10 October 2014

National Registration and Accreditation Scheme
C/- Australian Health Ministers’ Advisory Council
Level 14
50 Lonsdale Street
Melbourne
VIC 3000
nras.review@health.vic.gov.au

Attention: Kim Snowball

Dear Sir,

We write in response to the Consultation paper, Review of the National Registration and Accreditation Scheme for health professions’ dated August 2014.¹

We are a group of lawyers, health-care professionals and academics who are deeply concerned about the future direction of health-care in Australia. These concerns have led us to the conclusion that the existing prohibition under s 133 of the National Law² on the use of testimonials in advertising by registered practitioners must be removed as part of delivering a new paradigm for an affordable and accessible health-care system in Australia.

In this submission we use the word, ‘testimonial’ without limiting its meaning to expressions of appreciation or esteem. Instead we use it as meaning any comment or opinion about a thing, whether positive or negative. When we refer to ‘advertising’ in this submission, we are referring not only to public inducements to use or buy health-care services or products, we also refer to any public comment by a health-care practitioner. This is in line with the extremely broad understanding about what is advertising that is adopted by the Australian Health Practitioners Regulation Agency in its publication, Guides for advertising of regulated healthcare services³. It is also in

line with the very wide control that is exercised by AHPRA over public comments by registered health practitioners in Australia.

We unequivocally endorse the need for effective, efficient and fair advertising controls in respect of health-care products and information. The interests of public safety demand this, as do the values of concern for putting people first before systems, and honesty and decency in the conduct of our public life. However, the existing prohibition on the use of testimonials under s 133 is actually harming values that herald the future of medicine.

Clinical practice is increasingly complex. This, coupled with a new and emerging focus on patient-centred outcomes, more and more is seeing clinicians and quality improvement projects taking interest in patient experience as a counter-balance to traditional interventions and priorities that are dominated by randomised trials and quantitative surveys. (‘Patient experience’ means quite simply what did receiving care feel like for the patient.) Dismissing patient experience as dubious (unreliable or invalid), instead of seeing it as an ongoing source of learning and evaluation, ignores that patient experience and scientific-based ‘credentialed knowledge’ actually do not stand in opposition but are interwoven in multiple ways. The intermingling of the two, one deeply rooted in personal (first-person) experience and the other based in scientific (or ‘credentialed’) knowledge, often suggest new and critical advancements in our understanding of illness and disease and ways of improving approaches to health-care.

The ban does not support the delivery of a sustainable health-care system that is built on the values of personal self-responsibility for the health and well-being of the individual and the community, or a health-care system in which health-care is viewed as a collaboration between government, individuals and communities and in which a good outcome is understood in terms of what is meaningful and valuable to the individual patient as distinct from clinically-defined health outcomes. These values are collecting approaches to patient safety, quality in clinical research and practice, and the free exchange of patient experiences into a new relationship. It is imperative that advertising controls in Australia foster to this new relationship in a way that will enhance (not impede) the development of a sustainable health-care system.

An essential part of enhancing a sustainable health-care system is the removal of the existing ban on the use of testimonials in advertising regulated health services in Australia. Removing the ban on testimonials, as well as nourishing the values outlined above, will also see Australia adopt the approach currently seen in the United Kingdom, where qualified use of testimonials in advertising by registered practitioners is allowed (see below).
We note that several options for change are outlined in the Consultation Paper with respect to the ban on use of testimonials. The options are:

(a) Maintaining the existing provisions;

(b) Amending the provisions preventing the use of testimonials to clarify: when comment is possible by third parties; where a statement is a testimonial or simply a review confined to non-clinical aspects; and whether the matter is about clinical and non-clinical matters.

(c) Removing the ban.

We suggest that the current provision imposing a total ban would require clarification addressing the matters noted in (b), however due to the complex nature of the problem attempting the distinctions suggested by option b) (between clinical and non-clinical matters and whether the statement is a review or a testimonial) risks introducing unnecessary uncertainty in the legal framework.

We advocate that the time has arrived for the adoption of option c), the removal of the ban under the National Law on use of testimonials in advertising regulated health services by registered health practitioners.

