

Benefits and Risks of Dietary Supplements Licensed by Health Canada

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This essay will address some key questions about dietary supplements, also known as natural health products (NHPs). Facts about NHP benefits and risks, from Canada and USA publications, will be examined. A performance audit of Health Canada's oversight of the NHP Regulations will be presented. My perspective is based on education, personal experiences, medical research and mentors in the field of nutrition. References are linked to original sources to facilitate further study by interested readers.

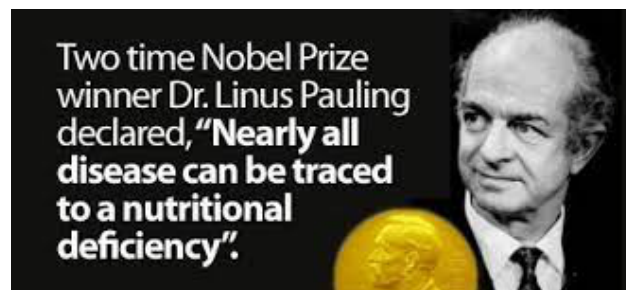
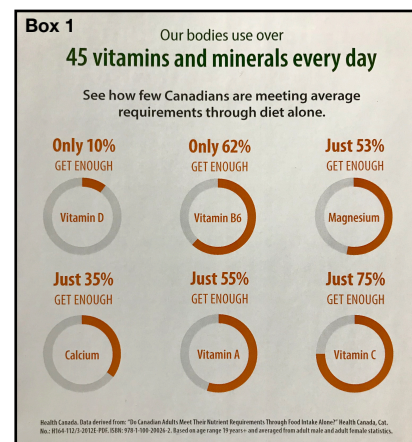
*"What I observe over and over in my private practice, is that **few individuals, including the obese, athletes, and children, are actually properly nourished.**"¹*

Dr Sheila Dean, Integrative Medicine Nutritionist

The intended use of NHPs is to supplement, not to substitute, for a well-balanced diet and a healthy lifestyle. I have been taking certified NHPs for more than 45 years. NHPs are not intended to be 'quick fixes'. The FDA has authorized a health claim for the reduced risk of coronary heart disease for omega-3 fatty acids and plant sterols, however, these outcomes typically take more than 28 days to achieve.²

When used properly, NHPs help promote overall good health and prevent disease by correction of nutrient deficiencies.³ Large-scale deficiencies of omega-3 fats, iron, folate, zinc, magnesium, and vitamin D have been well documented.⁴ In Spain, vitamin D deficiency was found in 82.2% of hospitalized COVID-19 cases as compared to 47.2% of population-based controls.⁵ A Health Canada publication detailed that only 10% of Canadians get enough Vitamin D. (Box 1)

In 2002, the American Medical Association reversed their long-standing anti-vitamin policy, that declared supplements were a waste of money in healthy people, after a comprehensive scientific review that confirmed an inadequate intake of several vitamins is associated with chronic disease. The authors' conclusion, *"we recommend that all adults take a multivitamin daily."*⁶



DNA damage is believed to be a sensitive early marker of risk of chronic health conditions. One recent randomized, double-blinded, placebo-controlled trial reported that 8 weeks of plant-based supplement use, when compared to placebo, significantly improved reactive oxygen species scavenging activity and prevented DNA damage.⁷

However, poorly designed studies, often involving NHPs of inferior quality, fuel the dietary supplement controversy by generating editorials such as, *“the case is closed, supplementing the diet of well-nourished adults with (most) mineral or vitamin supplements has no clear benefit and might even be harmful. These vitamins should not be used for chronic disease prevention. Enough is enough.”*⁸ This opinion was sharply challenged: *“Anybody who has spent even a brief amount of time evaluating medical research, especially as it pertains to the use of vitamins and minerals, knows that such a conclusion (“the case is closed”) is as arrogant as it is absurd.”*⁹

