Submission No 62

THE PROMOTION OF FALSE OR MISLEADING HEALTH-RELATED INFORMATION OR PRACTICES

Organisation: Health Care Complaints Commission

Name: Mr Kieran Pehm

Position: Commissioner

Date Received: 4/02/2014



Contact:

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Mrs Leslie Williams MP Chair Committee on the Health Care Complaints Commission Parliament House, Macquarie St Sydney NSW 2000

Dear Ms Williams.

Inquiry into the promotion of false or misleading health-related information and practices

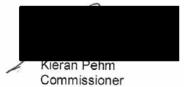
Thank you for your letter of 5 December 2013 inviting the Commission's submission to this inquiry. The Commission notes the terms of reference of the inquiry providing that the Committee inquires into and reports on possible measures to address the promotion of unscientific health-related information or practices which may be detrimental to individual or public health. The Commission notes that the Inquiry will focus on individuals who are not recognised health practitioners, and organisations that are not recognised health service providers. The Commission also notes that the Committee will have particular regard to:

- (a) The publication and/or dissemination of false or misleading health-related information that may cause general community mistrust of, or anxiety toward, accepted medical practice;
- (b) The publication and/or dissemination of information that encourages individuals or the public to unsafely refuse preventative health measures, medical treatments, or cures:
- (c) the promotion of health-related activities and/or provision of treatment that departs from accepted medical practice which may be harmful to individual or public health;
- (d) the adequacy of the powers of the Health Care Complaints Commission to investigate such organisations or individuals;
- (e) the capacity, appropriateness, and effectiveness of the Health Care Complaints Commission to take enforcement action against such organisations or individuals; and
- (f) any other related matter.

The Commission's submission is attached. Please note that the Commission requests appendix B of its submission be treated as confidential under section 72 of the *Health Care Complaints Act* as it contains confidential information relating to a specific complaint under the Act.

I trust that this information is of assistance to the Committee's inquiry and I would be pleased to elaborate on it at the Committee's convenience.

Yours sincerely



- 4 FEB 2014

Submission by the NSW Health Care Complaints Commission - Inquiry into the promotion of false or misleading health-related information and practices

The following submission will set out general issues from the perspective of the NSW Health Care Complaints Commission in relation to the promotion of false or misleading health-related information and practices, as well as discuss the specific areas set out in the terms of reference of the inquiry issued by the Joint Parliamentary Committee on the Health Care Complaints Commission.

In 2012-13, the Health Care Complaints Commission received 4,554 complaints about health service providers in NSW. This includes complaints about individual practitioners as well as health organisations. Specifically, 114 complaints were about unregistered health practitioners and 20 complaints about previously registered health practitioners. Complaints about both groups represent 2.9% of all complaints the Commission received during that period or 4.5% of all complaints about individual health practitioners.

The Commission records the type of issues raised in complaints. Some complaints may raise multiple issues. In 2012-13, 4.6% of issues raised in all complaints received related to the provision of incorrect or misleading information; 1.6% related to a practitioner engaging in illegal practices, and 0.7% related to the misrepresentation of qualifications. In the 2012-13 year, there were ten complaints about unregistered health practitioners for providing incorrect or misleading information, and an additional six complaints about alternative health facilities.

Legislation in NSW that is relevant to the provision of health-related information and practices in general includes the *Health Care Complaints Act 1993, the Public Health Act 2010, the Fair Trading Act 1987* and relevant Regulations. The *Health Care Complaints Act* is administered by the NSW Health Care Complaints Commission. The *Public Health Act* is administered by the Ministry of Health, and consumer protection legislation administered by NSW Fair Trading.

All three bodies have power to take action regarding false and misleading health-related information and practices depending on the particular circumstances.

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¹ Source: Health Care Complaints Commission's annual report 2012-13, p. 104.

Jurisdiction

Action under the *Health Care Complaints Act* ('the Act') is complaints-based and complaints must be about the provision of a health service by a health service provider, or must relate to the professional conduct of a health practitioner.