The current prohibition on use of testimonials does not deliver certainty about when the use of patient comments will infringe the prohibition and when will it amount to the exercise of a freedom to exchange views. Lack of certainty is unacceptable in any regulatory system. It is especially unacceptable in the context of a health-care system, which depends on the free exchange of information about patient experiences and available healthcare services and products.

The problem of uncertainty in the ban is exacerbated by the absence of any clear understanding of what exactly is a ‘testimonial’.

The Guides state that the expression, ‘testimonial’ bears its ordinary English meaning:

The National Law does not define ‘testimonial’, so the word has its ordinary meaning of a positive statement about a person or thing. In the context of the National law, a testimonial includes recommendations, or statements about the clinical aspects of a regulated health service.

[Emphasis added]
The reference to ‘clinical aspects’ in the *Guides* heightens our concerns that the testimonial ban is actually an attempt by the medical establishment to stifle challenges to its control of medicine. Careful reading suggests that the *Guides* apparently intends to differentiate between use of a ‘testimonial’ (which is prohibited) and use of a ‘review’ only commenting on non-clinical aspects of a service (which is allowed). The distinction between a ‘testimonial’ and a ‘review’ is vague. The distinction between ‘clinical’ and ‘non-clinical’ aspects of a service is equally unclear, though presumably it is concerned with aspects involving treatment and direct patient care as distinct from aspects that do not. Though even that classification is not always clear.

So understood, the aspects of a service that are allowed to be reviewed apparently are confined to non-clinical interactions with patients not actually involving the provision of medical care, and anything ‘behind the scenes’. The restraint (if properly understood) impedes the free exchange of ideas and experiences in an unacceptable way and cannot be justified.

We share the view that a central objective of effective advertising controls must be protection of the public interest. Yet it is our experience that the existing ban on testimonials goes too far, with the consequence that it operates as a gag on the free exchange of information and experiences. This threatens to stifle the emergence of new ideas and attitudes to the practice of medicine and health-care generally. It also impedes fully informed consumer choice. This latter point is of particular concern at a time when the diversity of healthcare services and products on the market means that consumers more than ever need access to all available information in making choices.

We recognize that retaining the existing ban on the use of testimonials currently finds support in different corners of medicine. In our view the ban is part of an old paradigm of medicine and scientific knowledge that is committed to stifling any challenge to its control of medicine.

We suggest that advocates of the ban on use of testimonials and old paradigm are driven by ideological adherence in a changing world to out-dated views about the nature of medicine and the place of individual experience in decisions about clinical care and medical research. It reflects an approach where doctors are seen as the ultimate authority or source of knowledge in health-care and which regards the subjective experience of individual patients as unreliable and invalid. However the assumptions of the past simply do not reflect our future, as we now set out.

Health-care in Australia is gradually but irreversibly entering a new era. This development reflects wider, far-reaching trends in society that expose gaping inadequacies in the old paradigm of medicine:

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4 Things behind the scenes would include medical billings, practice management, receptionists, Human Resources, IT, and administrative assistance.
(a) funding cuts, driven by aging populations and rising rates of chronic and lifestyle-related illness and disease, mean that sustainable health-care is increasingly understood as a collaboration between government, individuals and communities. Individuals who are better informed, and thus better able to make responsible health-care choices, are integral to the new model of healthcare.

(b) the prevailing assumptions of evidence-based medicine are increasingly under challenge. An appreciation of the multi-dimensional nature of health and well-being, in part driven by the sheer complexity of clinical practice, is gaining ascendancy, in step with a growing appreciation that there are many ways of defining what characterises medical science, adherence to rigidly narrow experimental based-approaches not being one of them.

