ADVANCED MEDICAL INSTITUTE PTY LIMITED
(ABN 21 117 372 915)

Supp. Submission No. 13.1
(Impotence)

29 September 2009

PN 29/09/09.

The House of Representatives Standing Committee on Health and Ageing
PO Box 6021
Parliament House ACT 2600

Roundtable on Impotence Treatments – Supplementary Submission

We refer to our submission to you dated 3 September 2009 and to the submissions lodged by third parties.

We make the following further submissions in response to those third party submissions:

Use of technology based consultations

Commentary has been made by each of Andrology Australia, Professor Christopher McMahon, Dr David Malouf, the NSW Medical Board and Pfizer Australia regarding the use of technology based consultations.

As set out in AMI's principal submission, premature ejaculation and erectile dysfunction are accepted by the medical profession as being separate conditions.

None of the submissions lodged by any party provide any independent evidence for requiring that patients with premature ejaculation should be required to have a physical examination as part of their diagnosis or treatment. As set out in AMI's initial submission, the American Urological Association's guidelines for the Treatment of Premature Ejaculation clearly state that "The diagnosis of PE is based on sexual history alone". In other words, physical examination is not considered necessary. We accordingly submit that the committee should find that physical examination is not required in relation to the treatment of premature ejaculation.

In terms of the various comments regarding the need for a physical examination in relation to the treatment of erectile dysfunction we make the following comments:

1. as set out in our submission, there are conflicting views regarding the need for a physical examination for the treatment of erectile dysfunction patients;
2. whilst Pfizer Australia's submission states that it believes that patients should be physically examined by a doctor following a detailed medical consultation, Pfizer continues to supply Viagra to Boots Pharmacy in the UK with full knowledge that Boots Pharmacy is supplying Viagra to patients who have not even been consulted by a doctor. In AMI's experience, the Boots Pharmacy initiative would only have been able to be implemented with lobbying and product information support from Pfizer. AMI believes that the committee should request that Pfizer provide the committee

with all information submitted to regulatory authorities in the UK in relation to this approval. Furthermore, AMI would have expected that Pfizer would have ceased supplying medication to Boots Pharmacy unless Boots Pharmacy ceased its current practices if Pfizer honestly believes that patients should not be provided with erectile dysfunction medication without first being consulted and physically examined by a doctor. AMI believes that the committee should ask Pfizer Australia why it is continuing to supply Boots Pharmacy with medication given its stated view that erectile dysfunction medication should not be provided without a full physical examination by a medical doctor prior to medication being supplied; and

3. as set out in our initial submission, Dr McMahon's professional practices do not accord with his written recommendations. Furthermore, as demonstrated by AMI's study of general practitioners, the vast majority of GPs do not conduct physical examinations in connection with the treatment and diagnosis of erectile dysfunction for the reasons set out in our initial submission. Any move away from technology based consultations is out of step with practices occurring elsewhere, will not improve client care and is in fact likely to reduce client care. As further support for this submission we attach an article from August 2008 regarding technology based consultations published by the Mayo Clinic which states that properly conducted technology based consultations produce superior patient outcomes to traditional consultations. The Mayo Clinic is a leading independent clinic in the sexual health field and we note that it is the source of one of the studies in Dr McMahon's submission (see note 5 of his submission).

For the reasons set out above as well as the reasons set out in our initial submission, AMI believes that any move away from technology based consultations is out of step with developments in other leading jurisdictions, will not lead to any improvement in patient care and will result in fewer people seeking help.

Product information

We note that Dr Malouf has made a written submission regarding lack of knowledge regarding the components of AMI's treatments. As set out in ACP's submission, these components are clearly set out on the product label for each AMI treatment. Furthermore, detailed information regarding these matters are set out in the comprehensive patient information booklets provided to patients, a copy of which has been provided to the committee and details of which is addressed in ACP's submission. In any event, the components of these treatments are well known and are clearly set out in AMI's original submission in any event. They are also commented on in Dr Malouf's submission (how is he able to comment on them if he does not know what they are?). Whilst Pfizer Australia may be unaware of AMI's patient information booklets and instructional DVDs, those booklets and DVDs are extremely comprehensive and in line with best practice in the sexual health field as demonstrated by the material included with AMI's original submission. We are able to provide a further copy of these documents to the committee if required.

