1998 REPORT OF THE MINISTERIAL COMMITTEE OF INQUIRY INTO

IMPOTENCY TREATMENT SERVICES IN NSW

Contents of report of Committee of Inquiry into Impotency Treatment Services

The Hon Dr A Refshauge MP
Minister for Health
Parliament House
Macquarie Street
Sydney NSW 2000

HCCC
HEALTH CARE COMPLAINTS COMMISSION

Dear Dr Refshauge

Report of the Committee of Inquiry into Impotency Treatment Services

It is with pleasure that I present the report of the Committee appointed by you under section 20 (4) of the *Health Administration Act 1982* to investigate and inquire into impotency treatment clinics.

You will note from the report that the Committee consulted broadly, received written and oral submissions from a wide variety of stakeholders and conducted extensive scientific, medical and legal research into this area of treatment. The Committee has made a number of evidence-based findings and recommendations which aim to promote an improvement in the standards and accountability in this area of practice. The recommendations include legislative reform as well as the introduction of patient information forms and consent guidelines in order to empower patients in their selection of treatment options.

While the terms of reference of the inquiry focussed on impotency treatment clinics and services, it appears to the Committee that the findings and recommendations may be applied without significant alteration to a number of other health care services.

Impotency treatment clinics tend to operate in a manner which concentrates on high turnover of patients, short practitioner/patient consultations and sales to patients of medication or associated products supplied by the clinics themselves at high profit margins. This pattern of practice may be considered to be analogous to the practices of other 'specialist' services which target one condition in isolation and advertise their treatment directly to members of the public, such as clinics for weight loss, cosmetic surgery, anxiety or tattoo removal.

I trust that you will cause this report to be presented to the public at your earliest convenience and that you will support the recommendations contained herein.

Yours sincerely

Merrilyn Walton
Chairperson
Committee of Inquiry into Impotency Treatment Services
Commissioner
Health Care Complaints Commission

Acknowledgements

The Inquiry conducted a thorough investigation into all relevant facets of impotency treatment services and has formulated substantiated and practical findings and recommendations. The implementation of the recommendations will provide an effective impetus for the improvement in standards of care and accountability.

This could not have been achieved without the involvement of both members of the public and the health care professions in providing written and oral evidence, nor without the participation of expert and experienced Committee members who were professional, dedicated and gave willingly of their time to ensure the successful completion of this project.

The Committee was assisted throughout by its Executive Officer, Sarah Crawford, who was responsible for compiling and producing this report.

My sincere thanks go to all participants,

Merrilyn Walton
Chairperson
Committee of Inquiry into Impotency Treatment Services
Commissioner
Health Care Complaints Commission

Recommendations of the Ministerial Committee of Inquiry into Impotency Treatment Services

1. The Committee recommends that single drug therapy should be the first treatment option for all patients receiving injections of pharmaceutical products into the shaft of the penis (intracavernosal injection therapy), with multi drug therapy as a salvage option only in the event of an unsatisfactory response.
2. Medical practitioners should be reminded by the NSW Medical Board in its "Medical Board Newsletter" of their obligations for the appropriate labelling of therapeutic substances under the *Poisons and Therapeutic Goods Act 1966*. Labelling should include the existence and amount of all constituent ingredients. Section 36 of the *Medical Practice Act 1992* should be amended to specify that the failure to comply with the *Poisons and Therapeutic Goods Act 1966* constitutes "unsatisfactory professional conduct".
3. Products used in intracavernosal injection therapy should be prepared under aseptic conditions, with their shelf life determined through independent sterility and stability testing, and through random batch testing.
4. The achievement of the necessary standards for the preparation of drug injections is unlikely to be achievable immediately without the imposition of significant hardship upon current users of these medications. Accordingly, the Committee recommends that practical interim measures should be introduced prior to the adoption of full sterility and stability testing (with a recommended lead-in time of three months to two years).
5. These interim measures should include mandatory distribution of patient information and consent forms, mixing under laminar flow and shorter designated shelf lives (with an arbitrary shelf life to the maximum period of one month given the lack of evidence supporting long lasting stability).
6. The Committee recommends that all medical practitioners providing treatment to patients suffering from erectile dysfunction follow guidelines which focus on quality and responsible patient assessment, diagnosis, monitoring and care rather than on the sale of medication (see Appendix for guidelines). The Committee further recommends that its guidelines be published by the NSW Medical Board in its "Medical Board Newsletter". It is the view of the Committee that a failure by medical practitioners to practice in accordance with these guidelines in their treatment and management of patients suffering from erectile dysfunction would be evidence of unsatisfactory professional conduct as defined in section 36 of the *Medical Practice Act 1992*.
7. The Committee recommends that all medical practitioners providing treatment to patients suffering from erectile dysfunction ensure that they maintain their skills in this area of treatment through participation in regular educational courses by appropriate professional bodies. In particular, all practitioners in this area should develop their sexual health counselling skills.
8. All clinics providing treatment to patients with erectile dysfunction must inform patients both orally and in writing as to the procedure for the management of priapism in accordance with the guidelines, patient information sheet and patient consent form in the Appendices. The clinics must ensure that either the treating practitioner or another identified practitioner with suitable expertise be available for consultation 24 hours a day to provide medical care in the event of an emergency situation associated with the treatment, such as priapism.

9. The New South Wales Medical Board and the Health Department should remind practitioners of their obligations to discuss with their patients the complete range of options available to treat erectile dysfunction. Failure to discuss options with patients due to commercial considerations may already constitute unsatisfactory professional conduct under the *Medical Practice Act 1992*.

10. Medical practitioners have a professional and legal duty to disclose any financial interests they have in the provision of any form of treatment, or in the sale of any pharmaceutical or related product. Section 36 of the *Medical Practice Act 1992* should be amended to include in the definition of unsatisfactory professional conduct the failure to disclose any financial interest in the treatment options recommended by a medical practitioner, or any other conflict of interest known to the practitioner.

11. Medical practitioners should not associate themselves with any service or product which is advertised in a manner capable of misleading patients or capable of bringing the profession as a whole into disrepute. To do so would amount to unsatisfactory professional conduct under section 36 of the Medical Practice Act.

12. The regulations under the Medical Practice Act should be amended to include that self-referral, symptom-specific clinics such as those providing impotency treatments should comply with guidelines approved by the Director-General of the NSW Health Department analogously to the provisions in relation to emergency, casualty or similar services.

13. The ACCC be approached to introduce a mandatory industry code of conduct under section 51AD of the Trade Practices Act for the provision of services for erectile dysfunction which includes the above provisions on disclosure of financial or other interests in the recommendation of treatment options, the advertising of these services and the appropriate standards of treatment.

Executive Summary and Findings of the Committee

On 26 August 1997, the Deputy Premier, Minister for Health and Minister for Aboriginal Affairs, the Honourable Dr Andrew Refshauge, MP appointed a Committee under section 20 (4) of the *Health Administration Act 1982* to investigate and inquire into impotency treatment services in New South Wales.

The Minister recognised the need for a broad, independent review of the standards applied in impotency treatment clinics following serious concerns raised by both the Health Care Complaints Commission and the Pharmaceutical Services Branch of the NSW Health Department during their investigations into consumer complaints.

Erectile dysfunction affects an estimated ten per cent of the male population on an age-related basis. The introduction of "specialist" clinics, the high level of advertising and media interest, as well as the recent release in the USA of the oral medication Viagra may have increased the awareness of the condition as a medical issue and that it is a condition which may respond successfully to treatment.

Sufferers and the broader community generally associate erectile dysfunction with a significant degree of personal embarrassment which may adversely affect the ability of patients to enforce their rights to adequate health care. The main form of treatment offered to patients is an injection of pharmaceutical products into the shaft of the penis to stimulate erections. These injections may cause side effects which are unknown to or unanticipated by the patient including priapism, the development of penile fibrosis or permanent scarring.

The Minister appointed individuals to the Committee who had experience and expertise in areas including consumer representation, health care and pharmaceutical policy and practice, the treatment of erectile dysfunction and the investigation of health care services and standards.

The Committee established a methodology within the terms of reference and sought submissions from the public and from key health related organisations regarding the practices of impotency treatment clinics. It received 56 written and 8 oral submissions from patients and members of the public, from professional associations and health care professionals as well as from people currently or previously associated with the clinics providing impotency treatment services. It obtained information from other health authorities within New South Wales, around Australia and internationally.

The Committee met on eight occasions and formed three sub-committees to address the main areas requiring analysis and the formulation of findings and recommendations. The report of the Committee is based on the written and oral submissions it received, on extensive scientific, medical and legal research conducted by the Committee members and on the members' professional experience in relation to the following four major areas.

The preparation of pharmaceutical products intended for patient self-injection

The Committee identified that only one drug (Prostaglandin E1) had been properly evaluated for safety and efficacy by the Therapeutic Goods Administration in Australia. The mixtures of products commonly provided in the treatment of erectile dysfunction have not been scientifically tested for effectiveness, sterility in composition, compatibility, stability, bioactivity or shelf-life when combined for patient self-administration over an extended period of time. The long-term safety of the ad hoc drug mixtures for injection therapy has not been established and there is little reliable information on their adverse effects, which may include the known complications of bruising, priapism and fibrosis as well as additional complications not yet determined.

Patient assessment, diagnosis and care

The majority of submissions to the Committee from consumers, professional associations and health care practitioners identified the lack of appropriate standards of care and treatment as a major issue. The Committee was informed by the main clinic operators that 95 per cent of patients are offered multi-drug injection therapy during the initial consultation.

This focus on a single method of treatment without standardised medical review or follow up was found by the Committee to be accompanied by a failure to assess adequately the medical or psychological history of patients or to provide them with sufficient information on their options for treatment. Patients received inadequate information concerning the risks of any complications which may develop from the therapy. The clinics also provided inadequate monitoring or support outside standard clinic hours or in the management of priapism after the patient had attended the initial consultation and purchased the medication.

The pricing of supplied appliances and medications, other related financial aspects of impotency treatment services

The charges to the patients of the impotency treatment services were found to be highly inflated, with evidence that the multi-drug mixtures and the associated products were sold to patients at up to or in excess of ten times the original cost to the clinics. The Committee found that commercial considerations were motivating the clinics' approach to medical treatment over and above the patient's best interests. There was evidence that individual practitioners had received a share of the profits on the sales of medication in the past, which is in breach of ethical standards of practice as well as a breach of the Pharmacy Act 1964. A clear conflict of interest is present where a practitioner profits either directly or indirectly from the provision of certain services to patients and fails to disclose the practitioner's interests in so doing. The Committee further considers that such activities militate against the practitioner's professional, legal and ethical obligations to provide the most appropriate treatment to patients.

Advertising of impotency treatment services

The Committee conducted a broad review of the nature and extent of advertising present in the media for impotency treatment services as well as for other, analogous 'specialist', self-referral health care services. The advertising was found to be sensationalised and capable of misleading members of the public. With this in mind, a survey was conducted of the legislative framework for the advertising of health care services around Australia in the context of the current national competition policy. The Committee considered the applicability and development of mandatory industry codes under the Trade Practices Act 1974. The Committee reviewed appropriate international standards, and considered favourably the Canadian model associated with the Regulated Health Professionals Act 1991 which links the professional's name with the service advertised, thereby increasing the level of personal responsibility and liability.

Glossary of terms and abbreviations

Adverse Drugs Reaction Advisory Committee (ADRAC): a Commonwealth body which is a sub-committee of the Australian Drug Evaluation Committee

Australasian College of Sexual Health Physicians: an educational body involved in the professional development of medical practitioners in the discipline of sexual health medicine

Australian Competition and Consumer Commission (ACCC): a Commonwealth body established under the Trade Practices Act 1974 to regulate the conduct of corporations in providing goods and services to the public

Australian Drug Evaluation Committee (ADEC): a Commonwealth body which evaluates and approves drugs for registration by the Therapeutic Goods Administration

Australian Medical Association (AMA): the largest medico-political organisation representing medical practitioners in Australia through voluntary membership

Australian Register of Therapeutic Goods (ARTG): a Commonwealth register of all goods approved for therapeutic purposes in Australia

Caverject: the brand name for alprostadil, a formulation of Prostaglandin E_1, which has been marketed in injection form in Australia and elsewhere by the pharmaceutical company Pharmacia Upjohn Pty Limited, and is available under the Commonwealth government's Pharmaceutical Benefits Scheme under authority prescription

Fibrosis: a thickening and scarring of connective tissue, most often a consequence of inflammation or injury

Food and Drug Administration (FDA): the body which regulates the import and marketing of goods and medications in the United States of America

Health Care Complaints Commission (HCCC): an independent New South Wales government authority which has been established to give members of the community a means of making a complaint about health services or individual health care providers. The Commission has the power to investigate complaints and, where necessary, make recommendations or institute disciplinary activity against breaches of health care standards in the public interest under the Health Care Complaints Act 1993

Intracavernosal injection therapy (ICT): injections of pharmaceutical products into the shaft of the penis to stimulate erections. The corpus cavernosa are the two cylindrical blood sinuses that form the erectile tissue of the penis. The penis also has a third sinus, the corpus spongiosum, which encloses the urethra and extends into the glans. All these sinuses have a sponge-like structure that allows them to expand when filled with blood

Medical Board of NSW: registers all medical practitioners in New South Wales under the provisions of the Medical Practice Act 1992

Papaverine: an alkaloid derived from opium which relaxes smooth muscle

Peyronie's disease: the presence of a dense, fibrous plaque in the penis which causes curvature or angulation on erection and may also cause pain. The disease may require surgical straightening

Phentolamine: phentolamine mesylate, brand name regitine, a drug that dilates blood vessels and is used to reduce blood pressure and to treat conditions of poor circulation

Priapism: a persistent painful erection of the penis that requires decompression. An unrelieved priapism results in eventual tissue fibrosis, preventing any further erectile capacity

Prostaglandin: one of a group of hormone-like substances with many actions including causing smooth muscle contraction or mediating in the process of inflammation (also see Caverject)

Pyrogenicity: the likelihood of any substance or agent to produce fever

Royal Australian College of General Practitioners: a national organisation concerned with the development and maintenance of standards for general medical practice and the training and education of general practitioners

Therapeutic Goods Administration (TGA): the Commonwealth body which regulates the import and marketing of goods and medications in Australia

Vasodilator: a drug that causes widening of the blood vessels and therefore an increase in blood flow

Viagra: the brand name for sildenafil, an active chemical compound marketed by the pharmaceutical company Pfizer Pty Limited which increases the blood capacity of the penile tissue, and therefore men's ability to achieve erections. The blood capacity is increased through the relaxation of smooth muscle cells. The drug has been found to be equally effective in men who suffer from either organic or psychogenic erectile dysfunction

1. Background to the Inquiry

Erectile dysfunction (commonly known as impotence) may be associated with a variety of both organic and psychogenic causes, and it is estimated that it affects approximately 10 per cent of the male population on an age-related basis. The condition has been predominantly linked to performance anxiety, vascular disease, diabetes mellitus, drug or alcohol abuse or the use of anti-hypertensives or anti-depressants, and has in the past been treated variously by psychotherapy, the use of vacuum erection devices or the more surgically invasive penile implant.

