Health Practitioner Regulation National Law and Other Legislation Amendment Bill 2022

Submission No: 2

Submitted by: Anand Deva

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Submitter Comments:

DEPARTMENT OF PLASTIC, RECONSTRUCTIVE AND MAXILLOFACIAL SURGERY

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31 May 2022

Submission regarding the Amendment to the Health Practitioner Regulation

Dear Sir/Madam,

On 11th May Yvette D'Ath QLD Health Minister introduced the above Bill into QLD Parliament. It amends the Health Practitioner Regulation National Law as agreed by all Australian Health Ministers on 18th Feb 2022.

As you know Australia's National Scheme for health professions commenced in 2010 with the adoption of the National Law by all participating jurisdictions. The scheme was established under the *Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions* (Intergovernmental Agreement) between all states and territories and the Commonwealth in March 2008. Under the Intergovernmental Agreement, Queensland is the host jurisdiction for the National Law. The National Law is set out in the schedule to the Queensland National Law Act, as amended from time to time and applied as a law of each participating jurisdiction, with local variations. Western Australia does not directly apply the National Law but has enacted corresponding legislation.

The amendment Bill is mostly about strengthening public safety and confidence in health practitioners and health services. However, there is a component of this Bill which appears to be contrary to the recent changes in public testimonials, and the advertising of health services etc.

On page 11 of the executive summary of the Bill it appears as below:

"Removing the prohibition of testimonials

To better balance public protection and consumer preferences, the Bill amends section 133 of the National Law to remove the prohibition against using testimonials in advertisements about regulated health services. The prohibition is out of step with consumer expectations and current marketing and advertising practices. Testimonials and reviews are common online, and new forms of advertising, particularly on social media, have blurred the lines between information and advertising. Consumers increasingly expect to have access to reviews and testimonials when purchasing health services and expect to be able to share their views about health services and practitioners. As a result of this amendment, testimonials will be treated the same as other forms of advertising. This is consistent with the treatment of testimonials under general consumer law. Advertisements, including those that use testimonials, will be prohibited if they are false, misleading or deceptive; offer a gift or inducement without stating the terms and conditions; create an unreasonable expectation of beneficial treatment; or encourage the unnecessary use of regulated health services."

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My points of concern with this particular amendment are as follows

1. The use of false and misleading testimonials (especially in commercially driven areas of Medicine like cosmetic surgery) has been associated with serious risk of harm and complications. The use of surrogate testimonials through social media (e.g., use of influencers) is currently the subject of a wide-reaching review by AHPRA. It would be prudent to wait till these findings are handed down before changing regulation around testimonials in medical advertising.

2. There is no way of policing whether or not the use of testimonials in medical advertising is compliant with AHPRA advertising standards. Failure to enforce these standards will only embolden the use of testimonials as a marketing and advertising tool rather than one that provides factual information to patients seeking a particular treatment or services of a practitioner.

3. We need to ensure that we hold the highest standards and protect patients from both misinformation and unscrupulous and undertrained practitioners.

I attach by way of background information my submission to the AHPRA enquiry into cosmetic practice to give further context to my concerns about the potential removal of restrictions on testimonials in medical advertising.

Please do not hesitate to contact me if you have any questions.

Sincerely,

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Submission to the Independent Review on Cosmetic Surgery

Cosmetic Practice
A Roadmap to better Regulation of the Industry

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APRIL 2022

Cosmetic Practice – A Roadmap to Better Regulation of the Industry

Historical context

Whilst reconstructive plastic surgical techniques have been described for centuries, the birth of modern cosmetic surgical practice has its origins in the treatment of facial trauma in the First World War. New techniques developed to treat the mutilating facial trauma encountered in returning soldiers from trench warfare were quickly realized to have an application in the wider public. In small private clinics, rich aristocrats and movie stars sought out the eminent surgeons proficient in these new techniques to alter their facial appearance[1]. Sir Harold Gillies, a New Zealander, is credited as one of the pioneers of this new and emerging specialty – Plastic Surgery - derived from Greek, *Plastikos,* to mould[2]. As time progressed, the demand for these procedures grew exponentially. However, they were not without risk and indeed, our very own Dame Nellie Melba was said to have suffered significant and ultimately fatal sepsis following a facelift[3].

Toward the end of our last century, an improved understanding of anatomy and refinements in reconstructive surgery techniques led to commensurate improved and predicable outcomes in cosmetic surgery. As an example, in the 1950s and 60s, advances in surgical anatomy, particularly vascular anatomy directly influenced techniques for breast reduction[4] and abdominoplasty (tummy tuck) [5]. The publication of large series of patients undergoing these procedures with improved outcomes have now established them as mainstream.
Later, the development of new implantable materials such as plastic and silicone allowed for the first time, a vast array of foreign devices to be used in medicine. In the 1960s, the manufacture of medical grade silicone allowed the development of breast implants[6]. While these novel implants heralded a new paradigm in cosmetic surgery when used for breast enlargement, they were not without controversy. From the very outset, the use of breast implants for augmentation has had a chequered regulatory history. Despite this, up until the recent impact of the COVID19 pandemic, breast augmentation using silicone breast implants was the number 1 cosmetic surgery procedure worldwide, and had been so for over a decade[6].

