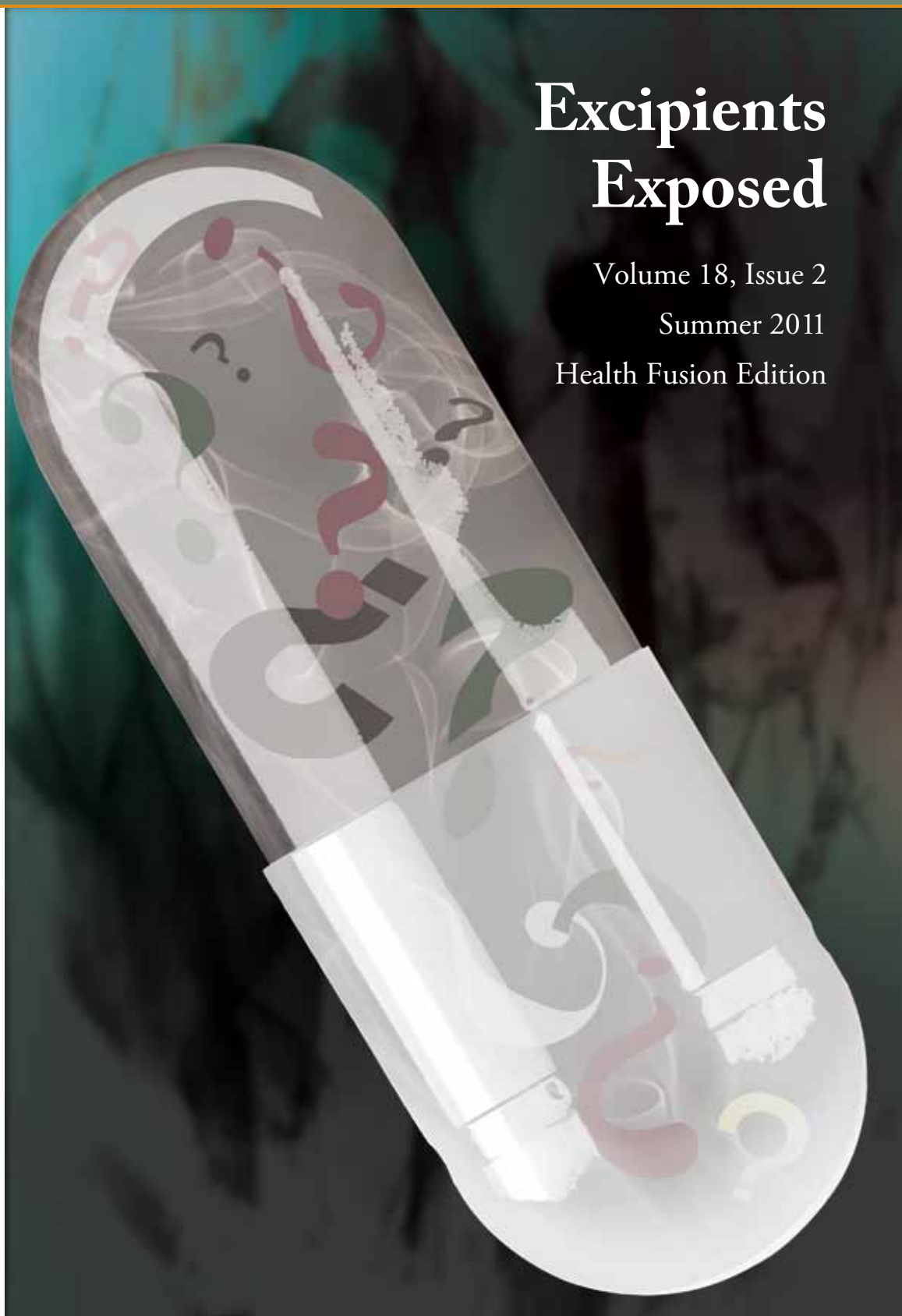
Vital Link

The professional journal of the Canadian Association of Naturopathic Doctors

Feature Articles



Excipients Exposed

Volume 18, Issue 2

Summer 2011

Health Fusion Edition

Canadian Association of Naturopathic Doctors

CAND

Association canadienne des docteurs en naturopathie

Vital

Ethical Omega, fish oil with a conscience….

- Sustainably harvested wild sardine, anchovy and/or mackerel, low on the food chain, short life cycle, naturally low in environmental toxins
- Sourced from the pristine ocean off South America's west coast
- Exceeds worldwide regulations and guidelines for contaminants, including lipid peroxides, heavy metals, pesticides, dioxins and PCBs
- Exhaustively tested and approved to the global quality and purity standards of the European Commission, Norwegian Food Safety Authority, Health Canada and the United States Food and Drug Administration
- Pharmaceutical grade, molecularly distilled
- The only fish oil to achieve the highest USP standard verification
- Exceeds IFOS quality standards
- Multiple fresh, high potency, odour and burp free EFA products for every patient need, available in softgel and liquid

Place your order today!

customer service 1·877·433·9860 • **fax** 1·877·433·9862
email customersupport@bioclinicnaturals.com

@bioclinic1

Complimentary Service

Proudly Canadian

PURE · POTENT · TESTED · TRUSTED

bioclinic™ naturals
natural solutions + clinical results
www.bioclinicnaturals.com

pure encapsulations®

— Your Trusted Source —

Targeted Support for Exercise Performance

Energy Xtra
-A blend of adaptogenic herbs suchs as eleutherococcus senticosus and ashwagandha for enhancing mental and physical stamina

Nitric Oxide Support
-Providing an optimal level of l-Arginine
-Helps support healthy circulation and oxygen delivery throughout the body to working muscles

WheyBasics
-100% Pure undenatured isolate
-Sweetened with stevia
-From grass-fed hormone free cattle

Amino-NR
-Natural ratio amino acid complex
-Supports athletic training efficiency
-Promotes immune and overall health

Please refer to our 2010/2011 product catalog for full product lisings

TO ORDER: **866-856-9954** • FAX: 888-220-9441 • www.purecaps.ca

552 Newbold St., London, ON N6E 2S5

Bridging the gap between nutraceuticals and evidence-based medicine

NFH *Nutritional Fundamentals for Health*

- Devoted to the integration and application of nutraceutical science in clinical practice
- We produce herbal, vitamin and mineral formulations of the highest quality for exclusive use by licensed health care practitioners.
- We focus on optimal efficacy combined with patient safety.
- Our Scientific Advisory Panel and Medical Consultancy Group provide the essential guidance in formulating our products and positioning our product line.
- Integrative, innovative and evidence-based approach.

Nutritional Fundamentals for Health • 3405 F.-X.-Tessier, Vaudreuil, QC J7V 5V5 • Tel. 1 866 510 3123 • Fax. 1 866 510 3130 • www.nfh.ca

Vital Link

Contents

Volume 18, Issue 2 | Summer 2011

Feature Articles

Plus

Vital Link

Volume 18, Issue 2, Summer 2011
Excipients Exposed

Naturopathic Editor in Chief
Dr. Iva Lloyd, BScH, RPE, ND, Past Chair, CAND

Editorial Advisory Board
Dr. David Lescheid, PhD, ND
Dr. Marcia Prenguber, ND, FABNO
Dr. Dugald Seely, ND, MSc
Dr. Marianne Trevorrow, ND, MA
Dr. Isis van Loon, ND

Managing Editor and Advertising
Alex McKenna • amckenna@cand.ca

Cover, Layout and Print
J Sutton Communications

Publisher
Canadian Association of Naturopathic Doctors

Mailing Address
Vital Link c/o Alex McKenna
CAND 20 Holly St., Ste. 200 • Toronto, Canada M4S 3B1
Phone 416.496.8633 • Fax 416.496.8634 • www.cand.ca

The *Vital Link* is the professional journal of the Canadian Association of Naturopathic Doctors (CAND). It is published primarily for CAND members and features detailed reviews of specific causal factors: philosophical and research-based papers, clinical practice articles and case reviews, as well as international updates on the profession. The *Vital Link* has an outreach to other health care professions and promotes qualified naturopathic doctors to corporations, insurance companies and the Canadian government.

Forthcoming Themes

Fall 2011
The Psychology of Healing

Submissions
When writing for the *Vital Link*, keep in mind its broad readership and outreach to other professions. Your contribution to the *Vital Link* will benefit the naturopathic profession as a whole and provide you with personal professional exposure. Previously unpublished material is preferred. Please contact the managing editor for submission guidelines.

Circulation
The *Vital Link* is published three times per year and is distributed to over 2000 qualified Canadian NDs and students of CNME-accredited naturopathic programs in Canada and the U.S. The *Vital Link* is also distributed to the CAND's corporate members and in our media kit. The journal is available electronically to members only.

Advertising
Professional vendors providing NHPD-compliant products or other services to NDs are encouraged to advertise in the *Vital Link*. The CAND's advertising partners enjoy unequalled exposure to qualified Canadian naturopathic doctors.

Naturopathic Notes

Dr. Iva Lloyd, BScH, RPE, ND

Excipients and fillers in natural health products and prescription medications have, to a large degree, been ignored or assumed inert for years. They, like many things, are starting to receive a lot of attention as specialized groups and government organizations are questioning whether the assumption of safety is true.

Naturopathic doctors have a history of addressing what others ignore and of highlighting concerns often long before they are commonly accepted. The concern about excipients and fillers in natural health products, prescription medications and personal care products is no exception. The question is no longer whether or not there is a concern; it is more about how big of a concern is it.

Excipients and fillers play an important role in the manufacturing of pharmaceuticals, natural health products and personal care products. But all excipients and fillers are not the same. Manufacturers can choose to make their decisions based on health or based on cost. Not that the two are always mutually exclusive, yet historically cost has too often been chosen at the expense of health. The good news is that many manufacturers are now choosing health.

Environmental Defence, Environmental Working Group and numerous other environmental activist groups are all stating the same thing – the chemicals in products are not necessarily inert. The issue surrounding these chemicals has even more significance as the public becomes more informed. This means that we, as naturopathic doctors, need to include excipients, fillers, chemicals and heavy metals in our assessment as contributing factors to a patient's symptoms or conditions.

The focus of government agencies such as Health Canada and the FDA is to regulate medicinal, and non-medicinal (including excipients and fillers) ingredients in products. The focus primarily has been on medicinal ingredients. There is growing concern that the regulations are too lax with respect to the non-medicinal ingredients and that there is some concern about the contamination of medicinal ingredients with heavy metals, pesticides and chemicals.

There are currently over 10,500 known chemicals that are used in natural health products, pharmaceuticals and personal care products. To-date less than 10% have been studied and even fewer have any regulation at all. The current focus is on a very few chemicals, such as magnesium stearate, silicon dioxide, talc, microcrystalline, titanium dioxide, glycerine, phthalates and parabens. I expect that the research in the next few years will start to address a much greater number of chemicals, and hence assist in clarifying which ones actually pose a health risk.

Unfortunately manufacturers that grow or source organic herbs or base ingredients are being lumped with those that simply do what is required to get products approved. There is also the concern of patients purchasing products from other countries and on-line that don't have the same standards. Any practitioner who has been in practice for any length of time knows that there is a difference in product quality between manufacturers. They also have experienced patients reacting to products where the reaction can't be explained by the action of the active ingredients. As people generally are becoming more sensitive, as environmental sensitivity syndrome is on the rise and the impact of EMF radiation and other intangible factors are increasing there is an overall increase in susceptibility to excipients, fillers and other toxins found in natural health products, pharmaceutical medications and personal care products.

What we are currently left with is a lot of questions.

1. How do you ensure that the products you prescribe are free of harmful heavy metals and chemicals?
2. How do you assess the benefits versus risk of different excipients and fillers?
3. When is it best to choose capsules, tablets or liquid?
4. How is the stability and quality of different products ensured?
5. Where do you go to stay current on this topic?

We trust that the articles in the *Vital Link* will provide some light on the questions above. Our aim is to bring awareness to this topic and we would like to thank the many writers that have contributed to this edition. We welcome your comments and your feedback.

Pure and Great Tasting Omega Oils®

I did my homework, and Nordic Naturals has everything I need to recommend with confidence.

And because it tastes great, my patients who need heart health support actually enjoy taking it.

NORDIC® NATURALS
Pure and Great Tasting Omega Oils®

Distributed by Ecotrend: 800.662.7060 • info@ecotrend.com

Four Corners: Updates on the Profession

CAND *www.cand.ca*

Naturopathic Medicine Week 2011 (May 9 – 15th) has just come to a close and by all accounts it was a great success. With the leadership of the NMW Committee and the support of the provincial associations, NDs across Canada engaged with the public on the benefits of naturopathic medicine and in seeing an ND. Participation in NMW continues to grow year over year with over 200 events taking place for 2011. Thanks to everyone involved for all their hard work and stay tuned for NMW 2012!

In April the CAND participated in meetings with the CNME, AANMC and the AANP's Naturopathic Coordinating Council. These meetings provide an opportunity for the organizations to come together to update on work in progress, discuss issues of importance to the profession in North America. Details are outlined in the updates provided in the AANP report below.

Last year marked the launch of a revitalized Canadian Naturopathic Foundation (CNF). New by-laws were completed, a new logo was designed representing the road to health and a new website was created to educate the public – www.ExploreYourHealth.ca. Response to the site has been very positive from both the public and the profession. The CNF is your foundation with a focus on public education, research to support naturopathic medicine and bursaries for naturopathic students. Please take the time to take a look and more importantly link it to your website and help share the information with patients, colleagues, family and friends.

With the election of a Conservative majority and the return of the same Ministers to health and finance we will be able to continue the government relations work we were engaged in before the election. The continuity of departmental and ministry staff will mean that we are not starting from scratch this time around. We will continue to focus on access to substances and the inclusion of NDs within the definition of "Practitioner" under proposed amendments to the Food and Drugs Act. While work at the federal level ground to a halt during the election campaign, the provincial associations continued their efforts to secure effective legislation/regulation for the profession. The latest exciting news comes from PEI where the Health Minister recently announced they will be moving forward with umbrella legislation, specifically mentioning naturopathic doctors as one of the professions that will be included.

Here at the CAND we are busy gearing up for Health Fusion 2011 – Environmental Medicine: From Microscopic Understanding to Macroscopic Application. It promises to be the most exciting Health Fusion yet with a public event – Dr. Rick Smith author of *Slow Death by Rubber Duck* and an outstanding line up of experts in the field, and of course amazing food as Ed Borsuk once again works his magic with the hotel chefs. Have you registered yet? Complete details can be found at www.cand.ca/index.php?id=healthfusion. We look forward to seeing you there!

AANP *www.naturopathic.org*

AANP held its 8th Annual DC Federal Legislative Initiative, the yearly lobby day for NDs and students to travel to Washington, DC and meet their legislators on Capitol Hill. The event culminated with our annual reception attended by more than 500 Congressional staff and Members of Congress. This year 165 people sacrificed work, school and family to take the AANP message to the Hill. Implementation of the Patient Protection and Affordable Care Act (PPACA) remains a top priority for the AANP. Our specific "asks" of Congress include defining the term Integrative Health Care Practitioner, and inclusion in key loan, scholarship and primary care residency programs.

The health care reform law clearly identifies 'complementary and alternative medicine' and 'integrative health care' providers, but nowhere does it define the term integrative health care practitioner. Somewhere inside our Department of Health and Human Services, an office has been assigned to define the term in regulation. However, no one inside HHS responds to our queries, so we continue to ask Congress to advocate for our proposed definition. We believe all licensed health care practitioners, including NDs, can provide true health care services based on their defined scope of practice - not just the reimbursement schedules for Medicare and Medicaid.

