#### **COMPLAINT**

That pursuant to the Therapeutic Goods Act 1989 and the Therapeutic Goods Advertising Code 2007, Health Care Provider *The Australian Vaccination Network, Inc.* and *Meryl Dorey* are risking the health of consumers by;

- (1) promoting by advertisement the use of Black Salve for the successful, safe and superior treatment and cure of cancer,
- (2) promoting by advertisement the sale of a DVD which strongly promotes Black Salve as a successful, safer and more superior treatment for cancer than conventional methods and
- (3) promoting and personally endorsing the use of Black Salve as a safer and more superior treatment for cancer, to conventional methods.

The promotion is designed in a manner which advertises Black Salve as safer and markedly more effective than conventional cancer treatments, including by itself "curing" people "who have been told they had only months to live".

The advertisement further presents the conventional treatment drug Aldara, (Imiquimod) as "dangerous and ineffective", known to cause cancer and to cause "systemic and fatal reactions". It is "poison".

The suggestion of conspiracy by "Big Pharma", "Big Government" and "Big Medicine" in preventing access to a seemingly miraculous cure for the motive of profit is strongly inferred. Meryl Dorey's personal endorsement is not based on evidence or experience. Ms. Dorey does not advise consumers or patients to consult a health practitioner.

No scientific evidence is provided. No verification of proffered testimonials is provided. No warning of the adverse effects of Black Salve or the published TGA Consumer Warning of March 19th, 2012 about Black Salve is presented.

Please find below the advertisement, location and **nine items** detailing consideration of relation to the Therapeutic Goods Act 1989 and the Therapeutic Goods Advertising Code 2007.

With regards, Paul Gallagher.



The AVN internet shop carries the following advertisement (see URL below):



# They Don't Want You To Know About... One Answer to Cancer

For those of you who have read Elaine Hollingsworth's groundbreaking book - How to Take Control Of Your Health and Escape the Sickness Industry, this new DVD will open your eyes to:

- Why a dangerous and ineffective drug called Aldara has continued to be used in Australia and overseas despite serious systemic and fatal reactions. In fact, this drug is known to CAUSE cancer!
- How a safe, effective and natural remedy called Black Salve (amongst other names) or 'nature's scalpel' has been used for over 2,000 years to treat skin cancers and other cancerous conditions, leading to a total remission of the disease.
- Personal stories of people who have been told they had only months to live, being completely cured by black salve without surgery, chemotherapy, radiation or drugs.
- Elaine's tale of how she was almost killed by Aldara. Her search to discover the truth about this dreadful poison has brought her into contact with thousands of people from around the world whose lives have been ruined or cut short by Aldara while doctors, government watchdogs and those who were supposed to protect us have put personal profit ahead of morality or their duty of care.
- Witness first-hand the reactions to Aldara and the subsequent success stories of Black Salve.
- Meet the doctors and natural therapists who brave the wrath of Big Pharma, Big Government and Big Medicine to help people cure their own cancers sometimes at the cost of their own careers.

"This DVD should be viewed by ALL Australians. Statistically speaking 50% of us will face cancer in our own lives at one time or another. That means that either we or someone we love will have to face the choice of how to treat our illness - using toxic drugs or safe, effective, time-tested natural remedies. I feel that Elaine's work will be life-changing and indeed life-saving for many. If you or someone you know is facing this issue or if you just want to be prepared for any future cancer diagnoses, this will be the best \$25 you have ever spent!" *Meryl Dorey, Australian Vaccination Network* 

http://shop.avn.org.au/products/One-Answer-to-Cancer.html

There are manifest problems with this advertisement including direct contradictions to the Therapeutic Goods Act 1989 (The Act) and The Therapeutic Goods Advertising Code 2007 (The Code).

#### DEFINITION

Under Section 2 DEFINITION The Code states.

Advertisement in relation to therapeutic goods as defined in the *Therapeutic Goods Act 1989* includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

The advertisement for the DVD and the statement by Meryl Dorey is "intended, whether directly or indirectly, to promote use" of Black Salve.

#### Consideration of The Act

Black Salve is intended and promoted here as a Therapeutic agent and is thus subject to The Act. The Act states in Section 2(a)(i):

**Therapeutic goods** are defined in the *Therapeutic Goods Act 1989* as goods:

- (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
  - (i) for therapeutic use;
- (1) Black Salve is not listed or registered with the TGA as specified in Division 2 Registration and listing Sect 23 of The Act.
- (2) Consequently Black Salve has no approval number and this is apparent in the above advertisement. See 42B Definitions, approval number and approved advertisement(a) (b) of The Act.
- (3) Division 2 Therapeutic goods advertisements for which an approval is required of The Act, states under 42C:

#### Offences relating to publication of advertisements

- (1) A person is guilty of an offence if:
  - (a) the person:
    - (i) publishes or broadcasts; or
    - (ii) causes to be published or broadcast;

in specified media, an advertisement that is required by the Therapeutic Goods Regulations to be an approved advertisement; and

(b) the advertisement is not an approved advertisement.