Safety

There is a perception that because NHPs are often labelled as being ‘natural’ that they are safe. The reality is most supplements are not tested for either efficacy or safety.¹⁰



Canadian consumers have experienced serious and unexpected adverse reactions to NHPs, including septic shock, disruption of liver function and other symptoms that required hospitalization.¹¹ In May 2015, the American Association for the Study of Liver Disease and the National Institutes of Health, held a 2-day symposium to review the increase in liver injuries observed from dietary supplements.¹² Analysis by the Drug-Induced Liver

Injury Network showed that NHPs now account for 20% of all liver toxicity cases, up from 7% just 10 years ago.¹³

Every year, in the USA, supplement use was linked to 23,000 trips to the Emergency Department resulting in 2,000 hospital admissions.¹⁴ In addition to hospital admissions, calls to poison control centres provide evidence of the harms resulting from consumption of adulterated or poor quality supplements. From 2000 to 2012 in the USA, poison control centres received nearly 275,000 calls, one every 24 minutes, related to dietary supplements.¹⁵ There is no reason to believe that population statistics for Emergency Department visits, hospital admissions and calls to poison control centres linked to NHPs would be different in Canada than those in the USA.

Adulterated supplements are a very common problem; and suspected to be the root cause of the many adverse reactions. Between 2007 and 2016, the FDA identified 746 dietary supplement brands that were adulterated with harmful prescription drugs.¹⁶ In 2015, federal prosecutors brought criminal and civil charges against more than 100 U.S. manufacturers of bogus dietary supplements that put consumers health at risk.¹⁷

The magnitude of the safety problems are illustrated in a case where the Department of Justice court-ordered a New York-based company to stop distributing adulterated and misbranded dietary supplements and to destroy, within 15 days, any inventories that are in their possession, custody, or control. The company had to undertake a massive, nationwide recall of all lots of dietary supplement products manufactured and sold between January 2013 and November 2019, almost 7 years. This recall was historic

because of the extended time period and fact that this manufacturer made products for 850 supplement brands.¹⁸

Efficacy

All NHPs are NOT created equal. Many claim to be from 'natural' sources, however real nutrients come from food or plants, not from a lab. One industry insider said, "... *about 70% of supplements are junk, costing less than 10 cents per serving. What do you get for that price? You get chemicals and fillers. You do not get real nutrients.*"

The Truth Behind Centrum: Supplement Or Chemical Cocktail? is a very informative article written by Canadian nutritionist Meghan Telpner.¹⁹ She provides revealing facts about Centrum®, claimed to be "Canada's #1 Selling Multivitamin brand."²⁰ This product is made by Pfizer, whose army of sales reps deliver samples to physician offices. She states, "*I would never go so far as to suggest that they make shoddy supplements to keep consumers needing their medications, but they are making shoddy supplements.*" This is a summary of some of her findings:

- The dosages of most 'nutrients' are negligible and not close to therapeutic levels.
- The 'nutrients' are present in the cheapest and the least absorbable forms.
- Supplements that come in tablet form contain many non-medicinal fillers, binding agents and texturizers; which are often hard to digest.
- There are more "non active" ingredients than actual vitamins and minerals.

She concludes that, "*Centrum, along with Kirkland, Walgreens and other store brands collectively set the bar very low.*"²⁰

In 2015, the New York Attorney General issued cease-and-desist letters to stop selling adulterated products to four national retailers, Walmart, Target, Walgreens, and GNC, the largest vitamin chain. Only 21% of their popular store brand herbal supplements had verified DNA from plants listed on the labels.¹⁰ No active ingredients were found in 4 out of 5 of their herbal supplements; instead tested products contained cheap fillers like rice and ground-up house plants.²¹

In 2020, ConsumerLab published another review of 27 multivitamin/multimineral supplement brands and 12 (44.4%) of them failed analytical tests. Some had lower levels of nutrients than the label claimed, some had higher amounts, some were contaminated with toxins (PCBs, lead, mercury), and some took longer than permitted to disintegrate ("break apart") in solution.²²