The use of liposuction to remove unwanted fat had its origins in the 1920s but was not well described until the 1980s, when better instrumentation and the use of a new type of regional anaesthesia called tumescent infiltration was described[7,8]. "Tumescent local anaesthetic infiltration" involves the preoperative infiltration of large volumes of a dilute local anaesthetic and adrenaline solution into the surgical area. It resulted in a significant decrease in blood loss, and for the first time, allowed the procedure to be performed as an ambulatory outpatient operation without the need for a general anaesthetic, making liposuction safer and more accessible.

In 1981, cosmetic soft tissue augmentation using the injection of bovine collagen was introduced. Because of allergic reactions to the bovine collagen, an alternative product was required, and now this augmentation is almost exclusively performed using a naturally occurring biological sugar called hyaluronic acid [9]. Simultaneously, research into botulinum toxin which was then being used to treat muscle spasm in patients with cerebral palsy[9], expanded its use into the cosmetic treatment of frown lines. Paralleling the translation of

reconstructive surgical techniques used to treat WW1 soldiers into the surgically treatment of facial ageing in the 1920's, the use of botulinum toxin has been similarly translated into the cosmetic treatment of naturally occurring facial ageing wrinkles.

These two procedures, the injection of hyaluronic acid for soft tissue augmentation, and the injection of botulinum toxin to reduce or eliminate naturally occurring frown lines, are now the most common cosmetic procedures performed world-wide. Because they can be performed without surgery, they have been marketed to the general public on a commercial mass scale, often without the regulatory checks and training required in traditional surgical practice.

Despite its very real, and well documented risk of instantaneous and permanent blindness[10], hyaluronic acid soft tissue augmentation is mostly performed in shopping centres or small cosmetic clinics by nursing staff, or medical practitioners with only a basic registration and with no, or at most, basic, knowledge of the critically important vascular anatomy. And people have gone blind, unaware of the risk. More than ever, the rapid proliferation of poorly trained practitioners performing this high-risk procedure in poorly equipped facilities highlights the pressures faced by regulators in keeping up with this rapidly changing environment and the to date, failure, of the existing regulations to adequately protect the public.

This new form of cosmetic practice, encompassing surgical and non-surgical interventions, has undergone rapid and exponential growth in demand over the last decade and is predicted to reach a total value of $66.96 billion by 2027 in the United States alone [11]. That is, in less than five years time.

This growth has been fueled by an increasing acceptance of these procedures in society, medical tourism, media fascination with body and facial transformation, availability of disposable income (and access to cheap finance) and the growth of competition and clinic chains that have lowered entry price and the translation of more aggressive commercially based sales and marketing strategies into medical care.

Cosmetic interventions - statistics

Table 1 lists the top 5 surgical and non-surgical cosmetic treatments in the United States in 2020.

Rank	Cosmetic Surgery	Cosmetic Treatment
1	Nose reshaping	Botulinum Toxin Type A
2	Eyelid surgery	Soft tissue fillers
3	Facelift	Laser resurfacing
4	Liposuction	Chemical Peel
5	Breast augmentation	Intense Pulsed Light

Commercial drivers and ethics in Cosmetic practice

The schism between what should be and what actually occurs in the marketplace in Cosmetic practice can be explained by the inherent tension between the pull of commercial forces and the need for the highest standards of ethical and safe practice[12]. In some instances, the two forces work together as patients become better informed to seek out practitioners and practices who practice with an appropriate level of skill and care. In some instances, however, the need to generate a profit, leads to unsubstantiated claims, underskilled and dangerous practice and poor outcomes, morbidity and in rare circumstances, mortality.

Ethical conflicts related to the discretionary, commercial and elective nature of cosmetic interventions have been well described[13]. In landmark essays on ethics and Plastic surgery, C.M. Ward concluded that ethical scenarios share one common theme – "the patient should have the final authority to decide"[14]. The four principles of medical ethics include 1. Respect for the autonomy of the patient 2. Beneficence or promoting what is best for the patient 3. Nonmaleficence – do no harm 4. Justice. Related to this are principles of disclosure and informed consent. It is easy to see how in cosmetic treatments, the promotion of a particular procedure or practitioner, downplaying of risks, use of suggestive images to entice patients, organising of cheap finance options and/or access to superannuation funds and failure to properly disclose financial or other conflicts of interest would breach these ethical principles on many levels.

As the regulator of all medical practice and practitioners, the Australian Health Practitioner Regulation Agency (AHPRA) should always ensure that patients interests, and safety are protected. The move of cosmetic practice out of the fringes of medicine into a more regulated and traditional practice of medicine, backed by good clinical evidence, will ultimately support a legitimate way toward improving the quality of patients' lives that can achieve safe, predictable and satisfactory outcomes in the majority of cases.

Table 2: key differences between Cosmetic Practice and Mainstream Medical Practice