NDs and students also lobbied for equity in education, seeking access to loans, scholarships and a new primary care residency program created in PPACA. Currently, the federal government funds all residency programs for MDs and DOs. This program is unique in that it is funded through the Public Health Service Act and is specifically designed to increase the number of primary care providers – not specialists. The law currently allows only MDs, DOs and PAs to access the program.

HepatoDR®

Tried, Trusted and True

For your digestive health trust HepatoDR®

This exceptional formula contains potent herbal ingredients that have been used with great success in herbal medicine over the years. Modern clinical and laboratory work confirms that they are effective in protecting and restoring the liver, which not only aids digestion and the regulation of blood sugar, but also detoxifies the body.

Detoxify and enjoy!

NEW
Powdered Encapsulated Extract in Vegicaps

St Francis HERB FARM®

Products Professionals Prefer®

Made in Canada
Health Canada Site License 300242

www.stfrancisherbfarm.com
TO ORDER: info@stfrancisherbfarm.com, 1-866-562-9131

In other news, North Dakota has become the 16th state to license naturopathic doctors! Thanks to the tireless and collaborative efforts of both alumni and students from several ND schools, this legislative change can be expected to create increased employment and practice opportunities for NDs, along with better care overall patient health.

CNME *www.cnme.org*

The mission of the Council on Naturopathic Medical Education (CNME) is to promote high quality naturopathic medicine education in the U.S. and Canada through the accreditation of naturopathic doctoral (ND) programs. Graduation from a CNME-accredited or pre-accredited ND program is a requirement for taking the NPLEX exam and becoming licensed or regulated as a practitioner. Currently, the CNME accredits two programs in Canada and four in the U.S., and also pre-accredits one program in the U.S.

The Council is governed by a Board of Directors composed of from 9 to 12 members from Canada and the U.S., including 3 representatives drawn from naturopathic colleges, 4 – 6 naturopathic practitioners, and 2 – 3 public members. The Board meets twice a year in person to review ND programs, review and revise accreditation standards and policies, regulate naturopathic residency programs, and conduct other business. The day-to-day operations of the Council are managed by an executive director.

The Council last met in April 2011 in Denver, Colorado. At that meeting, it reviewed three colleges that had recently been visited by a CNME evaluation team: Canadian College of Naturopathic Medicine, Southwest College of Naturopathic Medicine, and the University of Bridgeport College of Naturopathic Medicine. All three institutions demonstrated great progress in their ongoing development. The Council also addressed several other issues, including: reporting requirements, a policy to cover branch campuses, the possibility of developing a policy to allow for distance/online education, and second-degree naturopathic programs designed for people trained in other medical fields.

AANMC *www.aanmc.org*

At the April Board meeting of the AANMC, the Council of Chief Academic and Clinic Officers (CCACO) presented course level learning outcomes guidelines for five modalities: Botanical Medicine, Health Psychology, Homeopathy, Nutrition, and Physical Medicine. The guidelines are designed to ensure that course level training is in alignment with learning outcomes.

These documents are intended to honor the uniqueness of each individual naturopathic program while at the same time standardizing the language for learning outcomes. The documents provide basic and embraceable guidelines that are accessible to all practitioners, versus specifying educational requirements of the schools. In addition, the CNME has requested defined learning outcomes as they relate to meeting the CNME standards.

The CCACO process for developing and approving the draft documents was inclusive, and unanimous in its endorsement. Faculty members at each school were given an opportunity to respond to the draft documents, and their comments were reviewed one-by-one by CCACO at its February 2011 meeting. Careful consideration was given to each comment and appropriate changes were made accordingly.

The Board approved the draft documents, requesting an annual update on the documents and expressing its gratitude to CCACO and Dr. Becky Clark for their work in this arena. CCACO now turns its attention to working with the Foundations Project on the development of similar learning outcomes guidelines for naturopathic philosophy.

Excipients in Dietary Supplements: The 'Other Ingredients'

Dr. Christine Toomasi, ND
Dr. Lise Alschuler, ND, FABNO

Many of you may recall having looked at your favorite dietary supplement labels and noticing some unfamiliar "other ingredients". Confused and frustrated as to why these ingredients are in your supplements you may have questioned the quality and purity of the products. You may have asked, "What are these ingredients and are they safe to add to health promoting products?" or, "Will the use of supplements containing these unfamiliar ingredients cause health problems in patients?"

Many of these "other ingredients" are considered inert and are called excipients. Excipients play a vital and also controversial role in the manufacturing of dietary supplements, pharmaceutical drugs and even certain food items. They are defined as "components of a finished drug product other than the active ingredient" and they are added during formulation for specific purposes. Excipients are classified by the function they perform, with the most common categories being: binders, fillers, flavors and sweeteners, coloring agents, and lubricants.[1]

"Other ingredients" do serve an important role in the manufacturing of supplements. For example, binders keep our supplements (especially tablets) from crumbling and shedding. Microcrystalline cellulose and colloids (a substance characterized by evenly dispersed particles within another material) are commonly-used binders that come from vegetarian sources and are considered fibers. Fillers are excipients used to take up empty space in a capsule or tablet. Some suppliers use non-food grade fillers such as talc, which can be easily substituted with food-grade filler such as cellulose, an insoluble plant fiber. Although, talc is generally recognized as safe (GRAS) to use as an anti-caking agent in very small concentrations, some serious health concerns do exist. These health concerns which can be as serious as cancer would only be a concern in individuals with long-term exposure to natural talc or regular vaginal application of talc powder.[2]

Flavors are used when manufacturing liquids and chewables, especially for children and consist of sweeteners such as sorbitol, maltose, sucrose, lactose, glycerin or fructose. Xylitol has grown in popularity as a flavoring agent for chewable and liquid supplements. An article published in *Clinical Pediatrics* gathered information on excipients in forty one chewable/liquid multivitamin and mineral preparations. Sucrose was the most common sweetener, listed as an "other ingredient" in 63% of supplements analyzed. Lactose, glycerin and sorbitol were also popular sweeteners found in the preparations. On average, two sweeteners were found in the preparations analyzed. Many sweeteners found in dietary supplements have dose dependent adverse effects and although the regulations require excipients to be labeled the dosage is not required and as such, some dietary supplement manufacturers choose not to disclose the dosage. For patients with sensitivities (may be immune mediated or the result of direct neurological or gastrointestinal toxicity) to sweeteners such as sugar alcohols it would be best to avoid sweetened supplements or to use capsules.[4]

Coloring is added to products primarily for appearances and identification. Many high quality suppliers will use carrots and beets as food grade coloring agents,[1, 3, 4] but others use agents such as FD&C red # 33 (used primarily in cosmetic products), FD&C yellow #6 (most common dye), FD&C red #40, and FD&C blue #1. FD&C red #33 appears to be relatively non-toxic when used externally, may produce leukocytosis when taken internally, but does not demonstrate mutagenic or carcinogenic properties. FD&C yellow # 6 is an azo dye and can cause anaphylactic reactions, angioedema and contact dermatitis. It should also be used with caution in patients taking aspirin, acetaminophen, sodium benzoate and other azo dyes because of cross reactivity concerns. FD&C red #40 has been shown to produce DNA damage in coloncytes of mice[5] and may be linked to hyperactivity in children.[6] FD&C blue # 1, a triphenylmethane dye has caused bronchoconstriction in asthmatic patients.[7]

Certain excipients are used to allow for better lubrication during processing of dietary supplements. Popular lubricants are magnesium stearate, stearic acid and silicon dioxide. The use of magnesium stearate in dietary supplement manufacturing is controversial. Although magnesium stearate is a cost efficient method to lubricate during manufacturing and keep the supplements from clumping, many individuals are concerned about possible side effects and toxicities. Magnesium stearate is commonly sourced from palm oil and cotton seed oil after it has been hydrogenated and these sources may contain high levels of hazardous pesticides. Additional concerns with magnesium stearate include: overdose (companies using high amounts to speed up the manufacturing process), adverse effects on the immune response, and problems with absorption of nutrients. These concerns would require significantly higher levels of magnesium stearate than what is typically added to produce a dietary supplement.[8, 2] Another controversial excipient is titanium dioxide. It is an inorganic white pigment that is used in supplements as a whitening agent.

Titanium dioxide is a pro-oxidant that is also found in cosmetics, paints, paper, inks, fibers and food. Some individuals believe liver toxicity can result by ingesting titanium dioxide.[3]

You may be wondering, why there is so much fuss about excipients? Over the last decade many recalls and deaths have taken place because of excipient contamination and adulteration all around the world. Quality standards are set by committees such as U.S. Pharmacopeia Convention Inc. and are regulated by Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) by country specific regulatory agencies. Regional industry associations such as International Pharmaceutical Excipients Council (IPEC) promote voluntary guidance utilized by the industry. Even with these regulations and resources, in 2006, 21 people died in Panama after taking a cough syrup formulated with diethylene glycol that was mislabeled as glycerine. During 1990-1996, a total of 371 people died in Nigeria, India and Haiti because of glycerine contaminated with diethylene glycol. Glycerine is a very common excipient used not only in drug manufacturing, but as a base for botanical syrups and non-alcohol tinctures (especially for children's formulas). These adulterations and contaminations are a result of poor GMP and GDP, and differences in excipient monograph specifications among the major pharmacopoeias (PhEur, JP and USP).[1, 9, 10, 11]

Although it is very challenging to manufacture dietary supplements without the use of excipients, some companies have found ways to employ minimal amounts of natural non-toxic excipients. Some examples of natural excipients included natural polysaccharides. Monosaccharide polymers are inexpensive, highly stable, safe, non-toxic, and hydrophilic and gel forming in nature. These monosaccharide excipients include pectin alginates, starch, gums, and volatile oils.[12] The salt form of alginates, sourced from sea weed, can be used in liposomal delivery systems. Starch acetate can be used to create slow release capsules. Gums, such as guar gum, facilitate controlled drug delivery by releasing the active components in the colon. Gums can also be used to protect active constituents in compaction or compression processes (tablets). Volatile oils can increase the bioavailability of poorly water-soluble actives.

Reputable companies are careful to use only the smallest amounts of the least toxic excipients needed to manufacture dietary supplements. For patients who are hypersensitive it would be advised to consider using vegetable encapsulated supplements, as tablets must be manufactured with excipients. It is hard to find a manufacturer who does not use excipients, however if you keep a close eye on these ingredients you will be able to find companies using food-grade non-toxic excipients (such as: cellulose, beets, carrots or hypo-allergenic plant fibers) that may be more appropriate for your sensitive patients. Lastly, make sure the manufacturer is trustworthy and has an excipient quality control process in place, ask for the results of any audits; this will help you determine whether the supplier is trustworthy. While suppliers are unlikely to share the specific findings from third party certification audits, they will share results from both third party and governmental audits and you can find those on line as well. If you are particularly concerned about the quality of the excipients, you inquire about third party cGMP certification of the suppliers of the excipients. Additionally, you can ask the supplier for the certificate of analysis on their most recent receipt of a particular excipient. This will attest to nature of their quality monitoring of the excipients that they are using in their products.

What's in a capsule?

Gelatin capsule	Ingredients: pharmaceutical grade gelatin (86%) (extracted from animal skin and bone collagen), water (14%)
Gelatin capsule (used in some pharmaceuticals)	Ingredients: pharmaceutical grade gelatin (usually over 85%, extracted from animal skin and bone collagen), water (approx. 13%), methylparaben (0.6%), propylparaben (0.1%), sodium lauryl sulphate (0.1%), coloring (optional)
VegiCap (Capsule Connection® and Capsugel®)	Ingredients: hydroxypropylmethylcellulose, also known as hypromellose (derived from vegetable cellulose) (92%), water (8%), glycerin (optional), coloring (optional)
NPcaps (Capsugel®)	Ingredients: pullulan (water-soluble polysaccharide of vegetable origin) (92%), water (8%), glycerin (optional), coloring (optional)
Caplet also referred to as Gelcap	Ingredients: tablet covered with a layer of gelatin
Softgel	Ingredients: gelatin (animal derived or vegetable origin), plasticizers, water, coloring (optional)

Note: All empty capsules should be tested free of heavy metals, microbiological organisms, loss on drying, viscosity, parabens, ethylenes. The consumer should make sure that the manufacturer has done the due diligence and has confirmed that they are using paraben-free gelatin capsules.

Natural Health Products Information Resources

Canada
Health Canada Natural Health Product Regulations
www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php

United States
Food and Drug Administration's Overview of Dietary Supplements
www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm

Clinician Considerations for Assessing Dietary Supplement Quality (Natural Medicine Journal) and Supplier Certification Questionnaire Compliance Guide
http://www.naturalmedicinejournal.com/article_content.asp?edition=1&section=4&article=107

ecoNugenics

Promoting Prostate & Cellular Health with Scientific Innovation*

ancient wisdom

modern science

PectaSol-C®

for optimal cellular health*

The only Clinically Tested Modified Citrus Pectin product proven to support cellular and prostate health*

PROMEDICS
Quality with Care

Distributed by: ProMedics Nutraceutical Ltd, Vancouver BC
ph: 604.268.5057 toll free:1.877.268.5057 email: order@promedics.ca

Ortho Sleep

A Natural Solution to Promote Restful Sleep

www.AOR.ca

Prevents Insomnia

Restores restful sleep patterns

Promotes relaxation and reduces anxiety

About the Authors

Dr. Alschuler is board certified in naturopathic oncology and has been practicing naturopathic medicine for 17 years. Dr. Alschuler is the immediate past-President of the American Association of Naturopathic Physicians. She is co-author of The Definitive Guide to Cancer: An Integrative Approach to Prevention, Treatment and Healing, now in its 3rd edition. Dr. Alschuler is the Vice President of Quality and Education at Emerson Ecologics. Emerson Ecologics, LLC is the leading provider of professional-grade nutritional supplements, products and services to the integrative healthcare community. *lalschuler@emersonecologics.com*

Dr. Christine Toomasi is a Medical Educator at Emerson Ecologics. She supports professionals in their product selections, quality understanding, and educational patient support. In addition, Christine specializes in promotional compliance and nutrient, botanical and supplement quality education. She is also the Program Coordinator for Emerson Ecologics Student Representative program. Dr. Toomasi received her Doctorate of Naturopathic Medicine from the Canadian College of Naturopathic Medicine in Toronto, Canada; where she focused most of her training and research in Diabetes and Cardiovascular Disease. She completed her Bachelors of Science degree in biology, chemistry and health education. The synergism of her undergraduate concentrations sparked her passion for complementary health care.
ctoomasi@emersonecologics.com

References

1. *International Pharmaceutical Excipients Council of the Americas*. N.P. 2009. Web accessed 05 May 2011. http://ipecamericas.org.
2. No Author listed. Talcum Powder and Cancer. Web accessed 13 May 2011. Last Revised 11/04/2010. http://www.cancer.org/Cancer/CancerCauses/OtherCarcinogens/AtHome/talcum-powder-and-cancer
3. No author listed. "What are excipients?" *HealthLine*. Web accessed 08 May 2011.
4. Frampton A. "Excipients: An Overview" Now. Web accessed 08 May 2011
5. Shimada C, Kano K, Sasaki YF, Sato I, Tsudua S. Differential colon DNA damage induced by azo food additives between rats and mice. *J Toxicol Sci*. 2010;35(4):547-54.
6. Boris M, Mandel FS. Foods and additives are common causes of the attention deficit hyperactive disorder in children. *Ann Allergy*. 1994 May;72(5):462-8.
7. Kumar, Ashir et al. Sweeteners, Dyes, and other Excipients in Vitamin and Mineral Preparations. *Clin Pediatr* 1996 35:443
8. *Encyclopædia Britannica*. 2006. Encyclopædia Britannica Online, 2011. Web accessed 09 May 2011. <http://www.britannica.com/EBchecked/topic/564584/stearic-acid>.
9. USP International Excipient Workshop. N.P., 2011. Web accessed 05 May 2011.http://www.usp.org/meetings/workshops/internationalExcipientWorkshop.html
10. USP Guidelines for Submitting Requests for Revision to USP-NF. N.P. Web accessed 03 May 2011. http://www.usp.org/pdf/EN/USPNF/revisionHistory.pdf
11. McGlue, Kevin et al. European Excipient Regulation: Implications for Manufacturers and Suppliers. *Innovations in Pharmaceutical Technology*. 2007. Web accessed 05 May, 2011. http://www.iptonline.com/articles/public/IPT_23_p74nonprint.pdf
12. Shirwaikar A, Shirwaikar A, Prabu SL, Kumar GA. Herbal excipients in novel drug delivery systems. *Indian J Pharm Sci*. 2008 Jul-Aug;70(4):415-22.