(c) health practitioners are aware that sections of the population, especially people with a psychiatric illness, often simply do not access available treatment. The best interventions are of no assistance if people do not seek them out. Studies show that positive patient testimonials can make treatment more appealing and accessible for such people;

(d) the internet has produced a ‘flatter’ world. Information is no longer accessible only from traditional sources or authorities. People are better informed and they are better able to participate in decisions affecting them. Patient-led research is one example of this (below);

(e) the range of regulated health services available today has grown rapidly in the last twenty years. Health-care consumers today are confronted with a bewildering array of choices. Prohibitions on the use of patient comments restrict the flow of information between healthcare providers and consumers, and individuals and government that is necessary for people to be able to make informed choices;

(f) the contemporary reality is that a practitioner’s reputation is frequently influenced by their online reputation. The prevalence of doctor-review websites rating doctors, such as Healthgrades, RateMDs.com and Vitals, are features of this new online world, at present possibly more so in the United States than elsewhere, though in time, inevitably, in Australia too.


7 (See Reddy, S, 'Doctors Check Online Ratings from Patients and Make Changes', Wall Street Journal, 19 May, 2014, accessible at <http://online.wsj.com/news/articles/SB10001424052702304422704579571940584035918>; see also
testimonials limits the ability of practitioners to manage their online reputation. This is especially concerning in the face of comments posted by patients who may not be giving honest or fair assessments. Professionals who are targeted by detractors who post unfavourable reviews motivated by malice are left unable to counter the effect of negative content in light of the ban, and are often left without recourse except costly and slow legal action;

(g) advocates of the ban promote the view that testimonials are inherently misleading. This view ignores trends in medicine and health-care that recognise the importance of patient experience for clinical and quality improvement projects and the increasing importance of ‘participant-lead research’. Testimonials are not inherently misleading;

(h) there is a growing recognition that many questions that patients have are currently left unaddressed by the medicine system. Is my experience normal? Is what I’m doing working? Is there anyone else out there like me? What can I expect for the future? The exchange of patient experiences is essential to addressing these questions;

(i) where such questions have been limited to small and informal discoveries they have gone mostly unnoticed. However patients with serious conditions such as ALS or MS have begun applying such questions to the ‘sanctified realm’ of the double-blind randomized control trial. Today participant-lead research is becoming more widely accepted as a new level on the pyramid of evidence leading to a hybrid approach, whereby conventional (‘credentialed’) research can bring its objective view of a topic and its methodological rigour to the table, while patients bring their authority (expertise) in the lived experience of illness and disease, their ability to activate networks, and the authenticity of their experience in making compelling arguments for change so that true co-creation harnesses the best of what both offer;

(j) it should not seem unusual to ask whether patients are good, or even the best, judges of a clinician’s quality of care. Why shouldn’t people exchange information about the cost and value of treatment options or a physician’s care, or be able to share that a doctor has had expertise in treating like patients in

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8 See Wicks, P, ‘Patients leading the direction of clinical research’, an Interview with Paul Wicks, accessible at <http://www.biomedcentral.com/1741-7015/12/118>.
the past. Why shouldn’t people’s personal (subjective) assessment offer a reliable guide for decisions about patient care and management or research? People do know how their body feels. People are the ultimate authorities in this area.

The ban on use of consumer comments on the clinical aspects of health care services is predicated on the view they, patients and clients, have nothing reliable to say. This view is simply inconsistent with the reliance on patient reporting already seen in health research, including reporting adverse effects associated with vaccines and medicine. and the wide use of self-rated health as a measure in national and international health surveys, as a predictor of mortality in various populations. Nor is this view in line with the more recent focus on the role of subjectivity in health maintenance policies and programmes or the renewed interest in the sciences of subjectivity in health and in patient-centred care and individual needs as distinct from an evidence-based approach that necessarily focused upon general populations (not individual experience). Epstein and Street (2011) propose that this ‘debate has been laid to rest; proponents of evidence-based medicine now accept that a good outcome must be defined in terms of what is meaningful and valuable to the individual patient. Patient-centred care, as does evidence-based medicine, considers both the art of generalizations and the science of particulars.’

In this sense a patient’s perception of their care and outcomes are a valid measure for assessing clinical outcomes overall.