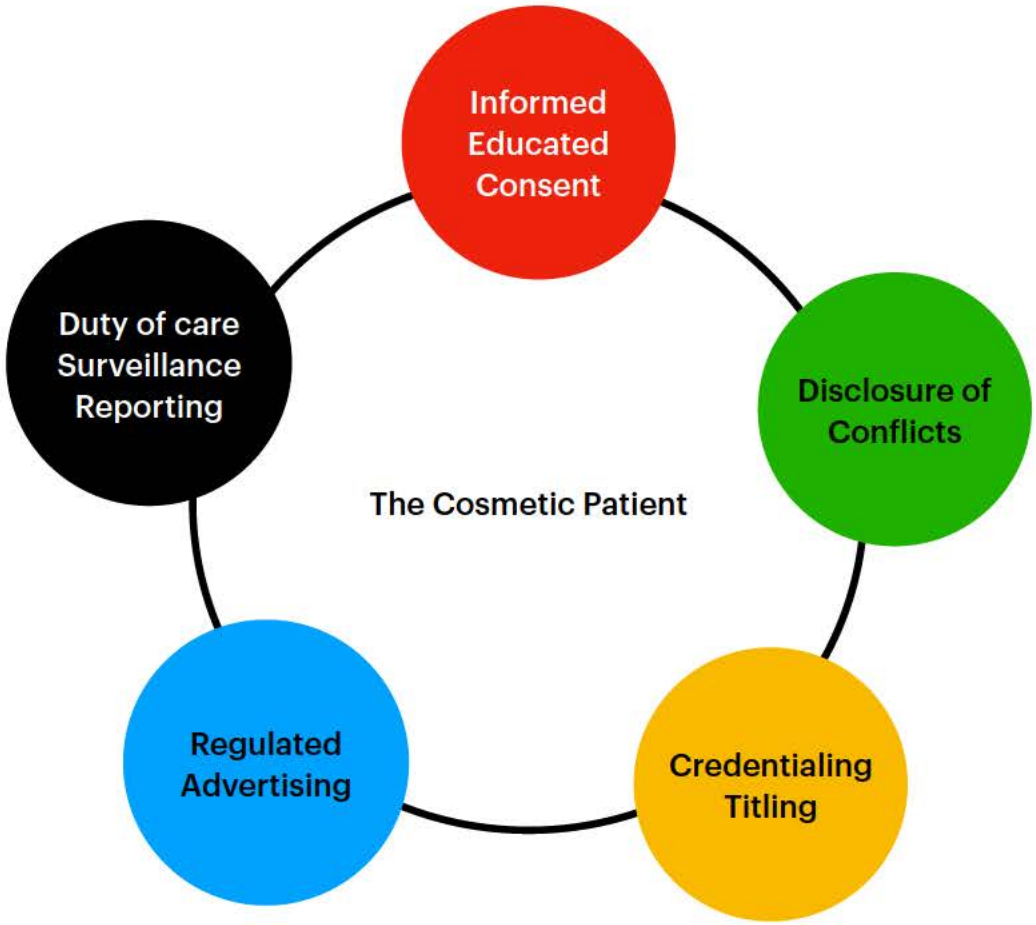
Cosmetic Practice	**Mainstream Medical Practice**
Market and sales driven	Outcome driven
Commercial gain	Patient gain
Discretionary	Needed to improve Quality of Life or treatment of life-threatening illness
Poor credentialing, regulation	Highly regulated, recognized credentialing
Poorly defined scope of practice, lack of audit and peer review	Well defined scope of practice, audit and peer review and quality control
Overlap with beauty and wellness industry e.g., medispa, conducted in variety of premises with lack of standardization of standards and licensing	Conducted in recognized health facilities, governed by strict standards and licensing

Roadmap to reform in Cosmetic Practice

The approach to reform in cosmetic practice requires five key areas to be addressed:

1. Informed (educated) consent
2. Declaration of Commercial Conflicts of Interest
3. Credentialing and Titling
4. Advertising in Cosmetic Practice
5. Ongoing duty of care, Surveillance, and Reporting of adverse events

Figure 1: the Roadmap to Reform in Cosmetic Practice



The context of each of these five areas will be summarised, outlining current deficiencies and propose suggested strategies to address these deficiencies in turn.

1. Informed Educated Consent

Every patient undergoing a medical or surgical intervention has to give their informed consent[15], which must be documented as part of the medical record. This is traditionally given during a pre-operative consultation after a discussion between proceduralist and patient and confirmed with a signature of patient (or proxy) and the clinician (or witness). The details of the procedure and risks that are explained to the patient are usually also documented in the patient's medical record. The ethically valid process of informed consent includes five elements : voluntarism, capacity, disclosure, understanding and decision[15]. Many studies have shown that whilst documentation of the process may be completed, the patient's knowledge of risk and benefit of a proposed medical treatment and the ability for the patient to withdraw consent for the intervention at any time was not well understood[16]. Ingelfinger wrote in 1972 that "the trouble with informed consent is that it is not educated consent"[17]. In cosmetic surgery and medicine, the stakes are raised higher, as the proposed treatments are both elective and discretionary.

The Agency for Clinical Innovation (NSWHealth) has recently released a toolkit for the management of breast implants, which outlines a specific process of clinical assessment and a proposed informed educated consent checklist for women who are considering cosmetic breast augmentation (see Appendix 1)[18].

Similar frameworks for the process of both informed and educated consent should be formalized and instituted for all areas of Cosmetic practice. Principles that would support the consent tool include;

1. Empowerment of patients and encouragement of shared and protected decision making with, where possible, multiple time points for discussion
2. Education of patients about risks, benefits, and alternatives for treatment. In the case of cosmetic treatments, the option of not proceeding with the elective and discretionary intervention should be discussed at multiple time points prior to surgery with a mandatory cooling off period prior to signing up for a treatment.
3. Management of patient uncertainty and anxiety
4. Providing options and choice for a variety of treatments
5. Outlining ongoing duty of care and post-operative surveillance

The use of customised checklists that are simple, easy to comprehend and are performed twice with the treating practitioner (as opposed to a proxy) would be a good first step and preferably this consultation would be performed face to face with the patient (rather than through telehealth). The use of a mandatory cooling off period between the first and second reading of this checklist, would ensure that patients are given the time and space to better understand a proposed cosmetic intervention and offered the opportunity to return to ask questions of the treating practitioner.

