From: Les Blackstock
Sent: Friday, 29 May 2015 9:14 AM
To: medboardconsultation
Cc: Dr. Les Blacstock
Subject: Submissions to the consultation process of Cosmetic Medical Practice by the Medical Board of Australia.

Thank you for the opportunity to provide comments on the best way to protect consumers seeking cosmetic medical and surgical procedures provided by medical practitioners.

Consumers making rushed decisions to have cosmetic medical and surgical procedures provided by medical practitioners, without adequate information is an assumption. As a medical professional who provides cosmetic services, I find it very displeasing that there is an assumption that there is currently a problem, when thousands of cosmetic procedures are being carried out every day in a safe environment with the appropriate amount of care given to consumers.

Any proposed changes must be based on evidence based medicine and at present there is no evidence based research that says that cosmetic surgery is only performed safely by any one group of practitioners.

As mentioned in your impact statement, exact numbers of cosmetic medical and surgical procedures are not known as there is no national data collection for this area of medical practice. If the assumption of consumers not having adequate data is also being based on the insurance claims against medical practitioners performing cosmetic procedures, then we take figures from our own company data, we illustrate the following:

In 2015 alone we performed 509 surgeries. (mostly Breast Implants, liposuction, labiaplasty, and blepharoplasty). In that period zero complaints were made. In the past 10 years of performing cosmetic services, we've performed over 2500 surgeries, with only 3 complaints to insurers. Out of these 3 complaints, 1 was for breast enhancement, 1 was for labiaplasty and the other liposuction. Thus with a percentage of less than 1% (00012%) over all, and only one complaint per surgical category, (in 10 years) we find it hard to come to the conclusion that the current guidelines and code of conduct doesn't regulate safe practise.

These statistics are for complaints, we obviously have complications, all surgery has complications. For example, for our most common breast enhancement surgery, we use Mentor Gel Breast Implants, and the product information guide including risk associated with the procedures are listed as follows according to the Mentor Memory Shape Breast Implant Core Study. Using information from Mentor's Memory Shape Breast Implant Core Study, the risk of a patient experiencing any complication (excluding rupture) at some point through 3 and 6 years after implant surgery was calculated. This risk through 3 years was 35% for primary augmentation patients and 41% for revision-augmentation patients. This means that 35 out of 100 primary augmentation patients and 41 out of 100 revision-augmentation patients may experience a complication (of some kind) within 3 years after receiving implants. Through 6 years, this risk was 45% for primary augmentation patients and 53% for revision-augmentation patients. This means that 45 out of 100 primary augmentation patients and 53 out of 100 revision-augmentation patients may experience a complication (of some kind) within 6 years after receiving implants.

Our complication levels are much better than these statistics and are comparable with other levels of practitioners performing the same surgeries at the same utilisation level.

What we feel distracts the numbers that the impact statement mentions is the increase in the level of surgeries. Simply put with a 1% rate of complications doing 100 surgeries you would see 1 problem, doing 1000 you would see 10. If you see the rate go from 1 to 100 it may be indicative of a problem. There is not a problem.

I have acquired my skills through a concerted and extensive effort of learning and mentoring by multiple practitioners in many countries. I perform the surgery I do safely and to levels that are world's best practice.

I submit that attempting to restrict the right to perform cosmetic surgery by a single profession group, plastic surgeon v cosmetic surgeons is a restraint of trade and is only an effort by those groups to increase a monopoly and not in the interest of patients.

There is not government recognised training in Australia that allows for any practitioner to train in cosmetic surgery. I have been working to try to change that.

I submit that there should be support of organisations that aim to create a training scheme for the skill sets of cosmetic surgery not the membership of a professional group.

One of my concerns with the proposed draft guidelines, would be to insist on a day surgery or hospital setting for certain procedures. This is a drastic change and would certainly have detrimental effects to not only our business and others who have invested heavily to provide safe facilities but also to the consumer, by driving up the prices and forcing people overseas. If such a change were to be introduced I would be taking action for compensation.

There is no evidence that cosmetic surgery can only be safely performed in a Day Surgery.

There is evidence supporting for safe practice in an office based setting:

The study of **Tumescent Anaesthetic Breast Surgery (TABS): Primary and Secondary Breast Augmentation Surgery in an Office-Based Surgical Centre** - *The American Journal of Cosmetic Surgery Vol. 29, No. 3, 2012.*

From December 1, 2008, to November 15, 2011, 448 primary and 56 secondary breast augmentation surgeries were performed on 504 patients using tumescent lidocaine anaesthesia (55 of the original 504 patients were operated on again; 1 patient was not an original patient). The age of the patients ranged from 19 to 68 years. All surgeries were performed at the Perfect Image Cosmetic Surgery MedSpa in El Paso, Tex. No patient asked for the surgery to be terminated because of pain or anxiety. In 502 of the 504 surgeries, patients said they would repeat the surgery using tumescent lidocaine. Lidocaine toxicity was dose-dependent. Complications were equal to or lower than those listed by the Allergan Corporation for general anaesthesia. They concluded that Tumescent lidocaine used in TABS is a safe and effective form of conscious anaesthesia without sedation in cosmetic breast surgery in an office-based surgical centre.

At our practice we use the same method and I was instructed by the same surgeon who taught the author of the study.

