Project Name:	Lifechoice (LOSS)	**Start Date:**	2017-01-26
Project Number:	1704	**Completion Date:**	2018-07-26

Project Details:

Scientific or Technological Objectives:

Measurement	Current Performance	Objective	Has results?
Arterial plaque reduction (%)	100	95	Yes
Replace intravenous with oral (Yes 1/ No 0)	0	1	Yes

[34] Project 3 is a natural health product to remove arterial plaque. Dr. Dahl hypothesized he could create an oral chelatory form that would deal with chelation (binding) to take the arterial plaque from the blood vessels, to vasodilate the blood vessels to increase circulation to the extremities, and to take the plaque off the organic material from the brain stem. EDTA was being used in intravenous form for this purpose. Dr. Dahl believed that, if EDTA were instead used in oral form with complementary ingredients to accomplish the same thing, it could be available over the counter for home use and would lessen damage to other organs such as the liver and pancreas.

[36] Dr. Dahl wished to use EDTA in a manner that was complementary with other ingredients. He understood Health Canada would not allow EDTA as a medicinal ingredient. Health Canada would, at some later time, permit it to be added as a supportive non-medicinal ingredient. Dr. Dahl studied the research and methodology of a German doctor and read studies from that doctor's institute. Dr. Dahl analyzed his research on the German studies. He described his "real activities" as isolating the two components he was going to use and then formulating a final product within his mind and on paper, while also incorporating other selected ingredients that would not compete with the two ingredients needed for the chelation process itself.

Field of Science/Technology:

Nutrition & dietetics (3.03.02)

Project Details:

Intended Results:	Develop new materials, devices, or products
Work locations:	Commercial Facility
Key Employees:	Eldon Dahl (Naturopathy - PhD (2000) / President Lifesource)
Evidence types:	Records of resources allocated to the project, time sheets

Scientific or Technological Advancement:

Uncertainty #1: Technological uncertainty

[35] Dr. Dahl had studied the matter for several years; he did systematic reviews on what makes up the blockage in arteries. The blockage was known to be caused by inorganic material, including heavy metals forming within the blood vessels and the brain. It was his belief that EDTA being administered by medical doctors intravenously was not complete and could further impact other areas of the body.

[37] Dr. Dahl said he knew certain chelating ingredients but he realized through further study that some were antagonistic to each other. Therefore he said he decided through hypothesis which would be the most effective. He said he originally wanted to choose between EDTA and DMSA, but Health Canada would not allow the use of DMSA as a medicinal ingredient in over-the-counter products. So he then set out to create a formulation with the EDTA that would not be toxic to the body.

[41] Dr. Dahl said he had undertaken lots of literature review before beginning his third project. He had studied the subject immensely. He referred again to his fascination with another doctor's work, findings, results and discoveries. He consulted several articles and had one translated from German.

[46] I am prepared to accept that there was scientific uncertainty in each of the three Projects. There was uncertainty that natural health products could be effective in mimicking the existing pharmaceuticals in use. There was uncertainty as to whether other supplemental complementary natural ingredients could minimize adverse effects of the principal new mimicking natural ingredients in an effective manner. Once the Projects were reformulated to use the existing

pharmaceutical instead of a mimicking ingredient, as in Projects 2 and 3 described above, there remained the uncertainty of identifying supplemental complementary natural ingredients that would be effective in lessening or removing adverse side effects of the existing chemical ingredients.

The most significant underlying key variables are:

antagonistic effects of ingredients (unresolved), EDTA vs DMSA (unresolved), effects of chelation process (unresolved)

Technology or Knowledge Base Level:

Benchmarking methods & sources for citings:

Benchmark Method/Source	Measurement	Explanatory notes
Internet searches	36 Articles	Dozens of articles references
Suppliers	8 products	Performed analysis, studies; incorporating the use of outside sources like Dicentra, the -- my raw material supplier who has his master's degree as a pharmacist.
Queries to experts	5 responses	cited consulting with several naturopathic doctors

Activity #1-1: Activity 1 (Fiscal Year 2017)

Methods of experimentation:

Method	Experimentation Performed
Analysis / simulation:	100 alternatives

[40] Dr. Dahl stated that "[my original formulation, once effective, would achieve the desired results," However, once acetyl-L-carnitine was taken off the restricted schedule by Health Canada and could be used in over-the-counter formulations, as described above, Dr. Dahl reformulated Project 3 as well to incorporate that ingredient in lieu of EDTA which was not allowed to be used as a medicinal ingredient. Acetyl-L-carnitine is also a vasodilator. So he analyzed existing documentation he had and checked for compatibility. He described acetyl-L-carnitine coming off Health Canada's restricted schedule as a godsend since he knew clinical studies, especially those by another particular doctor, and he had used it on patients for 20-plus years. He knew it would accelerate the effectiveness.