Proposed reform 1

Development of customised informed educated consent checklists for common cosmetic medical and surgical interventions to be discussed between patient and treating practitioner face to face at two separate consultations with an intervening mandatory cooling off period.

2. Declaration of Commercial Conflicts of Interest

There has been much written about potential conflicts of interest and the relationship between the medical profession and industry[19]. There is little doubt of the existence of a conflict of interest when the doctor derives a direct financial benefit (e.g., royalty payments, ownership of shares in a particular medical company) through recommending a particular medical product or treatment to a patient. A particular cosmetic treatment or device e.g., particular brand of breast implant, may be recommended over alternatives because of commercial arrangements between the supplier and the practice such as competitive pricing. A particular resurfacing device may be recommended over another because the practice has just acquired the device and has to justify the expenditure or lease of the equipment. There are also financial conflicts inherent in a for-profit private practice. Advice given to patients to encourage them to undergo a higher fee-paying procedure, discounts for early sign up for a procedure, failure to provide non-operative or alternative methods of achieving a particular outcome and minimising or omitting to discuss risks are other means of ensuring that the practitioner or practice secures higher revenue and return by recommending and proceeding with a particular cosmetic intervention.

Proposed reform 2

In the setting of a proposed cosmetic treatment, disclosures of financial conflicts of interest for both the practitioner and practice and beneficial commercial arrangements with a particular medical supplier or finance supplier should be disclosed to the patient in writing at the time of initial consultation and prior to patient consenting to undergo cosmetic treatment.

3. Credentialing and titling

In Australia, the Australian Health Practitioner Regulation Agency (AHPRA), records and regulates the registration and practice of appropriately qualified health professionals and also deems if a particular practitioner holds specialist registration in a defined and structured way in line with recognized credentialing for specialist medical or surgical practice. Additional "Specialist" registration beyond basic, or "General" medical training is certified by the relevant college responsible for delivering that advanced training, examination and certification of the practitioner to a pre-determined standard set by the independent Australian Medical Council (AMC). In order to maintain specialist registration, the practitioner needs to ensure that he/she maintains ongoing education and audit/peer review of his/her practice. The standard and scope of this *continuing professional development*, or CPD, is also set by the AMC. Specialist medical practitioners must adhere to their scope of practice, and

enforcement of this scope of practice is delivered by the relevant AMC Accredited College and by the individual hospital's Medical Board at which the medical practitioner operates.

As we stated above, many cosmetic surgical procedures can be performed in an ambulatory setting, outside licensed hospitals, in some jurisdictions. In such circumstances, the oversight and regulation of a medical practitioner's scope of practice, audit, credentialing and CPD is not subject to the same scrutiny and rigour that would ordinarily occur, should that practitioner have performed the exact same procedure inside a licensed hospital.

Cosmetic practice, as it operates in the grey zone between a doctor's office and a licensed hospital in some States, allows some practitioners to practice outside these regulatory frameworks, and to perform operations that would not be allowed had that practitioner attempted to perform the same operation in a licensed public or private hospital. As the recent Four Corners program "Cosmetic Cowboys" revealed, major cosmetic surgical procedures, such as large volume liposuction, can still be performed in a practitioner's day procedure centre with lax quality control, no formal oversight, and at a standard significantly below that which is both acceptable and safe.

All surgery has risk. Cosmetic surgery is no different. All surgical procedures that are invasive and carry inherent risks of both the procedure and associated anaesthetic require a pre-determined nationally consistent minimum standard of care and safety. Just as in all other areas of surgical practice, the performing of invasive procedures under anaesthetic or deep sedation also requires appropriate training, certification and credentialing of the anaestheist providing the anaesthesia required for the procedure to take place.

This training and the subsequent surgical (and anaesthetic) practice must be of the highest standard and should reflect current *best practice*. Accreditation, supervision and continued professional development of all surgical training must be underpinned by an objective nationally recognized pathway of selection, advanced training and certification of appropriate skills to the standard set by the AMC.

You could not perform neurosurgery, for example, unless you hold both a valid Fellowship of the Royal Australasian College of Surgeons detailing your surgical training in neurosurgery, with appropriate certification of that training from the Board of Training in Neurosurgery, and formal objective accreditation of your scope of practice and surgical training at the hospital at which you intend to operate. That is, in order to be appointed as a Neurosurgeon in either a public or a private hospital, you must present appropriate AMC accredited qualifications detailing your training and scope of practice, and valid AHPRA registration to the Hospital's Medical Board in order to be appointed and permitted to perform Neurosurgery at that hospital.

AHPRA should be aware of the existence of a number of organisations that do not have AMC recognition, yet still seek to claim legitimacy. Several attempts by these self-styled "cosmetic practitioners" to accredit their various training programs have been made to the AMC. All have been unsuccessful. Their training programs have not been recognized as being of a sufficient standard by the Australian Medical Council to meet their requirements.

It is these same practitioners, with no recognised AMC accredited specialist qualifications, that seek to obfuscate and denigrate the training, scope of practice and CPD of legitimate specialists who have been trained to the standard set by the AMC. For recognized specialists in surgery, the skill in performing these techniques, honed over many years of practice in surgical units, competitive selection into an advanced training program (ensuring the best candidates are chosen), a 5 year long advanced training program with hands-on supervised procedural instruction and final certification through a specialist surgical fellowship examination ensures that a properly qualified specialist surgeon does have the requisite skill set to practice safely and to an acceptable standard. All surgery has an intrinsic cosmetic element (a surgeon does not seek to deliberately create a poor aesthetic outcome), is integral to all congenital, trauma and cancer reconstruction, and as noted above –all cosmetic procedures have as their historical basis in Plastic & Reconstructive surgery.