A health service under the Act is defined to include the following services, whether provided as public or private services:

- (a) medical, hospital, nursing and midwifery services,
- (b) dental services.
- (c) mental health services,
- (d) pharmaceutical services,
- (e) ambulance services,
- (f) community health services,
- (g) health education services,
- (h) welfare services necessary to implement any services referred to in paragraphs (a)-(g),
- (i) services provided in connection with Aboriginal and Torres Strait Islander health practices and medical radiation practices,
- (j) Chinese medicine, chiropractic, occupational therapy, optometry, osteopathy, physiotherapy, podiatry and psychology services,
- (j1) optical dispensing, dietitian, massage therapy, naturopathy, acupuncture, speech therapy, audiology and audiometry services,
- (k) services provided in other alternative health care fields
- (k1) forensic pathology services,
- (I) a service prescribed by the regulations as a health service for the purposes of this Act.

Is the provision of false/misleading information a 'health service'?

A significant amount of misleading health-related information is published on internet websites. It can be a difficult question to begin with whether or not the provision of such health-related information constitutes a 'health service' as defined by the Act. Examples would include weight loss products or programs; allergy testing/cures; personal and/or spiritual development programs.

This issue was discussed with the members of the Commission's Consumer Consultative Committee and the recent television broadcast 'The heart of the matter' on the ABC's Catalyst program was raised. That program included interviews with a range of practitioners who questioned the belief that saturated fat and cholesterol were conducive to heart disease and stated that they were a 'huge misconception' and '100% wrong'. As a result of this program, a number of patients discontinued their medication, which may have had adverse effects on their health, and many patients have questioned their general practitioners about their prescriptions of Statins, which is a common medication that is used to manage cholesterol levels.

In this context, member organisations of the Committee, who represent key consumer bodies in NSW, raised the question of the advertising of drugs and medication through the media and asked whether the broadcasting entity could be considered providing a health

service under the Commission's legislation, if the definition were widened to include organisations not conventionally recognised as health service providers

Health-related information, if provided <u>and</u> intended to educate or train may be a health education service. If this is the case then the Commission has jurisdiction to deal with a complaint about the health information provided. A health education service is specifically defined by the Act as a health service.

However, where the purpose of the provider of information is unclear and the purpose in doing so does not relate to the treatment of clients, it cannot be considered a health service under the *Health Care Complaints Act*.

Where the provider of such information is not a health practitioner, for example voices a personal opinion, it will not fall under the Commission's jurisdiction. Documentation concerning a recent complaint which demonstrates the complexities of the law in this area is set out in appendix B. As the *Health Care Complaints Act* requires the Commission to treat all complaint information confidentially, the Commission requests that appendix B be treated by the Committee as confidential under section 72 of the *Health Care Complaints Act*. The Commission also receives complaints about organisations whose names may suggest that they provide a health service, for example by using terms such as 'medicine' or 'heal', but where the actual services provided may not be health services as defined by the Act. For example, one organisation who was the subject of a complaint provided generic accommodation and support to survivors of childhood sexual abuse that did not affect or was likely to affect the clinical management and care of the residents, and it was unclear whether the organisation was within the Commission's jurisdiction.

It appears that the current definition of a health service under the Act is a list of specific health services that may not cover some type of health-related information and services as discussed above.

A broader definition of a health service can be found in the Queensland *Health Ombudsman Act 2013*, which under section 7 defines a health service as follows:

7 Meaning of health service

- (1) A health service is a service that is, or purports to be, a service for maintaining, improving, restoring or managing people's health and wellbeing.
- (2) A health service may be provided to a person at any place including a hospital, residential care facility, community health facility or home.
- (3) A health service includes a support service for a service mentioned in subsection (1).
- (4) Also, without limiting subsection (1), a health service includes—
 - (a) a service dealing with public health, including a program or activity for—
 - (i) the prevention and control of disease or sickness; or
 - (ii) the prevention of injury; or
 - (iii) the protection and promotion of health; and

Example of health service mentioned in paragraph (a)—

- a cancer screening program
- (b) a service providing alternative or complementary medicine; and
- (c) a service prescribed under a regulation to be a health service.
- (5) A health service does not include a service prescribed under a regulation not to be a health service.

