The Australasian College of Cosmetic Surgery
Raising Standards, Protecting Patients

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VIA EMAIL

Re: Medical Board of Australia, Consultation – Registered medical practitioners who provide cosmetic medical and surgical procedures

Executive Summary

The Australasian College of Cosmetic Surgery welcomes the opportunity to provide comment on the Medical Board of Australia's Consultation on Registered medical practitioners who provide cosmetic medical and surgical procedures.

The ACCS shares many of the concerns that prompted the series of national consultations, which began with the 2010 Inter-Jurisdiction consultation, and some of the proposals presented in the current consultation, which would provide additional guidance for practitioners working outside of any of the medical colleges that already provide similar guidance, to better protect patients.

These concerns are particularly germane in the context of Cosmetic Medical Practice, where, due to the elective and largely self-referral nature of these procedures, there is a far greater need to ensure that patients seeking such services have the necessary information in order to make informed decisions.

The College believes that the Consultation paper makes an important contribution towards improving regulation of cosmetic medical and surgical procedures, and is of the view that most of the recommendations contained in it, including most of the draft guidelines (ie "Option 3"), should be supported, with the noted caveats, reservations and objections that are discussed more fully below. The College also believes that more should be done to provide consumer education, as stated in Option 2.

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- The College's primary concern is the lack of attention to the development of national standards of education, training and accreditation as recommended in the 1999 NSW Cosmetic Surgery Report (*Cosmetic Surgery Report*). Without such national standards, the Medical Board is left with few options but to consider, as it has, prescribing procedure-specific rules for medical practitioners – an undertaking that is potentially limitless, usurps medical judgement, may inhibit efficiency and best practice, and for which the College believes the Medical Board is not well suited.

- The College is concerned that the Board has not attempted to establish a case, as required under COAG guidelines, for the proscription on the use of telemedicine in cosmetic medical practice. Although the College does have strong concerns about the abuse of remote prescribing, the College believes that further consultation and investigation on the use of telemedicine issue is required before regulation, beyond the existing telemedicine guidelines that apply to all health care practitioners, is considered.

- The College is also concerned that the Board appears to undervalue the role of college or association codes of practice. College and association codes assist in several ways. First, the Medical Board has finite enforcement resources, and there is a question, particularly in view of fiscal restraint, that the Medical Board may not have the resources to properly enforce new guidelines. According to its latest annual report, the Board fielded more than 6,000 complaints, while the NSW HCCC received some 5,000 complaints and undertook 300 formal investigations. As the ACCC has noted, organisations act as deputies to assist regulators to raise standards by enforcing their own codes of practice. Second, codes are admissible as evidence of professional standards in proceedings by the HCCC against health practitioners whether or not they are members of a particular college or professional association.

- The College believes that more effort can be applied to consumer education, as alluded to in Option 2. This can be done collaboratively, between government and stakeholders, as has been recommended by the Consumers Health Forum and the College.

- The lack of a recognised pathway to measure the quality and relevance of a medical practitioner's qualifications specifically for cosmetic medical and surgical procedures applies to all medical practitioners, whether or not they hold an existing recognised specialist title, and is discussed below.

Rather than answer each of the consultation paper's questions, the College prefers instead to focus on the areas where it has concerns, reservations or objections.

Background

The primary goal of the ACCS is to ensure the safe provision of cosmetic medicine and cosmetic surgical procedures to the Australian general community through the supply of appropriately trained and certified health care practitioners.

Established in 1999, the ACCS is a not-for-profit, multi-disciplinary fellowship based college of general surgeons, cosmetic surgeons, plastic surgeons, maxillofacial surgeons, cosmetic physicians, dermatologists, ear nose and throat surgeons, ophthalmologists, general practitioners and other doctors who practice in cosmetic medicine and surgery. The College also admits nurses as affiliate members.

The factor which unifies this divergent group of medical practitioners is that they all need to obtain additional specialised education, training and experience beyond their original area of practice or postgraduate specialisation before becoming competent in cosmetic medicine and surgery ("Cosmetic Medical Practice").

The ACCS is the only medical college which provides education and training leading to fellowship specifically in cosmetic medicine and surgery. Fellows of the College are medical doctors who have completed post-graduate education and training and demonstrated competency specifically in cosmetic medicine and surgery. To become an ACCS Fellow, doctors must typically complete a minimum of 12 years of medical and/or surgical education and training.

The College also seeks to work cooperatively with government and other stakeholders to improve standards and safety and to educate health care consumers. Its fellows and spokespeople are regularly quoted in the media and consulted by federal and state health and consumer regulators. As the Medical Board is aware, the College has advocated for reform and acted to improve standards and patient safety.

The College was the first medical College to establish a code of practice authorised by the Australian Competition and Consumer Commission in 2009. Many of the provisions of that code, now in its third version after a recent review, are also now reflected in the 2010 National Law, the Medical Board's health advertising guidelines and the proposed new draft guidelines.

