The Royal Australasi
College of Physicians

Adult Medicine Division

Australasian Chapter of Sexual Health Medicine

Submission No. 7
(Impotence)

PW 7/9/09

4 September 2009

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

Submission to the House of Representatives Standing Committee on Health and Ageing Roundtable on Impotence Treatments from the Australasian Chapter of Sexual Health Medicine, The Royal Australasian College of Physicians.

The internet, printed and audio-visual media, unsolicited SPAM email and postal mail, contain advertisements and testimonials for multiple "remedies" for erectile dysfunction (ED), premature ejaculation (PE) and female sexual dysfunction (FSD) and other sexual dysfunctions. Many of these remedies contain drugs or herbal remedies or use alternate methods of drug delivery, which are not supported by published randomised clinical trials (RCTs) adhering to the rigors of evidence-based medicine. Many of these remedies make unsubstantiated and often astonishing efficacy claims, are available without a physician's advice or prescription and are priced far in excess of TGA approved medication dispensed in a pharmacy. Men and women with sexual dysfunction are embarrassed, distressed, secretive, and are particularly vulnerable to unscrupulous individuals or companies who make unsubstantiated claims of sexual healthcare provider expertise or high treatment outcomes but focus more on inappropriate high charging and deny sufferers basic medical care and cost-effective proven treatment. As a result, these men and women are likely to make impulsive and ill-informed treatment decisions and to be medically disadvantaged and placed at substantial risk.

The **Australasian Chapter of Sexual Health Medicine** (AChSHM) wishes to express serious concerns regarding the quality of medical care provided to patients with erectile dysfunction (ED), premature ejaculation (PE) and female sexual dysfunction (FSD) by the Advanced Medical Institute (AMI) and other similar companies conducting business within Australia. These concerns relate to several different aspects of their business and healthcare provider conduct.

Introduction

Erectile dysfunction can be associated with a variety of co-morbid medical conditions and lifestyle risk factors including diabetes mellitus, hypertension, high cholesterol, coronary artery disease, depression and cigarette smoking. The majority of men with ED are in an age group where the incidence of cardiovascular disease and prostate cancer is increased and a valuable opportunity exists during a consultation for general health screening.

Premature ejaculation is a common sexual dysfunction which is associated with negative psychological consequences including distress, bother and frustration which may affect quality of life, partner relationships, self-esteem, self-confidence, and can act as an obstacle to single men forming new partner relationships. There is evidence suggesting that PE has a genetic basis or is related to sexual performance anxiety related to previous sexual failure, psychological or relationship problems and/or ED. Premature ejaculation treatment strategies include psychosexual counselling and drug treatment, either alone or in combination as part of an integrated treatment program.

Female Sexual Dysfunction comprises several distinct clinical problems which may prevent a woman from enjoying sex and include a lack of sexual desire, an inability to become aroused, the lack of orgasm and/or painful intercourse. These problems may have physical or psychological causes. Physical causes include conditions like diabetes, heart disease, nerve disorders, hormonal disorders or side effects of prescribed or recreational drugs. Psychological causes may include work-related stress, anxiety, depression, marital and/or relationship problems and/or past sexual abuse.

Management of sexual dysfunction involves initial patient evaluation by an appropriately trained medical practitioner, psychologist or other sexual healthcare provider. This should involve a detailed medical and sexual history, a physical examination and appropriate investigations. Effective treatment and optimal treatment outcomes can be achieved with psychological counselling, drug treatment and/or surgery, according to individual patient/partner needs, either alone or as part of an integrated treatment program.

