

SUPPLEMENT

NEWSLETTER OF THE NEW YORK BUYERS' CLUB

Volume V, No. 18



Fall 2010



SUPPLEMENTS & REGULATIONS

AN IN-DEPTH ANALYSIS OF THE STATE OF THE LAWS GOVERNING NUTRITIONAL SUPPLEMENTS

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REVIEW: MAYO CLINIC GUIDE TO ALTERNATIVE MEDICINE

AN EVENING WITH NELSON VERGEL

FIVE THINGS TO KNOW ABOUT MULTIVITAMINS

The FDA is going to ban all supplements! The Codex Alimentarius is going to cause supplements to be prescription-only here in the U.S.! Supplements are horribly dangerous! Supplements have no physiologic effects whatsoever!

Sorting through the truth about what supplements can do, how and when they can help and what the laws are all about regarding them is no easy task. Pools of interested parties compete for our attention. The manufacturers and purveyors of dietary supplements resist regulation. Some trade organiza-

tions, such as the Council for Responsible Nutrition, accept the need for some regulation (e.g., for quality prod-

tions upon them and even deny access altogether (e.g., to herbs considered dangerous, such as chaparral, comfrey

is the very access to supplements under threat?

ucts and ethics –see the NYBC blog for this and other relevant links). By contrast, some in the government and some consumer advocate organizations would like to place heavy restric-

and others). Yet others, notably in the drug industry, fear their potential to compete with highly profitable, costly and often toxic drugs.

So who to believe? There is yet an-

other pool of interested people. Those of us who USE these interventions: the consumer. Here at NYBC, we are living with chronic diseases such as HIV, hepatitis C, chronic fatigue, Lyme disease, among others, not to mention the simple fact we're all getting older. So while we sell supplements, we do so both as a non-profit and as people living with chronic disease. Where vitamin stores may try to get you to buy more and more, we are more interested in understanding if, when, how and why to use supplements to manage health, offset side effects all while trying to assure it fits in your budget. Is it a help? Is it a waste of time? And for this article—is the very access to supplements under threat?

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PLEASE NOTE This article appears in condensed form: visit NYBC's blog for the complete text including hyperlinks to relevant websites:
www.newyorkbuyersclub.org/blog

Five Good Things To Know About MULTIVITAMINS

1 The published, scientific evidence about multivitamins and HIV: a multivitamin can increase survival of people with HIV (AIDS, 2003); a multivitamin can delay progression of HIV disease in people not yet taking HIV meds (New England Journal of Medicine, 2005); a multivitamin + select antioxidants can increase CD4 counts in people taking HIV meds (Journal of AIDS, 2006).

3 Special-formula multivitamins are available: For example, NYBC stocks **Women's Blend**, **Perfect Kids**, and **Simply One** (SuperNutrition); **Multi Easy Swallow Powder** (Jarrow); and **Ultra Preventive Beta** (Douglas), which, among other features, has reduced Vitamin A, of concern to people with liver disease.

4 Not just for HIV: Multivitamins may be useful for people with many other chronic conditions as well. Recent studies have shown that people with Type 2 diabetes can benefit from taking a multivitamin, which appears to minimize the kinds of infections typically found in diabetics.

5 Low-cost options are out there! NYBC offers the very affordable **MAC-Pack** and **Opti-MAC-Pack** regimen combos - these provide close equivalents of the multivitamin and antioxidant combination that was used in Dr. Jon Kaiser's groundbreaking research on micronutrient supplementation for people with HIV (published in 2006—see above) - at less than half the price of Dr. Kaiser's proprietary blend, K-Pax.®



NYBC's pride and joy: the MAC Pack.



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THE BASICS

The term “dietary supplements” has a specific meaning within the laws and regulations of the Food and Drug Administration (FDA) of the United States government. By the FDA definition, a dietary supplement “is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.”