In the early 1980s, intracavernosal injection therapy was developed as another treatment for erectile dysfunction. Injection therapy relied on vasodilator agents such as papaverine and phentolamine, neither of which have been officially registered in Australia or elsewhere for use in the treatment of erectile dysfunction.

Over the past few years, a large number of "specialist" clinics have developed in New South Wales and throughout Australia which have marketed their services exclusively to the treatment of erectile dysfunction. These clinics rely on medical practitioners who prepare and administer injection therapy often combining one or more of the above agents with the drug prostaglandin E_1. According to the clinics, different combinations and doses are prepared according to the patient's individual need. Prostaglandin E_1 (alprostadil) was officially approved for marketing in Australia as Caverject in 1996 after having been specifically designed, developed and clinically tested for its safety and efficacy in intracavernosal injection therapy. Given the highly personal nature of erectile dysfunction, it would appear that the significant level of success of these "specialist" clinics relates to their ability to improve public awareness and acceptance of the "validity" of impotence as a medical problem as well as that it may be amenable to successful medical treatment with patient anonymity after as little as one consultation. These clinics have targeted the male population suffering from erectile dysfunction through extensive advertising on billboards and in metropolitan and regional newspapers. They advertise consultations at no cost to the patients through bulk billing arrangements, with treatment by "experienced" and "expert" practitioners.

These services have developed and expanded concurrently with the introduction of other narrow interest medical services. These services advertise the availability of quick, effective and reasonably priced treatment options for a select variety of medical conditions. Advertised services often target conditions which the community associates with some level of personal embarrassment such as sexual dysfunction, incontinence, haemorrhoids, drug and alcohol dependency or the need for plastic or cosmetic surgery. According to those managing the impotency treatment services, they have provided one-off or continuing treatment to over one hundred thousand men suffering from erectile dysfunction or from premature ejaculation.

In April 1998, Pfizer introduced the drug Viagra in the USA following approval by the US Food and Drug Administration (FDA). The drug is currently being assessed by the Commonwealth Therapeutic Goods Administration (TGA) for local release, and in the meantime it is available under the personal import scheme. This scheme allows people to import up to 3 months' personal supply of a product on the understanding that it has not been formally approved for use in Australia, and where Australian authorities have not deemed it to be a prohibited substance. Viagra has had "one of the most successful debuts in pharmaceutical history",[1] with media commentators expecting it to "rewrite pharmaceutical sales history".[2]

The imminent release of this product in Australia is expected to replicate its US success, where it has captured almost 95 per cent of the market share.[3] This is despite reports of Viagra-related deaths in men who have taken the drug while suffering from pre-existing heart conditions, or who have over-exerted themselves sexually.[4] Viagra will undoubtedly affect the provision of

services for erectile dysfunction in Australia to a considerable extent. However published scientific trials have found the drug to be medically effective in only 55-70 per cent of men who suffer from this condition. The availability of this new drug has further increased the awareness of men who may now be willing to seek treatment for impotence.[5] Treatment options such as intracavernosal injection therapy will still therefore be relevant for large numbers of impotent men.

In the two years up to July 1997, the New South Wales Health Care Complaints Commission (HCCC) had received twelve written complaints and a number of telephone inquiries regarding impotency treatment services, and is currently investigating eight complaints about these services. These complaints raise a number of serious clinical and ethical issues. Investigations conducted by both the Commission and the Pharmaceutical Services Branch of the New South Wales Health Department indicated that the services often employed medical practitioners who had no prior experience in treating erectile dysfunction or in the preparation of injectable mixtures. Their induction training is reportedly limited to the observation of a more experienced practitioner for one to two days or the attendance at a seminar for one to two days.

The services' profitability is linked to high patient turnover with the maximisation of sales of pharmaceutical mixtures which are prepared by the practitioners on site. According to the evidence before the Inquiry, drugs intended for patient self-administration at home are prepared in environments with inadequate sterility. The pharmaceutical preparations are sold to patients at prices reported to be up to 10 times the value of the constituent ingredients, with practitioners allegedly in the past or currently receiving a fixed percentage of the price as a sales commission.[6]

The complaints received and being investigated by the Commission appear to indicate that the maximisation of profit is the central factor in patient treatment. This leads to concerns that patients receive insufficient preliminary assessment or testing with partial or incorrect diagnosis of their condition. There is also a lack of information provided to the patient on the availability of alternative treatment options or on the risks of injection therapy which relies on combinations of unregistered and clinically untested drugs. Drugs are provided to patients either in multi-dose bottles or in individual syringes for injections prepared by the medical practitioner which they keep refrigerated for up to six months. There is no evidence as to the stability or effectiveness of the mixtures over this period of time. Patients receive minimal instructions on self-injection technique during the first, and in many cases, the only, consultation, which they are required to employ in order to stimulate erections. Minimal or no patient review would seem to be planned by the clinics.

This form of treatment involves a potentially inappropriate and dangerous use of injection therapy on uninformed patients with inadequate control during preparation to ensure stability and sterility. The mixture of drugs is considered to increase the incidence of priapism and may be linked, in conjunction with inadequate injection technique, to the development of penile fibrosis or scarring.

While the Commission continues to conduct individual investigations into these services, the Minister for Health recognised the need for a broad, independent review of the standards of practice applied in these clinics. This review is designed to increase the levels of consumer protection in an area where the disease process affects a significant percentage of the population and where the treatment carries risks generally unknown to patients. These concerns were examined in the context that the degree of personal embarrassment associated with seeking treatment for the condition of erectile dysfunction may seriously diminish the ability of most patients to express any level of dissatisfaction or to seek to enforce their rights as consumers of health care services.

2. The Committee of Inquiry into Impotency Treatment Services

2.1 Terms of reference

On 26 August 1997, the Deputy Premier, Minister for Health and Minister for Aboriginal Affairs, the Honorable Dr Andrew Refshauge, MP appointed a Committee under section 20 (4) of the *Health Administration Act 1982*[7] to investigate and inquire into impotency treatment clinics and services in New South Wales and to report to the Minister in relation to:

a. the current standards of practice provided by impotency treatment clinics and services in the areas of infection control; the preparation of pharmaceutical products intended for patient administration by injection; patient assessment, diagnosis, monitoring and care; the pricing of supplied appliances and medications and other related financial aspects of the impotency treatment services;

b. the establishment of standards or a code of practice in relation to impotency treatment services; and

c. the adequacy of current legislation in the context of practices undertaken by impotency treatment clinics and services in New South Wales.

2.2 Membership of the Committee

Committee members were then individually selected and appointed by the Minister in consideration of their proven experience and expertise in areas including consumer representation, health care policy and practice, pharmaceutical policy and practice, the treatment of erectile dysfunction and the investigation of health care services and standards. The Committee members were:

- Commissioner Merrilyn Walton, Health Care Complaints Commission (Chairperson of the Committee)
- Dr Andrew Wilson, Chief Health Officer, NSW Health Department (with alternate Dr Glenn Close, Centre for Clinical Policy and Practice)
- Mr John Lumby, Chief Pharmacist, NSW Health Department
- Mr Andrew Dix, Registrar of the NSW Medical Board

Independent medical experts:

- Dr Phillip Stricker, Urological Surgeon
- Dr Michael Lowy, Sexual Health Physician
- Dr Christopher McMahon, Sexual Health Physician
- Dr Thomas Cromer, Endocrinologist
- Professor David Handelsman, Endocrinologist

Consumer Representative:

- Mr Sydney Doleman of the Combined Pensioners' and Superannuants' Association of New South Wales

Staff of the Health Care Complaints Commission:

- Ms Sally Anne Forsstrom, Head, Investigation Team 2
- Mr David Harris, Legal Officer

2.3 Methodology of the Committee

One of the first actions of the Committee was to seek public submissions in relation to the practises of impotency treatment clinics and services in New South Wales. Advertisements calling for submissions were placed in The Australian Financial Review, The Australian, The Sydney Morning Herald, The Daily Telegraph, The Sunday Telegraph and The Sun Herald in early September 1997. The inquiry received considerable interest, with regional and national print, and broadcast media providing publicity to the issues and conducting interviews with the Chairperson and with other members of the Committee. Information was also obtained from health authorities and relevant organisations from other states, territories and internationally.

Following the receipt of written submissions, the Committee identified key organisations and individuals to attend meetings of the Committee and to provide oral submissions during February and March 1998. These meetings allowed members to examine in detail the most significant issues relating to the provision of services for erectile dysfunction. Legal advice was obtained from the Committee's legal officer in relation to the current laws which regulate the services, on their adequacy and on the ways in which they may be altered in order to improve regulation in the public interest.

The Committee identified three main areas which required analysis and the formulation of recommendations. These were:

a. infection control and the preparation of pharmaceutical products intended for patient administration by injection;

b. patient assessment, diagnosis, monitoring and care; and

c. pricing of supplied appliances and medications, other related financial and advertising aspects of impotency treatment services.

3. Submissions

Despite the high level of advertising and other publicity surrounding the review, the Committee members accepted as a general principle that many patients and their partners may experience personal embarrassment in discussing their concerns about erectile dysfunction and its treatment. In addition, the Committee members recognised that other health care professionals including those who had previously worked at the clinics may be wary of professional retribution as a result of highlighting some of the practices of these clinics as well as the adverse effects suffered by a proportion of the patients. The Committee provided a guarantee of confidentiality to all who made contact in order to assist people to make submissions or to advise of any problems or concerns associated with the options for treatment, the quality of the service, its cost and its advertising. From September 1997 onwards, the Committee received over 60 telephone calls and over fifty written submissions from members of the public, health care providers and professional associations within New South Wales, around Australia and internationally. The Committee carefully assessed all written submissions received, identifying some eight key stakeholders and organisational representatives from whom oral submissions were sought during February and March 1998.

3.1 Written submissions from patients and from members of the public

The Committee was briefed about the nature of the complaints made by consumers to the HCCC. The Commission was also concurrently and separately investigating eight complaints against medical practitioners working in clinics which specialised in the treatment of erectile dysfunction. The submissions received by the Committee from members of the public covered a wide range of experiences, and raised the following issues:

a. high costs, service monopoly and misleading, inaccurate or offensive advertising;

b. inconvenience of treatment, insufficient injection instructions or follow-up care;

c. a lack of adequate or appropriate physical or psychological assessment, counselling, range of treatment options or informed consent; and

d. poor labelling of pharmaceutical products and unsatisfactory results.

Case example 1: Mr A and Dr B

Mr A had suffered from premature ejaculation for a number of years. He visited a "specialist" clinic where, following a short initial consultation, Dr B provided him with 6 months' supply of pre-prepared mixture of drugs for self-injection. After the second injection at home, Mr A's penis developed a 90 degree bend, and he discontinued the treatment. The bend recurred whenever Mr A had an erection, so he returned to the clinic. When Mr A complained, the clinic denied responsibility and refused to refund Mr A's substantial financial outlay. Mr A was subsequently diagnosed with Peyronie's disease by a specialist and was advised that either the condition would continue for 12 to18 months prior to returning to normal, or that it would require surgical intervention to remove the bend.

Around a third of the written submissions from consumers identified their treatment as wholly or substantially satisfactory. One man advised that he was 75 years of age and had suffered decreased potency since a heart attack four years previously, however that the injections had been *"completely successful and without any side effects"*.[8] The importance of treatment for erectile dysfunction was stressed by a number of men who advised that the ability to develop and maintain an erection was essential to their self-respect as a man as well as to the creation and maintenance of satisfying sexual relationships, in particular as they became more advanced in age.[9]

Some people wrote to express their concern at the prevalence of the advertisements and the terminology used in them, considering it to be distasteful and objectionable. A few of the men who responded had found it difficult and frustrating to get information about the costs involved and the treatment options available from the free call number advertised by the services. One person wrote that he was advised by the telephone operator *"this was a private matter and they could not divulge any details or send me any literature"*.[10] These men discovered that the only way in which they could receive information was to attend the clinics, where one observed that the patients coming in were *"not let...past the men coming out...to prevent clients comparing treatment, costs and procedures"*.[11]

Case example 2: Mr C and Dr D

Mr C had a long-term inability to develop or maintain an erection. He visited a clinic and bought a multi-dose bottle containing 30 treatments from Dr D. Mr C was unsatisfied with the results after a number of injections, so he returned with the bottle and asked for a stronger mixture. Dr D added two separate pharmaceutical products to the used multi-dose bottle, using the same syringe for the two transfers. This is in breach of infection control guidelines issued by the NSW Health Department.

The first consultation was considered by many patients to be rushed and mostly focused on the repeated recommendation that they purchase large supplies of pharmaceutical products for self-injection, rather than the discussion of any other treatment options. Many of the patients thought that the emphasis on purchasing was a betrayal of the wording of many of the advertisements, which indicated that there was no cost associated with the consultation. While the consultation was bulk billed under the Medicare system, the costs of the medication recommended by the medical practitioners could amount to over $500 for 30 doses (6 months' treatment) with additional costs for auto-injectors, syringes and instructional videos.

Many men were concerned about the lack of preliminary assessment of their physical or emotional state of health, as well as with the lack of explanation or discussion of the possible implications or side effects of injection therapy, or the contents of the injections provided. When patients combined this with a lack of follow-up monitoring, they thought the clinics failed in the provision of any effective continuity of care. One 66-year-old man advised that, after leaving the clinic with a supply of medication, he read the leaflet he had been given which explained what to do in the event of a priapism. He stated that he *"started to panic, thinking a trip to the hospital was going to be needed, but thank God it wasn't necessary...could you imagine how embarrassing that would have been?"*[12]

Case example 3: Mr F and Dr E

Mrs F lodged a complaint about the treatment provided to her husband, who had since died as a result of widespread cancer. According to Mrs F, Mr F visited a clinic to receive assistance with sedation at night which he feared would make him incontinent. Mrs F was concerned that Mr F was talked into purchasing over $700 worth of injections for erectile dysfunction which he did not use as he suffered rapid physical deterioration over the next few months prior to his eventual death. Mrs F considered that Dr E should have referred Mr F to a specialist rather than treating him for impotence. Dr E advised he had sold Mr F medication as Mr F was concerned about his erectile dysfunction, however, according to both Dr E and the medical records, neither of the 2 test injections conducted by Dr E prior to the sale of medication gave Mr F an erection sufficient for penetration (a minimum of 50 per cent of erectile response).

