary Care's 2015 survey of more than 650 practitioners indicates that while many clinicians recognize that the existing regulatory framework is far from perfect, the majority is highly confident in the quality and integrity of practitioner channel brands.

The survey, fielded just six weeks after the New York AG's initial actions, included this question: *"Over the last year, what net effect has the published research & media coverage on nutrition, dietary supplements & natural products had on your practice patterns?"*

Nearly half (49%) reported being more confident in using supplements, 6% reported being less confident, and 45% said their confidence has not changed one way or the other.

When asked to rate the ability of the current regulations to ensure quality and safety of supplements, 17% said the existing rules are fully adequate and 48% said the rules would be adequate if properly enforced, while 35% saw them as totally inadequate and in need of a complete overhaul.

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† Dyerberg J, *et al.* Bioavailability of marine n-3 fatty acid formulations. *Prostaglandins Leukot Essent Fatty Acids* 2010 Sep;83(3):137–141.

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

Testing Takes Guesswork Out of Omega-3 Supplementation

By Janet Gulland
Contributing Writer

For many practitioners, omega-3 fatty acids are a standard part of patient care, especially when working with people at high risk of heart disease or inflammatory conditions like arthritis or chronic pain.

Holistic Primary Care's 2015 practitioner survey, which drew responses from over 650 clinicians, showed that 81% of those who routinely recommend supplements are recommending omega-3s.

Yet the vast majority takes a very broad-stroke approach.

Most practitioners base recommendations on general population guidelines like those laid out by the Dietary Reference Intakes or by organizations like the American Heart Association (AHA).

Others simply tell people to take omega-3s, and leave patients on their own to follow "serving size" recommendations on the product labels.

Either way, both practitioner and patient are flying blindly, and patients may not be getting the actual benefits of omega-3 supplementation simply because they're not taking enough.

That's unfortunate because it is easy and relatively inexpensive to test omega-3 levels in blood and tissue, and to then tailor supplementation to each patient's actual needs, based on objective measurements.

"Standard" Doesn't Mean Adequate

One could argue that there's no such thing as a "standard" dose of omega-3s guaranteed to be effective for all people. People show variability in how people digest, absorb, transport and integrate fatty acids. A number of studies have shown that the same daily dose of combined DHA and EPA results in widely divergent blood and tissue levels.

In one such study of 30 cardiac patients, a 1,000 mg daily dose of EPA/DHA (the AHA's recommended level for people with coronary artery disease) resulted in Omega-3 Index measures ranging from 4.3% to 11.2%.

The Omega-3 Index, developed by William Harris, PhD, indicates the amount of DHA and EPA incorporated into red blood cell membranes, expressed as percentage of total membrane fatty acids. It tells a lot about tissue uptake of omega-3s, correlates strongly with CVD risk, and is an important factor in considering risk reduction.

According to Harris' research, the Omega-3 Index target value is around 8%. Measurements up over 10% are highly cardioprotective; levels below 8% correlate with increased risk.

To put it in perspective, the "typical" American eating a diet low in fish and plant-based foods but high in saturated fats, refined carbs, and processed foods has an Omega-3 Index of around 4–5%.

In Harris' studies, 60% of the CVD patients on 1,000 mg of EPA/DHA failed to reach 8%. Only about 20% got up over the 8% threshold and into the really healthy zone.

Tissue Is the Issue

"The tissue is the issue," says Doug Bibus, PhD, paraphrasing Bill Lands, the pioneering biochemist who first discovered the relationship between omega-3s and omega-6s, and the role of omega-3s in improving human health.

"It's not what you put in your mouth that really matters. It's what gets into the blood, and ultimately into the tissue, that matters," Dr. Bibus told *Holistic Primary Care*.

The wide variability in individual response to a given dose of omega-3s goes a long way in explaining the divergent messages that have come from large omega-3 clinical trials.

> **"It's not what you put in your mouth that really matters. It's what gets into the blood, and ultimately into the tissue, that matters."**
>
> ***—Doug Bibus, PhD***

"In the big CVD studies of late, not all of them actually measured fatty acids," said Dr. Bibus. "They were giving about 1 gram a day in those studies. There wasn't a whole lot done to measure compliance. For many people, 1,000 mg of EPA/DHA per day won't put you into the recommended blood levels."

That's important to consider when reading and interpreting the trials. Without baseline and post-intervention fatty acid measures, there's no way of knowing whether the omega-3 doses were adequate or continued long enough to bring blood and tissue levels up to the point where actual clinical benefit could be expected.

Testing in the Clinical Setting

In patients with clear cardiovascular risk, or signs of other inflammation-related disease, it makes a lot of clinical sense to test, said Dr. Bibus, who worked closely for many years with Dr. Ralph Holman, the University of Minnesota biochemist who coined the term "Omega-3," and who laid the groundwork for subsequent research in this field.

Dr. Bibus now heads a company called *Lipid Technologies* (www.lipidlab.com) that leverages more than 60 years of analytical chemistry experience for clinical as well as research applications.

Lipid Technologies has translated Dr. Holman's decades of work in fatty acid analysis into a simple finger-stick bloodspot test that can provide clinicians with a wealth of information about a patient's actual fatty acid profile.

The Holman Bloodspot Test provides:

- Total omega-3 score based on circulating blood levels
- Omega-6 levels
- Omega-3 as percentage of total highly-unsaturated fatty acids (HUFA)—the so-called "Lands Test"
- Omega-3 Index
- Arachidonic acid to EPA ratio (indicator of inflammation)

Dr. Bibus explained that each of these tests, while useful, has limitations on its own.

For example, the Omega-3 Index tells you about incorporation of omega-3s into cell membranes, but does not give any indicators about omega-6 or arachidonic acid—two key players in chronic inflammation.

Likewise, it does not tell anything about docosapentaenoic acid (DPA), an important predictor for CVD risk.

DPA: The Unknown Omega

The importance of DPA was underscored in a nested case control study of 6,438 adults. Among them, there were 94 heart attacks within a 7-year period. DPA was highly predictive of heart attack risk (low levels confer greatest risk). In fact, it was actually more predictive than EPA and ALA (Simon JA, et al. *Am J Epidem.* 1995; 142(5): 469–476).

DPA may serve as a reservoir of EPA and DHA. It is structurally similar to both, and very slowly oxidized. It may be present in human blood at twice the level of EPA and half the level of DHA in non-supplemented individuals. DPA inhibits platelet aggregation more efficiently than EPA or DHA, and stimulates endothelial cell migration more efficiently than EPA. Available research suggests DPA is both anti-inflammatory and neuroprotective.

Though the story on DPA is still in an early stage, it appears to be an important piece of the essential fatty acid puzzle, one worthy of greater clinical attention.

Eliminating Guesswork

Without testing, omega-3 supplementation is largely a game of guesswork: you make a recommendation, then hope that the patient will comply and that the recommended dose will confer the expected benefit.

Testing enables you to give much more intelligent and personalized guidance. Plus, it's inexpensive! The comprehensive omega-3 test costs under $100, usually as low as $70. There is even a CPT code for it (82544—EFA testing). Insurers' willingness to pay varies widely, but this is technically a billable service.

Years ago, Dr. Lands worked out a series of equations to guide supplementation based on baseline omega-3 percentages.

- If someone scores below 30% (of total HUFA as omega-3), the suggested daily dose is 2–3 g/day of EPA/DHA.
- If someone's in the 30–40% range, 1–2 g usually suffices.
- If they're in the 40–50% range, a 0.5–1.0 g dose is fine.

Without knowing someone's baseline values, you really don't know how much to recommend.

"The reality is, for many people at the low end of the omega spectrum, 300 mg per day isn't going to cut it. Even 1,000 mg is going to be too low. You need 2,000–3,000, or even more, to get levels up to where you want them," said Dr. Bibus.

He added that even at the topmost end of Lands' dosing guidelines, one is still well within recognized safety ranges. For example, according to the European Food Safety Authority's most recent guidelines (2012):

> *"Long-term supplemental intakes of EPA and DHA combined up to about 5 g/day do not appear to increase the risk of spontaneous bleeding episodes or bleeding complications, or affect glucose homeostasis, immune function, or lipid peroxidation, provided the oxidative stability . . . is guaranteed."*

Is it possible to obtain a truly healthy omega profile without supplementation? Yes, says Dr. Bibus, provided you love to eat fish.

He noted that his mentor, Dr. Holman, religiously ate two cans of sardines with two cups worth of mixed green vegetables every day. He lived to be 94 years of age, in good health, and at last measurement he had more omega-3 in his blood than omega-6.

Lipid Technologies has partnered with Nordic Naturals to familiarize more clinicians with the value of omega-3 testing by providing two free Holman Bloodspot Tests per year for practitioners and staff. To learn more, visit: lipidlab.com/get-test.

NIH Confronts Fears

cont'd from page 1

on good meaningful accurate data. The aim of our new center is to help determine which interactions are really significant and require attention and which are not."

Many physicians wring their hands when patients mention that they're taking—or even considering—a botanical in conjunction with drug therapies. Yet, many patients "are on 10 active pharmaceuticals and the potential for drug–drug interactions is so enormous that the minor agents in dietary supplements are unlikely to change that."

Dr. Briggs voiced irony that many in the medical community are quick to vilify herbal medicine, while turning a blind eye to what she sees as two of the most pressing public health issues: prescription opioid addiction and antibiotic overuse. (For one physician's answer to the overuse issue, visit www.holisticprimarycare.net and read "What to Do When Patients Demand Unnecessary Antibiotics.").

Clear Need for Alternatives

"Every time I open the paper, I see stories on overuse of psychoactive drugs . . . for pain, for sleep, for common colds." According to CDC data, recorded death rates from cocaine and heroin have been more or less stable over the last decade, while deaths from prescription opioids have soared, from 4,000 in 1999 to over 16,000 in 2010. Newer data are consistent with this, she said.

"I am ashamed of the medical profession in this regard. The overuse and inappropriate use of opioids is incredibly shocking. In certain communities drug-related deaths are exceeding motor vehicle fatalities."

