

## Complaint

That pursuant to the Therapeutic Goods Act 1989 [the Act] and the Therapeutic Goods Advertising Code 2007 [the Code] Meryl Dorey, president of *The Australian Vaccination Network Inc.* and Leon C. Pittard, publisher of *Resistance Media (Fairdinkum Radio)* did respectively insert and publish in specified media or broadcast media on May 5th, 2012 an advertisement for Black Salve, that may breach conditions of the Act and the Code (please see Appendix 1. Section of transcript of “Australian Government Threatens Health Freedom”).

Material was directly intended to promote Black Salve as a safer alternative to dangerous medical treatments for cancer. Emphasis was placed on tales of the seeming unfailing efficacy of Black Salve and the supposedly dangerous and potentially lethal nature of conventional cancer treatments.

No scientific evidence was provided. Undocumented testimonials were offered.

No recommendation or caution to consult a medical practitioner was offered.

A significant amount of misleading material regarding the regulation of Therapeutic Goods as corrupt and flawed was presented. This began with Ms. Dorey relaying the fact she had been contacted by the TGA over an advertisement for a DVD promoting Black Salve.

No reference to the [19 March 2012 TGA Warning on Black Salve](#) or the published reference to existing CRP investigations into Internet Advertising of Black Salve that appears within the same Alert was made.

Further invitations to access the media containing the advertisement were made in social media and pitched toward a demographic that may reasonably be deemed particularly vulnerable to the biased nature of this material regarding Black Salve (please see Appendix 2, Figures 1 and 2). The material is subject to access by a large global audience.

I submit this information with the aim that the CRP may order a withdrawal of the material or publication of a retraction and/or correction as per Section 42ZCAI of the Therapeutic Goods Regulations 1990, and/or the Secretary may invoke Section 42DC of the Act to ensure deletion of the material and thus prevent further dissemination.

Sincerely,  
Paul Gallagher.

[Redacted signature block]

Ph: [Redacted]  
Mobile: [Redacted]



13 May 2012

## Consideration of the Code

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.

**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

### • Preamble and Justification for a Complaint:

Statements made about Black Salve during the discussion of “government threats to health freedom” went far beyond that needed to convey that a complaint had been made to the CRP (**2012/04/022**) and that the TGA had subsequently contacted Ms. Dorey.

I would submit that Ms. Dorey carefully chose and omitted statements with the intention of inserting in media, promotion of Black Salve as safer and superior to the “mainstream cancer treatment” which has been “banned in many countries” and “almost killed [Elaine Hollingsworth]”, the subject of the DVD that The AVN sells, named *One Answer To Cancer*.

Ms. Dorey made three references to this DVD, providing the title once. Ms. Dorey provided a synopsis of the DVD and two unrealistic testimonials of impossible effectiveness of Black Salve. These were presented without any proper scientific verification or notification of the current TGA warning about Black Salve (<http://www.tga.gov.au/safety/alerts-medicine-black-salve-120203.htm>).

Ms. Dorey presented the TGA and the Act and the Code in a misleading manner that would evoke distrust, distress and fear of the TGA and approved medicines and/or vaccines respectively. Ms. Dorey exploited the lack of knowledge of consumers to present an in depth fallacy purportedly explaining how the TGA is beholden to the whims of drug companies, thereby failing in it's duty to “protect the health and wellbeing of the Australian population”.



Please refer to Appendix 1: Transcript “Australian Government Threatens Health Freedom”.

In chronological order Ms. Dorey:

- 1) Leads in to promoting Black Salve as superior to conventional medical options by describing *Cost Recovery* funding of the TGA as “a fairly evil policy”. Ms. Dorey contends that once availed of pharmaceutical company research that, “without any further checking the TGA licences the drug or the vaccine”.
- 2) Ms. Dorey further suggests that if the TGA were to “stop licencing drugs or vaccines they won’t have money to operate” and that “[the TGA is] totally dependent on the multi-national corporations that they are meant to oversee”.
- 3) Ms. Dorey further argues that whilst the TGA “are meant to protect the health and wellbeing of the Australian population” the arrangement presented in (1) and (2) above makes it “impossible for them to do that”. Ms. Dorey also contends that this failure of regulation has been the subject of “many enquiries into the TGA”.