Pharmaceutical excipients as possible adverse reaction triggers

Dr. Petra Eichelsdoerfer, ND, CN, RPh

Medications, whether available over the counter or by prescription, nearly always include ingredients beyond those labeled as "active" ingredients. The manufacturing process necessitates the addition of one or more other ingredients, termed excipients. Although once considered largely inert, there is increasing awareness about excipients' significant contributions to the safety, tolerability, and biological activity of pharmaceutical agents.

Recognition of the need to regulate excipients and include them in product labeling have increased in parallel. In 1995, the International Pharmaceutical Excipients Council defined excipients as "Substances, other than the active drug substance or finished dosage form, which have been appropriately evaluated for safety and are included in a drug delivery system to either aid the processing of the drug delivery system during its manufacture, protect, support, enhance stability, bioavailability, or patient acceptability, assist in product identification, or enhance any other attributes of the overall safety and effectiveness of the drug delivery system during storage or use".[1]

The history of modern pharmaceuticals is rife with examples of excipients that proved toxic. In 1937, Massengill marketed a sulfanilamide elixir in which the less-expensive diethylene glycol replaced the usual propylene glycol and glycerin. Tragically, more than 100 people died from acute renal failure brought on by the diethylene glycol. In recent years, this tragedy repeated itself across South Africa, Bangladesh, Nigeria, Haiti, Panama, and Nigeria when diethylene glycol once again appeared in acetaminophen, cough syrup, and teething powder products.[2] In early 1984, a recently introduced injectable vitamin E product (E-ferol) was associated with severe illness and fatalities in low-birth-weight infants, many of whom exhibited thrombocytopenia, renal dysfunction, hepatomegaly, cholestasis,and ascites. E-ferol was withdrawn from the market after being linked to 38 deaths and 43 cases of severe illness. The symptoms have been attributed to the use of polysorbates as preservatives.[2] After decades-long inclusion in vaccines and numerous vaccine-safety debates, the mercury-derived preservative thimerosal is gradually being phased out.[2] An equally important, if very different issue arose with an extended release formulation of oxycodone, OxyContin. After crushing, this product could be smoked or injected, resulting in very rapid absorption of the full dose of oxycodone. This in turn posed significant overdose risk with the potential for fatality.[3]

These historical examples help illustrate the role of excipients in medicinal products. Despite its nephrotoxicity, diethylene glycol was added to these products because of its solvent properties, while polysorbates and thimerosal are both used as preservatives. In general, excipients receive less regulatory scrutiny than active pharmaceutical ingredients and often excipients have prior approval for use in foods. Continued use of others may be allowed based on decades of use; in the US, they might qualify as "generally recognized as safe" (GRAS). As the 21st Century dawned, the International Pharmaceutical Excipients Council's Safety Committee outlined and introduced new guidelines detailing toxicologic testing of new excipients.[1,2,4]

Interestingly, not all excipients are deliberately added to the final product. Some are impurities left behind by the extraction, synthesis, or purification processes used to produce the active ingredient and others may be added for a wide range of reasons. Excipient selection allows for slow-, timed-, and controlled-release formulations, while enteric coatings protect acid sensitive active ingredients from the low pH gastric environment. Excipients may also allow for longer product shelf-life. For very potent agents, diluents or fillers improve dosing. While colours are often added for appearance, they are also important contributors to product identification. By increasing palatability, sweetening and flavouring agents allow chewable, sublingual, and oral liquid formulations and ease pediatric dosing. In summary, excipients significantly alter bioavailability, pharmacokinetics, stability, appearance, and palatability.[4]

There is, however, a downside to all these additives. A controlled-release formulation of oxycodone, OxyContin, proved readily abusable when snorted or injected – it was easily crushed and dissolved. Recognition of this high abuse potential led to a (US) 2010 reformulation specifically to reduce abuse. The reformulated product is more difficult to cut, chew, break, or crush. The excipient polyethylene oxide forms a viscous gel upon contact with water, so it cannot easily be injected or snorted.[5,6] At present, the Canadian formulation of OxyContin does not contain polyethylene oxide.[7]

Comprehensively detailing the allowable excipients and their functions in this space is impractical. Table 1 summarizes common excipients and their uses in pharmaceutical products.

INTRODUCING

PREVU*

NON-INVASIVE CHOLESTEROL TEST

THE WORLD'S FIRST
NON-INVASIVE CHOLESTEROL TEST

AN EXCLUSIVE ADVANCE SHOWING...

OF THIS REVOLUTIONARY RISK ASSESSMENT TECHNOLOGY
FOR CORONARY ARTERY DISEASE WILL TAKE PLACE DURING

HEALTH FUSION 2011

SEE A DEMONSTRATION AND LEARN HOW THIS ADVANCED CLINICAL TOOL CAN BENEFIT
YOUR PATIENTS AND GENERATE REVENUE FOR YOUR PRACTICE

(Not currently licensed for sale in Canada)
For demonstration purposes only

CAND

Proud Platinum Sponsor
Health Fusion 2011
Calgary, Alberta
June 24th-26th

COME VISIT US
AT BOOTH #40

miraculins

www.miraculins.com
www.prevu.com

Table 1 - Properties of Common Excipients[19]

Function	Excipient examples
Coloring agents	Food dyes, including tartrazine (FD & C yellow 5)
Coating agents	
Tablet-coating agents	Fibers (e.g., hydroxypropylmethylcellulose); Waxes
Coating color agents	Food dyes; Titanium dioxide (usually combined with dye)
Coating agents	Fibers (e.g., methylcellulose)
Enteric coating agents	Cellulose; Acetate phthalate
Diluents/fillers/vehicles	Starches; Lactose; Fibers; Vegetable oils
Disintegrants	Starches; Fibers (e.g., microcrystalline cellulose)
Emulsion vehicles	Vegetable and nut oils (e.g., sesame oil, corn oil)
Flavouring agents	Food flavouring agents
Granulating agents	Sucrose; Fibers (e.g., methylcellulose)
Lubricants	Talc, Stearates (e.g., magnesium stearate, stearic acid); Hydrogenated vegetable oils
Preservative	Alcohol, Parabens (methyl, propyl)
Surfactants	Polysorbates
Suspending agents	Gums (e.g., tragacanth, sodium alginate); Fibers (e.g., sodium carboxymethylcellulose)
Thixotropic suspending agent	Gums (e.g., xanthum gum)
Solubilizing agent	Alcohol, Propylene glycol
Sweeteners	Sugars (e.g., sucrose); Polyols (e.g., mannitol, sorbitol); High-intensity sweeteners (e.g., aspartame)

Pharmaceutical products are required to include information on "other ingredients" in the product monograph (also called the package insert). These monographs are provided to pharmacies with every bottle of the product. Many can also be found through online searches of the company websites or by using Health Canada's Drug Product Database. The Canada Vigilance Adverse Reaction Online Database provides information about reported adverse drug reactions, and adverse reactions may be reported directly to Health Canada online. The links for all three websites are included below. Unfortunately, Health Canada's Drug Product Database allows only searches using brand name or active ingredient, posing a challenge to anyone hoping to assemble a list of products that contain or are free of any particular excipient. Table 2 lists examples of pharmaceutical products and a short sampling of the excipients they contain.

Table 2 - Excipient examples from Canadian brand-name pharmaceuticals.[20-26] Excipient origin stated where listed in the product monograph.

Brand Name (generic)	Selected Excipients and other Ingredient Notes
Clavulin (amoxicillin/clavulanic acid)	Aspartame; Dry flavours (golden syrup; orange 1; orange 2; raspberry)[20]
Depo-Testosterone (testosterone cypionate injection USP)	Testosterone synthesized from soy[21]
Fosavance (alendronate sodium/cholecalciferol)	Gelatin; modified corn starch; lactose anhydrous. Gluten-free[22]
PMS Testosterone (testosterone undecanoate capsules)	Outer capsule contains pork gelatin[23]
Prometrium (progesterone capsules)	Peanut oil[24]
Singulair (montelukast)	- 10 mg tablets: Lactose monohydrate; Coating contains carnauba wax, ferric oxide, titanium dioxide, yellow ferric oxide[25] - 4 mg and 5 mg chewable tablets: Aspartame; mannitol; red ferric oxide, cherry flavour[25] - 4 mg oral granules (comprehensive excipient list): - Hydroxypropyl cellulose; magnesium stearate; mannitol[25]
Synthroid (levothyroxine sodium USP)	All strengths contain acacia, confectioner's sugar, lactose, magnesium stearate, povidone, and talc. Colour-coding used to differentiate potency. 50 mcg is the only strength that contains NO colour additives.[26]

Excipients can interact with the pharmaceuticals that they come into contact with. For example, esters may form between cetirizine and polyols (e.g., sorbitol, glycerol) present in liquid formulations.[8] While only a tiny percentage of the cetirizine forms esters, this illustrates how excipients may contribute to, or detract from, stability. Presence or absence of certain excipients may also contribute to abuse potential and others may trigger drug interactions by altering metabolic pathway function. A team of Chinese and Canadian researchers tested 22 common excipients, demonstrating varying degrees of cytochrome P450 3A4 inhibition in both in vitro and in vivo animal models.[9]

Including an excipient that enhances bioavailability through inhibition of metabolic pathways may inadvertently increase toxicity of that or another agent.[9] This practice is not limited to pharmaceutical agents. In the U.S., a number of dietary supplements contain grapefruit (e.g., naringin) and/or black pepper (e.g., piperine) extracts, for the purpose of increasing bioavailability (as stated on the label). Among other mechanisms, these constituents increase drug bioavailability partly through inhibiting CYP 3A4 and p-glycoprotein.[10-14] Grapefruit and black pepper are widely accepted foods and generally considered healthy additions to the diet. Naringin and piperine are both allowable food and natural health product ingredients in Canada.[15] However, as with any food, avoiding these foods or food extracts may be advisable for some people. Avoidance is easy enough if labeling is clear and people are aware of the need to do so.

Beyond potential for interactions or abuse, there are other reasons for concern about excipients. The potential for patient sensitivity or allergy is well worth considering. For example, E-Ferol's toxicity has been ascribed to low birth weight infants' inability to adequately metabolize the polysorbates it contained.[2, 9] Starches and oils from corn, soy, or nuts are common. Logically, these are as equally likely to provoke allergic reactions (e.g., rashes, asthma, anaphylaxis) as the foods they are derived from. Although not always the case, (non-anaphylactoid) symptoms may be related to the site of exposure. Thus, oral products may provoke more gastrointestinal symptoms, where inhaled products may lead to respiratory symptoms.

Lactose and polyols (e.g., sorbitol, mannitol) are also very common excipients. For these excipients, tolerance is often dose-dependent. In other words, while the amount in a single product/dose may be tolerable, this changes if the individual takes multiple products that (each) contain a small amount of the same excipient (e.g., lactose). The unintended additive effect may be significant gastrointestinal distress.[16] High intensity sweeteners such as aspartame and saccharin are also relatively common and may trigger sensitivity reactions, just as they would if consumed in foods.[16] Most allowable colouring agents in Canada are also approved for use in foods. Most are also widely used in the U.S. One example is the coal-tar derivative tartrazine, or FD & C yellow #5. Considered among the more sensitizing of the azo dyes, tartrazine has been heavily studied since the 1970s, yet much remains unclear about tartrazine sensitivity. A 2009 Cochrane review found no clear evidence that eliminating tartrazine had

significant effects on asthma control, unless an individual had proven sensitivity to it.[17] While few countries have evaluated the prevalence of tartrazine sensitivity, it is estimated to be 0.12% in France.[18]

Excipients are far from inert. When evaluating a possible adverse drug reaction, first determine whether the reaction is due to the active ingredient, or possibly an excipient. For example, if the patient has a known corn allergy, and the product in question contains corn starch, s/he could easily be reacting to the starch. Start by asking the patient for more information about their symptoms. Symptoms that resemble a previous reaction the patient recognizes (for example, "I feel like I do when I eat corn"), strongly suggests a possible excipient reaction. Identifying an alternative medication that does not contain the offending excipient may solve the problem. If there are no commercially available alternatives, and the medication is clearly indicated, it may be custom formulated by a compounding pharmacy.

About the Author

Petra Eichelsdoerfer, ND, CN, RPh graduated from the University of Washington and Bastyr University and holds degrees in Pharmacy, Nutrition, and Naturopathic Medicine. She has practiced clinically in community and public health settings, the Washington Poison Center, and taught courses in nutrition, biochemistry, and many other basic and clinical science courses at Bastyr University.

In 2010, Dr Eichelsdoerfer completed a postdoctoral research fellowship funded by a grant through the National Center for Complementary and Alternative Medicine (NCCAM), with projects exploring the prevention and treatment of obesity, cost of a healthy diet, and the human gut microbiome. Areas of clinical and research interest include healthy aging, obesity, gastrointestinal health, traditional/natural diet and healing approaches, and how modern clinical medical practices intersect with those of traditional healing.

