COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON HEALTH AND AGEING

(Subcommittee)

(Roundtable)

Reference: Health impacts of impotence medications

FRIDAY, 21 AUGUST 2009

CANBERRA

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HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON HEALTH AND AGEING

Friday, 21 August 2009

Members: Mr Georganas *(Chair)*, Mr Irons *(Deputy Chair)*, Mr Bidgood, Mr Coulton, Mrs Gash, Ms Hall, Mrs Irwin, Ms King, Mrs May and Ms Rishworth

Members in attendance: Mr Irons, Ms Rishworth

Terms of reference for the inquiry:

To inquire into and report on:

The health impacts of impotence medications in Australia.

WITNESSES

Subcommittee met at 9.06 am

BIRD, Dr Peter Howard, Head, Office of Non-Prescription Medicines, Therapeutic Goods Administration

DOYLE, Mr Richard, Legal Adviser, Advanced Medical Institute Pty Ltd

FITZSIMONS, Mr Michael, Policy Manager, Medicines Australia

HANDELSMAN, Professor David J, Board Member and Adviser, Andrology Australia

LORDING, Professor Douglas William, Andrology Australia

McCANN, Mr Brett David, Chief Executive Officer, Impotence Australia

MACKEY, Mr Paul, Director, Policy, Pharmaceutical Society of Australia

McMAHON, Associate Professor Chris G, Member, Chapter of Sexual Health Medicine, Royal Australasian College of Physicians

MALOUF, Dr David John, President, Urological Society of Australia and New Zealand

MARSHALL, Professor Villis Raymond, Director, Freemasons Foundation Centre for Men's Health

MASKELL-KNIGHT, Mr Charles Andrew, Principal Adviser, Regulatory Reform, Therapeutic Goods Administration

PINSKIER, Dr Nathan, Member, Royal Australian College of General Practice

SPIERINGS, Mrs Desiree, Sex Therapist, Impotence Australia

VAISMAN, Dr Jack, Chief Executive Officer, Advanced Medical Institute Pty Ltd

VARTTO, Ms Kaisu, Chief Executive Officer, Sexual Health information networking and education, South Australia

WEERAKOON, Dr Patricia, Coordinator, Graduate Program in Sexual Health, University of Sydney

ACTING CHAIR (Mr Irons)—Good morning and welcome, everyone, to the House of Representatives Standing Committee on Health and Ageing roundtable forum on impotence treatments. I declare open this public forum on impotence medications in Australia. I am standing in as the chair today because the chair of the committee, Steve Georganas, is unable to be here. I know he has a deep interest in this, and he apologises for being unable to attend.

According to Andrology Australia's website, erectile dysfunction or impotence affects one in five men over the age of 40 and there is evidence that younger men are also afflicted. While

there are many possible causes for erectile dysfunction, it can, in some cases, be a symptom of serious health conditions like diabetes and heart disease. Given the fact that erectile dysfunction can be caused by serious underlying health conditions, the House of Representatives health committee has decided to better inform itself about the provision and sale of impotence medications in Australia. The committee is concerned that some people are purchasing prescription medicine online and using telephone services to obtain prescriptions. Treatments for impotence which do not involve a face-to-face consultation with a medical practitioner may have an adverse impact on men's long-term health by discouraging them from seeking treatment from a GP in the future or failing to identify significant ongoing health problems.

The failure of men to present to a GP when they experience erectile dysfunction is part of a broader problem of men not seeking one-on-one medical assistance. The government is developing a men's health policy which aims to address the specific health concerns of men and reduce barriers men may experience in accessing health services. This forum is therefore an opportunity to explore some of the particular concerns about some of the treatment of erectile dysfunction and to perhaps understand why men are choosing not to use their GP in the first instance.

I remind all participants that today's proceedings are covered by parliamentary privilege. Essentially, this means that no legal action can be taken against participants in relation to the evidence given during this roundtable. This immunity does not apply if, after the hearing, any participant repeats statements made in evidence. Although the committee does not require you to speak under oath, you should understand that these hearings are formal proceedings of the Commonwealth parliament. Giving false or misleading evidence is a serious matter and may be regarded as contempt of parliament.

Again, I welcome you all. It is important to reiterate that time limits for the day will be strictly adhered to, and statements about each of the two discussion topics should be made at the beginning of each discussion session. The secretary will ring a bell when you have 30 seconds remaining to enable you to complete your statement within the three allocated minutes. Do any of you have any comments on the capacity in which you appear today?

Mrs Spierings—I am also the Vice President of ASSERT New South Wales, which is the Australian Society of Sex Educators, Researchers and Therapists.

Ms Vartto—I am the CEO of SHine SA, formerly known as the Family Planning Association of South Australia.

Prof. McMahon—I am a sexual health physician, here representing the Royal Australasian College of Physicians chapter of sexual medicine.

Prof. Lording—I am an endocrinologist. I am here representing Andrology Australia, which is an Australian government initiative, a centre for excellence in male reproductive health. I have also practised in this area for over 30 years.

Prof. Handelsman—I am the Director of the ANZAC Research Institute but representing Andrology Australia here. I have a background in this area and, in particular, was present in part

of the 1998 New South Wales Health Care Complaints Commission inquiry into virtually the same issues.

Mr Fitzsimons—Medicines Australia represents the innovative pharmaceutical industry. A number of our member companies make medicines used for erectile dysfunction.

Mr Mackey—The Pharmaceutical Society of Australia is the professional body for pharmacists in Australia.

Mr Doyle—I am the legal adviser and a major shareholder of Advanced Medical Institute, which operates one of the largest chains of impotence clinics in Australia.

ACTING CHAIR—Thank you. As we are ahead of time already, which is great, we will move on to the first session. That is a briefing from the Therapeutic Goods Administration on regulations governing the prescription and sale of impotence medications in Australia. I invite the representatives of the TGA to give us a presentation.

Mr Maskell-Knight—Thank you, Mr Chair. I am going to talk non-stop for about a quarter of an hour, so feel free to interrupt and ask questions as we go. The answer in many cases may be, 'I am coming to that later on.'

ACTING CHAIR—I will just interrupt there; I am sorry. Only committee members are able to ask you questions at this stage.

Mr Maskell-Knight—Okay. At the Commonwealth level the regulatory scheme for therapeutic goods is set out in the Therapeutic Goods Act 1989. The act confers a wide range of powers on the secretary of the Department of Health and Ageing who, in turn, has delegated those powers to officers of the Therapeutic Goods Administration, which is where Dr Bird and I work. Broadly it is an offence to import, export, manufacture or supply a therapeutic good, and that includes medicines and therapeutic devices, unless it is included in the Australian Register of Therapeutic Goods, which is established under the act. It is also an offence to manufacture a therapeutic good unless you have a manufacturing licence granted under the act. Just to cap it all off, it is an offence to advertise a therapeutic good unless you comply with the rules set out in the act.

The act is, of course, part of a much wider regulatory framework for the governance and supply of medicines in Australia. The first caveat on its reach is that the Commonwealth act is governed by the Constitution, so it essentially applies to corporations and persons engaging in international trade or interstate trade. It does not apply to sole traders trading within state boundaries unless the state has passed complementary legislation, and so far only four states have done that.

The next thing is that the professional activities of doctors prescribing medicines and pharmacists dispensing them are regulated by the states, not the Commonwealth. That is going to change in the near future with a national registration and accreditation scheme which will create a single national registration and accreditation system for a number of health professionals, including doctors and pharmacists. But even under that arrangement the control of pharmacy

ownership and the requirements for pharmacy premises will continue to be the subject of legislation by the states.

Another element of the framework is the scheduling framework, which determines whether medicines are 'prescription only', 'pharmacist only', 'pharmacy only' or available for general sale. A committee established under the Commonwealth decides which schedules medicines should be put into, and the states then adopt that standard through their own legislation.

I said at the start that the general framework of the act is that it is an offence to do anything by way of import, export, supply or manufacture unless you are registered. There are exceptions, of course. There are a number of exemptions set out in the act, and the act allows regulations to be made to set out other exemptions. An important one which is relevant to what we are talking about today is the compounding and dispensing of medicines. These provisions are in the act and the regs and are intended to allow pharmacists to continue the long-established practice of preparing a medicine for an individual patient in response to the patient's needs. A medicine might be prepared in response to a medical practitioner. For example, a dermatologist might write a script for a particular preparation to be made up by a pharmacist. It is up to the pharmacist to manufacture their own cough mixtures, for example. Those exemptions are intended to recognise the one-off nature of such medicines and the professional training of the pharmacists who prepare them.

There are two exemptions available to pharmacists. One is the requirement under part 3-2 of the act for medicines to be included on the register. The other is the requirement under part 3-3 of the act to be licensed as a manufacturer. Under schedule 5 of the regulations there is an exemption from registration for medicines that are dispensed or extemporaneously compounded for a particular person for application to that person. Under schedule 8 there are a number of exemptions from the operation of part 3-3 of the act dealing with manufacturing licenses. Essentially, the first exemption relates to medical practitioners who are basically allowed to compound medicines for their own patients. The second and perhaps more relevant one is for pharmacists. It relates to goods produced by the pharmacist in a pharmacy where the pharmacist practices and which is open to the public for supply other than by wholesale on or from those premises.

Part 5-1 of the act deals with the advertising of therapeutic goods. The key elements of the regime are that advertisements to health professionals are not captured by the act and that prescription-only medicines may not be advertised to the public; that advertisements for other medicines in print and broadcast media are subject to pre-approval by the secretary of the Department of Health and Ageing—in practice, that power has been delegated to industry associations; and that all advertisements for medicines must meet the requirements of the Therapeutic Goods Advertising Code established by the minister under the act.

There has been considerable debate about advertisements for particular impotence services in recent years. All of the advertisements the TGA is aware of are structured in such a way that they are not covered by the act. They refer to a particular medical condition and advise that there is a service or treatment program available. As the advertisements do not mention a specific identifiable therapeutic product or substance they are not advertisements for therapeutic goods in a legal sense.

I talked about extemporaneous compounding earlier. There is a review of extemporaneous compounding underway at the moment. As the activity is essentially covered by a combination of Commonwealth and state law, concerns with the current framework are being addressed by the National Coordinating Committee on Therapeutic Goods, which is a subcommittee of the Australian Health Ministers Advisory Council and includes representatives from the Commonwealth, states and territories.

In 2005 a consultant conducted a review of the growth in the practice of extemporaneous compounding and the concerns that this was raising. That review is available on the TGA website. After considering the review, the Australian Health Ministers Advisory Council acknowledged that there were legitimate public health concerns and asked the NCCTG to develop an appropriate regulatory response. In April 2008 the NCCTG published a consultation paper seeking comments on a proposal to amend the current exemptions. Essentially the NCCTG was proposing a three-tiered approach: traditional low-risk extemporaneous dispensing for individual patients would continue to be self-regulated against professional standards; moderate levels of compounding would be regulated by credentialling of pharmacists and accreditation of pharmacies by a professional pharmacy body against new professional standards; and higher volume compounding and the compounding of high-risk medicines would be brought under the scope of the TGA, and people carrying out those activities would be required to hold a manufacturing licence. Submissions were received from 26 groups and a number of individuals. The NCCTG is considering those submissions and refining a proposal for amendments to the regulations.

There is a related but separate exercise. The Therapeutic Goods Administration has established a Pharmacy Manufacturing Technical Working Group bringing together expertise from pharmacy regulators and the pharmacy industry to consider how to apply good manufacturing practice codes to compounding pharmacies. It has recommended to the NCCTG that the standard that should apply under a TGA licensing system should be the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme, or PIC/S—a guide to good preparation of medicinal products in healthcare establishments that was produced last year. As that code is intended to cover a wide range of settings, the working group is working on some associated guidelines to implement that.

Ms RISHWORTH—I have a question about compounding. Obviously with that three-tiered approach it was recognised by the TGA that the original purpose of compounding medications was about pharmacists doing something very specific. Obviously the third recommendation recognises that things have changed and that medications were being compounded in large quantities. Is that correct?

Mr Maskell-Knight—Yes.

Ms RISHWORTH—And, even though it seems quite clear that it is for individual patients going into the pharmacy, manufacturing in large quantities did not breach that particular guideline?

Mr Maskell-Knight—The legalities are that it does not matter what volume you produce, as long as you produce each prescription in relation to a script.

Ms RISHWORTH—So one would expect then that, even though they are being manufactured in large quantities, if you did a random sample of 10, each of them would have a different make-up of the medication in there because—

Mr Maskell-Knight—Not necessarily, but you would expect that there would be a script available from a medical practitioner, authorising the production of that particular item.

Ms RISHWORTH—So it is more about the specifics? Even though you can compound the exact same medication for a large group of people and that would still meet the existing rules—

Mr Maskell-Knight—Yes. The rules do not go to what is in the medicine; they go to whether it is identified into individual—

Dr Bird—I do not have anything to add today.

ACTING CHAIR—We could take some questions from the floor, but we will have to moderate those, because other people could answer those questions as well. Are you happy to do that?

Mr Maskell-Knight—Sure.

Prof. McMahon—I would just ask that, for the benefit of the participants of the committee, that you actually qualify what 'extemporaneous' means. My understanding is that 'extemporaneous' means that a medication is prepared, one-off, specifically for that particular patient, based on a script. It does not mean that there is an existing stock of medication prepared at a previous time, which is then used to fill that script.

Mr Maskell-Knight—That is exactly right. I do not believe 'extemporaneous' is defined in the regulatory framework, so it has the ordinary meaning of the word, which is exactly as you have described it.

Ms RISHWORTH—Just following on from that, without that definition is there some vagueness about that definition in the act?

Mr Maskell-Knight—I think 'extemporaneous compounding' is a term of art and it has a very well-understood meaning.

Mr Mackey—Within the PSA's professional practice standards we have a definition of 'extemporaneous compounding,' which I am happy to read out, if that is of assistance. It comes to the same point that Professor McMahon made: it is for a single unit that is prepared for an individual patient.

ACTING CHAIR—Are you able to read that out?

Mr Mackey—In the society's professional practice standards there is a statement that reads:

Compounding occurs when the prescribed formulation or a suitable alternative cannot be obtained commercially. Commercial products are preferable to compounded products because they are subject to formal quality control procedures.

And further, the definition of 'compounding' in the standards:

Compounding is the preparation and supply of a single unit of a product intended for immediate use by a specific consumer. When the prescribed product is not commercially available, a pharmacist may need to compound it in the pharmacy. The pharmacist must ensure product quality when compounding a product.

ACTING CHAIR—Thank you.

Ms RISHWORTH—When you are compounding, obviously the medications that you are putting together have all individually been through the TGA process?

Mr Mackey—Yes.

Ms RISHWORTH—So you are just sort of mixing them up for this individual, specific prescription, usually from a doctor—I am just trying to get my head around this—that says, 'We don't really have anything on the shelf, so we'll put these medications together for you individually. I won't manufacture it in a large quantity; I will make it on demand.'

Mr Mackey—It is on demand.

Mr Maskell-Knight—There is actually no requirement that the ingredients must, as such, be approved by the Therapeutic Goods Administration. In fact, one of the proposals that were in the compounding discussion paper was such a requirement. I think it is fair to say that views about that were very mixed.