Telephone Technology Based Patient Consultations Conducted Without a Physical Examination

The Australian Joint Medical Boards Advisory Committee (JMAC) Good Medical Practice Guide National Policy for Technology based Patient Consultations (National Policy No. NAT-005-2007), which has the status of a Code of Professional Conduct, states that a telephone based patient consultation must include an " *...adequate assessment of the patient's condition based upon medical history and that the doctor must be confident, especially with patients where the doctor has no prior knowledge or understanding of the patient's condition, that a direct physical examination would not add important information to assist in informing patient of treatment decisions and advice.*" The current consensus of expert international medical opinion is that men seeking treatment for ED and other sexual disorders cannot be evaluated and treated without an opportunity for the consulting medical practitioner to perform a physical examination. This is, and will always remain as one of the basic tenets of medical practice. The findings and recommendations of the WHO Second International Consultation on Sexual Dysfunction [1] and the International Society of Sexual Medicine "Standard Practice in Sexual Medicine" [2] both states that "*...the physical examination remains an essential component of sexual dysfunction evaluation.*"

AMI's initial evaluation of men with ED involves a medical history taken by a nurse, a subsequent telephone consultation with a doctor, and concludes with an interview with a sales person. There is no direct face-to-face consultation or physical examination with a medical practitioner. A failure to examine and further investigate men presenting for treatment of ED denies the doctor an opportunity to diagnose comorbid disease which may be associated with significant increases in both morbidity and mortality. Undiagnosed diabetes mellitus has been reported to occur in as many as 12% of men presenting for treatment of ED. [3] Erectile dysfunction has been reported to occur in 70% of men with chronic depression present for 6 or more months. [4] In addition, there is evidence

---

[1] Lue TF, Giuliano F, Montorsi F, et al. Summary of the recommendations on sexual dysfunctions in men. J Sex Med. 2004 Jul: 1:6-23

[2] Seftel A. Diagnosis of Erectile Dysfunction. In Porst H, Buvat, J ed, Standard Practice in Sexual Medicine. Oxford UK Blackwell Publishing, 2006:59-74

[3] Deutsch S, Sherman L. Previously unrecognized diabetes mellitus in sexually impotent men. *Jama*. 1980 Nov 28: 244:2430-2

[4] Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and its medical and

to suggest that men with ED, especially men with diabetes mellitus, raised blood lipids and testosterone deficiency syndrome, are at an increased risk of silent myocardial ischemia i.e. unrecognised coronary artery disease, and subsequent cardiac events. [5] A seemingly uncomplicated medical history of ED, the absence of a history of other co-morbid disease, allergies or prescribed medication, or a recent consultation with a primary care physician or other doctor does not absolve a second doctor from the responsibility of performing a physical examination. The absence of an opportunity to examine patients who present with ED, PE or FSD may substantially disadvantage the patient, represents an expedient approach to patient care, should be both deplored and condemned, and invites strong criticism from the Chapter.

The Use of Unproven Off-label Treatments for Sexual Dysfunction

As any branch of medicine evolves, many drugs are routinely used "off-label" but may be regarded as part of standard care for a condition until approval is achieved. Although regulatory approval is not always synonymous with superior treatment outcomes, it does assure prescribers that expert and regulatory peer review of clinical trial data has demonstrated drug efficacy and safety.

The Chapter has several concerns regarding the use of unproven off-label treatments for sexual dysfunction.

1. Responsible and safe prescribing of off-label drugs can only be achieved if there is a sufficient quantity of evidence from well-designed randomised clinical trials (RCTs) to support drug efficacy and safety. The notion that proven efficacy and safety of a drug administered by one method of delivery e.g. an oral tablet, can be extrapolated to an second method of delivery e.g. a nasal spray, is incorrect until proven in RCTs. The use of intranasal sprays of apomorphine and phentolamine or clomipramine for the treatment of ED or PE respectively by AMI, has no basis in clinical research and is not supported by **ANY** data from RCTs which has been published in a peer reviewed medical journal. These medications are not TGA approved for the treatment of ED or PE.