Currently a Staff Clinical Pharmacist at the Tulalip Clinical Pharmacy and an Assistant Research Scientist at Bastyr University, Dr Eichelsdoerfer is developing nutrition and integrative medicine projects applicable in a Native American tribal health clinic setting. *drpetra@hotmail.com*

References

1. Robertson MI. Regulatory issues with excipients. *International Journal of Pharmaceutics.* 1999; 187: 273 – 276. PMID: 10502633
2. Nordt SP, Vivero LE, "Chapter 55. Pharmaceutical Additives" (Chapter). Nelson LS, Lewin NA, Howland MA, Hoffman RS, Goldfrank LR, Flomenbaum NE: Goldfrank's Toxicologic Emergencies, 9e: http://www.accesspharmacy.com.offcampus.lib.washington.edu/content.aspx?aID=6515332. Accessed 7 May 2011.
3. Wright IV C, Kramer ED, Zalman M-A, Smith MY, Haddox JD. Risk identification, risk assessment, and risk management of abusable drug formulations. Drug and Alcohol Dependence. 2006; 83S; S68 – S76. doi: 10.1016/j.drugalcdep.2005.12.012. PMID: 16581201
4. Baldrick P. Pharmaceutical excipient development: The need for preclinical guidance. Regulatory Toxicology and Pharmacology. 2000; 32: 210 – 218. doi: 10.1006rtph.2000.1421. PMID: 11067777
5. New OxyContin (oxycodone controlled-release) formulation. *Pharmacist's Letter/Prescriber's Letter* 2010;26(12):261201.
6. (US) Product information for OxyContin. Purdue Pharma L.P. Stamford, CT 06901-3431. Revised 16 April 2010. Available from: http://www.purduepharma.com/pi/prescription/oxycontin.pdf. Accessed 8 May 2011.
7. (Canada) Product information for OxyContin. Purdue Pharma. 575 Granite Court, Pickering ON L1W 3W8. Revised 25 August 2009. Available from: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. Accessed 7 May 2011.
8. Yu H, Cornett C, Larsen J, Hansen SH. Reactions between drug substances and pharmaceutical excipients: Formation of esters between cetirizine and polyols. *Journal of Pharmaceutical and Biomedical Analysis.* 2010; 53: 745 – 750. doi: 10.1016/j.jpba.2010.05.001. PMID: 20627436
9. Ren X, Mao X, Si L, Cao L, Xiong H, Qiu J, Schimmer AD, Li G. Pharmaceutical excipients inhibit cytochrome P450 activity in cell free systems and after systemic administration. *European Journal of Pharmaceutics and Biopharmaceutics.* 2008; 70: 279 – 288. doi: 10.1016/j.ejpb.2008.03.019. PMID: 18499414
10. Pattanaik S, Hota D, Prabhakar S, Kharbanda P, Pandhi P. Pharmacokinetic interaction of a single dose of piperine with steady-state carbamazepine in epilepsy patients. Phytotherapy Research. 2009; 23: 1281 – 1286. PMID 19283724.
11. Bhardwaj RK, Glaeser H, Becquemont L, Klotz U, Gupta SK, Fromm MF. Piperine, a major constituent of black pepper, inhibits human p-glycoprotein and CYP 3A4. *Journal of Pharmacology and Experimental Therapeutics.* 2002; 302: 645 – 650. PMID: 12130727.
12. Velpandian T, Jasuja R, BHardwaj RK, Jaiswal J, Gupta SK. Piperine in food: Interference in the pharmacokinetics of phenytoin. *European Journal of Drug Metabolism and Pharmacokinetics.* 2001; 26: 241 – 247. PMID: 11808866.
13. Bressler R. Grapefruit juice and drug interactions. Exploring mechanisms of this interaction and potential toxicity for certain drugs. *Geriatrics.* 2006; 61: 12 – 18. PMID: 17112309.
14. Veronese ML, Gillen LP, Burke JP, Dorval EP, Hauck WW, Pequignot E, Waldman SA, Greenberg HE. Exposure-dependent inhibition of intestinal and hepatic CYP3A4 in vivo by grapefruit juice. *Journal of Clinical Pharmacology.* 2003; 43: 831 – 839. PMID: 12953340.
15. Health Canada Natural Products Ingredients Database. Available online: http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do?lang=eng. Accessed 8 May 2011.
16. Ursino MG, Poluzzi E, Caramella C, De Ponti F. Excipients in medicinal products used in gastroenterology as a possible cause of side effects. *Regulatory Toxicology and Pharmacology.* 2011, doi: 10.1016/j.yrtph.2011.02.010. PMID: 21354240
17. Ram AK. Tartrazine exclusion for allergic asthma. Cochrane Database Systematic Reviews. 2001; (4): CD000460. PMID: 11687081
18. Elhkim MO, Héraud F, Bemrah N, Gauchard F, Lorino T, Lambré C, Frémy JM, Poul J-M. New considerations regarding the risk assessment on Tartrazine: An update toxicological assessment, intolerance reactions and maximum theoretical daily intake in France. *Regulatory Toxicology and Pharmacology.* 2007; 47: 308 – 316. doi: 10.1016/j.yrtph.2006.11.004. 17218045
19. Shargel L, Wu-Pong S, Yu ABC. "Chapter 14. Biopharmaceutic Considerations in Drug Product Design" (Chapter). Shargel L, Wu-Pong S, Yu ABC: Applied Biopharmaceutics & Pharmacokinetics, 5e: http://www.accesspharmacy.com.offcampus.lib.washington.edu/content.aspx?aID=2481383. Accessed 7 May 2011.
20. Product information for Clavulin. GlaxoSmithKline Inc. 7333 Mississauga Rd., Mississauga, ON L5N 6L4. Revised 18 May 2010. Available from: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. Accessed 7 May 2011.
21. Product information for Depo-Testosterone. Pfizer Canada Inc. 17, 300 Trans-Canada Highway, Kirkland QC H9J 2M5. Revised 3 July 2007. Available from: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. Accessed 7 May 2011.
22. Product information for Fosavance. Merck Frosst Canada Ltd. 16711 Trans Canada Highway, Kirkland QC H9H 3L1. Revised 10 September 2010. www.merckfrosst.com. Available from: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. Accessed 7 May 2011.
23. Product information for pms-Testosterone. Pharmascience Inc., 6111 Royalmount Ave, Montreal, QC H4P 2T4. Revised 21 April 2009. Available from: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. Accessed 7 May 2011.
24. Product information for Prometrium. Merck Canada Inc., 16750 route Transcanadienne, Kirkland QC H9H 4M7. Revised 21 February 2011. Available from: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. Accessed 7 May 2011.
25. Product information for Singulair. Merck Frosst Canada, Ltd., 16711 Trans Canada Highway, Kirkland QC H9H 3L1. Revised 9 November 2010. www.merckfrosst.com. Available from: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. Accessed 7 May 2011.
26. Product information for Synthroid. Abbott Laboratories, Ltd., 8401 Trans-Canada Highway, St-Laurent QC H4S 1Z1. Revised 25 May 2010. Available from: http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. Accessed 7 May 2011.

Helpful links:

Health Canada's home webpage:

www.hc-sc.gc.ca

Canada Department of Justice link to Food and Drug Regulation (C.R.C., c. 870):

http://lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-292.html#h-160

Health Canada's Drug Product Database Online Query (English):

http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp

Health Canada Natural Products Ingredients Database. Available online:

http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do?lang=eng.

Canada Vigilance Adverse Reaction Online Database (English):

http://www.hc-sc.gc.ca/dhp-mps/medeff/databasdon/index-eng.php

Report an adverse event online to Health Canada

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

US Food and Drug Administration's Inactive Ingredients database:

http://www.fda.gov/drugs/informationondrugs/ucm113978

BIOMED

Superior to other krill & fish oils!

Asta-X-Krill™

The Ultimate Astaxanthin-Enhanced Omega-3

- ✔ **Outshines** fish oils and statins in lowering LDL and boosting HDL.
- ✔ **Unique** Omega-3 phospholipids deliver potent cell assimilation.
- ✔ **Superior** cardiovascular anti-inflammatory and anti-oxidant.
- ✔ **Boosted** Astaxanthin delivers elite muscle endurance.

The Only 'X'-tra Astaxanthin Formula!

NKO® Krill Oil is harvested and purified from Antarctic Krill (*Euphausia superba*) and has the highest naturally-occurring levels of Omega-3 phospholipids: EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid), and esterfied Astaxanthin. An 'X'-tra boost of Astaxanthin is added to our **Asta- X-Krill™** formula making it superior to other krill and fish oils! The extra Astaxanthin is harvested from naturally-occurring microalgae (*Haematoccus pluvialis*) and it delivers the most powerful antioxidant protection and muscle stamina support we can find.

NKO® is the only krill oil that can demonstrate clinically proven health benefits for cardiovascular, joint, cognitive and women's health. Our Asta-X-Krill™ Astaxanthin, by AstaReal has 40 clinical studies. It's the most studied Astaxanthin constituent in the world!

LIMITED TIME ONLY!

8% off

Price in effect until July 31, 2011.

$27.55

BIOMED

nature's path to vitality

1-800-665-8308

www.biomedicine.com

11AM12 • VL0511

Asta-X-Krill™... The only 'X'-tra Astaxanthin formula!

Imagine

using the best science in the industry to change unhealthy lifestyles.

It's Firstline Therapy® by Metagenics, a therapeutic lifestyle program that is based on science and research. Not only does FirstLine Therapy improve patient outcomes, it also makes patient compliance easier and provides a systematic way to add a new revenue stream to your practice.

You've been treating unhealthy lifestyles for years, so you probably already know that lifestyle interventions are considered a "first line" treatment for common conditions, such as high cholesterol, high blood pressure, high blood sugar, metabolic syndrome, type 2 diabetes, obesity, and others.

Now there's a better way to change a patient's life. Contact us to learn more.

FirstLineTherapy.com

Toll Free 877.769.7349

FirstLine Therapy® by Metagenics Lifestyle Medicine Simplified.™

Treat Your Supplement Delivery System Like You Do Your Patients... Individually

Dr. Bianca Garilli, ND

It's a common conversation with seemingly many variables and much emotion involved; which supplement delivery system is superior? Capsules, tablets or liquids? Some will argue for the efficacy of liquids, others for the patient compliance of capsules and still others for the dissolution control of tablet formulations. But is this simply assumption or truth? Hearsay or fact?

Dr. David A. Tallman, DC, ND notes in his October 4, 2010 Natural Products Insider article, "Naturopathic physicians .... are arguably the most highly trained physicians with regard to the use of natural products."[1] As naturopathic medicine becomes increasingly more integrated into society's medical system and our practitioners move more frequently into the media spotlight, we need to have this topic down to a science, not an opinion.

The purpose of this article is to lay out the facts on the subject. From there, as I tell my patients, you can decide what to do with the information.

First, just as there is no one treatment best for all patients, there is no one supplement delivery system that is best for all situations. In fact, tablets, capsules, liquids, powders, gels, sprays and topicals all represent effective delivery methods for the supplements you prescribe to your patients. The goal is to prescribe the delivery system which offers the greatest stability, bioavailability, convenience, tolerance and efficacy for the patient for that particular ingredient or combination of ingredients.

Liquids

Liquid delivery systems have a long history of use in medicine and are made using various methods including extraction of key constituents through the use of alcohol, water, honey, glycerin, vinegar or oils. The benefits of a liquid delivery system are multi-dimensional and may depend on the menstruum used for extraction. Liquids are easy to swallow making them particularly useful for the pediatric and geriatric populations as well as for dosing supplements via feeding tubes or supplementing a liquid diet.

Liquid formulations also have the benefit of bringing patients "closer" to their medicine and in certain cases, such as with bitters, will actually start their therapeutic actions as soon as the formulation hits the taste buds. Shelf life is another factor often favoring liquid delivery systems. The shelf life of alcohol tinctures in particular far exceeds the shelf life of other delivery systems making them valuable options for stocking a pharmacy with a slow rate of turnover or for medicines which are dosed only occasionally rather than on a routine basis.

On the other hand, tinctures are often stored in glass bottles which can easily break or leak. More frequent dosing often becomes challenging and if the taste is unpalatable may lead to decreased compliance. Tinctures, however, often come with a higher price tag and are not always financially viable for all patient populations.

Capsules

Capsules are another commonly prescribed supplement delivery system with their own set of pros and cons. For some patients, capsules have the advantage of being easier to swallow than tablets due to their smooth texture as well as being an effective system to conceal offensive odors and tastes. This is also the delivery system of choice for preserving the integrity of sensitive molecules such as CoQ10 and for delivering oil and fat-soluble nutrients to your patients in a convenient, usable form.

Hard shelled capsules are dependent on a patient's internal gastrointestinal environment and thus are restricted to a tight pH range which may differ from patient to patient. Soft gels do not have this constraint. (More discussion on disintegration standards and testing below.)

Moisture is the enemy of both capsules and tablets, while heat can easily lead to melting and sticking together of capsules resulting in damaged product and consequently reduced compliance. Instructing patients on storage instructions is necessary to ensure predictable, effective results, particularly when it comes to temperature related storage directions for capsules.

Tablets

Tablets offer manufacturers the ability to include higher quantities of material per tablet which lowers the number of "pills" required for a certain dose. Since the same quantity of ingredients can be incorporated into a lesser number of tablets than capsules, patients can take fewer tablets for their required dosage as well as pay less. Both characteristics increase compliance of tablet delivery systems

www.cand.ca/healthfusion.html

PLATINUM LEVEL SPONSORS

PREVU
NON-INVASIVE CHOLESTEROL TEST

Advancing the Science of Wellness
Rocky Mountain Analytical

SCRIPT
COMPOUNDING PHARMACY

GOLD LEVEL SPONSOR

Alberta Association of Naturopathic Practitioners

SILVER LEVEL AND SPEAKER SPONSORS

AOR
INNOVATIVE RESEARCH
SCIENTIFIC INTEGRITY

bioclinic naturals
natural solutions • clinical results
www.bioclinicnaturals.com

DOUGLAS LABORATORIES

pure encapsulations

Seroyal

CYTO•MATRIX

valentus medical
TECHNOLOGIES INC

BRONZE LEVEL SPONSORS

Amaranth Whole Foods Market

Bullfrog Power

CanPrev Natural Health Products

drinkme Beverage Co.

Electro Therapeutic Devices

Herbasante

Natural Pain Products

Partners Indemnity Insurance Brokers

The most comprehensive offering of saliva hormones to help you deliver wellness to your patients

Features:

- Testing offered for 12 Steroid Saliva Hormones

- Full flexibility in choices to suit each patient
  - Substitute tests without additional cost
  - Add-on tests at cost-effective rates
  - Customize panels to suit your approach

- Assessment-at-a-glance: Easy to assess graphical reports

Flexible Standard Panels:

- Adrenal Stress Index (4 point cortisol panel)
- Female Hormone Panel
- Premenopausal Hormone panel - 11 point cycle assessment
- Menopause Assessment Panel - 3 specimen assessment
- Male Hormone Panel

- **Specialty test:** Serum Reverse T3 measurement

Stero-Chrom
Analytical Laboratory

your specialty testing facility

7825 Edmonds Street, 2nd Floor, Burnaby, B.C., Canada V3N 1B9 | **T.** 604-540-7225 | **F.** 604-540-7205 | www.stero-chrom.com

VITAZAN
PROFESSIONAL

Now 320+ Hours of Testing & Research Each Week
Our team now consists of 1 PhD, 3 MSc and 4 BSc.

EACH CAPSULE CONTAINS:

Boswellic Acid 70%	200 mg
Bromelain 2400 GDU / g. . . .	100 mg
Curcumin 95%	200 mg
Quercetin Dihydrate 98% . . .	100 mg

- **Natural COX-2 inhibitor**
- **Reduces pain and inflammation**
- **Excellent for radiation support**

Your partner in natural health care since 1997

Ask us about our ND Promo package of 41 free bottles.

1 888 863-9274 | www.vitazan.com

leading to improved effectiveness of your recommendations. This brings up the highly debated and commonly held belief that tablets are often too highly compressed thus inhibiting disintegration of the tablet. If you are recommending supplements from a reputable supplement company you need not be concerned about this. Virtually all reputable supplement companies which NDs do business with are GMP (Good Manufacturing Practices) compliant and will have standard USP designated procedures in place to test each batch of tablets for proper disintegration times; some will even test each batch multiple times throughout the manufacturing process.

USP guidelines state that disintegration of tablets in an aqueous solution should be complete within a certain number of minutes depending on the type of tablet (sublingual, enteric coated etc.) As long as the company you are working with is GMP certified the disintegration time of tablets is a non-issue; the tablets you are buying will break down at the proper place and at the proper time. Finally, tablets can be notched allowing the patient to divide their tablets into smaller sizes for ease of swallowing or for changing dosage without buying a new size.