Ms RISHWORTH—And why were they mixed—if you are able to elaborate on that? For me, it seems quite simple. Okay, you are mixing some drugs together, but surely those pharmaceuticals should perhaps—

Mr Maskell-Knight—Firstly, you are not mixing drugs together; you are mixing ingredients together. I suppose the whole point about extemporaneous compounding is that it produces a product which is not being regulated by the Therapeutic Goods Administration. The whole point of the exemption from being included on the register is that the product is not on the register. In trying to summarise the views of 26 organisations and a number of individuals, I guess there was one school of thought that said, 'Public health would best be protected by saying you can only use things that are on the register and mix them up,' and another view was, 'The point of the exemption is to allow access to things that are not on the register.'

Prof. Handelsman—Through the chair, I wonder whether I could ask for a clarification about this three-tier level of risk. Underlying the question is that there is a huge difference between somebody making a cream to put on the skin, intended for topical application, as opposed to something intended for systemic administration with all the risks attendant in that. Would it be fair to say that the high level of risk would cover every compounding product that is intended for systemic effect?

Mr Maskell-Knight—I believe that is the intention, yes.

Dr Malouf—Basically what you are saying, Mr Maskell-Knight, is that the agents we are talking about, either in isolation or in combination, have never been tested from the perspective of safety effectiveness and cost-effectiveness to the same standard that commercially available preparations are subject to.

Mr Maskell-Knight—Firstly, the TGA does not concern itself with cost effectiveness. Secondly, the preparations may or may not contain ingredients that have been assessed for safety and efficacy.

Mr Doyle—I am not a pharmacist and I do not pretend to be a pharmacist. Unfortunately, our compounding pharmacist was not invited here today. Our understanding of the requirements are that in fact all of the ingredients that go into a compounded formulation do in fact need to go through appropriate tests before they can be included in a compounded medication. But, as I said, I am not an expert in that area.

Mr Maskell-Knight—That is not my understanding of the legislation.

Dr Pinskier—Can I just clarify: is the term 'extemporaneous compounding' identical to the term we use in general practice known as 'recipes'?

Mr Maskell-Knight—I have never heard of the term recipes; I use 'recipes' in a quite different context.

Dr Pinskier—I think if we are drilling down for like for like, it is actually an individual recipe for an individual patient.

Mr Maskell-Knight—That is the intention.

Dr Pinskier—In general practice and in dermatology there is certainly extensive use for, particularly for dermatological conditions, glycerol, aqueous cream, sorbolene and so forth. What is the evidence base in dermatology for those particular recipes? Is there any evidence base or is it expert opinion?

Mr Maskell-Knight—I have no idea. If they are extemporaneously compounded the TGA has not assessed the evidence.

Prof. Handelsman—Can I just ask for clarification again, through the chair, that the ARTG registers not particular ingredients but a particular product which is an ingredient in a complicated mixture which has been evaluated in clinical trials for safety and efficacy? In other words, if you take that ingredient and then put it in some other mixture, it may have quite different properties, different risks and there may be safety and efficacy effects. Consequently, compounding does not necessarily draw on any experience from the ARTG, even if those active ingredients are listed there in another product. Is that correct?

Mr Maskell-Knight—That is absolutely right.

Prof. McMahon—I think the issue extends beyond purely what the individual ingredients are. You also need to consider the method of delivery of that particular preparation. There are, for example, plenty of medications which may have proven efficacy if taken as an oral medication but may not have the same level of efficacy if applied to the skin or by inhalation, which is one of the issues that we need to discuss today—not just drug content or composition but method of drug delivery.

Ms RISHWORTH—Is the method of delivery outside the area that is up to the doctor or the pharmacist when you are looking at compounding medication?

Mr Maskell-Knight—What the TGA does for therapeutic goods is we register or list the therapeutic goods. That includes the preparation and the dosage formulation. An example near and dear to my heart at the moment is naltrexone. Naltrexone tablets for oral administration are on the register; naltrexone compounded into a subcutaneous implant is not. If something is exempt from being included on the register, under part 3-2 of the act, it does not matter whether it is nasal inhalation, topical application, subcutaneous implant or whatever; it is exempt.

Mr Doyle—There is a very good reason why medications are often provided in a different form. For example, there may be an issue with a particular patient not being able to take the medication in a particular form. For example, medications that are approved are often prepared for infants in a different form because of difficulties in delivery to those infants. That may not be relevant here because we are talking about adults, but it is certainly relevant to those issues. The second important point that I think people need to be aware of is that, whether or not something goes through a full TGA process, the individual professionals who are providing those medications are responsible for those medications and will be liable for any issues that arise out of the delivery of those medications. If there are any adverse health impacts for the individual, then the individual who has provided the prescription and the person who has compounded the product will both be legally liable for any adverse health implications that arise from the use of that product. I think that is a very important point that people need to be aware of.

Dr Malouf—For clarification with regard to the TGA: as a clinician, I am frequently in a situation where patients of mine come in and describe the use of a medication which is currently exempted under the act. On several occasions, both I and my colleagues have attempted to obtain information related to the composition of these agents. We are concerned about potential drug interactions. We are concerned about the safety and efficacy of the agent. There does not seem to be any ability under the act to obtain information as to the composition of the agents which our patients are using, from a safety perspective. Many of my colleagues describe instances of speaking with commercial erectile dysfunction clinics, attempting to obtain some information regarding the composition of the agents, and the responses ranged from no comment to abuse to the phone being hung up at the other end. I have a concern that, under the existing exemptions, there are safety implications for doctors, not just urologists but all doctors, with regard to drug interactions. When you have a patient who is on 15 medications come into your office, there are interactions that are possible. In this particular situation, there is no mechanism for us to validate or verify the content of injections which are being administered systemically. An injectable agent has systemic absorption. We are very much in the dark, and I think that has safety implications.

Ms RISHWORTH—Does the act say who needs to be made aware or does anyone need to be made aware legally?

Mr Maskell-Knight—The exemption from the act is an exemption from the act, so, while the TGA has information-gathering powers in relation to things that are included on the register or have been included, if something is exempt, we have no information-gathering powers.

Ms RISHWORTH—Richard suggested that the practitioners that compound these medications be held to account if there are any adverse side effects. Under what legal mechanism are they required to declare what they have put in there to be able to establish whether or not it was the medication that caused the adverse side effects?

Mr Maskell-Knight—You are asking me a question outside why I am here, but I think the answer would be that it is a matter for common law.

Mr Doyle—I am actually very happy to respond to that question. In order for someone to provide a compound formulation they need to in fact prepare a written prescription signed by a fully registered doctor. All medical clinics are required to maintain records of the treatments given to their patients. That is a legal requirement. Those records are available for inspection by the patient at any time.

Ms RISHWORTH—What about their doctor?

Mr Doyle—I will just come back to that, if I may. If there is in fact an adverse health implication, the records are required to be maintained. There will either be a complaint to a medical board or a health care complaints body or there will be action through the courts. In any of those circumstances, the medical board, the Health Care Complaints Commission, have the power to require that all papers be provided. Similarly, for anyone who has been through a court process, there is a formal discovery process. Again, all documentation is required to be made available. So there is a clear requirement under the law that all these records must be maintained and must be made available to appropriate people.

I also want to make a quick comment on a comment made by Dr Malouf about people asking what is in the medication and the issues of interaction. There are a few issues I want to comment about. First of all, the agents that our clinics use are very well-known. There are no surprises in terms of what is in there. The individual formulations and the active ingredients in those are very well-known, so there should be no surprises. The second thing is that we do not actually have any circumstances where someone has asked us for copies of records. We are quite happy to advise what the active ingredients are in the formulations. They are on the public record; they are well-known. So I actually dispute the comment that has been made.

I just want to make one other comment. On the issue about individual doctors not necessarily being aware of what other medication a patient has, patients often go to multiple medical services for different conditions. They may go to a doctor for one condition and another doctor for another condition. There is always the risk of one doctor not informing another doctor about what a patient does. It is not specific to this particular issue; it is a widespread issue. We have a large society, a large population and people often go to different medical clinics for different reasons.

Ms RISHWORTH—But I think the concern that Dr Malouf raised was that usually you can ask a patient what other medication they are on. They might not know, but you can certainly usually ring the other doctor or the other surgery. I have one question on that. You indicate that people are very well aware of what is in the product, but aren't you compounding these products for individuals? Aren't they individual formulas? Wouldn't they vary depending on who got them and so doctors would not be sure that that is the exact same formula for every single client?

ACTING CHAIR—Mr Doyle, can I just interrupt. We are actually into a session that we are going to have later. We will come back to that in one of the next sessions. Professor Handelsman?

Prof. Handelsman—It may fall under the heading of what you have just said about the next session, but I would just take Mr Doyle to task in the sense that what he has outlined is a pre-thalidomide level of responsibility for regulatory affairs in drugs. The public accepts that efficacy and safety are tested for systemically used compounds. It is not sufficient—it is pre-thalidomide—to regard it as being something between individuals and a corporation.

ACTING CHAIR—I think we will get into that in the following session. Dr Pinskier?

Dr Pinskier—What is the difference in the standard between a medication which is on the Australian register and has gone through a rigorous testing process and is required to be then disclosed as being on-label as opposed to a series of medications that have been compounded and then prescribed effectively off-label? Are they on any label? What is the difference?

Mr Maskell-Knight—I am not quite sure I understand the question, Dr Pinskier. If something has been evaluated by the TGA, one of the requirements is that there is product information available which sets out a fair summary of what is known about the safety of that product, the efficacy of the product, side effects, warnings, interactions et cetera. If something is not on the register but is produced for extemporaneous compounding, none of that information is publicly available.

Dr Pinskier—So there is a different standard, effectively?

Mr Maskell-Knight—The other point is that if something is on the register it must have been made by a licensed manufacturer—if it is made in Australia or by a manufacturer who the TGA has inspected and believes is meeting appropriate quality standards. If something is manufactured extemporaneously, we have no knowledge of the standards of manufacture.

Dr Malouf—Further to the statement I made before and Mr Doyle's response, I would just like to read one brief paragraph, if I may?

ACTING CHAIR—We are going to get into that session.

Dr Malouf—One brief paragraph. This is from a urological colleague, Stephen Brough, who is a urologist from Tasmania.

Secondly, and partly as a result of the above, I 'phoned AMI to ask what drugs they were prescribing for ED. In particular, I wanted to know about the nasal spray as a number of patients had asked me. They would not discuss the drugs over the 'phone and as soon as the guy had worked out that I was an urologist, he ABUSED me and hung up.

ACTING CHAIR—As I said, we can get into that in a session later.

Dr Malouf—I am happy to talk about that later.

Prof. Lording—Just in respect of the previous question, as I understand, a TGA approved product can be used for an approved indication on-label or for other uses. Compound medications can also be used for the approved indication of that product and for other uses. I think it is a little confusing, but that may clarify what you are asking.

Mr Maskell-Knight—Can I just interpolate there. If it is it is extemporaneously compounded, there is not an approved indication.

Prof. Lording—No, but, for instance, testosterone creams or troches will be used for testosterone replacement—that is what I was getting as—for indications that would have been approved for that product but may also be used for multiple other uses.

Ms Vartto—Just for you guys from TGA for my own clarification, I understand the substances that are used by the Advanced Medical Institute are off-patent medications. What is the difference with off-patent medication versus off-label medication?

Mr Maskell-Knight—When a drug is brought to market for the first time, it is usually patented, which means that the originator company is able to harvest the fruits of their intellectual labour in developing the product. After a period of time—and I am not an expert on patents law, but I believe it is 20 or 25 years—it comes off patent, which means that other pharmaceutical companies can then bring a generic copy of that drug to market. The difference between on-label and off-label use is that when a drug is registered, it is registered for particular indications. That means that the sponsor of the drug has produced evidence suggesting that it is efficacious for that particular indication. However, it is open to doctors to prescribe that medication for uses other than those for which the medicine has been approved. That is referred to as 'off-label'.

Ms Vartto—Are we talking here about off-label and also off-patent medications, Mr Doyle?

ACTING CHAIR—This subject is going to be discussed in topic 2. I take this opportunity to call a brief morning break. I would like to thank Mr Maskell Knight and Dr Bird for attending this morning, for your briefing and the clarity of the answers you gave us. Thank you for being here. What we have just entered into will be in topic 2 after lunch today.

Proceedings suspended from 9.50 am to 10.08 am

ACTING CHAIR—Welcome back. I have just taken a written submission. Is it the wish of the committee that the written submission from Eli Lilly Australia be accepted as evidence to the inquiry today and authorised for publication? There being no objection, it is so ordered.

Is it the wish of the committee that the document tabled by Dr Nathan Pinksier, his resume, be accepted as an exhibit and received as evidence to the inquiry? There being no objection, it is so ordered.

We will now begin the interactive roundtable sessions. However, before we commence I would like to remind participants of the format these sessions will take. At the start of each session I will announce the theme and provide each organisation with the option to speak to the theme for up to three minutes. Participants should note that they are not obliged to make a statement on the particular theme—for example, if they feel that an issue is outside their knowledge or that it has already been addressed in another organisation's statement. To ensure that everyone has an equal opportunity to speak and to maximise time for questions and discussion, a three-minute time limit will be strictly adhered to. Following the introductory statements, members of the committee will have the opportunity to ask questions. Following questions, I will invite members and participants to engage in general discussion relevant to the theme. The general discussion will be the focal point of each session. It will allow clarification of issues and will provide the setting for participants to exchange ideas.

The first topic is diagnosis and medication. The objective of this session is to explore the extent of the market for impotence medications and the proportion of men seeking treatments via their GP, the internet or over the telephone. This session will also focus on the health outcomes of these different modes of treatment for Australian men.

Prof. Marshall—I would like to start by indicating that I believe that erectile dysfunction is often under-recognised, so the issues that we are talking about are likely to become greater than they are at the present time. Obviously one of the reasons why it is under-recognised is that it is simply not asked about. The Florey Adelaide Male Ageing Study has been following 1,000 men for nearly five years now, and they have all had questions about erectile function. These men are aged from 35 to 80, and 57 per cent of those men have already reported that they have some issues with erectile dysfunction. This obviously indicates that there is likely to be an even greater incidence than the figure that we heard earlier this morning, of one in five, from Andrology Australia.

I think that the importance of this is that erectile dysfunction is now becoming increasingly recognised as being involved in a syndrome of a number of other conditions. We already know that men with erectile dysfunction will often have issues of erectile dysfunction before they are diagnosed with cardiovascular disease. So I think there does seem to be a link between erectile dysfunction and endothelial disorders. The other thing that we have been able to identify through the Florey Adelaide Male Ageing Study is that there is a higher incidence of depression in men with erectile dysfunction. Whether they are linked to the same causative factor or whether it is cause and effect is, I guess, still to be answered. Nevertheless, it does highlight that there are a number of other significant conditions associated with erectile dysfunction.

The other important thing is that there is now increasing evidence that lifestyle modification, particularly with reduction in weight and other activities, can be important. This can avoid the need to undertake medication or other more invasive forms of treatment. We are just about to report a study where men have gone on to a rapid weight-loss program. We have been able to identify that these individuals have had significant improvement in pre-existing erectile dysfunction. From that point of view, our belief is that we are dealing with a condition which is linked with many other conditions and it really is inappropriate to simply treat erectile dysfunction without a full medical assessment.

ACTING CHAIR—With the link between depression and erectile dysfunction, did you find it compounded? Would it take them into a further spiral downward?

Prof. Marshall—This study is really not going into the follow-up. What we are really doing is looking at the incidence and then possible correlations.

ACTING CHAIR—Thank you.

Mrs Spierings—From my experience at Impotence Australia as a sex therapist, I know that just giving these men some medicine is not always the most effective approach. Therefore, I feel it is important to discuss today that for any medical treatment to be most effective, it should really be a combination of prescribed drugs and additional support. When I say 'additional support' I mean three things: firstly, providing them with some additional guidelines around the medicine that they are going to take; secondly, giving them information around erectile dysfunction; and thirdly, having counselling support available to address additional issues that may influence their erectile dysfunction.