Efficacy of medication

Comments regarding the efficacy of medications used by AMI have been made by Andrology Australia, Dr McMahon, Dr Malouf and Pfizer Australia.

In terms of the comments made by Andrology Australia regarding the use of injectible medication, we confirm that the principal injectible treatment used by AMI to treat erectile dysfunction is trimix. Whilst the concentrations may differ, this is the same type of treatment referred to in Andrology Australia's own publications regarding recommended treatments as well as the treatment listed on Dr Malouf's own website as being an effective and appropriate treatment for erectile dysfunction.

We also note that no material has been presented to the committee which supports any adverse commentary regarding the treatments used by AMI in relation to premature ejaculation with the exception that some comment has been made that it may be more appropriate for patients presenting with psychological premature ejaculation to be treated using counselling rather than pharmacological agents. This argument was previously used some 15 years ago to suggest that patients with psychological erectile dysfunction should not be treated with pharmacological agents. The generally accepted position in modern medicine supported by independent clinical trials is that pharmacological agents are effective treatments for both physiological and psychological erectile dysfunction and premature ejaculation (see for example the attached article by Arthur L. Burnett).

The material which we have submitted with our original submission clearly demonstrates that the main active ingredient in AMI's premature ejaculation treatments (clomipramine) is widely accepted as the leading treatment in this area and we have also submitted extensive independent evidence which clearly demonstrates that nasal administration is an effective administration method.

As a consequence, we do not believe that any substantive material has been lodged with the committee which indicates that AMI's premature ejaculation treatments are ineffective or inappropriate or that AMI's injectible erectile dysfunction treatments are ineffective or inappropriate. We believe that the committee should make a finding this is the case.

As a consequence, we also believe that the only debate relates to the appropriateness of AMI's nasal and lozenge erectile dysfunction treatments.

Andrology Australia has commented that the use of AMI's erectile dysfunction nasal sprays is "experimental" and would require "ethics approval" at any major medical centre or teaching hospital. With respect, no "ethics approval" is required for use at any medical centre and AMI does not operate a teaching hospital. Doctors are entitled to use these treatments without any regulatory approvals and Andrology Australia's comments about "ethics approval" are ill-informed and inaccurate. Secondly, in terms of the comment regarding "experimental use", AMI has treated well over 50,000 patients using its erectile dysfunction nasal sprays and has provided the committee with copies of patient testimonials which clearly detail patient satisfaction with the treatments. Most clinical trials typically involve 10 patients to 2,000 patients. The volume of patients treated by AMI using this treatment is a major multiple of the number of patients typically treated in a clinical trial and is therefore not experimental. Finally, we note that the active ingredients used in AMI's treatments have been in use for a long period of time and are well recognised as effective erectile dysfunction mediations as demonstrated by the material included in our original submission. Finally, nasal delivery is a well recognised method of delivery of medication and is generally considered a more effective delivery method than tablet based medication. Given the widespread and longstanding use of these medications to treat these conditions and the well recognised method of delivery there is no reasonable basis on which Andrology Australia can reasonably state that this method of treatment is experimental.

Each of Dr McMahon, Dr Malouf and Pfizer Australia claim that they are unaware of clinical trials supporting the use of apomorphine or phentolamine in the treatment of erectile dysfunction and have made statements in their submission or previously that nasal delivery is not an effective delivery method. AMI has provided you with independent third party material which clearly demonstrates that apomorphine and phentolamine are well accepted effective medications for treating erectile dysfunction and that nasal delivery is an effective method of delivery of those medications. It is inconceivable that these parties are unaware of these clinical trials or publications and AMI believes that they have not referred to this material in their submission as it clearly contradicts the evidence which they have given. As set out in the