Another patient advised that he had been receiving treatment for a period of two and a half years, during which time the costs of the medication had increased thricefold, and that he required continually larger dosages, concluding that *"either the strength of the medication has been decreased or the level of impotency has increased."*[13] One patient summarised what he saw as the main problem, advising that *"because of the importance most men attach to their sexual performance, they are vulnerable to being ripped off, and indeed are being ripped off by the drug companies and impotency practitioners"*.[14]

3.2 Submissions from professional associations and other health professionals

The Committee received written and oral submissions from a variety of health care associations and professionals, including three colleges, sexual health and men's health organisations, urologists, social workers, sex therapists, psychiatrists and general medical practitioners. These submissions reflected similar concerns to those raised by the patients of the impotency treatment clinics. In particular, the following examples of poor practice by the clinics were addressed:

a. short and ineffective consultations with treatment by injections and minimal after-care to patients;

b. potential for abuse of patients with significant psychological vulnerability due to the targeting of the condition through widespread advertising;

c. high costs for patients and large financial gains for practitioners;

d. the manner of preparation and the contents of each dosage may not be disclosed to patients and may be inappropriately labelled; and

e. practitioners have minimal specialist experience or training in the area of treatment.

These submissions were unanimous in the view that the clinics offered a low quality, high cost treatment to men who were already affected by a psychological vulnerability either deriving from, or causing, their physical dysfunctions. Their vulnerability was considered in many of the submissions to be a barrier for patients seeking assistance from their own general medical practitioners, preferring instead to seek treatment from narrow interest, self-referral clinics which only offered treatment for erectile dysfunction. This specialisation of practice was also considered to appear to patients as a guarantee of anonymity in obtaining treatment. This vulnerability may further inhibit patients from demanding and receiving adequate information as to their treatment options and the inherent risks of each, from receiving high quality and responsible service, or from then expressing dissatisfaction and seeking refunds when the treatment failed to meet expectations.

The clinics were seen to profit by aggressively advertising and marketing their services rather than from the inherent quality of the service provided by the practitioners employed by the clinics. There was also a significant level of concern about the wide distribution of pharmaceutical mixtures of uncertain composition, quality and quantity for unsupervised patient self-injection without appropriate continuing treatment or monitoring.

The Committee sought oral submissions from a number of the colleges and professional associations. The Committee was advised of the importance of the maintenance of a patient focus in any medical or health care service. There was considerable support for the concept that a patient should receive high quality and comprehensive care from appropriately trained and qualified specialist health care professionals at reasonable cost. The Committee was advised that, where possible, patients should receive treatment within the context of a holistic service which offers continuity of care and which provides maximum patient information and

education in relation to their care options, the benefits and risks of each option, and what to do should they suffer adverse reactions to the treatment provided.

This standard of holistic treatment was not seen to be in operation at the clinics, with the associations and other service providers alleging that the clinics generally provided inadequate and inappropriate patient assessment, diagnosis and care. These concerns were increased by the nature and amount of the clinics' advertising which were considered likely to lead to unrealistic expectations from the psychologically vulnerable, leaving them open to financial exploitation.

3.3 Submissions from ex-employees of the clinics

The Committee received written and oral submissions from three professionals who had previously been employed by or associated with the clinics as medical practitioners or as an administrator: Dr X, Dr Y and Mr Z.

Information provided by Dr X, Dr Y and Mr Z confirmed the anecdotal advice provided by patients. They also confirmed the concerns expressed by other service providers. These men advised that the clinics had a track record of extremely aggressive marketing, with a predominant focus on the sale of pharmaceutical mixtures for self-injection. The sale of the drugs was often at the expense of either adequate assessment or appropriate treatment of patients.

Mr Z told the Committee that the clinics required no prior experience from their employed medical practitioners in either treating erectile dysfunction or in mixing products for patient self-injection.[15] Practitioners employed by the clinics reportedly tended to be younger doctors who had previously performed locum duties, often with the larger 24 hour medical centres. These employed doctors were advised that their positions would require a large amount of travel around the state and around Australia. Medical practitioners received either an hourly rate or a fixed percentage of their gross daily takings which were made up of the sales of the medication as well as the Medicare charges. The fixed percentage ranged from 20-25 per cent of the gross takings of the day based on the doctor's negotiations with the clinics. The ex-administrator advised that clinics charged over 10 times the estimated wholesale costs for injections and for syringes. Appointments were made for the doctors every 15 minutes, and patients were routinely advised they required 30 treatment doses provided in multi-dose vials as this was the basis of *"the treatment program"*. If the patients were not able to afford the initial significant financial outlay, then fewer doses were offered for sale. Mr Z advised that the management of the clinics monitored the *"conversion rates"* for sales to patients. If doctors failed to sell the injectable medication to a set percentage of their patients, the medical directors *"brought* [this] *to their attention"*. Training of the doctors was described as essentially limited to *"a few basic principles...as if...selling cars or selling real estate"*.

Mr Z told the Committee that the clinics were operating all around Australia, with the Sydney-based central service booking patients into the clinics closest to them. These clinics operated on a full-time or part-time basis, with regional centres available for bookings on a fortnightly or monthly basis. The Committee was told that medical practitioners would fly around Australia with suitcases full of the bulk injectable solution packaged in eskies with ice. These bulk solutions had been pre-prepared by the medical practitioners under conditions of inadequate sterility in the head office and were used then to prepare injections in the surgery at the time of consultation. The practitioners did not arrange follow-up consultations for their patients, irrespective of the patients' medical condition at the time of the original consultation.

Dr X and Dr Y provided submissions to the Committee which also raised concerns regarding the poor level of patient assessment, inadequate care and lack of continuing monitoring. Dr X told the Committee that, when he first worked with the clinics, he was told by other doctors that *"patients were really only interested in having erections...*[and] *that was what they were there to do, to help them get them. So they tended to push the injections as the preferred treat-*

ment...the management and financial structures were set up to encourage it."[16] Dr X considered that patients accepted the price and treatment without question as there was *"really no competing product in terms of price at that stage"*. He recalled that, on starting at the clinics, priapism was a recurrent issue for patients, with about six telephone calls a day from patients concerned at the duration of their erection following the administration of an injection. There existed *"no clear procedures or guidelines for management, no patient information or anything like that"*. While patients were reportedly advised on the basics of treatment for priapism (ie cold showers, taking pseudoephedrine and attending the emergency department of a local hospital if the erection did not wane), Dr X expressed concern that if a patient attended a hospital *"at 2 am and there was* [only] *an intern and they wouldn't have a clue what they were doing. There was no guarantee that the ongoing management would be relevant to it, nor that a specialist would be involved in the case."*

Dr X advised the Committee that doctors received between 25 per cent and 33 per cent of the income generated by them, with some having incomes of $300,000-$400,000 per annum. This provided a stark contrast to general medical practitioners in suburban medical centres who, according to Dr X, would be unlikely to receive more than $70,000-$80,000 per annum prior to the costs of indemnity insurance and other practice-related costs. Dr X was concerned that the managers of the clinics were interested in this area of treatment purely as a result of the profits that could be generated in the short-term, rather than from any broader additional commitment to or concern about the standard of services for consumers. He estimated that the centres (as a whole) would be generating around $300,000 a month net profit, with *"the idea just to make profits and get the profits out...the profits will drop and they will eventually lock the door and go home with their cash"*.

Dr Y provided a written submission to the Committee[17] and advised that the clinics "flourished" due to the blanket advertising of the services, the effectiveness of the treatment in around 90 per cent of cases, and from the privileged position that doctors occupy in the community. He wrote that doctors *"make good salesmen because of their perceived status and knowledge coupled with the patient's trust in the doctor's recommendations"*. Dr Y advised that the clinic's pharmaceutical mixtures tended to be more effective than Caverject, while also noting it was significantly more expensive to patients. The practitioner wrote that the doctors had *"a financial disincentive to offer cheaper medication such as Caverject"* given the remuneration by commission on sales. Dr Y advised that the clinics were aware that doctors practised contrary to their professional duties in that they disclosed neither their financial interest in the treatment offered nor that they were supplying medication at charges higher than the original cost. Dr Y considered that the clinics used an *"artificial arrangement designed to avoid the requirements"* of current legislation or professional standards.

3.4 Submissions from the clinics

The main operators of the "specialist" clinics gave both written and oral submissions to the Committee.[18] They advised that their success in targeting large numbers of men lay in their ability to heighten awareness of erectile dysfunction as an acceptable and prevalent condition for which there existed a number of effective and relatively simple cures. They also said the clinics were promoted as providing treatment within a non-threatening and completely confidential environment. According to the operators, the clinics have provided services to well over 100,000 men, with around 70 per cent of these returning for follow-up treatment and with fewer than 0.5 per cent of patients seeking refunds for treatment provided.

The written submission included testimonials from five satisfied patients attesting to the effectiveness of the product supplied and the professionalism of the practitioners involved with these clinics.

The assessment of the patients as described by the clinics appeared to be comprehensive, in contradiction to the reports of rushed and partial examinations from the patients who contacted the Committee directly. The written submission advised that, while there were currently six treatment options available in Australia, *"the most popular treatment has become penile injections [which] offer an effective and immediate response"*.

Dr A described injection therapy as the treatment of choice for most practitioners. Patients were only offered other choices when they refused or were unsuccessful with the injections.

Representatives of the "specialist" clinics told the Committee that medical practitioners were contractors rather than direct employees. They told the Committee that practitioners are not permitted to derive any profit from the sales of medication, which is sold to the doctors by the central organisation. The clinic representatives said that the practitioners derive their income only from the consultation fees and the injection fees (Medicare rebates where bulk-billed), as well as any profit made on the injection kits sold. However, they agreed that this situation was in contrast to what had occurred up until mid-1997, when practitioners' remuneration used to include a percentage of the sales income. The Committee was informed that the organisation monitors the receipts for all sales to ensure that the practitioner either sells the medication at the same or lower price than what the clinic had charged him for the same supply. Where the practitioner sells the medication for less, he subsidises the discount.

The price of the medication is fixed by the central organisation, and includes not only the costs of the drug ingredients but also the organisation's advertising and other costs together with an undisclosed profit component. This artificial fixing of the sale price by the organisation clearly results in patients being required to pay prices far in excess of the inherent value of the supplied injections.

The Committee was told that practitioners are trained in mixing products solely by observing more experienced doctors. The clinic operators acknowledged that stability testing of these products had not previously been performed to ensure that the drugs remained effective throughout their stipulated shelf life. The clinics now arbitrarily specify the shelf life to be of three months' duration, while previously it tended to be six months or unspecified. There was acknowledgement also that the extemporaneous preparation of the products for patient self-injection had not been conducted under pharmaceutically sterile conditions. The Committee was told that both of these issues were receiving attention by the major clinics and would be remedied in the future.

In response to a discussion about the possible adverse effects of injection therapy, such as the development of fibrosis or priapism, the operators advised that their contracted practitioners should be available by telephone to patients on a 24 hour basis. They said that where this is not possible patients are advised to take their information sheet which explains management techniques for the treatment of priapism to their local hospital. The clinic operators advised that, of 1500 patients a month, between 14 and 17 patients report that they have experienced priapisms from the injections supplied. The clinics did not have any formal affiliation with urologists or other medical specialists for the purposes of referrals for their patients. This was despite advertising which indicated some affiliation with specialists through statements such as *"diagnosis and treatment under the guidelines of world renowned urologists and sexologists"*.

The clinic operators advised that there was no above normal profit or particularly high income incentives for practitioners to work at the clinics, work which involved a considerable amount of travelling around Australia to staff the clinics. The operators advised that the incentive for practitioners was the very nature of the work involved. The Committee members were told that doctors would consider the work *"enjoyable"* as patients were generally

healthy, there was minimal after-hours work and that it was an extremely interesting and involving area of service for most practitioners where the treatment of erectile dysfunction was developing and evolving at such a rapid rate. Most doctors were reported to be working on a part-time basis, with earnings of approximately $100,000 to $150,000 per annum, with these earnings having decreased since the practitioners no longer received a percentage of the sales of medications. The clinic operators further advised the Committee that they believed strongly in improving their practices on a regular basis, and offered to provide any assistance to the Committee in either *"instituting certain programs or...doing some research"*, further commenting *"we have all the facilities available. We certainly have the patient load. It would be our pleasure"*.

3.5 Information obtained from other states and territories

The Committee sought advice from around Australia in relation to the experience of other states and territories with "specialist" services and impotency treatments. The Chairperson of the Committee wrote to all health care complaints bodies and to all medical registration authorities, while the NSW Chief Health Officer sought information from each public health authority in Australia. In general, the operations of these clinics were not considered of significant concern.

Outside of New South Wales, the number of complaints was minimal with most concerning the high costs associated with the treatment and the extensive advertising. This is not particularly surprising as the services have concentrated both their marketing efforts and their service provision activities in New South Wales as the most populous state, and more specifically in Sydney. Services in other states and territories have often operated as subsidiaries, with appointments for patients organised through the central offices based in Sydney.

The Tasmanian Office of the Commissioner for Health Complaints called for public submissions in order to provide current and relevant information to this Inquiry, and conducted a survey of 14 consumers. This survey revealed a significant degree of consumer satisfaction with the treatment provided within an area that was characterised by a high level of commercialism.

The Chairperson of the Committee sought information from the General Medical Council (UK), the Canadian College of Physicians and Surgeons, and the Federation of State Medical Boards (USA) in relation to their experiences of clinics that specialised in the treatment of erectile dysfunction, and was not informed of any international concerns about these clinics.

4. The preparation of pharmaceutical products intended for patient self-injection

4.1 Background

Intracavernosal injection therapy (ICT), first developed in the early 1980s, has had a remarkably rapid uptake reflecting an unmet need in the medical treatment of erectile dysfunction, and it is now widely used. Impotence had previously been treated either by invasive surgical implants or by less effective appliance-based mechanical therapies. Neither of these options was considered particularly attractive to the majority of men with impaired erectile capacity.