I submit that points (1), (2) and (3) are misleading and intended to evoke distrust and fear of the Australian Therapeutic Goods regulatory process, and by extension support a latter contention that Aldara is a dangerous medication, “banned in many countries” whilst leading to potentially fatal, and fatal consequences.

I further submit that the presented notion that the TGA is financially dependent upon drug companies is presented to convey a financial conflict of interest that leads into false comparative advertising. Namely that Aldara as a licenced drug has not been “safety tested” and that TGA regulation of Black Salve and advertising of Black Salve is void.

- 4) Ms. Dorey promotes the fact *One Answer To Cancer* is sold by The Australian Vaccination Network Inc. She continues with a general synopsis of the DVD in that Elaine Hollingsworth had cancer and **twice** argues that “a mainstream cancer treatment” (called “Altara” *sic*) “almost killed” Elaine Hollingsworth.
- 5) Presenting Black Salve benignly as “a combination of herbs and minerals that is applied topically”, Ms. Dorey provides a personal testimonial contending she had “a cancer” on her shoulder and that she used Black Salve safely and successfully. Working just like “Nature’s Scalpel” Black Salve “cut it out in a perfect circle” and “got rid of it completely”.
- 6) Ms. Dorey states that Black Salve is banned by the Australian Government for no good reason, suggesting it *is banned* only because it hasn’t been “safety tested” by the TGA.



Ms. Dorey insinuates in the same sentence that this is irrelevant because the TGA “licences drugs and vaccines which *also* haven’t been independently safety tested”.

7) Ms. Dorey refutes the logic of the Code as it applies to advertising Therapeutic Goods whilst omitting the Object, Definition and Principles of the Code.

8) Finally Ms. Dorey contends that a breach of Government legislation can result in unjust persecution.

I submit that the above statements constitute an advertisement in that however made, it intended whether directly or indirectly, to promote the use of Black Salve.

I further submit that the following Objects of the Code appear to apply:

- (1) The Object of the Therapeutic Goods Advertising Code 2007 (the Code) is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.
- (3) In interpreting the Code, emphasis will be placed on the Object and the Principles of the Code and the total presentation and context of the advertisement.

Specifically I would submit that the following Sections and subsections of the Code appear to apply to items (1) through (8) above, and the Advertisement in total (see Appendix 1) in that these Sections may have been breached.

#### **Section 4 General Principles**

- (2) An advertisement for therapeutic 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:



[...]

- (ii) that harmful consequences may result from the therapeutic good not being used.

[...]

- (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.

#### (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) Testimonials

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

### Section 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*

### Section 6 Minimum Requirements

- (3) An advertisement for therapeutic 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**

except:

- (i) in the case of direct marketing and Internet marketing, which must contain:
  - a full list of the active ingredients [...] 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);
- (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**

- (e) or, in the case of Schedule 3 therapeutic goods listed in *Appendix H* of the *Standard for the Uniform Scheduling of Drugs and Poisons*, words to the effect of -

### **YOUR PHARMACIST'S ADVICE IS REQUIRED;**

[....]



## Consideration of the Act

Section 42C (6)(b) of the Act states:

A person is guilty of an offence if:

- the person's action is in contravention of a condition to which the approval of the advertisement is subject.

It should be noted that:

Black Salve is not listed or registered with the TGA as specified in Division 2 - Registration and listing [Sect 23](#) of The Act.

Consequently Black Salve has no approval number. See [42B Definitions](#), approval number and approved advertisement(a)(b) of The Act.

Generic information provided by Ms. Dorey did not comply with principles of the Code as per Section **42DO** of the Act;

“Generic information to which this Division applies must comply with principles of the Therapeutic Goods Advertising Code specified in regulations made for the purposes of this section as if those principles applied to generic information in the same way as they apply to advertisements.”