2. The current consensus of expert international opinion is that different drugs should not be combined together for the treatment of any medical condition until well-designed pharmacokinetic, drug interaction and clinical efficacy and safety RCTs have demonstrated safety and efficacy. Both apomorphine and phentolamine produce vasodilation i.e. enlargement, of arteries and to a lesser extent veins and have, in clinical trials, been demonstrated to cause a reduction in blood pressure. It is also recognized that a combination of these medications may be associated with an additive blood pressure lowering effect in much the same way that phosphodiesterase type 5 inhibitor drugs such as Viagra and nitrate type medication such as Nitrospray are associated with profound and rapid decreases in blood pressure which far exceed that seen with either drug alone. It is also well recognized that a combination of phosphodiesterase type 5 inhibitor drugs and nitrate type medication can be associated with sudden cardiac death or a cerebrovascular accident due to this profound lowering of blood pressure. There are several reports of cerebrovascular accidents occurring following administration of sub-lingual apomorphine (Uprima®, Abbott, TAP) and sub-lingual phentolamine (Vasomax®, Schering-Plough). The intranasal administration of both drugs is likely to be associated with more rapid absorption of the drug and possible exacerbation of this potential additive blood pressure lowering effect. This potential adverse effect and the overall safety concerns associated with the use of combination therapy involving multiple drugs has not been addressed with any form of clinical trial.

3. One of the basic aspects of medical care is that patients must provide informed consent to that care. Informed consent extends beyond the basic acknowledgement by the patient that he is prepared to undertake a specific course of treatment and understands that

---

psychosocial correlates: results of the Massachusetts Male Aging Study. *J Urol.* 1994 Jan: 151:54-61

[5] Inman BA, Sauver JL, Jacobson DJ, McGree ME, Nehra A, Lieber MM, Roger VL, Jacobsen SJ. A population-based, longitudinal study of erectile dysfunction and future coronary artery disease. Mayo Clin Proc. 2009 Feb;84(2):108-13

treatment's potential risks and benefits. Informed consent must also include providing the patient with a complete list of medical treatment options including potential risks and benefits of each of those options. There are a large number of TGA approved and unapproved off-label treatments available for ED which include oral medications, self-administered penile injections, external vacuum constricted devices and surgery. Although many of these options may not be relevant to every patient, a prudent and responsible medical practitioner would alert a patient to these alternative treatments. Advanced Medical Institute routinely offers patients initial treatment with a nasal spray medication containing apomorphine and phentolamine. This medication appears unusually expensive and the requirement that a patient sign a binding contractual agreement for supply of this medication, is, whilst possibly a common commercial practice in general business, inconsistent with the current standard for the provision of ethical medical care and treatment by medical practitioners, health care professionals, pharmaceutical companies and dispensing pharmacists. Contrary to good medical care and inconsistent with the TGA approval derived prescriber assurance of proven efficacy and safety, AMI fails to offer patients TGA approved treatments as initial treatment or as "salvage treatment" in men unresponsive to intranasal sprays. It appears that the only medications prescribed by AMI doctors, are medications manufactured on behalf of AMI and on-sold to the patient. The management of sexual dysfunction by AMI appears biased towards the company balance sheet rather than quality patient care and the achievement of best possible treatment outcomes.

The use of unproven intranasal medication as a first line treatment for ED in a man who has not been previously treated with TGA approved oral medication such as Viagra, Cialis or Levitra, represents a significant departure from the minimum standard of care expected of a medical practitioner, may be potentially dangerous to patients and invites strong criticism from the Chapter.

Recommendations

1. Revision of the Australian Joint Medical Boards Advisory Committee (JMAC) Good Medical Practice Guide National Policy for Technology based Patient Consultations (National Policy No. NAT-005-2007) to require that an initial consultation which results in prescription of medication for the treatment of sexual dysfunction must include a physician conducted physical examination
2. The use of off-label treatments for sexual dysfunction should be limited as follows ...
    a. Evaluation of the off-label treatment/s in a well-designed properly conducted clinical trial, approved by a properly constituted human ethics committee and strictly adhering to the guidelines of the Helsinki Declaration and to any other local human clinical trial conduct guidelines
    b. Formal approval of the off-label treatment/s for sexual dysfunction by evaluation of all available clinical trial data by an independent panel of experts drawn from peak representative medical groups.

Yours sincerely

Assoc Professor Chris G McMahon MBBS FAChSHM
Australasian Chapter of Sexual Health Medicine,
The Royal Australasian College of Physicians