I will briefly explain as to why I think that additional support is so important. Firstly, as you would all know, the arousal response is basically affected by emotional stimulation and physical stimulation. With emotional stimulation I really mean thinking sexually to get in the mood. Emotional stimulation is really affected by other common life stresses such as relationship to stress, stress at the workplace and even performance anxiety, which seems to be very common in men with erectile dysfunction—I feel we cannot simply just ignore that. Also, their partner's sexual functioning can have an impact on their erectile function. By solely giving these men medicine, even though it might give them additional confidence, it does not necessarily address these issues.

Also from my experience at Impotence Australia, I have really seen how erectile dysfunction affects their emotional well-being, as the professor next to me was saying. They feel depressed, sad, angry and aggressive and it also seems to affect their relationship. As we all know, this can lead to further health implications. Therefore, I feel this additional support needs to be provided. Last but not least, I find that once men have been prescribed these medicines, they seem to be quite anxious about it. That can be because it is against a religious or cultural belief or they are scared of the side-effects or worried about how their body may react during sexual activity while taking these drugs. I find that, without giving them these additional guidelines, they may decide not to even to take it after or if they do decide to take it they might feel anxious, which can also affect the effectiveness of the drug itself.

To conclude, when taking to heart the best interests of men with erectile dysfunction, any medical treatment should be a combination of medicine plus additional support for the treatment to be most effective.

Ms RISHWORTH—In my previous role I was a psychologist, so I have no doubt about the importance of additional support. But as Professor Marshall said, this is a very embarrassing issue for many men. Some men may not want to sign up for this huge, comprehensive—

Mrs Spierings—That is right.

Ms RISHWORTH—My question is: should there not be this other avenue for men to deal with this? Is it allowing some men to deal with it to some extent—

Mrs Spierings—Yes, for sure.

Ms RISHWORTH—even if it does not address all these other issues because they are not going to sign up for a comprehensive treatment program?

Mrs Spierings—That is also not my point really, that it has to be comprehensive. I think it should be available for those men who will benefit. There should be the option for follow-up support. If it may not work or if they still have issues, they can ring back and there is this service, whether it is provided by the same provider or by someone else, but they can go there to address these other issues.

Ms RISHWORTH—So that there are pathways for the additional support?

Mrs Spierings—Yes. Obviously for all men that is not necessary but for some it is.

Ms RISHWORTH—How would you envisage that that be identified? Obviously some are choosing to go to their GP but a lot of people are just ringing up providers of the medication. Some in fact are ordering off the internet. Once again, there is no mechanism there for referrals. How would you see it working in terms of a referral for some support?

Mrs Spierings—Even if they do contact phone services or internet providers, they can see, 'Please let us know how you go. If this isn't the best solution for you or if it doesn't work, or there are other issues, we're here to give you support or to point you in the right direction.'

Dr Weerakoon—From our students' research and our own research, one of the main things is the lack of training in all levels of health professionals. We have just heard it said that erectile dysfunction is an early marker for diseases. It is an early marker for lifestyle concerns. If GPs with all their medical training and other health professionals, nurses, rehab counsellors, none of them are indicating that they can feel comfortable or have the knowledge to talk about it, I seriously doubt that somebody at the end of a telephone line can really have the training to be able to detect and manage lifestyle factors and early markers for diseases. That I think is our main thing as educators and trainers.

Ms RISHWORTH—You are suggesting that perhaps all levels of health professionals need more education when it comes to erectile dysfunction. Why do you think it has not happened in the past?

Dr Weerakoon—I think sexual health has always been on the backburner in terms of even curriculum time in training programs even for the best health professional programs. Also the fact that it is an early marker for lifestyle and for many diseases is fairly new research and it has been picked up fairly recently. But it is very significant. On a telephone line, when I have talked to people erectile dysfunction is uppermost in their mind rather than their blood sugar or hypertension.

Ms RISHWORTH—Do you think doctors and other health professionals ask about that directly? Obviously if you are talking about preventive health you need to ask that question directly. Do you think that is regularly asked in diagnosis across a whole range of areas?

Dr Weerakoon—All the literature reports, and I am sure colleagues here would support that, but not many do, especially GPs. There are time constraints and many other things, personal sensitivities, cultural values, but it is rarely asked.

Ms Vartto—I guess I am here from Shine because we see a very small proportion of men in our clinical services, about six per cent, but about 30 per cent of clients in our therapeutic counselling services are men and their partners. The interesting thing is that the men that we see in our services invariably have issues around sexual dysfunction or erectile dysfunction or impotence, premature ejaculation. That is the main reason we actually see them. We see men and their partners who invariably have already accessed an online telephone service and signed themselves up for a contract for the supply of patent medications. Those people have cited the Advanced Medical Institute as a place where they have got the substances, predominantly over the phone. We are here because of that concern as an advocacy for people in our community. We have been increasingly concerned about men's health status generally and we are pleased that there was the Senate inquiry into men's health and now we are looking at a men's health policy.

We are really concerned about men's sexual and reproductive health, and particularly the fact that men have a total lack of health seeking behaviour in Australia. This is well documented. If you read men's health magazines, I went to a newspaper shop last night and had a look at the latest men's health magazine and I have to say that those magazines portray men's health issues as more sex and better sex and have quite a considerable amount of advertising about sexual dysfunction. There is ample proof that there is actually a male sexual dysfunction industry out there which, according to some pundits, has been set up by pharmaceutical health-care professionals and advertising public relations firms which are using public relations, direct to consumer advertising, promotion of off-label prescribing and tactics to create a sense of widespread sexual inadequacy and interest in drug treatments. Where does this come from? We believe it comes from the fact that the sexual dysfunction industry is largely a product of our long history of social and political control of sexual knowledge and sexual discretion which have created shame and ignorance that make it difficult for many people to understand sexual satisfaction or cope with sexual problems in a rational way. The sexual dysfunction industry offers a relatively simple solution.

ACTING CHAIR—Thank you. You said that a lot of male clients who come to see you have been through an online or telephone service first. How do they end up with you? Why wouldn't they come to you first? How do they find you?

Ms Vartto—What has been reported to me by my staff, doctors and therapeutic counsellors, is that people end up coming to us as a bit of a last resort. They have tried to do the anonymous sort of approach because of their own sense of shame about their dysfunction. They have signed a contract and they have been supplied one, two or three different types of substances. These have not worked. It has not solved their problem, and now they are at their wits end to know what to do about it. They will then end up with an organisation like Shine, or if they use our sexual health line we will refer them immediately to a GP, which might then mean a referral to a urologist.

ACTING CHAIR—You said that some come with their partners. Is that quite a few, and have they said their partners have been involved when they have gone down the online or telephone approach first?

Ms Vartto—Some women report that they are the ones who have actually made the contact with the telephone and have been advised that their partner does not actually need to be assessed and all of the drugs can be sorted over the telephone.

Dr Malouf—I would like to thank the House of Representatives standing committee for the opportunity to speak on this subject. The practices of commercial impotence clinics have been a concern of mine and of my professional body for quite some time. I think it is important that we realise that these issues have implications for the whole community. You might think we are talking about 65-year-old men but we are actually talking about everybody from the age of 16 through to 85, and certainly some of the advertising material out there goes way beyond the 65-year-old audience. Urologists are medical specialists who treat disorders of the urinary and reproductive systems. We work in conjunction with general practitioners, who in an ideal model should be the first point of contact for men with erectile dysfunction. We address all aspects of the management of ED, from the initial assessment and diagnosis through to management, including counselling, medical therapy and surgical options. As such, I believe that urologist are well-placed to comment on this topic.

Commercial ED clinics are a story of bad medicine and bad marketing. ED is common and becomes more common as men age. The diagnosis includes disorders of libido or sexual desire, erection and ejaculation. There is no one-size-fits-all treatment. In younger men the condition is often an issue of confidence and counselling is all that is required. As men age, other important medical conditions may be present, including heart and other vascular disease, diabetes, obesity and disorders of the nerve and hormone systems. The practice of telephone assessment is incomplete and inappropriate. The qualifications of call centre operatives are unknown. No basic physical examination or blood tests are performed, no assessment of the associated medical conditions is undertaken. Australian men do not often visit doctors and a telephone interview is a lost opportunity for a doctor to assess and implement basic preventive strategies with regard to alcohol and smoking, obesity, blood pressure and cholesterol management. The psychosocial aspects of ED are not addressed through this model.

The treatment strategies employed by commercial ED clinics are similarly a sad tale. Men are enticed into anonymously calling ED clinics by clever advertising which promises a quick and simple fix. These men are often too embarrassed to speak to their GP. The reality is that a nasal delivery system rarely works. Apomorphine, which is one of the primary active agents, has been extensively evaluated by the medical and pharmaceutical industries and communities and has been shown to be less effective and have more side-effects than comparable agents. As a result, men who have signed expensive contracts ultimately end up with injectable agents, but these are expensive and poorly tolerated. It falls below the minimum standard of care that these men are never offered oral agents such as Levitra, Cialis and Viagra as first-line medical therapy. These drugs are effective, safe and relatively inexpensive. Many patients of mine who have been treated by commercial ED clinics before I see them are dismayed to learn that a simple tablet is all they need to fix the problem.

Patient selection is a concern. I know of a 17-year-old boy who was prescribed injectable agents by AMI to treat premature ejaculation. There is no medical evidence to support this and counselling should be the first line of therapy. We have seen an AMI marketing campaign to treat female sexual dysfunction. There are claims on the AMI website that disorders of desire, arousal, orgasm and painful intercourse can be addressed. There is no evidence that drug therapies are indicated for any of these conditions. Let me finish by telling you the story of a 45-year-old patient of mine. He was using injectable agents from an ED clinic. This was not the appropriate agent. Counselling or an oral tablet would have been effective for what was at the time a mild problem. He developed a prolonged erection, which permanently damaged his erectile function. He is now completely impotent as a result of this substandard management. We need to develop a system which will assess and treat men with ED appropriately. Amanda, going to your point, men's shyness should not be justification for the delivery of substandard medical care.

ACTING CHAIR—Thank you, Dr Malouf. I would ask that witnesses limit their contributions to three minutes. There will be further opportunities to make statements and ask questions. We will now hear from Professor McMahon.

Prof. McMahon—Men with ED are embarrassed to seek treatment. As a result they are a vulnerable group. They make impulsive and ill-informed decisions, but they should not be disadvantaged by an expedient practice of medicine which is focused more on the company balance sheet than on patient needs. Without the opportunity of a direct face-to-face consultation with a doctor, the patient is denied an ideal opportunity to discuss his symptoms and the doctor is denied the opportunity to examine the patient. The current consensus of international opinion is that men seeking treatment for ED cannot be evaluated properly without an opportunity for a doctor to perform a physical examination. This is and will always remain one of the basic tenets of medical practice. The findings and recommendations of the World Health Organisation's second and, recently, third consultations on sexual health and the International Society of Sexual Medicine's standards of medical care require that a physical examination remains an essential component of sexual dysfunction evaluation.

Furthermore, the national policy for technology based patient consultations framed and developed by the Joint Medical Boards Advisory Committee, which has the status of a code of professional conduct, requires that a telephone based consultation must include an adequate assessment of the patient's condition and that the doctor must be confident, especially with patients he has never seen before, that a direct physical examination would not add important

information to informing a patient of his treatment and to the diagnosis and management of that treatment. Just because a patient has a seemingly uncomplicated history of ED—he is young, does not have any risk factors such as diabetes and may have recently seen his own primary care physician—does not absolve a second doctor from the responsibility of performing a physical examination. It represents a casual, cavalier, careless and expedient approach to patient management. It should be deplored and condemned. It represents bad medicine and it should invite the strongest criticism.

Ms RISHWORTH—Like Dr Malouf, you have focused on the physical exam. There is no doubt that there have been reports about inadequate questioning and things like that, but in an age where we are going to telehealth and e-health, can you see a situation where there would be more information gathered and more alternatives offered? Can you see a situation where over-the-phone assessment could be combined with a good assessment that offers a number of treatments as well as alerting the doctor responding to preventive health issues? Could the two be mixed in with more comprehensive regulations or information gathering?

Prof. McMahon—Absolutely not. You can design a very good means of assessing a patient using a telephone interview—there are questionnaires—but you are denied the opportunity to examine the patient. With many of the risk factors associated with ED, such as diabetes et cetera, the first symptom may in fact be erectile dysfunction. We know that there is an accumulating body of data to suggest that men with ED are at a higher risk of developing coronary artery disease and subsequent cardiac death. These men need to be managed properly. This type of medicine is bad medicine. It is bad for patients and it is bad for doctors in general.

Ms RISHWORTH—How do you get them in to see their doctor if they do not want to present with this? They only want to make an anonymous telephone call. How do you get them into the surgery?

Prof. McMahon—One of the biggest challenges is how to encourage men to seek treatment. There is a lot of misinformation about how common ED is. Not all men with ED will actually require treatment. Men are hesitant about seeking treatment. There needs to be a grassroots education program for the community and for medical practitioners, particularly general practitioners. I do not believe this practice of medicine is a suitable substitute. I think we need to ensure that general practitioners, who really have the skills to manage the vast majority of men with ED, are educated and encouraged to provide a service. It is not without its challenges; it is difficult to do. But just because something is difficult does not mean you should replace it with something that is manifestly inadequate.

Dr Malouf—To respond to Amanda's question, there is a role for telemedicine but certainly not in the initial diagnosis and management of what is potentially a serious underlying medical illness. I think telemedicine is good for follow-up consultations, and I employ that regularly. Telemedicine is good if someone wants to ring up for a bit of general advice. They could be given some advice over the phone. A nurse might be able to direct the patient to a doctor or a clinic or a physiotherapist. But, in terms of the initial diagnosis of a condition which frequently reflects an underlying medical problem, telemedicine is entirely inappropriate.

ACTING CHAIR—We will now hear from Professor Lording.

Prof. Lording—I am going to change tack. But then I will come back to the theme of the other presenters. On internet prescribing, which is part of this, I do not have any idea of the amount of drugs obtained through unregistered internet pharmacy sites, but I do think it is substantial. I ask all my patients with ED whether they have sought medications in this way. Many of them have obtained perfectly effective drugs at a much cheaper price through the internet. However, I just need to make sure that everyone understands the significant risks associated with this. There are drugs that are fakes and do not work. There was a report in the *New England Journal of Medicine* earlier this year of 150 admissions to hospital in Singapore, including four deaths, of patients with hypoglycaemia who had accessed medication over the internet which either purported to be PDE5 inhibitors—drugs like Viagra, Cialis and Levitra—or other sexual function drugs. This is a very important area. Patients are led to seek drugs in this way because of the high cost of the current agents and the fact that, even in chronic illness, there is no PBS subsidy for them.

I would like to come back to AMI specifically. Andrology Australia gets a lot of comments from men about AMI and they are never positive. I will highlight a couple of points that have not been made so far. The advertising seduces men who, as we know, are embarrassed and the ease of contact is obviously a drawcard. The people manning these services, and the clinics, represent themselves to the public as specialists. In the true medical sense, there is no specialist aspect to this. I hear people say that they are talking to a consultant. In a medical sense, there are no consultants involved.

All reputable guidelines recommend the PDE5 inhibitor drugs—orally active, proven efficacy, substantial database, large safety studies—as the first-line treatment if a pharmaceutical agent is going to be used. This clinic, AMI, bypasses this. In fact, if they are asked about the use of PDE5 inhibitors, I have heard expressions like ‘these drugs are old-fashioned, not commonly used, dangerous and a cause of permanent blindness’. This is totally contrary to any established guidelines for the management of ED.