Another definition used for health services can be found in the Commonwealth *Privacy Act* 1988 that defines a health service as:

- (a) an activity performed in relation to an individual that is intended or claimed (expressly or otherwise) by the individual or the person performing it:
 - (i) to assess, record, maintain or improve the individual's health; or
 - (ii) to diagnose the individual's illness or disability; or
 - (iii) to treat the individual's illness or disability or suspected illness or disability; or
- (b) the dispensing on prescription of a drug or medicinal preparation by a pharmacist.

This definition includes disability related services, for which in NSW, the NSW Ombudsman appears to have some jurisdiction to deal with complaints about such type of services. The definitions in the Queensland legislation and Commonwealth privacy legislation move away from specifying occupational based health provision to generic descriptions which would include less conventional health services. The Queensland legislation extends the definition of a health service to include 'wellbeing' while the Privacy Act definition includes disability services, another grey area under the current NSW *Health Care Complaint Act*.

The Committee could consider whether the current definition of a health service in the NSW *Health Care Complaint Act* is too narrow and should be broadened.

Organisations – does the complaint relate to the clinical management or care of individual clients?

Information published by websites and effectively making claims which disparage conventional treatment and discourage readers from pursuing conventional treatment is widely accessible. Such claims, however, are rarely made in such black and white terms that it is safe to conclude they would 'affect, or be likely to affect, the clinical management or care' of clients. Generally, they are carefully worded, for example, rather than promising 'cures' they might say their product can 'assist with treatment of relevant conditions. The legal advice referred to above noted that for a health service to 'affect, or be likely to affect', the clinical management and care of a patient, it was not sufficient to show that the relevant health service affected the patient's decision-making, but the actual clinical management and care.

The disparagement of conventional treatment on such websites is often subtle and even though the underlying intent is clear it is unlikely to fall within the jurisdiction of the Act.

Possible action

Where a complaint about an organisation providing misleading and harmful information is within jurisdiction and capable of investigation by the Commission, the legal capacity of the Commission to take action is limited. As an outcome of an investigation into an organisation, the Commission can make comments and/or recommendations. Where the organisation strongly believes in its position, these are not adequate remedies because the compliance with the recommendations is voluntary.

The Commission does have the power to issue a public warning following completion of an investigation under section 94A of the *Health Care Complaints Act*, but only after the investigation is finalised.

Section 94A of the Act gives the Commission the power to issue a public warning if it reaches the view that a particular treatment or health service poses a risk to public health

and safety. Legal advice to the Commission states that such a warning must be limited to the treatment or service investigated and cannot relate to the general conduct of an organisational health service provider nor name individuals within the organisation responsible for providing the treatment or service.

Also, the power to issues a public warning relates to unsafe treatment and services, which may not include unethical services that may pose a risk to public health and safety. As such, the withholding of relevant information about alternative treatments or therapies when promoting the benefits of one particular treatment could not prompt the Commission making a public warning.

Currently, there are no provisions for the Commission to make interim warnings while completing its investigation, similar to the powers of the Commission in regard to unregistered health practitioners (see further below).

Individual practitioners

Complaints can be made about the professional conduct of an individual health practitioner independently of their provision of a health service to actual clients. This means that if a health practitioner provides false or misleading information or engages in unprofessional practices, the Commission has jurisdiction to deal with such complaints, regardless of whether or not it receives complaints about the treatment of clients.

There remain, however, difficulties with establishing whether a complaint against an individual for providing misleading health-related information is a complaint against a 'health practitioner' as defined by the Act. Mentioned above in relation to organisations were services such as weight loss programs, which may fall outside the Commission's jurisdiction depending on the circumstances of each individual case. As with organisations, it may not always be clear whether or not such practitioners, if they are not registered under the *Health Practitioner Regulation National Law (NSW)*, are providing a health service as defined by the Act.

Some examples where the answer is not clear are personal trainers; life coaches; individuals providing beauty treatments including laser hair removal; individuals working in group homes for disabled residents; workers in half way houses in the drug and alcohol and mental health areas and counselling, which may or may not be a health service, depending on the context.

Assuming that the practitioner is providing a health service as defined by the Act, then the Commission can investigate a complaint against them, if it:

- raises serious issues of public health or safety
- raises a significant question as to the appropriate care or treatment of a client
- would provide grounds to take disciplinary action against the practitioner, if substantiated
- would involve gross negligence, if substantiated
- would result in the practitioner to be found guilty of a relevant offence under the *Public Health Act*².

