SUTHERLANDIA "FAILS" SAFETY TEST

By Stuart Thomson, Director, Gaia Research Institute.

In January 02, I released a report titled: "Canavanine Toxicity: Is Sutherlandia a Healthy Herb or Potential Poison". What follows is an attempted rebuttal (denial) by Phyto Nova's Dr Carl Albrecht, and my detailed response, point by point to each comment made by Albrecht and to additional comments made by Phyto Nova on their two websites.

CA: *"Sutherlandia Passes Safety Test! Earlier this year Information condemning the indigenous medicinal plant Sutherlandia as a possible poisonous plant because it contained the amino acid L-canavanine (appeared). I believe this attack was based on unscientific reasoning."* (Full report: http://www.gaiaresearch.co.za/sutherlandia.html)

ST: Significantly, not just an amino acid, but a "non-protein" amino acid and a potentially highly toxic one at that! *"Unscientific reasoning""*, let's take a closer look. Phyto Nova's website in layman's terms makes incredible health claims for Sutherlandia, all totally unsubstantiated, even by the "published literature" references provided, which claims I showed via abstracts of subsequent research, rather than mere references, are not sustained scientifically.

Phyto Nova's van Wyk and Gericke have published two books based mainly on work poached from others. Regarding Sutherlandia, one states: *"a number of 'highly active' compounds (canavanine & pinitol) occur in 'high quantities'."* The other states: *"the plant is 'rich' in amino acids"* (and the formula of canavanine is illustrated). A photographic advertisement states: *"'Highly bioactive' compounds have been found in Phyto Nova Sutherlandia"*. A press release states: *"Analysis of the plant showed two 'particularly abundant' elements"*. The theme continues. Under "Chemistry and Pharmacology", the website states: *"'Significant levels' of L-canavanine are found in Sutherlandia leaves. L-Canavanine is a 'potent' L-arginine antagonist and a selective inhibitor of inducible nitric oxide synthase."* A high potency / concentration message is indisputable. To a toxicologist, all of this would indicate a very high potential for human toxicity under certain common circumstances, especially in AIDS.

What my report attempted was to balance, with some pertinent "scientific" toxicological facts, the ridiculously broad and overly optimistic anecdotal safety and efficacy sales propaganda, which might harm the gullible and desperate by raising false hopes and also by the recommended, let alone reckless higher doses. That the two faces of Sutherlandia cannot logically be reconciled is exemplified by Phyto Nova's about face on concentrations. Following my report, 'there is now an opposite trend - emphasizing how "low" the canavanine content is'. Albrecht, in response to a reporter emphasized the *"very low amounts of canavanine" (Shevlin, Sunday Tribune, 21 April 2002)* In a response to my report, titled "Sutherlandia Safety and Canavanine", Phyto Nova state: *"There is no scientific evidence that long term exposure to 'the 'very low amounts' of canavanine in Sutherlandia' can have any adverse effects"*. In another response titled "Safety of Phyto Nova Sutherlandia", Phyto Nova state: *"Alfalfa sprouts are widely sold as a health food in South Africa and the USA. Despite the presence of canavanine in alfalfa, the FDA has placed alfalfa in the category of food "generally regarded as safe" (GRAS). If the accusation is correct that daily ingestion of 'small amounts' of canavanine is harmful, this would have become evident from the millions (millions?) of people all over the world eating alfalfa sprouts (daily?), and alfalfa would have been banned"*.