Regulations for dietary supplements were carved out in legislation known as the **Dietary Supplement Health and Education Act of 1994 (DSHEA)** that President Clinton signed into law in 1994. It was an amendment to the 1938 Federal Food, Drug and Cosmetic Act, which gave FDA the authority to evaluate the safety and efficacy of a range of products on the market. The provisions of DSHEA define dietary supplements and dietary ingredients; establish a new framework for assuring safety; outline guidelines for literature displayed where supplements are sold; provide for use of claims and nutritional support statements; require ingredient and nutrition labeling; and grant FDA the authority to establish good manufacturing practice (GMP) regulations. The law also requires formation of an executive level Commission on Dietary Supplement Labels and an Office of Dietary Supplements within the National Institutes of Health.

CURRENT EFFORTS TO REFORM OR AMEND DSHEA

Often, we hear that dietary supplements live in some kind of wild west of no regulations and free-wheeling. This is inaccurate. Indeed, the DSHEA gives FDA numerous

opportunities to oversee what is on the shelf—but they have failed to do so. To the extent that FDA exerts such powers, it has been largely to go after supplement companies who make claims that a product can affect a disease condition. We look at this more in a moment.

One widely-shared concern about all products is quality, including:

Identity – it is what it says it is;

Purity – it doesn’t have adulterants or contaminants (and the label FULLY explains all ingredients)

Potency – it has the amount claimed (i.e., 500 mg of acetyl-L-carnitine, not 425 or 900)

assure that our food, dietary supplements and drugs are in what they say they are and excellent quality. THIS is how it would be nice to see our tax dollars spent; employing more people to do the good work of assuring the safety and quality of the products we consume, that our very lives depend upon!

Once the product is in your hands and you are consuming it, other aspects come into play, including **Safety, Bioavailability, and Efficacy.**

Safety refers to the potential for anything one consumes to cause problems. A drug like AZT can have a range of side effects. And a peanut

may present with hitherto unobserved effects. Understanding the complete range of potential side effects is critical to making a rational assessment of therapeutic options. That doesn’t mean something should be removed from the market. For example, people with peanut allergies can face death and, understanding their risk, assiduously avoid peanuts. Those that can consume them safely may continue to do so. In the meantime, it remains unclear how robust this new system is or how it is working.

Bioavailability refers to how well one’s body absorbs the substance or, in the case of a botanical (or “herb”), some active constituents.

Efficacy is whether it does what it claims to do. It’s that “claim” bit that gets regulators in a tizzy—and also some in the pharmaceutical industry who view with some considerable agitation the potential threat that any competition represents to their profits.

Claims about the effect of a dietary supplement are limited to “structure and function.” For example, one can talk about vitamin D3 and calcium sustaining bone strength. Any such claims on an effect on structure or function must be accompanied by a statement prescribed by DSHEA, one you have no doubt seen many times: “This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.”

By contrast, claims about efficacy to treat, mitigate or cure a disease are forbidden without the FDA’s approval. This approval can only be undertaken should the supplement be classified as a drug and undertake all the onerous and costly steps of new drug approval, including extensive clinical trials.

Unfortunately, with either structure/function claims or efficacy, the FDA has basically done little since DSHEA was enacted in 1994. There are only a few approvals of efficacy for supplements or structure/function claims made in the past 16 years. We urge FDA to develop a mechanism and meth-

Regulations for dietary supplements were carved out in legislation known as the Dietary Supplement Health and Education Act of 1994 (DSHEA) that President Clinton signed into law

On FDA’s website, they note: **“Does FDA routinely analyze the content of dietary supplements?”**

In that FDA has limited resources to analyze the composition of food products, including dietary supplements, it focuses these resources first on public health emergencies and products that may have caused injury or illness. Enforcement priorities then go to products thought to be unsafe or fraudulent or in violation of the law. The remaining funds are used for routine monitoring of products pulled from store shelves or collected during inspections of manufacturing firms.” ...