Section 41A of the *Health Care Complaints Act* gives the Commission the power to make an interim prohibition order during an investigation if it forms a reasonable belief that the practitioner has breached the Code of Conduct for unregistered health practitioners that is set out in Schedule 3 of the Public Health Regulation 2012 ('the Code of Conduct'), poses a

² Relevant offences are set out in Divisions 1 and 3 of Part 7 of the *Public Health Act 2010*, and include the advertisement or promotion of health services in a misleading manner, the provision of health services by persons who are de-registered or subject to prohibition orders, and advertising of health services if a person is de-registered or subject to a prohibition order.

serious risk to the public health or safety and that the interim order is necessary to protect the public. The kinds of orders that can be made are the same as prohibition orders, set out below.

The object of an investigation is to establish whether there has been a breach of the Code of Conduct and if so, whether the practitioner poses a risk to the public health or safety.

The most relevant clause of the Code of Conduct to the Committee's inquiry is clause 12:

12 Health practitioners not to misinform their clients³

- (1) A health practitioner must not engage in any form of misinformation or misrepresentation in relation to the products or services he or she provides or as to his or her qualifications, training or professional affiliations.
- (2) A health practitioner must provide truthful information as to his or her qualifications, training or professional affiliations if asked for information about those matters by a client.
- (3) health practitioner must not make claims, either directly or in advertising or promotional material, about the efficacy of treatment or services provided if those claims cannot be substantiated

The Commission has investigated a number of complaints which have raised a potential breach of clause 12 of the Code of Conduct. There have been no complaints solely concerned with misleading claims that have resulted in public prohibition orders although orders have been made in complaints where practitioners have misled clients about their qualifications along with other breaches of the Code.

The Commission's website contains details of all prohibition orders made by the Commission.

Monitoring and enforcing orders

Section 102(3) of the *Public Health Act* provides that it is an offence to breach a prohibition order and a practitioner can be prosecuted before the Local Court for breaching a prohibition order.

The Commission does not routinely monitor compliance with prohibition orders. The Commission has no powers to enter premises or ask question for this purpose and relies on the public to bring any suspected breaches to its attention.

The Commission has had reported to it a number of cases where practitioners appeared not to be abiding by prohibition orders, usually in terms of failing to advertise that they were subject to a prohibition order. These have mostly been remedied by the practitioner when the Commission made inquiries. To date, there is only one case where it appears a practitioner may have breached a prohibition order by proving a health service and the Commission is currently prosecuting that matter under the *Public Health Act*.

The Commission, as any other person or body, can prosecute a person who has breached relevant sections 99, 102 and 103 of the *Public Health Act* (see Appendix A). The possible outcome of such criminal proceedings is a fine being imposed on a person.

Although there is no direct sanction available to protect the health and safety of the public, the Commission can investigate practitioners found guilty of such offences, which would be a basis for further prohibition orders.

³ Clause12, Code of Conduct for unregistered health practitioners, Schedule 3 of the Public Health Regulation 2012

Alternative means

The primary objective of the *Health Care Complaints Act* is to protect the public health and safety. Consumers may dispute the effectiveness of a health-related services or products, however, where there is no threat to public health and safety those disputes may more appropriately be dealt with through consumer protection legislation.

A complaint about misleading or false health-related information may be more appropriately and effectively dealt with under the *Public Health Act* which does not require such information to affect or likely affect the clinical management or care of a person.

A complaint about certain medicines and medical devices and claims relating to these can be dealt with by the Therapeutic Goods Administration as summarised below.

Consumer protection legislation

Any person can make a complaint about wrong or misleading claims about a product or service to NSW Fair Trading. In contrast to the Commission's legislation, under the *Fair Trading Act*, complaints about information or services are not limited to health services and do not have to pose a risk to public health and safety. Section 86A of the *Fair Trading Act* provides that the Minister or Director-General can issue public warnings about goods, services, practices or persons, when it is in the public interest to do so.

The national *Competition and Consumer Act 2010* (Vol 3, part 1, Schedule 2) also contains extensive provisions prohibiting deceptive or misleading conduct and has extensive sanctions including warnings, bans and criminal prosecutions. It should be noted that these provision apply to 'trade or commerce' and, if the provider is not providing goods or services for money, then the provisions would not be applicable.