- Regarding Publication;

*The person apparently responsible for publication is [REDACTED]  
Fairdinkum Radio  
Resistance Media.*

[REDACTED]

In that Black Salve has no approval for advertisement;

### **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.

[REDACTED]

**Ms Dorey referred to the Act in a manner designed to convey persecution of advertisers and it's failure to "protect Australians".**

Thus I would draw attention to Section **42DL** of the Act: Advertising Offences -

(1) A person must not publish or broadcast an advertisement about therapeutic goods:

[...]

(e) that contains:

(i) reference to the Act other than in a statement of registration number, listing number or device number of the goods;

## 42DM Compliance with Code

(1) A person is guilty of an offence if:

(a) the person publishes or broadcasts an advertisement about therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

## 42DP Offences—publication of generic information

(1) A person is guilty of an offence if:

(a) the person publishes or broadcasts generic information about therapeutic goods; and

(b) the publication or broadcasting of that generic information does not comply with principles contained in the part of the Therapeutic Goods Advertising Code that are specified in Regulations.

In relation to the above consideration of the Act, I submit that there appears to be breaches of, and offences under, the Act, non-compliance with the Code and thus it appears to be illegal to continue to publish and/or allow unlimited access to the audio as transcribed in Appendix 1, as is presently the case.



## Appendix 1

**Transcript out-take from:**

### **Australian Government threatens health freedom**

Commentary between Leon Pittard (interviewer) and Meryl Dorey,  
President of The Australian Vaccination Network Inc. (guest)

Date: 5th May, 2012

• Audio of transcript: [REDACTED] 5 min, 35 seconds

• Back up audio of transcript:

<http://traffic.libsyn.com/firesnake/>

[Fairdinkum\\_AVN\\_BlackSalve050512\\_TGAref.mp3](#)

Source Web Page:

[REDACTED]

Live Link to full episode:

[REDACTED]

Backup audio of full episode:

[http://traffic.libsyn.com/firesnake/Fairdinkum\\_AVN\\_050512\\_TGAref.mp3](http://traffic.libsyn.com/firesnake/Fairdinkum_AVN_050512_TGAref.mp3)

[REDACTED]

**Meryl Dorey:** I got a call from the TGA. Now the Therapeutic Goods Administration, if I can give just a bit of background for the listeners...

**Leon Pittard:** Sure.

**Meryl Dorey:** Um, it's like the *American Food and Drug Administration*, they're the Government Department that licences and approves drugs and vaccines and therapeutic products. So all therapeutic products that are licenced in Australia have to go through the TGA. And um, the TGA, even though it is a Government Department receives no funding from the Australian Government. Um, since 1998 they've worked under something called *Cost Recovery*.

12:51 [00:33]

Um, and what that means, and I think it's a fairly evil, um, policy... it means that the government gives them no money to operate. All their operating expenses come from the licencing fees paid for drugs and vaccines. So when a pharmaceutical company wants to licence a new drug, the pharmaceutical company does all the testing, then they give the study to the TGA and based on that information, without any further checking, the TGA licences the drug or the vaccine.

Um, and if they stop licencing the drugs or the vaccines they won't have money to operate. So they are totally dependent on the multi-national corporations that they are meant to oversee. They are meant to protect the health and wellbeing of the Australian population but in the way that they're set up it's impossible for them to do that. And this has come out lately um, there are many ah, enquiries into the TGA that have been going on.

13:48 [01:29]

But what the complaint that was made about the AVN to the TGA says, and I've only just received this information, you're the first person I'm speaking with about it, um, is that we sell ah, a DVD on our website. Now we have a lot of books and DVD's about general health issues, vaccination, natural health, ah, instinctive parenting environmental issues. Um, we feel it's our responsibility to allow people to access information that they might not find elsewhere.

And one of the DVD's that we sell is by Elaine Hollingsworth and it's called *One Answer To Cancer*. Now Elaine runs a um, a health retreat up on the Gold Coast called *Hippocrates Health*, and she was almost killed by um, a mainstream cancer treatment called... um... I think it's called Altara (sic), I could have the name wrong, ah it's been banned in many countries and um, she had skin cancer, was given this treatment, and it almost killed her.

