



By Shawn Buckley | Dec 2015

THE FIFTH ESTATE EPISODE “MAGIC PILLS” HAS BEEN GENERATING SOME CONCERN AND I HAVE BEEN ASKED TO SHARE MY THOUGHTS ON THE PROGRAM

For those who did not see the program, it was largely based on a dated 2013 publication called *DNA barcoding detects contamination and substitution in North American herbal products*, published in the open access journal BMC Medicine (see BMC Medicine 2013, 11:222).

The first question that came to mind when watching the episode was: why is a 2013 study news now? After I read the study my main question became why would the Fifth Estate rely so heavily upon this publication? The publication was interesting for the questions it raised for me. The authors took a very small sample of 44 single ingredient products from 12 companies. They tested these products

using PCR amplification which is a technique used to “amplify” DNA in a sample. This was done to try to identify the plant species in the product. The authors reported 59% of the products (which the Fifth Estate reported as 60%) contained plant DNA of a species different than the plant on the label. They also reported that a third of the products contained contaminants and fillers not on the label. The message from the study and the Fifth Estate’s dramatization of the study findings to me was:

- 60% of natural health products are adulterated with ingredients not on the label, and

- 1/3 of natural health products have contaminants and fillers not on the label.

This message is truly shocking. It was meant to be shocking. However, what truly shocked me was how misleading this message seemed to be.

For starters you need to be aware of how sensitive PRC amplification is. It is designed to find trace-amounts of DNA and amplify them so that they can be identified. So that you have an appreciation of how sensitive this is, I will share an example from a law file. The police wanted to get a DNA profile of a person of interest. They followed this person who went into a restaurant for a meal. When the person left the police seized a glass the person had drank from. The glass went to the lab which used PCR amplification with the intention of getting this person’s DNA profile. As it turned out this exercise was not helpful for the police as the PCR amplification identified three separate human DNA profiles on the glass. For greater clarity, on a clean glass used by one person in a restaurant three human DNA profiles were found.

Turning to plants, if I grew a field of parsley beside a field of alfalfa, do you think it is possible to do PCR amplification on the parsley and not find alfalfa DNA? Perhaps, but I venture to guess it is not likely. Similarly, despite very appropriate and well done cleaning of processing equipment between the manufacture of different plant based natural health products, do we really expect we would not find through PCR amplification traces of DNA from previous products? Judging by my restaurant glass example, I would venture to guess it would not be unlikely to find other DNA.

Yet according to the study and to the Fifth Estate:

- finding DNA from a plant species not listed on the label is “contamination” or adulteration, and

- Finding DNA from common natural health product ingredients not listed on the label means there are unlisted fillers (the implication being you are being defrauded).

Nobody at the Fifth Estate seems to have asked themselves if we should expect genetic purity of food ingredients. Natural health products usually include plant and/or animal ingredients used for health purposes. The same parsley you can buy for cooking in your grocery store can be used as a natural health product ingredient. The only difference is that when it is put in a natural health product it is tested for things like microbial contamination. We wouldn't consider our food parsley to be adulterated or contaminated if PCR amplification could identify trace amounts of other plant DNA such as alfalfa. When we consider that much of the protein in common flour comes from the insect particles in it, I wonder how many distinct DNA profiles could be found in flour (plant, insect and animal). We don't consider flour to be adulterated.

I could go on with issues I see with the study such as whether their DNA profile bank has learned enough to recognize differences between strains of plants within a species, but I think my point is made. This DNA barcoding technique is a novel approach for ingredient identification of plants. It may develop into a useful tool for NHP manufacturers to even better identify their ingredients. However, the way the study was written, and the way the Fifth Estate presented the study, were in my opinion misleading and likely deliberately calculated to generate fear.

The same could be said about the rest of the Fifth Estate show starting with the title "Magic Pills" which connotes fraud. Other highlights I thought were meant to create fear and concern about taking natural health products included:

- an old story about a New York contract manufacturer that apparently manufactured vitamins with anabolic steroids;

- concerns we can take "too much" of a supplement;

- citing an editorial (yes, a personal opinion piece) to give us the message that the case is closed: supplements may be harmful;

- saying too much vitamin D is harmful;

- saying 83% of fish oils in New Zealand were found to have high oxidation levels;

- that people are being encouraged to take supplement amounts above Health Canada's Recommended Daily Allowances ("RDAs");

- that 40% of complaints to Health Canada's inspectorate are about natural health products.