This is not a valid argument. Many harmful foods are in common usage, often encouraged by medical authorities. By way of example, animal products cause millions of cancer and cardiovascular disease deaths annually, yet are not banned. I will explain shortly why alfalfa, in spite of containing more canavanine, is rendered less toxic in some cases and more so in others, sparing some, yet harming others, as applies also to Sutherlandia, but with the important difference that Phyto Nova are particularly targeting the ill, who are by far the most susceptible to canavanine toxicity, whilst those using alfalfa sprouts tend to be more well-nourished health conscious health food users, who are further spared by the fact that alfalfa itself is rich in the canavanine antagonist, L-arginine, a protein amino acid, besides its weight increasing and 'its canavanine decreasing at the leafing sprout stage. *(Rosenthal G, Metabolism of L-canavanine and L-canaline in leguminous plants. Plant Physiol, 94: 1-3. A 1990)*

Whilst Phyto Nova omit these relevant facts, they do acknowledge indirectly that diet are key factors. Proclaiming safety and lack of "severe" side effects, Gericke informed the press that: *"the Phyto Nova team tested Sutherlandia tablets in high doses (?) on ourselves, fellow doctors and family and friends"* (all well-fed "fat cats"). *"Having determined that the product was 'safe when administered with a balanced food diet'* (how many qualify?), *they distributed Sutherlandia to AIDS patients"*. The theme develops further: *"Remission is hoped for. This will require compliance of appropriate dose in addition to meticulous attention to diet"*. The preponderance of data at this point still clearly favours continued toxicological concern, in spite of, if not because of the bogus MRC tests, vindicating my charge of abuse of public funds for a private enterprise, which study achieved nothing other than to confirm that Phyto Nova has no intention of truly determining whether or not their recommended use of Sutherlandia could likely cause harm to ill and other susceptible people. It is my contention that for many, even a monthly R35.00-R100.00 would be better spent on good food, at least for the vast majority of poor malnourished persons whose resultant illness is often wrongly attributed to HIV-AIDS and might need no more than some good food and medication typed to their specific opportunistic infections, instead of their only means to the former being squandered on quackery.

(A) Let me address Albrecht's curt rebuttal of my ten-page report, before I address the bogus MRC "safety" study.

CA: *"Sutherlandia contains 2.5 mg L-canavanine per gram (dry). L-canavanine can be toxic at a very high dose."*

ST: **L-canavanine is also accumulatively toxic at much lower doses over time in several susceptible individuals, particularly those who are malnourished or otherwise deficient in protein / L-arginine and those who are ill (especially with prolonged illness or infections), using medications and or subjected to chemical exposures**, under which circumstances, **so widely prevalent in South Africa and especially in AIDS patients**, even relatively low doses of L-canavanine are readily substituted for arginine. Canavanine may have limited possible short-term minor anti-inflammatory drug benefits, but these are logically only likely at higher active doses, equally likely to be followed by potentially catastrophic consequences for health, as detailed in my report.

Arginine-rich protein, rather than mere canavanine concentration, is the arbiter of toxicity in this equation, having as it does, by its availability, the ability to prevent canavanine from being erroneously incorporated in the place of arginine. The degree to which arginine is deficient is the degree to which canavanine is likely to exert both beneficial drug effects, as well as toxic effects, the latter merely following the former, insidiously at first, some time later, depending on the other variables. In the absence of other susceptibility factors, **arginine is required in a ratio of 5:1 to canavanine to prevent canavanine uptake and toxicity** *(Tschiersch B, Pharmazie, 17, 621, 1962).* **Even conservative clinical supplemental suggestions are as high as 25g L-arginine per day** for immune function and host resistance to infection *(B Thomas, Manual of Dietetic Science, Blackwell Science, 1994)*.

Deficiencies or imbalances of essential amino acids result in increased urea production and excretion and thus, **any amino acid deficiency increases the demands upon available arginine**. Only high protein foods (a luxury in sub-Saharan Africa) are rich in arginine, with very **little available in the staple cereals, grains and vegetables**. **A protein / arginine deficiency, and hence canavanine toxicity, is far more likely to occur with poverty, malnutrition and poor protein** especially with excessive lysine, **and in pregnancy, rapid growth and trauma**. *(E Braverman, The Healing Nutrients Within: Facts, Findings and New Research on Amino Acids, Keats, 1995)*

CA: *"Analysis of the literature shows that the only well documented case of human toxicity involved the consumption of 80-160 g of ground alfalfa seeds daily. Ingestion of the seeds resulted in mild anaemia and leucopenia, which reversed when consumption of the seeds stopped (The Lancet, March 14, 1981, pg.615)."*