"There are 11 major drug interactions with coffee, yet doctors don't tell patients not to drink coffee based on possible interactions!"
—Josephine Briggs, MD

She and her colleagues at NCCIH have been active in developing a framework for researching non-pharmaceutical alternatives for treating pain syndromes. She has also been working jointly with the Office of the Army Surgeon General on a Pain Management Task Force to implement non-drug pain treatments throughout the Department of Defense and the Veterans Health Administration.

While oxycontin and other opioids are a big culprit in the overuse epidemic, benzodiazepines and other psychoactive meds are also causing their share of problems.

"There are 50 million prescriptions for Xanax per year. In 2008, 12% of women at age 80 had a benzodiazepine, and for men it's about 6%, even though guidelines call for great caution in using these drugs for elders." Citing major sleep disturbances as a common and dangerous side effect, Dr. Briggs said that the need for safe and effective non-pharmaceutical sleep remedies is clear.

"We all have to learn together about alternatives to these drugs." To that end, NCCIH is working on an initiative on natural products and inflammatory pain. It will begin with rigorous basic research, then move into identification of strong biological signatures for naturally occurring substances that could be tested in clinical studies.

For further information on non-drug alternatives visit www.HolisticPrimaryCare.net:

- "Lavender: An Effective, Non-Pharm Alternative for Anxiety & Depression"
- "Nutritional Treatments for Insomnia"
- "To Sleep, Perchance to Heal: Managing Sleep Disorders Without Meds"

The antibiotic overuse problem is another one for which the natural medicine world might have good solutions. Currently, there are about 16 million Z-Pak prescriptions per year, mostly for colds and other conditions for which they are inappropriate.

Citing the book *Missing Microbes: How Overuse of Antibiotics Is Fueling Our Modern Plagues,* by Martin J. Blaser, MD, Dr. Briggs stressed that overuse carries massive risks not only because it promotes drug resistance and the evolution of superbugs, but also because it decimates the microbial diversity which is essential for good health.

"This is enormously relevant to natural products research," Dr. Briggs said. "It is a reasonable hypothesis that a lot of the variability we see in peoples' responses to various natural products has to do with variations in their microbiomes, and in concurrent use of antibiotics."

The Alkaline Way: Ten Tips for Reversing Metabolic Acidosis

By Russell Jaffe, MD
Contributing Writer

There's a lot of talk these days about following an "alkaline" diet as a way of restoring health and prolonging life. In principle a lot of the core ideas behind this approach make good physiological sense.

Yet many people who try to follow an "alkaline lifestyle" are doing so based on observations that may be true in test tubes yet not true in physiology, in life, in reality.

To make sensible lifestyle choices on this matter, it is important to understand a little bit about the chemistry and physiology of acid-base balance.

All metabolic, neurohormonal, and immune system processes produce a net excess of acids. When foods induce immune reactions, additional acids are produced that lead to mineral loss in the urine, sweat and stool.

Adaptive, acquired immune responses directly and indirectly generate substantial amounts of acidic products (Jaffe R. *Townsend Letter for Doctors and Patients.* 2009; 316: 90–98). In people with B cell and/or T cell immune reactions and impaired buffering capacity, it is important to identify the causes of immune reactions by avoidance provocation or *ex vivo* lymphocyte response assays (LRA).

Simply put, when cells are more alkaline, they are more tolerant, better able to detoxify, and more able to maintain a high energy potential (as indicated by an ATP:ADP ratio of 100:1). The question is how to effectively shift the cellular milieu toward greater alkalinity. To understand that, we need to consider how cells alkalinize.

It is minerals such as potassium and magnesium along with short/medium chain fats that counter this acidity and alkalinize the body. This is mission-critical for cellular health.

Metabolic acidosis results when potassium and magnesium levels are too low to neutralize the normal production of acidic byproducts of metabolism. This impairs the body's protective physiologic mechanisms so toxins are more likely to harm and less likely to be effectively removed.

Another consequence is that metabolic acidosis burdens the cell battery that depends upon a proton gradient to eliminate excess acid and export ATP.

Latent Mg Deficiency

Many people are walking around in states of "chronic latent magnesium deficiency" or CLMD (Elin RJ. *Magnesium Research.* 2011; 24(4): 225–227). This is defined as being in the lower half of the usual serum magnesium range. It won't show up with red sirens as a frank deficiency, but it does indicate reduced capacity to neutralize ordinary metabolic acidosis.

It is important to understand that blood (plasma) pH is highly conservative: it is one of the most tightly controlled of physiological parameters. The body has numerous mechanisms for keeping the plasma pH within a very tight range.

Inside cells, however, the situation is very different. There can be significant mineral starvation and substantial net acid excess long before it would ever show up as a critical illness and significant changes in blood pH.

Assessing Acid Status

In a previous issue of *Holistic Primary Care* (Spring 2009), we covered the value of first morning urine pH as a simple method to assess metabolic status and need for minerals. While some question the value of this test, we continue to find that after six or more hours of rest the high contrast Hydrion pH paper (with at test range of 5.5–8) provides a useful measure of net acid status.

A healthy after-rest urine pH is in the range of 6.5–7.5. The body routinely uses the overnight rest time to concentrate excess acids in the urine, and this capacity varies based on toxin loads and an individual's ability to make energy, detoxify toxins, and actively excrete them.

Too much acid in the urine after rest indicates mineral deficits in the cells.

The clinical challenge, of course, is how to get magnesium and other minerals into the body, how to get them into the cells, and how to get them to stay there.

What follows is a brief summary of a clinical approach to enhancing magnesium uptake and chaperoning its delivery to the cells, all in the interest of reversing or preventing CLMD and its downstream consequences. I've described this approach in depth in a new book called *The Joy of Eating: The Alkaline Way.* It is available at www.perque.com, www.elisaact.com or by calling 1.800.525.7372 or emailing clientservices@perque.com.

One key to this is to combine balanced, soluble magnesium salts with concurrent choline citrate in a nano-droplet form that is readily taken up by cells uptake and absorbed (Jaffe R. *Enhancement of Magnesium Uptake in Mammals.* US Patent #8017160). The choline and citrate forms are each beneficial in primary cell metabolism.

Acid or Alkaline: It's a Choice!

A metabolically alkaline diet includes foods that have a buffering, alkalinizing effect on cell chemistry (Budde RA, Crenshaw TD. *J Anim Sci. 2003; 81: 197–208).* This is often different from the food's ash residue or physical chemistry (Gonick HC, et al. *Am J Clin Nutr.* 1968; (21): 898–903). Failure to recognize this distinction has led to a lot of confusion both among clinicians and among people eager to follow an "alkaline" diet.

For example, citrus fruits are alkalinizing because the metabolism of citrate, malate, succinate, and fumarate generates more than twice as much bicarbonate buffer as there is acid in the food itself (Brown SE, Trivieri L. *The Acid Alkaline Food Guide: A Quick Reference to Foods & Their Effect on pH Levels.* Garden City Park, New York: Square One Publishers, 2006). This means that citrus fruit and similar foods are acidic in their food state, yet alkaline-forming in the body.

Dietary sugars and refined flours lacking the naturally occurring potassium and magnesium are arguably the single biggest triggers of repair-deficit inflammation (Tzanavari T, et al. *Curr Dir Autoimmun.* 2010; 11: 145–156). Diets high in dietary sugars, low in fiber, high in pro-inflammatory omega-6 edible oils (soybean, safflower, canola and corn oil) and lacking in anti-inflammatory omega-3s (fish oil, borage, flax seeds and purslane) result in net acid excesses that impair immune defense and repair functions.

The diet and lifestyle described in *The Alkaline Way* approach reverses excess cellular acid and improves energy production, while enhancing detoxification and intestinal repair.

Ten Alkaline Way *Tips*

1. **Water/Hydration:** Drink 2 or more quarts of pure, mineralized water daily. Many people add their daily mineral ascorbates to a quart or so of water in the morning and sip on it during the day. Alkaline, mineral-rich (i.e., "hard") water is best. Fresh lemon, lime, or other citrus juices added to water and herbal teas are also recommended to further your alkalinizing efforts. Warm, hot or room temperature beverages are better than cold ones. Iced beverages slow down and impair digestion. Water rather than bottled or canned sodas helps with weight management and restorative sleep.
2. **Breakfast is important! Listen to your body:** Find out which breakfast your body prefers. Some people do better with a large protein-rich breakfast; some do better with a smaller breakfast higher in complex carbs. Either way, breakfast is a very important meal.
   - Fruit and fruit smoothies
   - Eggs and other protein-rich foods
   - Granola or steel cut oatmeal as sources of complex carbs
3. **Lunch:** If a full or big breakfast works better for you, try a salad or soup and salad for lunch. If you prefer a smaller breakfast, make lunch your main meal of the day. Either way, set your work aside when you're eating, so that your brain can focus on the food, not the busy work.
4. **Dinner:** Eat lighter in the evening. If you are managing your weight, drink a glass of room temperature or warm water *before* the meal. Consider digestive bitters like *Campari* or *Underberg* to strengthen digestion. Include roasted or baked alkaline-rich foods like sweet potatoes, yams, lentils, beans, chickpeas, and other root vegetables like parsnips, rutabaga, turnips, and kohlrabi. Herbs, seasonings, and spices are also nutrient rich. *Avoid* those to which you are sensitive or reactive by LRA tests.
5. **Evening:** Drink little within a few hours of going to bed if you want to reduce the need to urinate during sleep time. Snack on a small amount of nuts, sprouts and dried fruit or raw vegetables (if needed).
6. **Snacks:** Snacking is OK, so long as the snacks are healthy and portions aren't excessive. *Nuts* (almonds, walnuts, flaxseeds, pumpkin seeds, and cashews), *dried fruit* (raisins, currents or dates), *sprouts,* and *seeds* provide a variety of healthier choices. Find the ones that you prefer and choose the highest quality, least processed (organic certified or biodynamic) available.
7. **Omega 3 and 9 oils:** Whole fish from deep cold water or wild, line-caught fish are recommended. Omega 3 fatty acids (EPA and DHA) supplements are often helpful along with CLA and omega 9 fatty acids. We only use fish oils distilled under nitrogen to protect the easily damaged fats and remove toxic minerals and solvents from the oils. Increase ascorbates to compensate for toxic minerals in fish and shellfish.
8. **Balance carbs, fats, protein, minerals, and fiber:** Whole organic or biodynamically grown foods provide a better balance of healthy carbs, fats, protein, nutrients and fiber. Green, cloudy extra virgin olive oil, organic coconut, ghee (clarified butter), almond, grape seed and organic peanut oil are recommended dietary and cooking oils. Consume lots of colorful, fully ripened, nutrient-rich and uncontaminated vegetables, fruits, seeds, sprouts, nuts, lentils, pulses and beans. Avoid added sugar. Sweeteners like organic evaporated cane juice, whole blue agave, rice bran, maple syrup, *gur* (jaggery), and maple flakes are acceptable if needed.
9. **Movement, mood and mobility:** What is used gets renewed; what is not used atrophies. Movement increases metabolism that helps burn calories more efficiently. We recommend slow stretches to explore your limits on rising and before bed. Active movement during the day is critical to maintaining skeletal, intestinal and cardiac muscle strength and coordination. Practice stress-busting active meditation or therapeutic biofeedback to quiet and help focus the mind on solutions rather than problems. Increase the activities you enjoy. Connect with and appreciate loved ones.
10. **Personal care:** Use baking soda and buffered ascorbates as a dentifrice in place of toothpaste. Use washing soda for laundry along with natural fragrant oils like lavender. Since hormone disrupters often find their way into personal care and cosmetic products, use organically certified products with ingredients whose names show they are from plants rather than artificially produced.