As Steven Lewis of Simon Fraser University has commented:

‘The distinction between a technically defined clinical outcome and the patient's perception of outcome is breaking down. Traditionally the supply side defined clinical outcomes rather narrowly - did the patient survive the procedure; was there a readmission within 30 days. But since most interventions are now designed to improve quality of life rather than save a life, the metrics have had to change. The PROMs movement - patient-reported outcomes - gives primacy to the patient experience, as it should. This doesn't mean that technical quality and safety outcomes are unimportant or that patients may or may not misperceive the results. But if informed consent is robustly applied, patients will understand the range of possible outcomes and the likelihood of cognitive dissonance between the assessments of providers and patients should diminish. Interestingly, where efforts are made to give patients the complete picture about the potential benefits and risks of procedures - e.g., through

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11 Epstein, R.M. and Street, R.L (2011) The Values and Value of Patient-Centered Care, Annals of Family Medicine, Vol 9. No.2 100-103 http://www.annfammed.org/content/9/2/100
videotaped accounts of real patients' experiences - they often change their minds about undergoing treatment. You may be aware of the famous example of the Dartmouth videos on prostate cancer surgery, where many patients decided not to proceed with surgery after learning about their peers' experiences.

There are excellent, validated scales for measuring outcomes of interest to patients - the impact of the intervention on quality of life. Based on these factors, in a truly patient-centred system, patient perception and satisfaction should not only feature prominently in outcomes evaluation, they should be dominant. The great majority of patients are perfectly content to defer to clinicians on the technical aspects of interventions as long as the probabilistic outcomes are accurately presented and address the outcomes of interest to them.12

In summary, the face of medicine is changing, both in Australia and in developed western countries. Patient testimonials can be a valid form of evaluating outcomes and providing important information to consumers and clinicians alike. It has been suggested that patients may perceive outcomes differently to clinicians, however this is not a reason to exclude their perception from what is available as consumer information. What is more, testimonials can provide a valid evidence base that gives clinicians a broader understanding of clinical outcomes.

While the public does not know the circumstances or the reliability of a particular testimonial, this is equally true of any form of advertising.

Proponents of the view that the ban on testimonials ensures that health consumers are not misled throw the ‘baby out with the bathwater’. Protecting consumers from being misled is a necessary end of any system of advertising controls. However, this can be achieved not by prohibiting particular forms of advertising (as the current ban on use of testimonials under the National Law presently does), but by prohibiting advertising that makes a false or misleading representation concerning the need for services, as the provisions of s 151(1)(l) of the Australian Consumer Law (ACL) in schedule 2 of the Competition and Consumer Act 2010 already provide.

The ban on misleading advertising under the National Law and the surrounding legal order afford health consumers adequate protection. Even if (which we reject) testimonials were inherently misleading (which they are not), the National Law prohibits misleading and deceptive advertising in any event, with the result that the testimonial ban is unnecessary and not rationally connected to the problem. Concerns that allowing testimonials will lead to a proliferation of unsubstantiated medical claims, ignore that medical or other objectively verifiable claims will engage the ban on false

12http://www.researchgate.net/post/Can_patients_judge_clinical_outcome_by_their_satisfaction_perception
and misleading statements if they cannot be supported by objective evidence or were made without any reasonable basis.

Mere expressions of opinion are not regulated by the existing prohibition on false, misleading or deceptive advertising, if the opinions are honestly held and do not claim support from conventional science or medicine and do not make medical claims or other statements that purport to be objectively verifiable. Only expressions of opinion that are not honestly held, and opinions that make claims that are objectively verifiable, but which are not true or based on reasonable material, are caught by the existing prohibition on false, misleading or deceptive advertising. Client testimonials should not be subjected to any greater control.\textsuperscript{13}

Allowing health practitioners to use testimonials in medical advertising only if the advertising was not misleading or deceptive would place responsibility for ensuring that the testimonials were not misleading with the practitioner wishing to use the testimonials in advertising. This places responsibility where it rightly belongs - on the practitioner using them.

The Consultation Paper states\textsuperscript{14} about the intent of the current advertising provisions:

\begin{quote}
The intent of the provisions is to prevent advertising that contains false and misleading information that may compromise health care choices and that is not in the public interest.'
\end{quote}

The intention of the provisions, according to the Consultation Paper, is apparently to prevent advertising of broadly two classes, firstly, advertising that 'contains false or misleading information that may compromise health care choices'; and, secondly, 'advertising that is not in the public interest'.