This is not an exhaustive list but you get the message. I want to discuss three of these topics which I believe to be exceptionally funny or misleading by omission.

The funny example was one of the themes the Fifth Estate used to suggest we may be taking too high of doses of nutrients in supplements. They compared the amounts of nutrients in foods to the amounts in supplements. One example was you can take a supplement with 1000 mg of vitamin C but to get this amount of vitamin C from cantaloupes you would have to eat 8 of them. You cannot eat 8 cantaloupes at once – the message being that 1000 mg of vitamin C must be too much. I am smiling as I write this as it is truly humorous that this cantaloupe example can in any way inform us as to how much vitamin C is too much. I thank the Fifth Estate for their humour.

The second example I wanted to discuss was the Fifth Estate's use of Health Canada's recommended daily allowances for vitamins and minerals as a guide for what is too much. The implication I was left with was that exceeding the amount of these RDAs may be dangerous. Now I

accept that taking too much of anything can be dangerous, but I am skeptical that exceeding a Health Canada RDA for a vitamin or mineral in any way informs us as to how much is too much. My understanding is that RDAs are not even meant to tell us what an optimal amount of a vitamin or mineral is for good health. I am open for correction on this, but I thought RDAs were developed in the Second World War for D-day. The concern was that after the invasion it would be difficult to re-supply the invading soldiers and they had to determine the minimum amount of vitamins and minerals necessary to enable a soldier to continue to function for roughly two weeks. These guidelines later morphed into our RDAs. The RDA amounts are extremely conservative and are meant to be extremely conservative.

The last fear meme I wanted to address was the report that 40% of complaints to Health Canada's inspectorate are about natural health products (without any indication of the number of complaints this represents which is necessary for it to be meaningful). Part of my law practice involves assisting people and companies who make natural health products deal with Health Canada when there is a complaint. In my experience most complaints to Health Canada about natural health products are from professional complainers. Years ago I was defending three different companies in three different Provinces with charges that began with complaints to Health Canada. If my recollection is correct all three Health Canada investigations were begun by complaints from the same person whom I am told (but have not verified) has ties to a pharmaceutical company.

Health Canada tries to never disclose the identity of the complainer to the person or company being complained about, despite a Court decision saying they should. Despite this, in another file I had it became apparent that the complainer was

from a skeptics group that was clearly antagonistic to natural health products. Although I have been dealing with complaints to Health Canada for almost two decades, as I write this I am not certain I have ever had to deal with a complaint from more than one actual consumer, although I might have but don't know because of Health Canada's policy of not disclosing the identity of the complainer (or I cannot recall more than one). My point being, however, that to say 40% of complaints to Health Canada are about natural health products does not inform us as to whether there are many at all, or as to whether these are complaints about product quality or adverse events. I should also add that some complaints I have dealt with are complaints by one natural health product company against another natural health product company. Some of these complaints I have interpreted as an attempt to use Health Canada to shut down or cripple a competitor for economic gain.

Finally, the majority of complaints I have recently dealt with concerns claims made by natural health product companies. When NHP's become licensed, the license contains a "label claim" that the company can use and is expected to put on their label. Apart from some specific prohibitions, I can say that overall there is no prohibition from making other claims, providing they are not fraudulent. However, despite there being no clear legislative authority, Health Canada takes the position that only the authorized label claim is allowed. This leads Health Canada to try to censor other claims, even if they are truthful. This puts natural health product companies in an awkward situation. They may have evidence a product can truly help people but cannot share it without risking Health Canada's wrath. And it is not an answer to say they could apply for the claim as overwhelmingly Health Canada restricts label claims to what they call structure function claims in the U.S. (although

the *Natural Health Product Regulations* do not have this restriction). Where I am going with this is to point out that advertising complaints are not necessarily a safety issue, and often the complainer risks creating a safety issue by taking truthful information away from consumers.

The Fifth Estate episode repeatedly brought to my mind that a core message was also that natural health products are poorly regulated and that we need stronger regulation. There was no discussion about the risks stronger regulations would bring, let alone the risks our current regulations have caused by removing some NHPs. I am passionate about protecting our access to NHPs because I have run across person after person whose very lives have depended on them, when the chemical drug model failed them. I have called some of these as witnesses in Court. The number whose quality of life is dramatically enhanced by NHPs is even larger. We cannot have a rational and helpful discussion of how to best regulate NHPs without also looking at the benefits and considering the risks of removing or restricting them.