Got Fractures? Milk Raises Risk

By Kristen Schepker
Assistant Editor

From a young age, Americans are taught that milk is an essential component of a healthy, well-rounded diet. But new research on the long-term health effects of drinking dairy questions some age-old assumptions about milk's protective benefits.

A study published last fall in the *British Medical Journal* found a positive association between high milk intake and increased fracture incidence among women, contradicting the common understanding that dairy consumption reduces the risk of osteoporotic fractures. The study also revealed a correlation between high milk consumption and higher mortality among both men and women.

Conducted by researchers at Uppsala University in Sweden, the study examined milk intake in two large cohorts of Swedes across three counties. One cohort included 61,433 women between the ages of 39–74 years at baseline; the second included 45,339 men aged 45–79 years at baseline. Both groups completed food frequency questionnaires regarding their average consumption of common foods, including milk, fermented milk, yogurt, and cheese (Michaëlsson et al. *Brit Med J.* 2014; 349: 7981).

Within the female cohort, the researchers found that during a mean follow up of 20.1 years, 15,541 women had died and 17,252 had experienced a fracture, 4,259 of which were hip fractures. In the male cohort, a mean follow up of 11.2 years revealed 10,112 deaths and 5,066 fractures, with 1,166 hip fracture cases.

Women who drank three or more glasses of milk per day were found to die at nearly twice the rate of those who drank less than one glass a day, with an adjusted mortality hazard ratio of 1.93 (95% confidence interval 1.80 to 2.06).

The authors also concluded that higher milk consumption did not appear to reduce fracture risk among either women or men.

Increased Oxidative Stress

Significantly, they observed an additional positive association between high milk intake and increased levels of oxidative stress and inflammatory biomarkers. In subsamples of two additional cohorts, one male and the other female, urine 8-iso-PGF2α, a biomarker of oxidative stress, and serum interleukin 6, an inflammatory biomarker, increased with milk consumption.

They attribute this finding to the presence of the monosaccharide sugar D-galactose in dairy products. Milk is the primary dietary source of galactose, and consuming it either by injection or in the diet, the study notes, is an "established animal model of aging by induction of oxidative stress and inflammation."

Pros & Cons

The Swedish study is just one recent example of the conflicting data on milk's purported health benefits.

Milk is praised for its broad nutrient profile, which includes protein, carbohydrates, and—in some milk types—fat. It's also a convenient source of many essential vitamins and minerals, including phosphorus, potassium, calcium, and vitamin D.

Adequate calcium and vitamin D intake play key roles in bone growth and strength throughout all stages of development. Some researchers have argued that a focus on bone disease prevention should begin prenatally, promoting the maintenance of healthy calcium and vitamin D levels during early childhood in order to "maximize peak bone mass and to prevent osteoporosis-related bone disease in adulthood" (Sopher et al. *Cur Op Endo, Diab & Ob.* 2015; 22(1): 35–40).

While a significant body of research supports the notion that milk helps to promote bone growth and prevent osteoporotic fractures, it's also been shown that fracture rates among the elderly are significantly higher in countries with high calcium intake and high mean bone mineral density (BMD) than in countries with lower calcium intake and a low mean BMD (Klompmaker TR. *Med Hyp.* 2005; 65(3): 552–558).

In the US, the USDA recommends consuming two to three cups of dairy products per day, depending on one's age.

Milk and other dairy items have become many Americans' go-to source of calcium. From ubiquitous school cafeteria milk cartons to the FDA's former food pyramid and newer My Plate nutrition models, children and adults alike learn that milk is a necessary component of a well-balanced diet.

But what's often left out of the dominant conversation about milk is the fact that it's simply not good for everyone.

At birth, most people can readily digest lactose, the primary carbohydrate found in breast milk and an important source of nutrition during infancy. However, in most mammals, including humans, the natural production of lactase—the enzyme responsible for lactose digestion—decreases after weaning.

A Rare Trait

Some humans do continue to produce lactase into adulthood, a trait known as lactase persistence. But we haven't always possessed the ability to digest lactose as adults; rather, it's an adaptation we've developed in response to our ongoing consumption of non-human milk beyond infancy (Gerbault et al. *Philos Trans R Soc Lond B Biol Sci.* 2011; 366(1566): 863–877).

Lactase persistence is a relatively rare trait. An estimated 75% of the world's population eventually loses the ability to digest milk sugar and becomes lactose intolerant at some point in life (Mattar et al. *Clin Exp Gast.* 2012; 5: 113–121). Rates of lactose intolerance are even higher in countries with minimal milk intake.

Notably, humans are the only species that routinely consumes milk produced by other animals. This curious fact, alongside the striking number of lactose intolerant adults, raises important questions about why we eat and drink so much dairy.

Calcium intake is certainly one motivating factor. But a long list of non-dairy calcium-rich foods reveals many other sources of this essential nutrient. Among them are green peas, chickpeas, quinoa, sesame seeds, oranges and fortified orange juice, and soybeans and other soy products such as tofu.

Additionally, leafy green vegetables like kale, spinach, and collard, mustard, and beet greens are high in calcium. One cup of raw kale contains approximately 90 mg of calcium; a 3.5 cup kale salad exceeds the amount of calcium—300 mg—found in one cup of milk.

If dairy is required to achieve adequate nutrition, some food items may offer better choices than others. The Swedish milk study found that a high intake of fermented milk products—such as yogurt and soured milk and cheese—was actually associated with lower rates of bone fracture and mortality.

Beyond dietary considerations, many forms of exercise and healthy activity are known to support healthy bone growth and fracture prevention.

Those at risk of osteoporosis should have their bone mineral density tested regularly and take efforts to reduce the risk of falls in the home. Physical activity, especially weight-bearing exercise, also helps to build and strengthen bones. Additionally, exposure to natural sunlight promotes vitamin D production and calcium absorption.

Drinking milk may not be the most healthful approach to osteoporosis prevention.

How to Test for Dysbiosis

By Madiha Saeed, MD
Contributing Writer

Disturbance of the gut microbiome, also known as dysbiosis, has a major detrimental effect on human health. As microbiome research continues to explode worldwide, we are learning that microbial dysregulation within the gut is an important contributing factor in a wide range of common disorders.

Those 70 trillion to 100 trillion beneficial bacteria lining our digestive system are responsible for multiple physiological functions including:

- **Immunity:** Our digestive tract is base camp for 70% of our immune system: a good relationship between the body and the beneficial bacteria is important to fight off colds and common infections.
- **Neurotransmitter Production:** Every class of brain neurotransmitter has been found in the gut, including about 80% to 90% of our serotonin.
- **Energy Harvesting:** Gut microbes extract energy from undigested food products as they pass through the digestive system.
- **Metabolic Regulation:** The microbiome plays a role in regulating everything from appetite and fat storage to sleep cycles.
- **Production of Key Vitamins & Cofactors**

A number of things can adversely affect microbiome composition, such as chronic stress, age, environmental toxins, food sensitivities, genetics, malnutrition, obesity, smoking, use of antibiotics, proton pump inhibitors and other medications, and most importantly, diet.

Some bacterial strains once present in the upper GI tract can cause gas, bloating, fat malabsorption diarrhea and constipation (or both). Ultimately, they damage the lining of the small intestine and prevent the body from absorbing essential nutrients.

Eluding the Radar

Dysbiosis is most prominent in the digestive tract and the skin, but really, it can be found on any exposed surface or mucous membrane, such as the vagina, lungs, mouth, nose, sinuses, ears, nails or eyes.

The only way to properly treat dysbiosis is to remove bad bacteria, yeast and parasites, all of which can be considered infections that elude the radar of conventional medical tests (Amit Dutta, et al. *Gastroenterology & Endoscopy News.* 2015; 66: 4).

But that doesn't mean we as clinicians must fly completely blind or rely totally on guesswork. There are a number of testing methods—some of which have been around for decades, others of which are very new—to help guide us. Just because they're not (yet) part of the conventional gastroenterological toolkit doesn't mean they should be ignored.

A Basic Approach

There are a number of effective ways to test for dysbiosis and a number of laboratories that test for it: Genova Diagnostics; Metametrix Laboratories; Doctors Data Laboratory; Enterolabs; QuinTron Breath Test; Commonwealth Laboratories and Cell Science Systems are among the top labs providing tests to evaluate potential dysbiosis.

It is also possible for patients to get genetic analysis of their gut microbiome for $89, from a company called *uBiome*.

Here's a basic outline for how to approach patients whose symptoms fit the picture of dysbiosis.