We do not identify any compelling 'public interest' that needs protection by means of advertising controls that are wider than the protection already afforded to consumer safety through the provisions specifically prohibiting false or misleading or deceptive advertising under the \textit{National Law}. Indeed the Consultation Paper does not identify any wider public interest.

In summary we are of the opinion that the current provisions of the \textit{National Law}, excluding the ban on testimonials, are strong enough to ensure public safety and prevent risks to consumers.

With the removal of the prohibition on use of testimonials, the \textit{National Law} would still prohibit advertising that:

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\textsuperscript{13} Cf \textit{Noone (Director of Consumer Affairs Victoria) v Operation Smile (Aust) Inc [2012] VSCA 91}.  
\textsuperscript{14} Snowball, K, Review of the National Registration and Accreditation Scheme for health professions, Consultation Paper, dated August 2014, p24.
\end{flushright}
(a) Is false, misleading or deceptive, or is likely to be misleading or deceptive;

(b) Offers a gift, discount or other inducement to attract a person to use the service or business, unless the advertisement also states the terms and conditions of the offer;

(c) […]

(d) Creates an unreasonable expectation of beneficial treatment;

(e) Directly or indirectly encourages the indiscriminate or unnecessary use of regulated health services.

The advertising controls under the National Law do not operate in isolation

The National Law is not the only applicable regime regulating false and misleading advertising and the use of testimonials. In fact the advertising controls under the National Law overlap with advertising controls established, for example, under provisions of the ACL in schedule 2 of the Competition and Consumer Act 2010; chapter 5 of the Therapeutic Goods Act 1989; and state Fair Trading Acts.

The controls in the National Law largely mirror provisions of s 151 of the ACL, with the exception of the ban on use of testimonials under the National Law which does not find a counterpart in the provisions of the ACL.

The mirror provisions of the ACL do include prohibitions in connection with advertising the supply or use of goods or services that involves:

(a) Making false or misleading representations that goods or services are of a particular standard or quality [para (a)];

(b) Making a false or misleading representation that purports to be a testimonial by any person relating to goods or services [para (e)];

(c) Making a false or misleading representation concerning a testimonial by any person; or a representation that purports to be such a testimonial relating to goods or services [para (f)];

(d) Making a false or misleading representation that goods or services have uses of benefits [para (g)];

(e) Making a false or misleading representation concerning the need for any goods or services [para (l)].

Offering rebates, gifts and prizes in connection with advertising the supply or possible supply of goods and services is also regulated by the ACL: s 154.
However, the ban on the use of testimonials under the National Law goes further than the ACL. Yet there is no indication that the powers under the ACL are ineffective in regulating misleading medical advertising or advertising using testimonials. Indeed, experience is to the contrary.

The provisions of the ACL are already effective in controlling the use of false or misleading testimonials, as shown by the decision of the Federal Court in ACCC v P & N Pty Ltd [2014] FCA 6, where the Australian Competition and Consumer Commission (ACCC) successfully prosecuted a supplier of solar panels, that had marketed its products in conjunction with testimonials that were purportedly by retail customers when in fact it did not have any such customers.

More generally, the ACCC is vigilant, and effective, in regulating misleading and deceptive advertising of healthcare services, especially in the direct-to-consumer segment, as is apparent from the Federal Court’s decisions in:

(a) ACCC v Francis [2004] FCA 487, where the ACCC successfully prosecuted a party advertising a moulded plastic ear device which represented that use of the device for ‘just a few minutes a day eliminates craving for food’;

(b) ACCC v Allergy Pathways Pty Ltd [2011] FCA 74, where the ACCC successfully prosecuted a group that advertised it could test for allergens and cure or eliminate virtually all allergies using ‘muscle testing’;

Most recently, action taken by the ACCC against breast imaging providers, Safe Breast Imaging Pty Ltd (SBI) and Breast Check Pty Ltd (BC), for falsely representing that breast imaging using their devices could provide an adequate scientific basis for assessing whether a woman may be at risk from breast cancer and, if so, the level of such risk and that there was an adequate scientific basis for using their devices for breast imaging as a substitute for mammography, resulted in hefty fines totalling $250,000 and a banning order imposed on SBI and its director. (BC is yet to be dealt with in the courts.)