Initially ICT used the drugs papaverine and phentolamine, which were often combined in mixtures. This is a use which was neither recommended by the manufacturers of the individual drugs or approved for use in Australia. This early era of treatment was marked by wide variations in claims of efficacy and safety for patients, with unintended side effects of priapism and fibrosis. These wide variations were a result of the lack of systematic or rigorous studies of clinical experience with ICT.

The only drug properly evaluated for safety and efficacy by the TGA in Australia in ICT is prostaglandin E_1. A formulation of prostaglandin E_1 specifically designed for ICT called Caverject has been tested for safety and efficacy via well-designed clinical trials. The results were published in 1996 and it was approved for sale in the Australian market with the availability of government subsidies.

A further development has been the arrival of a non-injectable form of prostaglandin E_1 administered as a transurethral gel called MUSE. MUSE was evaluated for safety and efficacy, and the results of the clinical studies were published in 1997. It was approved for marketing in the USA and Astra intends to apply for registration of MUSE in Australia. Most recently, a new oral drug (sildenafil, known as Viagra) has been the subject of clinical trials. Sildenafil has undergone FDA evaluation, has recently been released in the USA by Pfizer and is currently being evaluated by the TGA for Australian marketing approval.

4.2 Evidence on pharmaceutical products intended for patient self-injection

i. The "need" for multidrug therapy

The international research of ICT comprises a relatively large number of scientific publications. Apart from two US-based multicentre clinical registration studies for prostaglandin E_1, there are virtually no high-quality clinical studies in the field of medical therapy of impotence. Clinics have developed a large number and variety of practices and protocols for ICT based on mixtures of the 3 drugs, ranging from reliance almost exclusively on single drug therapy to routinely advocating multi-drug therapy. These differences are present primarily as a result of the lack of objective clinical guidelines and due to the high level of patient demand. The scientific or practical basis for such treatment is dubious and the risk-benefit analysis quite unfavourable, despite assertions of a need for multi-drug therapy.

It needs to be borne in mind that any proof of the effectiveness of self-administered ICT can only be based on the patients' own reports of their sexual activity. This makes it essential to have placebo controls to interpret the findings of any study. As expected, a striking placebo response to ICT is a feature of the few reported placebo-controlled clinical trials. The significant placebo response presumably also explains the regular observation that some men starting ICT ultimately stop treatment due to spontaneous recovery of sexual function. Despite the obvious requirement for placebo controls, the literature consists almost exclu-

sively of uncontrolled studies. The lack of objective controls makes it difficult either to analyse the data or to extrapolate from it.

In the absence of placebo controls, quantitative claims about the efficacy of ICT are largely meaningless since they include a major but unmeasured component of patients who recover their erectile function, and may have done so irrespective of the composition of the products used in the ICT. It is therefore impossible to make comparisons about the efficacy of different products as trialled in unrelated studies.

Additionally, the "need" for multi-drug therapy is reinforced by the claim that men who fail monotherapy can be "salvaged" by multi-drug therapy. The truth of this remains untested. It is a basic pharmacological principle that in any therapeutic setting single drugs should always be used first before introducing combination drug therapies. When multi-drug therapy is introduced because monotherapy failed, the reasons given for the failure can be highly subjective or arbitrary.

"Failure" in this setting can mean anything from insufficient effectiveness, adverse side effects, the costs being too high or a variety of other practical, medical or non- medical situations. For example, at one extreme, the "specialist" clinics have instituted a practice of assuming that all patients will fail to respond to prostaglandin E_1 monotherapy, and therefore that all patients should be started on multi-drug combinations. Even when monotherapy is used first on patients, an awareness of the ready availability of combinations will make it easier for practitioner and patient alike to introduce mixtures either prematurely or unnecessarily.

In the anecdotal experience of clinicians on the Committee, approximately 70-85 per cent of patients suffering from erectile dysfunction may be managed effectively with monotherapy. It remains to be established whether multi-drug therapy, with its attendant risks, offers any genuine help to those resistant to monotherapy.

Publications in this area confirm that prostaglandin E_1 is the drug of choice for treating erectile failure. It appears that combinations not including prostaglandin E_1 are now clinically obsolete. The published studies which are of varying quality in terms of reported design, sample size and control groups, generally fail to provide sufficient information on mixture formulation, sterility, pyrogenicity or shelf life of the mixture of pharmaceutical products to allow an objective assessment of their results. The results of the studies do not indicate any more than a marginal or dubious advantage of efficacy to multi-drug therapy over monotherapy.

In summary, despite the use of multi-drug therapy (for various reasons), there is no reliable clinical evidence that shows it is any more effective in clinical practice than monotherapy. Given the lack of proven clinical benefit over monotherapy, it is debatable whether having additional therapeutic options for the treatment of impotence warrants the risk of side effects from drug combinations. Nevertheless, the clinicians on the Committee experienced in the treatment of impotence consider that combination pharmacotherapy has a demonstrated benefit for a minority of patients.

Although there are unusually good opportunities for high quality clinical research in the treatment of impotence (given the population affected), the knowledge base is by far the weakest in clinical reproductive medicine.

ii. Current practice in providing multi-drug ICT

Virtually every clinic providing ICT uses different policies and protocols for the dosage size and use of monotherapy or multi-drug therapy. The practice in many clinics appears to consist of ad hoc mixtures of drugs under office-type clean procedure standards (gloves, sterile

drug stock, needles and syringes) but without the preparation of the products under laminar flow conditions or with microbiological monitoring. The mixing also involves multiple fluid transfers between nominally sterile vials.

Registered doctors and pharmacists are permitted by law to make extemporaneous drug mixtures for their individual patients. This generally occurs when mixed drugs are required immediately for intravenous or intramuscular injections (such as for hospital in-patients) or for longer-term use where the medication is administered topically or orally. Sterility is not as significant an issue for medication which is not injected as it carries a lower risk of infection and adverse side effects. Diabetic patients also prepare mixtures for self-administration of insulin. This is usually prepared and injected immediately, or within very short periods of time. It is inappropriate and may be regarded as a significant oversight that the same standards are applicable to patients who may self-inject drug mixtures over a period of several months where these mixtures have not been prepared under aseptic conditions.

iii. Problems with current practice in multi-drug ICT

A drug formulation which is administrated by injection is required by law to comply with infection control protocols. Such standards are needed to prevent cross-infection of viruses and are particularly relevant where multi-dose vials are used by patients, as supplied by the impotency treatment clinics.

There is no clinical evidence showing that the solutions of different drugs used by the clinics retain their effective preservative activity when they are made into combination mixtures. The product information of the three drugs most commonly mixed together for self-injection (prostaglandin E_1, papaverine hydrochloride and phentolamine mesylate) is insufficient to be able to determine the compatibility of their mixtures; whether the drugs remain in solution and stable; or whether any irritating chemical products arise from the mixtures which could cause unexpected adverse effects. This means that variable mixtures of these three drugs based mainly on prostaglandin E_1 and papaverine cannot be reasonably assumed to have reliable chemical stability and bioactivity.

In conventional pharmaceutical manufacturing of a drug mixture in solution, rigorous evaluation of the chemical and biological stability of each of the components of the mixture are required to establish its shelf life. This includes microbiological determination of its shelf life for sterility, allowing for adequate margins for safety for individual dosage units as well as for patient usage beyond the stated shelf life. The chemical and biological tests for each compound would need to show that it remained stable and at full nominal strength for at least the full shelf life.

It appears from some publications as well as from the evidence provided by the clinic operators to the Committee that ad hoc drug mixtures are given an arbitrary shelf life of three months. There does not appear to be any basis for this allocated period apart from "wishful thinking". This is a highly simplistic view as it is unclear how much degradation of sterility, chemical stability or other limitations are introduced by tampering with chemical formulations. It is virtually certain that the shelf life of mixtures cannot be as long as the original formulation of each ingredient in its own right.

The arbitrary designation of a three month shelf life for the combinations virtually amounts to deceptive and potentially dangerous packaging. The clinic operators further provided evidence that to their knowledge patients had used the mixtures for up to 18 months.

The safety of Alprostadil has been adequately established. The long-term safety of papaverine, phentolamine and mixtures of them has not been established. In fact, there is little reliable information in Australia on the safety of any ICT drug mixtures or of their adverse effects.

References held by the Adverse Drugs Reaction Advisory Committee are exclusively associated with Alprostadil. There are a number of chronic complications of regular ICT, whether the injections include Alprostadil alone or a drug mixture. These complications include bruising, priapism and fibrosis, the origins of which remain poorly understood. The role of low-grade infection and/or chemical irritation is yet to be clarified. Given the poor follow-up and short-term nature of the uncontrolled studies so far reported, it is quite conceivable that other medium and long-term complications of such drug mixtures have yet to be determined.

Neither papaverine nor phentolamine are registered in Australia or anywhere in the world for use in impotence.

Papaverine was listed on the Australian Register of Therapeutic Goods (ARTG) without having gone through a formal regulatory evaluation of its method of manufacture, formulation or clinical safety or efficacy. Further, it is one of a small number of drugs on the ARTG which has no registered indication at all meaning that its safety and efficacy has never been established for any medical indication. Its availability may be regarded virtually as a historical loophole in the registration system. Recently, a submission for registration of papaverine for use in impotence was rejected by the Australian Drug Evaluation Committee (ADEC) for a variety for reasons including inadequate evidence of its safety.

Phentolamine is registered in Australia for treatment of hypertension. It has virtually never been used alone for ICT. It has been almost exclusively used in conjunction with papaverine, with no proof of its safety as an adjunctive therapy.

In summary, the current practice of ICT in Australia is largely based on unsubstantiated claims of the increased effectiveness of drug combinations over the use of prostaglandin alone. The combinations tend to be mixed under non-aseptic conditions for unsupervised use by the patient over extended periods of time. The drugs used in the mixtures are not registered for this purpose in Australia and there is no scientific certainty as to their chemical combatibility, their safety or the duration of their effectiveness.

4.3 Findings on infection control and the preparation of pharmaceutical products intended for patient administration by injection

1. As of June 1998, there have been no independent or double blind placebo controlled clinical studies conducted to verify that mixtures of pharmaceutical products are of the same or greater efficacy than single drug therapy in intracavernosal injection therapy. There have also been no adequately evaluated clinical trials to test the drug interactions either within the penile tissue or within the body as a whole.
2. The preparation of the drug mixtures in intracavernosal injection therapy does not meet adequate standards of safety with regard to infection control, in particular in relation to cross-infection which may occur through the use of multi-dose vials.
3. The effectiveness of the remaining preservatives from the solutions when combined into mixtures does not appear to have been established.
4. The product information of the drugs prostaglandin E_1, papaverine hydrochloride and phentolamine mesylate (the three drugs most often used in combination in ICT) is insufficient to determine the compatibility of mixtures, whether the drugs remain in solution and stable or whether any irritating chemical products arise from the mixtures.
5. The insufficiency of the product information means that variable mixtures of these 3 drugs based mainly on prostaglandin E_1 and papaverine cannot be reasonably assumed to have reliable chemical stability and bioactivity.

6. Ad hoc drug mixtures for ICT appear to be given an arbitrary shelf life of three months which may amount to deceptive and potentially dangerous packaging.

7. The long-term safety of papaverine, phentolamine and mixtures including them has not been established, and there is little reliable information on the safety of any ICT drug mixtures. There are a number of chronic complications of regular ICT including bruising, priapism and fibrosis. The role of low-grade infection and/or chemical irritation remains to be clarified, and there may well be other medium and long-term complications of such drug mixtures which have yet to be identified.

8. Neither papaverine nor phentolamine is registered here in Australia or elsewhere for use in impotence. Recently, a submission for registration of papaverine as a treatment for erectile dysfunction was rejected by the ADEC for a variety for reasons including inadequate evidence of its safety. Phentolamine is registered in Australia only for the treatment of hypertension.

4.4 Recommendations on infection control and the preparation of pharmaceutical products intended for patient administration by injection

1. The Committee recommends that single drug therapy should be the first treatment option for all patients, with multidrug therapy as a salvage option only in the event of an unsatisfactory response.

2. Medical practitioners should be reminded by the NSW Medical Board in its "Medical Board Newsletter" of their obligations for the appropriate labelling of therapeutic substances under the Poisons and Therapeutic Goods Act 1966. Labelling should include the existence and amount of all constituent ingredients. Section 36 of the Medical Practice Act 1992 (MPA) should be amended to specify that the failure to comply with the Poisons and Therapeutic Goods Act 1966 constitutes "unsatisfactory professional conduct".

3. The products should be prepared under aseptic conditions, with their shelf life determined through independent sterility and stability testing, and through random batch testing.

4. The achievement of the necessary standards for the preparation of drug injections is unlikely to be achievable immediately without the imposition of significant hardship upon current users of these medications. Accordingly, the Committee recommends that practical interim measures should be introduced prior to the adoption of full sterility and stability testing (with a recommended lead-in time of three months to two years).

5. These interim measures should include mandatory distribution of patient information and consent forms, mixing under laminar flow and shorter designated shelf lives (with an arbitrary shelf life to the maximum period of one month given the lack of evidence supporting long lasting stability).

5. Patient assessment, diagnosis, monitoring and care

5.1 Background

The lack of appropriate or adequate patient assessment, diagnosis or care was one of the first issues brought to the attention of the HCCC by dissatisfied patients and their families. Their concerns about the standards of care were reflected in the majority of the written submissions from consumers and from members of the public to the Committee of Inquiry. Accordingly, this issue was considered in depth by the members of the Committee in order to establish practical and effective guidelines for practitioners. Written submissions to the Committee confirmed that both indications and contraindications for injection therapy needed to be clarified and established in order to address issues such as the treatment for men suffering from premature ejaculations, psychogenic or neurogenic causes of impotence, for men wanting inappropriate augmentation of erections or for high risk patients, such as those suffering from prostate conditions.

5.2 Evidence

The Committee sought oral submissions from professional organisations and from practitioners associated with the clinics regarding the standards of patient care. Representatives of the Royal Australasian College of General Practitioners[19] (RACGP) submitted that the clinics tended to isolate one particular aspect of patient management rather than operate under a philosophy of whole patient care. They said that this practice gave *"inappropriate"* expectations in an area *"highly emotionally charged at the best of times"*. The RACGP recommended that management should occur through the patient's own general practitioner with appropriate referral to a health specialist, whether it be a sexual health specialist or a urologist, in order to ensure continuity of care, and to deal with any complications that arise. The RACGP concluded that the clinics operated in an unco-ordinated way within a narrow range of practice which ultimately created *"a false sense of what is being offered, coupled with a lack of an understanding that patient care is much more than simply advertising or offering to provide something in isolation from the totality"*.