Using the available mechanisms through Fair Trading, consumers may be granted compensation or achieve a legally binding order by the Consumer, Trader and Tenancy Tribunal (CCCT) that can prohibit the provision of certain types of services or goods.

Public Health Act

There is also a relevant offence under section 99 the Public Health Act, which provides that:

A person must not advertise or otherwise promote the provision of a health service in a manner that:

- (a) is false, misleading or deceptive, or
- (b) is likely to mislead or deceive, or
- (c) creates, or is likely to create, an unjustified expectation of beneficial treatment.

In the absence of any specific provisions, anyone can prosecute a person for a breach of s99, 102 and 103 of the *Public Health Act*. Where a person was convicted for an offence under the *Public Health Act*, if aware, the Commission then can take action under its legislation.

It should be noted that this section does not require that the promotion for a health service in such a manner is a risk to public health and safety and is therefore broader than the Health Care Complaints Commission's core function to investigate serious risks to public health or safety. It should be noted that section 99 of the *Public Health Act* refers to a 'health service', as defined under the *Health Care Complaints Act*, with the limitations discussed earlier.

Therapeutic Goods Administration⁴

Consumers can report problems they experience or are aware of in relation to medicines and medical devices to the Commonwealth Therapeutic Goods Administration. It can review therapeutic claims made about a particular health care product, including medicines and medical devices. Such review may include an assessment of relevant evidence that companies, who have registered a particular medicine or device with the Therapeutic Goods Administration, are required to hold to support these claims. If the necessary evidence is not provided, the Therapeutic Goods Administration can cancel the listing on its register. It can also issue alerts about therapeutic goods and publically inform consumers that it is currently monitoring certain medicines or devices or related claims whilst assessing its safety or the accuracy of claims.

The Commission informs health consumers about the possibility to report concerns to the Therapeutic Goods Administration, where appropriate.

Advertisements for therapeutic products in Australia

With regard to the advertising of non-prescription medicines and medical devices, an integrated system of co- and self-regulation exists under the overall responsibility of the Therapeutic Goods Administration. The standard for advertising such products to consumers in Australia is set out in the Therapeutic Goods Advertising Code⁵. In addition, there are relevant industry codes of practice.

The Therapeutic Goods Advertising Code Council⁶, which is a partnership between government and relevant stakeholders, including consumers, manufacturers and suppliers, advertising industry, media, and healthcare practitioners, is primarily responsible to ensure that the Therapeutic Goods Advertising Code is current, relevant and reflects community values and standards. The Council can make recommendations to the Commonwealth Minister for Health.

In addition, a Complaints Resolution Panel⁷ was established that deals with complaints about advertisements directed to consumers in TV, radio, the internet, newspapers, magazines, displays (except inside individual shops) and cinematographic film.

Where an advertisement is determined to contravene the relevant Therapeutic Goods legislation or Code, the Panel may request that the advertiser withdraws the advertisement; publishes a retraction or correction; or withdraws a particular claim or representation. The Panel's website includes a public register⁸ of complaints and determinations made.

In relation to advertisements directed to consumers in all other media (e.g. leaflets, brochures, catalogues, shelf talkers) and complaints about advertisements directed to healthcare professionals, there are industry complaints panels⁹ to deal with such complaints.

⁴ Relevant legislation: *Therapeutic Goods Act 1989* and Regulations 1990.

⁵ The Code can be accessed at http://www.tgacc.com.au/codeList.cfm.

⁶ http://www.tgacc.com.au/history.cfm

⁷ http://www.tgacrp.com.au/

⁸ http://www.tgacrp.com.au/index.cfm?pageID=13

⁹ (Medicines Australia - prescription medicines; Australian Self-Medication Industry (ASMI) OTC/complementary medicines; Complementary Healthcare Council (CHC) complementary medicines; Medical Industry Association of Australia (MIAA) medical devices). Information retrieved from http://www.tgacrp.com.au/

Opportunities for reform

In the following section, the Commission discusses possibilities to reform the current legislative framework that would address some of the issues identified in this submission.

Definition of a health service

Consideration could be given to broaden the current definition of a health service contained in the *Health Care Complaints Act* by introducing a more general definition of a health service.