In other words—they could be evaluating supplements—but they’ve never bothered to lobby Congress for the funds, equipment and people-power to do so! Why not? This is the kind of jobs creation America needs! This is the kind of effort that will

can be lethal if you have an extreme allergy. For the most part, dietary supplements are much safer than over-the-counter medications, though problems may arise if too much is used (e.g., high doses of selenium are toxic); it may have side effects (as mild as GI upset to liver toxicity) or it may interact with medications (like St. John’s wort).

FDA has developed a system to enhance reporting of **adverse events** related to a dietary supplement, but it is a passive effort. If you think a supplement has caused some kind of negative effect, you and/or your physician may report this. While for the most part, the potential for side effects is pretty well understood for the majority of dietary supplements (as they are defined at the outset, from historical empiric observation, to be Generally Recognized As Safe (GRAS)), some newer agents and even older ones

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REVIEW: THE MAYO CLINIC GUIDE TO ALTERNATIVE MEDICINE 2011 GREEN LIGHTS FOR MANY SUPPLEMENTS, YELLOW AND REDS FOR OTHERS (PLUS A FEW QUESTION MARKS FROM US)

This is an easy-to-read, magazine-style guide created by the Mayo Clinic, the world-famous healthcare facility known for many excellent qualities, including its long-standing openness to alternative and complementary therapies for wellness and prevention. That's one reason why it was frequently cited in our recent national health insurance debate as an example of best practices in American healthcare. These are the kind of practices that need to be more widely imitated, both because focusing on wellness and prevention makes good medical sense, and because it's obviously less costly for all to maintain good health and to prevent as much as possible the development of serious illness.

The Mayo Clinic guide covers a lot of territory--yoga, vitamins, herbs, acupuncture, meditation--but we'll limit ourselves here to just the part concerned with dietary supplements. This section gives capsule reviews of the scientific evidence for the safety and effectiveness of 57 items, from botanicals like Ginseng, Echinacea, and St. John's Wort, to vi-

tamins C, D, E, B-3 (niacin), and B-9 (folate or folic acid), as well as minerals like iron, selenium, calcium and zinc. Also discussed are categories of supplements, including probiotics (which are typically obtained from yogurt products or from supplements) and omega-3 fatty acids (generally obtained from fish or fish oil supplements).

The guide rates these supplements with a green, yellow,

or red light symbol, depending on the strength of the evidence for their use and their safety profile. We weren't too surprised by most of the ratings. For example, green for probiotics, omega-3 fatty acids, niacin, folic acid, Vitamin C and Vitamin D, but a yellow caution light for Vitamin E, which has been the subject of much controversy in the past decade,

leading some researchers to wonder if the standard "alpha-tocopherol" form of the vitamin is the best format for supplementation, and leading others to question whether taking more than 400IU per day is a good idea. (There's basic agreement that Vitamin E is an important protector against oxidative processes that can damage the body, and may have specific protective effects for people with HIV, as well as for people at risk for heart disease,

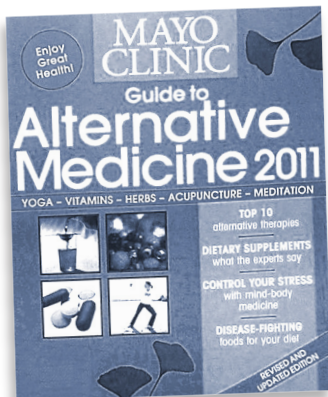
ment, while avoiding some of the unwanted side effects of prescription anti-depressants.

Other supplements getting the green light from the Mayo Clinic editors: SAME (for depression, arthritis and perhaps liver disease); saw palmetto (for enlarged prostate); green tea (for cardiovascular health, possibly for cancer prevention, and apparently--according to a large epidemiological study--for longevity); gamma linolenic acid (for peripheral neuropathy); CoQ10 (for cardiovascular health, for which it's used by millions in Japan, and to counter side effects of statin drugs); glucosamine chondroitin (for osteoarthritis--for this application it rivals prescription meds like Celebrex, without the harmful side effects); and Valerian (a traditional botanical, long used as a tranquilizer and as a remedy for insomnia).