The representative of the Australian Medical Association[20] (AMA) supported the RACGP's contention that the patient's own general practitioner was the most appropriate person to co-ordinate the holistic care provided for any condition, including erectile dysfunction. The AMA considered that aggressive advertising such as that used by the clinics may result in *"the wrong patient get[ting] to the wrong doctor"*, with a fragmentation of service delivery in a context of high patient vulnerability. The AMA confirmed that it had received anecdotal reports of clinic practitioners being more interested in selling medications at marked up prices and administering injections than in the provision of quality care, under circumstances where *"if the patient is not interested in that and won't sign an agreement, then they are shown the door"*. The AMA considered that the management of erectile dysfunction was a clinically complicated matter, requiring *"detailed history, detailed examination, investigations which don't come back overnight, a great deal of counselling of the patient, and more often than not a great deal of counselling of the patient with his sexual partner"*. According to the AMA, the advertised claims that treatment requires only one consultation would not allow this sort of quality service to be provided. The poor standard of service was considered to *"bring the profession into disrepute"*.

The representative of the Australasian College of Sexual Health Physicians[21] (the College) commented that erectile dysfunction is defined as either a purely psychological problem or a purely physical problem, while in fact *"it is obviously both"*. The College said the clinics appear to have *"an element of exploitation"* inherent in their approach to patient assessment and care.

The College recognised that such exploitation is often assisted by the psychological distress of these patients. The College advised the Committee that it has arranged public sexual health services for men who have previously been *"seriously mismanaged"* by the private clinics. Anecdotal evidence to the College confirms that private clinic consultations are *"quick, with very little counselling and certainly no assessment of other sexual health related issues or cultural factors that might affect expectations about their potency"*.

The College considered that the element of exploitation would decrease as the availability of public services increased. The development of additional treatment therapies including oral medication would also improve the availability of services from local general medical practice. The representative of the College submitted that many patients may not accept that their ability to perform sexually has decreased with age, and so they may be *"led into the diagnosis of impotence"* when in fact the patient had appropriate age-related functions.

The College recommended that clinics employ practitioners with basic counselling skills and with some form of accredited training in respect to human sexuality. The College noted that *"often for these men it is the first time they have ever gone to anybody else about matters to do with their sexuality"*.

Dr X, a medical practitioner previously associated with the clinics, considered that his colleagues *"had been corrupted by the management process and by their own complicity in it"* in terms of the quality of service that they were willing to offer to patients, and that they *"were quite frank and open about the fact that they were there to sell the product"*.[22] He said the clinic set-up allowed practitioners to see up to three patients at the same time, with the consultations including cursory assessment, the administration of a test injection, finalised with the sale of the medication.

Mr Z, an ex-administrator of one of the clinics, said patients waited for up to three hours in crowded waiting rooms with other men.[23] He described these men as being advanced in age, and that, *"when they were 20 or 25 no-one talked about sex, no-one talked erections, so it is quite an embarrassing and traumatic time for them"*. Mr Z advised that the patients were then *"rushed...through"* following the administration of the test injection and the sale of the injection.

The main clinic operators acknowledged that approximately 95 per cent of their patients would be offered ICT during their initial consultation, and that, of those, virtually all agree to have an injection in the clinic.[24] The clinics reported that, while approximately 40 per cent of patients subsequently purchase the medication for self-injection, only a negligible proportion of the remainder would seek alternative treatment from the clinics, such as psychotherapy, the use of vacuum erection devices, or referral for urological surgery. It was explained that this was due to the persuasiveness of the practitioners in presenting the use of ICT, and that *"the other options are far less attractive. If [patients] don't go ahead with the injection therapy, then they would rather not receive treatment. Injection therapy is not attractive either but it is the least unattractive."*

The Medical Director of the clinics further advised that *"if the patient doesn't leave with treatment, in a lot of ways you are not providing him a good service because he is probably worse off than he was before. He has come in and it has taken him a lot of courage to do so. He is petrified. It has probably been sitting on his mind for 12 months or more. Once he is in the clinic, that is the biggest breakthrough he has probably had most of his life."*

In the vast majority of cases, the clinics prefer to use their own mixtures and supply them in vials containing 30 doses for use by the patient up to three times per week. The clinic operators advised that they had recently indicated a shelf life of three months for the medication, as previously there had been no indication of how long the mixture should be kept

and used by the patient. Medical practitioners have the option of charging their patients less for the drug mixtures where they are prepared to incur the financial loss themselves, while the government-subsidised Caverject is supplied only where this is specifically asked for by name by the patients.

The clinics advised that they had recently implemented a follow-up procedure, under which telephonists will contact patients two weeks after the first visit and then three months after that whether or not they have had treatment, in order to facilitate a further consultation *"if the patient does experience a problem or if he experiences any dissatisfaction"*, as well as to improve the clinics' knowledge as to the outcomes for patients. The clinics advised that they give patients detailed advice on how to deal with priapisms during the initial consultation together with a printed information sheet. This includes the ability to ring the clinic, the treating doctor or a 24 hour emergency service which will either refer the patient to an affiliated medical practitioner or advise the patient to attend the local hospital.

In summary, the evidence on patient assessment, monitoring and care confirmed earlier concerns regarding the speed with which patients were reviewed during their initial consultation as well as the information provided to them about their condition and the options available to them. The clinic operators themselves agreed that ICT based on the clinics' own drug combinations is offered to the overwhelming majority of patients, with the clinics providing alternative services to approximately 1 per cent. The level of follow-up and monitoring provided by the clinics has recently been enhanced by the introduction of the telephone service, however there would not appear to be any institutionalised medical monitoring after the initial consultation unless the patient attends to purchase further medication or suffers a priapism.

5.3 Findings on patient assessment, diagnosis, monitoring and care

1. Clinics specialising in the treatment of erectile dysfunction have promoted multi-drug ICT to patients as an initial, and often sole, treatment option.
2. Clinics assess, diagnose and offer treatment to patients within the first consultation, without a formal system of medical review or follow-up treatment.
3. Clinics tend to assess inadequately the medical and psychological history of their patients, do not conduct appropriate physical examinations or tests, and do not provide sufficient information to patients on the options for treatment of their erectile dysfunction.
4. There is little evidence that the clinics provide useful, appropriate or adequate information or care to patients after the initial consultation and the sale of the medication. This is particularly the case in relation to the management of priapism and when complications arise outside of the standard clinic hours of operation.

5.4 Recommendations

1. The Committee recommends that all medical practitioners providing treatment to patients suffering from erectile dysfunction follow guidelines which focus on quality and responsible patient assessment, diagnosis, monitoring and care rather than on the sale of medication (see Appendix for guidelines). The Committee further recommends that these guidelines be published by the NSW Medical Board in its "*Medical Board Newsletter*". It is the view of the Committee that a failure by medical practitioners to practice in accordance with these guidelines in their treatment and management of patients suffering from erectile dysfunction would be evidence of unsatisfactory professional conduct as defined in section 36 of the Medical Practice Act 1992.

2. The Committee recommends that all medical practitioners providing treatment to patients suffering from erectile dysfunction ensure that they maintain their skills in this area of treatment through participation in regular educational courses by appropriate professional bodies. In particular, all practitioners in this area should develop their sexual health counselling skills.

3. All clinics providing treatment to patients with erectile dysfunction must inform patients both orally and in writing as to the procedure for the management of priapism in accordance with the guidelines, patient information sheet and patient consent form in the Appendices. The clinics must ensure that either the treating practitioner or another identified practitioner with suitable expertise be available for consultation 24 hours a day to provide medical care in the event of an emergency situation associated with the treatment, such as priapism.

6. The pricing of supplied appliances and medications, other related financial aspects of impotency treatment services

6.1 Background

The cost of the impotency treatments was the primary concern raised by most consumers and by many health professionals in the written submissions to the Committee. Other financial issues included commissions apparently received by medical practitioners employed at the clinics for their treatment of patients and, in particular, from the sale of pharmaceutical preparations to the patients; the extremely inflated prices charged for the penile injections provided by the clinics; the failure to disclose the precise constituents of the substances provided to patients for self- administration; the readiness to prescribe a lengthy course of penile injections to new patients at initial consultations; and the use of multi-drug preparations as the first line of treatment.

Medical practitioners have a clear conflict of interest when they receive remuneration on a commission basis for the provision of clinical treatment and care to their patients. The main clinic operators advised that medical practitioners no longer received a percentage of the profits from the sale of either medication or associated appliances. The Committee was advised that, up until June 1997, medical practitioners working at the clinics signed contracts that provided them with a commission on the gross sales. While the practices of the clinics have changed, these contracts are still used. Whether the medical practitioners are deriving profits directly from the sales of the medication or not, the sale of the product is clearly at the heart of their practice at the clinics. Practitioners and an administrator previously associated with the clinics as well as anecdotal reports from patients described the apparent keenness of the doctors to sell the medication as the only form of treatment, which is consistent with the operators' own reports of the promotion of injection treatment to 95 per cent of patients and the failure to provide alternative treatment options to the vast majority of their patients.

6.2 Evidence

i. Legal position

Medical practitioners owe duties of a fiduciary nature to their patients. The general principles of fiduciary duties in this regard include that:

> *A person who occupies a fiduciary position may not use that position to gain a profit or advantage for himself* [sic]*, nor may he obtain a benefit by entering into a transaction in conflict with his fiduciary duty, without the informed consent of the person to whom he owes the duty* [25]

The High Court of Australia recently considered the fiduciary obligations of medical practitioners, though in a different context, in **Breen v Williams**.[26] In that case, it was argued that a medical practitioner's fiduciary duties required that copies of the medical records be provided to a patient upon request. The High Court unanimously refused to find that there was a fiduciary duty in this regard. Dawson and Toohey JJ said, in a joint judgment:

> *Whilst duties of a fiduciary nature may be imposed upon a doctor, they are confined and do not cover the entire doctor-patient relationship. Thus a doctor is under a duty to protect the confidentiality of information given by a patient. And the doctor-patient relationship is such that any substantial benefit received by the doctor from a patient (other than proper remuneration) is presumed to be the result of undue influence with the doctor bearing the onus of rebutting the presumption.*

Later, their Honours said:

> *Equity requires that a person under a fiduciary obligation should not put himself or herself in a position where interest and duty conflict or, if conflict is unavoidable, should resolve it in favour of duty and, except by special arrangement, should not make a profit out of the position...Of course, fiduciary duties may be superimposed upon contractual obligations and it is conceivable that a doctor may place himself in a position with potential for a conflict of interest - if, for example, the doctor has a financial interest in a hospital or a pathology laboratory - so as to give rise to fiduciary obligations.*

In the judgment which considered the issue of fiduciary duties in the greatest detail, Gummow J said:

> *Conformably with the reasoning of Gibbs CJ and Brennan J in **Daly v Sydney Stock Exchange Ltd**, the relationship between medical practitioner and patient who seeks skilled and confidential advice and treatment is a fiduciary one. That will be so regardless of whether it is because the relationship between the parties is one which gives the medical practitioner a special opportunity to affect the interests of the patient who is vulnerable to abuse by the fiduciary of his position, or because the medical practitioner undertakes to exercise professional skill for the benefit of the patient, and particular reliance is placed upon the medical practitioner by the patient.*
>
> *...The fiduciary will be brought to account for any benefit or gain which has been obtained or received in circumstances where a conflict or significant possibility of conflict existed between the fiduciary duty and personal interest in the pursuit or possible receipt of the benefit or gain or was obtained or received by use or by reason of the fiduciary position or opportunity or knowledge resulting from it.*

The other judges of the High Court in **Breen** (Brennan CJ, Gaudron and McHugh JJ) each recognised that the duties of a fiduciary nature were owed by a medical practitioner in circumstances involving the receipt of financial benefits.

If any further confirmation is required, the decision of the NSW Court of Appeal in **Breen v Williams**, 23 December 1994 (which was the subject of the appeal to the High Court) also recognised fiduciary duties in relevant circumstances. Thus, in one of the majority judgments, Meagher JA said:

> *...one could not quibble about a doctor being treated as owing a fiduciary duty towards his patient. But, if this be so, it is generally only to generate the usual fiduciary duties in certain circumstances - not to profit at his patient's expense (beyond his agreed fees) and not to put himself in a position where his interest would conflict with his patient's...*

ii. Professional and ethical obligations

In the Medical Tribunal decision of **Re: Dr J.H. Bannister**,[27] it was recognized that it is a breach of professional standards to fail to disclose direct financial interests which medical practitioners have in treatment provided to patients. In discussing the nature of the doctor-patient relationship, the Medical Tribunal stated:

> *That relationship is not one of equals. The practitioner has special skills and he can require the patient to submit to all forms of examinations, treatment and indignities. The patient on the other hand is dependent upon the practitioner. The patient is ill and comes to the practitioner for relief and cure for that illness. The patient being dependent upon the doctor is in a position where he can easily be exploited as the doctor chooses (be he so minded), for he will often do anything to relieve the distress of his illness. The varieties of exploitation are innumerable. Sexual exploitation may be the most obvious but there are many other possibilities, including*

unjustified financial gain. The primary rule, therefore, must be that everything done by a medical practitioner in the professional relationship shall be done only for the benefit and the welfare of the patient. It must not be done for any other motive. Amongst the prohibited motives would be financial gain for himself or another person.[28]

The Tribunal in that case stated that the majority view of the expert evidence before it was to the effect that:

...if a direct financial benefit is received by virtue of the practitioner prescribing a particular form of treatment or appliance to a patient, then the existence of the interest giving rise to the benefit should be disclosed. The underlying reason is that the practitioner can be confronted with a conflict of interests, namely the interests of his patient and the financial interests of the practitioner him/herself. By laying all the relevant facts before the patient, the doctor enables him/her to make an informed decision.[29]

However, the Tribunal did state that *"there are some forms of remote benefit arising out of an indirect financial interest in respect of which the obligation to disclose may not arise ..."*.[30] The Tribunal gave as an example where a practitioner had a sum of money invested in a financial institution which held in its portfolio of investments a substantial share holding in a private hospital. If the practitioner refers patients to such a hospital, the expert evidence before the Medical Tribunal in that case was that there would be no obligation upon the practitioner to disclose that situation.