ST: More thorough analysis of the literature actually indicates that this was but the first case of clear canavanine **toxicity from acute overdose due to the large quantity consumed in a short period of time, rather than my concern of insidious smaller dose accumulative chronic auto-immune toxicity**, which latter became evident following informed vigilance *(Roberts J, et al, (letter), N Engl J Med, 308, 1361, 1983); (Ames B, Science, 221(4617), 1983); (Malinow M, et al, Science, 216, 415, 1984); (Alcocer-Varela J, et al, Arthritis Rheum, 28(1), 1985); (S Chan, Women's Health and the Environment, Environmental Care 86, China).* **This condition, especially if chronic, may never resolve, or may do so only with immunosuppressive drugs, since once an auto-immune reaction is triggered, it may perpetuate itself** *(Klein J, Horejsi V, Immunology, Blackwell, 1997)*.

In the early eighties, eating of alfalfa sprouts was popular amongst natural health faddists, who because they were unlikely to be malnourished and **because alfalfa is relatively rich in arginine and low in its competitor, lysine, toxicity from alfalfa, in spite of its high canavanine content, was moderated** and generally healthy consumers spared otherwise more serious long-term canavanine auto-immunotoxicity, as witnessed in those less fortunate, more susceptible cases extensively documented above and hereunder. Much the same applies to today, health foods being eaten mainly by the health conscious, affording them protection from canavanine, so informed health professionals continue to advise auto-immune patients to avoid alfalfa, surely not all because of an allegedly single well-documented case of alfalfa overdose some 20 years ago, as Phyto Nova would have us naively believe.

Contrary to Albrecht's mischievous claim, a number of clinical reports and experimental studies have shown that auto-immune responses and/or auto-immune diseases and disorders are frequently induced in humans by xenobiotics, including food sourced alfalfa derived canavanine. By the end of the 80's, Professor Varro Tyler, a pharmacognosy authority at Purdue University, warned of reports of **patients with clinically and serologically quiescent systemic lupus erythematosus (SLE) had even had the disease reactivated by merely ingesting canavanine-containing alfalfa tablets** *(V Tyler, et al (Eds), Pharmacognosy, Lea and Febiger, 1988).* The cautionary trend continues to this day. Quoting Belmont H, MD, director of the lupus clinic at Bellevue Hospital and chief medical officer at the Hospital for Joint Disease in New York City, *"There are foods that aggravate lupus and chief among them is alfalfa" (Lupus Advocational Resource Centre, January 30, 2001)*.

The following **published reports relate to subsequent toxic human canavanine exposures**: *(Morimoto I, Kobe J Med Sci, 35(5-6), 1989); (Rosenthal G, et al, J Biol Chem, 264(23), 1989); (Morimoto I, et al, Clin Immunol Immunopathol, 55(1), 1990); (Ames B, et al, Proc. Natl. Acad. Sci. USA, July 17, 1990); (D Metcalf, in: Food Allergy: adverse reactions to foods, D Metcalf, et al (Eds), Blackwell Scientific Publications, 1991); (Yoshida S, Gershwin M, Semin Arthritis Rheum, 22(6), 1993); (A Mongey & E Hess, in Dubois' Lupus Erythematosus and Associated Disorders, D Wallace & B Hahn (Eds), Lea and Febiger, 1993); (Herbert V, et al, Amer J Clin Nutr, 60: 639, 1994); (Leporatti M, Fitoterapia, 67(6), 1996); (Bigazzi P, Toxicology, 119(1), 1997); (Brinker F, Herb Contraindications and Drug Interactions, Eclectic Medical Publications, 1998); (Powell J, et al, Environ Health Perspectives, 107(Suppl 5), 1999); (Brown A, J Renal Nutr, 10(4), 2000); (Capasso R, et al, Fitoterapia, 71:1001, 2000); (Gebbers O, Schweiz Rundsch Med Prax, 90(44), 2001); (Siddhuraju P, Becker K, Nahrung, 45(4), 2001); (E Hess, The Environment and Lupus, Fourth Intl Lupus Patients' Conference Barcelona, Spain, Mar 2001); (Patavino T, Brady D, Altern Med Rev, 5(6), 2001)*. All of these reports consider canavanine to be undesirable.