On the effect of going through this process, usually drugs that do not work are prescribed. Men do not usually want to go onto injections. From my experience it takes them a long time to resurface in the medical system. They are bruised by this experience, so they do not resurface. This further delays the potential opportunity to diagnose their underlying problems. But also—and this has not really been touched on enough—it causes a further spiralling deterioration in their relationship, which impacts on themselves, their partners, their family and people around them in the workplace and so on.

Ms RISHWORTH—Do you think it is because of the cost that people are seeking Viagra and those sorts of things over the internet, or is it because of the anonymity? From talking to people and from hearing some of the witnesses already, it seems that compressive service is the last port of call.

Prof. Lording—I think it is both. Anonymity is an important issue in this condition, as has already been discussed. But men tell me they will have a prescription and then subsequently investigate what is available on the internet, and they find it is substantially cheaper.

Ms RISHWORTH—You say that, when you see people after they have tried different medications that have not been prescribed through a comprehensive assessment, their relationships are deteriorating even more. What are some of the causes of that?

Prof. Lording—The longer the time that the sexual interaction between a couple is not working properly, the more distant they get. The male withdraws from the process, and the relationship changes substantially. We know from commentary that has been made that the duration of erectile dysfunction is an important factor in relationship distress.

Ms RISHWORTH—Dr Malouf said one of his patients had adverse and long-term physical side-effects from medications they have obtained over the telephone or the internet. Have you seen that with any of your patients?

Prof. Lording—I have not personally come across any internet experience like the one I reported from Singapore. For any man injecting drugs into their penis, there will be a rate of priapism or prolonged erection. I have certainly come across that. This happens not just with injectable drugs from the various sources of obtaining drugs, including the AMI, but also where people get them on prescription.

ACTING CHAIR—This session was about trying to explore the extent of the market for impotence drugs, but I get bombarded daily, at three different email addresses, with emails about Cialis and Viagra. There must be a huge internet market if people are being bombarded with emails on a daily basis. Have any of the people you see had negative experiences with internet ordering?

Prof. Lording—Yes, and I tried to communicate that. Sometimes these drugs are genuine copies, generic drugs, which work perfectly normally, but sometimes they do not work. Presumably some fake products are being sold. You can see that from the naming—sometimes one letter is different, or something like that—but patients are not always alert to do that.

I have not seen the catastrophic consequences that I mentioned from that Singapore experience, and I have not heard of that happening in this country. But you are right: we are all bombarded all the time with internet advertising for these drugs. I know a number of men, who have never even presented with ED or thought themselves to have ED, who have purchased drugs because of that lure of getting drugs on the internet. I believe that most of the places they get them from are unregistered pharmaceutical outlets overseas—and not necessarily in the country that the brand of the pharmacy relates to.

Prof. Handelsman—I just want to make two points. One, it is inconceivable that we would accept that hypertension—which we all know is a serious risk factor for stroke and heart disease—would be managed by phone consultation and phone prescribing. It is common but it has been integrated into the primary medical care in the community and it is quite feasible to do that for erectile dysfunction. Two, it is a common myth—the facts are contrary to the myth—that men do not visit doctors. From the MATeS study and from several other sources, men over the age of 40 do, on average, visit their GP approximately once a year. It is not for these reasons but it is a matter of recustomising the way that interaction occurs so that erectile dysfunction is normalised—the way hypertension is—so it is not such a difficult task to get this onto the agenda. But we have to have that as the standard of care in the community, and we must not

return to the second-rate, return to the 19th century practice of selling proprietary medicines out of the back of a van in the 21st century.

Dr Pinskier—The Royal Australian College of General Practitioners is the largest peak body that focuses on and is the custodian of quality and safety in general practice. It provides the educational curriculum for postgraduate and also postvocational training, and it is responsible for overseeing the quality assurance program for general practice. The college is a not-for-profit organisation and has over 19,000 members, so it is well placed to make some general comments in this area.

The college has reviewed the BEACH program—Bettering the Evaluation and Care of Health. This is a longitudinal study and has now collected data in relation to over 900,000 patients in relation to GP consultations. Interestingly enough, the BEACH program does not record impotency issues within its section on problems managed by the coding section. That means that impotency issues account for less than 0.5 per cent per 100 key encounters in general practice. BEACH does, however, note that prescriptions in general practice are recorded at the rate of 82 in every 100 encounters, which really highlights the role that therapeutics play in the general treatment process. So any regulation of this process needs to be carefully considered. BEACH is regarded by the profession as a reliable reflection of what happens in standard general practice.

The concern that the college has is that the way in which this impotency medication is being distributed, particularly in relation to the issues being discussed today, falls outside standard general practice. The question one would ask, given that there is a gap occurring within general practice, is: what do we need to do to raise the awareness within general practice and within the community so that this issue is brought back into the fold of general practice? General practitioners are well trained across the sector, but there are always specific disease focuses from time to time that raise their heads. Typically people comment, 'GPs are not qualified to do this; they should focus on this.' Every week there is a different issue, whether it is swine flu one week and diabetes the next week. There is a general concern that there is an insufficient focus on a particular topic, and it is normally sectorally driven. But GPs are holistically trained and they are well trained across the board.

The other issue is around the quality assurance framework. The college of general practitioners has developed the largest accreditation program in Australia. It covers most general practices. It also developed standards for detention centres, which have now been released, and that has now rolled on to prisons. So the college has a very strong focus on quality assurance for its accreditation process. That process provides a level of public transparency and professional and peer review, and it allows peers to walk into other practices and to assess the standard of that practice against the benchmark. In this particular instance that we are talking about, what appears to be happening is there is a process that is occurring, but no-one really understands what is occurring and there is no quality assurance that underpins it. We are concerned that it is operating outside the guise of traditional general practice; there is no relationship back into general practice. If we refer to a specialist, we receive a report back. That is conveyed by the normal channels.

ACTING CHAIR—I ask you to bring your opening statement to a conclusion.

Dr Pinskier—Increasingly we are moving to an e-health environment. My focus in my other work—I am also a clinic leader with the National E-Health Transition Authority. We are working on the concept of integrating the sector. The National Health and Hospitals Reform Commission is now focusing on the concept of a patient centred record, which will contain information from all providers. We are not sure how this particular process will be incorporated into that process.

Ms RISHWORTH—That report back obviously does not happen with every single doctor. So if I go to my GP and then I go to a specialist, the specialist will report back to my GP, but I might be in another state or something like that. What is the industry standard? Obviously with the record those notes will be more cohesive, but what is the usual practice in those sorts of situations?

Dr Pinskier—There is a general ethical requirement and also an accreditation requirement that if you move from one practitioner to another that your records are freely made available to the practitioner you have moved to. That is done by a simple request and it could be transmitted electronically or in hard copy or by secure mail. But there is a general acknowledgement that the information in that record is your information. The record is the record of the practice.

ACTING CHAIR—I just remind people that we will have time for further discussions and questions after this, so if you can keep your statements to three minutes, it would be appreciated.

Mr Fitzsimons—I would like to thank the committee for inviting Medicines Australia along to this roundtable discussion. For those who are unfamiliar with Medicines Australia, we represent the innovative pharmaceutical industry. Our members comprise 80 per cent of the prescription pharmaceutical market and are engaged in research, development, manufacture, supply and export of prescription medicines. Medicines Australia also administers the code of conduct, which sets the standard for ethical marketing and promotion of prescription medicines.

The prescription medicine market for erectile dysfunction is currently worth about $97 million annually. These medicines include Viagra, Cialis, Levitra and Caverject. It should be noted that to market these proprietary products here in Australia, they have undergone extensive investigation by clinical trials to establish their effectiveness and safety and evaluation by the Therapeutic Goods Administration of that clinical trial data and subsequently approved for marketing in Australia at considerable expense to these companies. In addition, Viagra, Cialis, and Caverject are currently subsidised by Veterans' Affairs for veterans who have acquired erectile dysfunction as a consequence of their war service.

As impotence is a secondary symptoms usually resulting from other comorbidity, such as cardiovascular disease, diabetes and depression, Medicines Australia strongly advocates that men seek personal medical assessment from their general practitioner to not only treat the impotence, but to also diagnose underlying conditions that are causing the impotence. In this regard, a consultation by telephone is unlikely to provide an appropriate setting for diagnosis of an underlying condition. Certainly key concerns with telephone consultations revolve around the potential to miss information that would otherwise be observed from a patient's general appearance, behaviour and non-verbal cues derived from any physical examination that was thought necessary and, as a consequence, any reduced trust or honesty inherent in a face-to-face doctor-patient exchange and ongoing relationships and due in particular difficulties that would be experienced by patients with sensory or cognitive impairments.

Overall, the adverse health outcomes that could arise from inappropriate prescribing can range from ineffective treatment to death. For example, if a person is prescribed with a certain prescription erectile dysfunction product, but that patient was also taking a drug such as nitrates, this combination could potentially reduce blood pressure to dangerous levels. In summary, certainly the proprietary prescription medicines available in Australia are effective at treating erectile dysfunction. Men should seek appropriate diagnosis of the importance to investigate potential underlying conditions so that the most appropriate treatment can be prescribed and to provide the best health outcome.

Ms RISHWORTH—My question is the same question I asked Professor McMahon: do you think that if there was a consultation broad enough and detailed enough that you could have an effective consultation over the phone, or do you feel that physical consultation is always required?

Mr Fitzsimons—I think in this particular case a physical or face-to-face consultation is the best way to not only assess erectile dysfunction, but also to assess the patient for any other underlying conditions, such as taking blood pressure and things like that. It is a bit hard to take blood pressure over the phone.

Mr Mackey—Thank you very much for the opportunity to appear today. Before going to my opening statement, I was remiss earlier in not offering an apology from the president of our Victorian branch, Mark Feldschuh, who was to have represented the society today. Unfortunately, Mark had to have an urgent operation and is unable to travel. He was very keen to attend and is quite disappointed that he cannot be here.

The Pharmaceutical Society of Australia, and I will refer to it as PSA in shorthand, is the peak national professional body for pharmacists and we represent around 75 per cent of pharmacists across Australia. Our core functions are similar to Dr Pinskier's description of RACGP. We aim at practice improvement through continuing professional development and practice support.

The underlying principle that informs the practice of pharmacy in the treatment of impotence, as across all other areas, is the quality use of medicines, which has three components: select medicines wisely by considering the place of medicines in treating illness and maintaining health, and recognising that non-drug therapies may be the best option for the management of many disorders; choose suitable medicines, if a medicine is actually considered necessary, so that the best available option is selected by taking into account the individual, the clinical condition, risks and benefits, dosage and length of treatment, any co-existing conditions, other therapies, monitoring considerations and the cost to the individual, the community and the health system as a whole; and use medicines safely and effectively to achieve the best possible results by monitoring outcomes, minimising misuse—overuse and under use—and improving people's ability to solve problems related to medication, such as adverse effects or managing multiple medicines. In the context of this policy, the role of pharmacist relates not only to medicines use and management, but also in providing advice on non-drug management where appropriate, providing support and information and working across the whole spectrum of health from the maintenance of good health to the management of ill-health.

I have a couple of examples of how we attempt to support pharmacists specifically in the area of erectile dysfunction. Last year our professional journal, *Australian Pharmacist*, had an issue

devoted to men's health. The issue consisted of a range of articles dealing both with general men's health issues as well specific topics, including erectile dysfunction. There was a clinical update on erectile dysfunction, which canvassed different aspects of the condition, including medications used in treatment. The clinical updates form part of our continuing professional development programs. In a recent clinical weekend that focused on a range of aspects of men's and women's health we also conducted professional development courses on erectile dysfunction.

Our pharmacy self-care program has also focused on erectile dysfunction. A consumer fact card has been produced on the condition as well as guidance for pharmacists and pharmacy assistants and is provided in our information magazine. Those information resources were distributed last year to the 1,800 pharmacies that subscribe to the program. Also, there is the Men's Health Information Services Tasmania Alliance, or MISTA, which aims to raise awareness on issues impacting on men of all ages and to advocate on their behalf in order to improve their health and wellbeing in a holistic way. PSA's Tasmania branch is a founding partner of MISTA.

In these endeavours, the Pharmaceutical Society tries to provide a structured approach to equip pharmacists to deal with issues around erectile dysfunction by describing the condition; canvassing treatment options, including medication and appropriate referral; identifying side-effects and how to manage and resolve them; providing resources for further information; and testing the knowledge gained.

ACTING CHAIR—Thank you.

Ms RISHWORTH—We heard earlier from the TGA about the compounding of medicines, and the focus seemed to be that if a client goes to a pharmacist for something that might have been prescribed by a doctor, a pharmacist could combine a number of medicines to provide a solution. How often do your members do that? What are the typical areas in which they might use that exemption from the TGA to provide a service to their patients?

Mr Mackey—I do not have any hard data to give you, unfortunately, in this area. It is not something that we have collected any information on. Anecdotal feedback—and this is across all conditions, not just impotence—is that there might be perhaps around one per cent of patients who require a compounded product from time to time. I would have to say also that the overwhelming instances would be on prescription from a general practitioner or a specialist. As I said at the outset and read the definition out of our professional practice standards, it is very much focused on the needs of an individual patient where there is not a commercially available product that is suitable for their needs. So it would be the exception rather than the rule. And it would not be first-line therapy; it would be second-line. If there is nothing available in the commercial sphere for the needs of that particular patient, the doctor may consider prescribing a compounded product, which the pharmacist would make up according to those instructions.

Ms RISHWORTH—Thank you.

ACTING CHAIR—Does the Pharmacy Association have any guidelines that would be applicable to someone who walked into a pharmacy and said: 'I've got ED. Can you help me

with it?' Would they follow a guideline that recommended they see a GP or would they try and help that person?

Mr Mackey—We would recommend that the pharmacist have an initial discussion with the patient. As I said before, we have a consumer fact card on erectile dysfunction, so they could talk to them around the general issues. I would have thought the best practice in this area would be referral to a GP and that would be the most immediate action that the pharmacist would undertake.

ACTING CHAIR—Thank you. Mr Doyle?

Mr Doyle—We would like to thank the committee for asking us to speak today. We very much appreciate it. We want to try and separate fact from fiction. A lot of claims are made about the AMI and many of those are based on anecdotal experience rather than scientific analysis, and many of those claims are in fact incorrect. AMI have treated more than 500,000 patients with sexual dysfunction issues over the last 16 years in Australia, New Zealand, Asia and Europe. It has two core components to its male sexual dysfunction business: premature ejaculation and erectile dysfunction. Premature ejaculation represents 50 per cent of its business. There are no medicines on the TGA's register listed as specific for premature ejaculation. There are registered medications used for that purpose but they are not registered for that purpose.

In terms of AMI's treatment of patients using technology based consultations, around 50 per cent of those patients are treated in that way. There are a number of reasons why people are treated in that way. Firstly, 75 to 88 per cent of patients who have erectile dysfunction do not seek treatment, and that is based on independent studies. Secondly, even when people go to see their doctors about other issues, only about one third of them broach erectile dysfunction issues with their GP, and that is based on the MATeS study. Many people sit for two to three years with a severe problem before they will speak to their GP, and that is based on the Impotence Association study in Britain.