Also getting the green light, an herb that most have probably never heard of, but which is featured in the Health Concerns formula Cold Away, available from NYBC: Andrographis (useful as a cold remedy, showing promise where many other products, such as Echinacea, have disappointed).

Other notable points that we found in the Mayo Clinic dietary supplement reviews, including a couple of assertions that surprised us and will send us back to our search engines to learn more:

"Vitamin C may decrease the risk of mouth and other cancers in some people, but more study is needed. Vitamin C appears to lower cancer risk more in men than in women. Researchers suspect that may be because men have a lower intake of antioxidants than do women and therefore may benefit more from supplementation." We didn't know men consumed less antioxidants than



Supplements that received a "green light" from the Mayo Clinic include probiotics, omega-3 fatty acids, niacin, folic acid, Vitamin C, and Vitamin D.

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eye disease, certain cancers, and Alzheimer's.) Also getting a yellow light is the botanical St. John's Wort, not because it isn't effective for mild to moderate depression, but because it's known to interact with many other medications. And a red light for DHEA--again, not because this steroid hasn't shown effectiveness for depression, but because the Mayo people are concerned about possible side effects for those with abnormal prostate function (a concern we share), and because earlier claims that DHEA might be a life-extending wonder drug fell flat when tested. We will add that two significant NIH-funded studies of DHEA published their findings in the past decade, one dealing with people with HIV and one with middle-aged people experiencing moderate depression. In both cases, the researchers concluded that DHEA was an effective treat-

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Probiotics @ NYBC: Jarrow Formulas **Green Defense** Vibrant Health **Green Vibrance** Nutricology **ProGreens** Biocodex **Florastor** Pure Encapsulations **Colostrum** Jarrow Formulas **Ultra Jarro-Dophilus + FOS**
Omega 3s @ NYBC: Jarrow Formulas **Max DHA Omega-3 Fish Oil**, **Organic Flaxseed Oil** Nordic Naturals **ProOmega** Douglas Laboratories **Lecithin**

Vitamins C & D @ NYBC: Super Nutrition **Super C Powder** Jarrow Formulas **C1000 Ascorbic Acid plus Olea Fruit Extract** Jarrow Formulas **Vitamin D3** in **400, 1000, 2500, and 5000 IUs!**
Also @ NYBC: Douglas Laboratories **Niacin** and **Niacin TR**, **Folic Acid**
Note that prices displayed on the website are significantly lower on many items when you become an NYBC member!

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odology to assemble experts to evaluate the literature and make approvals of claims in a timely fashion.

NEW LEGISLATION

The Senate Food Safety Modernization Act bill (S.510) and its companion House bill HR875 are essentially designed to address issues arising out of incidents like the recall of billions of eggs in the summer of 2010 for salmonella contamination, among other issues (such as *E. coli* contaminated spinach and so on). It would amend the Federal Food, Drug, and Cosmetic Act and provide regulators with the capacity to punish offenders with increased fines and prison sentences of up to 10 years. It has yet to be voted upon as of early November, 2010. (See the NYBC Blog for links to a summary and to comment.) Part of the issue here is that it is being merged with language from S.3767, Senator Patrick Leahy's original bill. S.510 essentially had exempted dietary supplements from the purview of the bill, but the original Leahy bill did have relevant language.

With regard to dietary supplements, the problems have been to what degree FDA may be given powers that are beyond the law's intended purview—the language of the bill may sound good but the devil is in the interpretation. For example, the Leahy bill includes language that

would seek jail terms for people who knowingly or recklessly adulterate or misbrand products. Which sounds eminently reasonable! What would not be so reasonable is if FDA were to interpret this to mean they have latitude to threaten imprisonment to anyone who cited scientific literature to discuss a product as a form of “misbranding.” Thus, the concerns turn on the precise definitions of “misbranding” and “adulteration” which some view as potentially being distorted by overly FDA zealous officials to use

about the relative scientific merits of a potentially therapeutic effect. Clearly, if a manufacturer sells products with adulterants in it or made out of grass clippings, we say “nail ’em!” But good faith efforts to discuss scientific evidence should not be prosecuted with threats of jail time if there is a good faith effort to provide clear references to scientific data.