Additionally, the College or its fellows have been asked to advise state and federal health ministers, regulators, coroners, and health care complaints commissions. The College also played a key role advising the Commonwealth Minister for Health, the Chief Medical Officer and the Therapeutics Goods Administration on the response to the PIP breast implant recall and, subsequently, is working with Monash University and other stakeholders set up an effective breast implant device registry. The College has also been working with the TGA to roll out a cosmetic injectable public information resource on the Commonwealth Government's HealthInsite website, and is working with a national health accreditation organisation to develop a set of cosmetic practice specific facility accreditation standards.

Since the seminal *Cosmetic Surgical Report*, chaired by former Health Care Complaints Commissioner Marrilyn Walton, the College has provided more than a dozen written submissions to federal and state governments and regulatory agencies in response to major public consultation papers and requests for expert advice or opinion on matters which directly or indirectly concerned Cosmetic Medical Practice. These submissions include:

- Minister of Health (Queensland) regarding proposal to restrict use of title of "Surgeon", January 2002.
- Medical Practitioners Board of Victoria regarding Draft Advertising Guidelines for Registered Medical Practitioners, August 2007.
- Queensland Health regarding regulation of teenage cosmetic procedures, November 2007.
- NSW Health regarding regulation of advertising of cosmetic medical and surgical procedures, December 2007.
- Senate Community Affairs Committee Inquiry: The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants, April 2012.
- Australian Medical Board's "Draft supplementary guidelines on cosmetic medical and surgical procedures for *Good Medical Practice: A code of conduct for doctors in Australia*", May 2012.
- ACCS response to the "Australian Commission on Safety and Quality Health Care (ACSQHC) *Australian Open Disclosure Framework – Consultation Draft*", August 2012.
- Australian Commission on Safety and Quality in Health Care device registries consultation paper", November 2012.
- AHPRA regarding advertising guidelines, use of social media and mandatory notifications , May 2013
- Dental Board of Australia regarding dental scope of practice and use of botulinum toxin for cosmetic medical treatments, June 2013.
- Australian Health Ministers Review of the National Registration and Accreditation Scheme for health professions, August 2014.

As in the present case, the College has welcomed the opportunity to contribute to those consultations. Although some of the issues have been revisited, each consultation provides another opportunity to make the case for improved standards and patient safety in a variety of discreet areas of practice such as advertising or informed consent.

However, the College believes that the best way to achieve the goals set out by the Medical Board, along with other objectives, is through a recognised comprehensive set of national standards of education, training and credentialing of the developing specialty of cosmetic medical practice, either though specialty recognition, endorsement of an area of practice, or through a national council such as proposed by the *Cosmetic Surgery Report*.

The Problem

The number of Australians seeking cosmetic medical and surgical procedures has increased dramatically in the decade-and-a-half since the *Cosmetic Surgery Report*. Certain areas of Cosmetic Medical Practice such as Botulinum toxin injections are growing at 20 per cent per year. Recent market information provided to the College by manufacturers and suppliers suggests previous College estimates of $1 billion spent annually in Australia on cosmetic medical and surgical treatments and procedures may be too conservative.

However, regulation has not always kept pace with this growth. The College agrees with many of the Board's stated problems – there is inappropriate advertising and there is confusion in the community about titles, memberships and qualifications, which adversely impedes informed consent, leading in some cases to rushed decisions, and there is a need for a national approach. This is very relevant in the case of elective procedures such as cosmetic medicine or surgery, where the harm caused to a patient may be that their expectations have not been realised as result of the procedure they have had.

Plastic and Reconstructive Surgery, properly so called, has two core aims related to the restoration of form (the aesthetic component) and function, this specialty is taking something "abnormal" and trying to recreate "normality". As such, less than ideal outcomes are sometimes to be expected and accepted. No such leeway exists in cosmetic medical practice where *primum non nocere* requires that any normal patient seeking discretionary cosmetic procedures has higher expectations as to the likely outcome and there should be careful consideration of the rationale for the requested procedures so as to do no harm, both physically or psychologically – by having a discontented patient who failed to realise unrealistic expectations.

Advertising and promotional activities can inform but may also mislead and interfere with informed consent, and has the potential to have adverse consequences for patients when it is false, misleading or deceptive, leads to the provision of inappropriate or unnecessary health services or creates unrealistic expectations. There is therefore a higher ethical standard which applies when cosmetic medical or surgical procedures are being considered, which impacts how advertising, informed consent, and clinical assessment are approached. The College believes that informed consent is a paramount concern in considerations for regulatory change within Cosmetic Practice. Changes should emphasise that information about the services provided by health practitioners is accurate and appropriate.

Properly presented information, which includes information or reference to adverse events, practitioner training and experience, however, can play a useful role to inform health consumers so that they have additional necessary information to make decisions about their own health care. As the Australian Competition and Consumer Commission has noted:

> "There is a public benefit in each medical practitioner being permitted to distinguish his or her services from another's to the fullest extent. This benefit takes the form of consumers receiving accurate, relevant information and so being better placed to make more informed decisions in their dealings with medical professionals."[1]

In this respect, the College has put a very strong emphasis on the importance of appropriate advertising, patient communication and informed consent. In 2009, the College developed a Code of Practice, which was the first medical practitioner code to be authorised by the ACCC. The Code, which was authorised after extensive public stakeholder consultation, covers among other things, advertising and other promotional conduct, informed consent guidelines, monitoring of the code and an extensive governance regime.