There are a number of serious reasons why people do not want to speak to their GP about this issue. Firstly, in 2006, the *Australian Doctor* reported, based on a study, that many doctors were very uncomfortable taking a sexual history. Secondly, research shows that men are very embarrassed about their condition, they are very reluctant to talk to a doctor, particularly one who is uncomfortable with taking a sexual history. Independent studies, again reported by *Australian Doctor*, show that men do not believe that their family GPs understand what the impact is of ED on their lives. Those are the many reasons why they use the telephone consultation. A telephone consultation is very advantageous for a range of reasons, as long as it is performed professionally and appropriately. Firstly, it gives the patient anonymity and that is very important for many patients with this condition. Secondly, they can do the consultation when and where they want and they do not need to go to a pharmacy to pick up their medications afterwards. They are often very embarrassed to do that. I do want to speak about a number of the other issues which have been covered but, unfortunately, I have run out of time.

ACTING CHAIR—Thank you for your contribution.

Ms RISHWORTH—In terms of the phone consultation, just so that I get that process in my mind, who is on the end of the phone when someone rings?

Mr Doyle—Every patient must speak to a fully registered and qualified doctor before being given a treatment. Every medication which is used for premature ejaculation or erectile dysfunction is an S4 medication, which means it is prescription only. No-one can obtain a treatment without speaking to a properly qualified doctor.

Ms RISHWORTH—So they might ring up, someone answers the phone and then they get transferred to a doctor?

Mr Doyle—Firstly, they will ring and speak to a telephone operator who will arrange a consultation. There are only so many doctors who can engage at one time. Then, when the doctor becomes available, they will speak to the doctor who diagnoses the condition, discusses treatment options with them and then prescribes an appropriate treatment option.

ACTING CHAIR—How do they get their medication?

Mr Doyle—A prescription is written. AMI has a contracted compounding pharmacy. It is the largest compounding pharmacy in Australia. That pharmacy then prepares the medication, based upon the individual prescription. It is illegal to make up medication before an individual prescription is received. That medication is then sent to a location selected by the patient. Many patients do not want the medication sent to their home, so they may choose a PO Box or they may come into a clinic and collect the medication, because it is a very private condition that we are speaking about.

Ms RISHWORTH—Coming back to the question I asked in the last session, obviously one of the requirements to compound medications, as we found out this morning, is to prepare it for that individual, after you have spoken with the individual concerned. I guess the level of ingredients—you have four particular ingredients that you use, which are on the website—might vary. Why would it not be then advantageous to give that information to their treating GP for other issues?

Mr Doyle—We are very happy to provide it to a treating GP. If someone wants to contact the CEO of the organisation rather than trying to call a call centre operator who is obviously not qualified to deal with third parties, who might be competitors and so on, it is just a matter of someone making appropriate contact and, unfortunately, people do not do that.

Ms RISHWORTH—This matter was raised previously by, I think, Dr Pinskier. How would you see your prescriptions being involved in an e-record system? This is one of the health reform issues, it is a patient-driven system in which everyone sort of links in, and obviously it will be linked to a number with different prescribing doctors and pharmacists—and all the rest is a potential option. Would your organisation be willing to participate in putting what you are prescribing on that e-record so that other medical professionals can make use of it?

Mr Doyle—We would have absolutely no issue with that. AMI actually has a fully computerised database, which is web based. For every single person who interacts with our clinics every interaction is recorded on our patient database. For us to interact already computerised records into another computerised system is not difficult at all.

Ms RISHWORTH—What would your reaction be in relation to the TGA discussion paper—I am not sure if you responded to the discussion paper—about the three-tiered system of looking at compounded medications. So having low-risk and low-volume with no changes, but looking at perhaps where the high-volume medication would actually coming under the TGA as a high medication. How would you respond to that.

Mr Doyle—The first thing I would say is that the level of volume is actually unrelated to risk. In fact, the higher the volume that you have the less likely that there is to be a risk because it is something you are preparing all the time. The real question here is whether the medications you using are high-risk medications or low-risk medications. High-risk medications should be subject to a higher degree of regulation than low-risk medications. Volume I think should actually be irrelevant. You are more likely to have an error with someone who does not know what they are doing than with someone who does.

Ms RISHWORTH—With their proposal of looking at volume/risk, you would reject the volume but look at the risk?

Mr Doyle—We would 100 per cent accept the risk but we 100 per cent disagree with the statement on volume.

ACTING CHAIR—Would you have on record any percentage or situations of cases where your potential client has interviewed with your in-house GP and the GP has said, 'From the information you have given me you really need to go face-to-face with a GP. You have underlying health problems that our medicine cannot deal with. You have to go to a GP.' Would you have instances like that happening?

Mr Doyle—I am very pleased that you raised that issue. Erectile dysfunction is a precursor of heart disease. It is a standard recommendation of our doctors that all patients who front with erectile dysfunction should go and have a physical examination with their GP and deal with that health issue with an appropriate professional.

Proceedings suspended from 11.12 am to 11.22 am

ACTING CHAIR—Now that everyone has had a break, we will reopen for a general question and discussion forum. I would like to refocus that this session is about the market for impotence medications and the proportion of men seeking treatments, and we will also focus on the health outcomes of different modes of treatment for Australian men. The regulation session will be after lunch, so if we can keep our focus on those particular areas that would be great. I have a question for Professor Marshall in regard to the program he is running in South Australia and generally about health outcomes for men. Have you seen any improvement in men seeking assistance in your group of 1,000 men over the course of the program?

Prof. Marshall—We have not seen very much change. I think what Professor Handelsman said is that it is something of a myth that men do not go to see their general practitioners. The evidence that we have been gathering though is that they have not really found in the experience of the men we have talked to that it has been to their satisfaction. They do not really feel that they have had the opportunity to discuss lots of matters with their general practitioner. We are trying to work out what those factors are. One curiously enough is just the waiting because they get very angry if they have to wait for long periods of time. They are quite happy to deal with just what needs to be dealt with and then get out of the waiting room. I use that as a rather trite thing but, nevertheless, there are lots of very important things that I do not think we really understanding such as how we achieve a satisfactory interaction between our client and the sort of health profession. Also in a way it is not something that medical schools spend a lot of time on in terms of actually producing what used to be called 'bedside manner' or very good customer interaction. I think all of these things need to be looked into because the medical profession at large has to take some responsibility for the situation that we are discussing this morning. Quite clearly there is a segment—and we do not even know how big the segment is—of the male population who do not feel comfortable with addressing their problems with the traditional practice of medicine.

We have not put enough research into understanding why men feel uncomfortable, why they want to go anonymously. Surely we must be able to answer some of those questions. What we are discussing today is part of what I think is potentially a much bigger issue of how you get both men and women to effectively engage with the health service. It is obvious that we are concerned about the issue of erectile dysfunction, but equally we know that there is a huge market in other non-proprietary medication because I think there has been an increasing concern that our service does not meet the needs of the community. I think this is just one good example of where are practise in medicine is not always meeting the needs of the community.

ACTING CHAIR—Does anyone else have any thoughts on that?

Prof. Handelsman—If I can add to that, it is an important admission of ignorance that we do not know even the answer to simple questions such as how common erectile dysfunction is in the Australian community. We have fragmentary data from parts of Australia but we do not have national data. As part of the men's health policy formulation, Andrology Australia spent several years trying to put together a large men's health Australia longitudinal study which is meant to sample across the whole country to get an idea of the evolution of erectile dysfunction and other conditions that affect men's health generally, and their reproductive health. To design interventions to minimise the embarrassment, to minimise the barriers to men taking medical

care—which is there but they just do not discuss it with their GPs; the fault may well be on both sides—to understand the evolution of it, we simply need more factual information to develop interventional studies to do what you are suggesting, which would be to improve management in a medical sector. The groundwork is there. Men do visit doctors, but we need to make them and their doctors more comfortable—we do not know how to do that—and we need to know how to target it to be most effective.

Mr Doyle—We think what Professor Marshall said is 100 per cent correct. Generally traditional medicine is not giving men what they want. Men are extremely embarrassed about these conditions. In fact, half of our business is done through our clinics. We have an individual waiting room for every single patient so that they are not required to sit in a public area and see who else has a problem. That is a very important issue to these men. They do not want to run into friends, acquaintances or anyone else. They do not want people to know that they have this problem. Most medical practices are not set up to cater for that issue.

ACTING CHAIR—I guess if they are visiting your rooms, they are there for that reason, are they not?

Mr Doyle—They are definitely there for that reason. Even when a person goes to a general practice, if they see a young attractive woman or someone else, it reinforces the issue that they themselves have and makes them feel inadequate.

Dr Pinskier—We are dealing with a number of overlapping and complex issues. I think we should address each separately. Men do attend general practitioners—we know that, but there is a gender imbalance. The rate at which men attend doctors versus females and children is substantially different. There is a societal expectation and a linkage that illness equals weakness. Men see themselves as stoic and do not get stick. The only time they start attending as when they do get stick. So preventative health in men is a major issue. Women are more sociologically and culturally attuned to attending doctors because they attend for their own reasons throughout child-bearing years and then they bring in their children subsequently. There is an expectation that they will attend and they continue to intend on an ongoing basis.

Clinics tend to be more women friendly. Women's magazines sit in the middle of the waiting room but you do not see the men's health magazines or car magazines sitting there. The GPs who do it better tend to have a focus on men's health. That is something we need address. I agree that there is an issue as to how we manage our practices.

Patients having to wait is an issue of workforce planning. Successive governments, both Labor and Liberal, over 15 years have underplanned the GP workforce. We are now at a point where there are only 97 GPs per 100,000 in the community—that is this year's data. When there is a shortage of GPs you end up with time pressures. The primary care system is going through an evolutionary process. We are moving increasingly towards primary care delivery through collaborative team-based arrangements. We are increasingly seeing the advent of practice nurses and other health educators. It is not just about training GPs; it is about how we train the whole primary health care sector, how we provide holistic coordinated comprehensive care within the sector, how we underpin and support it and also how we change the expectation so that men see GPs more often.

A new item number was introduced two years ago, the 45- to 49-year-old men's check. I am not sure what the uptake has been. I do not think it has been widely accepted, but we need to go beyond 45. We need to look at from 20 to 45. If we are not picking them up at 20 to 45 for regular health checks, by the time men get to 45, they have probably missed the boat.

Mr McCann—I have worked in various other services. One of the services I have worked in is an STD clinic. Men do present to an STD clinic. I have heard people say that one of the reasons why men do not present with erectile dysfunction is embarrassment. It is pretty embarrassing if you think you have an STD, yet we know that more men present to an STD clinic. Part of the reason is that they know that service is specifically for that problem. That is part of the health department and meets a whole lot of guidelines. The other part is that men have been seeing erectile dysfunction as a medical condition for only a short time. We need to get more information out to the general public that it is a medical condition and they may make choices of going to AMI or to their GP.

We talk to about 150 men a week and it is not uncommon, when a GP is suggested, for them to question, 'Can a GP deal with this? Why would I go to a GP?' There is also a lack of knowledge that a GP can deal with it. it is not as simple as embarrassment. There are a lot of other elements.

ACTING CHAIR—What would you suggest for how to get over that?

Mr McCann—We are certainly moving along. Men are starting to get some information around sex and sexual difficulties, that it is a health condition. The media is starting to convey that message, but usually with sex the media conveys having to do it better rather solving a problem. That is now getting a better balance on it but the health department has to take a role in putting sexual health or difficulties as a serious medical condition, to start playing more of a role around it.

Ms RISHWORTH—Are there strong clinical guidelines for what to do about erectile dysfunction? Is it separate from premature ejaculation? It does. So do you think the majority of GPs are following those guidelines?

Mr Doyle—In terms of premature ejaculation, the American Urological Association has published guidelines on the management and treatment of premature ejaculation. Those guidelines make it absolutely clear that the diagnosis is based purely on sexual history, that there is not requirement at all for a physical examination. I am happy to provide a copy of those guidelines to the committee. Secondly, concerning erectile dysfunction, while there is a large body of material saying that the physical examination is necessary, there are some contrary opinions and there are a number of reasons for it. We also conducted a survey of 30 doctors in New South Wales earlier this month in terms of how they diagnosed and treated both premature ejaculation and erectile dysfunction. The 30 doctors, with the exception of Dr McMahon, were selected at random. The doctors were unaware that it was someone from our organisation who was contacting them. In 28 of those 30 consultations, no physical examination occurred and, in fact, no physical examination was given by Dr McMahon himself.

Ms RISHWORTH—I guess you do not need to talk about physical examinations when you are looking for other problems, as we have heard during this committee inquiry. It is a beacon to suggest that there are other underlying health issues. If you look at the clinical guidelines, you

might not need a physical examination but you might want to check about a whole lot of other things. Do your doctors do that and where do they refer people to?

Mr Doyle—Our doctors have a standard questionnaire. It asks a very broad range of health related questions about smoking, diabetes, heart disease, MS, blood pressure and a whole range of very detailed issues like what medications you are on, what has happened in terms of your sexual history and your sexual interaction with your partner—very detailed questions, detailed advice. All those questions must be addressed by each of our doctors, so it is a very thorough discussion with the patient. It is not a two-, three- or four-minute consultation; it is a lengthy consultation. There is an ongoing discussion with patients about their general health issues. We do not claim that our doctors are specialists—that is, specially qualified—but we do only deal with sexual dysfunction. Where an issue is identified, we advise patients that we think that they may have a concern or an issue and that they should go and see their family GP who ordinarily treats them for those issues.

Coming back to the survey that we performed, we found that almost none of the doctors asked questions about these other issues and none of them asked people to go and have a check-up for heart disease and so on. So that diagnosis is in fact not occurring from general GPs and there is a lot of misinformation out there.

Ms RISHWORTH—Absolutely. I am not suggesting otherwise. Whether it is your organisation or whether it is GPs, I say that is the problem. The government—and I think it is pretty bipartisan—want to move towards preventative medicine. That is the way of the future. I would say that that is probably a problem whether it is AMI or whether it is doctors. I think that was recognised. Chris mentioned that there does need to be a cultural change there. I do not think—putting my own two bits in—that that can be an excuse not to do it.

In a more general way—and this is, I suppose, to everyone—how can we move into that preventative health sphere of not only looking at coexisting problems or chemical interactions? Considering the evidence that erectile dysfunction is an early indicator—not just a comorbidity factor but an early indicator—how do we move into that sphere of identifying and treating it?

ACTING CHAIR—Dr Mackey was next on the list. Do you have a contribution to make?

Mr Mackey—I had a comment that was slightly different, so I am happy if this continues.

Ms RISHWORTH—No, go for it.

Mr Mackey—I just wanted to pick up on a statement that Mr Doyle made in relation to the AMI's model whereby the patient does not have to go to a pharmacist to pick up the prescription. With commercially available products, there is a consumer medicine information leaflet available that gives the patient some sort of understanding, and the pharmacist has the opportunity to go through a counselling process with the patient. With a compounded product, there is obviously no consumer medicine information, so the patient-pharmacist interaction is even more important.

Prof. Lording—Just on that theme of community education, Andrology Australia has a responsibility under its agreement with the Australian government to look at education of

community and healthcare professionals across a range of male reproductive problems, including sexual dysfunction. With its limited resources, it has been doing this avidly through information that can be sent out to patients, websites, support for men's groups that are having meetings with professional information and education on health care. There is a high pick-up of these materials. I think there is something in evolution. I think Brett McCann make made a good point before, saying that it is only relatively recently that it has been in the cerebral domain of everybody that ED is a serious medical problem. It is not therefore surprising that there is a lag time before proper clinical practice permeates through all general practitioners.