Overall, we at NYBC support the Food Safety Bill, particularly if language can be added that clarifies that FDA should not abuse its authority or

touch on a few of concern to people living with chronic diseases, but a more complete survey is beyond the scope of this article.

In Europe, member nations of the European Union are having their laws harmonized with respect to a wide range of policies. The two main pieces of legislation we briefly review here are the **Codex Alimentarius** and the **Traditional Herbal Medicinal Products Directive (THMPD)**.

The **Codex** is “a collection of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety”.

Overall, the general principles of assuring food safety are sound and important. However, a fly in the ointment arose when a delegation from Germany insisted that dietary supplements should be reclassified as drugs. This happened in 1996 and while it was agreed to, loud protest halted its implementation. In 2005, “Guidelines for Vitamin and Mineral Food Supplements” was adopted by the Commission. These guidelines were ostensibly meant to help prevent people from overdosing on vitamins, claims the UN's Food and Agriculture Organization (FAO) and to assure the product safety

To the extent that this concern is true, it is rational. To the extent that these Guidelines may serve as a stepping stone to more restrictive laws that prohibit access to supplements, we object. Each EU nation is grappling with this—but sadly, it would appear that science is left in the lurch, as are we who are trying to survive and thrive despite chronic disease.

In the United States, there is a concern expressed by many that the Codex will somehow affect access to supplements by forcing us to change our laws to “harmonize” with the Codex Guidelines. One consumer protection group, the Center for Science in the Public Interest, has analyzed the potential and points out ways in which the Guidelines may be addressed in a June 1997 report. This group sees Codex as

Overall, we at NYBC support the Food Safety Bill, particularly if language can be added clarifying that the Food & Drug Administration should not abuse its authority or waste precious resources on assaulting legitimate efforts to sustain our health.

the law and its threat of incarceration to cow anyone who would dare share scientific data that underscores a therapeutic effect.

Specifically, one trade industry group, the Alliance for Natural Health, says, “the FDA contends that any food or supplement producer who mentions the potential of a product to prevent or treat disease is guilty of misbranding—even if they have piles and piles of scientific research from Harvard or some other top institution. So this bill would create a potential ten-year jail term simply for citing the best science.”

There is a clear distinction between misbranding that is outright fraudulent (i.e., selling black cohosh that is actually lawn clippings) and good faith efforts to provide information

waste precious resources on assaulting legitimate efforts to sustain our health. Indeed, we support a positive role of government in weeding out and, where necessary, prosecuting the unscrupulous. As noted, we advocate significantly increased resources for FDA to set up labs around the nation to routinely evaluate dietary supplements found on the market, publishing *all* data and findings transparently on a website and issuing alerts for products found to be inadequate or adulterated or also if they passed the tests.

THE INTERNATIONAL SITUATION

Laws affecting what we here in the US refer to as dietary supplements vary from nation to nation. We will

SUPPLEMENT YOUR KNOWLEDGE

Center for Science in the Public Interest
www.cspinet.org

National Center for Complementary and Alternative Medicine (NCCAM)
nccam.nih.gov

Alliance for Natural Health
www.anh-usa.org

Food and Agriculture Organization of the United Nations (FAO)
www.fao.org

U.S. Food & Drug Administration (FDA)
www.fda.gov

ON THE 'NET

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AN EVENING WITH NELSON VERGEL:

“SURVIVOR WISDOM: ADVANCES IN MANAGING SIDE EFFECTS, LIVING WELL, AND AGING WITH HIV”

How could you not be impressed by the schedule HIV treatment activist Nelson Vergel keeps? A few days before he arrived in New York to share his “Survivor Wisdom” with New York Buyers’ Club members and guests, he was an invited participant at the 12th International Workshop on Adverse Drug Reactions and Comorbidities in HIV in London. The founder and moderator of the “po-zhealth” group on Yahoo—the largest online discussion group for HIV issues—Nelson also finds time to answer questions on a forum hosted by thebody.com. In addition, he serves as a community member of the federal government’s Department of Health and Human Services HIV treatment advisory board. And did we mention that he’s the author of a new book, “Testosterone: A Man’s Guide,” especially useful for people with HIV who are considering testosterone therapy to address fatigue and other problems?