It is recognized that for cosmetic surgery, the Board of Training of Plastic & Reconstructive Surgery, General Surgery, Ear Nose and Throat Surgery and Urology all include cosmetic surgical procedures as part of their formal curriculum and assessment of training. As such, a fellowship of the Royal Australasian College of Surgeons, or from one of the other AMC accredited training programs with a significant surgical component (Royal Australasian College of Obstetrics and Gynaecology, Royal Australasian College of Ophthalmologists and Oral and Maxillofacial Surgery) is the *only* objective and reproducible method to ensure a medical practitioner has the adequate skill, training and certification to perform surgery safely, and manage complications should they arise.

Attempts to bring these non AMC accredited "specialist" practitioners into line with standards of safe practice and recognized credentialing are met with claims that this is a "turf war" and an unfair fight to protect access to the lucrative cosmetic surgical and medical dollar. Whilst these claims do make the news, they are designed to confuse an unknowing and medically illiterate public and detract from the real aim – which is to ensure that practitioners in this area are properly credentialed, have the requisite skills and are safe. By continuing to allow this regulatory blind spot, AHPRA has failed to adequately protect the unsuspecting cosmetic patient from unsafe practice and from harm from the undertrained and sometimes unscrupulous practitioner.

Unfortunately, in Australia in 2022, what we call "cosmetic" surgical practice is currently being delivered by a disparate group of practitioners, some of which have undergone appropriate selection, training, certification and registration as specialists and some of which have not. In NSW and Victoria, recent changes to the legislation have mandated that invasive cosmetic surgical procedures are now only permitted in licensed private hospitals, most of which require appropriate specialist credentialing and require oversight by the individual hospital's medical board. This, however, is not uniform, nor is it nationwide. Performing invasive surgery in a licensed facility with oversight by the hospitals medical board would ensure that standards of surgical safety with respect to infection control, anaesthesia/sedation and patient monitoring are satisfied.

The title "Cosmetic Surgeon" and the recent public push to create a new specialty of "Cosmetic Surgery" has added to further confuse a vulnerable public and is another important factor in preventing proper regulation, patient protection, and establishment of minimum

standards of safety and quality in this space. The title "*Cosmetic Surgeon*" is not AMC accredited nor is it backed by the rigorous selection, training and attaining of competence that is mandatory of all other areas of surgical practice. Naively and falsely, many patients believe a practitioner calling themselves a "*Cosmetic Surgeon*" is better trained and has more experience than any other practitioner in any operation with a significant cosmetic component. This misconception is not accidental, and its messaging has been deliberately crafted.

Right now, any doctor with a basic medical degree and no formal training in surgery could insert a breast implant, perform major liposuction, or perform an abdominoplasty. All these operations are major surgical procedures and carry a significant and very real risk of injury, infection, and death. Up until recently, any doctor could perform this procedure in his/her back office in any part of Australia. In NSW and Victoria at least, this has now been made illegal.

It is vital that any patient undergoing any invasive surgical procedure has the assurance that the doctor performing that procedure has the recognized and sufficient level of skill to carry out the procedure safely and appropriately, to treat the intra or post-operative complications should they arise, to provide the aftercare to an accepted standard and that such an invasive procedure be performed in a licensed and accredited facility. This assurance needs to be transparently and readily available. Further, patients need to be able to easily and reliably double check the claims made by an individual about their surgical training and compare the standard of that training against a nationwide, objective independent easily understandable benchmark before undertaking surgery. It would make sense that this benchmark is set by the AMC.

Ultimately, clarity and restrictions around training, titling and certification will enable patients to be confident that the doctor performing their procedure has the skillset to achieve the best outcomes, as well as keeping them safe before, during and after their operation.

Proposed Reforms 3a-e

3a. Jurisdictional and/or National legislation to ensure that all invasive Cosmetic Surgery in Australia is performed in an appropriately licensed medical facility. These facilities must be licensed to acceptable standards by the Jurisdictional and/or National health regulators and must be able to provide an audit of safety standards and patient outcomes.

3b. Protect the use of the title 'Surgeon' to appropriately credentialed and qualified specialist registered practitioners with appropriate Surgical training and qualification to a predetermined, independent, objective benchmark. We would suggest this is to the standard set by the AMC.

3c. Restrict the use of the medical practitioners' titles and post nominals to only those formally approved by AHPRA. Fabricated titles (such as the term "Cosmetic Surgeon") lack uniformity and are not necessarily linked to recognised skill, credentialing and certification. These titles have the potential to mislead the general public and make it difficult for a prospective patient to accurately and transparently assess the practitioner's level of skill and training. Patients are therefore potentially put at risk of harm.

3d. AHPRA and AMC work towards formalising standards of certification and training in Cosmetic Practice with AMC recognized Colleges and training programs. For any major invasive surgery, the minimum standard should be a fellowship of an AMC Accredited College with a significant surgical scope of practice, that is, the Royal Australasian College of Surgeons, The Royal Australasian College of Ophthalmologists, The Royal Australasian College of Obstetrics and Gynaecology and Oral and Maxillofacial Surgery.

