8 May 2012

Committee Secretary
Senate Standing Committees on Community Affairs
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By email to Community.Affairs.Sen@aph.gov.au

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.

Thank you for your letter dated 1 May 2012 asking me to respond to "adverse comments" about me that the Inquiry has received.

The submissions are objecting to my role as an advisor on the TGA Expert Committee dealing with PIP breast implants and the same objections would apply to my membership of the Chief Medical Officer's Clinical Advisory Committee concerning PIP implants. The concerns in the four extracts you have sent to me are based on the following opinions:

1. I am insufficiently qualified to give expert advice regarding breast implants.
2. As a surgeon who has implanted a substantial number of PIP breast implants I have a conflict of interest and may give biased advice for my own benefit and to the detriment of patients. For example a specific allegation suggesting that I would not recommend removal of all PIP implants "or offer discounts" and another suggesting I would not recommend all of my patients "to be tested for rupture."

In this submission I will address these concerns in the following way:

a) I will detail my qualifications and experience on the basis of which I am considered an appropriate expert in breast augmentation.
b) I will address the allegations of conflict of interest.
c) Having shown that the concerns expressed in the adverse submissions are misinformed I will address how the authors of these submissions have been led to their misplaced concerns. I will provide proof that dangerous and irresponsible reporting by some segments of the media have deliberately set out to frighten and alarm patients in pursuit of media ratings. This has very seriously undermined the confidence of patients in the evidenced based advice given by the TGA, the Chief Medical Officer (CMO)and the Government. In so doing this has caused, and continues to cause very substantial harm to a large number of Australian women and their families.

Qualification as an expert in breast augmentation specifically able to advise on the PIP issue

My position on both of the advisory committees is as the nominated representative of the Australasian College of Cosmetic Surgery. You have already received and decided to publish a submission from the College so I will not repeat details about the College and its role here. Suffice to say the College is the only organization in Australia which offers training, examination, accreditation and recertification in cosmetic surgery. The Senators should be aware that the College's submission was in large part written by me and therefore the views expressed in it may also be attributed to me and in effect are an annex to this submission. It should be noted that some of the views in the College submission are critical of the TGA and the Government particularly with regard to the communication of information to PIP patients.

I qualified as a medical practitioner in 1984. Since 1995 I have practiced exclusively in the field of cosmetic surgery. I hold the qualification Fellowship of the Australasian College of Cosmetic Surgery and am Board Certified in cosmetic surgery by the American Board of Laser Surgery, an examination I passed, according to the Board, with one of the highest scores ever recorded.

I am a past president of the College and have a record of advocacy for patients in ensuring standards of practice in cosmetic surgery in

Australia are world leading. As President of the College I developed a Code of Practice for cosmetic surgery to better protect patients and submitted this Code to the Australian Competition and Consumer Commission for authorization under the Trade Practices Act. The Code is attached as Appendix 1. Despite vociferous opposition during a public submission process from other elements of the profession, the ACCC authorized the Code as being in the public interest.

I am accredited by the College in, and have wide experience in a diverse range of cosmetic surgical procedures including face-lifting, liposuction, laser procedures, eyelid surgery and cosmetic surgery of the breasts. In the last 5 years my practice has become focused almost entirely on breast augmentation for both primary patients and patients needing revision surgery. I am one of Australia's most experienced breast augmentation surgeons having performed approximately 3,500 procedures. More than 60% of my patients are referred to me by word of mouth.

I am recognized around the world as an expert in breast augmentation, in particular in the use of implants and techniques to reduce complications and the need for revision surgery. For some years I have been invited to teach, and have taught, plastic and cosmetic surgeons both in Australia and around the world on this subject. This year alone I have already lectured by invitation in France (twice) and in Brazil. I have further invitations to lecture and/or perform live surgery demonstrations later this year in Germany, Israel and Hungary. My presentations on how to reduce complications in breast augmentation have been either given by me, or given by plastic surgeons who have asked to use my material, in every continent in the world except Africa. I was invited to write, and have written and had accepted, the chapter on the use of polyurethane foam covered breast implants to reduce complications of breast augmentation in the 2012 textbook, "Biomaterials in Plastic Surgery: Breast Implants" (Woodhead Publishing, UK). This textbook is edited by academic material science engineers and professors of Plastic Surgery from Washington University in the USA. Other contributors are world renown experts in breast augmentation.

While lecturing in Marseille in February this year I had a meeting with one of the surgeons who had initiated the French investigation into the activities of PIP. I also attended in Paris a special session of the National European and the International Societies of Aesthetic

Plastic Surgeons held specifically to address the PIP issue. These meetings provided me with valuable information I was able to share with the committee members upon my return to Australia.

Alleged conflict of interest

Any surgeon who has implanted PIP breast implants could have, or could be perceived to have a conflict of interest in giving advice about them. One of the comments you have sent me alleges that, as a surgeon who has a substantial number of patients with PIP implants I may play down the problems with them to "cover his own arse". Interestingly it has also been put to me the exact opposite, that I may have a conflict of interest causing me to have a grudge against PIP and its Australian distributor, Medical Vision Australia. This goes to the reason I was using PIP implants in the first place.