As you might expect, Nelson also covered a lot of territory in his NYBC talk on November 9, which was co-hosted by the City University of New York’s Graduate Center. He briefly updated the audience on new treatments and guidelines, then reviewed the exceptional case of the HIV+ “Berlin patient,” whose apparent cure following a bone marrow transplant has opened up, at least tentatively, some new lines of research about curing HIV.

Most of Nelson’s talk, however, dealt with familiar issues in managing HIV symptoms and medication side ef-

fects: cardiovascular health challenges, lipoatrophy (facial wasting especially) and body fat accumulation (lipohypertrophy), aging with strong bones, fighting off fatigue, minimizing the risk of anal cancer.

Amid this discussion of symptoms and side effects, Nelson spent time on the topic of supplements. His first point, which NYBC would certainly agree with, is that a lot of good evidence has accumulated about the benefit of multivitamin supplementation, and a multivitamin plus antioxidant combination, for people with HIV. These “micronutrients,” as they’re called in the scientific literature, can enhance survival, delay progression of disease in people not yet on HIV meds, and increase CD4 counts in people taking the meds.

We have to admit we were pleased when Nelson also took a moment to praise NYBC (and especially our Treatment Director George Carter) for making available an inexpensive, “close equivalent” of the multivitamin/ antioxidant combination that was the subject of Dr. Jon Kaiser’s well-known research and that led to the development and marketing of K-PAX. New York State residents, as Nelson pointed out, have access to many such supplements through formularies. But for residents of other states, this half-price version of the multivitamin/antioxidant combination (MAC-Pack or Opti-MAC-Pack) can provide welcome relief in the budgetary department.

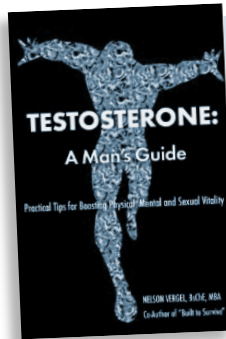
Our speaker then ran through a list of about a dozen supplements that have reasonably good evidence to support their use by people with HIV. He chose to focus more closely, however, on just a few:

Niacin. Despite “flushing” that makes it difficult for some to use, niacin can be very effective in bringing up levels of HDL

(“good”) cholesterol in people with HIV. Since cholesterol control is a major long-term health issue for many people on HIV meds, and since recent research suggests that raising HDL cholesterol levels may be an extremely important factor in reducing cardiovascular risk, niacin may be a top choice for many. (Fish oils/omega-3 fatty acids, plant sterols, pantethine, carnitine, and CoQ10 are other supplements that NYBC and many others put in the category of “supports cardiovascular health.”)

promise for dealing with neuropathy.)

Probiotics. The vulnerability of the gut in HIV infection, and the well-documented problems people with HIV experience in absorbing nutrients, make probiotics a very helpful class of supplements for long-term health maintenance. (Probiotics, good or “friendly” bacteria residing in the gut, are available in a variety of products, from yogurt to supplements. There’s quite a bit of research about the effectiveness of different varieties, and note as well that there are some newer for-



Testosterone - A Man’s Guide by Nelson Vergel. Paperback; \$19. Nelson has been a guiding light in the fight against HIV as a survivor for over 25 years. His knowledge and understanding of how best to use anabolic steroids and testosterone replacement therapy are unparalleled. *Testosterone* is a must-read for anyone considering use of testosterone, how to maximize the benefits while limiting the potential side effects. Available now in the NYBC Members Store: www.NYBCsecure.org.