[42] At the end of his examination-in-chief, counsel for the Appellant asked Dr. Dahl to evaluate his time spent on all three Projects. He answered as follows:
Well, it's -- my review is commensurate with my work that I perform due to analysis, studies; incorporating the use of outside sources like Dicentra, the -- my raw material supplier who has his master's degree as a pharmacist; consulting with several naturopathic doctors; and my staff who help me do the research and do some of the leg work.

[43] At the end of his testimony, I asked Dr. Dahl to please clarify what he meant when he used the phrase systemic review or systematic review. Specifically, I asked what it was he systematically reviewed and how he performed that systematic review. He answered that he did a systematic review of the analysis he had extracted of the clinical studies of others by completing a literature review and correspondence and dialogue with other authorities such as naturopaths, professors and pharmacists. He added that he did additional analysis by evaluating the calculation of the ingredients in his formulations by drawing on his accumulated knowledge and expertise and then submitting his formulations to Health Canada for licensing. He said he did not have clinical trials done because of the expense; he had earlier testified that clinical trials were not needed for natural health product licensing by Health Canada. He said his testing of his hypotheses was based upon evidence he received from other authorities like the World Health Organization.

He said his formulations were "tested through hypothesis and in evaluation based on evidence". It was clear from his earlier testimony this was pre-existing evidence of others and his own accumulated knowledge and clinical observations. He described his final testing, short of clinical trials, was to submit his formulations to Health Canada for approval which, once obtained, deems the formulations to be effective.

[44] Dr. Dahl was even more clear and succinct when then asked by counsel for the Appellant what scientific analysis or work was done. Dr. Dahl said he first evaluated the condition that was to be treated. Secondly, he reviewed the human body concerning the diseased state and produced a formulation to address that condition. His analysis was done using clinical evidence from a review of authoritative scientific studies. He used this combined research to formulate a unique product that would address these authorities analyzed as part of his literature review.

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[45] Dr. Dahl's answers were consistent with paragraph 29 of Life Choice's notice of appeal: "The Plaintiff asserts that the formulas were developed in a scientific manner, requiring analysis of available information collected from existing literature, suppliers, regulatory bodies and analysis of ingredients."

Results:

- Arterial plaque reduction: 98 % (40% of goal)
- Replace intravenous with oral: 0 Yes 1/ No 0 (no improvement)

[50] It is the absolute absence of testing of the natural health products by Life Choice after their formulations were hypothesized by Dr. Dahl that is fatal to this appeal. It is a clear conclusion from the evidence that, not only was no such testing done, neither Life Choice or Dr. Dahl ever intended to do any as part of these Projects. The jurisprudence has clearly, consistently and correctly interpreted the definition of SR&ED as requiring some form of testing of the hypotheses developed in order for there to be systematic investigation or search carried out by means of experiment or analysis. Question 2 of Northwest Hydraulic, above, in point 5 of its five-step process requires consideration of whether there was methodical and systematic testing of the hypotheses. Question 3 of Northwest Hydraulic requires consideration of testing as an included step in the scientific method. Question 5 requires consideration of whether records of the testing of the hypotheses and those results were maintained as the work progressed.

Conclusion:

[52] It is not the absence of clinical testing that is fatal to Life Choice's appeal. It is the absence of testing in any form or fashion that could be said to have been performed in a systematic fashion. Systematic testing for any or improved effectiveness of Life Choice's formulations could have been done by Life Choice and could have been performed to assess, verify, statistically infer, or gauge effectiveness without full-blown clinical trials sufficient to satisfy Health Canada if the products were restricted pharmaceutical products, which they were not. Any such testing could have been performed in a manner that met the requirements of the SR&ED definition even though it would not have satisfied a Health Canada requirement, or if, as in this case, there was no Health

[53] My decision in this case is in no way intended to suggest that literature reviews and consultations with other researchers cannot be qualifying activities giving rise to qualifying expenses as legitimate constituent parts of SR&ED activities. This appears to be clear from a fair, liberal and purposive reading of the SR&ED definition, including paragraph (d) thereof, and from former Chief Justice Bowman's comments on the role of intuition, creativity and sometimes genius in Northwest Hydraulic, above. Nor is this decision intended to suggest that a person performing SR&ED cannot use the data or results of the completed research of others in developing and/or testing their own hypotheses or theories.

[54] Having found that there was no testing by Life Choice of any of its formulations or reformulations after they were hypothesized by Dr. Dahl, much less testing performed in any systematic fashion, the appeal must be dismissed

Documentation:

- Uploaded to RDBASE.NET: 2017_TCC_21 Lifechoice Systematic Investiation LOSS.pdf (392KB)

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