1. **History:** It's important to listen to patients and their symptoms, diet, and past medical, family, and social history. This wealth of information can often give you a lot of diagnostic clues. It's also the cheapest option and most patients prefer it.
2. **Comprehensive Stool Test:** This non-invasive test gives you a picture of some of the organisms present in a patient's GI tract, as well as some sense of bacterial balance and presence of yeast. This test is recommended for patients with diffuse and non-specific symptoms. Some clinicians question the value of stool testing because it does not give much information about organisms that may be deep in the mucosal walls or ensconced under biofilms. Likewise it may not tell much about bugs living upstream in the upper GI tract. But it can be a good place to start with many patients.
3. **Urine Test:** This method looks for unique products of microbial metabolism in the urine. It can indicate presence of small bowel yeast, bacterial overgrowth, and unfriendly intestinal microorganisms that manufacture high quantities of compounds not normally produced by human cells, such as D-arabinitol. These compounds are absorbed into the blood from the intestines and eventually appear in the urine. The virtue of urine testing is that is very easy to do.
4. **Intestinal Permeability Assessment or Mannitol-Lactulose Intestinal Permeability Test:** This test involves having the patient drink a premeasured amount of two sugars: lactulose and mannitol. The relative presence of these sugars in the urine will show how permeable the intestine is. An elevated ratio of lactulose to mannitol will indicate dysbiosis and leaky gut syndrome.
5. **Hydrogen or Methane Breath Test:** This is the gold standard for assessing dysbiosis. Though fairly simple in principle, it can be cumbersome and time-consuming. It tests for Irritable Bowel Syndrome (IBS), Small Intestinal Bacterial Overgrowth (SIBO), and other digestive disturbances related to sugar or food intolerances.
   a. After a baseline breath gas measurement, the patient ingests a standardized solution of lactulose or another substrate that is normally indigestible by humans but highly digestible by bacteria.
   b. Measurement of hydrogen and methane in the breath at regular intervals—typically every 20 minutes—will indicate the degree of microbial fermentation of the lactulose within the upper GI tract.
   c. Rapid and steady rises in hydrogen and methane are proof-positive of dysbiosis.

These tests can be repeated as needed to gauge progress with treatment of leaky gut.

It's important to note that dysbiosis cannot be found through an endoscopy or colonoscopy, nor does it show up definitively on standard blood work, so many practitioners miss it.

Watch the B Vitamins

That said, according to Raphael Kellman, MD, a functional medicine physician in New York City, there are a few major clues to be found among measurements of basic blood nutrient levels.

"If B vitamins are low, and zinc is low, the patient's microbiome is unhealthy," says Dr. Kellman, MD. "There are many other things you can measure—butyrate, short chain fatty acids, the microbiome composition itself. But start with the B's. If they're low, the microbiome is not healthy."

There are additional tests that can be useful in evaluating someone's gut health.

1. **Food Sensitivity Tests:** These tests involve measuring IgG and IgE levels to various food antigens, along with celiac panels.
2. **Genetic Tests:** It's now possible to measure how effectively patients' enzymes are functioning, especially the enzymes involved in liver detoxification pathways and those that regulate brain neurotransmitters.
3. **Toxin Load Assessment:** This looks for heavy metals, solvents or pesticides. If a patient has a high toxin load, the next step is to discuss detoxification interventions.
4. **The Pulse Test:** A change in the pulse and/or heart rate greater than 10 beats per minute will often follow exposure to a problematic food or toxin. Though not a definitive testing method by any means, this is certainly an inexpensive tool, and it can add information when it's correlated with symptoms and data from other tests.
5. **Antigen Tests for *H. pylori, C. difficile* and Other Bacteria:** These tests can help you get a better sense of who's living in the neighborhood, so to speak, and what may be contributing to the symptom patterns.

Identifying and reversing dysbiosis can be life-changing for many patients. It's a condition that can be effectively addressed by targeting and eliminating pernicious bugs or those that are not where they should be in the GI tract, by removing processed bad foods, adding back healing good foods and probiotic flora, and by helping to restore the damaged intestinal lining with specifically targeted herbs, nutrients and foods (like bone broth).

It's exciting to see new research showing that dysbiosis plays a role in metabolic pathways that lead to obesity, diabetes, cardiovascular disease, gastrointestinal conditions, autoimmune disease and cancer. More study in this field can help reduce the burden of disease in society. In the meantime, trust thy gut—it may already know what thy head hasn't yet figured out.

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Big Pharma Discovers a Gluten Goldmine

By August West
Contributing Writer

First there was categorical dismissal: Gluten allergies are "psychosomatic," leaky gut syndrome is a made-up diagnosis, and celiac disease is a rare condition you might encounter once or twice in your medical career.

Then, begrudging acknowledgment: Mayo Clinic researchers note that nearly 2 million Americans—and 1% of the Caucasian population—likely have celiac disease.

And now, the latest phase in mainstream medicine's long, strange relationship with gluten-triggered disorders: a Big Pharma gold rush.

Indeed, drug developers have finally caught on to what food marketers recognized 15 years ago: there's a huge number of people whose chronic digestive problems are—or could be—related to gluten sensitivities, and who are desperate for meaningful solutions.

According to a recent *New York Times* article, several pharma companies are scrambling to be first to market with a drug solution to the celiac equation. All are still in early-stage development, and no actual drugs are expected to emerge until 2018 at best.

But the action is clearly heating up.

Mega-player GlaxoSmithKline recently teamed with Avalon Ventures, a financing firm, to create Sitari Pharmaceuticals, which is pursuing celiac treatments.

Alvine Pharmaceuticals, a small, privately-held drug company based in San Carlos, CA, has been working on a formula known as ALV003 that contains two enzymes that—at least in principle—break down gluten into non-allergenic fractions before it ever reaches the intestines.

AbbVie, a Chicago-based pharma development company with revenues of $18.8 billion in 2013, recently paid $70 million to Alvine for an option on the global rights to ALV003.

Alba Therapeutics, a Baltimore company, has been working on a drug called larazotide acetate that blocks gluten from slipping through the tight junctions between epithelial cells. In other worlds, it purports to treat one of the key features of that once-imaginary leaky-gut syndrome. Alba was recently acquired by global drug giant Teva Pharmaceuticals.

The FDA has clearly taken note of the gluten-drug bonanza.

Late in March the agency held a day-long workshop entitled "Gastroenterology Regulatory Endpoints & the Advancement of Therapeutics" (GREAT), focused on scientific issues around establishing and measuring meaningful endpoints in celiac disease, irritable bowel syndrome, and other related conditions.

Ain't it funny how a condition can go from "imaginary" and "psychosomatic" to significant and worthy of serious investment, as soon as someone sees a large and lucrative market?

Vitamin D May Improve Colon Cancer Survival

By Kristen Schepker
Contributing Writer

Among its many other known benefits, vitamin D may improve survival rates in colon cancer patients, according to new research presented at the American Society for Clinical Oncology's 2015 GI Cancers Symposium.

Kimmie Ng, MD, PhD, of the Dana-Farber Cancer Institute, studied patients with newly diagnosed metastatic colorectal cancer and found that those with higher blood levels of vitamin D lived longer and experienced greater disease-free survival following conventional treatment than those with lower vitamin D levels.

Previous studies have shown correlations between higher levels of 25-hydroxyvitamin D [25(OH)D] and improved survival in colorectal cancer (CRC). Ng's research adds to the body of evidence, and more specifically explores the relationship between 25(OH)D and metastatic CRC outcomes.

Her study involved 1,043 previously untreated patients enrolled in a randomized phase III trial of chemotherapy plus additional drugs including either bevacizumab, cetuximab, or both. Participants' plasma 25(OH)D levels were measured at baseline by radioimmunoassay. The median plasma 25(OH)D was found to be 17.2 ng/mL (range 2.2–72.7).

Those in the highest quintile for vitamin D had a median overall survival of nearly 33 months versus 26 months among those with the lowest levels. Patients with higher vitamin D levels lived a median of 8 months longer than those with lower levels. Those in the highest vitamin D quintile had a median overall survival (OS) of 32.6 months, versus 24.5 months in those in the lowest quintile (HR 0.67, 95% CI, 0.53–0.86; *p* trend 0.002).

The study also identified a correlation between higher vitamin D levels and improved progression-free survival. Patients with high vitamin D counts experienced a median 12.2-month period before disease progression, versus a median 10.1 months in the lowest quintile (HR 0.80, 95% CI, 0.64–1.01; *p* trend 0.02).

Interestingly, there were no significant differences in progression-free survival based on chemotherapeutic treatment type.

Ng and colleagues concluded that higher concentrations of plasma 25(OH)D are associated with significantly improved survival in metastatic CRC patients treated with chemotherapy and other anti-cancer drugs.

In addition to its key role in maintaining bone health, vitamin D is a natural anti-inflammatory agent that possesses numerous anti-cancer properties, including the capacity to suppress tumor growth and metastasis. It can also promote diseased cell death, while inhibiting angiogenesis (Chakraborti CK. *Ind J Pharmacol.* 2011; 43(2): 113–120).

Though it may be too soon to suggest vitamin D as a treatment for colon cancer, the results of Ng's study suggest that supplementation could help to improve the outcomes of patients receiving conventional cancer therapies. She encouraged practitioners to recommend vitamin D testing for cancer patients and to consider supplementation where appropriate.

Microbiome

cont'd from page 1

What we do know is that bacterial cells outnumber human cells in the body by a factor of 9:1. "We are basically bacteria dressed up in a suit," quipped Dr. Kellman at the *Functional Forum,* a monthly NYC-area practitioner meet-up.

The microbiome has tentacles into every aspect of our physiology. It is involved in production of vitamins, amino acids, bile acids, and fermentation of non-digestible substrates. It plays a key role in glucose and fat metabolism, calorie extraction, genetic signaling, and weight regulation.

When healthy, the microbiome protects the gut mucosa from colonization by pathogens, regulates innate and adaptive immunity, and modulates inflammatory reactions.

Some authors have referred to the microbiome as the "forgotten" or "hidden" organ. Others see it as the "software of the body."