3e. Consider the development of post fellowship training pathways for excellence in Cosmetic Practice

4. Advertising in Cosmetic Practice

Historically, advertising of medical or surgical services by doctors in Australia was heavily restricted. When Anand's father began practicing as a GP in the 1970s, he was only allowed to have a single line entry in the White Pages listing his name, address, and telephone number.

In 1994 the Australian Competition and Consumer Commission (ACCC) allowed doctors to advertise their services, initially through print in the yellow pages and then subsequently onto other media platforms such as radio and television and more recently social media. This led to an explosion in both the amount and extent of medical advertising that targets consumers directly.

As outlined by current AHPRA guidelines, advertising for any health service must **not**

Be false, misleading, or deceptive
Offer a gift, discount, or other inducement
Use testimonials or purported testimonials
Create an unreasonable expectation of beneficial treatment
Encourage the indiscriminate or unnecessary use of regulated health services

For cosmetic practice, advertising an elective or discretionary intervention could potentially involve breaching any of all of the above principles.

a. Patient images used for advertising Cosmetic practice

Images of patients before and after undergoing cosmetic interventions are widely utilised in advertising for Cosmetic Practice. The use of before and after photos has an important role in educating patients about the likely outcomes of a cosmetic intervention. There are standards that have been described to properly document the effect of a cosmetic surgical intervention[20]. Images can also be misleading and used to try to entice patients to sign up for treatments. The images that are displayed on websites, social media and marketing materials are highly curated and capture a single time point during the patient's journey, usually taken at the time when the patient looks their best.

The use of lighting, make up, varied angles to improve contour, facial expression and clothing may also provide an unrealistic and misleading image of the results of a cosmetic intervention.

Examples of where the use of imagery may be misleading or enticing include:

1. The use of glamorous, sexualised and posed images, lifestyle shots accompanied by captions that minimise the risk or complexity of a procedure can be considered potentially false, misleading, and deceptive.
2. The tagging or naming of a particular patient, especially one with a large following on social media platforms ("influencers") may constitute a surrogate testimonial.
3. Claims relating to likely outcomes as a result of a cosmetic surgical procedure e.g., "cutest person in the world", "looking great" may create an unreasonable benefit or expectation of a proposed treatment or procedure

Proposed reforms 4a-e: Images used for Cosmetic practice

4a. Should be standardised i.e., Taken at the same angle, with the same lighting and background both before and after the intervention

4b. The after image should clearly state the time in days, months or years following the intervention.

4c. Should not name individual patients or link to individual patients' social media or digital media accounts

4d. Should not be accompanied by testimonials and/or subjective description(s) of the benefit or apparent result of the procedure

b. Financial incentives to entice patients

The use of financial incentives such as discounts and time sensitive "specials" to entice a patient to undergo a cosmetic intervention is an area that requires careful scrutiny.

Examples of financial incentives to entice patients include

1. Giving a fee discount if the patient undergoes the surgery before a certain date
2. Offering other benefits, such as discounted airfares, accommodation, spa treatment as part of a treatment package etc.
3. Offering a gift or prize for promoting a particular cosmetic practitioner or practice
4. Entering into any arrangements with patients to assist them in obtaining finance to pay for a procedure, or offering financing schemes to patients, either directly or through a third party

Supplying services by a practitioner to a patient for free or for a reduced fee in exchange for some benefit, including the endorsement of the practitioner through media and social media can be construed as a breach of AHPRA advertising guidelines. This practice is termed influencer marketing. This involves endorsement of a product or service by a person with a large following or a high public profile in exchange for reduced or no cost access to a cosmetic intervention. Recent moves to delineate sponsored content have been introduced but there is sufficient opacity here so that many incentives remain hidden. This type of marketing is often successful because it appears to be organic and may seem to reflect the influencer's genuine assessment of the service they received. The strategy has been employed widely by most sales driven industries but is now also being employed to promote cosmetic practice, with social media personalities flaunting the results of procedures they have undergone and publicly crediting the doctors who performed them.

These arrangements may be informal, verbal or written and may be obfuscated through false receipts and invoices. In many cases, the influencer has no intention of disclosing these arrangements and may be inappropriately bound by non-disclosure agreements.

Proposed reform 5

Consider banning the naming of any individual patients or conversely the naming or tagging of a practitioner or practice in relation to a cosmetic treatment through media/social media

c. False claims of efficacy and expertise

Review of the advertising material for both cosmetic practitioners and cosmetic interventions reveal a large number of potentially unsubstantiated claims of efficacy. While there have been a number of attempts to reign in content and appropriateness through, there is little evidence that these are adhered to[21]. A recent study in the UK found only 41 per cent of medical websites complied with published guidelines, with 34 per cent of advertisements for breast augmentation containing (deliberately) false and/or misleading information including minimising risk and down time after surgery[22]. The study also noted frequent exaggerated claims such as "a true artist", "one of the top doctors", "prescribing the power to be beautiful", "kissable lips, just a click away"[22].

Recently the TGA has introduced penalties for claims that are in breach of regulatory approval and/or unsubstantiated benefits not backed by evidence. These penalties apply to both the practitioner making these claims or by individuals promoting such treatments. There is a real danger that an unproven treatment or medical device utilised outside of regulatory approval place patients at risk of adverse events from a particular intervention or device.

Additionally, we have seen many claims made by cosmetic practitioners to be true pioneers and innovators in their field, being the first or only surgeon to practice a certain technique in Australia including eponymous "lifts" and "smart" techniques. Innovation is important in medicine, but the real risk is that self-styled "new" techniques have not been properly evaluated by scientifically valid comparative studies or published in peer reviewed journals and simply do not have good evidence to back their claims.