In my opinion the Fifth Estate did not bring this balance to their program. When I was receiving the message: "we need more regulation", I thought maybe we do: of mainstream media programs which may be influencing people's health decisions.

The Fifth Estate is a widely watched television show with credibility. In delivering this program, they are likely influencing peoples' health by affecting their attitude towards natural health products. If I did not have my extensive background to draw on, this episode would have strongly discouraged me from taking natural health products.

I strongly hope that in the future they will be as balanced as they can on these issues. Everyone wants the best regulatory environment possible, but in the issue of

health nothing is simple or clear cut. Creating a demand for stricter regulation without balance can ironically lead to poor health outcomes.



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VIEW THE CBC "MAGIC PILLS" EPISODE (NOV 2015) AT:

www.cbc.ca/fifth/episodes/2015-2016/vitamins-and-supplements-magic-pills

CBC News | Jan 2016

CBC RETRACTS SUPPLEMENT REPORT

Some *Marketplace* reports about vitamins and supplements published in November contained incorrect information, CBC has learned.

Last fall, *Marketplace* commissioned lab testing for samples of fish oil, vitamin C and protein powder supplements to see if consumers are actually getting what they

pay for. Based on those test results, *Marketplace* reported that Emergen-C and two protein powders: GNC Lean Shake 25 and Cytosport Muscle Milk failed to live up to label claims.

However, subsequent re-testing of the samples has found that the lab results and analysis provided to *Marketplace* were incorrect, and that there is no evidence of problems with those products. The original lab tests were performed by an independent lab in Michigan, which is ISO-17025 accredited, registered with the U.S. Food and Drug Administration, and used by the supplement industry.

The lab was recommended by Neil Thanedar, co-founder and CEO of LabDoor, a company that has products tested and makes those results public to help guide consumers about vitamins and supplements. LabDoor's investors and partners include Rock Health, a San Francisco-based venture fund that invests in health-care research, and the Mayo Clinic. Thanedar agreed to analyze the test results for *Marketplace*. The supplement companies strongly disputed those results. When *Marketplace* learned there might be a problem with one of the tests, CBC re-tested some of the products at other independent, accredited labs. None of them found problems with the samples.

Emergen-C, protein powders cleared

In his original analysis, Thanedar concluded that the popular vitamin C supplement Emergen-C, made by Pfizer, contained only one third of the 1,000 mg

of the vitamin that the package promised. However, the re-testing concluded that there is no issue with the amount of vitamin C in that sample of Emergen-C.

Marketplace also tested popular brands of protein powder for evidence of "spiking," in which manufacturers use filler because it is cheaper. Two brands in the initial testing and analysis — Cytosport's Muscle Milk and GNC's Lean Shake 25 — appeared to have evidence of spiking. The GNC product appeared to be more than half spiked. Subsequent re-testing of both brands of protein powder found no evidence of spiking. Re-testing of fish oil confirmed the initial result that some fish oil was rancid.

Re-testing shows no problems

Thanedar admits some of the lab results were wrong.

"We're apologizing to your audience. And we're promising to improve ourselves," Neil Thanedar told *Marketplace*'s Erica Johnson. (CBC) "We've done this test (of protein powder) more than a hundred times. And we haven't seen an issue like this. And it's incredibly frustrating for us because this is all the work we do," he says. "We're constantly testing products, this is our day-to-day job. And there's no one we can put that blame on other than us." While Thanedar admits some of the lab results he provided to *Marketplace* were flawed, he was still unable to explain how the mistakes were made.

Stuart Phillips, a scientist at McMaster University who studies the effects of protein supplements on humans, says:

"There are all kinds of reasons why things can go wrong. "Like anything else in life, I think when a lab gets something wrong, human error, contaminated dirty glassware, machine malfunction."

Phillips hopes this error doesn't undermine public trust in lab testing, "because it undermines everybody else, industry and scientists, researchers alike, who do this sort of thing on a day-to-day basis."

Marketplace evaluating testing protocols

In response to the discovery, *Marketplace* is evaluating its protocols around the use of lab testing. In a report to be broadcast on *Marketplace* on Friday at 8 p.m., (8:30 p.m. NT), host Erica Johnson says, "We regret giving you incorrect information and any harm it may have caused the companies in our report. We're sharing this story with you because your trust is important to us. We work hard to make sure we deliver the kind of journalism you've come to expect."