Microbiome changes have been linked to a host of common disorders including:

- **Type 2 Diabetes:** Diabetics show reduced populations of *Bifidobacteria.*
- **Obesity:** Obese people show low ratios of *Bacteroides* to *Firmicutes.*
- **Atherosclerosis:** Linked to low levels of *Bacteroides* and high levels of *Ruminococcus.*
- **Irritable Bowel Syndrome:** Patients typically show low levels of *Bifidobacteria.*
- **Inflammatory Bowel Disease:** Patients typically show high levels of *Enterobacter,* but low levels of *F. prausnitzii.*
- **Colorectal Cancer:** Associated with low levels of *Bacteroides.*

> **"If you treat autoimmune diseases, you must treat the microbiome . . . it's part of the deep causes."**
>
> ***—Raphael Kellman, MD***

Microbiome & Autoimmune Conditions

"If you treat autoimmune diseases, you *must* treat the microbiome, because that's part of the deep causes," stressed Dr. Kellman. "I almost always find microbiome abnormalities in autoimmune diseases. Improve that and you see overall improvement of the disease."

IBS, IBD and ulcerative colitis are clearly associated with dysbiosis and poor microbiome diversity. Protocols aimed at restoring microbiome health often confer significant improvements in these patients.

In a double-blind, placebo controlled study published a decade ago, Elizabeth Furrie and colleagues at the University of Dundee, Scotland, treated 35 patients with ulcerative colitis with either placebo or a "synbiotic" combination of probiotics (*Bifidobacterium longum* derived from healthy rectal epithelium) and a prebiotic (inulin-oligofructose derived from chicory).

After one month, patients underwent sigmoidoscopy. The researchers saw major reductions in visible inflammation and ulceration, as well as reduced levels of pro-inflammatory cytokines (IL-1, TNF-α), and mRNA for human β-defensins—indicators of active ulcerative colitis. They found no such changes among the patients on placebo (Furrie E, et al. *Gut*. 2005; 54(2): 242–249).

In 2010, researchers at McMaster University, Hamilton, ON, published a systematic review of 19 trials of probiotics for IBS, and concluded that "probiotics appear to be efficacious in IBS, but the magnitude of benefit and the most effective species and strain are uncertain" (Moayeddi P, et al. *Gut*. 2010 Mar; 59(3): 325–332).

Dr. Kellman said the Furrie study underscores an important point: "This looked at probiotics and prebiotics together. You need the combination. Just using probiotics without endogenous changes within the gut ecology won't work well."

The microbiome communicates to the brain via the vagus nerve, via the production of neurotransmitters, and via its communication with the immune system.

"The crosstalk is what's most fascinating," said Dr. Kellman, author of *The Microbiome Diet,* a patient-friendly guide to restoring and maintaining gut health.

CNS Communication

"The gut and the brain speak the same language. Gut bacteria produce neurotransmitters. The bacteria can speak to the brain via the immune system, and they also send messages via endocrine pathways, especially via the HPA axis."

Echoing a view held by many microbiome researchers, Dr. Kellman suggested that the microbiome actually played a role in the evolution of the human nervous system, and that it continues to do so. "Microbes replicate quickly, exchange genes quickly, evolve quickly. It's a massive library of genomic information. Flexibility and plasticity of the microbiome is very important to giving us evolutionary advantage."

The microbiome "speaks" to the central nervous system via cortisol, DHEA and other hormones. It also produces short chain fatty acids; neurotransmitters like GABA, tryptophan, and serotonin; and catecholamines and cytokines, all of which can act locally within the gut or systemically via vagal nerve pathways.

As Irish psychiatrist Paul J. Kennedy pointed out in an intriguing article entitled "Irritable Bowel Syndrome: A Microbiome-Gut-Brain Axis Disorder," the microbes produce these signals to communicate with each other; it so happens that they also affect us (Kennedy PJ, et al. *World J Gastroenterol.* 2014; 20(39): 14105–14125).

Discoveries like this add an important new dimension to our understanding of depression, anxiety and other psychological disorders.

There is some evidence that translocation of Gram-negative enterobacteria is a trigger in the onset of depression, especially the fatigue and insomnia components. The mechanism has to do with activation of immune cells and production of IgA and IgM in response to lipopolysaccharides produced by the bacteria (Maes M, et al. *J Affect Disord.* 2012; 141(1): 55–62).

There's a growing consensus in the mental health field that chronic inflammation and oxidative stress play a major role in depression (Berk M, et al. *BMC Med.* 2013; 11: 200).

The idea that microbiome dysregulation may underlie the inflammation opens a new possibility for treatment.

Assessing the Microbiome

Microbiome research is fueling a surge of clinical testing methods for characterizing the flora in and on the human organism. There are dozens of labs offering tests for assessing the health of the microbiome.

How many of these tests prove to be practical, clinically useful, and economical over the long term remains to be seen.

According to Dr. Kellman, one need not get overly fixated on extensive testing in order to get a basic handle on what's going on with most patients. A few simple tests can give a lot of useful information.

A basic blood nutrient profile offers plenty of clues. Look closely at the B vitamins. If they're low, and if zinc is also low, it's a strong indicator that the patient has dysbiosis, particularly small intestinal bacterial overgrowth (SIBO). That's because unhealthy bacteria in the small intestine love these nutrients and preferentially absorb them, at the expense of their host.

Dr. Kellman says he's not a big fan of stool testing: "It doesn't' go deep into microbiome in the gut wall. What's in the stool is not necessarily representative of what's really going on. Frequently I use breath-testing on provocation to determine if there's bacterial overgrowth. I find it to be more effective than stool (see "How to Test for Dysbiosis," p. 8).

"Paleo" Diet, Modern Microbiome?

Restoring and maintaining a healthy microbiome is heavily dependent on diet.

The dietary recommendations need to be individualized to each person's age, overall health (or comorbidities), nutritional needs and preferences. Unfortunately, there's no one-size-fits-all approach.

That said, certain core principles do apply: reduce or eliminate refined carbs, heavily processed foods, food additives, trans-fats, artificial sweeteners, high-glycemic foods, and heavy loads of saturated fat. Increase intake of green vegetables, fermented vegetables, fermented dairy (for those who are dairy-tolerant and non-vegan), and prebiotic veggies like jicama, Jerusalem artichokes, leeks, and Kiwi fruit.

Dr. Kellman said he's agnostic on the vegetarian vs. carnivore debate. "I've seen people get better who are vegetarian, and I've seen people get better while eating meat. Either way, you can be healthy once you get the microbiome right."

However, he urged caution with meat and fat. "Excessive meat consumption, excessive fat consumption can be as problematic for the microbiome as excessive carb consumption." The key, he says, is balance.

He questioned the wisdom of heavily meat-centric "paleo" diets for people with microbiome disturbances.

"The paleo premise is that you should eat a lot of meat. In general, I think the paleo thing is unhealthy for the microbiome. Some paleo principles are true, like eliminating refined carbs. But those principles are not unique to paleo; they are key to any healthy diet.

Another oft-heard paleo premise is that our health problems stem from the fact that our ancient primate genes couldn't keep up with agricultural changes.

"But those theories leave out the microbiome," says Dr. Kellman. "Our genes may not have changed, but the microbiome sure has! It quickly adapts to a changing environment."

The point, he says, is to help each patient figure out what works best. Once you eliminate junk foods and identify and minimize potential allergens and triggers, the game becomes about experimenting with different foods to see which are most beneficial, and which are harmful.

In general, he encourages patients to eat organic as much as possible, and to avoid GMOs. "We don't want to throw unknown genes into the microbiota."

Pre Before Pro

"We shouldn't be focused as much on the probiotics. We need to focus on the prebiotics," says Dr. Kellman. "The probiotic bugs are like tourists, they come to town and improve the economy for a few days or weeks, but they don't have long lasting effects. We need stable citizens, and a healthy, stable environment that supports them. Food, diet, lifestyle factors, and prebiotics are the keys to supporting healthy bugs. Clinically, we need to focus on that."

The microbiome can change for the worse pretty quickly, but changing it positively doesn't happen overnight. Patients need to understand this. The idea of probiotic quick-fixes is definitely misguided, especially in the absence of dietary changes.

As microbiome researchers continue to shed light on the fascinating world within our GI systems, our clinical approaches to assessing and treating dysbiosis will no doubt improve.

"The probiotics of the future will be put together in specific ways to improve various and specific conditions," Dr. Kellman predicted. "Right now, the challenge is to find the right combos, or else you have to find individual ones and put together your own combos. We are just at the very beginning of all of this."

Breaking the Mold: How to Get a Grip On Household Mycotoxin Exposure

By Jill Carnahan, MD
Contributing Writer

Indoor air pollutants, including mold and mycotoxins, may be contributing to more than 50% of our patients' illnesses.

The environmental movement has rightly focused our attention on smog, smoke, and outdoor pollution as disease drivers, but to some extent it has caused us to be a bit myopic to the fact that for many people, poor indoor air quality may be an even bigger threat to health.

Many patients are unaware that a toxic home or workplace—especially one contaminated by mold—is contributing to their symptoms.

Exposure to chronically water-damaged indoor environments is associated with exposure to molds. The most common types found indoors include *Cladosporium, Penicillium, Alternaria,* and *Aspergillus.*

Stachybotrys chartarum (sometimes referred to as "toxic black mold") is a greenish-black mold, which grows on household surfaces that have high cellulose content, such as wood, fiberboard, gypsum board, paper, dust, and lint. The unwelcome—and all-too-common—presence of *Stachybotrys* is usually an indicator that there has been elevated moisture present or previous water damage.

Some molds secrete mycotoxins that can be measured in the urine, such as *ochratoxin, aflatoxin,* and *trichothecenes.*

Inflammatory Triggers

Exposure to mold and mold components is well known to trigger inflammation, allergies and asthma, oxidative stress, and immune dysfunction in both human and animal studies.

Mold spores, fungal fragments, and mycotoxins can be measured in the indoor environments of moldy buildings and in humans who are exposed to these environments.

Most of the time, we are exposed to molds like *Stachybotrys* via skin contact, through ingestion, and by inhalation. Sites of exposure typically include water-damaged and poorly ventilated homes, schools, office buildings, court houses, hospitals, and hotels. It is estimated that as many as 25% of buildings in the US have had some sort of water damage.