Although the Code's authorisation was opposed by ASPS, which had the time did not have its own code, the College's Code has provided cosmetic medical consumers with an additional layer of protection and it requires all College members to meet strict standards – stricter in some areas than that required by the *National Law* – and provides an additional pathway for patient redress.[2]

The additional guidelines, as presented in the consultation paper ("Option 3"), mirror or build upon many of these provisions and will provide additional guidance for practitioners and information for patients, although the College has some concerns, reservations and objections.

The missing elephant: national standards of education, training and accreditation

The draft guidelines ("Option 3") go to practitioner medical judgement. Medical judgement is informed by a matrix of legislation, regulation, guidelines, ethics, practice codes, education, training, competency and experience, which all play a vital role. A heavy reliance on prescriptive practice regulation, particularly at the procedural level, cannot alone improve professional standards. In that sense, the College believes that the consultation paper is, in part, misguided.

Without a greater emphasis on national standards of appropriate, relevant education and training, the emerging specialty of Cosmetic Medical Practice will continue to grow substantially, and, with it, the incidence of the types of problems identified in the consultation paper, as greater numbers of medical practitioners work outside of any recognised training and accreditation regime.

Australian health consumers will be best protected and better equipped to make informed decisions if they are able to choose medical practitioners who have undergone appropriate, relevant training, assessment and accreditation specifically in Cosmetic Medical Practice.

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1 ACCC comments on proposed revision of advertising guidelines, Commonwealth of Australia 2007.
2 The College's Code of Practice may be found on the College's website, at: http://www.accs.org.au/pdf/accs_code.pdf

There are at least three ways that relevant national standards of education, training and accreditation for Cosmetic Medical Practice can be developed in Australia.

1. Recognition of cosmetic medicine and surgery as a medical specialty, which would establish national standards against which any university or medical college training program could apply to have its standards accredited.

2. Approval for cosmetic medicine and surgery as an area of endorsement for medical practitioners.

3. Establishment of a national "Cosmetic Surgery Credentialing Council" of key stakeholders to develop and promulgate national standards of education, training and accreditation.

While is it true, as the Medical Board notes, that under the *National Law*, the Ministerial Council decides which areas of medical practice should be recognised as a specialty or approved for endorsement as a practice area, the Medical Board has a key advisory role, which can be undertaken in response to external groups, or *on its own initiative*.[3]

As the College has argued, Cosmetic Medical Practice is a well-defined, distinct and legitimate area of medical practice with a sustainable base in the medical profession – larger than many existing recognised specialties – and, taken as a whole, is capable of sustaining education, training and accreditation.

Some form of practice recognition or the establishment of a credentialing council, which includes cosmetic medical and surgical procedures, will provide clarity for consumers so that they can make informed choices. National standards of education, training and accreditation will enable any College or medical educational facility to apply to have their training program, qualifications and accreditation processes assessed.

As the former President of the British Association of Aesthetic Plastic Surgeons (BAAPS) and the European Societies of Aesthetic Plastic Surgery (EASAPS) Dr Nigel Mercer put it:

> *"There is no registerable qualification in cosmetic surgery anywhere in Europe or America, and that needs to change. There are no specialties recognised in law such as 'Facial Plastic Surgery' or 'Cosmetic Surgery'. The cosmetic surgery industry is a child of the 80s and 90s, and the law has been left behind in the last century, failing to keep pace with regulation and training."* [4]

3 Approval of Specialties under section 13 of the Health Practitioner Regulation National Law Act, Guidance for the National Board submissions to the Australian Health Workforce Ministerial Council, 29 July 2014. Such an initiative would allow for an assessment of the case for recognition by assessing the entire supporting base and training capacity of all Colleges which may wish to provide relevant specialist training.
4 Mercer, Dr Nigel, "Spin doctors create God complexes", Australian Advanced Aesthetics, Feb. 2010, p. 16.

And only as recently as 26 May 2015, the Royal College of Surgeons of England (RCSE) stated:

> *The (RCSE) will introduce a new system of certification to identify those surgeons that have the appropriate skills and experience to provide cosmetic surgery. However, enforcing the requirements will be difficult unless the GMC is given a new power to formally recognise these qualifications on the medical register. Without this change in the law, patients and employers will not always be able to tell a proficient cosmetic surgeon from a professional who has limited recognised experience in the specific procedure…*
>
> *Mr David Ward, Consultant Plastic Surgeon and Vice President of the Royal College of Surgeons, said:*
>
> *"It is a booming industry and the public must be able to check whether a surgeon is appropriately trained before consenting and paying for a procedure. This change in the law forms a vital part of our plans to improve standards in cosmetic surgery."*[5]

Unfortunately, in Australia there is as yet no government recognised training standard in Cosmetic Medical Practice against which medical practitioners can be assessed and qualified. As the Medical Board is aware, the College has applied to the Australian Medical Council to have cosmetic surgical and medical procedures recognised as part of a new medical specialty of Cosmetic Medical Practice, which would allow for establishment of a national standard for education and training of all doctors wishing to practice in the area.