About 1 in 12 of my breast implant patients have PIP implants. The vast majority of these had their surgery from late 2006 until early 2008 when I was a principal investigator for a trial of a particular type of PIP implant which was covered in a microscopic layer of titanium. The purpose of this TGA registered and ethics committee approved trial was to determine if the titanium layer would reduce the incidence of the commonest complication, and the commonest reason for re-operation for breast implant patients. This complication is called capsular contracture. It occurs when the capsule, or membrane, of the patients own tissue which develops around all breast implants, contracts like shrink wrap around the implant causing it to become hard and change shape. Unfortunately with standard implants this occurs in 1 in 5 patients by 10 years and so finding products or techniques to minimize this is of paramount importance for patients. During the first half of 2008 I became increasingly concerned that PIP and Medical Vision Australia were not reporting the interim results of the trial properly. Ultimately, I resigned as a principal investigator because of this and I reported the reasons for my resignation to the TGA and the relevant ethics committee. This documentation is attached as Appendix 2. I received no payment or other compensation for my role in the trial and all of the implants were supplied at normal commercial rates.

In fact I am neither biased for or against PIP and Medical Vision Australia in the advice I have given to the TGA and CMO Committees. The minutes of the meetings show that all of the advice I have given has been evidenced based or given in order to

get more evidence. I believe if the Senators ask the chairmen of the committees this will be confirmed. Nevertheless, the possibility of conflict of interest, or perceived conflict of interest does exist and has been addressed. My experience using PIP implants and my dealings with Medical Vision Australia were disclosed in writing by me to the chairmen of the committees. This information was made clear to the committee members and the documented interaction with Medical Vision Australia regarding the trial was a standing item on the conflict of interest register. Neither the chairmen or the members of the committees believed there was any disqualifying conflict of interest and of course have been able to assess any advice I have given in full knowledge of my use of PIP implants and interaction with their distributor.

Furthermore, both of these perceptions of conflicted interest have been disclosed directly to the public. The Inquiry has received links to the Australasian College of Cosmetic Surgery's video series which was produced to fill the gap in understandable evidenced based information for patients. In the first video I specifically addressed the conflict of interest issue.

http://www.youtube.com/watch?v=4jWDvY2jcuU&list=PL8F6BAEEF3FE97D60&index=1&feature=plpp_video

This video and the rest in the series was produced by me on behalf of the College. The advice to patients and their families in the videos is representative of the evidenced based approach I have adopted in advising the TGA and CMO's committees.

As a clinician with direct experience in PIP implants I have been able to offer information to the committees that may not have been available had I (or someone else from the College with similar experience) not been included. When a problem like this arises it is crucially important to be able to talk directly with clinicians who have experience using the device in question. If those who know the most about the implantation of the device are excluded due to real or perceived conflicts of interest, advisory committees would not be able to do their job, particularly where the investigation is urgent. Indeed, if experience in using the device was to be an exclusion criterion then the advisory committees would necessarily be relying on information from surgeons who had no experience in their use which seems unlikely to add to the overall quality of the advice received and therefore unlikely to help patients. It should also be noted that other clinicians on the committees including the plastic

surgeons, breast surgeons and radiologists could be perceived to have similar conflicts of interest because they all potentially stand to gain either in fees paid for removal or replacement surgery or from the new Medicare funded MRI scanning rebate.

I am one of three surgeons and one of eight medical practitioners on the CMO's committee. The same three surgeons are members of the TGA expert advisory committee. It is important to realize both of the committees are advisory, not decision making. At no time have there been motions which required voting by the members.

To correct the record I am not even close to being Australia's "largest" implanter of PIP implants as has been suggested by the adverse comments. I also note I am not the only surgeon on the committees who has used PIP implants. I do in fact recommend all of my patients with PIP implants, indeed all patients with PIP implants regardless of their implanting surgeon, be tested for rupture by having an MRI scan and have stated this recommendation in the Australasian College of Cosmetic Surgery PIP information video series. I was also a strong advocate for the introduction of a Medicare rebate for MRI scans for PIP patients. Regarding the allegation that I would not offer discounts to my PIP patients, this is also incorrect. Any of my patients with PIP implants who, having been informed of and considered the evidence, wants to have her implants removed will not have any gap beyond their private health insurance rebate for my fee. If she has no private cover I will bulk bill the removal fee.

Note: I have been advised by the Senate Community Affairs Committee today 8 May that if I wish to address the adverse comments prior to their publication the previously advised deadline of 11 May has been brought forward to 9 May. As this was less than 24 hours notice this submission will address (a) and (b) detailed above and the evidence in support of (c) will follow in a subsequent supplementary submission.

Yours sincerely

Dr Daniel Fleming

Cosmetic Surgery Institute of Australia

The Australasian College of Cosmetic Surgery

Raising Standards, Protecting Patients

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CONSUMER/PATIENT CODE OF PRACTICE

A. Introduction

Membership of the Australasian College of Cosmetic Surgery (ACCS) provides patients with an assurance that ACCS Members meet the highest standards. The aim of this Code is to protect the public by making these standards transparent and ensuring that they are met. The Code also establishes transparent complaints and external adjudication processes.

The ACCS promotes and endorses truthful, ethical and informative advertising, and the provision of appropriate information to patients and potential patients. It also requires a face to face consultation with the Member offering a procedure before any procedure is undertaken. These processes are designed to ensure patients are provided with comprehensive advice allowing them to make fully informed decisions before consenting to undergo a cosmetic procedure.

Whilst all medical practitioners must adhere to relevant laws and guidelines, which vary from state to state, the Code highlights those responsibilities and sets additional and higher standards for Members of the ACCS.

To assist in compliance with laws and guidelines, the ACCS will provide Members with a guide of their overall responsibilities to consumers and to each other.