Molds have the ability to trigger a wide range of symptoms, such as skin rashes, respiratory distress, various types of inflammation, cognitive issues, neurological symptoms, and immune system suppression. In day-to-day clinical practice, the most common symptoms associated with mold exposure that we're likely to see are allergic rhinitis and new onset asthma.

When in Doubt, Ask

I believe we need to raise our index of suspicion about mold exposure among our patients with chronic inflammatory conditions, especially when those conditions do not resolve with typically effective treatments.

I start to think about mold exposure whenever I see patients with the following:

1. Fatigue and weakness
2. Headache, light sensitivity
3. Poor memory, difficulty finding words
4. Difficulty concentrating
5. Morning stiffness, joint pain
6. Unusual skin sensations, tingling and numbness
7. Shortness of breath, sinus congestion, or chronic cough
8. Appetite swings, body temperature dysregulation
9. Increased urinary frequency or increased thirst
10. Red eyes, blurred vision, sweats, mood swings, sharp pains
11. Abdominal pain, diarrhea, bloating
12. Tearing, disorientation, metallic taste in mouth
13. Static shocks
14. Vertigo, feeling lightheaded

To be sure, there are many conditions that can lead to each of these symptom patterns, and mycotoxin exposure may not be the sole explanation for any of them. Yet many clinicians do not even consider the possibility, though given the prevalence of water damaged homes in many parts of the country, we certainly should.

Whenever I suspect that mold exposure may play a role in the underlying causes of someone's symptoms, I like to ask the following questions from a checklist developed by the EHCD (Environmental Health Center–Dallas)

- Do musty odors bother you?
- Have you worked or lived in a building where the air vents or ceiling tiles were discolored?
- Have you noticed water damage or discoloration elsewhere?
- Has your home been flooded?
- Have you had leaks in the roof?
- Do you experience unusual shortness of breath?
- Do you experience recurring sinus infections?
- Do you experience recurring respiratory infections and coughing?
- Do you have frequent flu-like symptoms?
- Do your symptoms worsen on rainy days?
- Do you have frequent headaches?
- Are you fatigued and have skin rashes?

A few "yes" answers to these questions, should prompt you and your patient to get serious about looking for—and eliminating—household or worksite molds, and doing whatever else is necessary to minimize exposure.

How to Treat Mycotoxin Exposure?

Dealing with the sources of exposure is obviously the first step. The patient needs to find the mold and to the best extent possible, eliminate it from their homes or worksites.

There are a number of companies across the country that specialize in household mold detection, elimination and remediation.

It is essential for patients to remove themselves from the contaminated environment—or remove the contamination from their midst. Don't even think about going on to other treatment modalities until they're able to minimize exposure by avoiding or cleaning up the contaminated environment.

Here are a few other steps for mitigating the physiological damage caused by chronic mold exposure:

- Use clay, charcoal, cholestyramine or other binders to bind internal mycotoxins. My favorites are Upgraded Coconut Charcoal or GI Detox and Glutathione Force!
- While using binders, the patient must maintain normal bowel function and avoid constipation. If needed, magnesium citrate, buffered C powder, or even gentle laxatives can be a big help. Make sure your patients understand that constipation is the enemy of detoxification!
- Look for and treat colonizing molds/fungal infections in the body. Common locations of colonization include sinuses, gut, bladder, vagina, and lungs.
- Test and treat for candida overgrowth. Living in an environment with mold leads to immune system dysregulation that allows candida to overgrow in the body.
- Enhance detoxification support. Some common supplements used to aid detox are liposomal glutathione, milk thistle, n-acetylcysteine, alpha lipoic acid, glycine, glutamine, and taurine.
- Methylation support is also key and involves optimal levels of methylcobalamin (B12), methyl-folate, B6, riboflavin, and minerals.
- Encourage patients to invest in a high quality air filter and home and at work. Some examples include Austin Air or E. L. Faust.

When detoxing from mold exposure, it's a good idea to avoid common mycotoxin containing foods. These include: corn, wheat, barley, rye, peanuts, sorghum, cottonseed, some cheeses, and alcoholic beverages such as wine and beer.

Other foods to avoid include: oats, rice, tree nuts, pistachios, brazil nuts, chili peppers, oil seeds, spices, black pepper, dried fruits, figs, coffee, cocoa, beans, and bread.

Other Treatment Options

- Follow Dr. Jill's Low Mold Diet. Many of my patients do well on a paleo, grain-free diet, like the one I've developed. Grains are often contaminated with mycotoxins and molds, which can exacerbate the effects of airborne or cutaneous exposure to molds in the environment.
- Sublingual immunotherapy (SLIT)
- Anti-fungal herbs and medications
- Infrared saunas
- Detoxification support — oral and intravenous
- Create a "safe" place, with little potential for mold/allergens and great filtration system. This could be a bedroom or other room that is mold and chemical free.
- Some patients with severe symptoms may benefit from IV immunoglobulin therapy (IVIg).

***Jill C. Carnahan**, MD, ABFM, ABIHM, practices functional medicine with her medical practice partner Dr. Robert Rountree, at Boulder Wellcare and Flatiron Functional Medicine, in Boulder, CO. Dr. Carnahan is board certified in both Family Medicine and Integrative Holistic Medicine. She founded the Methodist Center for Integrative Medicine in 2009 and worked there as Integrative Medical Director until October 2010. She completed her residency at the University of Illinois Program in Family Medicine at Methodist Medical Center and received her medical degree from Loyola University Stritch School of Medicine in Chicago.*

Dr. Carnahan will be a featured presenter at the 2015 Heal Thy Practice conference, October 16–18, at the Coronado Island Marriott, San Diego, CA.

Heal Thy Practice 2015 Sneak Peak

Heal Thy Practice returns to the West Coast this year, with a stellar program aimed at giving you the tools and support you need to truly transform your practice.

Chaired by HTP alum, Mark Menolascino, MD, founder of the thriving Meno Clinic Center for Advanced Medicine, *Heal Thy Practice 2015* will give you directional roadmaps to greater practice freedom, better clinical outcomes and increased satisfaction.

Whether you're considering incremental changes or major shifts, you'll find the guidance and peer support you'll need to move from vision to action.

Featured faculty include:

- **Erik Lundquist, MD**: ***Making Holistic Medicine Work in an Insurance Practice.*** Dr Lundquist's Temecula Center for Integrative Medicine has literally "cracked the code" on reimbursement for holistic care. He'll offer tips on how to provide concierge-style service in an insurance context, and how to nurture an interdisciplinary team.
- **Jill Carnahan, MD**: ***Microbiomics in the Clinic.*** Dr. Carnahan is at the vanguard of functional medicine. She'll describe how microbiome assessment shapes her patient care strategies.
- **Decker Weiss, NMD:** ***New Perspectives on Inflammation.*** Among the nation's only naturopathic cardiologists, Dr. Weiss brings his unique view on the role of inflammation in heart disease, as well as practical approaches for ameliorating chronic inflammatory states.
- **Miriam Zacharias:** ***Making PEACE with Marketing.*** HTP veteran Miriam Zacharias returns with strategies from her new book, The PEACE Process. This 5-step program (Purpose, Establish, Attract, Connect, Engage) brings conscience and consciousness to the marketing process.
- **Jacques Simon, Esq:** ***Medicolegal Perspectives for Holistic Practice.*** Get a healthy dose of preventive lawyer-ing from one of the nation's top attorneys in the field of holistic and integrative medicine.
- **Mark Menolascino, MD:** ***Selecting & Integrating Ancillary Services.*** Ancillary services can make or break an independent practice. But with so many different options available, how do you pick the winners? Dr. Menolascino offers his top choices… and a few lessons learned along the way.

The 2015 program is evolving quickly. Check **www.HTPconference.com** for updates. Register by 4th of July and take advantage of the special Early Bird discount.

Aluminum, Alzheimer's & Autism: Understanding the Connection

By Erik Goldman
Editor in Chief

Back in the late 1890s, James Tyler Kent, a forefather of American homeopathy, described the nature of someone suffering from aluminum toxicity as follows: "There is confusion of mind, a confusion of ideas and thoughts. . . . The consciousness of his personal identity is confused . . . he is in a dazed condition of mind. . . . Confusion and obscuration of the intellect."

Kent might very well have been describing an elderly person in the throes of Alzheimer's disease—or an adolescent who, today, would receive a diagnosis of autism or one of the related "spectrum" disorders.

There's a reason for that: in high-enough concentrations, aluminum becomes neurotoxic. Next to bauxite miners, factory workers, and people who live in highly polluted industrial areas, children and elderly people are the populations at greatest risk of exposure to potentially harmful levels, says Jared Skowron, ND, a naturopathic physician in Wallingford, CT.

"Aluminum is the 3rd most abundant mineral on earth. It is literally all over the place, in small amounts. It is in the soil, in the air, in the water, in the foods we eat. Our bodies have adjusted to it in natural forms and its natural distribution. But when you extract it from the earth, concentrate it, and make it into things to which we have constant daily exposure, it can create problems," he said at the 10th annual meeting of the New York Association of Naturopathic Physicians.

Oral intake of 330 mg/kg/day or more results in decreased myelination of nerves in experimental animals, and even 230 mg/kg/day is enough to cause neurological damage, said Dr. Skowron. Bearing in mind the caveats that go along with drawing human conclusions from animal toxicity studies, the point here is that humans living a modern lifestyle can very easily reach these daily dose levels.

Antacids & Other Aluminum Sources

In modern industrialized countries, aluminum is found in a very wide range of consumer products: processed foods, baked goods, grains, and dairy products as well as deodorants and antiperspirants, cosmetics, personal care products and over the counter medications like antacids and buffered aspirin.

The latter two are among the main reasons that elderly people are at elevated risk of accumulating neurotoxic levels. Many elders are taking aluminum-containing aspirin tablets every day to help reduce cardiovascular risk. Many also take antacids, which typically contain 300–600 mg of aluminum hydroxide.

To put it into perspective, a typical sample of pond or lake water in the US will contain less than 0.1 mg/L of naturally occurring aluminum. The average adult not taking any aluminum-containing drugs ingests roughly 10 mg per day from food and water.

Someone who is taking a buffered aspirin and an antacid is getting between 840 and 5,000 mg of aluminum-containing compounds per day.