The College notes that the Medical Board's consultation paper states that "Plastic surgery includes both cosmetic surgery and reconstructive surgery". Although it is true that many specialist plastic and reconstructive surgeons practice cosmetic surgery – some part-time, some full-time – the Australian Medical Council has never assessed or formally recognised cosmetic surgery as part of plastic surgery. The UK National Confidential Enquiry into Patient Outcome and Death (2010),[6] has also warned that "The present reliance on inclusion on the specialist register does not give [a patient] any assurance that a surgeon has received adequate training in cosmetic surgery".

Indeed, the only mention of cosmetic surgery in any AMC assessment of the Royal Australasian College of Surgeons (RACS) education and training program was in 2002, when the RACS Board of Plastic and Reconstructive Surgeons was quoted conceding that it was merely endeavouring to expose some of its trainees to cosmetic surgery as well as the specialty of maxillofacial surgery.[7]

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5 "RCS calls for new powers to protect cosmetic surgery patients," media release, 26 May 2015 https://www.rcseng.ac.uk/news/rcs-calls-for-new-powers-to-protect-cosmetic-surgery-patients#.VWT2Acsw-Ul

6 "The National Confidential Enquiry into Patient Outcome and Death (2010): On the face of it", p. 5.

7 "Accreditation Report: Review of the education and training programs of the Royal Australasian College of Surgeons", Specialist Education Accreditation Committee, Australian Medical Council, 2002 , p 21.

That such an aspirational statement to the AMC was made contemporaneously to public claims by the Australian Society of Plastic Surgery (ASPS) that plastic surgeons were comprehensively and universally trained in cosmetic surgery, should inform assessment of subsequent ASPS claims about training and standards.

Although Cosmetic Medical Practice (encompassing cosmetic medicine and surgery) is a distinct, well-defined medical and surgical discipline, historically, there has been a multi-disciplinary development and provision of the techniques and technologies involved in cosmetic surgery and cosmetic medicine. No existing specialty can claim cosmetic medicine and surgery as solely its own domain. Indeed, there are few if any areas of traditional, ie therapeutic, plastic and reconstructive surgery that are not also addressed by other medical practitioners even though they may not call themselves "Specialist Plastic Surgeons", eg dermatological, general, gynecological, maxillofacial, ophthalmological, orthopedic and and podiatric surgeons.

The ACCS defined Cosmetic Medical Practice as:

> *Operations, procedures and treatments that revise or change the appearance, colour, texture, structure or position of normal bodily features with the sole intention of improving the patient's appearance or self-esteem.*[8]

Cosmetic Medical Practice is distinct from other specialty areas such as plastic and reconstructive, dermatology or general practice – whose members may also perform cosmetic procedures – in that no defined medical abnormality need be present. In that sense, the proposed specialty is *sui generis* among all medical specialties.

Cosmetic Medical Practice uses non-invasive and invasive procedures to enhance an individual's appearance according to the patient's own subjective criteria. As has been seen with the development of other specialties, the provision of invasive treatments will increasingly be provided by providers with a non-surgical background. Gastroenterology, radiology and cardiology are all examples of this. New techniques such as tissue engineering, fat cell transfer, lipomodelling and the placement of permanent and semi-permanent filler materials are some current examples of a similar evolution.

The success or otherwise of treatment is judged by whether the patient's expectations have been met. This is also different from all other areas of medicine, where objective outcome criteria such as morbidity and mortality rates exist. Uniquely, the majority of cosmetic patients, do not have any pathological condition or, as in obstetrics, a condition which is potentially so. But they require careful physical and psychological assessment by an appropriately trained and experienced

8 Adapted from definition adopted by the UK Department of Health. Expert group on the regulation of cosmetic surgery: report to the Chief Medical Officer, January 2005, p. 3. And see e.g. Provision of cosmetic surgery in England: Report to the Chief Medical Officer Sir Liam Donaldson, 2004.

practitioner in order to determine if they are likely or not to benefit from a proposed course of treatment.

To take some examples, it is suggested by some plastic surgeons that there is essentially no difference between reconstructive breast surgery and cosmetic breast augmentation; that the surgical techniques are the same and it is simply a matter of performing the surgery on both sides instead of usually one in reconstruction patients. This argument is false. Based on an over-simplification, it reveals the deficiencies in the understanding of, and the need for, a specialised holistic approach to best practice cosmetic breast augmentation.

Reconstructive breast augmentation is usually performed on patients who have had all or part of one breast removed for breast cancer. The surgery aims to provide a cosmetically acceptable breast which approximates in size to the unaffected side. In other words, the surgery is being performed to *restore* a surgically disfigured breast to as near *normal* as possible in a person who has disease. A breast implant may be used for this but commonly tissue is recruited from the back or abdomen and relocated to the breast area. This is because in many patients it is not possible to achieve an acceptable appearance or feel of the breast by having a unilateral implant. These reconstructive techniques are not used in cosmetic breast augmentation.