On the downside, tablets, unlike capsules, cannot hide undesirable odors or tastes potentially lowering patient compliance and can be more difficult to swallow for some. Tablets are susceptible to moisture and need to be stored in a cool, dry place.

Disintegration Testing

The United States Pharmacopeia (USP) outlines the disintegration testing process that companies must follow in order to be GMP compliant. Disintegration is defined by USP as *"that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the disk, if used, is a soft mass having no palpably firm core"* [2]

Table 1 – USP Disintegration Method and Immersion Media Information

Dosage Form	Form Preparation	Procedure	Immersion Fluid	Media Temp.	Immersion Time
tablet	uncoated, sublingual	standard disintegration	water	37°C ± 2°C (body temperature-BT)	30 minutes
	coated (plain and film)	standard disintegration	water	37°C ± 2°C	5 minutes at RT then 30 minutes at BT
tablet capsule	delayed-release (enteric-coated)	standard disintegration	simulated gastic fluid (SGF), simulated intestinal fluid (SIF)	37°C ± 2°C	1 hr in SGF then in SIF for the allotted time according to form preparation
capsule	hard gelatin, hard shelled	standard disintegration	acetate buffer (pH 4.5 ± 0.05)	37°C ± 2°C	30 minutes
	soft shelled, soft gelatin (softgels)	rupture	water	N/A	15 minutes

**Information in this table was obtained from USP 32. The equipment used was the Hanson Research QC-21, 2 basket test system (6 tablet capacity per basket).

The table above summarizes the USP disintegration testing process.[3] The procedure requires water to be used as the testing solution for disintegration of tablets and soft gel capsules while hard shelled capsules and extended release delivery systems must use an acetate buffer or gastrointestinal simulated environment for testing. This confirms the need for hard shelled capsules to be used cautiously in patients with suspected or confirmed hypochlorhydria, whereas the status of gastrointestinal pH does not necessarily affect the disintegration of other delivery forms. As noted previously, if a company is GMP certified, they will use USP standard testing and their tablets and capsules will disintegrate as necessary for reproducible, effective results in your patients.

Excipients within Capsules and Tablets

Supplement excipients are added to formulations for various reasons such cellulose, a non-reactive plant fiber, to hold a tablet together and regulate the rate at which the tablet disintegrates in the stomach. Hypermellose (HPMC) from cellulose is also an ingredient in vegetarian capsules. Still other ingredients are used to protect fat-soluble ingredients from oxidation or to protect active ingredients during storage; for example silicon dioxide is used to absorb moisture and also doubles as a "space filler" in some capsules.

The majority of pharmaceutical and dietary supplements today contain minute traces of stearates. Stearates, the most common of which is magnesium stearate, are used to ensure that finished products are of uniform size, weight, texture, and shape. These agents are necessary to ensure reproducible and reliable results dose after dose in both capsules and tablets.

Magnesium stearate is widely used for pill manufacturing both in the pharmaceutical and nutraceutical worlds, and consequently is one of the most studied excipients used today with a long and recorded safety track record. Magnesium stearate, the salt of stearic acid, has been granted GRAS (generally recognized as safe) status whereas other less frequently used excipients may not have a similar safety track record.

Concerns over whether excipients such as magnesium stearate inhibit the body's ability to absorb the nutrients are grossly misunderstood. Stearic acid is one of the most common long-chain fatty acids found in a large number of animal and vegetable fats including olives, beef, and chocolate (see Table 2) and is extremely well-absorbed. In fact, the absorption of stearic acid is comparable to palmitic acid and oleic acid (the major constituent of olive oil).[4]

Table 2 – Stearic Acid Content of Common Foods[5]

Food	Stearic Acid Content
Fish oil, cod liver (1 oz.)	784 mg
Fish oil, salmon (1 oz.)	1,176 mg
Olive oil (1 oz.)	700 mg
Sesame oil (1 oz.)	1,344 mg
Soybean lecithin (1 oz.)	812 mg
Soybean oil (1 oz.)	1,064 mg
Sunflower oil, linoleic (1 oz.)	1,260 mg
½ chicken breast (w/out skin)	100 mg
Cheddar cheese (1 oz.)	1,120 mg
Butter (1 pat)	500 mg
Semi-sweet chocolate (1.45 oz.)	4,800 mg

To help put it into proper perspective, a high quality tablet may contain 20 mg of stearic acid which means that a daily recommendation of six (6) tablets would contain approximately 120 mg of stearic acid. In comparison, mean stearic acid intake from food sources is 5.7 g per day (5700 mg or 2.3% of calories) for women and 8.2 g per day (8200 mg or 2.8% of calories) for men, 20 years of age and older, based on data from the National Health and Nutrition Examination Survey (NHANES), 2001-2002.[6]

Patented ingredient.
Patented technology.

THERE IS ONLY ONE COLD-FX®.

The COLD-FX® difference

When it comes to a clinically proven natural cold and flu remedy, consider COLD-FX. It's Canada's #1 selling* natural cold remedy brand.

- Exclusive patented extract of poly- and oligosaccharides from North American ginseng
- ChemBioPrint® – a patented standardization technology
- 18 years of research and 12 clinical trials
- Unique mechanism of action targeting toll-like receptors

®/TM–Owned by Afexa Life Sciences Inc. *Nielsen Brand Overview, National All Channels (Drug + Grocery + Mass Merch + Club), Total Cold Remedies and Natural Supplements for 52 weeks ending July 3, 2010.

There is only one

www.cold-fx.ca

Helps to reduce the frequency, severity and duration of colds and flu by boosting the immune system.

The average patient will receive far more stearic acid from their diet than from their supplements. And, unlike other long chain saturated fatty acids (lauric, myristic, and palmitic acids) stearic acid has not been shown to raise both total and LDL cholesterol levels.[7,8,9]

In Summary

There are several key takeaways from this article:

Be sure to do business with reputable companies who are cGMP compliant (via third party inspection and certification) and using USP standards where applicable. Recall that GMPs are guidelines that outline the aspects of production and testing that can impact the quality of the products you are recommending.

Ensure the company you are working with has efficacy and safety data for the supplements and protocols they are recommending. When considering which supplement delivery systems to prescribe consider stability, bioavailability, convenience, tolerance and efficacy.

A company that has a "one size fits all" philosophy in regards to ingredient delivery system may not be giving your patients the best delivery form for each of the different formulations.

In conclusion, do your homework, work with reputable companies and treat your supplement delivery systems like you do your patients - individually.

About the Author

Dr. Garilli is a former U.S. Marine turned Naturopathic Doctor, graduate of Bastyr. Currently, Dr. Garilli lives and practices in Northern California specializing in the treatment of obesity and other lifestyle related chronic diseases through FLT as well as seeing children with autism, ADHD/ADD and congenital heart conditions. Additionally, she consults with Metagenics to support the ND specific educational platform, speaking events and clinical support.

biancagarilli@metagenics.com

References

1. Tallman, D. A., Berry-Tallman, R. Naturopathic Market Offers Opportunity. *Natural Products Insider*. Oct. 2, 2010. http://www.naturalproductsinsider.com/articles/2010/10/naturopathic-market-offers-opportunity.aspx?pg=3
2. USP Guidelines, Dietary Supplements/(2040) Disintegration and Dissolution of Dietary Supplements. http://www.usp.org/pdf/EN/USPNF/genChapter2040.pdf
3. Middleton, A., Holden, J., et. al. Preliminary Disintegration Analysis of Commercially Available Multivitamin/Mineral Dietary Supplements in the Adult US Market. United States Department of Agriculture – ARS – Beltsville Human Nutrition Research Center, Nutrient Data Laboratory, NIH – Office Of Dietary Supplements. Beltsville, MD. http://www.ars.usda.gov/SP2UserFiles/Place/12354500/Articles/AOAC09_Disintegration.pdf
4. Bonanome, A., Grundy S.M. Intestinal Absorption of Stearic Acid after consumption of High Fat Meals in Humans. *J. Nutrition*. Nov. 1989;Vol. 119 no. 11, 1556-1560.
5. Metagenics Educational Document, Tablet Delivery & Stearic Acid.
6. What We Eat in America, NHANES, 2001-2002. Nutrient Intakes: Mean Amount Consumed per Individual, One Day, 2001-2002. http://www.ars.usda.gov/SP2UserFiles/Place/12355000/pdf/Table_1_BIA.pdf
7. Yu S, Derr J, Etherton TD, et al. Plasma cholesterol-predictive equations demonstrate that stearic acid is neutral and monounsaturated fatty acids are hypocholesterolemic. *Am J Clin Nutr*. 1995;61:1129-1139.
8. Bonanome A, Grundy SM. Effect of dietary stearic acid on plasma cholesterol and lipoprotein levels. *N Engl J Med*. 1988;318:1244-1248.
9. Stearic Acid Monograph. Beef Facts, Human Nutrition Research, 2008. http://www.beefresearch.org/CMDocs/BeefResearch/Stearic%20Acid.pdf

Botanical Extraction: An Insider's Look

Dr. Michaël Friedman, ND

The botanical medicine market is experiencing continued growth due to an increased consumer interest in personal health and wellness. In an aging population more and more people are looking to preventative and alternative measures to positively influence their health. The Food and Agriculture Organization (FAO) of the United Nations estimates that over 50,000 plant species may have medicinal uses.[1]

This increasing consumer demand for botanical extracts has had many impacts; primarily on the development of new extraction process technologies, but also on the creation of new standardized extracts.

Botanical medicines contain many different bioactive compounds (also known as marker compounds), which can vary significantly in products of different manufacturers. The reason for this is mainly because the manufacturing processes used by the different companies can extract varying levels of specific compounds, partly by molecular weight and hydrophilic or –phobic nature of the compounds, and partly due to the differences in raw materials. To overcome this, the industry has focused on "standardizing" ingredients based upon a specific marker compound. However herbs have numerous active compounds, some of which may not even have been identified.

The production of botanical extracts involves six major processes; cultivation, identification, extraction, drying, formulation and testing.

Cultivation

The majority of botanical medicines are harvested from their natural habitat (known as 'wildcrafting'), which has led to environmental consequences such as over harvesting leading to species endangerment and loss of genetic diversity.[1,2] Over harvesting is not limited to a specific region of the world and has been seen in the U.S. in the case of American ginseng and yew trees (*Taxus* species) including Pacific yew native to the U.S. and Chinese yew which are used to product the anti-cancer drug, Taxol. Some botanical species sought for their medicinal properties, such as hoodias, ginseng, and goldenseals, are listed by the Convention on International Trade in Endangered Species of Wild Fauna and Flora as endangered species due to over harvesting.[3] *C. wightii*, (locally know as guggul), is commonly found in Northern India but may grow in regions from Northern Africa to Central Asia. The oleo-gum of *C. wightii* has historical use in obesity and lipid metabolism disorders and is harvested by tapping the branches by incision. Due to the slow-growing nature of *C. wightii*, poor germination rate and excessive tapping for its gum resin, however, the plant has been listed in the data deficient category of the International Union for Conservation of Nature's (IUCN) 'Red List' of Threatened Species™.[4] The IUCN Red List evaluates conservation status of plants and animals using a scientific approach to determine risk of extinction and is recognized by both the World Health Organization and various governmental and non-governmental agencies worldwide. Harvesting of species listed on the Red List must be conducted in accordance with national and/or regional legislation.

With a recent rise in consumer environmental awareness, some manufacturers are turning to organic cultivation and offer "organic certified" botanical extracts. At present, however, there are very few certified organic extracts available to consumers. In order to be certified organic, a manufacturer must produce a finished product which is grown organically and is manufactured using water or certified organic grain alcohols as solvents. Some challenges in producing organic certified botanical extracts include avoiding synthetic chemical inputs such as pesticides, solvents used in extraction and preservatives, use of farmlands free from chemicals for three or more years and maintaining physical separation of organic products from non-certified products, which ultimately leads to increased manufacturing costs.

Identification

Good agricultural practices and good collection practices should be followed to ensure that correct species of botanicals are collected.[5] At minimum a visual inspection should be performed to prevent cross-contamination by unwanted plants and/or plant parts as well as evaluation for appearance, damage, size, and other organoleptic qualities. Some regulatory agencies (e.g., Health Canada), require botanical extracts to be identified using physical and chemical identification tests including macroscopic or microscopic techniques, DNA fingerprinting (genetic profiling) and spectral fingerprinting (chemical profiling) via Ultra Violet (UV), Infrared (IR), Mass Spectroscopy (MS) or chromatographic methods, such as High Performance Liquid Chromatography (HPLC), Thin Layer Chromatography (TLC) or Gas Chromatography (GC) to prevent

9th Annual International

RESTORATIVE MEDICINE CONFERENCE



Portland, Oregon
October 4-7, 2011

Practical Clinical Skills in
Endocrinology and
Reversing Chronic Disease

- Integrative Treatments
- Effective Protocols
- Nutritional Supplementation
- Botanical Medicines
- Bio-identical Hormones

AARM
Association for the Advancement of Restorative Medicine

Restoring patient wellness. Building physician practices.

CME Credits

18 CME Credits have been approved
for the Restorative Medicine Conference.

REGISTER ONLINE at www.RestorativeMedicine.org

It's NEW!

Environmental Pollutants

- phthalates, parabens, volatile solvents
- convenient dip 'n' dry urine collection strip
- easy-to-understand report
- regular price $159 + GST

$139
*only until July 31, 2011

Advancing the Science of Wellness
Rocky Mountain Analytical

Changing Lives, One Test At A Time.

info@rmalab.com | 866.370.5227 | www.rmalab.com

misidentification of the herb.[6] Misidentification, leading to use of incorrect plant parts or substitution of different species can lead to serious health consequences. This is the case for the Chinese herbal preparations of *Aristolochia fanghi* and *Podophyllum emodi* where misidentification of plant constituents in therapeutic products have been linked to sequelae as serious as nephropathy and urothelial carcinoma.[7,8,9] Once the plant/plant part has been identified and sorted, processing techniques such as extraction, standardization and drying may commence.

Extraction and Standardization

Botanical extracts are prepared in various forms including, but not limited to, essential oils, fluid extracts, solid extracts, native extracts, tinctures, and spray-dried extracts. Extraction from plant or plant materials (i.e., roots, stems, leaves) may be achieved through processes such as percolation or maceration.[10] Percolation involves reducing plant material to suitable size, mixing with solvent and transferring to a percolator. The mixture is allowed to percolate slowly and become concentrated. In the case of maceration, plant material is reduced to suitable size and solvent added. With frequent agitation, the soluble matter is dissolved and filtered prior to concentration. These processes may involve the use of relatively benign solvents such as water, ethanol and methanol or volatile organic chemicals such as benzene, chloroform or acetone. Note: some solvents such as chloroform and benzene are not allowed for use in some countries. The solvent is then evaporated or removed and the resulting extract may be standardized to meet final specifications for the ingredient. Standardization refers to adjusting the content of a characterized bioactive constituent by increasing the active compound, decreasing unwanted constituents or both. Contrary to popular belief, however, standardization does not necessarily mean a stronger product; the author has had tested through HPLC analysis at third party accredited laboratories, 8:1 extracts of lemon balm and 10:1 bugleweed have significantly lower rosmarinic acid, lithospermic acid than using unprocessed dry lemon balm or bugleweed directly from the garden. Standardization may be achieved in various ways, such as, mixing raw material lots, varying extraction conditions, varying extraction ratio of plant material to solvent or normalizing by varying the quantities of excipients among others.[10] Additionally, some botanical extracts may be fortified (or 'spiked') with another marker or ingredient and are not standardized products. A fortified product will normally be labelled in an unambiguous manner such as 'rose hips with added vitamin C'.[6]

In order to improve physical characteristics of the botanical extract, diluents (a filler or thinner such as water or microcrystalline cellulose), and in some cases, anti-microbial agents or preservatives, may be added. Natural health products (NHPs) containing extracts often present an extract ratio on the label (e.g., 4:1, 1:20). The ratio does not indicate the amount of the particular herb, but rather the ratio used in preparing the extract. In the case of tinctures, this ratio indicates the solute to solvent ratio, whereas in the case of spray dried extracts, the ratio is indicates the amount of inputted plant material to output. For example, a label stating "Licorice root extract (4:1), 20mg" indicates that 20mg of the extract is present in the finished product, but was prepared from 80mg of licorice root. Thus when assessing the safety and efficacy of the ingredient and potential contraindications, NDs should consider the product as having 80mg of licorice, in this case, or whichever plant compound is listed on the label.