The Australian Medical Association stated at paragraph 4.2.3 of the 1989 edition of its Code of Ethics:

The following practices are deemed unethical ...

c) to receive any money in connection with services rendered to a patient other than the acceptance of a proper professional fee, or to pay any money in the same circumstances without the knowledge of the patient.

The Code also declared at paragraph 11.1.1 that:

A general ethical principle is that a doctor should not associate himself [sic] with commerce in such a way as to let it influence, or appear to influence, his attitude towards the treatment of his patients...

At paragraph 11.13, it said:

A doctor should not have a financial interest in the sale of any pharmaceutical preparation he may have to recommend to a patient. If such be unavoidable for any good and sufficient reason, he should disclose his interest when ordering that preparation or article...

The most recent AMA Code of Ethics (1996 Edition), at paragraph 1.3 (n), obliges medical practitioners to:

Not refer patients to institutions or services in which you have a financial interest without full disclosure of such interest...

It also stated, at paragraph 2.2 (a), that medical practitioners should:

not enter into any contract with a colleague or organization which may diminish the maintenance of your patient's autonomy, your own, or your colleagues' professional integrity.

The Committee considered that the provision of service by medical practitioners at the impotency treatment clinics is almost exclusively based on the use of multi-drug penile injections. These injections are not necessarily in the best interests of the individual patients and may reasonably be described as being promoted in the financial interests of the practi-

tioners or the clinics, or indeed both. There was a recognition by the clinic operators that "*the treatment is the injection, the injection is medication, the medication is the product of a company whose profits depend on sales*," however there was a lack of understanding that this may constitute a conflict of interest between on the one hand the doctor's ethical and legal duties to his patient and on the other his appreciation of the importance of sales-based profits to the organisation. The Medical Director advised that *"as long as the doctor is happy in his job and he sees patients and he is enjoying his work and patients appear to be satisfied with the work that he is providing, I don't think they have a conflict of interest there"*.

Prostaglandin is the most expensive component of the preparations and a vial of the same quantity bought separately would cost up to $50. Accordingly, the increase on the price of preparations being supplied to patients for injection is in the order of tenfold at a minimum. An accurate assessment of this price inflation is not possible because the ingredients of the supplied preparations vary and are not disclosed to the patients. Inadequate labelling of the medications provided to patients also has implications for subsequent treating doctors who are unable to ascertain the precise treatment delivered. Medical practitioners have a duty to disclose to patients the elements of the treatment, including the medication prescribed and supplied.

It appears that the requirements of the *Pharmacy Act 1964* are being avoided by the clinics becoming licensed wholesalers. This means that the clinics sell the medications to individual doctors employed at the clinics for the same "price" as the doctors subsequently charge the patients.[31]

Where medical practitioners are paid commissions by the wholesaler for selling products, any arrangements for the "purchase" of such products by medical practitioners from the wholesaling clinic could be inappropriate as it represents a contract or agreement which diminishes patient autonomy and the professional integrity of the medical practitioner (based on the AMA Code of Ethics, 1996, as referred to above). This reportedly occurred in the clinics up until June 1997.

In effect, the scheme is much the same as a medical practitioner being employed by or having a retainer with a drug manufacturer and selling the drugs of his/her employer to patients on a commission basis without any disclosure to the patients of the medical practitioner's interest.

Further, the arrangements may constitute a breach of the price fixing or price collusion provisions of the trade practices legislation.[32] The arrangement is illusionary as there is never any real "sale" between the wholesaling company and the medical practitioner prior to the supply of the substance to patients. This aspect also raises the issue of whether greater regulation is required in the licensing of drug wholesalers in view of the circumstances in which the operators of the clinics have been able to sell their product using registered medical practitioners.

It appears to the Committee that auto-injectors have been provided at excessive prices to patients in an apparent routine manner. For example, the devices are provided to patients as an "essential" item in the self-administration of injections. However, auto-injectors are not necessary and for some patients can be inappropriate. It appears that the routine supply of auto-injectors to patients is taking place for commercial rather than clinical reasons.

The use of multi-drug therapies as a first line of treatment greatly increases the risks of priapism, and it should be reiterated that monotherapy is the appropriate treatment in the first instance in any penile injection treatment therapy.

In summary, the Committee considered that time is required for adequate history taking, the required investigations, diagnosis, explanation of treatment options, administration of

test injection and teaching of self-injection technique to first-time patients. The high number of submissions to the Committee which referred to the provision of extended courses of treatment at initial consultations demonstrates that commercial considerations are motivating the clinics' approach to medical treatment over and above the patient's best interests.

6.3 Findings on the pricing of supplied appliances and medications, other related financial aspects of impotency treatment services

1. The elevated price of the medication supplied by the clinics to the patients is up to or in excess of 10 times higher than the actual cost. An accurate assessment of the cost is difficult to determine given the failure of the clinics to label the supplied medications in sufficient detail as to their exact composition.
2. Auto-injectors have been marketed by the clinics to patients at excessive prices in an apparently routine manner.
3. Long-term courses of injection therapy with multi-drug mixtures are marketed to patients as the first line of therapeutic treatment without adequate concern for the patient's wellbeing.
4. The failure to label the supplied medications in sufficient detail may adversely affect the ability of subsequent care givers to provide appropriate treatment to patients.
5. The clinics have become licensed wholesalers for the selling of medications to individual practitioners. The practitioners then sell the medication at the same price to the patients, thereby avoiding an offence under the *Pharmacy Act 1964*.
6. Practitioners employed by or under contract to the clinics have in the past received commissions of up to 25 per cent of the sale price of pharmaceutical products without disclosing this commission to their patients, which contravenes ethical medical practice.
7. There is a clear conflict of interest between the interests of the patient to receive the most appropriate and effective form of medical treatment and the financial interests of practitioners who receive profits from the sale of certain products.
8. The principles requiring disclosure to patients of financial interests and benefits as exist under the *Pharmacy Act 1964*, the AMA Code of Ethics, and in relation to a practitioner's professional standards and responsibilities, do not appear to be well understood by the medical profession as a whole.

6.4 Recommendations on the pricing of supplied appliances and medications, other related financial aspects of impotency treatment services

1. The New South Wales Medical Board and the Health Department should remind practitioners of their obligations to discuss with their patients the complete range of options available to treat erectile dysfunction. Failure to discuss options with patients due to commercial considerations may already constitute unsatisfactory professional conduct under the Medical Practice Act 1992.
2. Medical practitioners have a professional and legal duty to disclose any financial interests they have in the provision of any form of treatment, or in the sale of any pharmaceutical or related product. Section 36 of the Medical Practice Act 1992 should be amended to include in the definition of unsatisfactory professional conduct the failure to disclose any financial interest in the treatment options recommended by a medical practitioner, or any other conflict of interest known to the practitioner.

7. Advertising of Impotency Treatment Services

7.1 Background

Advertising was considered in conjunction with the financial management of the operation of these clinics and as part of the review by the Committee of the adequacy of current legislation affecting the provision of impotency treatment services. Advertising by doctors until the 1980s was confined to signs indicating the doctor's area of practice and hours of service. The development of 24 hour medical centres and the high number of doctors per head of population has led to a change in the way medical services are advertised, including extensive advertising campaigns involving billboard and newspaper advertisements.

7.2 Evidence

i. Current environment

Much of the promotional activity involving medical practitioners is generated by medical entrepreneurs (including doctors) who target particular sections of the community. The services are profit driven and dependent on a high turn over of patients. One of the advertisements for the clinics which limit their practice to erectile dysfunction directs its services *"for men from 18 to 90 years"* and asserts that *"our medical doctors can now diagnose and treat your problem from only 1 visit"*, irrespective of whether the person is suffering from diabetes, high blood pressure, cardiovascular disease, other heart or psychological problems.

Since 1996, there has been a change in the frequency and type of medical advertisements. Examples of such promotions include treatment for bladder problems, impotence, anxiety, drug and alcohol dependence, tattoo removal and laser surgery. These are routinely appearing in the printed media.

The commercialisation of health, though not of recent origins, has received a helping hand from the reforms in national competition policies. Medical Boards have been required to ease their restrictions on doctors advertising their services in the market place. The Australian Competition and Consumer Commission (ACCC) has informed the medical community that restrictions on doctors advertising their services are no longer necessary provided that advertisements are not misleading or deceptive.

Medical practitioners are permitted under the *Medical Practice Act 1992* regulations to advertise their services in any manner within certain parameters. For example doctors are not allowed to advertise on television, radio broadcast, film or video unless the advertisement carries a health promotion or preventative health message and does not imply that the service is only available from the particular practitioner or corporation. The advertisement must not be false, misleading, deceptive or likely to mislead or deceive the public. It cannot be vulgar or sensational or claim their services are superior to others. Testimonials from patients or endorsements from other practitioners are not permitted. The advertisement must be professional and must not bring the profession into disrepute.

The regulations clarify that an advertisement is taken to be false, misleading or deceptive if:

a. it contains a material misrepresentation of fact; or

b. it is likely to create an unjustified expectation of beneficial treatment.

The regulations also require a practitioner to be in regular attendance at the place cited in the advertisement. There is a general prohibition relating to advertising emergency casualty or

similar services unless the service complies with the guidelines (if any) notified to medical practitioners by the Medical Board with the approval of the Director-General.

The regulations give examples of information that would be appropriately contained in an advertisement.

The HCCC rarely accepts a complaint about advertising for investigation. These complaints are dealt with by the Medical Board.

The New South Wales Medical Board receives approximately 100 complaints about advertising per year, with the majority of these made by telephone. Almost without exception, complaints are made by other practitioners rather than by members of the public. The Board's method of handling the complaints is to make an in-house assessment as to whether they are in breach of the advertising regulations of the *Medical Practice Act 1992*. Given the broad nature of the regulations, the conclusion is usually reached that advertisements are not in breach.

Where an advertisement does appear to be in breach, the Board will generally write to the practitioner concerned, advising of the regulations and indicating its concerns about the particular advertisement. In the case of repeat or blatant advertisements, the Board instructs the Crown Solicitor to advise it in relation to prosecution. It is rare to proceed to prosecution, and the Board has not successfully prosecuted a complaint concerning advertising by a registered practitioner or company providing medical services in recent years.

The Board has expressed the view that seeking to control activities through advertising regulations is a poor option. In the last 20 years, enforcement has proved virtually impossible due to the divergence of opinion within the profession, the short- lived nature of most advertising, the subjective nature of the regulations, and the willingness of some practitioners to go to great lengths to test the limits.

In response to the ACCC position on advertising, states and territories are proceeding to update their advertising regulations under their respective medical practice legislation by widening the provisions permitting advertising. Most medical registration authorities which have liberalised their advertising rules have not reported significant problems, apart from those states where niche marketing of medical services is a growing industry.

The Medical Board of the Northern Territory has published guidelines setting out the conditions under which practitioners are permitted to advertise. The purpose of advertising is to help the public locate a doctor and to identify the medical services offered. It is not to promote the use of particular *"medical practices or practitioners or techniques."* Similar provisions exist to that in New South Wales in relation to false and misleading statements. Doctors are not permitted to advertise emergency services or advertise in a manner that implies the availability of emergency or casualty services unless the practitioner has been approved by the Medical Board. There are more restrictive provisions about signs. The Board has not reported any concerns about mass marketing of impotency treatments via billboards.

The Medical Council of Tasmania has amended its advertising regulations in response to the ACCC's advice that the Board should not take any action to limit the ability of a practitioner to advertise. The amended *Medical Practitioners Registration Act 1996* refers to the contents of advertisements but makes no reference to format, size, medium, frequency or other limitation. The following offences carry a standard financial penalty if proven:

> *Section 66 (1) A person must not advertise a medical practice or medical services in a manner which -*
>
> *a. is or is intended to be false or misleading; or*
>
> *b. offers a discount, gift or other inducement to attract patients; or*

c. refers to or cites actual or purported testimonials; or

d. unfavourably compares another medical practice or other medical services with that medical practice or those medical services.

(2) A person who, in good faith, publishes or prints an advertisement that contravenes sub-section (1) on behalf of another person is not guilty of an offence under the sub-section.

The Medical Board of South Australia's publication *"Guidelines for the Advertising of Medical Services"* sets out what is acceptable and unacceptable advertising. The guidelines take into consideration the attitudes of the courts, management by lay persons, and the desire for consumers to be adequately informed. The guidelines are similar to New South Wales in that they permit the advertising of medical services in any manner, and are prohibited from advertising on television, internet, other electronic displays or radio.

The Medical Board of Queensland recently introduced new by-laws governing advertising. The new standard which came into effect on 16 October 1997 represents a significant deregulation of advertising by medical practitioners. Statements must be true and not misleading or deceptive and must not assert superior expertise. Testimonials and endorsements are not permitted and practitioners are not permitted to advertise in a way that is demeaning or vulgar. There are no restrictions on size, medium, or frequency of the advertising.

In the Australian Capital Territory, the Medical Board recognises that practitioners may have a legitimate need to inform the public about their services. A breach of the advertising regulations constitutes unsatisfactory professional practice under the *Medical Practitioners Act 1930*. A body corporate is prohibited from advertising medical services irrespective of whether a medical practitioner is named or otherwise. This means that only a registered medical practitioner, not a company, can advertise medical services.

Medical practitioners cannot advertise medical services in a manner which:

a. is false, misleading or deceptive, or likely to mislead or deceive;

b. is vulgar or sensational;

c. claims or implies that any particular practitioner is superior to any other medical practitioner;

d. contains testimonials or other endorsements of a particular medical practitioner; and/or

e. is unprofessional or likely to bring the profession into disrepute.

The Medical Practitioners Board of Victoria can initiate action against a practitioner if it is considered that a breach of section 64 of the Medical Practice Act 1994 has occurred, which section advises that:

(1) A person must not advertise a medical practice or surgical services in a manner which -

(a) is or is intended to be false, misleading or deceptive; or

(b) offers a discount, gift or other inducement to attract patients to a medical practitioner or medical practice unless the advertisement also sets out the terms and conditions of that offer; or

(c) refers to uses or quotes from testimonials or purported testimonials; or

(d) unfavourably contrasts medical or surgical services provided by a medical practitioner or medical practice with services provided by another medical practitioner or medical practice.

(2) If a body corporate contravenes sub-section (1) any person who is concerned in, or takes part in, the management of that body corporate who was, in any way, by act or omission, directly or indirectly, knowingly concerned in or party to the commission of the offence also commits an offence under sub-section (1) and is liable for the penalty applicable to a natural person for that offence.

(3) A person who, in good faith, publishes or prints an advertisement which contravenes sub-section (1) on behalf of another person, is not guilty of an offence under that sub-section.