CA: *"The dose of alfalfa seeds contained 1200-2400 mg L-canavanine per day, about 500-1000 times the amount in two Sutherlandia tablets, the recommended daily-dose. On the basis of this Sutherlandia was condemned."*

ST: In this instance **more than 1 kg of seeds ground dry seeds, not canavanine-reduced sprouts, were consumed** in a short period of time rendering it an **acute, rather than chronic poisoning** case. In view of the foregoing reports, I have to reject Phyto Nova's blatantly mischievous choice of this one extreme case as their basis for comparative and extrapolative purposes. Furthermore, **Phyto Nova on their website advocate not just 2, but 6 (2X3) tablets daily, thereby tripling the possible toxicity stakes**. A photographic advertisement gives as the suggested dosage, that: *"AIDS and cancer patients should take Phyto Nova Sutherlandia on an ongoing basis under supervision of a health care professional"*, leaving determination of the dose to the discretion of one of several class of possible quacks considered to be health care professionals. We have no indication of how much arginine the **Sutherlandia contains**, but it is certain that it is **nowhere near the** abovementioned **5:1 protective ratio, nor the established safe supplemental dose of 25g of arginine for preserved immune function.**

CA: *"I believe the lesson to be learnt here was expressed by Paracelsus centuries ago - "No substance is a poison by itself, it is the dose that makes the substance a poison"."*

ST: Yes, but not only the dose. **Several variables are being totally ignored** in this over-simplistic equation. As I have already pointed out, health food eaters using alfalfa sprouts tend to be more well-nourished and are further spared from canavanine poisoning by the fact that alfalfa itself is rich in the L-canavanine antagonist, L-arginine, besides the bulk/weight of sprouts increasing and the canavanine content decreasing at the leafing sprout stage. **The essential points to bear in mind is that with Phyto Nova's target users (cancer and especially AIDS), we are not dealing with healthy consumers, but with those more likely to be suffering protein/arginine deficiency and exposed to chemicals, rendering them more susceptible to adverse auto-immune outcomes from Sutherlandia, especially considering that bacterial and viral agents are also likely to be triggering factors for auto-immune diseases, rendering such persons far more vulnerable to canavanine toxicity.**

Several chemicals increase auto-immune susceptibility, including herbicides, preservatives, dyes, plastics, rubber products, hydrazine, silicone, gold, mercury, cadmium, tobacco smoke and **paraffin** (in many sub-economic households), *(A-B Mongey & E Hess, The Role of Environmental Agents in Systemic Lupus Erythematosus and Associated Disorders, in Dubois' Lupus Erythematosus, D Wallace & B Hahn (Eds), Academic Press, 1996),* **factors to which many workers suffering from cancer and especially AIDS might be chronically exposed. There are also more than 70 medications with a likely or definite association with auto-antibody production and lupus-like syndromes**, some in high likely usage within Phyto Nova's target group for Sutherlandia, eg Isoniazid (anti-tuberculosis) and Quinidine (anti-malaria). *(A-B Mongey & E Hess, Drug and Environmental Lupus: Clinical Manifestations And Differences, in Systemic Lupus Erythematosus, R Lahita (Ed), Academic Press, 1998)*

Medical treatment for SLE-like conditions is in itself complicated and includes immunosuppressive corticosteroids and non-steroidal anti-inflammatory drugs, as well as cytotoxic drugs to reduce steroid dosage. **Treatment results are variable, with debilitating side effects.** Prednisone causes musculoskeletal complications like avascular necrosis and the NSAIDS cause gastrointestinal damage. The cytotoxic drugs often fail to achieve remission and cause side effects such as cytopenia, hepatitis, nausea, vomiting, stomatitis, and central nervous system disturbances. Although **SLE** occurs in all age groups and gender, **the target population is women and in addition, certain ethnic groups including Africans, have a higher susceptibility and incidence than Caucasians**. *(Patavino T, Brady D, Altern Med Rev, 6(5), 2001)* It is no coincidence that I subtitled my report "HIV Positives and AIDS Sufferers Beware: The Remedy May be Worse than the Alleged Disease".