Drying

Powdered botanical extracts used in natural products are almost always spray dried. Spray drying produces free flowing powders. The main reason for spray drying is to create a powdered extract that can be encapsulated. Without spray drying, botanical extracts would remain as a liquid in the form of a tincture or fluid extract. Spray drying usually involves five steps: concentration, atomization, droplet-air contact, droplet drying and separation. The botanical extract is usually concentrated prior to introducing in the spray dryer. The second stage, atomization, creates prime conditions to evaporate a product to desired characteristics. The atomized liquid is then brought into contact with the drying medium, most commonly hot air and allowed to continue until the desired moisture content is obtained at which time the particles are separated from the air. Particles may be separated utilizing specific properties of the compound of interest such as filtration or electrostatic precipitation.[11,12,13,14]

Formulation of the Finished Product

The finished NHP may be a single botanical extract or a combination of botanical extracts or other natural ingredients. In most cases, ingredients are blended together and either tabletted or encapsulated. Encapsulation involves filling the ingredients into a capsule shell. Non-medicinal agents may be added for a variety of purposes including lubrication, binding, coating and diluting.

Product Specifications and Analysis

Products may be tested at the ingredient stage, finished product stage or both by the manufacturer of the ingredient and/or finished product or by third party contract laboratories. Testing can be done in-house and does not always involve a third party. Most of the manufacturers of finished products provide their own test results to Health Canada in product applications.

Testing requirements depend on the type or nature of the ingredient or finished product and regulatory mandates. Botanical extracts (ingredients and/or finished products) are required by Health Canada to be tested for residual solvents, especially in cases where potentially toxic or carcinogenic solvents are used (e.g. styrene divinyl benzene, acetone, carbon tetrachloride), pesticide residues, heavy metals and microbes, however this may not always be the case as there are still numerous botanicals on the market in Canada that have not been assessed and approved by Health Canada.[6,9] Though not common practice, it may be necessary to sterilize raw materials or finished products to reduce microbial loads where found to exceed pharmacopeial limits to meet regulatory requirements. In such cases, pasteurization or

irradiation may be used. Though irradiation is not approved for use in the United States, it may be permitted by the Natural Health Products Directorate of Health Canada as a method of reducing microbiological loads or as a sterilization procedure for plant materials.[6] When irradiation is used as a means of sterilization, testing is imperative to ensure residual radioactivity is below the upper allowable regulatory limits. Currently, labelling of irradiated products is voluntary, and if labelled, will bear a statement to the effect "Treated with irradiation," "Treated by irradiation" or "irradiated".[6]

Pesticide Use

Most cultivated botanical species are grown with conventional agriculture methods using various pesticides and herbicides. There are no global regulations on the use of pesticides and thus testing requirements on botanicals is necessary to ensure consumer safety. Many pesticides contain chlorine and are referred to as organochlorides (examples include DDT, endosulfan and endrin). Many organochlorides have been banned in various countries, however only few have been banned worldwide (DDT and endosulfan to be banned globally in 2012). The continued allowance of pesticides such as 2,4- Dichlorophenoxyacetic acid in many regions including the U.S. and E.U., has consequences on watersheds and soils, those involved in the farming (farmers and agriculture workers) and manufacturing (those involved in extraction of the compounds) and ultimately those using these products. The state of Wisconsin regulates the amount and type of chemicals which may be sprayed on ginseng farms, although pesticides may still be used. Other countries cultivating ginseng, however, including China and South Korea, do not impose strict guidelines on pesticide use. An analysis conducted by ConsumerLab reported the presence of quintozene (pentachloronitrobenzene or PCNB) and hexaclorobenzene in some samples of East Asian ginseng. These pesticides are banned from most crop use throughout the world, including in Wisconsin, as they are possible carcinogens.[17,18] Ginseng, in this example, illustrates the critical importance for dispensaries and consumers to know the quality and source botanical extracts used in the dietary supplements. One such method may include reviewing NHPs to determine if they have been assessed and approved for use/sale in regulated countries such as Canada.

As the NHP industry continues to grow, manufacturers will need to review and evaluate current collection and manufacturing procedures in order to ensure well characterized, efficacious, safe, environmentally conscious products are available to consumers and medical professionals. Emphasis must be placed on the correct identification and characterization of botanicals used to prevent potential serious health consequences. Naturopathic doctors, as well, should be able to inform their patients on the safe use of NHPs. However, individual NDs can also play an important role by requesting both certified organic extracts and independent testing, which ensures that toxic solvents and processes are not used. In order to do this, the industry in turn must be more transparent with the methods employed to manufacture their finished products and unambiguously detail all ingredients and their amounts in the finished product.

About the Author

Michaël Friedman, ND is a naturopathic physician and medical herbalist. He graduated from the Canadian College of Naturopathic Medicine in 1998 and was adjunct instructor of endocrinology at the University of Bridgeport in Connecticut. He is also the founder and director of the Annual Restorative Medicine Conference. Dr. Friedman is the author of the medical textbook Fundamentals of Naturopathic Endocrinology and Healing Diabetes. His research on the use of SR T3 has been published by the University Puerto Rico Medical School. Dr. Friedman has lectured at three naturopathic and allopathic medical schools including NCNM, UB, CCNM and at the Dehradun Medical School of Physicians and Surgeons in India. He currently is the executive director of the non profit Assoication for the Advancement of Restorative Medicine.
customerservice@restorativemedicine.org

References

1. Schippman U, Leaman DJ and Cunningham CB. Impact of cultivation and gathering of medicinal plants in biodiversity: Global trends and issues. FAO, biodiversity and the ecosystem approach in agriculture, forestry and fisheries, interdepartmental working group on biological diversity for food. 2002.
2. Medicinal plants: Rescuing a global heritage. World Bank. Washington DC. 2001. World Bank technical paper no. 355.
3. Convention on International Trade in Endangered Species of Wild Fauna and Flora. International Environment House. Geneva, Switzerland. April 2011. Available from: http://www.cites.org/eng/app/appendices.shtml
4. CAMP Workshops on Medicinal Plants. Commiphora wightii. In: IUCN 2010. IUCN Red List of Threatened Species. Version 2010.4. Cited 2011 Apr 16. Available from: www.iucnredlist.org.
5. WHO guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization Geneva. 2003. Available from: http://whqlibdoc.who.int/publications/2003/9241546271.pdf
6. Evidence for Quality of Finished Natural Health Products. Health Canada. Ottawa, Canada. June 2007.
7. Nortier JL, Martinez MC, Schmeiser HH, Arlt VM, Bieler CA, Petein M, et al. Urothelial carcinoma associated with the use of a Chinese herb (Aristolochia fangchi). *N Engl J Med.* 2000;342(23):1686-1692.
8. Van Breemen RB, Fong HHS, Farnsworth NR. Ensuring the safety of botanical dietary supplements. *Am J Clin Nutr* 2008;87(suppl):509S–513S.
9. Mosihuzzaman M, Choudhary MI. Protocols on Safety, Efficacy, Standardization, and Documentation of Herbal Medicine (IUPAC Technical Report). *Pure Appl Chem* 2008; 80(10):2195–2230.
10. Botanical Extracts (General Chapter 565). In: USP 32–NF 27. Rockville, MD: United States Pharmacopeia Convention, Inc.; 2009:196.
11. Masters K. 1985. *Spray Drying Handbook* (4th ed.). England: Longman Scientific and Technical.
12. Papadakis SE, Babu RE. The sticky issues of drying. *Drying Technology*, 1992; 10(40):817 - 837.
13. Mujumdar AS. 2007. *Handbook of Industrial Drying*. CRC Press
14. Patel RP, Patel MP, Suthar AM. Spray Drying Technology: An Overview. *Indian J of Sci and Tech*. 2009; 2(10): 44-47.
15. Rubinstein MH and Eastwood BA. The effect of lubricant type and concentration on the bioavailability of frusemide from 40mg tablets [proceedings]. *J Pharm Pharmacol* 1978; 30 Suppl:12P.
16. Søndergaard D, Meyer O, Würtzen G. Magnesium stearate given perorally to rats. A short term study. *Toxicology.* 1980;17(1):51-5.
17. Wisconsin Farm Bureau® Federation. http://wfbf.com.
18. ConsumerLab.com News Report. 2005. Quality Problems Widespread Among Ginseng Products Sold in Japan - Nearly Two-Thirds of Products Fail ConsumerLab.com Testing Due to Pesticide Contamination and Missing or Substandard Ingredients. Available from: http://www.consumerlab.com/news/Ginseng_Japanese_Contamination/6_20_2005/

Developed exclusively for you by the leader in omega-3

Visit us at Health Fusion booth #23

Ascenta Professional™

- Clinical potencies
- Evidence-based formulations
- Guaranteed purity and potency that patients can check for themselves
- Innovative and unique antioxidant that ensures stability and great taste throughout the product's shelf life
- Delicious citrus flavour that ensures compliance

Contact us

Call us today to learn more about this unique product line and to find out about our special Health Fusion show special for CAND members. 877.806.7328.

Pure™ quality guaranteed

1% FOR THE PLANET | MEMBER

ascentaprofessional.com

Omega-3 oxidative stability: an overview of lipid oxidation and its relevance to product quality, patient compliance and clinical outcomes

Marc St-Onge

The importance of omega-3 fatty acids in naturopathic practice is well established. While the clinical applications of omega-3 fatty acids are well understood, the qualitative aspects (product quality and in particular lipid peroxidation) and its impact on patient care is not.

Oil chemistry is a very complex subject and presents a significant technical challenge to manufacturers of omega-3 fish oils. At the root of this complex subject is lipid oxidation. This article attempts to review the basics of lipid oxidation and its impact on product quality and patient compliance. The focus will be placed on 3 primary factors that influence overall quality and sensory impact 1) capsule vs. liquid format, 2) ethyl ester vs. triglyceride form, and 3) the importance and efficacy of additive lipid antioxidants.

What is oxidation?

Oxidation is a chemical reaction that occurs between oxygen and an unsaturated fatty acid, such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA),1 resulting in fishy and/or rancid flavors that are often found in fish oil supplements. Though oxidation is a problem in all oils and oil-containing foods, the high concentration of polyunsaturated fatty acids (PUFA) and the high number of double bonds in EPA and DHA (PUFA oils have at least one double bond. EPA and DHA have 5 and 6 respectively) make fish oil very susceptible to oxidation.[2] There are a number of factors that can initiate or accelerate the rate of oxidation.

Table 1 – Catalysts and factors that accelerate lipid oxidation

Ultraviolet light
Elevated temperatures
Oxygen
Metals
Free radicals
Ethyl esters
Free fatty acids

How does oxidation occur?

There are many different types of oxidation, the mechanism that occurs in fish oil and other edible oils is known as "free radical oxidation" or autoxidation.[1] Free radicals formed from any one of the sources mentioned in Table 1 attack the double bonds of unsaturated fatty acids,[3] generating more free radicals, as seen in Figure 1. This is referred to as the *initiation* phase of oxidation[1].

Figure 1 - Initiation phase: Oxidation at a double bond (RH) gives a free radical (R•) and a hydrogen atom (H•)

Once enough free radicals have built up in the oil, oxidation proceeds to the next phase, propagation1. This oxidation phase results in the formation of more free radicals as well as hydroperoxides and hydroperoxide radicals (Figure 2). Hydroperoxides are relatively stable at room temperature, but will readily breakdown at elevated temperatures, or in the presence of metals[4]. The propagation phase is comprised of chain reactions; the more oxidation that occurs, the more free radicals are formed, causing more oxidation. As a result, hydroperoxide formation is rapidly occurring. Eventually, all of the fatty acid substrate will be oxidized and no more hydroperoxides will form. This is known as the *termination* phase, and it is at this point that rapid breakdown of hydroperoxides begins.

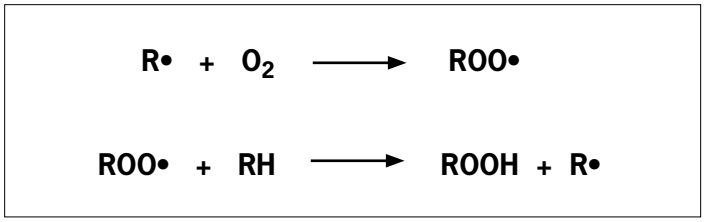


Figure 2 - Propagation phase: A free radical (R•) reacts with oxygen to from a lipid hydroperoxide radical (ROO•). The hydroperoxide radical then reacts with another double bond (RH) to form a hydroperoxide (ROOH) and another free radical (R•)

It should be noted that peroxides on their own do not cause negative flavours in fish oil, but they break down into other volatile compounds, such as aldehydes, ketones and acids, that have very strong tastes and odours[4,5] (Figure 3). These volatile compounds are known as secondary oxidation products and are formed rapidly during the termination phase. Though the most rapid breakdown occurs during termination, hydroperoxides are degraded throughout the oxidation process, sometimes quite slowly.[5] This constant breakdown can result in the formation of off-flavours

From Left to Right: Cecilia Ho ND, Adriana Restagno ND, Tanya Salituro CanPrev Founder, Janet Neilson HD, Natalie Lauzon HD

Working together with you.

CanPrev Natural Health Products Ltd., based in Richmond Hill, Ontario, is an all-Canadian company that develops and markets premium natural health products to healthcare professionals and select health food retailers.

Tanya Salituro, a three-time breast cancer survivor, founded CanPrev in 2005 as a response to her search for alternative health solutions and to the perceived need for highly comprehensive, premium quality, natural health products.

Our product development process merges the best creative and critical thinking with the very latest scientific research.

Our goal is to create the world's most innovative and effective natural health products.

Our in-house Research & Development team and Scientific Advisory Panel is composed of experienced, licensed natural healthcare practitioners, process and quality control engineers and experts in natural ingredients.

We encourage you to visit our newly redesigned website **www.canprev.ca** and see our complete line of 35 premium natural health products.

CanPrev™
PREMIUM NATURAL HEALTH PRODUCTS

even if the peroxide value remains very low. For this reason it is commonly misunderstood that peroxide value (PV) does not relate to fish oil taste and smell.