We know that in general practice there is a wide variety of standards. Some will never pick up on the right way to do all things. But my impression from talking to lots of GP groups and running lots of workshops is that there is a high interest in this topic and that people are engaging in the notion of the comorbidities. There is the idea that case detection of men with ED within their practices, even if they are not seeking restoration of a sexual activity, particularly in that middle age group of men, it is important as a healthcare issue. I do believe we are seeing a gradual evolution. Obviously, anything that can be done to continue to elaborate and support that community health message is important.

Prof. Marshall—I was just going to follow up on that question about guidelines. One of the issues is that often the guidelines are developed but our system does not really have any resources to then implement the guidelines and, even more importantly, to be able to measure any change. One of the difficulties that we have in our system is that we really have very few means of measuring community outcomes. If you look at the clinic, we could say that this is not the way to practice medicine from past history, but we do not have any measures of the community outcome or the outcome of the AMI. One of the real weaknesses of medicine in this country that we have rarely put resources into measuring outcomes to see, if we have implemented guidelines, whether there has been an improvement and, if we are not following it correctly, whether there have been undesirable outcomes.

Ms RISHWORTH—Is that a bigger problem for those medicines that are approved by the TGA or compounded medicines? My understanding is that a lot of the community outcomes for trialled medications would have a community impact.

Prof. Marshall—They would do, but one of the things we have to understand is that even in randomised controlled trials conducted perfectly appropriately there are always inclusion and exclusion criteria. Once that drug is actually able to be marketed, then quite often the patients that get prescribed that drug may not have been the groups of people that would have been incorporated in those trials, because of the exclusions. That is one of the difficulties, if you do not have some ability to look at the outcome of those drugs in the general community. We also know that drugs are used in what we call off-licence. They are, again, perfectly accepted but we do not have any community outcome measures.

Prof. McMahon—Somewhere in the last 10 minutes we seem to be flipping back and forth between ED and premature ejaculation. They are very, very different disorders. PE is a very mixed population of men, some of whom will require a physical examination as a part of their valuation—for example, a man who has ED and premature ejaculation. But for other men, particularly young men who present in their early 20s with premature ejaculation, it may not be appropriate to do a physical examination.

I find it interesting that I am sent a survey without disclosing the source of that survey—somewhat slippery, but certainly interesting. I accept that AMI have seen a large number of patients with both ED and PE. I think you quoted 500,000. I would see that perhaps as one of the reasons why we are here today. I also find it interesting that you are quoting that 50 per cent of your patients are managed with telemedicine. Is that 50 per cent of that entire 500,000 or is it 50 per cent of your current patient load?

Mr Doyle—Current patients. The company—and its predecessors—has been operating for 16 years. Telemedicine is probably, I would say, since about 2003?

Dr Vaisman—Yes.

Mr Doyle—It is over probably a six-year period. It started with more video conferencing. Some of our telemedicine is not actually telephone consultation; some of our telemedicine is in fact video consultation.

Prof. McMahon—Sure. I understand what telemedicine is. So 50 per cent of your current patients do have a direct face-to-face consultation with a doctor?

ACTING CHAIR—I would ask you to direct your questions through the chair, if possible. Mr Doyle, you had a common to make before. If you would like to answer that and then—

Mr Doyle—Sure. We have been through different models at different times, depending upon where patients are located and what makes sense. We obviously have a situation here where Australia is a very large country and it has a lot of people in remote areas. So depending upon whether those people are located in, for example, Sydney or Melbourne, we have a quite different approach to where they are located in places where it is often not possible to have clinics, or, if you have clinics, that they are manned infrequently. It varies quite a lot.

Prof. Handelsman—I want to respond to the committee member who asked a very pertinent question, which is: how do we get to where we want to be. The first step is to recognise what is a minimum standard and what we should aim at. I would endorse the comments that Dr Malouf, Dr McMahon and others have made that this is simply substandard to accept that we can get evaluations of erectile dysfunction over the telephone. You cannot measure blood pressure over the telephone. If we think of the area of hypertension, which is a significant risk factor for disease, it would be quite possible to prescribe that over the telephone, except we have never descended to that level and I do not think we ever should. Not in this kind of country, not in the 21st century. The idea that we need face-to-face contact with a physical examination should be at least the standard we set, which may be difficult under some rare circumstances—very far away communities and so on. But in the urban centres where the vast bulk of this would be going on, it is just not an acceptable standard. So the first thing is we have to set a reasonable standard we should aim at.

The second point is there are other things which are potentially embarrassing and difficult which GPs manage—for example, oral contraception for teenagers. These are not easy problems. They can involve confidentiality and embarrassment. GPs have learnt over time how to handle those things. They are integrated into our medical care systems. As Brett McCann has pointed out, the embarrassment of sexually transmitted illnesses is no worse and no different, but it can

be integrated if the will is there and if we set the standard that this is the minimum that Australia should expect in its care.

Ms RISHWORTH—I have a further question specifically on that: you recognise that some other medications can be prescribed over the phone, although they are not regularly done so—is that correct?

Prof. Handelsman—I am not aware of any area of medicine where that is considered a regular standard. It is an exception for people who are very remote and it is possible through, say, the Flying Doctor Service. This is a statement of ignorance: I am not aware of any other areas where that is done routinely.

Ms RISHWORTH—Are those standards part of the TGA process where the guidelines are set out for how you can prescribe, where you can prescribe? Or are they standards that the medical profession adheres to?

Prof. Handelsman—I think they are medical practice standards. I cannot speak for the TGA, but I understand that they are medical care standards. I do not know of any area of medicine that accepts the idea of a close to a first-line method of management, which is to do things over the telephone.

Dr Malouf—It is timely to talk about standards of care. You can talk about medical registration. Medical registration reflects what is a minimum standard of care. It should potentially reflect an acceptable standard of care, but most of the guidelines talk about a minimum standard of care. That can be defined by peer practice or by legislation. But prescribing of medications for erectile dysfunction over the phone falls way below that minimum standard of care. Fundamentally, the protocols that are spoken about in the guidelines for premature ejaculation, for example, the AUA guidelines that Mr Doyle refers to—the American Urological Association guidelines—talk about counselling as being the fundamental basis of managing premature ejaculation. There are some pharmaceutical options, but a 17-year-old does not need an injectable agent to manage premature ejaculation. He needs to be told that he falls within the normal range, he needs to be reassured. If it is a problem, there are sexual therapies that are available from organisations which are very well-publicised. But injectable agents fall outside what anybody would define is a minimum standard of care for managing premature ejaculation.

If we are talking about erectile dysfunction, again: counselling, taking history, physical examination. But in terms of standard of care, we have very safe, very effective oral agents which are first-line therapies. They should be employed as a minimum standard as a first-line therapy. We should not be accepting as a standard of care the prescription over the telephone, without an examination, of agents which are less effective, more costly and more dangerous. That is fundamental to the delivery of good standards of care.

Ms RISHWORTH—About these standards of care, are you suggesting—I have not got my head completely around it—that these should be the minimum standards that are adopted, or are you suggesting that these are current minimum standards that are already there?

Dr Malouf—These are current standards of care which are already there. In the New South Wales medical legislation, there is a mandatory reporting obligation for a doctor who is operating outside the minimum standard of care. As a leader of my organisation, as a leader of the urological society, I would say that the prescribing of injectable agents as a first-line therapy for erectile dysfunction lies outside that standard of care. The problem is they are unidentified doctors.

Ms RISHWORTH—So that is the reason you are saying that those standards of care cannot be prosecuted?

Dr Malouf—There are international and local guidelines, and at common community practice—at a general practice level, at a specialist level, at a sexual health level—there would not be one professional in this organisation that would recommend an injectable agent, or even a nasal delivery agent, as first-line therapy over an oral agent such as a PDE5 inhibitor. It is just inappropriate clinical practice; it is negligent clinical practice.

ACTING CHAIR—Before we move on to Professor Lording, just remember that we are going into regulation in the next session. If we can stick to the session subject, that would be good.

Prof. Lording—We briefly touched on data and the lack of data. I want to come back to something that Richard Doyle mentioned before—that is, we are making a number of anecdotal comments about AMI. While I have some sympathy with the notion that that can be misleading, it is all we have to go on. This organisation, which has the largest database of ED sufferers and ED treatments in the country, does not publish any information about its treatments, its success rates, its continuation rates in therapy, its adverse event rates. I do not expect it necessarily to publish the complaint rates, but there is nothing else other than anecdotal material for us to go on. A number of people around the table would be familiar with qualitative research, and when themes keep re-presenting themselves enough times, this becomes valid qualitative research. My experience, and it seems to be mirrored by others around the table, is the constant theme that comes through from users of AMI products that we have alluded to. I do not think that anecdotal data is invalid for us to discuss; it is in fact the only material we have, and the volume of data that comes through to us in this way validates it in itself.

ACTING CHAIR—Mr Mackey, we only have about seven minutes left until lunchtime, so could you keep your comments brief because there are some people who have not had a chance to ask questions yet.

Mr Mackey—Sure. It is a very quick one, just returning to a comment that Ms Rishworth asked earlier about compounded products. I think it is important to make the distinction on a compounded product that is for an individual patient. A doctor prescribes, realises there is nothing available commercially, so the pharmacist makes up the particular product according to the doctor's instructions—a patient, doctor, pharmacist triad, if you like. The opportunity is actually there to monitor, to assess health outcomes—not saying it always happens, but the opportunity is there on that individual basis. When you move to the manufacturing of compounded products, it is a different situation completely.

Dr Pinskier—I want to continue along the lines of these similar themes. We have certainly moved into an area of what we call evidence based medicine, which has been widely accepted by the profession. This is where we should be focusing: where is the evidence and where are the subsequent guidelines that are derived from this evidence? Is there any evidence? If there is a lack of evidence, has there been a literature review? What does Cochrane say about this? Unless we can actually obtain some clear, unequivocal evidence, we have no way of knowing whether this treatment is effective, safe, poses a risk to the public or otherwise.

What is the monitoring process? In my general practice, if I have a steriliser and I throw an instrument into that steriliser and I package it up and I use it on a patient for a procedure, I am required, under the accreditation framework and under accepted infectious disease control guidelines, to track and trace that device so that if something goes wrong and a patient contracts an infectious disease one, two, three, five years down the track, I can identify that point of failure. I am not clear what is happening in this particular organisation, whether there is a tracking and monitoring process for these compounded products.

We seem to be suggesting that this is a brave new world and, because it is a brave new world, we require a specialist approach outside of conventional medicine and GPs are not equipped to deal in this brave new world. That may or may not be the case, but there is a well-established process for postgraduate GP education. If there is an issue around the education and capacity of general practitioners to deal with that, then as a collective we need to sort that out. We have well-developed educational training processes and a well-distributed network through the divisions of general practice, which is funded by and large by the Commonwealth. So we have ways of getting to mass numbers of GPs quickly and of providing them with evidence based guidance on how they should manage men's health and also how they should manage these particular issues. I might remind that you 20 years ago, when ACE inhibitors were first introduced for the treatment of hypertension, general practitioners were not allowed to prescribe them. The inhibitors were prescribed at a rate of 6.25 milligrams. Not only did a patient have to lie down; they had to be in a hospital. The world has moved on. There are lots of things that GPs did not do 10 or 20 years ago that have become a routine part of general practice.

The other issue that I want to pick up on concerns a comment made by Mr Doyle that all our doctors are registered and qualified. Frankly, I have no idea what 'qualified' means. To be a qualified general practitioner in Australia means that you are on the vocational register as defined by Medicare Australia, and to be on the vocational register means that you have to undergo continuing quality assurance and continuing professional development to obtain a certain number of points over a certain range of activities as defined by the RACGP over a three-year period. If you do not meet that requirement, you do not stay on the vocational register and you are no longer known as a general practitioner. So I would be curious to know what the background is of those doctors who are working in these clinics, what the training process is, how that process is quality assured, how the public can evaluate that and how the profession can evaluate that.

Mr Doyle—As I said, unfortunately a lot of allegations and innuendo are coming out through this discussion. The first point that I want to talk a little bit about is effectiveness of treatments. The reality is that oral agents are effective in only 50 to 65 per cent of patients. There is a wealth of clinical data that supports that. We always ask people who come to AMI: 'Have you tried

this? Have you tried that?' Many of them say. 'We've tried it and it is completely ineffective.' That is why they have come to us in the first place.

The second point I want to make is that published clinical studies show that injectable agents are much more effective in treating erectile dysfunction than oral agents. It is just that quite a few people have needle phobias and do not wish to have that type of treatment, but there is also a significant proportion of people who do. Everyone is talking about quality of care. The reality is that we treated more than 4,500 patients last year with injectable agents. That is not unusual. The number of priapisms we had was less than 0.3 per cent of total patients—not per use but total patients. More than half of those patients continued to use the treatment. They simply went and had blood drained and then continued with the treatment without any issues. The number of patients who have had issues is at a minimum.

The other treatments we use range from nasal sprays through to suppositories and lozenges and so on. Firstly, we use a sub-therapeutic dose. That is much lower than the dose of active ingredients for which those medications are listed on the register. This means that the likelihood of an adverse side effect from the medications is substantially reduced. The types of side effects that we are talking about are headaches, crustiness of the nose, flushing and other minor issues. If we had loads and loads of patients with significant adverse health outcomes, someone would have done something about it quite some time ago.

There are people who make complaints, and the vast majority of those complaints relate to financial issues, not to medical issues. You only need to open up yesterday's *Sydney Morning Herald*, which I did, to see this. It is complaining about an ophthalmologist charging $800 for a 20-minute procedure. We do not charge $800 for a 20-minute discussion. In fact, we do not charge anything unless someone takes a treatment with us, and that treatment does not just involve giving someone medication; it also involves access to a 24/7 help line. We follow up our patients and we deal with them professionally. There is a lot of innuendo here, but frankly it is not accurate.

Ms RISHWORTH—In terms of the injectable treatment, how do you assess things like needle phobia? A number of my constituents have talked to me about their experience and have indicated that the injectable treatment is a second-line treatment if the nasal delivery does not work. How do you diagnose needle phobia, which is a very serious issue? A few people have complained about having to go through contractual issues, and we will get onto that later. What is your response to and treatment for needle phobia?

Mr Doyle—There are a few things that I want to talk about regarding that. When we talk about needles and so on, what you need to understand is that AMI supplies all patients who are on an injectable treatment with an auto-injector. It is shaped like a pen and the needle sits inside it. It is not as if someone has to grab a whopping great needle. It is a little bit different to what you might anticipate it to be. That does not change the fact that there are some people who have needle phobia.

First of all, first line of treatment is based on an assessment by the doctor of the individual patient. Many patients have already tried a range of other medications or have issues, and so a nasal spray or other treatment is contraindicated for them. In fact, about one-third of people who contact us are contraindicated for all medications and told: 'Unfortunately, we can't help you.' A

significant proportion are turned away. We do not give medication to just anybody. It is a professional process that is gone through.

Where individual patients have needle phobia or other issues, that is really a matter for discussion with the patients. Patients are advised, as a rule that is strictly enforced, that they may be required to undertake a number of different forms of treatment if they enter into a contract and that they are not obliged to. One of those treatments specifically includes an injectable treatment. That is a fundamental requirement which is strictly monitored by the company. Everybody knows, before they enter into an arrangement, that that is going to be a requirement. They are not required to sign up; it is a free country. If someone then gets to a later stage where a treatment has been ineffective, we have a discussion with the patient and we try to work through issues with them. We routinely, every day, refund money to people in circumstances where we can contractually require them to go through a treatment, but we often just say, 'Look, that's fine.' Depending upon the interaction, we take up different issues with those patients. That is how it is dealt with.