There is a story about a woman who went to the hospital complaining of abdominal pain. Doctors believed it to be gallstones, but x-rays showed 50 undissolved vitamin pills in her abdomen.²³ Also, city staff in Tacoma, Washington removes more than 250,000 pounds of undigested multi-mineral and vitamin pills from the city sewage filters every 6 weeks; many with the brand names still readable.²⁴ Salt Lake City removes 150 gallons of undigested vitamin and mineral tablets from their municipal water treatment plants every month.²⁴

Health Canada

Beginning January 1, 2004, all NHPs sold in Canada became subject to the *Natural Health Products Regulations*. Health Canada is responsible for licensing each NHP under the regulations to ensure they are safe and effective.¹¹ NHPs that have been authorized for sale in Canada are identified by an eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the label.

More than 91,000 licences have been issued for NHPs since the regulations came into force. Under them, Health Canada only requests that site-licence applicants attest, by means of written declaration, that they are compliant with good manufacturing practices (GMPs). And.... Health Canada considers NHPs to be safe if the benefit outweighs the risk when used according to directions. Though Health Canada is responsible for overseeing products and sites after the NHPs appear on the market; the primary responsibility for the safety and efficacy of products and manufacturing sites rests with the industry!¹¹

Health Canada's oversight of NHPs was the subject to a performance audit conducted in 2020 by the Office of the Auditor General of Canada.¹¹ The report was tabled in the House of Commons in April 2021. Two of the critical observations:

- ◆ Health Canada did not verify that facilities followed GMPs before products arrived on the market.
 - Health Canada relied on NHP manufacturers' attestations that their facilities followed GMPs and had not conducted an inspection before products went on the market.
 - Fewer than 5% of licence holders informed Health Canada which licensed facilities manufactured their NHPs before selling them, making it extremely difficult to adequately monitor the safety of production practices.
 - In 22 of a sample of 25 site-licence renewals approved by Health Canada, they did not verify that all sites followed GMPs; making it impossible to determine if those products were safe and effective.
 - Some of the notable deviations reported involving quality assurance activities:
 - There was no quality assurance person responsible for guarantee the quality of the product before it is released for sale.
 - Individual or team responsible for quality assurance were not qualified by training, experience and technical knowledge.
 - Quality assurance is not a distinct or independent unit; with evidence that quality assurance decisions are overruled by production department or management.
 - There was no testing of finished NHPs.
 - Test results that suggested a negative impact on product quality were not documented, reported or investigated.
 - Misrepresented or fabricated analytical samples, tests results or raw data.
 - Deleted tests results or raw data used to support release.

- ◆ Health Canada left NHPs unchecked after they entered the market and were not always successful in responding to serious problems.
 - Between 2017 and 2019, Health Canada inspected only around 6% of the 766 active licensed manufacturers.
 - In a sample of 75 licensed products, auditors found 88% were advertised with misleading product information. Health Canada did not sufficiently oversee if product label information and advertisements met the licence conditions.

The Auditor General's report should trouble Canadian consumers. The shocking details call into question whether the 91,000 products on the Canadian market were adequately assessed for safety, quality and health claims. It would be impossible to determine if any NHP was safe and effective by sole reliance on written attestations about GMPs.

Health Canada licensing does not necessarily guarantee better quality because independent testing undertaken by ConsumerLab has shown similar problems with the quality of Canadian supplements, like those with USA supplements.²⁵

Certification and Testing

What does proper certification and testing look like? NSF is an independent certification organization, receiving accreditation by the American National Standards Institute (ANSI) in 1991. This company launched a testing and certification program for NHPs in 2001. This global enterprise has service teams, composed of microbiologists, toxicologists, chemists, engineers, environmental and public health professionals, who test, audit and certify products. These teams utilize analytical techniques, including gas and high-performance liquid chromatography, mass spectrometry and DNA authentication of botanical ingredients, to confirm that ingredients are present in levels indicated on the label with the ability to detect any other potentially harmful contaminants. The NSF mark assures consumers, retailers and regulators that certified products has ingredients as listed on the label and that each product is free from toxins or other potentially harmful substances.²⁶



My take....