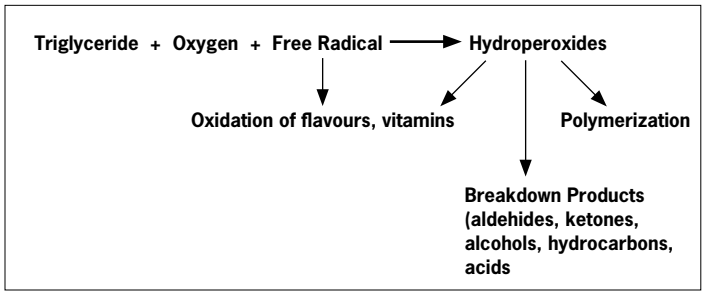


Figure 3. Termination phase: Triglycerides react with oxygen and free radicals to form hydroperoxides. These hydroperoxides break down into secondary oxidation products. Free radicals can also oxidize flavours and vitamins that are present in the oils. Modified from Labuza[1] (1971).

Oxidation in fish oil supplements

Now that we've detailed the process of oxidation, the next step is to examine how this process is influenced, positively and negatively, by the various forms and attributes of fish oil supplements – capsules vs. liquids and ethyl esters vs. triglycerides. The result of preventing oxidation is a fish oil with pleasant sensory properties as well as preserving levels of actives (EPA & DHA) and endogenous antioxidants.

Capsules vs. Liquids

Fish oil supplements are generally sold as soft gelatin capsules and free flowing liquids.

Although the liquid format is more convenient for swallowing it is less preferred due to the negative sensory attributes of most fish oils. To overcome the fishy taste and smell, many fish oil liquids incorporate very strong citrus based flavours which in themselves may reduce patient compliance. The capsule format on the other hand bypasses the initial sensory impact but can still result in what is referred to as fish burp back, which occurs after the capsule contents are released high in the GI tract. Some manufacturers have attempted to minimise fish burp back by using an enteric coating on the capsule which results is the capsule releasing its contents further down the digestive track.

Because oxygen is the primary catalyst for oxidation, one strategy to prevent lipid peroxidation is to minimize oxygen contact with the oil. Oxygen, and other catalysts, come into play at three time points: 1) processing/refining, 2) bulk and finished storage/shelf life, and 3) breakdown in the intestinal milieu. The impact of the processing of the fish oil applies equally to both liquids and capsules. Oxidation as it relates to finished product storage, however, slightly favours capsules over liquids. The gelatin based capsule provides a barrier against oxygen and thus slows the rate of oxidation of the oil inside. Liquids are bottled in such a way that there is space left in the top of the bottle known as headspace. Careful purging of the headspace with nitrogen gas removes the atmospheric oxygen and slows the rate of oxidation.

Once the bottle is opened, capsules offer further protection against oxidation because the oil is still protected by the gelatin capsule. Liquids on the other hand, once opened, introduce atmospheric oxygen into the headspace which can accelerate the rate of oxidation.

Once the oil is orally consumed, in either liquid or capsule form, the oil is exposed to the harsh environment of the gastrointestinal tract where the rate of oxidation is again accelerated.

While the capsule format inherently offers greater protection to the fish oil, there are two other variables that predominate as determinants for overall oxidative stability and sensory impact 1) ethyl esters vs. triglycerides, and 2) antioxidants.

Ethyl esters vs. triglyceride form

Omega-3 fatty acids in the form of ethyl esters (EEs) are much less stable than those in the natural triglyceride (TG) form, and readily oxidize. The oxidation kinetics of DHA as an EE or as a TG was assessed by measuring the concentration of oxygen found in the head space of a reaction vessel.[6] The EE form of DHA was more reactive, and quickly oxidized, demonstrating that EEs are far less stable and can more readily produce negative sensory by-products and free radicals. In another study the stability of a phospholipid, triglyceride and EE containing DHA was assessed. After a ten-week oxidation period, the EE DHA oil decayed 33% more rapidly.[7] Due to the oxidative instability of the EE form, the goal of minimising oxidation would necessitate that only the TG form be used.

Antioxidants

Antioxidants are molecules that inhibit or neutralize free radicals that occur during oxidation reactions.[8] In the case of fish oil, antioxidants can be added to the product to inhibit or neutralize oxidation reactions that lead to the development of fishy or rancid notes. Without the use of antioxidants, refined fish oils would be completely unpalatable and potentially harmful to consume due to the oxidative stress impact on the body. The efficacy of antioxidants in fish oil varies considerably. Common antioxidants such as vitamin E are minimally effective and do not prevent oxidation, leading to fishy tasting oils.

Optimal stability, sensory, and patient compliance

In addition to improving compliance, the oxidative stability of the product confers further benefit once consumed. Because the stability of the fish oil has a negative correlation to the amount of free radicals generated during the digestive process, it follows that less stable fish oils increase the oxidative stress burden on the body.

While fish oil chemistry is a complex process as it relates to oxidation, the human sensory organs for taste and smell are highly effective in detecting oxidation by-products. Our senses easily tell us when a piece of fish is not fit to eat, it equally can tell us when a fish oil has undergone even low levels of oxidation. For patients and practitioners, tasting a teaspoon of liquid or biting down on a capsule will tell us if the product is fit to be consumed.

In addition to fishy taste and odour, rancid fish oil may also taste metallic, like mushrooms or grass. Many of the compounds that are responsible for these off-notes can be detected at parts per million or parts per million levels. Table 2 shows some of these compounds, their taste and their detection limit when tasted.

PASCOE CANADA

Your Supportive and Reliable Partner

We are celebrating 50 years of research in 2011!

PASCOE is a world leader in the field of natural medicine, with the initial formulas being developed well over 100 years ago.

SAFETY - All of our products are gluten, flavouring and preservative free.

EFFICACY - We test for long-term stability to ensure that the last dose gives the same therapeutic effect as the first one.

QUALITY - All of our products are produced and stored according to the strictest pharmaceutical guidelines.

ENVIRONMENTALLY FRIENDLY - We won an award in 2008 as a top innovative company for being the first pharmaceutical company worldwide to have entirely paperless production.

INNOVATION - We won an award in 2010 for excellent performance in the categories "Innovative marketing" and "Innovative processes and organization".

905.737.9837 | 866.535.0099
info@pascoecanada.com
www.pascoecanada.com

PASCOE
NATURAL MEDICINE

Table 2 - Some common oxidation products found in fish oils

Compound	Odour/Flavour	Sensory Threshold (ppm)
1-octen-3-ol[9 10]	Mushroom[9]	0.01[9]
trans-2-heptenal[9,10]	Fatty, bitter almond[11]	0.20[9]
trans,trans-2,4-heptadienal[9]	Painty, fatty[9]	0.055[9]
trans,cis-2,6-nonadienal[9]	Cucumber[11]	0.022[9]
2-nonenal[9,10,11]	Tallow, cucumber[11]	0.1[9,10]

An unopened bottle of liquid TG fish oil stored in an amber bottle, out of direct sunlight will maintain its quality for approximately two years, sometimes longer depending on the product. An opened bottle of liquid TG fish oil stored in the refrigerator will maintain its quality for approximately 100 days. Encapsulated fish oil does not need to be stored in the refrigerator after opening as the capsule material protects the oil from oxygen. Fish oil capsules stored in an amber bottle at room temperature out of direct sunlight can maintain their quality for over two years. These estimations are approximate and may vary from product to product. Every fish oil product has an expiry date for unopened product that is clearly noted on the label. In order to sell fish oil in Canada, the shelf life of the product must be verified by the manufacturer. For liquid fish oils, a time period is also stated for opened products stored in the fridge. It is recommended that patients follow the guidelines on the package.

About the Author

Marc St-Onge is the founder and CEO of Ascenta. He is a renowned expert in the field of omega-3 and formulator of the Ascenta product line. Marc passionately pursues the goal of establishing Ascenta as a world leader in health, environmental stewardship and social responsibility. Marc has a Bachelor of Science degree from Dalhousie University in Halifax, Nova Scotia, Canada. He is a contributing author of "Walking with the Wise for Health & Vitality" and was a 2005 Ernst & Young Entrepreneur of the Year finalist and the 2005 BDC Young Entrepreneur of the Year.
mstonge@ascentahealth.com

References

1. Labuza TP (1971). Kinetics of lipid oxidation in food. *CRC Critical Reviews in Food Technology.* 2(3):355-405
2. Yoshi H, Furuta T, Siga H, Moriyama S, Baba T, Maruyama K, Misawa Y, Hata N, Linko P (2006). Autoxidation kinetic analysis of docosahexanoic acid ethyl ester and docosahexanoic triglyceride with oxygen sensor. *Bioscience, Biotechnology and Biochemistry.* 66(4):749-753.
3. Colakoglu AS (2007). Oxidation kinetics of soybean oil in the presence of monoolein, stearic acid and iron. *Food Chemistry.* 101:724-728.
4. Choe E, Min DB (2006). Mechanisms and factors for edible oil oxidation. *Comprehensive Reviews in Food Science and Food Safety.* 5:169-186.
5. Adhvaryu A, Erhan SZ, Liu ZS, Perez JM (2000). Oxidation kinetic studies of oils derived from unmodified and genetically modified vegetables using pressurized differential scanning calorimetry and nuclear magnetic resonance spectroscopy. *Thermochimica Acta.* 364:87-97.
6. Yoshii H, Furuta T, Siga H, Moriyama S, Baba T, Maruyama K, Misawa Y, Hata N, Linko P. (2002). Autoxidation kinetic analysis of docosahexaenoic acid ethyl ester and docosahexaenoic triglyceride with oxygen sensor. *Biosci Biotechnol Biochem.* 66:749-753.
7. Song JH, Inoue Y, Miyazawa T. (1997). Oxidative stability of docosahexaenoic acid-containing oils in the form of phospholipids, triacylglycerols, and ethyl esters. *Biosci Biotechnol Biochem.* 61(12):2085-8
8. Frankel EN (1996). Impact of antioxidants on food quality. *Food Chemistry.* 57:51-55
9. Frankel EN. (1985). Chemistry of autoxidation: Mechanisms, products and flavour significance. In: Min, DB, Smouse, TH (Eds) *Flavour Chemistry of Fats and Oils, American Oil Chemists Society,* Champaign, Illinois
10. Frankel EN. (2005). Lipid Oxidation, 2ed. *The Oily Press,* Bridgwater, England

Chemicals in Personal Care Products

Dr. Iva Lloyd, BScH, RPE, ND
Stephan Wilmes

The chemicals used in personal care products are largely unregulated and untested. Only within the last five years has it been mandatory for companies to include a list of ingredients on product labels, however, companies are not required to list the amounts of each ingredient. It is the opinion of the authors that chemicals have replaced bacteria and viruses as a major threat to health.

In personal care products (PCPs), it is the low-level, long-term exposure to chemicals that is the main concern. As currently there are no standards for using the terms "natural", "organic", "green", "fresh", "pure", "eco-friendly" or "botanical" on cosmetic labelling, there is a high potential for consumer confusion.

The Concern

In the United States, the FDA Office of Cosmetics and Colors reports that cosmetic manufacturers can use nearly any raw material as an ingredient without premarket approval.[1] Under this policy, the FDA has only reviewed the safety of 11% of the more than 10,500 chemicals, additives and fillers used in the PCP industry. The only ingredients prohibited under the FDA include: bithionol, chlorofluorocarbon propellants, chloroform, halogenated salicylanilides, methylene chloride, vinyl chloride, zirconium-containing complexes and prohibited cattle materials.

The following ingredients may be used in cosmetics under the restrictions stated in the regulations: hexachlorophene, mercury compounds and sunscreen ingredients. The presence of lead and other heavy metals is virtually unregulated.

The PCP Industry in Canada is regulated by the Food & Drug Act and the Cosmetic Regulations. Health Canada (HC) provides an extensive list of chemicals in personal care products (http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/hotlist-liste_ac-eng.php), referred to as the "Cosmetic Ingredients Hotlist", where caution or prohibition is advised. The list is a good first step, but it does not carry the same authority as legislated regulations and there are products that are banned from use in Europe, such as dibutyl phthalate, that are not on HC's Hotlist.[2] With the growing research linking chemicals to chronic health issues, the authors recommend that naturopathic doctors continue to take more of a precautionary approach and include an assessment of PCPs and the chemicals involved as part of the search for causal factors of disease.

In a recent report titled, "Heavy Metal Hazard" from the Environmental Defence (www.environmentaldefence.ca) it was found that cosmetic products contain heavy metals. Although the intentional adding of heavy metals is banned, the concern is that they are still appearing in the products. In the report seven of the metals were found throughout the products, and all items had at least two heavy metals in them. The main metals that were present included arsenic, cadmium, lead and mercury. To read more about this report go to https://www.greenbiz.com/news/2011/05/18/canada-under-pressure-regulate-heavy-metals-cosmetics.

One of the groups that focuses on identifying concerns in cosmetics is the Environment Working Group (www.ewg.org). They also have a cosmetic database (http://www.ewg.org/skindeep/browse.php?maincat=skincare) to assist consumers and practitioners in identifying "clean" products. In 2004 the EWG evaluated 14,841 name-brand personal care products and found that more than one-third contained at least one industrial chemical ingredient linked to cancer and 79.1 per cent of the sample contained harmful impurities that include known or probable carcinogens, pesticides, reproductive toxins, plasticizers or degreasers.[3] The average consumer (including teens) uses 15 to 25 cosmetic PCPs a day, amounting to an exposure rate of approximately 200 chemicals per day.[4]

The Largest Organ - Skin

Like all aspects of health, the safety of PCPs depends not only on the chemicals that are in the products, but also on a person's susceptibility to these chemicals based on medical history, genetic variability and individualized biochemistry. The skin contains a very fine, slightly acidic film on its surface, often referred to as the skin mantle, that serves as a barrier against bacteria, viruses, and other potential contaminants. This film is composed of sweat and sebum and it provides the skin with its protective abilities. This protective layer is supported or injured depending on which PCPs we choose, the internal health of the body, and how we treat and support the skin.

P. Jentschura®

Alkaline Health

Attain and maintain optimal health and vitality with Dr. h. c. Jentschura's 3 step program.

Step 1: Alkaline Cleansing
Detoxification and deep cell cleansing.
AlkaHerb herbal tea is an exclusive blend of 49 specially selected herbs.

Step 2: Alkaline Regeneration
Mineralize the body to neutralize acids and toxins with delicious, nutritious, alkaline-generating foods.
WurzelKraft aromatic and fruity are both whole food supplements loaded with alkaline-generating minerals & vitamins.
MorgenStund' breakfast porridge is gluten-free, sugar-free, wholesome goodness.
TischleinDeckDich is an alkaline-generating quinoa-millet meal with vegetables.

Step 3: Alkaline Purification
Internal and external cleansing.
AlkaBath alkaline mineral bath salts with the ideal pH-level of 8.5 for a deep release of toxins and acids.
Alkaline body care activates the self-oiling process of the skin, releasing oil from the sebaceous glands and thus naturally moisturizing the skin.