Canavanine is a potentially deleterious arginine antimetabolite whose toxicity is expressed in canavanine-sensitive organisms including humans *(Rosenthal G, et al, J Biol Chem, 264(23), 1989).* Canavanine bears strong structural analogy to its protein amino acid counterpart, arginine. As a subtle structural mimic of L-arginine, L-canavanine can function in all enzymic reactions for which arginine is a substrate. Therefore, canavanine potentially can inhibit any enzyme-directed reaction employing arginine as the preferred substrate. **Canavanine assimilation can alter protein conformation and adversely affect normal biological function and biochemical activities.** It is reasonable to propose that **'administration of L-canavanine to a human would result in the formation of L-canaline, a highly toxic nonprotein amino acid' that is a powerful inhibitor of pyridoxal phosphate-dependent enzymes** via a direct reaction between canaline and the vitamin B6 moiety of an enzyme. *(Rosenthal G, L-canavanine: A Novel Chemotherapeutic Agent for Human Pancreatic Cancer, 2001)*

Why anyone would promote canavanine with its potential to form anomalous, structurally aberrant protein with such health damaging, even life threatening toxic potential, in particular for AIDS is beyond me. Immunocompetent cells rely on amino acids as energy substrates. Arginine in particular is a modulator of immunity and greater availability improves the nonspecific immune response. *(Walrand S, et al, Am J Clin Nutr, 72(3), 2000)* **Nitric oxide synthases (NOS) catalyze the oxidation of L-arginine to nitric oxide (NO)**, which plays a key role in neurotransmission, control of blood pressure and cellular defense mechanisms *(Boucher J, et al, Cell Molec Life Sci, 55(8/9), 1999).* **Host defense epithelia with their antimicrobial armament, including T-cells and natural killer cells, are incapable of ensuring survival of the host against commensal organisms in the combined absence of phox and NOS. Sustained production of NO requires extracellular arginine uptake and endows macrophages with cytotoxic activity against viruses, bacteria, fungi, protozoa, helminths, and tumor *cells*** *(MacMicking J, et al, Annu Rev Immunol, 15: 323, 1997); (Nathan C, Shiloh M, Proc Natl Acad Sci, 97(16), 2000)*.

The cytotoxic and pro-inflammatory potential of NOS advances the case for its therapeutic inhibition only in diseases that are not infectious in etiology, or in those infectious diseases where the inflammatory effect of NOS outweighs its antimicrobial effect, emphasizing the possibility of adverse consequences attendant on its inhibition. Expression of NOS sometimes makes a profound difference to the course of infection or inflammation, acting both as a direct effector and as a regulator of other effectors. These complexities do not preclude experimental therapeutic intervention, but demand caution when trials are with nitric oxide synthase inhibitors. *(Nathan C, J Clin Invest, 100(10), 1997)* Inhibitors of NOS (agents that prevent binding of substrate L-arginine) are potentially beneficial only in the treatment of conditions associated with overproduction of NO, eg septic shock, neurodegenerative disorders, and inflammation. *(Hobbs A, et al, Annu Rev Pharmacol Toxicol, 39; 191, 1999)*

The production of NO represents an important component of the host immune response against viral infections, including retroviruses. Antiviral effects occur through its microbiostatic and microbicidal activity and through its pro-inflammatory and immunoregulatory properties. Macrophages are suspected to play a major role in human immunodeficiency virus infection. AIDS viruses stimulate NO production by human macrophages and thus NO concentration is increased in the sera of patients with AIDS, especially in those with neurological disorders and pulmonary disease caused by intracellular opportunistic pathogens. *(Blond D, et al, J Virol, 74(19), 2000)* Increased expression of NOS might be expected in AIDS infections, yet elevated NO levels in serum are related only to active AIDS-related bacterial, protozoan, and fungal infections, rather than chronic viral infection alone. NO plays a role in the local control of chronic viral infections at tissue level. *(Lake-Bakaar G, et al, Dig Dis Sci, 46(5), 2001)*