Orders/warnings about health organisations

In relation to the provision of unsafe treatments or services, consideration could be given to providing a quicker methods of making a public warning or allow for the making of an interim warning, similar to the current power of the Commission to make interim prohibition orders concerning individual unregistered practitioner under the Code of Conduct for unregistered health practitioners.

Consideration could also be given to broaden the current power to make public warnings under s94A of the Act to include warnings about particular individuals, not themselves health service providers, as well as unethical services.

An alternative to broadening section 94A of the Act as described above could be to consider making the Code of Conduct for unregistered health practitioners applicable to health organisations that are not licensed health facilities under current legislation. This would allow the Commission to issues prohibition orders and make public statements about such organisations where it finds a breach of the Code of Conduct that poses a risk to public health and safety.

Reforming the process for investigating breaches of the Code of Conduct

The current model provides for investigation and the making of prohibition orders by the Commission. Consideration could be given to a model soon to apply in Queensland that provides for unregistered health practitioners to be prosecuted before the Queensland Civil and Administrative Tribunal. In NSW, this would mean that instead of the Commission both investigating and potentially issuing prohibition orders, the Commission would investigate such complaints and then act as prosecutor before the NSW Civil and Administrative Tribunal. This would mirror the procedures for disciplinary proceedings against registered practitioners. While the current system is reasonably effective, prosecution before an external Tribunal, holding its proceedings in public, would enhance transparency and increase public awareness about the relevant issues.

Appendix A - Relevant sections of the Public Health Act 2010

Part 7 > Division 1

99 Advertisement or promotion of health services

A person must not advertise or otherwise promote the provision of a health service in a manner that:

- (a) is false, misleading or deceptive, or
- (b) is likely to mislead or deceive, or
- (c) creates, or is likely to create, an unjustified expectation of beneficial treatment.

Maximum penalty:

- (a) in the case of an individual—100 penalty units for a first offence or 200 penalty units for a second or subsequent offence, or
- (b) in the case of a corporation—500 penalty units for a first offence or 1,000 penalty units for a second or subsequent offence.

Part 7 »Division 3

102 Provision of health services by persons who are de-registered or subject to prohibition orders

- (1) Before providing a health service, a de-registered health practitioner must ensure that:
 - (a) the person to whom the health practitioner intends to provide the health service or, if that person is under 16 years of age or under guardianship, a parent or guardian of the person, and
 - (b) if the health service is to be provided by the health practitioner as an employee, the health practitioner's employer,

are notified, in accordance with the regulations, that the health practitioner's registration under the Health Practitioner Regulation National Law or interstate health registration legislation has been cancelled, or is suspended, as the case may be.

Maximum penalty: 100 penalty units, or imprisonment for 6 months, or both.

- (2) Before providing a health service, a health practitioner who is subject to a prohibition order must ensure that:
 - (a) the person to whom the health practitioner intends to provide the health service or, if that person is under 16 years of age or under guardianship, a parent or guardian of the person, and
 - (b) if the health service is to be provided by the health practitioner as an employee, the health practitioner's employer,

are notified, in accordance with the regulations, that the health practitioner is subject to the order.

Maximum penalty: 100 penalty units, or imprisonment for 6 months, or both.

(3) A person must not provide a health service in contravention of a prohibition order.

Maximum penalty: 200 penalty units, or imprisonment for 12 months, or both.

Part 7 » Division 3

103 Advertising of health services if person is de-registered or subject to a prohibition order

(1) A person must not advertise a health service that is to be provided by a de-registered health practitioner unless the advertisement specifies that the health practitioner's registration under the Health Practitioner Regulation National Law or interstate health registration legislation has been cancelled, or is suspended, as the case may be.

Maximum penalty: 100 penalty units, or imprisonment for 6 months, or both.

(2) A person must not advertise a health service that is to be provided by a health practitioner who is subject to a prohibition order unless the advertisement specifies that the health practitioner is subject to the order.

Maximum penalty: 100 penalty units, or imprisonment for 6 months, or both.

(3) A person is not guilty of an offence under this section if he or she did not know, and could not reasonably have known, that the health practitioner had been de-registered or was subject to a prohibition order.