Vitamin D. Seems that, even at the London conference Nelson had just attended, the “sunshine vitamin” was a hot topic. Partly that’s because people with HIV have recently been found to have a high prevalence of Vitamin D deficiency, and then because Vitamin D, calcium and other mineral supplementation is a logical approach to addressing long-term challenges to bone health in people taking HIV meds. (Look on the NYBC blog for a whole host of other recent studies about Vitamin D’s potential benefits, from reducing cardiovascular risk to cancer prevention—even as a way of warding off colds and flu.)

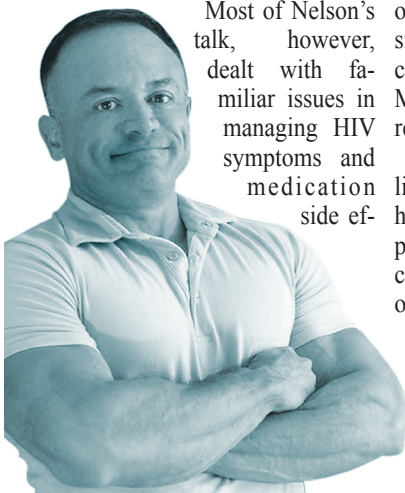
Carnitine. This is a supplement, Nelson told the audience, that he’s taken for many years. Reported/perceived benefits: to improve fatigue, lipids, brain function and neuropathy. (NYBC Treatment Director George Carter put in that “acetyl-carnitine”—a form of the supplement that crosses the blood/brain barrier—has shown the most

mats that don’t require refrigeration.)

Above and beyond the treatment issues involving supplements, meds, and other strategies, Nelson referred several times to areas where there’s a need for advocacy. He mentioned the cure project, for one, but also a national watch list to help people follow and respond to the devastation created by recent funding cuts and the resultant waiting lists in the ADAP programs of many states, such as Florida.

By now you’re probably getting the impression—and you’d be right—that “Survivor Wisdom” was an information-rich presentation. We have to say, though, that Nelson is not only a very well-informed lecturer, but also an engaging and witty speaker. So, no surprise that the audience of 80 stayed pretty much “glued to their seats” for two hours, with many lingering for further questions at the close.

Thanks again to all who attended! And please do stay connected to the NYBC website and blog, so that we can continue the conversation.





SUPPLEMENTS & REGULATIONS

(continued) potentially diluting some of the more stringent standards in the US (e.g., for bottled water). By contrast, CSPI supports *more* restrictive laws for dietary supplements. Interestingly, they note that “The U.S. delegation told the Committee that herbal medicines in the U.S. are regulated as dietary supplements pursuant to the DSHEA, and need not be reviewed for safety or approved by the FDA prior to marketing. The U.S. delegation, however, did not fully inform the committee about the difficulties that the FDA has had trying to restrict the sale in the U.S. of harmful herbs such as ephedra, chaparral, comfrey, and other substances.” This hardly paints a picture of an overly draconian FDA! (By contrast, as with substance like tobacco and alcohol, outright ban of substances should not be in the purview of the government. Assuring adequate labeling to identify risks is what is important. Prohibition may be good for the prison industrial complex but it doesn’t solve anything.)

A second area of concern is the Traditional Herbal Medicinal Products Directive (THMPD), destined to become law on April 1, 2011. This EU law was designed explicitly to address the use of botanical agents, requiring “herbs” have licenses in order to be sold on the market. While it has relatively successfully been able to evaluate and license many European botanical agents, it has left aside botanicals from other nations—and thus the benefits of entire realms of healing knowledge as reflected in the systems

of Chinese medicine and Indian traditional systems of medicine like Ayurveda, Siddha and Tibetan medicine.

While practitioners may be able to prepare their own formulae of raw herbs, finished products will not be permitted. Thus, if you live in Britain or France and want to use Health Concerns’ Marrow Plus, for example—you will be “protected” from

genocide). Whether this law will impact the United States is unknown, however you can be sure regulators will be watching keenly to see how it plays out in Europe.