Not only is there no rationale for promoting canavanine-containing Sutherlandia for persons with AIDS (wasting would also be addressed by feeding arginine rich protein), but on the strength of the scientific information summarised here, canavanine would be clearly contraindicated. Canavanine or a deficiency of dietary protein or of arginine impairs constitutive and inducible NO synthesis *(Wu G, et al,* J Nutr *129: 1347, 1999)*. A recent review of the literature indicates that **NOS inhibitors (of which Sutherlandia canavanine is one) exacerbate infection by 80 species of viruses, bacteria, fungi, and protozoa** *(M De Groote & F Fang, in: Nitric Oxide and Infection, F Fang (Ed), Kluwer/Plenum, pp. 231-264, 1999); (Nathan C, Shiloh M, Proc Natl Acad Sci, USA, 97(16), 2000).*

Since the tuberculosis-exacerbating effect of corticosteroids is quantitatively indistinguishable from the effect of NOS deficiency, and corticosteroids suppress NOS, this may be an important mechanism for the tuberculosis-promoting effects of corticosteroids *(Nathan C, J Clin Invest, 100(10), 1997).* **Tuberculosis, the leading cause of death from infectious disease and AIDS, poses an even greater threat as immunodeficiency spreads among the host population and drug resistance rises. NOS is necessary to control primary tuberculosis. The absence of NOS leads to rapid bacterial growth, necrotic granulomatous pneumonitis, and death.** The sterile eradication of Mtb is rarely achieved. Long-term $CD4^+$ memory T-cells must continually enlist the aid of macrophages to maintain bacterial dormancy **The fact that NOS is necessary to control mycobacterial growth, has implications for the global incidence of AIDS and human tuberculosis.** *(MacMicking J, et al, Proc Natl Acad Sci, USA, 94 (5243), 1997)*

Besides canavanine, further concern is the suggestion of prolonged use of pinitol-containing Sutherlandia, especially for AIDS, due to the fact that Enterobacteria, including Klebsielleae, Yersinia, Erwinia and Salmonella, are capable of metabolizing pinitol and using it as a source of energy *(Talbot H, Seilder R, Appl Environ Microbiol, 37(5), 1979); (Talbot H, Seilder R, Appl Environ Microbiol, 38(4), 1979)*. Of particular concern is Klebsiella, especially K pneumoniae, which causes primary pneumonia, one of the main causes of death in AIDS, and also meningitis, and in infants, septicaemia. Many strains are now antibiotic resistant and cause serious infections, especially nosocomial and community-acquired, particularly in infants and AIDS patients. *(Feldman C, et al, J Infect, 20(1), 1990); (Feldman C, et al, Respiration, 58(5-6), 1991); (Cotton M, et al, S Afr Med J, 91(2), 2001)*

What of modern canavanine cancer research? Because no promising safe chemotherapeutic drugs have ever been discovered, researchers are desperately trying anything remotely promising. Canavanine is a case in point. L-Canavanine and its arginase-catalyzed metabolite, L-canaline, are two novel anticancer agents in development. Immunotoxic evaluation is a critical component of the drug development process and were evaluated in vitro. Both **L-canavanine and L-canaline are cytotoxic to peripheral blood mononucleocytes. A series of arginine compounds that may act as metabolic inhibitors of the toxic action of L-canavanine and L-canaline** (including L-arginine, L-ornithine, D-arginine, L-lysine, L-homoarginine, putrescine, L-omega-nitro arginine methyl ester and L-citrulline). The capacity of these compounds **to overcome the cytotoxic effects of L-canavanine or L-canaline** was assessed in order to provide insight into the biochemical mechanisms that may underlie the toxicity of these two agents. The results of these studies suggest that **the mechanism of L-canavanine toxicity is mediated through L-arginine-utilizing mechanisms and that the L-canavanine metabolite, L-canaline, is toxic to human PBMCs by disrupting polyamine biosynthesis.** *(Bence A, et al, Anticancer Drugs, 13(3), 2002)*

(B) Finally, let me expose the April 2002 MRC/NRF "Toxicity Study Of Sutherlandia" report for the sham that it is.