Consideration of the Therapeutic Goods Advertising Code (The Code):

Under Section 4 General Principles The Code states:

### **4** General Principles

- (1) An advertisement for the rapeutic goods *must*:
  - (a) comply with the statute and common law of the Commonwealth, States and Territories; and
  - (b) contain correct and balanced statements only and claims which the sponsor has already verified.
- (2) An advertisement for the rapeutic goods *must not*:
  - (a) be likely to arouse unwarranted and unrealistic expectations of product effectiveness;
  - (b) be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases;
  - (c) mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions;
  - (d) abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress;
  - (e) contain any matter which is likely to lead persons to believe:
    - (i) that they are suffering from a serious ailment; or
    - (ii) that harmful consequences may result from the therapeutic good not being used.

- Sunscreen preparations are exempted from (ii) if the claims made in the advertisement are consistent with current public health messages.
- (f) encourage, or be likely to encourage, inappropriate or excessive use;
- (g) contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- (h) contain any claim, statement or implication that it is effective in all cases of a condition;
- (i) contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects; or
- (j) be directed to minors, except the therapeutic goods listed in **Appendix**5.
- (4) In respect of the above it appears the Black Salve Advertisement within the AVN online shop is in breach of Sections 4(1)(a)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(2)(d), 4(2)(e)(ii), 4(2)(f), 4(g) and 4(h)(i).
- (5) The advertisement appears in breach of section 4(4) of The Code which states:
  - (4) Scientific Information

Any scientific information in an advertisement should be presented in a manner that is accurate, balanced and not misleading. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed. Publication of research results must identify the researcher and financial sponsor of the research.

- (6) The advertisement appears in breach of section 4(5) of The Code which states:
  - (5) Comparative Advertising

Comparative advertisements must be balanced and must not be misleading or likely to be misleading, either about the therapeutic goods advertised or the therapeutic goods, or classes of therapeutic goods, with which it is compared. Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the therapeutic goods, or classes of therapeutic goods, with which comparison is made, are harmful or ineffectual.

- (7) The advertisement appears in breach of section 4(7) of The Code which states:
  - (7) Testimonials

Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.

(8) The advertisement appears in breach of section 5(2) of The Code which states:

#### 5 Prohibitions

- (2) An advertisement for therapeutic goods must not refer, expressly or by implication, to serious forms of diseases, conditions, ailments or defects specified in Part 2 of Appendix 6, unless prior approval is given under the *Therapeutic Goods Act 1989*
- (9) The advertisement appears in breach of sections 6(3)(b), 6(3)(c), 6(3)(c)(i) and 6 (3)(d) of The Code which states:

#### 6 Minimum Requirements

(3) An advertisement for the rapeutic goods shall contain:

[...]

- (b) a reference to the approved/permitted indication(s) for the use of the goods; and
- (c) where applicable, a list of ingredients or the following statement prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood:

#### "Always read the label"

- i) in the case of direct marketing and Internet marketing, which must contain:
- a full list of the active ingredients. (Where the product name is also the single active ingredient, the pack shot displaying the product name will be sufficient to meet this requirement); and
- the mandatory warning statements prominently displayed on each page of the catalogue or internet that features therapeutic goods;
   and

- any mandatory advisory statements required to be included on the product label, prominently displayed on each page that features the relevant medicine/s; and
- · if the medicine, when used according to the directions:
  - has known serious adverse effects (in terms of severity and clinical importance); or
  - is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI);

an appropriate warning of those effects must be given, prominently displayed on each page that features the relevant medicine/s";

(d) words to the following effect, prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood:

#### **USE ONLY AS DIRECTED**

and, in all advertisements other than radio commercials that are 15 seconds or less, for claims relating to symptoms of diseases or conditions,

## IF SYMPTOMS PERSIST SEE YOUR DOCTOR/HEALTHCARE PROFESSIONAL

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Presently Black Salve and other such corrosive products are the subject of a TGA warning, issued March 19th, 2012. Ms. Dorey has no information about this or any other warning as to the corrosive effects and shocking injuries that can and do eventuate.

There is no recommendation to consult a health professional with respect to illness or use of Black Salve.

The Complaints Resolution Panel is already conducting an investigation into illegal advertising of Black Salve.

http://www.tga.gov.au/safety/alerts-medicine-black-salve-120203.htm

These products, professional concerns and the TGA warning were discussed on ABC "The World Today" on March 1st, 2012.

http://www.abc.net.au/am/content/2012/s3443284.htm

#### The Australian Vaccination Network's contact details are as follows.

Australian Vaccination Network, Inc.

BANGALOW NSW 2479
AUSTRALIA

Sincere Regards,
Paul Gallagher

Sincere Negards

April 19th, 2012