material provided to you, apomorphine and phentolamine nasal sprays are effective treatments for erectile dysfunction – contrary to the claims made by Dr Malouf, Vectura's studies indicate that the pulmonary delivery of apomorphine (which is similar to nasal delivery) has similar levels of efficacy to Viagra. Furthermore, contrary to the statements made by McMahon, Malouf and Pfizer, the use of off label treatments to treat erectile dysfunction is reasonably widespread, particularly in the US where off label treatments are more readily accepted than in Australia. In the circumstances, we believe that the statements made by these parties regarding the efficacy of AMI's treatments are ill informed and inaccurate. We note that no party has submitted any material to you which demonstrates that apomorphine and phentolamine are not effective treatments for erectile dysfunction and we note that overseas regulatory approvals for the sale of apomorphine and phentolamine based products to treat erectile dysfunction remain in force. Furthermore, contrary to the submissions made by various parties there is no regulatory requirement that Viagra, Cialis or Levitra be used in preference to apomorphine or phentolamine based products whether in Australia or elsewhere.

As a related issue, we note that Dr McMahon has admitted in his submission that intranasal administration is a more rapid absorption method than sublingual or tablet delivery – something he has previously denied. By way of example, Dr McMahon was quoted earlier this year in the Sydney Morning Herald as stating that the nasal administration of drugs was akin to crushing a tablet and applying that mixture to your scalp, a view no serious health physician would ascribe to. As set out in the material which we have provided to you, nasal administration of medication is widely recognised as an effective method of delivery of medication. It enables rapid absorption of medication into the bloodstream and bypasses the blood-brain barrier. This clear contradiction between Dr McMahon's submission to you and his statements to the media is characteristic of Dr McMahon – he frequently cites material on a selective basis with him only providing material which supports the proposition which he is propounding as demonstrated by the clear contradictions between his public statements regarding physical examinations and his personal failure to provide them.

In terms of the comments made by Dr McMahon regarding side effects from tablet based apomorphine and phentolamine, AMI notes that both Uprima and Vasomax obtained regulatory approvals in a number of leading jurisdictions indicating that the medications were considered safe for use. AMI further notes that it is unaware of ***any*** serious adverse issues arising from its erectile dysfunction nasal sprays despite having treated thousands and thousands of patients with these treatments. As set out in AMI's original submission, the dosage of active ingredients used in AMI's nasal sprays is much lower than the dosage used in Uprima as a result of the efficiency of AMI's delivery system. This reduced dosage substantially lowers the risk of any adverse health outcomes. The comments made by Dr McMahon in relation to this matter are a smokescreen – as set out in ACP's submission each of the ingredients used in AMI's medications have been the subject of appropriate safety and efficacy tests and there are no major health concerns arising from the use of these medications.

Furthermore, most patients are aware of the various options which are available to treat erectile dysfunction. Independent research indicates that men generally see an advertisement for erectile dysfunction medication a minimum of 14 times before responding to the advertisement and the treatment options available to men for this condition are well publicised with television and billboard advertising being undertaken by the major multinationals) (eg the Respond Again and Welcome Back Tiger advertisement campaigns as well as the major campaign featuring Pele). A significant portion of AMI's patients have already tried Viagra, Cialis or Levitra and have contacted AMI because they are not satisfied with the treatment which they have received due to efficacy issues, the treatment is contraindicated or they simply want to try another type of medication. As set out in the independent material provided to you, the term "off label" is simply a regulatory term and has nothing to do with the efficacy or appropriateness of treatment options. We believe that no change should be made to the

existing regulatory regime which permits patients to choose their own treatment provider and treatment method.

We note that quite a few of the submissions to the committee clearly state that the ongoing ability to provide compounding and off label treatments are essential components of the existing pharmaceutical regulatory regime – a view we agree with. Any change to this regime will seriously impede the ability of physicians to treat patients. Many patients are contraindicated for Viagra, Cialis and Levitra as a result of being on nitrate medications or as a result of other health issues.

Relationship between AMI and its doctors and AMI and its compounding pharmacy

Pfizer has made comment on the relationship between AMI and its doctors and AMI and its compounding pharmacy.

The remuneration of AMI's doctors is unrelated to sales volumes. As set out in the material provided to the commission, AMI's doctors frequently decline to provide prescriptions for patients in circumstances where those doctors believe that the relevant treatments are contraindicated. Such behaviour is inconsistent with claims that these doctors place profit above patient welfare.