In contrast, patients requesting cosmetic breast augmentation are seeking a *change* in the appearance of their already *normal* breasts. They are healthy individuals who are seeking a surgical procedure to alter their natural appearance. Both groups of patients are vulnerable, but in very different ways. Cosmetic patients are exposing themselves to completely avoidable surgical risks, have higher expectations and a lower tolerance for complications and, in some patients, a low tolerance of even minor imperfections. The success or otherwise of a cosmetic procedure is not determined by objective criteria as in other forms of surgery but only by whether or not the patient's expectations have been met. The breast cancer patient of course wants the best aesthetic result she can get but her motivations, expectations and tolerance of complications or imperfections are vastly different.

Essential, and unique, to the proper management of the patient seeking cosmetic breast augmentation is a specialised assessment of the patient's desires, expectations, understanding of the limitations of implant surgery and their ability to deal with an adverse outcome. Competence to make such an assessment accurately and appropriately advise the cosmetic patient can only be developed through specialised training and specific experience. The surgical options and decision-making are also different compared with reconstructive surgery. Although there is of course some overlap of the surgical skills required, as there is across any of the recognised surgical specialties, the knowledge and judgment needed for safe cosmetic practice is substantially different.

For example, reconstructive breast surgery is typically performed on patients who have had their breast tissue removed. Sub-muscular placement of an implant (if indeed an implant and not a flap reconstruction is being used) is mandatory to adequately disguise the implant. In contrast

cosmetic patients may get an optimal result with either sub-muscular placement of their bilateral implants or sub-glandular placement, or a dual plane approach depending on the nature and shape of their existing breast tissue. The avoidance of the complication of double bubble or double fold complication in cosmetic patients requires specialised planning and operative techniques which are not relevant in the reconstructive patient. Another example - many cosmetic patients seek to maximise the lifting effect from breast implant surgery while avoiding the extra risks and scarring of a formal breast lift. Again proper planning and specific surgical techniques unrelated to reconstructive surgery can help many such patients.

This is, in part, why surgeons who specialise in cosmetic breast augmentation frequently see avoidable adverse outcomes when surgeons who are specialists in reconstructive surgery have misapplied those skills, erroneously extrapolating them to cosmetic surgery without the appropriate specific additional education, training and experience.

A further example specific to the Australian context is instructive. Cosmetic breast augmentation is performed on well patients as day surgery. The minimisation of recovery period is very important for such patients who want and expect their lives, in particular their time away from work, disrupted as little as possible. When a rapid recovery technique for the procedure was introduced to Australia by a Fellow of the ACCS, the representative body for reconstructive surgeons publically dismissed it arguing that there was no surgical technique which could reduce recovery times and to suggest otherwise was potentially harmful. The technique is now widely used throughout Australia and it is patients who are the beneficiaries.[9]

In the example of eyelid surgery (Blepharoplasty), there is again an entirely different paradigm in assessing and managing this operation because of a functional or disease related circumstance versus a purely cosmetic one. For instance, a skin cancer BCC on the lower eyelid has a completely different imperative than a cosmetic improvement of the lower eyelid which may require a combination of surgery, laser treatment and filler injections to achieve the preferred result. Most commonly, these particular treatments or combinations do not feature in management of a BCC. This is quite different to trying to achieve an “aesthetic” result with a skin cancer reconstruction.

Lipoplasty (more commonly referred to as Liposuction), invented in 1974 by Italian gynaecologist Dr Giorgio Fischer, was later refined by French physicians Yves Illousz and Pierre Fournier. Early Lipoplasty was performed under general anaesthesia with its special attendant risks. American dermatologist Dr Jeffrey Klein developed the process of tumescent anaesthesia in lipoplasty, using large volumes of dilute lignocaine in normal saline solution. Tumescent anaesthesia (first

9 It should be noted further that had the ACCS not existed to provide alternative advice to the Commonwealth Government during the PIP breast implant crisis, and the Government had simply accepted ASPS’s initial recommendation for mass, asymptomatic explantation, thousands of Australian women would have suffered avoidable harm or have been subjected to unnecessary risk and all potentially at great economic cost to the Commonwealth and states as anticipated complications arose.

presented at a scientific meeting in Philadelphia in 1986) is today overwhelmingly the most popular method of lipoplasty because it offers much greater safety for patients than other methods. The first publication of the tumescent technique was in the American Journal of Cosmetic Surgery in 1987.[10]

Botulinum Toxin has become a household word in cosmetic practice as "BOTOX®". This derivative of a refined bacterial toxin was first used in the management of strabismus and facial tics. In 1991, Drs Alistair and Jean Carruthers (Canadian Ophthalmologist and Dermatologist) presented the first paper on the cosmetic use of Botulinum toxin. Botulinum toxin therapy, for the functional problem of spasm of the periocular muscles, or torticollis in the neck, is entirely different to the cosmetic application of Botulinum toxin to reduce wrinkles or to reshape the eyes, eyebrows, and face more generally. The required understanding of the anatomical and functional responses of muscles and other tissues to botulinum toxin combined with a taught appreciation of aesthetics is a wholly different skill-set.

And facelift surgery is clearly overwhelmingly cosmetic in application and purpose. The closest approximation in reconstructive surgery would be perhaps in restoration of burns injuries or management of skin cancers. Again, this requires a wholly different skill-set and appreciation of cosmetic surgery.