"Who's doing that? Elderly people!" said Dr. Skowron.

The rate of absorption of aluminum via the GI tract is relatively low, and true symptomatic aluminum poisoning is rare. Absorption ranges from around 0.01% for aluminum hydroxide to roughly 5% for aluminum citrate. Most aluminum ingested from food, water and drugs is excreted out in feces and urine.

Aluminum Sponges

The problem is that neurons are very good at absorbing whatever aluminum does make it into the bloodstream. Essentially, they're aluminum sponges. And unlike other types of cells that absorb aluminum, which die quickly and get replaced, aluminum-damaged neurons are not. The result over time is a gradual destruction of neural tissue.

Dr. Skowron noted that people on kidney dialysis who regularly take aluminum-containing antacids develop Alzheimer's very quickly. Why? Because they can't excrete the aluminum via the kidneys. This is a known phenomenon among renal specialists—they've named it "dialysis encephalopathy" or some other euphemism, but essentially it is aluminum-induced dementia.

Bone also absorbs aluminum fairly easily. This blocks the incorporation of other minerals into the bone matrix contributing to osteoporosis, a double-whammy for elders, and one that's compounded by the fact that generally, as people age, the ability to eliminate toxins like aluminum tends to decline.

Aluminum & Children

The so-called vaccine wars, which flared up once again this year, represent one of the most contentious issues in primary care, one that typically defaults to heated emotions on both sides.

Lost in much of the rhetoric are some subtle but important facts that have bearing on the question of why most children tolerate vaccines without problems while in others the same vaccines trigger unexpected problems.

Dr. Skowron, who is author of *Fundamentals of Naturopathic Pediatrics* and *100 Natural Remedies for Your Child,* is a long-time veteran of the vaccine debates. He says it's important to recognize that a big question about vaccines is not so much the principle behind immunization as the fact that most vaccines contain aluminum.

The amounts are small, typically less than 0.85 mg of aluminum per dose. But he stressed that while they are well below "safe" levels for adult weights, they approach potentially toxic doses for babies. It's also important to keep in mind that babies and small children are metabolically very different from adults. They're not just small versions of grownups.

Following a typical injection, 59% of the aluminum content is excreted within the first five days, but 25% may be retained long term. In some children, the aluminum may have a 10-year half-life.

Why do manufacturers put aluminum in vaccines? It "glues" the antigens together so the bolus will stay in the skin or muscle for longer periods and therefore generate greater immune responses as the B-cells keep hitting the vaccine material to create more and more antibodies, Dr. Skowron explained.

Assuming that each shot contains between 0.2 and 1.0 mg/kg of aluminum, a 12-pound baby getting the typical array of "required" vaccines, is getting up to 5 mg/kg directly injected. Not every infant can handle that.

Some children with compromised excretory function may build up toxic levels of aluminum fairly quickly. Dr. Skowron referred to the case of a two year old boy in whom aluminum was by far the most prevalent mineral in the blood.

Keep in mind that in infants, the blood-brain barrier is not fully developed, and that the aluminum an infant gets from vaccines is on top of that which she ingests from breast milk (there is evidence that aluminum does pass into mother's milk), soy or dairy formulas, and various food sources. In some cases, the cumulative amounts can reach neurotoxic levels fairly quickly.

The situation may be worsened if parents choose to treat common childhood ailments like headaches with aspirin or colic with antacids. Prolonged use of aluminum-containing drugs in young children has been associated with growth reduction, hypotonia, muscle weakness, and premature ossification of the skull.

Minimizing Exposure

The good news is that it is fairly easy for all people, regardless of age, to reduce exposure to aluminum. Given what we do know about its neurotoxic potential, it certainly makes sense to do so.

Dr. Skowron recommended:

- Avoiding processed foods
- Avoiding aluminum pots & pans
- Installing a home water filtration system
- Minimizing or eliminating use of antacids and buffered aspirin
- Avoiding aluminum-containing vaccines

In some extreme cases, it may make sense to consider detoxification interventions such as chelation with deferoxamine (DFO) or EDTA. The toxic effects of aluminum can be mitigated with Vitamin E, Vitamin C, selenium, and herbs like *Bacopa moniera* or curcumin. (Visit www.holisticprimarycare.net for more information use of curcumin and herbs.)

Heal Thy Practice Spotlight

Temecula Center for Integrative Medicine: *"We Need Other Clinics to Do This, Too!"*

By Erik Goldman
Editor in Chief

"There is such a big need for this kind of care. We need other clinics to be doing this too!" says Erik Lundquist, MD, of the comprehensive interdisciplinary model he developed for his new Temecula Center for Integrative Medicine.

Public interest in holistic approaches has never been stronger, and frustration with conventional models has never been more obvious, said Dr. Lundquist.

"People are so hungry for this. We were fully booked and profitable after the first six months!"

In an era when so many clinicians are convinced private practice is a relic of the past, and corporate control of medicine is inevitable, Dr. Lundquist's clinic, located roughly an hour north of San Diego, is a radiant example of what can happen when a group of practitioners are responsive to what their community really needs.

To be sure, building the Temecula Center for Integrative Medicine (TCIM) from the ground up had its challenges. But Dr. Lundquist told *Holistic Primary Care* that it was not nearly as difficult as many practitioners imagine it would be.

The practice, which is largely insurance-based, is founded on a team approach that includes naturopathic medicine, chiropractic, nutrition counseling, massage and bodywork, lifestyle education, and oriental medicine. Extended, unhurried office visits are the norm, and the center sees patients with a wide range of complex chronic disorders.

As a keynote speaker at *HPC*'s upcoming 2016 *Heal Thy Practice* conference, (www.HTPConference.com) Dr. Lundquist will share key insights on how to plan, develop, and manage an integrative clinic—particularly one that takes insurance!

Erik Lundquist is no stranger to challenges. Prior to his private practice life, he completed 8 years of active duty with the US Navy, including a stint in Afghanistan shortly after Sept. 11, and a subsequent deployment as a battalion surgeon with the Marines in Iraq.

After leaving the military, he joined a family practice in Southern California—one with a definite "wellness" focus. Dr. Lundquist, who had a strong leaning toward nutrition and natural medicine, was thrilled to be working alongside a PhD nutritionist with whom he could develop meaningful dietary interventions.

"But the clinic wasn't making money, so they fired the nutritionist and pushed me to see more patients. By the end I was seeing 35 people a day. It was crazy."

He left that practice for another large group that allowed him to bring in some holistic modalities, and to dispense supplements. But he quickly found himself running into limitations there too, especially when he broached the subject of IV nutrition. "I realized, in 2012, that I really needed to go out on my own."

But how?

Exceeding Expectations

He found some initial clues in the recordings from the 2012 *Heal Thy Practice* conference. "It was really inspiring. That's when I made the decision that I was going to do this." Attendance at *Heal Thy Practice* the following year solidified the commitment.

Today, not quite a year after opening its doors, TCIM is thriving beyond its founder's wildest expectations.

"We started out with five practitioners: myself, a chiropractor, a naturopath, another MD, and a lifestyle educator. Today we've got 10 practitioners, and another 10 employees. We're seeing close to 200 patients per week, and we've got a three-month waiting list."

He noted that he personally sees about 45–60 patients per week. "It's not crazy volume. We keep the numbers down and we give extended visits."

Even before TCIM opened, there were 150 patients ready to join the new practice. Dr. Lundquist estimated that roughly half of his previous patient panel followed him to the new clinic.

While many stars aligned to make the launch so prosperous, Dr. Lundquist said it was not entirely due to luck. A few core principles laid the foundation for success:

- **Teamwork:** From the get-go, TCIM was built around an interdisciplinary employee model in which each type of practitioner could shine at what s/he does best, and that true collaboration would be the norm.
- **Learning How to Bill Insurance:** Though TCIM does have a small cash-pay segment, the vast majority of patients use insurance. Partnership with coding experts has enabled the clinic to obtain reimbursement levels seldom seen for integrative medical services.
- **Listening & Responding to Patient Needs:** Dr. Lundquist recognized that he was not the only one frustrated by the limitations of conventional settings. His patients were equally dissatisfied. He was able to learn what they really wanted, and then to channel their enthusiasm into the new practice. Some of his strongest allies in creating TCIM have been the patients themselves.

"A few of my patients said, 'When are you going to open up your own practice? We want to help you.'" One such patient had been the director of a hospice, who then went on to train as a Reiki practitioner. She had time to spare, and worked with Dr. Lundquist to set up the new clinic.

The practice grew almost exclusively by word-of-mouth within Dr. Lundquist's patient base, and among people in the broader Temecula community who were excited about integrative care.

While there are a handful of other holistic or functional medicine practices around Temecula, they are all single-practitioner solo offices. "There was no true multidisciplinary center here until we came along."

That unique offering, plus the fact that TCIM was willing to take insurance made it highly appealing to residents of this 100,000-person community.

Temecula

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"I was known in my community, but we were able to bring in a physician from Florida who had absolutely zero patient base here, and we could completely fill her schedule in a very short time. That's how great the demand was."

Beyond giving occasional public lectures, and setting up a Facebook page, Dr. Lundquist did little marketing.

Eliminating Fear & Uncertainty

TCIM endeavors to provide patients with a complete healing experience without the fragmentation and frustration that characterize most conventional practices:

With its day spa atmosphere and unhurried approach, TCIM provides a level of service people might expect from a concierge or membership-style practice, but with one important difference: TCIM is largely insurance-based.

"A lot of people say you cannot practice good patient-centered care in an insurance model. They're wrong! We provide excellent care, and we do take insurance," says Nicole Fox, of the Integrative Medicine Consulting Group, who helped Dr. Lundquist found the TCIM practice model.

Careful Coding, Ample Returns

Ms. Fox, a former sales rep for Metagenics, was able to connect Dr. Lundquist with billing and coding experts who understand the nuances of functional medicine as well as the details of the coding system—a rare combination that has paid off amply for TCIM.

Though the clinic bills for services that do not always fit into the status quo of conventional insurance-based medicine, Dr. Lundquist says his coding is extremely "by the books." In most cases, the insurers will reimburse for the billed services. "I don't know of any other integrative clinic that's getting the level of reimbursement we're getting."