ACTING CHAIR—We have just gone over time. Mr Fitzsimons, you have a comment. You are next on the list. We will extend for a short time to let the people who have not had a chance to say something talk and then we will break for lunch. In the next session we will go into the regulation.

Mr Fitzsimons—From the proprietary medicines perspective, these companies have gone through clinical trials and a lot of rigour to get a drug to market. Yes, I understand that there are probably people who are not suitable for it, but we get concerned when proper drugs that are registered for a particular indication and are designated to be used as first line are not used first line. That is certainly a concern. Each company wants their medicine to be used appropriately and, as well, wants the appropriate diagnosis undertaken prior to the use of that medicine.

ACTING CHAIR—Ms Vartto, do you have any comments you would like to make before we break for lunch?

Ms Vartto—I think the rest of the panel have covered the questions I have.

Dr Weerakoon—Most times when people call a doctor the doctor answers with their name. I am wondering whether, when the people who call on the telephone line and are assessed by a doctor, the doctor gives their name.

Mr Doyle—Absolutely.

Dr Weerakoon—I have another quick question. Obviously, AMI are really concerned about education of the population and of GPs. Have you funded any education programs?

Mr Doyle—We are a commercial business; we are not a university. We train the staff who work with us and try to make sure that they have a very detailed knowledge of the issues with which they deal.

Dr Weerakoon—Are they trained by you?

Mr Doyle—Trained by doctors. I am not medically qualified so I would not be able to train.

Dr Weerakoon—Trained by your own group?

Mr Doyle—Within the group, yes.

Dr Malouf—I do not think we can close the session on medication without an explanation from—

ACTING CHAIR—We are just going to give Mrs Spierings an opportunity to speak.

Dr Malouf—Okay.

Mrs Spierings—I just want to make the comment that I agreed with Dr Malouf in that shyness should not be an excuse not to get appropriate treatments. Perhaps more should be done to address this issue of shyness, if that is the case, in terms of making people aware that they could go to their GP and that they are properly trained for that, instead of directing them to services that do not provide accurate assessment, evaluation or care. Additionally I was just wondering if I could ask a question in terms of: what if a patient presents to you clearly with performance anxiety, what are your next steps? Do you actually refer them to other healthcare workers?

Mr Doyle—As I said, we find that a large number of people who contact us are not suitable for treatment for medical reasons and we suggest that they go somewhere else. In relation to the other point that you made in terms of better health care, there have been a number of programs funded by the federal government to try and promote GPs and so on. But the reality is that if you are promoting something that someone does not want they are not going to go and do it. It does not matter how much you spend on it. If you are spending money and telling people that you must do this and you must do that and the person does not want to do it, they are not going to do it.

Mrs Spierings—I do not necessarily mean promoting the actual treatment but actually promoting that erectile dysfunction is something very common and that it is nothing to be ashamed of.

ACTING CHAIR—Dr Malouf, this will be the final question. We will then break for lunch. Anyone who has further comments to make on this particular subject can put a submission in writing to the committee.

Dr Malouf—Thank you, Mr Chairman. As I said I am not quite sure that we can wind up a session on medication without some sort of explanation as to why a commercial ED clinic that purports itself as a holistic treatment exercise can prescribe a range of therapies which exclude the most commonly prescribed, most effective and safe agent and that it is not part of their management regime. I just think that falls outside the standard of care. At no stage will an AMI doctor prescribe Viagra, Levitra or Cialis. Every international and local medical body would accept that that is a fundamental first-line therapy, and it just falls outside the standard of care of what is acceptable medical practice to deliver treatment for erectile dysfunction without having that treatment option available.

Mr Doyle—Actually that is not factually correct for a start. We often provide Levitra but we provide it in a different form. Often we Levitra and provide it in the form of a nasal spray. So it is one of our treatment options.

Dr Malouf—Could I respond to that? There is absolutely no evidence that the delivery of Levitra through any other form other than a tablet is in any way, shape or form effective, and that is simply another way of charging a very substantial amount of money for an ineffective agent.

Mr Doyle—That is absolutely false and we have just had published in *The Journal of Sexual Medicine*—

ACTING CHAIR—Can I just make sure that your comments are directed through me.

Mr Doyle—I am sorry, Mr Chair.

Dr Malouf—Properly conducted clinical trial.

Mr Doyle—It is a properly conducted, fully published and peer reviewed clinical trial and involves the delivery through an ultrasonic nebuliser, and that has just been published in *The Journal of Sexual Medicine*. I am very happy to send you the link.

ACTING CHAIR—I think that we will close the session now, and I thank you for your contributions. We just need to look at the focus of why this hearing is being held today and it is about moving forward and we can take that thought into the next session which will be on regulations. We can look a lot into the past, and I think that we have come a long way in the last 40 years with men evolving, especially in the parenting role, through education, and we can also look that in the overall look at men's health. I think this is what this forum is about.

Proceedings suspended from 12.09 pm to 12.47 pm

ACTING CHAIR—Welcome back to the second session of this forum. The focus of the discussion for this session is the effectiveness of current regulations governing the provision and sale of impotence medications. We will again ask organisations to make a three-minute statement on what they perceive the current problems are, and then we can look at making suggestions that we can put forward from this committee to the Minister for Health and Ageing and the appropriate bodies to change or fix regulations that you feel need adjustment. The focus should be on giving us initial thoughts and then moving on to suggestions, and then we will have another roundtable discussion. I invite Professor Marshall to give his opening statement on this topic.

Prof. Marshall—Thank you. I think the most important thing, which follows on from the earlier discussion, is the issue of what is the most appropriate way to do the assessment, particularly of injectable agents, in the management of erectile difficulties. It is very difficult to precisely legislate, but we need to adapt or develop evidence based guidelines for the management of men with erectile dysfunction. Some of those already exist. However, what has not been incorporated in those guidelines is the appropriateness of teleconference or electronic communication in the assessment of that individual in terms of the appropriate management, follow-up and assessment of that individual and the importance of collecting outcome data as to the response to the various treatments.

Ms RISHWORTH—You might or might not be the most appropriate person to answer this. Are there general guidelines for telemedicine or teleprescribing that currently exist?

Prof. Marshall—I am personally not aware but it is obviously, as you say, not an area of my expertise. I can say, though, having served on the medical board in South Australia, that it was incredibly difficult to establish guidelines for telemedicine, particularly when it crossed different jurisdictions as far as medical registration and also then medical accountability for the advice that was given.

Ms RISHWORTH—If I understand your position correctly, you think that in the general guidelines for erectile dysfunction perhaps we should be looking at incorporating some guidelines on the electronic telephone videoconferencing purveyors into those general guidelines.

Prof. Marshall—One of the key issues that has emerged is the suitability of managing men with erectile disorders without a face-to-face contact and an appropriate examination.

Mr McCann—I guess my focus will be different, from what the consumers are expecting. Consumers tell us that they expect that with respect to any medication that is being prescribed or used in Australia, firstly, they feel that there is some sort of inherent thing that the government has some regulation over that. Then they are quite surprised that there is no testing of that medication. The other part is that they seem to expect that any service that is being provided has some level of independent accreditation and standards, whether it is from a professional body or from the government. They are our two main areas where we want any government policies to ensure that the standard is met, not left at the self-regulation area.

Ms RISHWORTH—General practitioners, for example, are really left to their industry body, so to speak. If they are to be regulated in any way, someone makes a complaint and it goes to a medical board. Why should the doctors at these services have to have extra regulation if there are currently sufficient industry, but really professional, mechanisms to deal with it?

Mr McCann—One is that consumers seem to know the mechanism for a general doctor but some are unsure whether they actually seeing a doctor, which is surprising, and therefore they may not know where to complain. Sometimes the issues they have come under various different departments, which seem to say, 'No, you go to that department,' and the consumer is worn down and they lose that sort of wanting to complain about different services. Often they may not even know the name of doctor they have seen. That may not be anything to do with the service. It is why they need to be given something that says who they have seen.

Dr Weerakoon—Picking up on the comments that came through about this factor of shame and the need for anonymity and privacy and doctors not including it, I think this is a time when we really need to start demythologising the penis and men's health in general. It should be okay for a macho Aussie male to get out there and feel vulnerable in terms of men's health, and maybe we should look at non-formal types of education, AFL and rugby league matches and Bledisloe matches and things like that to talk about it being okay. The other point about training and education is that I think we also need to recognise that there are other health professionals than doctors, everyone from occupational therapist and physiotherapist, and often men will talk to these allied health professionals about these issues. I think there is a need to sensitise and train all of them to include it in their practice.

ACTING CHAIR—Had difficult do you think it is for GPs to talk to their patients about ED, to bring up the subject?

Dr Weerakoon—The data seems to indicate that, whether it is time or values and attitudes or whether it is prioritising, sexual health takes a low priority. Whatever the reason, the research reported data seems to indicate that it is not happening as often as we would like to see it happen.

Ms Vartto—I would like to comment on the issue about how easy it is for GPs. I want to say that SHine and the family planning organisations around Australia actually do the professional education around sexual and reproductive health for doctors who are undertaking their registrar training who are doing the family medicine program training, and we also contribute in South Australia to the training of obstetricians and gynaecologists. Included in that training program is a component around erectile dysfunction and I think without a doubt the evaluation from delivery of those courses demonstrates that there is a much greater competence and awareness around GPs and others providing a good quality level of services to their clients once they have had access to the training.

I want to draw your attention to a fairly recent event that occurred to three women who came to SHine. They had been made aware of the Advanced Medical Institute's new female sexual dysfunction treatment on the radio and subsequently went to the website to find out more information about the skin application technology which was advertised as, 'Try our new scientific development for women who experience sexual arousal dysfunction. Our treatment can help you reach full orgasmic satisfaction. Click here for more information.' These three young

women had attended the Advanced Medical Institute location in Adelaide. I have some information subsequently from a pharmaceutical expert on the treatments they were supplied. For support the young women, in their early 20s, attended together. They were met by a worker who was an administrative support reception type of worker. That is how the young women described her. She stated that, as there was no doctor employed by Advanced Medical Institute in Adelaide, they would each consult a doctor based interstate on the telephone. I understand that consultations occurred but there really was not a history taken, and this was a very clear statement made by these three young women. Subsequently, however, each of these women signed a 12-month contract for $4,000 for the supply of treatments for sexual dysfunction. The substances did not have the desired therapeutic effect and the women had attempted to get out of their contracts but that was refused. They were supplied with morphine lozenges three milligrams and glyceryl trinitrate gel.

I cannot think of any other circumstance where there is a therapeutic substance that needs to be prescribed, for instance if I was still young enough to go on the pill I do not actually have to sign a contract for $4,000 to go on a particular oral contraceptive. So I am questioning something here about business practices. It does not seem as if it is something that anybody has to do when they go to a general practitioner and are supplied with a drug.

Ms RISHWORTH—From your clients' perspective, and I am summarising, it perhaps was the consumer information that they did not feel was as available, but, as previously mentioned, it is a free country and they signed it. What would be your response to that?

Ms Vartto—It is almost as if the heavy amount of advertising that occurs on billboards, radio, TV, shopper dockets and magazines seduces people to take the step of getting into contact with this organisation that is promising not only longer lasting sex but also a better quality of orgasm. I think that simply seduces people to believe that there is a treatment out there for them.

Dr Malouf—Is the supply and dispensing of impotence medications adequately regulated? The answer is absolutely no. What we are seeing is a system which allows ongoing, inappropriate clinical practice. Fundamentally there is a failure of the system to protect patients and consumers from aggressive and predatory commercial impotence clinics. We have heard plenty of evidence today to support that premise. Clearly the system needs to change, because we have an obligation to protect consumers. I agree with Ms Vartto that the advertising is misleading at best—and you could probably go one step further if you wanted to—particularly with reference to female sexual dysfunction. There is an absolute vacuum of evidence that any topical agent, such as apomorphine or glyceryl trinitrate, has any impact on female sexual dysfunction. If you are going to make those claims in a public forum then there needs to be a level of evidence. If the system does not demand that level of evidence then the system needs to change.

Ms RISHWORTH—You have suggested that the system is letting clients down, particularly for not meeting minimum clinical standards. As I mentioned before, GPs are peer reviewed and peer regulated; they go to a medical board. What would you suggest to ensure that there are minimum standards?

Dr Malouf—All health professionals are becoming increasingly accountable, and no-one could argue that that is not a good thing. In a teaching hospital environment, in which I work, we

have regular morbidity/mortality meetings and regular journal clubs. There is ongoing education, peer review and accountability. There is absolutely no accountability in terms of the clinic structure that commercial impotence clinics run. Most of the time, you do not know who is issuing the prescriptions. I know that complications are not followed up. We heard that there is a 0.3 per cent complication rate for prolonged erections, or priapisms. A number of patients in my practice have been through priapisms. They try to report complications, but the clinics are not interested. So the patients give up and discontinue the medication. When they get referred to a specialist, they are absolutely dismayed to hear that there is a commercially available, safe and evaluated agent available that was never offered to them. I am not talking about novel modes of delivering Vardenafil or Levitra; I am talking about a commercially available product which should be first-line therapy, and it is not offered through commercial impotence clinics. So I do not think their outcomes are evaluated properly. The fact that they are reporting a 0.3 per cent priapism rate shows how out of touch they are with the true complication rate out there in the community.

Prof. McMahon—Apart from the practice of medicine in remote areas of Australia, I believe the only role for telephone prescribing is to provide a repeat prescription to a patient who the doctor believes has had adequate follow-up. That is commonly done by general practitioners. This is the national policy for technology based patient consultations, and nowhere does it specifically talk about prescribing. So, presumably, the only legislation that covers telephone prescribing is the requirement that a doctor be a registered medical practitioner in that state. One wonders how a doctor in New South Wales can prescribe medication to a patient in another state of Australia, unless of course he is registered in that state.

What I would like to talk about is that informed consent is one of the most basic aspects of medical care in developed societies like ours. Informed consent must necessarily extend beyond the mere acknowledgement of the patient that he wants to take that medication and understands the risks. It must also include informing the patient that there are other treatment options and of the risks and benefits of those options. There are a large number of TGA approved treatments and several off-label non-approved treatments for erectile dysfunction. Although many of these options may not be relevant to every patient, a prudent and responsible medical practitioner would alert a patient to these alternative treatments. AMI routinely offers patients initial treatment with a nasal spray, in the majority of cases, which contains apomorphine and phentolamine, and these medications are not TGA approved. Furthermore, the efficacy and safety of these treatments, and of the nasal delivery system, have not been the subject, as far as I am aware, of any well controlled large clinical trial which has been published in an international peer reviewed journal. The medication appears unusually expensive. As to the requirement that a patient sign a binding contract, while it might be commercially common it is inconsistent with good medical practice. To use a nasal spray as a first-line treatment in a man who has not been previously treated with a TGA approved oral treatment, such as Viagra, Levitra or Cialis, I believe represents a significant departure from the minimum standard of care and invites strong criticism.

Prof. Handelsman—I would like to make a couple of points. It has been widely known for quite a while that AMI is essentially an unlicensed pharmaceutical manufacturer selling mass compounded drugs without taking the responsibility for approving the safety and efficacy of their products in the way that every pharmaceutical company, including generic manufacturers, has to do. Here we have a company which manages to act as a pharmaceutical company but

evades all the responsibilities of that. That is why it out of line with public and regulatory standards in Australia.