Part V of the *Trade Practices Act 1974* (Commonwealth) (TPA) contains a range of provisions aimed at protecting consumers. The ACCC administers the Act in relation to unfair practices, product safety and information standards as well as banning orders. The Federal Bureau of Consumer Affairs is responsible for product safety policy and product recalls.

The relevant sections are sections 52 to 65A. The general prohibitions are found in section 52 which is a broad provision prohibiting corporations from conducting their business in a misleading or deceptive way or in a way likely to mislead or deceive. This means that sellers of goods and services are required to tell the truth or refrain from giving an untruthful impression. If a corporation fails to disclose material information this may be a breach of the Act, but each case will depend on the particular circumstances.

Corporations are specifically prohibited from making false and misleading representations about:-

(1) the particular standard, quality, value, grade, composition, style, or model of goods and services or that they have a particular history or particular previous use;

(2) the particular standard, quality, value or grade of goods and services;

(3) whether goods are new;

(4) the agreement of a particular person to acquire goods and services;

(5) the sponsorship approval, performance characteristics, accessories, uses or benefits of goods and services;

(6) the sponsorship, approval or affiliation of a corporation;

(7) the price of goods and services, for example that it is less than a competitor's price;

(8) the availability of repair facilities or spare parts;

(9) the place of origin of goods;

(10) a buyer's need for any goods or services; and

(11) the existence of exclusion or the effect of any condition, warranty, guarantee, right or remedy.

In June 1996 the ACCC successfully prosecuted ON Clinic, Men Only Medical Clinic and Potent-C Clinics[33] under section 53 of the TPA in relation to misrepresentations made in advertising about the efficiency, cost and advantages of treatments and advice offered to men suffering impotence. Justice Tamberlin of the Federal Court ordered that the clinics place corrective advertisements offering to refund any payments by dissatisfied customers who went to the clinics as a result of the advertisements and providing a free call number for refund claims.

The clinics claimed that:

(a) the treatment offered was the only one proven to work;

(b) there were no costs to the patient as the treatment was covered by Medicare;

(c) the treatment took only two visits; and

(d) the diagnosis used "unique" medical equipment.

In November that same year Proctology Centres of Australia gave enforceable undertakings to the ACCC to correct representations made in advertisements about the treatment of haemorrhoids. In this case the corporation made claims that the treatment was 100 per cent successful, engendered minimum discomfort, gave instant relief and only required one consultation. The undertakings given to the ACCC included the placement of an advertisement in The Daily Telegraph and The Sunday Telegraph informing consumers of the correct situation.

The New South Wales *Fair Trading Act 1987* authorises the Commissioner for Consumer Affairs to receive and deal with complaints about goods and services. Professional services by medical practitioners are also covered. Many of the provisions set out in Part V of the Act mirror provisions under the TPA. Section 44 of the *Fair Trading Act* is identical to section 53 of the TPA. These provisions relate to false and misleading advertising.

Enforcement and remedies are outlined in Part 6 of the *Fair Trading Act*. Again these are similar to those provided in the TPA. It also permits public warning statements. Section 86A permits the Minister for Fair Trading or the Commissioner to make or issue a public statement identifying and giving warnings or information about any of the following:

a. goods that are unsatisfactory or dangerous and persons who supply those goods;

b. services supplied in an unsatisfactory manner and persons who supply those services;

c. unfair business practices and persons who engage in those practices; and/or

d. any other matter that adversely affects or may adversely affect the interests of persons in connection with the acquisition by them of goods or services from suppliers.

The *Fair Trading Act* permits the identity of persons, particular goods, services or business practices. The caveat on such statements is that any identification must be in the public interest.

The *Fair Trading (Public Warnings) Amendment Act* was enacted in order to provide the Minister and departmental head with the authority to name unsatisfactory traders. Before they are permitted to do this they must be satisfied that the publication is in the public interest. Amendments to section 10 clarify and extend the protection from defamation liability for such statements.

Naming traders occurs in the following circumstances:

a. Where there is an immediate and urgent need for a warning because members of the public are likely to suffer personal injury, or financial or other loss. Examples include imposing a product ban or a sudden and widespread practice with the potential to cause extensive losses.

b. As part of the Department's longer-term compliance and enforcement strategy to achieve one of the following:

   - influence problem traders to change their unfair practices or comply with specific legislative provisions;

- deter other traders from such practices;
- warn the public about particular unsatisfactory traders; or
- provide information to the public about consumer rights and ways to avoid or deal with problems.[34]

The Act also permits industry wide warnings. These are announced when:

a. the particular practice is widespread, it is not appropriate to single out or name any particular trader and the warning is expressed in general terms; or

b. the practice is seen to be an industry problem, but whilst not confined to one trader it is engaged in by some leading industry members and their identity is clearly apparent from the terms of the warning statement.

The objective of naming is to ensure an informed and fair marketplace, but not at the expense of procedural fairness. Serious adverse consequences can arise for traders publicly named. The department has stringent criteria for naming, which will usually only occur after a full investigation has established that the trader has acted illegally, or the trader's conduct has been grossly unfair or otherwise seriously detrimental to the public interest, with efforts to make the trader remedy the conduct having failed. There are some circumstances where a trader can be named without a full investigation. These cover public health and safety, immediate danger or substantial public loss or detriment, "fly-by-night" operators or traders with a bad record.

The Department of Fair Trading guidelines for public naming of unfair traders advises that most of these statements are made by the Minister in Parliament or in the Annual Report. These statements have absolute privilege but the need to name a trader may not necessarily coincide with parliamentary sittings. Traders are also named outside Parliament. In the absence of statutory protections these only have qualified privilege in defamation proceedings by an aggrieved trader. The Department is currently updating its guidelines for naming traders.

ii. International advertising standards

The College of Physicians and Surgeons, Ontario introduced a new set of rules governing advertising when the *Regulated Health Professionals Act 1991* was proclaimed in January 1994. The advertising regulations[35] were significantly changed in accordance with the following principles:

a. Physicians can advertise in any medium available to all other physicians;

b. The information advertised must not be false or misleading;

c. Advertisements cannot contain testimonials, or comparative or superlative statements;

d. Advertisements cannot contain references to specific drugs or equipment;

e. Physician advertising must not be associated with the advertising of products or services.

The rules permit members to communicate any factual, accurate and verifiable information that a reasonable person would consider material in the choice of a physician. But the information communicated must not:

a. be false, misleading or deceptive by the inclusion or omission of any information;

b. contain a testimonial or any comparative or superlative statements; or

c. contain any reference to a specific drug, appliance or equipment.

No member is permitted to:

a. allow his or her name to appear in any communication offering a product or service to the public; or

b. allow himself or herself to be associated with the advertising or promotion of any product or service, other than the member's medical services in accordance with the above principles; or

c. participate directly or indirectly in a system in which another person steers or recommends people to a member for professional services. A member may do this if the referral or transferral of patients is done honestly and with no conflict of interest.

In New Zealand most of the surveillance of advertising or self promotional statements comes under the *Commerce Act, Fair Trading Act,* and the Advertising Standards Complaints Board. Practitioners are advised that section 33 of the Code of Ethics published by the NZ Medical Association requires that they *"only advertise professional services or make professional announcements where the chief purpose of the notice is the factual presentation of information reasonably needed by any person to make an informed decision about the appropriateness and availability of services that may meet his or her medical needs"*. Canvassing or touting for patients who do not come of their own free will and who may be patients of other doctors is discouraged by the Medical Board although technically possible under the Commerce Act.

iii. Impact of the national competition policy

The primary method identified for monitoring and setting minimum standards in advertising has traditionally been achieved through regulating what can and cannot be done. The effect of the national competition policy has been to widen the conditions under which health professionals can advertise. A major criticism of professional regulatory schemes was that the regulatory structures had gone far beyond what is needed for client protection and are more directed at protecting the professions than their clients. Many of the rules governing professional conduct and practice have been criticised on the grounds they are anti-competitive and have been introduced to further the different professions' own interests.[36]

The outcome of this shift in public policy has been to remove the rules about advertising away from the professional regulation acts and invest those powers in the TPA. This Act embodies *"the capacity to balance the public interest against practices that may be considered anti-competitive and to authorise them"*.[37] The remaining issue is how does the ACCC determine what is and what is not in the public interest. The ACCC has published *"A Guide to the Trade Practices Act for the Health Sector"*. The guide argues that any restrictions on the means, manner or frequency of advertising are inherently anti-competitive. The ACCC maintains that there should be no restrictions placed on the right of a professional to undertake business activities in addition to their core professional service.

However, the TPA does provide scope for limiting advertising where public benefit can be shown to justify such action. Through its authorisation provisions, the ACCC enables restrictions on advertising. The establishment of public benefit is central to the authorisation and notification processes under the Act. *The Trade Practices Act* does not define "public benefit". Fortunately the ACCC considers the concept capable of wide interpretation, and accepts that it may constitute *"anything of value to the community generally, any contribution to the aims pursued by society"*.[38]

Such an interpretation captures not only economic benefits but also benefits such as improvements in health and safety, avoiding conflicts of interest and the provision of equi-

table dealings. Before the ACCC will contemplate issuing an authorisation notice the applicant must:

a. satisfy the Commission that there is public benefit;

b. show a nexus between the claimed public benefit and the restrictions for which authorisation is sought;

c. show the benefit is to the public or at least a large cross-section of the community (ie not a private benefit for the members of the profession);

d. satisfy the Commission that the relevant tests in the Act have been met (this is done by providing arguments in support of an application);

e. include in their applications information that:

- shows how the conduct or arrangements the subject of the application will operate in practice;
- shows who will benefit;
- shows how the conduct or arrangements contribute to community objectives;
- shows what effect if any there will be on competition;
- shows who will be adversely affected, how and why they will be affected; and
- shows how the detrimental effects will be minimised.

f. be aware that authorisation is a public process; and

g. be aware that the authorisation process need not be overly legalistic and is not adversarial in nature.

There are basically three options for limiting the advertising of medical services that identify a particular disease process or target audience in their advertisements. The first is to control advertising by using an enforcement model which relies on regulations to specify and to limit or prohibit the type of matters permitted to be advertised. This may be achieved through the introduction of a mandatory industry code under the new section 51AD of the *Trade Practices Act*.[39] Remedies via the *Medical Practice Act* appear limited, however there may be some scope in relation to requiring medical practitioners to abide by set professional standards, and disclose financial interests.

The ACCC has advised that it is receptive to concerns about the unintended adverse consequences of the national competition policy and is willing to help address the problems. As a first step the Commissioner advises that it would be normally preferable to develop "industry" guidelines and then if those fail to remedy the problem, proceed down the authorisation path. There are precedents to the development of collaborative guidelines. In April 1998 the ACCC and the Private Health Insurance Complaints Commissioner published a *"Guide to the Trade Practices Act for the promotion of private health insurance"*. The Commission indicated its willingness to develop a similar document in conjunction with the HCCC and the Medical Board.

The Committee considered this option and determined that it would not be functionally successful for "specialist" clinics (such as those focussing on erectile dysfunction) in contrast to the private health insurance industry. The private health insurance industry is distinguishable as there are very few insurance bodies, which are well known to the community and are stable corporate entities. By contrast, "specialist" clinics appear to be multiplying rapidly in number and do not have the same public corporate profile. These factors will operate to

undermine the likelihood of the compliance by the "specialist" clinics with any purely voluntary code of conduct.

The Committee determined that enforceable measures were required, with the introduction of authorised exemptions to the TPA with advertising restrictions imposed in the public interest, or the establishment of a mandatory industry code under the new Part IVB of the TPA. The Committee considered that such actions would increase the protection of the public and improve the quality of information available without having an adverse effect on either the level of competition or the efficiency of the delivery of services in health care.

The Committee also reviewed the provisions of the *Medical Practice Act*, including its restrictions on advertising.[40] The regulations of the MPA specify certain minimum standards for the advertising of medical services, including that such advertising must not be false, misleading, unprofessional or deceptive, with the further qualification that any advertising of emergency, casualty or similar services must comply with guidelines approved by the Director-General of the NSW Health Department and be notified to medical practitioners by the NSW Medical Board.

The Canadian model associated with the *Regulated Health Professionals Act 1991* was reviewed with approval by the Committee, with particular approval of the linkage of the professional's name with the service and the increase of personal responsibility and liability.

In summary, the options available to regulate the advertising of medical services appear limited. The option of mandatory industry codes is furthermore relatively untested. Without the sort of widespread advertising used by the 'specialist' clinics, there would not have been the same level of market success or the same awareness by the public that there exist treatment options for erectile dysfunction. Current national competition policy seeks to provide to consumers of health and other services maximum availability of information and competition while maintaining an underlying protection against misleading or deceptive practices.

7.3 Finding on the advertising of impotency treatment services

1. Advertising placed by the clinics appears generally to be sensationalised and is capable of misleading members of the public.

7.4 Recommendations on the advertising of impotency treatment services

1. Medical practitioners should not associate themselves with any service or product which is advertised in a manner capable of misleading patients or capable of bringing the profession as a whole into disrepute. To do so would amount to unsatisfactory professional conduct under section 36 of the MPA.
2. The regulations under the MPA should be amended to include self-referral, symptom-specific clinics such as those providing impotency treatments to comply with guidelines approved by the Director-General of the NSW Health Department analogously to the provisions in relation to emergency, casualty or similar services.
3. The ACCC be approached to introduce a mandatory industry code of conduct under section 51AD of the *Trade Practices Act* for the provision of services for erectile dysfunction which includes the above provisions on disclosure of financial or other interests in the recommendation of treatment options, the advertising of these services and the appropriate standards of treatment.