Currently the practice is only able to accept PPO plans, but is able to work with most of the major players in the area including: Anthem Blue Cross, Medicare, Aetna, UnitedHealthcare, Cigna, Blue Shield of California, and Tricare.

"Everything goes through an MD gatekeeper, and is billed under medical services," he explained.

"All patients must first see me or Dr. Narayan for an initial visit, and then they are referred to other practitioners within the center based on what they need. If they're seeing the practitioners within our center, we can bill insurance for these services as incidental to the initial MD visit. Of course, patients do have the option to see chiropractors or coaches or any other practitioners outside our center, and we honor those choices."

TCIM has a small number of direct-pay patients, but the vast majority does use insurance to cover at least part, if not all services.

The practice also has several ancillary cash revenue streams including an onsite supplement dispensary, and a series of classes focused on specific conditions such as chronic fatigue and autoimmune disease. Attendees pay $30 per 90-minute class. Ms. Fox noted that these classes, though not formal group visits, are a step in that direction.

TCIM practitioners also do teleconsults with patients on a cash basis, charging for increments of online time. So far, they have not sought insurance reimbursement for online consults, though that may change at some point.

Dr. Lundquist and Dr. Lee Hazen, the group's chiropractor, are co-owners of TCIM, along with a third business partner. All the other practitioners are salaried employees. The group currently includes a naturopath, a nurse practitioner, a behavioral health specialist, two lifestyle educators, a licensed acupuncturist, and two certified massage therapists.

"To have all the resources for complete patient care right at my fingertips is fantastic. I used to do all the nutrition consults myself, but now I have people working with me who are dedicated just to that. Having all the services integrated under one roof, and then to be able to bill insurance is just remarkable, and very rewarding. The camaraderie and collaboration are phenomenal."

He stressed that cultivating a spirit of teamwork has been essential to TCIM's success.

"One of the big challenges we face as physicians is that we tend to be very independent. We want to control everything. We're not so good at playing in the sandbox with others. To make a thing like this work, you really need to recognize the value of other types of practitioners and other healing disciplines, and to realize that what they bring to the table can help your patients just as much as you can."

Cultivating Teamwork

Staffing is one of the biggest challenges facing any practice, and Dr. Lundquist says he was initially concerned about how he was going to attract the right team.

"I was fortunate because a lot of the right people just came to me. With every one of our practitioners, when there was a need, a door opened and someone really good showed up. We actually did very little recruiting."

While there may be an element of kismet at work, Dr. Lundquist says attitude also plays a role. "I think it happened the way it did because I was really open. I did not need this to be 'Erik Lundquist's Clinic.' From the start, I was open to advice, to letting others take over certain aspects of the practice. That really helped me attract the right people."

A Touch of Tech

The care at TCIM is high-touch, but Dr. Lundquist and his team are firm believers in utilizing digital technology when appropriate.

New patient questionnaires and several other key forms are available electronically and provided to patients with the expectation that they will complete these prior to the actual office visits. This saves time and also helps engage patients before they ever set foot in the Center.

Dr. Lundquist has found Google Glass to be a valuable tool. He uses the head-mounted optical display system to connect to the Internet via Skype, so he can interact with an offsite

DR. LUNDQUIST, MD

medical scribe. The system allows him to securely live-stream each encounter to the scribe, who records all key details in the patient's medical record.

He says he prefers this approach because he found it difficult to truly pay attention to patients while simultaneously trying to enter case notes. "This allows me to communicate that info to the scribe, who will then document what's going on in real time. I can be more focused on the patient and be thinking about why he or she is experiencing what they're experiencing."

Finding the right EMR system was definitely a challenge for TCIM. Ms. Fox said the group tried three different systems before finally settling on HealthFusion. Though far from perfect, she says the team is generally happy with it.

Is the TCIM model replicable by other doctors in other communities? Dr. Lundquist definitely thinks so.

He hopes his presentation at *Heal Thy Practice,* and the Integrative Medicine Consulting Group's ongoing efforts will help physicians across the nation develop new clinic models that truly deliver on the promise of holistic and functional medicine.

FDA Rethinks Homeopathy Regulations

By Erik Goldman
Editor in Chief

For the first time in nearly 30 years, the Food & Drug Administration is considering revision of how homeopathic medications are regulated.

In April, the agency's Center for Drug Evaluation & Research held a two-day "information-seeking" public hearing on the use of homeopathic products, in preparation for a reevaluation of the regulatory framework governing the manufacture and marketing of these increasingly popular remedies.

A panel of nine FDA officials, including lawyers, a pediatric ethicist, and the director of the agency's OTC drugs division, heard testimony from 45 people, including some of the nation's leading advocates of homeopathy, such as Alison Teitelbaum, director of the National Center for Homeopathy, Bruce Shelton, MD, PhD, of the Arizona Homeopathic & Integrative Medical Association, and J. P. Borneman, of the Homeopathic Pharmacopoeia Convention of the US.

Some of the discipline's most vehement detractors—including Yale neurologist Dr. Steven Novella—see the current hearings as a welcome first step toward curtailment of what they view as a worthless and pseudoscientific practice.

Under the Spotlight

Since the late 1930s, when the FDA was initially formed, the agency has viewed homeopathic drugs as a category distinct from both pharmaceutical drugs and dietary supplements.

The FDA currently recognizes the US Homeopathic Pharmacopeia, maintained by a non-government organization—the Homeopathic Pharmacopeia Convention of the United States (HPCUS)—as the primary governing framework for homeopathics. The pharmacopeia includes 1,200 monographed homeopathic remedies in use since 1897, and it defines how these remedies are to be manufactured.

FDA does not currently require safety reviews for the manufacture or sale of homeopathic medicines. Since 1988, any "drug products" labeled as homeopathic have been able to be sold and manufactured without FDA approval, based on manufacturer adherence to the Compliance Policy Guide (CPG) published in the Federal Record that year.

Homeopathy's critics say these standards are too lax to ensure public safety, and even some people who are sympathetic to homeopathy in principle are in agreement that existing standards leave room for questionable manufacturing practices.

Some homeopaths cite the fact under the existing regulatory framework, unethical companies can market "homeopathics" not produced in accordance with the principles of homeopathy and containing potentially dangerous, undisclosed pharmaceutical or synthetic ingredients.

Ambiguous Signals, Veiled Motivations

FDA has been deliberately vague about what sort of regulatory revisions might be under consideration, other than to say that the agency is "Seeking to obtain information and comments from stakeholders about the current use of human drug and biological products labeled as homeopathic, as well as the Agency's regulatory framework for such products."

In an article on Bloomberg.com titled "FDA Might Finally Crack Down on Homeopathy," FDA's Cynthia Schnedar, who chaired the hearing, is quoted as saying, "We've seen a huge expansion of the market and we've also seen some emerging safety and quality issues."

Schnedar noted the agency was trying to determine whether consumers have "adequate information to make informed decisions" about homeopathic remedies.

The FDA says the hearings were not intended as a forum on the efficacy of homeopathy, or the right of practitioners to utilize the modality. Likewise the hearings were not intended as prelude to categorical prohibition of retail sale of homeopathic remedies. The focus, according to the agency, is on regulations and labeling requirements for OTC homeopathic products.

Those reassurances are of little comfort to some homeopaths, including Dr. Shelton, whose own personal and clinical experience made him a strong advocate.

"This could reverse a 75 year history that has helped make homeopathy as respected and as popular as it has become," Shelton notes on a post to the Arizona Naturopathic Medical Association's website. He is concerned that if the FDA opts to apply pharmaceutical-style regulations, it would all but eliminate free public access to OTC homeopathic remedies.

Though these initial hearings in and of themselves may be insignificant, they are taking place in the context of increased scrutiny—some would say overt hostility—toward all non-pharma products, as exemplified by the recent actions against botanicals by the New York Attorney General, and the letter from 14 state AGs calling on Congress to increase regulatory stringency on supplements.

It remains to be seen what will come out of the FDA's homeopathy review. *Holistic Primary Care* will be following the developments closely.

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1) Enhanced glutathione levels in blood and buccal cells by oral glutathione supplementation. J.P. Richie. Published in the European Journal of Nutrition, May 2014

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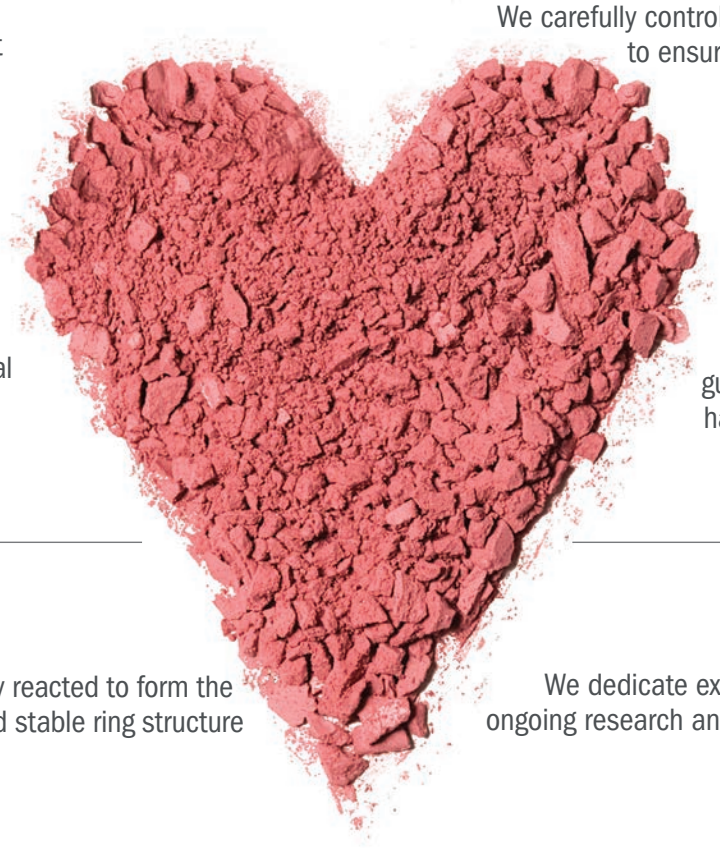

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