B. Interpretation

"**Advertising**" applies to all promotional material and is to be interpreted broadly. It includes websites and all electronic media. It also includes any advertising carried out on behalf of a Member and conduct by a Member's employees or agents or representatives. Those representatives include any third parties acting on behalf of members.

"Cosmetic Medical Practice" is defined by the College 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.[1] It includes non-surgical cosmetic medical procedures and cosmetic surgical procedures.

"FACCS" means a Fellow of the Australasian College of Cosmetic Surgery.

"FFMACCS" means a Fellow of the Faculty of Medicine of the Australasian College of Cosmetic Surgery.

C. Code Administration Committee

There will be a Code Administration Committee, comprised of at least 3 members. There is to be an independent Chair, being someone with experience of developing codes. Another member is to be a consumer representative

1 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.

nominated by an organisation such as the Australian Consumers Association. Further there is to be at least one member representing the College.

The Committee will review the Code tri-annually and report to the College on its review. It is able to make recommendations to the ACCS about the Code and its administration.

In its review the Committee shall consult with relevant regulatory bodies.

In its review the Committee will have access to matters considered by the Complaints Panel and the Appeals Committee.

The College will adopt the recommendations of the Committee unless it gives written reasons why a recommendation is not accepted.

The review and the ACCS response will be placed on the ACCS Website and will be submitted to the ACCC.

The ACCS must collect and keep data that will assist the Code Administration Committee in its reviews.

The Code

1. General Considerations

Australasian College of Cosmetic Surgery Members have a duty to the public and to each other. That duty is not a duty to legal minima, but one that seeks to constantly improve standards and consumer welfare.

Members must:

1.1 practice with integrity and honour, in the best interests of their patients, with the patient's safety and quality of care being paramount;

1.2 conduct their professional affairs in accordance with all applicable laws, relevant professional guidelines and ethics, and in a manner that upholds the good reputation of the medical profession;

1.3 strive for the advancement of the speciality of cosmetic medical practice through research and development, ensure the maintenance of the highest standards through continued medical education and training, keep themselves up to date on legislative and ethical requirements relevant to being a medical practitioner and specialising in cosmetic procedures; and

1.4 adhere to the College Constitution, By Laws and Codes.

In addition ACCS members must comply with the following guidelines:

2. Advertising and promotion

2.1 Advertising must not contain false, misleading or deceptive statements, or create misleading impressions about the doctor or clinic or the services offered. It should provide balanced information on the procedures or products advertised and should not suggest these are risk free. Critical omissions can also be misleading.

2.2 Members must not mislead consumers about the need for any procedure.

2.3 Superlatives should not be used in any advertising unless they can be readily proven to be correct and as such are not misleading. For example, to claim that a particular breast implant has the “least” risk of a specific complication would be acceptable if true and supported by the peer reviewed literature. Such information is of value to consumers. To claim a practitioner is the “best” in any way is not permissible as it is a value judgement, not readily proven, which could mislead consumers.

2.4 Members must be able to substantiate any claims made in their advertising at the time the claims are made.

2.5 Comparative advertising should be used with caution. It can be valuable in conveying information to consumers but it must be correct and readily proven. For example, to claim a type of treatment is safer than another type of treatment is acceptable if true and supported by the peer reviewed literature. Again, such information is of benefit to consumers.

2.6 Photographs may be used to display the results of treatment and or complications. ‘Before and after’ photographs should be presented with

similar pose, presentation, lighting and exposure. Any uncomplicated results shown should be typical and be likely to be reproduced in a similar patient. Photographs must not be altered in any way other than to protect a patient's identity. 'Before and after' photographs must be of the advertising doctor or clinic's own patients and contain accurate and informative captions.

Where before and after photographs are used the procedure being referred to must be the only change that has occurred to the person being photographed. Further, a clear statement that the procedure being referred to is the only change that has occurred to the person being photographed be included when photographs are used in advertising. This requirement is especially relevant in Victoria.

2.7 Testimonials should not be used in advertisements.

2.8 Medical or surgical procedures should not be offered as inducements or prizes in competitions or contests, or as a way of generating business.

2.9 Offers of gifts or other inducements (for example time sensitive discount periods) shall not be used in order to attract potential clients.

2.10 Discounts for early payment should not be used as an inducement to commit to a procedure.

2.11 No Member will offer finance facilities as part of the services provided, except a credit card facility. In no circumstances should a Member accept any commission from a credit provider.

2.12 The College notes that in Victoria advertisements of a surgical (invasive) procedure shall include in a prominent place and in a visible fashion the following statement:

"*Any surgical or invasive procedure carries risks. Before proceeding, you should seek a second medical opinion*".
Whilst this is not mandatory in other States and Territories, Members advertising in other States and Territories are encouraged to use such a statement.

College and Certification logo and post nominals

2.13 The College logo or relevant Certification logo may only be used by doctors who are currently accredited Fellows, or Fellows of the Faculty of Medicine of the College. Additionally, the Certification logo can only be used if the doctor is currently compliant with the College CME programme, as evidenced by the CME certificate.

2.14.1 If any doctor who holds an FACCS or FFMACCS wishes to perform any invasive surgical procedure for which he or she is not accredited by the College, then that doctor shall not be entitled to use their College post nominals, nor mention the College in any way which might be seen or heard by a patient considering undertaking such a procedure.

2.15. College members are required to comply with all relevant laws and guidelines in jurisdictions where they practice. Where an inconsistencies this Code and relevant laws or guidelines arises, College members must adhere to the relevant between laws or guidelines.