More than 70% of Canadians regularly use dietary supplements to maintain their health and to decrease their risk of acquiring a chronic disease.¹⁵ Sales of vitamins, minerals and other health supplements amounted to approximately Canadian \$1.17 billion in the fourth quarter of 2021 alone.²⁷ Yet the health of the great majority of the general population is absolutely dreadful. This was confirmed by a 2019 publication reporting that 44% of Canadian adults over 20 have been diagnosed with 1 of 10 common chronic diseases.²⁸ Might this be a signal that the majority of the NHPs on the Canadian market, like those in the USA, may not contain real nutrients or that the quality of the majority of NHPs is so poor they end up in sewers and septic tanks? ²⁴

One of Health Canada's responses to the audit was to propose user fees for NHPs to "offset the costs of licensing and post-market activities."¹⁵ This proposal should be abandoned. In my mind, it would be impossible to fulfill mandates ensuring NHPs are

safe and effective with the current attestation and paper based regulatory processes that requires Health Canada to rely on the veracity of manufacturers and distributors.²⁵

It would take a radical overhaul of the regulations for Health Canada to guarantee Canadians are not harmed by dietary supplements. My recommendation would be for Health Canada ask NHP manufacturers to submit certification and testing results obtained from an independent certification organization. Though this will undoubtedly drive up the price of NHPs, Health Canada reported that consumers were willing to pay more, as long as the products were of high quality, the government had approved a product licence, and there was improved labelling.²⁹

This bold strategy of requiring testing and certification by independent, third party organizations would help Health Canada ensure safety without incurring additional costs. In fact, it may save taxpayer money if Health Canada were to streamline the approval process by automatically licensing NHPs from previously certified manufacturers who submit have proof of independent testing. Poor quality NHPs that do not contain a 'mark' (e.g. NSF, Isura, Informed Sport), indicating proof of independent testing, would eventually disappear from the marketplace. Concerns or complaints about loss of access to favourite brand(s) may be alleviated by sponsoring information programs that educate consumers about the harms due to 'shoddy' dietary supplements that lack testing for safety and effectiveness.



In Summary

Many people are eating and living in a “standard” Western way are functionally insufficient in many vital nutrients due to genetics, stress, nutrient-depleting foods and drugs, poor digestion, and much more.³⁰ The number of studies showing beneficial supplemental and therapeutic uses of nutrients is too numerous to count.³⁰ Most NHPs are not tested for either efficacy or safety, are frequently contaminated or adulterated; and many consumers don't recognize or appreciate the risks that accompany their use.¹⁰



NATURAL HEALTH PRODUCTS

“Overall, Health Canada’s oversight of natural health products available for sale in Canada fell short of ensuring that products were safe and effective.”

Report 2 | Reports of the Commissioner of the Environment and Sustainable Development

The Auditor General’s report about Health Canada’s oversight of NHPs is not comforting to Canadian consumers who may have questions about the safety of the 91,000 products on the Canadian market. This may be due in large part to a process where Health Canada relied on NHP manufacturers’ attestations, by means of written declaration, that their facilities followed these GMPs and had not conducted an

inspection before the products went on the market.¹¹ “This is really not much different from the situation in the USA where consumers rely on supplement manufacturers to live up to the law, which requires that products be made according to GMPs and that products contain, at the time they are used, 100% of what they claim.”²⁵

When committing to a long term supplementation program, consumers are encouraged to apply the principle of “*first, do no harm*” by undertaking more investigation prior to buying NHPs to help decrease the risk of harm.

My best advice would be to limit NHP choices to brands that have evidence for efficacy (e.g. preventing DNA damage) from published trials and have proof (e.g. NSF Mark) of certification for safety by an independent organization.



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