CA: Sutherlandia dried leaf powder was recently tested, independently, for toxicity/safety.

ST: In my report I outlined the links between the members of Phyto Nova and Dr M Matsabisa, project co-ordinator, which negates any possibility of this fraudulent exercise even remotely qualifying as being "independent".

CA: AFTER THOROUGH STATISTICAL ANALYSIS OF THE DATA, NOT A SINGLE VARIABLE COULD BE FOUND THAT INDICATED TOXICITY. For the full report http://www.sahealthinfo.org/traditionalmeds/firststudy.htm

ST: A PERFECT BOGUS STUDY, DESIGNED AND INTERPRETED TO WHITEWASH ANY TOXICITY ISSUES.

1. No animals were reportedly ill, in fact all were characterised as healthy, so in no way resembled target users.

2. No animals were reportedly receiving medication, in particular, auto-immunity disease risk-increasing drugs. The MRC report in fact acknowledges that: "The results in a study such as this do not preclude response to the consumption of herbal medicines or any other medicinal compound".

3. No animals were reportedly exposed to chemicals, in particular to auto-immunity disease risk-increasing ones.

4. No animals were females, so in no way resembled the most frequently susceptible target users. The report fails to note this, but acknowledges that: "Sutherlandia was not tested in pregnant and young animals and the results cannot be extrapolated to these groups".

5. No animals were malnourished, so in no way resembled most likely malnourished AIDS target users. In fact, unspecified micro- and macronutrients were supplemented, most likely negating any likelihood of acute toxicity.

6. No animals were monitored beyond 12 weeks, whereas 24 weeks is the point at which well-fed healthy animals on high doses significantly (10%) develop auto-antibodies (Prete P, Can J Physiol Pharmacol, 63(7), 1985).

7. No animals received 3X and 9X the recommended human dose as claimed, since the doses were adjusted to body-weight (30kg monkey = 60kg human) and as shown previously, X2 and X6 tablets daily are commonly recommended doses, with no maximum dose set anywhere, but left to the discretion (supervision) of a health care professional, particularly in cancer and AIDS patients (those most likely to be on higher risk medications).

8. Besides the time frame, the number of animals and frequency of monitoring variables were grossly inadequate. Previous criticisms aside, on this basis alone the study is rejected, since the information generated is for all intents and purposes, useless. Assessing the results of the variables, as well as the subsequent meaningless interpretations and conclusions, amply validates this position. The report admits as much, stating: *"Results and observations are reported mainly in terms of possible treatment effects and not biological variation".* Treatment effects in healthy animals? Statistically significant fluctuations only in the control? What curious nonsense!

This position is confirmed by assessing the report's appendiced charts, where in virtually every variable, the baseline values reflect greater significant differences than both quarter and the end-points and where the control group, which should reflect the greatest consistency over time from the start, is the most erratic of all. In fact, the control group appears to have received constant dietary manipulation, so that even were no other criticisms valid, this fact alone would serve to invalidate the entire study. Note eg the charts for Calcium, Magnesium and Total Protein (figs 15, 16 & 22). Clearly, no real comfort at all is provided by this MRC report.