In particular, College members practising in **Victoria** should be aware that

Victorian *Advertising Guidelines for Registered Medical Practitioners,* developed by the Medical Practitioners Board of Victoria (MPBV) to advise medical practitioners about the provisions of the *Health Professions (Vic)* (the HPR Act) and how the MPBV interprets these provisions, state that:

• It is an offence under section 80 of the HPR Act for a medical practitioner to hold him – or herself out to be a specialist, either explicitly or by implication, or attempt to convey that perception to the public unless his or her registration has been endorsed under section 27 of the HPR Act.

• "The Board considers that consumers are best protected when practitioners advertise only qualifications that have been awarded by institutions accredited by the Australian Medical Council."

Note.

Members should be aware that there are no cosmetic surgery qualifications that have been awarded by any institutions accredited by the AMC and the AMC has not yet recognised cosmetic surgery as a medical specialty.

3. Guidelines for informed consent - applicable to all procedures

3.1 Informed consent is a process, not simply the signing of a consent form**.** Members should give information about the risks of any intervention, especially those that are likely to influence the patient's decisions. Known risks should be disclosed when an adverse outcome is common even though the detriment is slight, or when an adverse outcome is severe even though its occurrence is rare.

3.2 All Members must provide to patients, before any procedure is agreed to, a College produced information brochure about cosmetic procedures. This must include information about what College qualifications mean and also outline the College's complaints process. The brochure must inform patients how to obtain a full copy of this Code of Conduct. To the extent possible the same information is to be on the College's website and on Members' websites, either directly or via a link to the College's website. The brochure will contain information about other routes for patients to make a complaint; for example, medical boards and statutory health care complaint bodies. The brochure will also advise patients that a second opinion is advisable before making any decision to have a procedure. The brochure is to be provided to patients at their first consultation or where the first consultation is other than face to face, by mail or email prior to that first consultation.

3.3 Additionally all Members must have available for patients a written summary (for example in the form of a resume) of their own training and experience. The summary is to be provided to patients at their first consultation or where the first consultation is other than face to face, by mail or email prior to that first consultation

3.4 All Members must, before any procedure is agreed to, provide the patient with full disclosure of the fees and charges, and likely total cost of the procedure. Patients should be made aware that further costs could be incurred in the event of complications occurring.

3.5 Members must, before any procedure is agreed to, provide patients with information about:

- how and where the procedure is performed;
- who will be assisting in the procedure;
- possible complications and side-effects, their frequency and severity;
- any anticipated post operative scarring;
- whether the patient be required to go to a hospital;
- whether the patient will need to take time off work;
- the post-operative course and expected recovery time;
- possible alternative treatments where appropriate including the option of no treatment at all; and
- the expected realistic outcome.

3.6 No procedure should take place unless the Member has consulted with the patient beforehand and has fully explained to the patient the procedure and any associated risks. Patients should be encouraged to ask questions at this consultation.

3.7 If a Member offers an invasive procedure to a patient which that Member has performed less than 100 times previously, then the Member must disclose to the patient, at the initial consultation, how many times the Member has performed the procedure before.

Guidelines for informed consent for more invasive procedures with a significant risk of an adverse long term outcome

3.8 The guidelines described in this section are in addition to the rules concerning Members' conduct described above. These guidelines refer to invasive procedures which have a significant risk of an adverse long term outcome. They are not relevant to temporary fillers or botulinum toxin treatment for example, to which all statutory requirements and the additional requirements for ACCS members as detailed above apply. They would apply, for example, to laser resurfacing, chemical peels with the potential to affect the dermis and to permanent fillers.

3.9 The patient must have at least one consultation, with the Member performing the procedure before the day of surgery.

3.10 For geographical reasons it is sometimes impractical for patients to meet the doctor face to face for their initial consultation. In these circumstances it is acceptable for the patient to send photographs to the doctor and then for the doctor to have a telephone or video consultation with the patient. This can be considered to be the initial consultation with the doctor performing the procedure. If the patient elects to proceed, the doctor must see the patient face to face before the procedure, preferably at least one day before. It is accepted that there may be instances where, for logistical reasons, this face-to-face meeting can only occur on the day of surgery, but this should not be considered the norm. If the face-to-face meeting, being the exception, does not occur at least a day before the procedure, the reason for this must be properly documented.

3.11 It must be clearly stated to the patient that, if either the Member or the patient decides at that meeting not go ahead for any reason, then a full refund of any monies paid will be provided. If a cancellation fee from the anaesthetist and/or the hospital might be incurred, the patient must be advised of this prior to paying any monies.

3.12 If there is a consultation with someone other than the Member performing the procedure, this is not an acceptable substitute for the process described in 3.8, 3.9 and 3.10 above, which must still occur.

3.13 If the Member is inexperienced in the specific procedure contemplated, either because the Member is new to the procedure or because the procedure itself is new, this should be disclosed to the patient at the first consultation, as per the 100 case rule indicated above.

3.14 At the end of the initial consultation the patient should be provided with a procedure-specific consent form to consider at home.

3.15 The patient should be told, and it should be stated on the consent form, to contact the Member, by telephone or at another consultation, if they have any questions or need clarification of the consent form.

3.16 If there is doubt about which procedure would be most appropriate for a patient, or if the patient is unsure about having the procedure, the desirability of a second opinion should be emphasised, reinforcing the advice in this respect contained in the information brochure.