Appendix 1: Schedule of written and oral submissions to the Committee of Inquiry

Written submissions

1. Submission from Mrs H received 1 October 1997
2. Submission from Mr S dated 29 September 1997
3. Submission from Mr A received 2 October 1997
4. Submission from Mr D dated 7 September 1997
5. Submission from Mr H dated 7 September 1997
6. Submission from Mr L dated 12 September 1997
7. Submission from Mr W dated 9 September 1997
8. Submission from Mr L dated 5 September 1997
9. Submission from Mr T dated 16 September 1997
10. Submission from Mr B dated 16 September 1997
11. Submission from Mr S dated 17 September 1997
12. Submission from Mr W dated 19 September 1997
13. Submission from Mr P dated 14 September 1997
14. Submission from Mr A dated 20 September 1997
15. Submission from Mr D received 29 September 1997
16. Submission from Mr B dated 24 September 1997
17. Submission from Mr W received 25 September 1997
18. Submissions from Mr A dated 24 & 30 September 1997
19. Submission from Dr X (general practitioner) dated 30 September 1997
20. Submission from Dr Y (general practitioner) dated 29 September 1997
21. Submission from Mr Z (administrator) dated 8 October 1997
22. Submission from Family Planning NSW dated 3 October 1997
23. Submissions from Australian Men's Health dated 23 September & 8 October 1997
24. Submission from The Australasian College of Sexual Health Physicians dated 1 October 1997
25. Submission from The Royal Australian College of General Practitioners dated 8 September 1997
26. Submissions from the Urological Society of Australasia dated 1 September & 14 October 1997
27. Submission from the National Gay Men's Health Network dated 30 September 1997
28. Submission from the Victorian Psychosexual Society received 30 September 1997
29. Submission from Osbon (Australia) received 1 October 1997
30. Submission from Pfizer Pty Limited dated 25 September 1997
31. Submission from Jaspa Appliances dated 14 September 1997
32. Submission from Dr N (psychiatrist) dated 23 September 1997
33. Submission from Dr M (urologist) dated 19 September 1997
34. Submission from Dr B (urologist) dated 26 September 1997
35. Submission from Liverpool Health Service dated 19 September 1997
36. Submission from Dr B (general practitioner) dated 23 September 1997
37. Submission from Dr M (sexual health physician) dated 8 October 1997
38. Submission from Victorian Health Services Commissioner dated 25 September 1997
39. Submission from ACT Commissioner for Health Complaints dated 25 September 1997

40. Submissions from Medical Board of South Australia dated 18 September 1997 & 10 December 1997
41. Submission from South Australian Health Commission dated 15 October 1997
42. Submission from Queensland Health Rights Commission dated 14 October 19997
43. Submission from ACT Department of Health and Community Care received 15 October1997
44. Submission from Mr M dated 16 October 1997
45. Submission from NT Health Services received 27 October 1997
46. Submission from Health Department of WA dated 17 October 1997
47. Submission from General Medical Council (UK) dated 3 December 1997
48. Submission from Medical Board of Western Australia dated 21 November 1997
49. Submission from WA Office of Health Review dated 11 November 1997
50. Submission from Medical Board of the Northern Territory dated 10 November 1997
51. Submission from Royal Hobart Hospital dated 14 October 1997
52. Submission from Community and Health Services, Tasmania dated 10 November 1997
53. Submission from Queensland Health dated 22 January 1998
54. Submission from The Medical Board of Queensland dated 19 January 1998
55. Submission from Medical Practitioners' Board of Victoria dated 19 September 1997
56. Impotency Clinic Review, Tasmania from the Office of the Commissioner for Health Complaints, Tasmania dated March 1998

Oral Submissions

On 12 February 1998:
Dr X, a medical practitioner previously employed by the clinics

On 26 February 1998:
Representative from the Australian Medical Association
Mr Z, an administrator previously employed by the clinics
Representative from the Australasian College of Sexual Health Physicians

On 26 March 1998:
Medical Director & Administration Manager of Australian Men's Health
Representatives of the Royal Australian College of General Practitioners

Appendix 2: Schedule of meeting dates of the Committee of Inquiry

Full committee meetings were held on the following dates:

15 October 1997
5 November 1997
11 December 1997
12 February 1998
26 February 1998
26 March 1998
7 May 1998
21 May 1998

Sub-committee on patient assessment, diagnosis, monitoring and care

30 October 1997

Sub-committee on financial and advertising aspects of impotency treatment services

29 October 1997

Appendix 3: Patient Information Sheet

The technique of penile injection to produce erections with Prostaglandin E_1 (Caverject) has become a recognised practice. Since 1988, Prostaglandin has been used either alone or in combination with Phentolamine and/or Papaverine.

Caverject is approved by the Commonwealth Therapeutic Goods Administration for the treatment of impotence. Physicians are able to prescribe combinations of this drug with Phentolamine and/or Papaverine, however these combinations have not been approved. Caverject should be the first treatment option for all patients. While multi-drug mixtures are commonly used, there is little good scientific evidence to show that they are more effective than Prostaglandin E_1 alone. Many experienced practitioners believe that patients who do not respond to Prostaglandin E_1 alone will respond to multiple drug mixtures, or that mixtures may be useful when patients develop side effects to Prostaglandin including pain from the injection. Many patients appear to respond favourably to these mixtures, however there is a serious lack of knowledge about the chemical stability, the compatibility of mixtures and the shelf-life of these mixtures.

Side effects of injection treatment

1. Priapism

There is a small chance that the penis may develop priapism, when the penis develops an erection which will not subside even after two to three hours. In this situation, it is necessary to call your doctor for instructions to return the penis to its flaccid state. Failure to notify the doctor that the penis has remained erect after four hours could delay treatment and could lead to **permanent damage** of the penis. The damage could include a future inability to achieve erections either spontaneously or with medication. In rare cases, treatment for priapism may include the removal of blood from the penis by injection or the administration of drugs to end the erection.

2. Discomfort or bruising

Occasionally the medication is injected in the wrong position. This can cause discomfort under the skin. If the injection is mistakenly made into the urethra (the tube that conducts urine from the bladder to the exterior), then it may cause blood in the urine and no erections. Incorrect injection technique may also cause bruising.

3. Scar tissue

Scar tissue may form within the penis especially with long term use of injections. It is important to be examined by your doctor at regular intervals to prevent this.

4. Pain

Some patients may experience penile pain with the injections. Sometimes the pain is very severe and the treatment is stopped. Multiple drug mixtures may overcome this problem.

5. Other complications

All of the short- and long-term problems connected with these medications and injections are not known and therefore regular follow up with your doctor is necessary.

Other options

It is important to consider all possible treatment options before deciding on injection therapy. These include oral medications, vacuum devices, counselling or surgery including implants. These options should be fully discussed with your doctor before you make a decision.

Follow up

As side effects may occur with injection treatment, it is important that regular follow up occurs. One of the most likely side effects from long term use is scarring, which can be identified either by self-examination or examination by your doctor.

NB Caverject is the only TGA approved treatment and should always be tried before multiple drug mixtures.

The use of penile injections offers no protection against sexually transmitted diseases. Bleeding at the site of injection may increase the risk of transmission of blood borne viruses such as HIV/AIDS.

Appendix 4: Consent to Medical Treatment

Dr _____ (name of doctor) and I have discussed my present condition and the various ways it may be treated. The doctor previously recommended the medication _____ which I have used for a course of treatment and have found to be unsuitable. The doctor has now recommended _____

_____

_____

The doctor has told me that:

- this medication is not available as a marketed product and is not approved for the treatment of this condition by the Therapeutic Goods Administration, the Commonwealth government body that approves prescription medicines according to their quality, effectiveness and safety;
- he/she has mixed this medication in his/her surgery and therefore the medication may not be sterile. To minimise the risk of developing an infection from using the medication, the doctor has advised me to store the medication in the refrigerator;
- he/she does not know how these chemicals affect each other when mixed together and therefore does not know how long the medication can be used before it needs to be discarded.

I have been given a Patient Information Sheet which informs me of the possible side-effects and complications of this medication. I have read the Patient Information Sheet.

The doctor has shown me how to use this medication and what to do if I experience certain side-effects.

The doctor has disclosed to me all his/her financial interests in this clinic and in this treatment.

I understand that undergoing the treatment carries risks and that it may not give the expected result, even though the treatment is carried out with due professional care. I have had the opportunity to ask questions. I am satisfied with the explanation and the answers to my questions. I accept the risks involved in the treatment.

Signature of patient _____

Print name of patient _____Date _____

I, Dr _____ have informed this patient as detailed above, including the nature, likely results and relevant foreseeable side-effects of the recommended treatment. I have disclosed to the patient all my financial interests in this clinic and in this treatment.

Signature of medical practitioner _____

Name of clinic (if applicable) _____Date _____

Appendix 5: Patient treatment guidelines

1. Guidelines on the assessment & diagnosis by the primary care physician:

- on the first visit, there should be a detailed patient history taken which includes sexual history, a physical examination including of the prostate, the arrangement of appropriate blood tests, and a discussion of treatment options
- on the second visit, following further discussion a physician may initiate treatment where appropriate, or may perform pharmacological testing and/or other appropriate investigations, with documented informed patient consent (per attached consent and information forms), including a monotherapy challenge with Caverject
- on the third visit, the physician should discuss results of investigations and treatment options with patient, and, if appropriate, initiate treatment

2. Guidelines on patient self injection therapy education:

- Caverject monotherapy is recommended as the drug of first choice for self injection therapy
- multiple drug therapy is indicated only when the patient is unresponsive to monotherapy or experiences significant adverse drug effects from monotherapy
- patients are to be educated in the technique of self injection either by the treating doctor or by a clinical nurse. Most men can be instructed in a single visit but a small number may require subsequent visits
- titration of the drug dose can be managed by the patient away from the clinic after having received the direction of the doctor or of the clinical nurse. The doctor or the clinical nurse should be reasonably available by telephone to answer simple questions about patient treatment.

3. Guidelines on monitoring of the patient:

- patients on injection therapy should be reviewed 4-6 weeks after starting treatment and thereafter every 6 months (there will be more frequent reviews required when multidrug therapy is used, per the above recommendations including a maximum shelf-life of one month)
- review consultations should include an assessment of the patient's response and progress; an examination for adverse effects such as penile nodules or curvature which may indicate fibrosis; a review of the drug, its dosage, prescription and supply; as well as the patient's injection technique

4. Guidelines on patient care:

- specific attention should be directed to the management of the two most common adverse effects of injection therapy - priapism and cavernosal fibrosis

5. Guidelines on the management of priapism:

- initial use of Caverject monotherapy both for the diagnostic injection and for ongoing therapy where possible
- use of drug dose recommended by the treating doctor
- if a full erection is still present 2 hours after the injection, the patient should take 120mg pseudoephedrine (ie 2 Sudafed tablets)
- if a full erection is still present 4 hours after the injection, the patient should take a further 120mg pseudoephedrine and take a brisk walk
- if a full erection is still present 6 hours after the injection, the patient should contact his doctor regardless of the time of day or night for urgent treatment

9. Endnotes

1 David J Morrow, 'Insurers limiting payments for use of impotence pill', *The New York Times*, 29 April 1998, pp. A1 & D4 at p. D4

2 Editorial from *USA Today*, 1 May 1998

3 David J Morrow, ibid

4 There have been at least 16 deaths attributed to complications arising from the use of Viagra, *"including seven men who reportedly died during or after sex"*, from 'Viagra deaths up as risks ignored', *The Sydney Morning Herald*, 11 June 1998, p. 3

5 The *USA Today* editorial cited above commented that *"30 million American men suffer from chronic impotence. Until Viagra, only 3% were undergoing treatment."*

6 It is noted that it is illegal for medical practitioners to derive any profit from the sales of pharmaceutical agents under s. 28 (2) of the *Pharmacy Act 1964 (NSW)*

7 s. 20 (4) of the *Health Administration Act 1982* allows the Minister to appoint such committees as he may consider appropriate, with functions directed by the Minister under s. 20 (5) and with Chairperson and members appointed by the Minister under s. 20 (6)

8 submission 9 from Mr T dated 16 September 1997

9 Mr H, an 80-year-old male advised that his relationship with a 73-year-old woman proved *"that age does not diminish our sexual needs or feelings",* submission 5 dated 7 September 1997

10 submission 11 from Mr S dated 17 September 1997

11 submission 17 from Mr W received 25 September 1997

12 submission 15 from Mr D received 29 September 1997

13 submission 14 from Mr A dated 20 September 1997

14 submission 12 from Mr W dated 19 September 1997

15 oral submission from Mr Z dated 26 February 1998

16 oral submission from Dr X of 12 February 1998

17 submission 20 from Dr Y dated 29 September 1997

18 submission 23 from Dr A, Medical Director of Australian Mens' Health (now Health Services for Men) dated 8 October 1997, oral submission from Dr A, Medical Director, and Ms P, Administrator, dated 26 March 1998

19 Oral submission of 26 March 1998

20 Oral submission of 26 February 1998

21 Oral submission of 26 February 1998

22 Oral submission from Dr X of 12 February 1998

23 Oral submission from Mr Z of 26 February 1998

24 Oral submission from Dr A and Ms P of 26 March 1998

25 Gibbs CJ in *Hospital Products Limited v United States Surgical Corporation* [1984] 156 CLR 41 at 67

26 *Breen v Williams* (1996) 138 ALR 259

27 *Re: Dr JH Bannister*, NSW Medical Tribunal, unreported, 28/4/92

28 ibid, p. 84

29 ibid, p. 85

30 ibid

31 Under s. 28 (1) of the *Pharmacy Act 1964*, only a pharmacist or a person acting under the personal supervision of a pharmacist may dispense or compound any medicine. s. 28 (2) provides that:

> *This section does not prevent a medical practitioner from dispensing medicine in the ordinary course of medical practice:*
>
> *if the practitioner does not charge for the medicine more than its cost to the practitioner...*

32 *Trade Practices Act 1974 (Cwth)* and the *Fair Trading Act 1987 (NSW)* are discussed in further detail below in relation to advertising

33 *ACCC v On Clinics Pty Ltd,* then only Medical Clinic Pty Ltd and Poten-C Clinics (Australia) Pty Ltd CLS 1996 Fed 440

34 Department of Fair Trading, *Public Naming of Unfair Traders: Procedures and Guidelines* (draft), 19 February 1998, p. 2

35 Ontario regulation 114/94 made under the *Medicine Act 1991* Part II

36 Daryl Williams , *Can the professions survive under a competition policy?*, paper delivered at a joint conference on Competition Law and the Professions – A Commonwealth View, Perth, April, 1997, p. 4

37 ibid

38 Bhojani S, *Public Benefits under the Trade Practices Act*, in the above collection of conference papers

39 Part IVB of the TPA came into effect on 1 July 1998 and includes the introduction of mandatory industry codes of conduct under section 51AD, which must not be contravened in trade or commerce by a corporation with penalties including injunctions, damages, the giving of undertakings to the ACCC, orders to disclose information or to publish corrective advertisements

40 Under s. 108 of the *Medical Practice Act 1992*, there are prohibitions against advertising cures for certain diseases (including AIDS, cancer, diabetes and leukemia), while under s. 114, neither a person nor a corporation may advertise medical services except in accordance with the regulations to the Act, and a corporation may only advertise where there is an appointment in force of a person responsible for medical services.