We would be very happy to provide our data collected over many years, that may be advantageous to analyse for this purpose, although we do not have the funding to do this ourselves, would be happy to share this data for your own research. We don't see the problems mentioned and would welcome a study on our clients.

One of the arguments to utilise a Day Surgery is that cosmetic surgery requires a general anaesthetic. There is also no evidence that the only safe way to perform cosmetic surgery is using a general anaesthetic.

Many practitioners, who are plastic surgeons, have never trained in methods that do not use a general anaesthetic, so they know no other method.

There is evidence that other methods are safe and effective. An example is **Surgeon-Delivered Sedation for Outpatient Cosmetic Surgery** -*American Journal of Cosmetic Surgery: September 2012, Vol. 29, No. 3, pp. 223-229* A retrospective chart review was completed on 150 patient records from a private cosmetic surgery practice. For the period studied, 218 surgeon-supervised sedations provided adequate and safe anaesthesia for outpatient facial and body cosmetic surgical procedures. Breast surgeries required significantly higher doses of ketamine and propofol compared with the other procedures. The lowest amounts of ketamine and propofol were used during facial surgeries. In

select patients, surgeon-supervised sedations are safe and effective for outpatient cosmetic surgical procedures, a great study to enforce our point.

In our practice we do not use propofol and using an even lighter sedation, we safely perform the surgeries and have low complication rates.

Again we would be very happy to provide our data collected over many years, that may be advantageous to analyse for this purpose, although we do not have the funding to do this ourselves, would be happy to share this data for your own research.

Costs associated with the changes required for most practises to meet the day surgery or hospital guidelines would be in the millions of dollars which for those practices who have always met the guidelines and codes of conduct is quite unreasonable. This would place such a disadvantage to those who have been practising safely and have minimal complaints.

As mentioned, Having spent millions of dollars ensuring our locations are fully accredited and meet the safety standards set, we would have to seek compensation to cover this expenditure. It would restrict trade for a substantial amount of time, and I'm sure those other medical practitioners affected would seek financial compensation. This would cost the government millions in compensation.

If they did impose the changes, it would result in detrimental increases in prices for procedures and the amount of consumers that can then afford the procedure, driving people to other locations that may not be as safe. Increasing the price of cosmetic procedures can also result in consumers looking for overseas options.

Medical tourism is estimated to be a $100-million-a-year industry that is growing rapidly. Increased utilisation based on price, will mean more complications, even if there is not an issue with quality, and such complications arising from overseas procedures will end up back on our doorstep with Medicare more than likely footing the bill.

I would make the point having taken the time to visit overseas hospitals in Thailand, there are facilities and practitioners in overseas countries that are much safer and better than Australian facilities. It is not appropriate to lump all non traditional practitioners with a slur on quality without evidence.

It is important to realise that price does not reflect safety or outcome.

We have reduced our prices over the years by ensuring productive and efficient policies and procedures are in place. However, the greatest reduction that we have been able to achieve is by reducing the profit margins on these main surgeries. We introduced Breast Implants for $6999, then others followed and now there are several others who match our prices for less than $6000.

These changes have really opened the availability of these procedures to a broader demographic.

People like what we do, we do it safely and if there were changes that increased our prices there would be a wide political backlash that would follow as it would be perceived that any actions that increased the prices, were not for safety, but simply maintaining the higher profit margin of a select group of doctors.

In your impact statement there is mention that in 2012, Australian researchers reviewed malpractice claims and complaints about cosmetic procedures and found the most common complaints were that the medical practitioner failed to disclose the risks of a particular complication and the potential lack of benefit was not explained.

We dispute this.

We have standard practice where we have our consultation in videos online, we have people see two levels of medical consults with nurse and doctors, we give information sheets, we use a 7 page consent, we have medical staff call or have people see medical staff to go over the consents before surgery, we write down any questions that patients have and the answers we give,

we go over the consent again before the surgery. There is usually over a 7 days time period before any procedure.

We would suggest that an increase in complaints about failure to disclose is in many ways a method that is driven by legal practitioners who use the compilations mechanism as a way to discover information about case and create pressure on doctors and Medical Defences to settle cases.

Finally there is the suggestion that the administration of botulinum toxin and dermal fillers needs to the sole professional practice of people with a medical degree or members of a professional organisation. Or that people who want these products should have face to face consultations before a nurse, appropriately trained and supervised be able to provide those services. The present system is that most of the cosmetic injecting that is done in Australia is done by nurse practitioners.

There is no evidence that medical practitioners are better or safer practitioners. We have a system using well trained, by us, nurses and we have never been the subject of any complaint.

Restriction to only having doctors doing cosmetic injection would drive up the price, cause a political backlash and not provide any safer outcomes. The answer is again in government recognised training.

Any change requiring face to face consultation would open a widespread problem with all forms of off site consultations and service provision in remote areas. Medicare accepts teleconference consulting, what is the difference with the present system in cosmetic injections?

Also products, such as vaccines to school children, are S4 products and are administered by nurses without face to face consultation with each child. Should that be changed as well?

In summary, the actions that are being suggested are more to do with restraint of trade action by certain practitioner groups, under the guise of claims of patient safety.

I am available for consultation and participation with the Medical Board as required.

Dr Les Blackstock
Enhance Clinic