3.17 Generally there should be a ‘cooling off’ period of at least five days between the initial consultation with the doctor performing the procedure and the procedure itself. It is accepted that there may be circumstances where, for practical reasons, this period may need to be shorter but it

should never be less than one night. If the 'cooling off' period is less than 5 days the reasons for this must be properly documented and acknowledged by both the Member's and patient's signature.

4. Post-Operative Care

4.1 Each Member must:

- provide full and adequate post-operative care for their patients, including provision for emergency after-hours care. The post-operative surveillance should be appropriate for the magnitude of the surgery performed and to allow for early detection of and intervention in adverse outcomes; and
- provide adequate and appropriate on-going care, either by his or her own assessment and treatment, or by appropriate referral.

5. Complaints Processes

5.1 Preamble

The Rules dealing with the Complaints regime and disciplinary process adopt the concepts of natural justice. In this context ***natural justice***, also known as procedural fairness, has three main principles:

1. The Member complained of is provided with:

- a fair hearing;
- all information within a reasonable timeframe required to answer the allegations made against him/her; and
- an opportunity to respond to all allegations or decisions affecting him/her and;

- their response is genuinely considered.

2. The decision maker is impartial; and

3. The Complainant must be kept properly informed at all times.

Complaints

5.2 All complaints must be in writing.

5.3 If a complaint is made to the College in writing that a Member has allegedly breached any part of the Code of Practice, the complaint will be handled in accordance with the procedures set out in the Code.

5.4 Upon the receipt of a written complaint the College will refer the complaint to the Chairman of the Complaints Panel.

5.5 On receipt of a written complaint, the College shall advise the Complainant and the Member involved in writing within 7 days that the matter has been referred to the Chairman of the Complaints Panel

5.6 The Chairman of the Complaints Panel shall not refer the matter to the Panel if:

(a) the Complainant does not agree, in writing, that their identity can be revealed to the Member complained of, unless their identity is not necessary for the Panel to investigate the matter;

(b) the information provided by the Complainant does not allege nor disclose a breach of the Code;

(c) it is more appropriate that the complaint be dealt with by a Court or an external complaints, disciplinary, conciliation, or arbitration body or procedure;

(d) the Complainant is seeking compensation or reimbursement only and is not alleging that a Member has been in breach;

(e) the act or omission giving rise to the complaint occurred before the date of commencement of the relevant ACCS Rules;

(f) the subject matter of the particular complaint was comprised in a same complaint by the same person (or any one or more of them) previously considered by the Complaints Panel and finalised;

(g) the complaint is against a non ACCS Member;

(h) the matter is being handled by a medical insurer; or

(I) the Chair of the Panel is of the view that the matter is frivolous or vexatious.

Any such decision by the Chair and the reasons is to be included in the Register of Determinations established pursuant to Clause 6.1.

5.7 If, in the view of the Chair of the Panel, the breach is of minor nature and can be dealt with by advice to the Member, the complaint will not be referred to the Panel. The Chair will inform the Complainant in writing of this decision and advise the Complainant that if he or she is not satisfied with this outcome the Complainant can insist the complaint be referred to the Complaints Panel and this then must occur.

Any such decision by the Chair and the reasons and action taken is to be included in the Register of Determinations established pursuant to Clause 6.1.

5.8 Any complaints resolved under the process described in 5.7 above are to be included by the Chairman of the Complaints Panel in the annual report described in Section 8 below.

Complaints Panel

5.9 The College Council will appoint a Complaints Panel. The role of the Panel is to consider complaints against an ACCS Member alleging breaches of the ACCS Code.

5.10 The Panel shall have a minimum of three members at least one of whom shall have legal qualifications and at least two of whom shall not be a Member of the ACCS. The Chair of the Panel will be independent of the ACCS and shall have legal qualifications. At least one of the members shall be an ACCS Member.

5.11 No Member who is in any way concerned with the matter in question, or who is connected in any business entity, firm, corporation, or department with the Member accused or the party who originated the complaint, shall be a member of the Panel.

5.12 Panel processes must be conducted in private.

5.13 The Member complained of may be legally represented before the Panel, provided that:

(a) the Panel is advised not less than 5 days prior to the date set down for any hearing of the intention of the particular party to have legal representation, and the name and contact details of each such legal representative, and

(b) the Panel may, if it is satisfied that legal representation has served or may continue to serve to delay the hearing of the matter, terminate the right of the party to have legal representation in which event the legal representative or representatives must depart the hearing and take no further part in it and the hearing must proceed in the absence of that legal representation.

5.14 No party may be compelled to appear at a hearing of the Panel, but any party to a hearing may provide written submissions and evidence to the Chair of the Panel at least 3 days before the hearing.

5.15 The Panel may make such procedural arrangements as it thinks fit, including directions for the provision of written submissions and evidence.

5.16 The Panel may conduct hearings as it considers fit, having regard to the necessity that adequate consideration be given to matters before it. However, the Panel shall hold a hearing if the Member complained of asks that there be a hearing.

5.17 The laws and rules of evidence do not apply to proceedings before the Panel.

5.18 The Panel may obtain legal advice and have legal advisers in attendance at a hearing.

5.19 The Panel may conduct hearings or other meetings of the Panel in person or by other means, provided that all members of the Panel are able to hear and speak to each other.