In terms of AMI's compounding pharmacy, as set out in ACP's submission neither AMI nor any of its shareholders has any financial interest in ACP and neither ACP nor its owner has any financial interest in AMI. The relationship between AMI and ACP is a fee for service relationship. AMI has selected ACP to provide services to AMI as AMI believes that ACP is the best qualified party to provide those services as it is the largest and most professional compounding pharmacy in Australia. AMI does not support the proposed regulatory changes to limit the number of prescriptions which a compounding pharmacy may perform as AMI believes that this will reduce the quality of services provide and lead to services being provided by less qualified pharmacies with lower quality standards.

Longer term treatment

Andrology Australia has commented that long term contracts should not be permitted. Similar comments have been made by Dr McMahon who has also commented on the expenses associated with AMI's treatments. Finally, a lengthy submission has been made by Legal Aid Queensland regarding contractual issues.

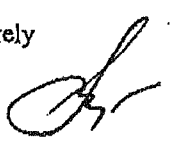
AMI makes the following comments on those submissions:

1. as set out in AMI's original submission, the average length of AMI's contracts is less than 6 months and AMI's average contract amount is less than $2,000. AMI's treatments incorporate the cost of medical services as well as the cost of medication. In evaluating the comparative cost of AMI's treatments the committee needs to consider the total cost of alternative treatment including consultations and medication. AMI believes that its treatments are cost competitive once all of these costs are taken into account;
2. independent clinical research supports the long term treatment of patients with sexual dysfunction. In this respect, attached are a series of articles which confirm that chronic rather than on-demand treatment of patients should be undertaken including an article written by Dr McMahon;
3. the comments made by Legal Aid Queensland only present one side of each of the relevant interactions with AMI clients. In particular, we note the following:
    a. many of Legal Aid Queensland's case studies relate to people who claim that they only entered into trial arrangements and did not enter into longer term

arrangements. Some of these complaints also allege that the patients did not understand the quantum of monies which they are committing to. Each of AMI's telephone sales is recorded. It is AMI policy that customers are required to be advised the total cost of treatment as well as the monthly cost of treatment in line with legal requirements. Each of these telephone sales are monitored for quality purposes with contracts being voided where these requirements are not met. As a result, AMI does not believe that Legal Aid Queensland's summary of the patient's interactions with AMI in relation to contractual arrangements (trials) accurately reflect those interactions;

b. Legal Aid Queensland has commented that patients have complained that they have not been advised of conditions attaching to refunds (ie the requirement that all treatment methods be tried before a refund is provided) with a further comment that patients would not have proceeded with a course of treatment if they were aware of this requirement. AMI's staff are specifically required to advise patients that all treatment methods must be trialled before a refund can be provided and are specifically required to advise patients that one of the treatment methods which must be trialled is injectible medication. These requirements are also clearly set out in customer terms and conditions which are provided to all patients. As set out above, each of AMI's telephone sales with patients is recorded and is monitored for quality purposes. One of the items which is specifically checked is whether patients are advised of the requirements attaching to refunds. As a result, AMI does not believe that Legal Aid Queensland's summary of the patient's interactions with AMI in relation to refunds accurately reflect those interactions;
c. Independent research confirms that erectile dysfunction can be an early indicator of heart disease and that the failure to treat mild erectile dysfunction can result in patients developing more severe erectile dysfunction. However, AMI agrees that cervical cancer is unrelated to erectile dysfunction and would consider any such claim to be inappropriate. AMI notes that the summary of case studies refers to a death reference in case study 16 but notes that there is no such reference in case study 16; and
d. Various submissions regarding AMI's cooling off period, dispute resolution and complaints handling processes. As set out in AMI's original submission, AMI provides patients with a voluntary 48 hour cooling off period as a matter of corporate policy. AMI notes the concerns which have been raised by Legal Aid Queensland that staff do not appear to follow those policies in all cases and that it has concerns regarding the implementation of AMI's dispute resolution and complaints handling processes. AMI believes that it is important for these policies to be effectively delivered and advises that it will be reviewing these policies to ensure that they are properly implemented and administered.

Yours sincerely



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