14:45

[02:26]



And as a result of that experience she found a treatment that's been used for at least two thousand years, called Black Salve. And it's a combination of herbs and um, and minerals that is applied topically to cancer and it... it's called Nature's Scalpel. Now, I've used it myself um, on a cancer that I had on my shoulder and I've gotta tell you it *is* like a scalpel, it cut it out in a perfect circle. Um, and it got rid of it completely.

So, the Australian Government several years ago banned the use of Black Salve on humans and you could only buy it for animals. As of a couple of weeks ago you're not even allowed to sell it for animal use...

**Leon Pittard:** Unbelievable.

**Meryl Dorey:** The only reason... they haven't actually given any reason, except that it hasn't been safety tested by the, by um, the organisation that, that ah, that licences drugs and vaccines which *also* haven't been independently safety tested: the TGA. But um, because they've banned this now and because, I'm assuming, someone from *Stop The AVN* - and I don't have information on this yet - has filed a complaint with the TGA, um, they've come to me and said that we have to remove um, our, our sales of this DVD. Because actually providing information via a DVD, according to the TGA, is exactly the same as advertising and selling the product.

16:11

[03:53]

And we've been in touch with several um, natural health practitioners who've been told the same thing. They may have an article on the use of X herb, for stomach ulcers let's say. And the TGA says even though they're not selling that herb, the fact that they are giving out information on it's use may influence someone to actually go out and find a retailer who sells this herb and to buy it. And therefore they're advertising it.

**Leon Pittard:** Mmmm. Yeah. And this is... this is incredible because what this is opening up... this is the thin edge of the wedge of total ah, *surveillance* of all information sharing... to... by government bureaucracies to oversee every piece of information that the public receives. And therefore even any information ah, sharing website that... and let's take the subject of fluoride... that may be opposite to public policy will be subject to litigation or court action. Even though you may not be selling fluoride, where the government's selling fluoride but you're the person that is sharing the other side of the story. Therefore you would be subject to litigation because it is *against* what the public system has already incorporated.

**Meryl Dorey:** That's exactly right. The government has a policy. They've put some policy in place and if you are giving out information that opposes that policy, then you can be prosecuted, or *persecuted* is more likely um, as a result of it. [...]

*End Transcript:* 17:57 [Total time - 05:38]



## Appendix 2 - Social media promotion

- Figure 1: Facebook Invitation



**Australian Vaccination Network** · 4,225 like this  
May 5 at 9:01am · 🌐

✓ Liked

Please have a listen to the story about the ongoing efforts to force the AVN to close down and to suppress information on the other side of the vaccination issue. The assault on health freedom and on freedom of speech is ongoing and accelerating in Australia. Our fight is not over – neither is yours.  
MD



**Vaccination | Fairdinkum Radio**   
fairdinkumradio.com  
Meryl Dorey of the Australian Vaccination Network joins Leon to discuss the current Legislation regarding Vaccinations in Australia. Parents can be Conscience Objector should they choose not to vaccinate. They also discuss current social trends and commentary regarding vaccination.23.3.12 Meryl Dore...

- Figure 2: Twitter Invitation



**Vaccination Network**  
@nocompulsoryvac

Follow 

Australian government's Assault on Health Freedom-radio interview with Meryl Dorey - Fairdinkum Radio. Please RT. [ow.ly/aIpHW](https://ow.ly/aIpHW) 

← Reply ↻ Retweet ★ Favorite

1  
RETWEET



10:47 AM - 5 May 12 via HootSuite · Embed this Tweet

## Contact Details for all parties

- Contact Details for The Australian Vaccination Network Inc (the advertiser or person who inserted the material).

Australian Vaccination Network Inc.

[REDACTED]

BANGALOW NSW 2479

AUSTRALIA

[REDACTED]  
[REDACTED]  
[REDACTED]

- Contact avenue for Leon C. Pittard (the person apparently responsible for publishing and broadcasting the advertisement).

Fairdinkum Radio

[REDACTED]

Resistance Media.

[REDACTED]

- Submitted by (the complainant):

Paul Gallagher.

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

Date: 13 May 2012

[REDACTED]

[REDACTED]