5.20 All determinations and decisions of the Panel are to be made by a majority of the members of the Panel.

5.21 The Member complained of in any matter shall be informed, at least 14 days prior to any hearing, of:

(a) the name of the Panel Chair and members of the Panel;

(b) the exact nature of the complaint and the disciplinary charge that the Member will be required to address;

(c) the time, date and place for the hearing;

(d) the right of the Member concerned to be heard in regard to the allegations;

(e) whether or not the person instigating the complaint may be called to give evidence and/or provide a written submission in statutory declaration form;

(f) whether or not other witnesses may be called to give evidence and/or provide a written submission in statutory declaration form;

(g) what material the Member should bring to the hearing.

5.22 The Complainant shall, at least 7 days prior to any hearing, be informed of the time, date and place of the hearing and whether or not they will be required to give evidence at the hearing.

Admission of Evidence

5.23 No documents will be admitted into evidence that have not been made available to the Member complained of within a reasonable time prior to the hearing. This timeframe will be at the discretion of the Chair of the Panel. If any party wishes to introduce additional documentary evidence, the Chair may, if necessary, adjourn the hearing to allow the other party sufficient time to consider the evidence.

Hearing Procedure

5.24 The procedures for the hearing shall be at the discretion of the Chair of the Panel.

5.25 A transcript of a hearing is to be kept and a copy given to the Member complained of and the person who instigated the complaint, if that person was asked by the Panel to be involved in the hearing. A fee may be charged by the College for the transcript.

Panel's Decision

5.26 The Chair of the Panel shall furnish in writing to the ACCS Council, the Panel's decision, the reasons for the decision and details of any sanction to be imposed.

Sanctions

5.27 Where the Panel determines that a Member has not been involved in a breach, the Panel shall make a determination to dismiss the matter.

5.28 Where the Panel determines that a Member has been involved in a breach, the Panel shall make a determination of breach against the Member complained of, and may impose one or more of the following sanctions:

(a) reprimand the Member;

(b) admonish the Member publicly;

(c) counsel the Member;

(d) suspend the Member from membership of the ACCS, for such period and on such terms or conditions as the Panel thinks fit;

(e) where the Member is already the subject of an order for suspension, continue that suspension for such period and on such terms or conditions as the Panel thinks fit;

(f) require the Member to take such steps as the Panel may determine to correct the effects of any breach found to have been engaged in;

(g) require a payment to the ACCS to be used as the Panel recommends, such penalty to be no more than $10,000.00 for the first instance and no more than $20,000.00 for any subsequent breach;

(h) require the Member to undertake such education or compliance program as the Panel thinks fit, provided that the purpose of such program is to reduce the likelihood of future breaches by the Member;

(i) expel the Member from membership of the College;

(j) adjourn the proceeding subject to compliance with such conditions as to sanctions as the Panel may otherwise impose in accordance with the ACCS Rules;

(l) order the Member to reimburse a patient; or
(m) impose any other Order that the Panel thinks fit.

5.29 Where the Panel considers the matter to involve a serious risk to public safety and patient welfare it must refer the matter to the relevant regulatory authorities in the relevant State or Territory.

5.30 Where the Panel is of the view that a Member has unreasonably failed or refused to co operate with the Panel then that non-cooperation can be held to be a breach of the Code and the Panel can impose an appropriate sanction until such time as the Member cooperates.

5.31 The Panel can award reasonable costs at its discretion against an ACCS Member involved in the matter before it.

5.32 The Panel shall have a pre-sentence process, to relay likely sanctions to the Member complained of, and give that Member an opportunity to state any objections to likely sanctions.

5.33 When determining any sanction, the Panel may take into consideration any penalty imposed on the Member as a result of external legal proceedings brought against that Member in relation to the same matter.

5.34 A suspended Member must comply with the ACCS CME requirements and provide a return for each year as normally required.

5.35 If a suspended Member breaches the conditions of suspension, then the penalty shall be expulsion from Membership.

5.36 The Panel shall have the power to stay any sanction pending an appeal. The member involved in an appeal must apply to the Panel for a stay and provide reasons for a stay or partial stay.

Notification of Decision

5.37 The Member complained of and the party who instigated the complaint shall be informed in writing of the Panel's decision, the reasons for the decision, and any rights of appeal against the decision.

5.38 The Panel will issue a written determination within 30 days of its decision.

5.39 The Member concerned shall be provided with a copy of the Panel's written determination.

External Appeals Committee

5.40 The External Appeals Committee, shall be a three-member appeal body, including the Chair, appointed from time to time by ACCS Council. The Chair, who must possess legal qualifications, shall be appointed by Council and shall not be an ACCS member. The Committee is not to be a standing Committee, but established when there is an appeal.

5.41 The Chair will recommend the other two members to the Council. The Council will accept the recommendations unless any appointments raise issues of conflict of interest. One member recommended by the Chair shall be an ACCS member with relevant experience in the matter before the Committee. The other member shall not be an ACCS member.

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Appeal Process

5.42 The Member complained of may, within 21 days of being notified of the Panel's decision, appeal against that decision by notice in writing to the Chair of the Appeals Committee.

5.43 The College can also appeal a Panel decision and must do so within 21 days of the decision.

5.44 The Chair of the Appeals Committee shall notify the Chair of the Complaints Panel when an appeal has been lodged and shall request copies of the relevant correspondence and records of proceedings held by that Panel. This documentation may include:
(a) the original complaint;
(b) the charge formulated from this complaint;
(c) all correspondence and written evidence in relation to the matter; and
(d) the record of the Panel's hearing, if any.

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5.45 This material will be provided to the Appellant.