Successfully helping people in 23 countries

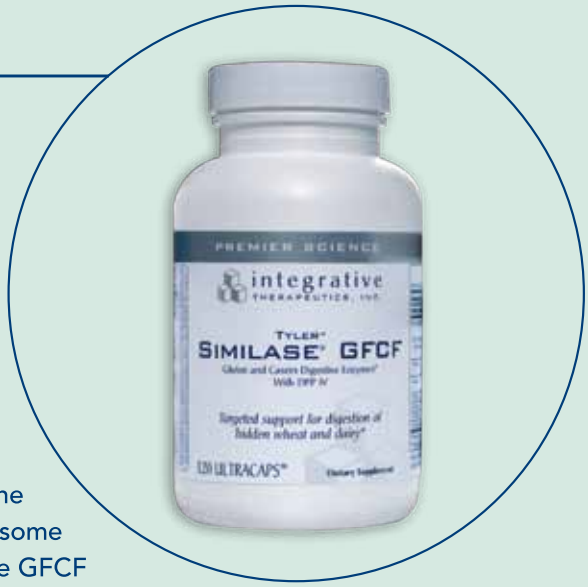
Made in Germany

22.09.2011 in Toronto
24.09.2011 in Vancouver
Reserve your seat at the Dr. h. c. Jentschura 1 day seminar on Complete Cleansing

www.YouInFocusProducts.com
info@youinfocusproducts.com · 1-780 483 5407

integrative
THERAPEUTICS, INC.®
When results matter™

digestion relief*



The Similase® line of digestive enzymes are physician formulated and provide independent, peer-reviewed clinical superiority with a higher potency and broader range of digestive enzymes than other products.* Similase provides proprietary Pure Plant™ enzymes for superior support of carbohydrate, protein, fat and fiber digestion.*

The Similase line of pure plant enzymes just got better!

Introducing Similase® GFCF

Digestive discomfort impacts people's lives in an immediate way. The digestion of hidden gluten and casein can be particularly difficult for some people causing indigestion, gas, bloating and constipation.* Similase GFCF enzymes gluten & casein digesting formula provides:

- Proprietary Pure Plant enzymes for broad spectrum digestive support*
- Supports a gluten-free, casein-free lifestyle by digesting hidden gluten and casein*
- Delivers superior DPP IV activity — 200% more protein-digesting capability per serving than leading competitor*

Proven Quality and Results*

The Similase Line of digestive enzymes offers offers unsurpassed quality and proven effectiveness for trusted results.* The enzymes in Similase products are effective under all gastrointestinal pH conditions, so they support digestion regardless of age, digestive function, and pH balance.*

When results matter™ choose Similase®

WWW.INTEGRATIVEINC.COM
800.644.3211

The Chemicals

Generally, over 80% of the ingredients in PCPs are synthetic. The side effects associated with PCPs include: mild to severe allergic reactions, disruption to the endocrine, nervous, respiratory or immune systems and have mutagenic and carcinogenic properties, especially with long-term exposure. Most cosmetic products are formulated for a shelf-life of over three years, and as a result these products typically contain large amounts of preservatives, such as parabens, for example, to prevent spoilage. These preservatives are known cellular toxins.[2]

The chemicals that are the most important to avoid are those that have a name ending in "acid", as well as alcohol, parabens, phthalates, sodium laureth and its derivatives, propylene glycol and synthetic colours and fragances.

Propylene glycol (PEG), is an inexpensive glycerine substitute found in hair products, facial moisturizers and cleaners, body wash and sunscreen. It is also used as an industrial petrochemical. The concern is that PEG is often contaminated with 1,4-dioxane or ethylene dioxide which are suspected carcinogens. Although 1,4-dioxane can be removed from products easily and economically there is no way to determine which products have undergone this process as companies are not required to list this information on labels. PEG has been linked to decreased skin moisture, weakening of protein and cellular structure, irritation of nasal and respiratory passages, kidney disease, liver abnormalities, neurotoxicity and endocrine disruption.

Sodium lauryl sulfate/sodium laureth sulphate (SLS) is used as a foaming agent and the concern is that it can form toxic nitrosamines. When sodium laurel sulfate is combined with ethylene oxide (ethoxylized) to create the milder sodium laureth sulfate, it too may become contaminated with 1,4-dioxane. SLS is found in shampoos, hair conditioners, body wash, facial creams, lotions and soaps. It is also found in car wash soap, engine degreasers and garage floor cleaners. It has been linked to corroding hair follicles and impedes hair growth; it is a skin and eye irritant and can enhance allergic responses to other toxins and allergens. In severe cases it can cause blindness and depression.

Diethyl phthalate (DEP), dibutyl phythalate (DBP) and butyl paraben (BP) are man-made petroleum-based chemicals that are commonly found in lotions and creams. It has been found that the concentration of these compounds peaked in urine 8-12 hours after exposure. The highest concentration of DEP was found in nail polish, but over ¾ of the products tested showed measureable levels.[6] The European Union has banned DBP, DEP and BP from use in cosmetics, but in Canada and the U.S. there are no restrictions on phthalates in cosmetics. Except for nail polish, phthalates are not generally listed as ingredients on labels because Canada's Cosmetic Regulations allow them to be included under the heading of "fragrance".[8]

Other concerns about the chemicals commonly found in PCPs include:

- Medicated soaps that destroy the beneficial bacteria on the surface of the skin.
- Alcohol in products which contributes to skin dehydration. Some products, such as mouthwash, may contain even higher concentrations of alcohol than beer, wine or liquor. The continual use of alcohol-based mouthwash has been linked to an increased risk or oral and throat cancer. Alcohol shows low acute and repeat dose toxicity and is related to mild liver toxicity.[6]
- Oils in bathing products and moisturizers can clog the skin pores reducing perspiration and waste transport from the subcutaneous tissues.
- Petroleum-based ointments, such as Vaseline, coat the skin surface with an insulating and waterproof film which prevents evaporation of secretions and the release of heat. It also creates swelling on the top layer with a sustained hydration.

The pH Perspective

Many of the toxic chemicals in PCPs are acidic by nature. The concern with this is twofold. The first being, that when the pH of the body is disrupted it will pull minerals from nearby sources in order to balance the pH. The result is a weakening of the skin structure in response to the acid in the products. Another problem is If the pH of the PCPs is more acidic than the pH of the toxins it will cause the toxic acids transported in the skin surface to be transported back into the subcutaneous tissues. Effectively, many PCPs are both suppressive and toxic in their mechanism of action.

Historically, body care products were alkaline in nature and included compounds derived from wood and plant ash. It wasn't until about 1930 that a shift occurred and the idea of acid-based personal care products became fashionable.[9] This change may have been due to the fact that when the pH of "skin mantle" was first measured it was believed to be around 6.0. Hence the belief was that acidic products were required to maintain the skin's integrity. Over time, the acidity of personal care products has become closer to a pH of 5.0 – 5.5, and as result the pH of the "skin mantle" is often said to be between a pH of 4.5 and 5.5. Not only must chemical ingredients in skin care products be considered, but also the overall pH of a product.

PCPs that have a pH closer to 7.0 or above have been found to normalize the skin's dryness or oiliness, improve the removal of surface deposits such as cellulite, increase the skin's ability to detoxify and greatly improve skin itchiness and irritation, and to treat blemishes, black heads and acne. pH-balanced cosmetics can also improve the tone and texture of skin, improve skin healing and strengthen its resistance to pathogens. Alkaline PCPs work by increasing the permeability of the skin's pores, buffering the acids in the subcutaneous layer and aiding in detoxification.[10]

TRUST. IN NUTRITIONAL HEALTH.

HIGHER PAYLOAD—
Increased amount and delivery of Essential Fatty Acids compared to other chewable forms

UNPARALLELED PURITY—
IFOS* tested to ensure uncompromised purity

INCREASED COMPLIANCE—
Better taste — more easily chewed

BETTER BIOAVAILABILITY—
Patent-pending emulsion technology
Increases bioavailability by 40%

*IFOS - International Fish Oil Standards

New...Omega Soft™ supplements. All the benefits you look for and a taste your patients will love!

Douglas Laboratories now offers great-tasting omega-3 supplements high in DHA for kids or EPA for adults. Omega Soft™ chewables are easy to swallow, naturally-flavoured and sugar-free. They are manufactured in Norway using a patent-pending technology that eliminates the unpleasant odor and taste associated with fish oil, while improving bioavailability. Trust Douglas Laboratories to provide the benefits you, and your patients, want.

1.866.856.9954 douglaslabs.ca

DOUGLAS LABORATORIES®

You trust Douglas Laboratories. Your patients trust you.

Considering only a small number of chemicals are tested for safety, and the challenges around the regulation and labelling of cosmetics, personal care products possess a great deal of potential to cause harm to human health. The solution is complex. It is of utmost importance that consumers learn to understand labels in detail in order to choose products that are pH-balanced and that contain few or no harmful chemicals. Supporting the health of the skin by encouraging alkaline body baths, dry skin brushing, regular exercise, adequate water, addressing underlying conditions and healthy skin hygiene are also beneficial.

About the Authors

Dr. Iva Lloyd is a naturopathic doctor, registered polarity educator and reiki master. In 2002 she founded Naturopathic Foundations, an integrated clinic with naturopathic doctors and other alternative health care providers that blend the naturopathic and energetic aspects of health care.

Dr. Lloyd teaches part-time at the Canadian College of Naturopathic Medicine. She is the author of four books: *Building a Successful Naturopathic Practice, Messages from the Body, a guide to the Energetics of health, The Energetics of Health, a naturopathic assessment and History of Naturopathic Medicine, A Canadian perspective*. Dr. Lloyd writes for various journals and magazines and gives seminars on naturopathic assessment, the integration of the mind and body, and the building blocks to health. She is current editor of the *Vital Link* and is Past-Chair of the board of the Canadian Association of Naturopathic Doctors. Dr. Lloyd is also the founder of www.ndhealthfacts.org
i.lloyd@naturopathicfoundations.ca

Stephan Wilmes is a former professional athlete and the founder of the Ayurveda Wellness Center in Munich, Germany. He is an internationally renown speaker on re-alkalizing the body and his company, YouInFocus Products is the Canadian distributor of Dr. Jentschura's alkalizing program from Germany.
info@youinfocusproducts.com

References

1. http://www.fda.gov/Cosmetics/ProductandIngredientSafety/default.htm
2. Ferlow Klaus Hidden Dangers Lurking in Your Cosmetics and Personal Care Products. *Positive Health*, March 2010, Issue 168.
3. http://www.ewg.org
4. http://www.ewg.org/node/22628
5. Veenstra G, Webb C et al., Human health risk assessment of long chain alcohols. *Ecotoxicology and Environmental Safety* 2009 May, Vol72(4):1016-30.
6. Janjua NR, Frederiksen H, Skakkebaek NE, Wulf HC, Anderson AM Urinary excretion of phthalates and paraben after repeated whole-body topical application in humans. *International J of Andrology*. 2008 April, Vol.31(2):118-130.
7. Koniecki D, Wang R, Moody RP, Zhu J Phthalates in cosmetic and personal care products: Concentrations and possible dermal exposure. *Environmental Research*. 2011 April, Vol.111(3):329-336.
8. http://www.lesstoxicguide.ca/index.asp?fetch=personal#commo
9. Steiner M. The Return To The Principle of Alkaline Body Care, in *Die Naturheilkunde*.
10. Jentschura Peter, *Health By Purification*

Skin care and Cosmetics Information Resources

Heavy Metal Hazard: The Health Risks of Hidden Heavy Metals in Face Makeup (Environmental Defence)
www.environmentaldefence.ca/reports/heavy-metal-hazard-health-risks-hidden-heavy-metals-in-face-makeup

The Just Beautiful Heavy Metals in Cosmetics Factsheet (Environmental Defence)
www.environmentaldefence.ca/reports/just-beautiful-heavy-metals-in-cosmetics-factsheet

The Just Beautiful Personal Care Products Pocket Shopping Guide (Environmental Defence)
www.environmentaldefence.ca/reports/just-beautiful-personal-care-products-pocket-shopping-guide

The Skin Deep Cosmetics Database (Environmental Working Group)
www.ewg.org/skindeep

Cosmetics Product and Ingredient Safety (U.S. Food and Drug Administration)
http://www.fda.gov/Cosmetics/ProductandIngredientSafety/default.htm

WHO booklet *Persistent Organic Pollutants: Impact on Child Health*:
http://www.who.int/ceh/publications/persistent_organic_pollutant/en/index.html

Specialist Training in Botanical Medicine

Holistic Science Methodology
Taste as a Guide to Clinical Uses of Herbs

July 22 and 23 $285.00 plus tax

Introduces a full array of herbal biochemistry and clinical applications in an easy to grasp format taught through discernment of tastes in the fresh plants.
Taught by Keith and Maureen Robertson.

Herb Camp

July 24 – 28 $550 plus tax

A 5 day immersion for practitioners and senior students Morning clinical discussion and round table dialogue. Afternoon lectures. Herb Walks. A 'meeting of the minds'.
Price includes camping and full meal plan.
Taught by Chanchal Cabrera.

Your instructors

Chanchal Cabrera has held the Faculty Chair in Botanical Medicine at the Boucher Institute of Naturopathic Medicine since 2004, and has over 20 years of clinical experience with a specialty in managing cancer and chronic disease. She is a certified Master Gardener and a certified Horticulture Therapist.

Keith and Maureen Robertson founded the Scottish School of Herbal Medicine, the first school in Europe to offer a Master of Science in Herbal Medicine, in 1992 and have over 40 years clinical experience between them. They have made the experiential meeting with plants a lifetime study and they delight in sharing their practical approach through herb tasting & con templative connecting with medicinal plants.

For information and registration go to
www.chanchalcabrera.com
250 336 8767

The Science of Being Well

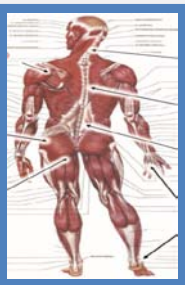
PHYSIOLOGICAL REGULATING MEDICINE (PRM) integrates the most up to date research in biochemistry & physiology, with evidence based metabolic factor influencers and nutritional components.
GUNA's PRM remedies provide low dose concentration similar to the levels in the biological milieu of metabolic factors (amino acids, hormones, neurotransmitters, cytokines, growth factor, etc.*), complimented with specific natural substance, sarcodes (healthy organ & body substances) and nutritional ingredients. Through **PRM,** the remedies provide a biofeedback mechanism capable of restoring the body's homeostatic balance, cellular regeneration, **metabolic function thus a natural physiological regulation.**
GUNA's scientific research department is one of the most active and prolific in the industry, providing a steady stream of industry **leading studies in all areas.**
We are dedicated to providing the highest level of **education,** with frequent seminars & web based education.

Vibrant Health* has a full range of products for Hormonal, Neurological and Allergic challenges.
(* Remedies include those metabolic factors recognized by the NHPD.)

Key Areas of Anti Age Focus

Aesthetics
From the inside out

Immunology
Balancing the TH's



Pain & Sports
Inflammatory or injury

Drainage & Detox
The foundation

Vibrant Health & Guna formulas integrate components which stimulate metabolic factors

Science has demonstrated that these **Metabolic Factors** are messenger molecules providing the signalling the cell requires to initiate or re-animate its processes.

Available in condition and cascade specific complexes.

Call us to learn more.

Vibrant Health Int'l Tech inc. (Exclusive Guna Distributor)
Canada: 1-877-486-2226 Info@GunaCanada.com , www.GunaCanada.com

A NOVEL SOLUTION for the prophylaxis of urinary tract infections (UTIs)

The **perfect combination** for keeping UTI producing E. coli bacteria away

Highly concentrated Cranberry Extract (35:1) equivalent to 20 g fresh fruit/day combined with 1.6 g of natural D-Mannose at recommended daily dosage

Ultra **convenient vegetarian capsules** allow for ease of use with even your most your most active patients

Cran-Mannose UTI™

A high potency combination for the treatment of acute recurrent urinary tract infections due to E. coli and the prophylaxis of recurrent infections.

CYTO•MATRIX®

Improving health and wellness…naturally

1 866 783-7504
www.cyto-matrix.com