This rapidly growing specialty area now involves cosmetic surgical intervention, non-surgical cosmetic intervention and the application of the evolving technologies associated with pharmacological approaches and regenerative medicine. These areas frequently overlap and are usually involved in a holistic multiple technique approach applied to meet patient goals.

While there is a broad spectrum of views about the value or merits of cosmetic procedures, the widespread and continuing growth of the specialty throughout the Australian community is an evident fact: men and women have and continue to exercise their consumer sovereignty to obtain the services provided by cosmetic medical and surgical practitioners and others. The key issue is how best to ensure high standards of care and patient safety.

As the 2004 National Health Workforce Strategic Framework noted:

> *Empowered consumers will demand to know more about the treatments proposed for them, their effectiveness and the track record of the practitioners involved in their diagnosis, testing and treatment… this will affect the management of knowledge and the development of procedures, protocols and guidelines for effective safe care… the workforce imperative is for up to the minute knowledge and skills and therefore an education and training environment that effectively*

10 AJCS 1987, vol 4, 263-267.

> *imparts, and promptly updates, this information. Consumers are also likely to seek out the most advanced, safest, lowest cost care options.*[11]

The Australian Competition and Consumer Commission (ACCC) has also expressed the view that consumers should be able to receive accurate and relevant information in order to make informed decisions in their dealings with medical professionals.[12]

Australian consumers would be better protected and more able to make informed decisions if they were able to choose practitioners who have undergone training, assessment and accreditation specifically in Cosmetic Medical Practice. A comprehensive set of national standards of education, training and competency will provide clarity for health care consumers so that they can make informed choices. Most importantly, such training will also improve standards of care, but national education and training standards remain an unrealised opportunity to improve those standards.

Remote prescribing and nurse injectors

Remote or technology-based diagnoses and treatment using telemedicine technology has been employed in Australia for several years. Specialist Dermatologists use telemedicine to consult and diagnose skin cancer, for example. Specialist Psychiatrists use telemedicine to diagnose and treat patients. Other areas of medicine also make increasing use of telemedicine in a variety of clinic contexts.

There are many patients in Australia who live in rural and regional areas who may rely upon telemedicine, including in the cosmetic context, to consult with their doctor who prescribes for a cosmetic nurse injector. And the College has consulted with large cosmetic practices and clinics that use this technology. Although the College has not undertaken widespread consultation, there examples where telemedicine appears to being used with specifically developed protocols and auditing practices.

Remote treatment, usually involving assessment for Botulinum toxin injection, in the Australian cosmetic context should be done in a team health care arrangement with a trained cosmetic physician and cosmetic nurse. The College provides training to doctors and nurses and has in place a cosmetic nurse diploma training program, and, recently, released a draft cosmetic nursing standard – the first of its kind in Australia. The College has considered developing a telemedicine module.

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11 Australian Health Ministers' Conference (2004), National Health Workforce Strategic Framework, Sydney, April 2004, p 11.

12 See e.g. ACCC comments on proposed revision of advertising guidelines [by the Medical Practitioners Board of Victoria], 2007 www.accc.gov.au/content/index.phtml/itemId/796393/fromItemId/7126

Currently, the College's cosmetic injectable prescribing protocol, developed in consultation with the NSW Health Care Complaints Commission and the Pharmaceutical Services Branch, states that nurses may give S4 substances such as Botulinum toxin to a patient if a doctor is not present so long as the patient has been properly assessed and reviewed by a doctor who has provided a written prescription or written orders for that patient and is under the supervision of a doctor.

Nurses may not supply S4 drugs and doctors may not resell or redirect S4 purchases made by them to nurses or others. Controlled drugs may not be ordered in a doctor's name and delivered to unauthorised third parties, drugs should be properly labelled with the patient's name, and stock should be properly secured.

As part of its protocol, the College reminds its doctors that they are responsible for ensuring that every step, from purchasing and ordering, to storage and patient administration, is controlled and documented properly. The College also reminds its members that they should ensure that they observe the Medical Board's *Guidelines for technology based patient consultations*, the *Good Medical Practice: A Code of Conduct for Doctors in Australia,* and the College's *Code of Conduct* as well as other relevant legislation and regulation.

Of more immediate concern to the College are instances where doctors are not seeing patients whatsoever, whether in the next room or further away, nurses who may be administering without proper supervision, or S4 drugs which are not being properly obtained, controlled or supplied. These and other concerns were raised by the College and other stakeholders at the February 2014 College-hosted Injectable safety roundtable attended by the Medical Board, state departments of health, the NSW HCCC, the Pharmaceutical Services Branch, the TGA, manufacturers, insurers, and other medical colleges and organisations.

The Medical Board's consultation paper notes that the UK GMC has stated that doctors must undertake a physical examination of patients before prescribing non-surgical cosmetic injectables such botulinum toxin, and may not use telemedicine for patient consultations, and has included this ban in its (Option 3) Draft Guidelines.