AHPRA is not acting alone. Frequently the ACCC conducts public awareness campaigns in concert with other relevant industry bodies. In recently taking action

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17 ACCC v Safe Breast Imaging Pty Ltd (No 2) [2014] FCA 998
against Safe Breast Imaging \(^{19}\) and Breast Check \(^{20}\) the ACCC issued a joint press release with Cancer Council Australia and the Therapeutic Goods Administration.

At the moment, the overlapping advertising controls under the *National Law* and the surrounding legal order can operate inconsistently and unfairly. This is particularly so in relation to the ban on testimonials under the *National Law*.

For example, the publisher’s defence under s 251 of the *ACL*, which is available to a person whose business it is to publish or arrange for the publication of advertisements, while available if proceeded against for an offence under s 151(1)(f) of the *ACL*, is not available if prosecuted for an offence under s 133 of the *National Law* even though arising out of the same matter. Significant reforms have been achieved in harmonizing the *ACL* and state fair trading legislation. The regimes now operate effectively and in a coherent way. Reforms are needed to harmonise the advertising controls under the *National Law* with the *ACL*. This is best achieved by removing the ban on use of testimonials under the *National Law* and inserting new provisions that correspond with s 151(e), (f) and (g) of the *ACL*.

Otherwise, the way to do this is simply to remove the ban on advertising under the *National Law*. The remaining prohibitions on false and misleading advertising under the *National Law* and the *ACL* are adequate.

**Other regulatory models are available**

If the ban is not lifted entirely, other regulatory models are available.

Thus, the US Securities and Exchange Commission, Division of Investment Management issued guidelines, *Guidance Update*, dated March 2014. The new guidelines permit investment advisers to publish public comments about their services that are posted on third party websites as long as they have no connection or influence over the review site and publish all the comments, both positive and negative. Whether this represents any advancement on the existing legal order is doubtful. Promotions that would accord with the *ACL* and the *National Law* would need a balanced use of testimonials (and include both testimonials that are favourable and less favourable) if they were to avoid contravening the prohibition on misleading and deceptive advertising. In any case, uncertainty will always exist in any particular case whether a practitioner has inadvertently contravened the prohibition by failing to post all comments.

**A suggested way forward**


The United Kingdom


**Testimonials**

These may be used in advertising but any statements must be in line with the indication for traditional use and must not suggest that the product has proven efficacy. Similar concerns arise as for references to clinical studies above and it would be very difficult to include testimonials that make personal efficacy claims for a THM product in brief advertisements because of the potential to mislead. In a more detailed piece such as a website, MHRA takes the view that it may be possible to include a genuine factual testimonial based on personal use. Any testimonial must be clearly set in the context that the product is a traditional remedy and it must be explicitly stated that this represents one person’s experience and the efficacy of the product has not been proven.

We suggest that the UK approach is sensible, but actually is already covered by the prohibition on false or misleading advertising.

The approach in the UK finds similarities with the approach in Canada.

Canada

In Canada, use of testimonials in advertising non-prescription drugs and natural health products is allowed, as long as the claims do not exceed the product’s terms of market authorization (or TMA).\(^2\)

The Canadian guidelines state:

**2.29 Testimonials / Quotations (See also: "2.7 Endorsements / Seals")**

**Guideline**

An advertisement must not be misleading by using a testimonial or quotation to state or imply a benefit that exceeds a product’s TMA.

**Application**


• Testimonials are acceptable, provided the claims do not exceed the product's TMA.

Example Product Y Echinacea

Indication / Use: Traditionally used for the relief of sore throat due to colds

Acceptable Claim: "Product Y Echinacea is traditionally used to relieve sore throats due to colds. Product Y contains Echinacea. It worked for me!"

Unacceptable Claim: "I tried Product Y Echinacea and I just couldn't believe the results. It was amazing! It's made my immune system stronger than ever"

Conclusion

In summary, we are of the opinion that the current provisions of the National Law, are strong enough to ensure public safety and prevent risks to consumers, without the current ban on the use of testimonials in advertising by registered practitioners.

Yours Truly,

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