Proposed reform 6a-c

6a. Claims of innovation be backed by published, peer reviewed articles
6b. Claims and use of medical interventions and devices are in line with TGA approved usage and breaches of this are to be reported to the TGA.
6c. Claims of efficacy of any new product or intervention be backed

d. Social media has changed the game – the regulator needs to catch up

The advent of social media, more recently, has turbo-charged the use of sales and marketing tactics and opened up a wide range of opportunities to specifically target individuals and build brand awareness in the cosmetic surgery industry[23]. There is increasing evidence, however, that the images and strategies used to target individuals may worsen feelings of low self-esteem and body image[24,25]. The use of operative videos on some social medial platforms has

also gained popularity. Ethical challenges with posting such material has been raised in the literature[26]. The posting of videos of surgery are designed to legitimise the "expertise" of the practitioner, whilst also giving the patient an opportunity for fame. Some patients seek out high profile surgeons offering to have their video and testimonials posted on either the practice or their personal social medial platforms to enhance each other's reputations. There are also risk in breaching confidentiality when videos are posted without consent and images and videos, once released may be copied, manipulated, and redistributed. More recent platforms such as Snapchat have transient posts, thereby making it more difficult for authorities to review and assess appropriateness of content.

Increasingly patients rely on social media to find their "ideal" cosmetic practitioner, often looking to online reviews to make their selection. It is a dangerous and unregulated area and borrows on the wider commercial drivers common to other sales-driven industries. Recent reports of deliberate censoring of poor reviews, paying patients and/or staff to post glowing endorsements and paying third party "cosmetic surgery forums" to promote a particular practice casts doubt over the independence and veracity of online information that patients use in good faith to make their choice.

Unlike traditional media, such as television, print and radio, social media lacks the checks and balances and vetting by journalists and broadcasters who moderate and sense-check what gets promoted to the public. A quick look through brand building manuals shows that much of what is displayed seeks to build a cult of celebrity, followers, and pre-eminence through flooding these platforms with highly sexualized images, music videos and luxury products.

A recent survey by the British Association of Plastic Surgeons (Think before you make over) showed that patients relying on social media for their information were not aware of the risks of their intended procedure (21%), are not clear on the likely outcomes of a procedure (27%) with 59% undergoing a cosmetic intervention within 2 weeks of first contact with a practice on social media[27]. Just over half of these patients (53%) sought to find the cheapest option for their intended procedure. These worrying statistics point to a targeted demographic of vulnerable and impressionable patients who are easy prey to marketing, pricing and sales tactics[27].

Proposed reform 7
Consider the establishment of a social media monitoring authority to study the content and report any potential or direct breaches to AHPRA

5. Ongoing duty of care, surveillance, and reporting of adverse events

All patients undergoing cosmetic interventions should have arrangements to receive appropriate post intervention care and follow up. It is also important that any adverse events of cosmetic interventions be properly documented and reported to a formal national register overseen by the respective jurisdictional Health authorities and to AHPRA.
Patients coming from interstate or regional parts of the State should be encouraged to remain close to the practice for a reasonable time-period after surgery, so that any early postoperative complications can be identified early and treated.

For breast implant surgery
Patients undergoing breast implant surgery should be given a postoperative surveillance plan and information relating to medium to long term risks of these devices (see Appendix 1). The breast implant must be registered with the Australian Breast Device Registry and the patient should be also informed of the need to report any future adverse events to both the registry and the Therapeutic Goods Association (TGA).

Proposed reform 8a-c

8a. Standardised post intervention care and surveillance plans be instituted and communicated
8b. Wider education of general practitioners on the risks and adverse events associated with cosmetic interventions
8c. Consider the development of a patient adverse event reporting line or portal to capture true risks and outcomes following cosmetic interventions

A history of regulatory failure

In 1999, the NSW health minister established an enquiry into the cosmetic medical industry with a report tabled by the Commissioner, Merrilyn Walton.

The key findings tabled were

1. Little published research on clinical standards and skills required to perform cosmetic surgery procedures
2. Little information on adverse outcomes but no disproportionate level of complaints or legal claims in the cosmetic surgery industry
3. A proliferation of professional and industry organisations responsible for training and representation of cosmetic surgery providers, with some providers who are not members of any such specialist groups
4. No uniform standards for information to consumers
5. Little understanding of the regulations governing promotional activity

The report provided an in-depth analysis of the industry and its failures. It called for a Cosmetic Surgery Credentialing Council (CSCC) to be established for all registered providers of cosmetic surgery to ensure that there was provision of reliable information for consumers and effective sanctions for those that fail to comply with standards of safe and ethical practice. It also called for an amendment to the Private hospitals and Day Procedure Centres Act and the Day Procedure Regulation to ensure that facilities who provided cosmetic surgery procedures adhered to safety standards to ensure that procedures were performed in properly licensed facilities.
The majority view was that medical practitioners performing invasive cosmetic surgery procedures should have a fellowship of the Royal Australasian College of Surgeons.

In March 2017, The Private Hospital and Day Surgery Act was amended in NSW response to the public outcry following the reporting of a number of patients who suffered local

anaesthetic toxicity at an unlicensed breast augmentation clinic (The Cosmetic Institute). Other recommendations from this report remain to be enacted and closely echo our recommendations.