The College is aware of the highly publicised case of a UK doctor, featured in a BBC report, who was found to be not having any contact with patients for whom he had prescribed. And as the Medical Board here is aware, there is a recent HCCC (NSW) case involving a Plastic Surgeon and a nurse who has had her licence suspended and restrictions placed on her registration after it was found that, in contravention of *Poison and Therapeutic Goods Act 1966* (NSW), the nurse concerned had administered restricted S4 substances in the absence of any consultation, review or assessment of patients by a medical practitioner, a prescription from a medical practitioner, written instructions or written orders from a medical practitioner, or supervision by a medical practitioner.

The College is also aware that, as in the UK, increasingly nurses in Australia are gaining increased prescribing rights. In Victoria, for example, nurse practitioners autonomously prescribe and may now prescribe Botulinum toxin to patients. The College believes that medical practitioners should remain responsible for the care of cosmetic medical patients in a patient-focused, team approach. Telemedicine run under strict protocols would appear to offer a way to achieve this and, in the College's view, would be preferable to an alternative arrangement in which medical practitioners have no involvement.

The Dental Board of Australia has recently withdrawn its interim policy for the administration of Botulinum toxin. The College is aware that there are growing numbers of non-specialist dentists providing cosmetic medical treatments to their patients using Botulinum toxin injections. The College has written again to the Dental Board to request clarification of its policy.

The College is concerned that any regulations or guidelines promulgated by the Medical Board in this area of cosmetic medical practice takes into account regulation and guidelines elsewhere in order to avoid unintended consequences of less medical oversight and reduced patient safety. It would be inappropriate, for example, that medical practitioners would be expected to practice under more prescriptive rules for medical procedures than non medical health practitioners providing the same treatments.

The College is also concerned that the Medical Board has not attempted to establish a case, as required under COAG guidelines, for the proscription of the use of telemedicine in cosmetic medical practice, specifically in the assessment of patient before prescribing Botulinum or other cosmetic injectable substances.

Last, detailed rules, promulgated by the Medical Board, concerning a particular area of medicine and a specific procedure such as telemedicine assessments for injectable cosmetic treatments, underline the College's point that the high-level policy setting role of the Board is being subjugated by quite granular focus ordinarily properly within the realm of medical judgement of individual practitioners due to the absence of national education, training and accreditation standards.

Although the College does have strong concerns about the abuse of remote prescribing, the College believes that further consultation and investigation on the use of telemedicine is required before regulation, beyond the existing telemedicine guidelines that apply to all health care practitioners, is considered. The College would welcome an opportunity to respond to a case for additional telemedicine regulation and make further recommendations.

Making misleading claims about qualifications and titles

The use of qualifications and titles is an area where the College has encountered instances where health consumers may be misled. There is a misperception among some in the general community that practitioners who may have other, recognised, specialist qualifications are specifically trained in and therefore a "specialist" in cosmetic medicine or surgery.

The College has for many years expressed its concern and disappointment over what it considers to be misleading statements made by the Royal Australasian College of Surgeons (RACS), ASPS and some of its members, about the cosmetic surgery qualifications of plastic and reconstructive surgeons and those of non-plastic surgeons. Those concerns were presented to the Medical Board in a detailed submission in 2010.

For example, ASPS has stated that its members "are accredited" by the federal government "through the Australian Medical Council (AMC)… to perform all aspects of cosmetic and reconstructive surgery". However, there is no such accreditation in cosmetic medicine or surgery. As noted above, the AMC's accreditation of the RACS-ASPS training program simply quoted the Board [of plastic and reconstructive surgery, which stated it was "endeavouring to maintain trainee exposure to cosmetic and maxillofacial surgery [the latter itself a separate recognised specialty] … principally via training in the private sector. It is estimated that 20 to 30 per cent of positions currently have some time spent in a private consulting or theatre environment. Trainees and supervisors were very positive about this initiative." [13]

The College also noted above that the UK, the Department of Health has cautioned that a practitioner's qualifications in plastic and reconstructive surgery **"**may not indicate that they have received any special training in cosmetic surgery, or that they have experience in doing cosmetic surgery or [in a] particular procedure".[14] And the 2010 UK National Confidential Enquiry into Patient Outcome and Death likewise warned that a specialist qualification "does not give any assurance that a surgeon has received adequate training in cosmetic surgery" or that they perform a procedure with enough regularity to achieve and maintain competence.[15]

The concern of the College has been that such misrepresentations ultimately interfere with informed consent – that health consumers may draw the incorrect conclusion that a plastic surgeon by virtue of his or her fellowship credential and ASPS membership is appropriately qualified to perform any given cosmetic medical or surgical procedure.

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13 "Accreditation Report: Review of the education and training programs of the Royal Australasian College of Surgeons", Specialist Education Accreditation Committee, Australian Medical Council, 2002, p 21. Emphasis added.
14 (UK) Department of Health, 2008 www.dh.gov.uk/en/Publichealth/CosmeticSurgery/DH_4124199 (Accessed August 2010).
15 "On the face of it: a review of the organisational structures surrounding the practice of cosmetic surgery", National Confidential Enquiry into Patient Outcome and Death (2010).

The coronial inquest into the preventable death of a Victorian woman following a liposuction procedure and the emergence of other cases involving a plastic surgeon and others, reinforced concerns about the truth of claims by RACS and ASPS that their plastic surgeons are "*fully qualified*" to perform cosmetic surgical procedures.