5.46 The Chair of the Committee will also advise the original Complainant of an appeal being lodged.

5.47 The Appellant is to notify in writing the basis of the appeal including all documentation within 21 days of lodging the appeal. If the Appellant considers more time is necessary to prepare the appeal, the Appellant may submit a request in writing to the Chair of the Appeals Committee for an extension of time.

5.48 Parties to the appeal, other than the Appellant, shall provide written responses to the Appellant's submission within timeframes determined by the Chair of the Appeals Committee.

5.49 If the Appellant does not comply with the timeframe determined by the Appeals Committee Chair and an approval for extension of time has not been granted by the Chair of the Appeals Committee, the appeal shall be deemed to be abandoned and the parties informed accordingly in writing.

5.50 Where the Chair of the Appeals Committee is of the view that the material submitted by the Appellant does not support a valid appeal, the Chair can dismiss the appeal and inform the parties in writing, Such decision is to be included in the Register of Determinations established pursuant to Clause 6.1.

Withdrawal of Appeal

5.51 An Appellant may withdraw an appeal by giving notice in writing to the Chair of the Appeals Committee.

5.52 A withdrawal must be received no later than seven days before the day scheduled for any hearing. After this time the Appellant will be responsible for any costs incurred by the Appeals Committee.

Conduct of Appeal Hearing

5.53 The procedure and conduct of the appeal hearing will be at the discretion of the Chair of the Appeals Committee, including the involvement of the original Complainant.

5.54 The Appeals Committee will not, except where the Committee requests additional material, accept any additional material once the hearing has commenced.

5.55 Appellants may be represented by legal counsel or other person on terms and conditions set by the Appeals Committee.

Consequences of Appeal

5.56 The Appeals Committee may uphold the appeal, dismiss the appeal or may vary the sanction imposed by the Panel.

5.57 The Appeals Committee must give written reasons for its decision.

5.58 The ACCS Council must be informed of the Appeals Committee's decision.

Action by Council

5.59 The ACCS Council cannot overrule or vary the decision of the Appeals Committee.

Costs Awarded by the Appeals Committee

5.60 Reasonable costs of the appeal may be awarded by the Appeals Committee, either in favour of the Appellants or against the Appellants;

Notification to Parties

5.61 The Chair of the Committee shall advise the parties of the Appeals Committee's decision in writing. The original Complainant is also to be advised of the outcome of any appeal.

Quorums

5.62 A decision of the Appeals Committee shall not be invalidated in consequence of a vacancy in its membership or the absence of any member provided that the decision is made by at least two Members, including the Chair of that Committee.

Keeping Complainants informed

5.63 The College may keep a person instigating a complaint informed of progress in handling the complaint, provided always that the College must not provide any information to a Complainant in relation to the progress of the complaint where:

(a) to do so may expose the College or the Complaints Panel or Appeals Committee to liability for civil damages;

(b) to do so would or could prejudice, impede or in any other manner adversely affect the investigation of the complaint or;

(c) to do so would deny procedural fairness to the Member, the subject of the complaint.

6. Publication of decisions

6.1 The College must maintain a Register of all determinations made by the Complaints Panel and the Appeals Committee and make the Register available for inspection by Members and relevant regulatory authorities. otherwise make available

6.2 The College may, publish to Members, any other persons or the public generally the content of, or an extract from, or précis of, any determinations by the Complaints Panel and the Appeals Committee and the register maintained by the College.

6.3 The College shall publish regular information about the outcome of disciplinary matters including an annual overview of the operation of the Colleges disciplinary regime.

6.4 Where a Member has been suspended or expelled the College shall advise relevant State and Territory Medical Boards.

7. Indemnities

7.1 The College will indemnify each member of the Panel and Appeal Committee against any claim, action or proceeding brought against that person by any other person arising out of or in connection with, a proceeding before the Panel or Committee, or any order, determination or decision made by the Panel or Committee, and this indemnity will extend to the conduct of the defence of any proceedings and the payment of any costs thereof.

7.2 The indemnity does not extend to actions brought by the College against any person.

8. Annual Report

8.1 The Complaints Panel and Appeals Committee shall submit an Annual Report to the ACCS.

8.2 That Report is to include details of,

- the number of complaints and appeals received by the College in relation to alleged breaches of the Code
- the key issues involved in each complaint or appeal
- the outcome of each complaint or appeal, including, if the complaint was dismissed by the Chair of the Complaints Panel or Appeals Committee without being referred to the full Panel or Committee, the reasons for this
- any sanctions imposed
- whether other complaints about the member in question have been received in the past.

The details to be provided in the report do not extend to personal details about the complainant or the member complained about, or information that would identify the complainant or member complained about

8.3 Those Annual Reports will also be submitted to the ACCC and to the Code Administration Committee. and put on the ACCS Website.

9. Assistance to the Complaints Panel and Committees

9.1 The College will provide appropriate resources to the Complaints Panel and Appeals and Code Administration Committees in order for them to undertake their tasks.

10. Compliance Audits

10.1 The College will engage an independent person to undertake periodic audit checks in relation to compliance with the Code, in particular, issues relating to informed consent, information provided to potential customers and claims made about procedures and need for procedures.

10.2 Such audit checks will include random checks on Members.

10.3 Apparent breaches of the Code so discovered are to be referred to the Complaints Panel as if they were complaints.

10.4 The results of such audits are to be provided to the Code Administration Committee and the ACCC annually, on or before the anniversary of the date of the ACCC authorisation of the Code coming into effect.