In all, the stew of laws and regulations bear close watching. We must advocate from our perspective of consumers and users of dietary supplements (and mainstream drugs!). We want to know what we use is safe and of good quality, whatever the source. The recent fine of \$750 million levied against Glaxo SmithKline for knowingly distributing contaminated and falsely labeled

native Medicine (NCCAM) to conduct clinical studies on the efficacy and limitations of micronutrients, botanicals, hormones like DHEA, fatty acids and other agents.

We further advocate for a more streamlined and appropriate process for FDA to review both structure/function and therapeutic claims. It took FDA nearly 40 years, despite mountains of data, to recommend folic acid supplementation for expectant mothers to prevent neural tube defects—it’s hardly as though there are not myriad other ways dietary supplements can help and improve our lives.

We know. We see it every single day.

NYBC’s Wish List for 2011
For the Food & Drug Administration
Comprehensive, robust and ongoing evaluation of the identity, potency, and purity of products.

For the National Institutes of Health
Funding for more clinical studies to evaluate dietary supplements.

For the National Center for Complementary and Alternative Medicine
Funding to conduct clinical studies on the efficacy and limitations of supplements.

doing so by the EU government, unless they are able to obtain a license, which doesn’t seem likely. (Currently, the EU Commission is also negotiating a “free trade” deal with India that may have the horrific impact of denying their capacity to make available antiretrovirals as generics with generic pricing; to our way of thinking, this is akin to a form of economic

drugs being a prime recent example.

And there’s more. We advocate for comprehensive, robust and ongoing evaluation of the identity, potency, and purity of products by the FDA. For NIH, we advocate for funding for more clinical studies to evaluate dietary supplements. We want an even more robust, better funded National Center for Complementary and Alter-

MAYO GUIDE (continued) women—what’s up with that? Does that mean women eat more fruits and vegetables, perhaps?

Artichoke leaf extract “may reduce symptoms such as nausea, vomiting and abdominal pain associated with indigestion (dyspepsia).” (NYBC literature suggests that Artichoke may have a liver protective effect; and there’s also some evidence for its ability to mildly reduce cholesterol levels, but we’d be interested to hear from any of our members who have used it for these gastrointestinal

symptoms.)

“Multiple trials indicate that SAME [S-adenosylmethionine] can relieve pain from osteoarthritis as effectively as nonsteroidal anti-inflammatory (NSAIDs) drugs, with fewer side effects.” (We knew that SAME continues to be studied, and with very promising initial results, for major depression. We also knew about its capacity to normalize liver enzymes in some people with liver disease. But we hadn’t seen such a strong affirmative statement about its ability to relieve osteoarthritis pain.

We do know that SAME can have unwanted mood-changing effects on some, so it’s definitely to be taken under a doctor’s supervision.)

“Numerous human trials have found Echinacea can reduce the duration and severity of upper respiratory infections, particularly when the herb is taken at the earliest onset of symptoms.” But, as the Mayo people go on to say, “there’s still no cure for the common cold,” and the latest study results suggest that Echinacea “isn’t an effective method for cold prevention or treatment, as once

thought.” As for us, we’ve been following the recent studies suggesting that the “flu season” may in fact be the “Vitamin D deficiency season,” and that supplementing with Vitamin D3 at about 2000IU/day in the winter months could help keep many colds and flus away. See also the comment above on the lesser-known cold remedy Andrographis.

The Mayo Clinic Guide to Alternative Medicine 2011 is available at bookstores, select newsstands, and on Ebay.com.

SUPPLEMENT
NEWSLETTER OF THE NEW YORK BUYERS’ CLUB

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New York Buyers’ Club is a non-profit organization with the goal of increasing awareness about and access to vital nutritional supplements, with a focus on the needs of those affected by HIV/AIDS, Hep C, and other conditions.

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