The Victorian coroner specifically noted that "irrespective of a practitioner's provenance or primary qualifications, there was a need for specific training and experience in performing liposuction surgery".[16] As noted above, Liposuction requires specific training to understand the procedure, patient selection and, critically and clearly demonstrated in that case, *recognition and management of post operative complications.*[17]

The coroner found it "disturbing" [18] that the plastic surgeon had "failed in his obligation to provide adequate post-operative care despite "being appraised of sufficient facts" to recognise the cause of the patient's deteriorating condition and "her departure from the normal or expected clinical course",[19] though the medical practitioner claimed that as a plastic surgeon (rather than a cosmetic surgeon) he was "more aware of the anatomy, the physiology, and having the ability to look after any possible complications that may occur".[20] In response to the question, "What is your training in Liposuction?" The plastic surgeon claimed only, "during the [FRACS (Plast)] training there was teaching in practical and in theory aspects of liposuction. I assisted many liposuction procedures…" [21] though he provided no corroborating evidence (e.g. surgical trainee log books, relevant supervised audited CPD or procedure specific certification) that he had performed them himself as a part of his fellowship training.[22]

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16 Finding into death with inquest: Inquest into the death of Lauren Katherine James, Coroners Court of Victoria, 6 August 2010, Ct ref: 300/07, p. 11.
17 A US review of liposuction recommended education of plastic surgeons about risk reduction in lipoplasty careful postoperative monitoring after very high mortality/morbidity rates among plastic surgeons versus others. CE Hughes, Reduction of lipoplasty risks and mortality: An ASAPS survey. Aesth Plast Surg 2001; 21:120-127.
18 *Supra* note 16, p. 18.
19 *Ibid*.
20 Transcript of Testimony, Finding into death with inquest: Inquest into the death of Lauren Katherine James, Coroners Court of Victoria, 5 November 2009, pp. 102-4.
21 *Ibid*.
22 [redacted]

Many plastic and reconstructive surgeons perform cosmetic medical and surgical procedures, some full time, some part time or only infrequently.[23] Plastic surgery fellowship training provides a medical practitioner with the surgical competencies to undertake cosmetic surgical training and some have obtained appropriate relevant education and training in cosmetic medicine and surgery after completing their RACS plastic surgery fellowship training and can be expected to practice at an acceptable standard. Such training is voluntary, organised privately (sometimes with members of the ACCS) and not part of the RACS or ASPS accredited training program. Many plastic surgeons do not choose to obtain such training and thus cannot be said to be "*fully qualified*" in cosmetic surgery.

As former RACS Board of Plastic and Reconstructive Surgery Chair Dr Jim Katsaros stated, cosmetic surgical training and qualification is obtained after the award of the FRACS qualification, is not obtained by all plastic surgeons, is arranged privately and is not supervised by RACS:

> *"Candidates who have completed the Part 2 FRACS and wish to obtain further sub-specialty training then proceed to fellowships in designated areas such as cosmetic surgery. Currently these fellowships are available in Sydney, Melbourne and Adelaide and are arranged personally by those surgeons. The Board does not supervise post-graduate fellowships which also exist overseas."*[24]

Plastic and reconstructive surgeons' qualifications are neither recognised nor accredited by the AMC specifically for cosmetic surgery. Claims by RACS, ASPS and its members that an FRACS (Plast) and ASPS membership is evidence of specialist training in cosmetic surgery undermine informed consent. Indeed, this problem was recognised at least as long ago as 1999, before the establishment of the ACCS and its training program, when the *Cosmetic Surgery Report* found:

> The only information available to consumers to assess competence is membership of medical colleges and professional associations, but this provides no guarantee of skill and experience in cosmetic surgery.[25]

While the ACCS believes that the preventable death noted above highlights the need for relevant recognised national standards of education, training and accreditation, it also underscores the

23 The UK's National Confidential Enquiry into Patient Outcome and Death agreed that performing cosmetic procedures occasionally is unacceptable practice. "On the face of it: a review of the organisational structures surrounding the practice of cosmetic surgery", National Confidential Enquiry into Patient Outcome and Death (2010), p. 4-5.
24 Correspondence from Dr James Katsaros, Chairman, Board of Plastic and Reconstructive Surgery, Royal Australasian College of Surgeons, 1 July 1998.
25 The Cosmetic Surgery Report: Report to the NSW Minister for Health, Health Care Complaints Commission (NSW), 1999, p. vii.

misperception in the Australian community that practitioners who may have a recognised specialist qualification in plastic and reconstructive surgery or general surgery are specifically trained in and therefore a "specialist" in cosmetic surgery.

The College suggests that the guidelines make it clearer that practitioners holding a specialist title should be careful to avoid stating or implying that the specialist title and qualification they hold in one area of medicine or surgery is recognition or accreditation of "specialist" status in an area in which their training may not be to a specialist level, whether it is a recognised area or not.

Once again on behalf of the ACCS, I extend our appreciation to the Medical Board of Australia and AHPRA for their efforts to produce consultation. Should you have any questions or require additional information from the College, please do no hesitate to contact me directly or Alan Jones, the College's corporate and government affairs adviser.

Yours sincerely

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President