11. Enforcement

11.1 The College Council will enforce any Orders of either the Panel or the Appeals Committee.

11.2 Where a Member fails or refuses to comply with an Order of the Panel or the Appeals Committee, the Council will either suspend or expel the Member, as the Council deems appropriate

By email

18th April 2008

Stan Racic
Managing Director
Medical Vision Australia

Dear Stan

Re: Letter from you titled "PIP Titanium Coated Breast Implant trial – interim report".

I have been forwarded a copy of the above letter dated 26th February 2008. As I am the principal investigator listed on the trial approval documentation I am surprised I was not shown a copy of this letter before it was sent out nor was I even on the distribution list. It seems the letter was sent to selected investigators only and that I was not one of them. Interestingly, neither was the investigator who works in the same practice as me. When you visited me recently you did not mention the letter. I am inevitably left with the impression you did not want me to see it.

I have very serious concerns about the content of the letter which I believe contains false information which you describe as "facts of the trial to date" and that this is misleading to investigators. Specifically:

1. "We can confirm however we are extremely positive about the results at this point. We have had less than 1% Baker III capsular contracture and I should point out that 80% were from one investigator."

I have personally contacted 6 other investigators to ascertain first hand what their results have been. They have reported a total of 16 patients already having Baker III capsules out of 240 patients (6.6%). 3 of these patients had bilateral contractures. I would remind you contracture rates are conventionally quoted on a per patient not a per implant basis. I specifically asked the investigators if they had reported all of these cases to you and they confirmed they had. The population total includes patients who have only recently been implanted and have not yet the time to develop a contracture if they are destined to do so.

As you know I reported 8 patients out of 102 (7.8%) in a period of recruitment from November 2006 until October 2007. This makes the current contracture rate of your longest serving and most prolific investigators 7% (24 out of 342) not "less than 1%". I note this only includes the contractures I have personally been able to confirm.

As I am known to be the principal and the first investigator, recipients of the letter have, not surprisingly, assumed that I am the one investigator said to be responsible for 80% of the contractures. Not only is this false it is also misleading. There have been at least 24 contractures of which 8 have been reported by me. This is 33% not 80%. My rate of contractures is not statistically different to the rate experienced by the group of 6 other investigators contacted even though the average implantation time for my patients is longer. The implication, confirmed by the other investigators, is in the context of a claimed "less than 1% contracture rate", one doctor had 80% of the contractures and therefore this is related to the doctor and not the product. To make this statement without mentioning that this doctor had performed many more cases and had a significantly longer follow up period is misleading. This is compounded when the figures quoted are false. Not only have those investigators to whom you chose to send the letter been misinformed, my reputation has been impugned.

2. You state that "One investigator is no longer recruiting new subjects".

This is also not correct. At least three others I have spoken to have come to the same conclusion as me - these implants do not reduce capsular contracture rates, and are no longer recruiting patients for the study.

3. You say "MVA is continuing with recruitment drive for both trial subjects and surgeons and I am pleased to report we have several new key surgeons enrolled and several surgeons going through the process of enrolling in the study."

Given the false and misleading letter sent to some of the current investigators and your statement "that we are extremely positive about the results at this point", I have reason to believe this "recruitment drive" is not accompanied by an informed choice by new investigators and nor therefore, new patients.

As the principal investigator I cannot allow this to continue and I am obligated to ensure the real facts are presented to existing and potential investigators as well as patients.

I have previously told you a contracture rate that is already 6-7% when many of the study population have not had their implants for even 6 months is, in my opinion, sufficient evidence to halt further recruitment and wait to see if the 1-2 year results confirm this. You argued it was too soon to do make this decision and I reluctantly accepted this. However I cannot accept the correct information being withheld from investigators and incorrect information being given instead.

I require that a new letter be sent to all investigators informing them of the facts and correcting the misinformation in the letter of 26th February. I also require, as the principal investigator, I see this letter before it is sent out to confirm its veracity.

It has also come to my attention that Belberry Human Research Ethics Committee has not yet received a progress report. Please see the attached letter to me from Belberry. The study approval document from Belberry which I signed as principal investigator, and of which you have a copy, required such a progress report be submitted in November 2007. I therefore also insist an accurate and up to date progress report be sent to Belberry as soon as possible with a copy to me.

Once these documents have been sent I will resign as the principal investigator as I no longer have confidence in the integrity of the study. Should you not send the documents I will resign and take whatever action I feel is necessary to ensure both investigators and patients are fully informed and my undertakings to the Ethics Committee are fulfilled.

Stan, it gives me no pleasure to be sending this letter but it is in response to a situation entirely of your own and PIP's making. The statement in your letter "we cannot draw any definite outcomes because the trial is continuing" is not a carte blanche to make claims which are not supported by the facts. We cannot let disappointment at the true interim findings or commercial considerations affect our ethical responsibilities and I sincerely hope you will now act accordingly.

Yours sincerely

Dr Daniel Fleming

Monday, 16 June 2008

Stan Racic
Managing Director

Re: Titanium Study

Dear Stan,

You have not responded to my email of 23rd May. Other than to acknowledge its receipt, you have also not responded to my letter of 18th April in which I detailed my concerns about the Titanium Study.

I have now no option but to resign as the Principal Investigator of the study. I will be contacting the TGA, Bellberry and other investigators to inform them of this and the reasons why.

I will continue as an investigator in order to follow up the more than 100 patients who are enrolled in the study under my name.

Yours sincerely,

Dr Daniel Fleming