Proposal 9

Establishment of an AHPRA cosmetic practice authority to monitor and investigate any breach of advertising claims and guidelines (this was originally proposed in NSW 1999 submission)

This authority has the power to call for urgent s150 hearings to question practitioners and/or practices that are potentially in breach

Make clear that the consequence of multiple and/or significant breaches of advertising guidelines could result in restriction of medical practice.

Conclusions

This enquiry brings with it the real opportunity for AHPRA to establish a framework for better regulation of cosmetic practice. We have proposed a number of strategies for you to consider and a roadmap to real reform in cosmetic medical and surgical practice. Lasting reform should rightly be focused on patients and educating them on how best to navigate this complex space. It is, after all, the choice and power of an informed and educated patient that will ultimately drive better standards of care and call poor practice to account.

There are those within this industry that have repeatedly called for reform and for protection of the patient[28,29]. Both our practices are now seeing an increasing number of patients, mainly women, who have been harmed physically, psychologically, emotionally, and financially by the consequences of their engagement with the industry. We have witnessed the growing divide between aggressive sales and marketing tactics and profit seeking and the need for the highest standards of clinical skill, patient informed educated consent, clinical assessment, and treatment. The advent of social media, enticing imagery, celebrity and influencer marketing are moving the industry ever further away from the profession of medicine into a highly geared commercial enterprise, aimed at preying on the vulnerable and commoditising medical interventions. It has been 23 years since the NSW Health Minister commissioned the first enquiry into cosmetic surgery. The problems that existed then still exist today, albeit now scaled to a level that was unimaginable at that time. We call on AHPRA to consider our proposals and to engage with those of us that are committed to bringing change and to better regulate cosmetic practice. Rather than be reactive and respond when stories of patient harm are aired in the media, let us be proactive to deliver real and meaningful reform to ultimately prevent patients from being harmed in the first place and to ensure that cosmetic practice delivers safe and effective treatments with the power to improve the quality of life of our patients.

Mark Ashton & Anand Deva April 2022

Summary of Proposed Reforms to Cosmetic Surgery Practice

Proposed reform 1

Development of customised informed educated consent checklists for common cosmetic medical and surgical interventions to be discussed between patient and treating practitioner face to face at two separate consultations with an intervening mandatory cooling off period.

Proposed reform 2

In the setting of a proposed cosmetic treatment, disclosures of financial conflicts of interest for both the practitioner and practice and beneficial commercial arrangements with a particular medical supplier or finance supplier should be disclosed to the patient in writing at the time of initial consultation and prior to patient consenting to undergo cosmetic treatment.

Proposed Reforms 3a-e

3a. Jurisdictional and/or National legislation to ensure that all invasive Cosmetic Surgery in Australia is performed in an appropriately licensed medical facility. These facilities must be licensed to acceptable standards by the Jurisdictional and/or National health regulators and must be able to provide an audit of safety standards and patient outcomes.

3b. Protect the use of the title 'Surgeon' to appropriately credentialed and qualified specialist registered practitioners with appropriate Surgical training and qualification to a predetermined, independent, objective benchmark. We would suggest this is to the standard set by the AMC.

3c. Restrict the use of the medical practitioners' titles and post nominals to only those formally approved by AHPRA. Fabricated titles (such as the term "Cosmetic Surgeon") lack uniformity and are not necessarily linked to recognised skill, credentialing and certification. These titles have the potential to mislead the general public and make it difficult for a prospective patient to accurately and transparently assess the practitioner's level of skill and training. Patients are therefore potentially put at risk of harm.

3d. AHPRA and AMC work towards formalising standards of certification and training in Cosmetic Practice with AMC recognized Colleges and training programs. For any major invasive surgery, the minimum standard should be a fellowship of an AMC Accredited College with a significant surgical scope of practice, that is, the Royal Australasian College of Surgeons, The Royal Australasian College of Ophthalmologists, The Royal Australasian College of Obstetrics and Gynaecology and Oral and Maxillofacial Surgery.

3e. Consider the development of post fellowship training pathways for excellence in Cosmetic Practice

Proposed reforms 4a-e: Images used for Cosmetic practice

4a. Should be standardised i.e., Taken at the same angle, with the same lighting and background both before and after the intervention

4b. The after image should clearly state the time in days, months or years following the intervention.

4c. Should not name individual patients or link to individual patients' social media or digital media accounts

4d. Should not be accompanied by testimonials and/or subjective description(s) of the benefit or apparent result of the procedure

Proposed reform 5

Consider banning the naming of any individual patients or conversely the naming or tagging of a practitioner or practice in relation to a cosmetic treatment through media/social media

Proposed reform 6a-c

6a. Claims of innovation be backed by published, peer reviewed articles

6b. Claims and use of medical interventions and devices are in line with TGA approved usage and breaches of this are to be reported to the TGA.

6c. Claims of efficacy of any new product or intervention be backed

Proposed reform 7

Consider the establishment of a social media monitoring authority to study the content and report any potential or direct breaches to AHPRA

Proposed reform 8a-c

8a. Standardised post intervention care and surveillance plans be instituted and communicated

8b. Wider education of general practitioners on the risks and adverse events associated with cosmetic interventions

8c. Consider the development of a patient adverse event reporting line or portal to capture true risks and outcomes following cosmetic interventions

Proposal 9

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Appendix 1: Toolkit for the management of breast implants

Appendix 2: The Cosmetic Surgery Report – Report to the NSW Minister for Health October 1999