Whilst no toxicity indications were apparent, none would be expected under current conditions so suited to the bland result planned for, but then again, with no apparent assimilation of canavanine, nor would any beneficial effects be possible either, so what is the point, other than pretence at safety via a pseudo toxicological study? Phyto Nova's Dr Carl Albrecht, in a recent newspaper article cited the MRC report, but when pressed for a response to my report, "Canavanine Toxicity: Is Sutherlandia a Healthy Herb or Potential Poison", admitted to the reporter that: *"long term trials are essential to establish safety beyond doubt, but that, well, took time. In the meantime they were free to market the product". (Ingrid Shevlin, Sunday Tribune, Sunday Magazine, 21 April 2002)*

Concluding remarks

Finally, a word of caution when evaluating information of this nature, in particular when human lives are at stake. Abstracts from accredited journals are generally true reflections of the contents of the papers cited, though these conclusions themselves may be argued with competing hypothesis and data, as per the successful Gaia reports. As with the original report titled "Canavanine Toxicity: Is Sutherlandia a Healthy Herb or Potential Poison", and this rebuttal to the above critiqued toxicity study, titled "Sutherlandia 'Fails' Safety Test", it is important to evaluate information purporting to represent points and conclusions made, especially the context and the original source.

A case in point here is a rather impressive sounding "international" reference: "*Trends in Plant Science",* claiming that: *"Sutherlandia frutescens microphylla is gaining international attention as a cheap, readily grown herbal medicine that can improve the health of AIDS patients through weight gain and energy boosts."* (Note the sobering limited extent of the reported claims, albeit still inaccurate, since weight gain and energy boosts, even if eventually established as fact, do not necessarily equate to improved health. - ST) *"The plant is native to South Africa where indigenous people refer to the plant as insisa: the one that dispels darkness. Insisa contains canavanine, pinitol and gaba, chemicals already patented by drug companies. A team of traditional healers, scientists and general practitioners have joined together to try to ensure that insisa remains in the public domain. The medicine will enter drug trials later this year* (following which, an "application" will be made for registration and all competitive Sutherlandia products forced from the market - ST)*." (Chaffey N, Stokes T, Trends in Plant Science, 7(2), 2002).*

A very impressive claim and reference, but for the fact that when one evaluates the source, one finds that this information is derived from a totally non-scientific source: *(Duval Smith, A. The Independent (Lond), p. 18, 30 November, 2001)* and as I have shown in my first report, the media are often as much a part of the misinformation problem as the marketers and vendors, not to mention the institutions responsible for the pseudo-scientific reports so eagerly seized upon by the aforementioned parties. Even the claims to try to ensure that Sutherlandia remains in the public domain, is a sham, since Phyto Nova have contracted widely to control the majority of all raw material.

The currently hyped phenomenon around Sutherlandia for AIDS and other serious conditions is entirely a non-factual fabrication by the members of Phyto Nova, together with their allopathic Tramed Project connections with the Departments of Pharmacology and Pharmacy at the Universities of Cape Town and Western Cape, the Medical Research Council and the Medicines Control Council [Gericke (UCT), Matsabisa (UCT & MRC), Eagles (UWC & MCC) and Mayeng (UCT & MCC)], which personalities and affiliated institutions are collectively contributing to the fraud by allowing Phyto Nova members to abuse the facilities, personnel and auspices of these institutions, sadly perpetuating a life-threatening health fraud at the taxpayer's expense, for the financial benefit of a privileged few.

Saddest of all is the official blind eye turned to Phyto Nova's illegal activities by the MCC, who frequently harass truly efficacious herbal interests, but due to one Dr Mayeng, a member of Phyto Nova in their ranks, have done nothing to regulate the outrageous activities of Phyto Nova, who have conducted illegal trials, made illegal claims for their product, manufactured and sold medicines illegally and generally subjected thousands of ill people to unknown risks to their health and lives. In fact, the abuse extends to the MCC, in spite of these transgressions, actually approving clinical trials and effectively, through a deliberate loophole left in legislation, exempting indigenous substances from regulation, based on a recommendation by a MCC committee influenced, if not led by Mayeng. Folb, Eagles, Matsabisa, Mayeng, Gericke and Albrecht all have a long association through the ethnopiracy Traditional Medicines Project (Tramed) and they and this entire debacle begs a judicial investigation.

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