The second point I would like to make is that, for very good reason, it is very well established under the Therapeutic Goods Act that the direct public marketing of therapeutic drugs is not allowed in this country. It is one of the most pernicious and destructive things you will see. If you go to America, there is direct advertising to patients who do not understand the sophistication and subtleties of it. They are pressured to go to doctors and there is ramping up of a lot prescribing for no purpose. In Australia that has always been illegal. But because this pharmaceutical company is unlicensed it is not subject to that regulation. So it can go into public advertising, direct to the consumer, in a way that the Therapeutic Goods Act, for very good reason, is precisely calculated to avoid, and.

None of this is new, I am sorry to say. I was involved in the 1998 Health Care Complaints Commission. We heard from AMI that they had been operating for 16 years, and it is not as if that has not been commented on. In 1998 there were already many complaints to the New South Wales Health Care Complaints Commission. That led to an inquiry at which we heard from not only many of the patients who had complained but also a number of the doctors who worked in those clinics. Hearing about how low-quality this sort of medical care can be was one of the most scarifying experiences I have had as a medical practitioner.

The practices we are hearing about combine the worst of the pharmaceutical industry—at the end where it is not regulated properly—with the worst of medical practice. It really should not occur in Australia in the 21st century. As I said in a previous context, it is a pre-thalidomide type of regulatory standard. This is not the only company involved, but it is certainly the most egregious one. It is time to bring it under the manufacturing licensing regime of the TGA. That is what the public expects and what they should get. It is what they assume is happening, but it is not happening. It does not need a change in law; it needs policing the law that is there.

ACTING CHAIR—Thank you. Dr Pinskier.

Dr Pinskier—The college recently came across some ABS data that suggested that approximately 60 per cent of Australians do not have adequate levels of health literacy to fully comprehend a medical consultation. That information is, essentially, information that is provided on a one-on-one, face-to-face consultation. Once you remove that face-to-face component from the consultation, you end up in the situation where body cues are no longer available and that probably increases that percentage. Telemedicine is a relatively complicated area. It requires very clear boundaries in order for a telemedicine consultation to occur in a manner that is safe for the patient and for the practitioner. There is some telemedicine that occurs around the country that is well accepted, particularly around nurse call centres. Those call centres use well defined and well developed algorithmic processes. What they are not doing at the end of the day is selling medication. They are prescribing advice. They are advice lines only.

The college has done some recent work with the AMA and the Rural Doctors Association and developed some guidelines around the principles for telemedicine. What is needed are clear guidelines as to what care is appropriate via email, telephone or other media; how to define a clinically significant event that requires a holistic approach to care; clear communication back to

all providers and with the patient; and the treatment by a medical professional with whom that patient has an ongoing relationship.

What we require is a process around standards, education, quality assurance, continuing professional development and accreditation. If this is a primary care process, operating in a fashion similar to a general practice, most general practices now undergo accreditation as part of their peer review process. It is not sufficient to say that the medical board has peer power because the medical board only intervenes on the basis of a complaint, on the basis of an exception, and not on the basis of peer review. If this practice is going to be subject to the same scrutiny then it needs to be brought under an accreditation framework and it needs to conform with evidence based medicine.

I do have a concern that the scripts that are issued here are private scripts. They do not fall under the remit of Medicare or the PBS. One wonders how many scripts are issued and where they end up, and who actually monitors that. What is the tracking process? What is the adverse event reporting process? How well-defined is it? I would make this final comment: if insulin was developed today and specialist clinics purporting to specialise in diabetes started to appear around the country and all they offered to consumers was insulin without going through a proper framework of dietary advice, holistic counselling, weight loss counselling and so forth, I think we would all be horrified that the first choice for treatment for diabetes was insulin. I make a similar analogy here on this.

Ms RISHWORTH—I have a question about the GP accreditation of clinics. Who requires that to happen? Is it something that the GP clinics choose to do so that there is assurance that they meet certain standards?

Dr Pinskier—Yes. The standards were developed by the Royal Australian College of General Practitioners. It now goes back to as early as 1996. We are into the third edition and are about to commence the fourth edition of the accreditation process. Approximately 6,000 general practices around the country are accredited. They get accredited for reasons of quality and safety. It is a marker of accountability. It also provides them a gateway to the practice incentive payments, which is a Commonwealth funded scheme. It means that every three years a GP and a non-GP, usually a practice manager—people like me who are trained surveyors—walk through that practice and assess that practice against the standards. They either meet the standards or they do not need them. If they do not meet them, they are advised to undertake a remediation. We assess the medical records. We assess the state of their infection control processes. We assess their cold chain, so that when you get a vaccination you can be assured it is safe and effective, and it is going to work—unlike 30 or 40 years ago when we used to drive around with vaccines in the boot of our car. Our peers understand the process and it is an open and transparent process. I strongly urge that if these clinics are allowed to continue to operate, a similar type of scheme needs to be introduced.

ACTING CHAIR—What would happen to the clinic if they did not meet the accreditation?

Dr Pinskier—If they fail to meet the accreditation, they are given advice around remediation by the various accreditation organisations. Ultimately, if they fail to meet that they then lose their accreditation which means they lose their practice incentive payments funding.

ACTING CHAIR—Can they still practice?

Dr Pinskier—Because the individual GPs are still registered under the various state boards—soon to become a national framework—yes. The practice is not prohibited from continuing, but there is a substantial financial penalty.

Mr Fitzsimons—As you are all aware, all prescription medicines, including prescription impotence medicines, are regulated through an extensive framework of legislation, supervision and industry self-regulation. The aim of the framework is to ensure that patients receive safe, appropriate and effective treatment for their medical conditions. This is certainly relevant for the treatment of impotence, as it is associated with other co-morbidities. If you wanted to look at potential regulation of the telephone prescription of medicines, you would need to be directed by the following principles: ensuring patient safety, ensuring that telephone prescription is consistent with best practice for diagnosing a condition and prescribing treatments of patients, ensuring that it does not contravene any state or Commonwealth legislation requirements for prescribing and dispensing prescription medicines and ensuring that it is consistent with quality use of medicine processes. Manufacturers of proprietary prescription medicines need to prove the safety and efficacy of their medicines before they can be sold here in Australia.

There are also regulations and audits of the manufacturing process for these medicines under the good manufacturing practice protocols to ensure the quality and consistency of the final product. Also, the promotion claims and marketing of proprietary prescription medicines are highly regulated, particularly around advertising to consumers. Currently, it is illegal for prescription medicines to be advertised direct to consumers.

The regulation of all medicines and devices claiming to treat impotence should be subject to the same level of assessment by the Therapeutic Goods Administration to ensure that the treatment is not only safe to use by patients but also has proven effectiveness and is manufactured to a high and consistent standard. In summary, regulation of the prescribing of medicines for impotence should ensure that those patients are able to access safe, appropriate and effective treatment. Regulation requirements should be consistent for all medicines used in the treatment of impotence, ensuring that the safety, efficacy and quality of these medicines are assessed for marketing in Australia.

Ms RISHWORTH—In terms of the principles for telephone prescription, do you think that they would vary from disorder to disorder or should there be some general principles and general regulation about how a telephone consultation should occur?

Mr Fitzsimons—I am not a medical doctor, so I could not necessarily comment on that side of things. There are plenty of things to suggest that good practice involves seeing the person face to face. There is a certain amount of analysis required to provide a diagnosis. Then assessing what treatment is right for that patient depends on the situation and other co-morbidities or issues specific to the patient need to be taken into consideration. Whether the treatment is going to be safe or not also needs to be considered. Having that face-to-face contact means that there is an opportunity to ensure that the patient is going to use the medicine in the right way. For instance, for something like Caverject, which is an auto-injector proprietary product, there are instructions on how to use it appropriately. Having a face-to-face discussion on that gives you an opportunity to ask questions, raise issues and further explain those instructions as well.

Mr Mackey—I want to make a couple of points. In our view, best practice pharmacy must be underpinned by the quality use of medicines. We would also say that it needs to be in line with the professional practice standards, the competency standards and our code of professional conduct. We look forward to working further with the TGA and the AHMAC subcommittee in the firming up of the regulations, particularly around the three tiers for compounding. It is a very important move. I would also like to echo what Dr Pinskier and Dr Weerakoon said about education and health literacy. Empowerment of the patient is a really important part of this. I think a lot of what we are actually talking about is bypassing the patient in many respects. One way of trying to deal with health literacy—and is the way we have tried to deal with it—is through our self-care program. I mentioned before that we have a fact sheet on erectile dysfunction and 79 other topics. It is sort of set at a year 6, 11- or 12-year-old reading age so that it is very understandable. It also, most importantly, gets that interaction between the health professional and the patient going on. I just make the point that, in terms of the first two points that were made if a patient is experiencing erectile dysfunction, your local doctor is the best place to start inquiries about ED. And be very wary of responding to advertising about ED treatments.

ACTING CHAIR—Where is that available?

Mr Mackey—I am happy to table that.

ACTING CHAIR—How do you get that out into the public arena?

Mr Mackey—It is a service that pharmacies subscribe to. We put it together and it is a series that goes out. The fact cards go out twice a year and we have a monthly magazine.

ACTING CHAIR—They are in pharmacies, are they?

Mr Mackey—They are in pharmacies. There are stands to enable interaction between the pharmacist and the patient. We also utilise particular weeks, like Diabetes Week and Asthma Week, to have particular health campaigns. We are trying to get that encouragement going for the patient to see their GP, talk about the problems that they are experiencing and offer suggestions for treatment.

ACTING CHAIR—Do you wish to table that as an exhibit?

Mr Mackey—Perhaps I could send a kit to the secretariat later, which gives you an example of it.

ACTING CHAIR—I will put that in as a submission.

Mr Doyle—Once again we seem to be covering a number of issues, and I will try and cover as many as I can. The first issue, again, relates to telephone consultations. For telephone consultations there is a national standard that applies to all telemedicine, which all medical practitioners are required to comply with. There seems to be a lot of discussion about how the practice in clinics, where face-to-face consultations occur, seems to somehow be different to what occurs over the telephone. As our survey earlier this month revealed, there is in fact less occurring in the clinics than there is occurring over the telephone. As I said, less than 15 per cent

of doctors actually perform a physical examination. The quality of questions asked by those doctors is fundamentally less comprehensive than the questions asked in our clinics. One-third of doctors do not give any advice on side effects at all. The suggestion that people should talk about alternative treatments is one that we actually support but unfortunately is not one that occurs in general practice. Almost invariably, with a few exceptions including Dr McMahon, most doctors do not advise multiple treatment options. As I also indicated earlier, the reality is that patients in general do not want to go into clinics for consultations, and when they go to see a doctor the doctor is ill-equipped to assist them and that results in people not going to see them. So in reality changing the law is only going to result in worse healthcare outcomes rather than better healthcare outcomes.

The second issue is that AMI's technology based consultations are not covered by Medicare. If you change it to a face-to-face consultation process the amount of funding from the federal government will be increased and requirements will be in the manner of millions. We do not think that that is in the interests of the public.

There have also been a lot of comments here about side effects, inappropriate medication and so on. Quite frankly, if there were major recurring side effect issues, then these issues would have been dealt with before. There reality is that there are not. Most of these medications have been the subject of clinical trials in an overseas setting. Some of those are in the same form—for example, nasally delivered, in an inhalation form or in a tablet form. But each of the medications has been through some form of clinical trial. Not only that, but they have been used over a very extended period in commercial practice. If there were major adverse health outcomes coming from those, with people suffering a morbidity event or some other major health outcome, then there would have been an outcry some time ago. The reason you had an outcry in Singapore was because four people died and there were a lot of other major adverse health outcomes. The reality is: that does not occur.

I have a final point in relation to the pharmacy issues and quality control. The compounding pharmacy that provides that service to AMI is inspected regularly by the TGA, does have quality controls in place, and there have not been any major issues. We are not a manufacturer. AMI does not itself supply the medication, and everything is done on an individual prescription basis. Thank you very much.

Ms RISHWORTH—In terms of the pharmacy and the accountability, that pharmacy—you are saying it is separate to yourself—does not have a pharmaceutical manufacturing licence, does it?

Mr Doyle—I cannot comment on what they do and do not have. Unfortunately they were not invited to attend today's session. We have suggested that they put in a submission. I do not believe that they actually need a manufacturing licence; but, in any event, this whole issue about what should happen in relation to pharmacies is the subject of a separate inquiry, and detailed submissions have been made in relation to that—including by that pharmacy. I think that is the appropriate place for those issues to be dealt with. We are not qualified to comment on those issues and nor are most of the people here at the table.

Ms RISHWORTH—In terms of telemedicine, I think that the public's expectation would be, whether it be for prescriptions or general health care, that they would be able to speak to the

same practitioner each time they phone. That obviously cannot always happen, because doctors do not work 24 hours a day, but there would be an expectation that you could continue if you rang back at a certain time, et cetera, that you could keep having the continuing care from one person at the place. How often does that happen, and is that available through your telemedicine?

Mr Doyle—I do not have statistics here and now that would involve a rigorous analysis of a customer database, and I do not wish to give inaccurate information. But clearly we do try to give proper health care to our patients. We have a centralised computer system which is accessible to all of the doctors, so if an issue comes in they actually have the history there, so they can assess and understand it before they speak to the patient when the patient rings back. Clearly it is also in the best interests of patients if they continue to deal with the same physician on those issues, and we recognise that.

ACTING CHAIR—You were talking about a minimal amount of people who come back and make complaints. First of all, is that mostly about the contractual side or is it about the success side?

Mr Doyle—Over 75 per cent of our complaints relate to contractual issues. They do not actually relate to medical issues. Where people are complaining about medical issues, it may minor irritation-style issues where someone has tried the medication and they have had a minor side effect. You can have an adverse reaction with a medication. The same thing can happen with Viagra or any other medication. What happens then is that there is often a medicine exchange, or there may be other issues. There are a variety of ways that you need to deal with that issue.

ACTING CHAIR—As you said, people come and see you because they prefer to have some degree of anonymity. Do you think that might be a reason why they would not come back if the prescribed medicine has not worked? They might think, 'It was difficult to go there in the first place, but I am not going to go back and make a complaint to anyone, because I do not want to look stupid.'

Mr Doyle—Mr Irons, we have a system in place which requires follow-up to all patients within one to two weeks after they have received their medication. We actually have a system in place in which we need to call people and see how they are going and talk to them about their treatment. It is precisely for that reason. There is actually a statistic that shows that. I have already indicated the difficulty of getting someone to get to a doctor, which is 75 per cent to 88 per cent of people based on independent studies. They do not even go to a doctor. There is another study which says that 50 per cent of those who were given a prescription do not even go and fill the prescription and collect it. There are clearly some serious issues there that people need to recognise and deal with. People may not like our campaigns and advertising, but the reality is that we are raising the awareness of this issue in the community and we are trying to destigmatise the condition in the way that we advertise.

Ms RISHWORTH—Obviously, as we have heard, you have a distinct, I guess, benefit to be able to advertise directly to the public, which other pharmaceutical companies and specialist products through TGA do not. My understanding is that they do not get to do that. If you have so many complaints—and certainly I have heard quite a few about contractual arrangements—are you making any moves to improve how you explain exactly what people are signing up to? As

we have heard, there are issues about health literacy out there in the community. That is certainly a concern that has been raised with me in my electorate a number of times. I do not know which company it was, but it is certainly an issue that has been raised in this sort of system.

Mr Doyle—I think there are two questions in there. I will deal with the first one first, which is in relation to advertising. We do not advertise pharmaceuticals; we advertise the fact that we have a service. There are numerous medical companies which provide services which advertise. I am not sure at what stage it was decided that doctors could advertise their services, but if you want to ban us from advertising basically you will be banning most of the doctors from advertising. I am not sure that that is a good thing.

The second issue is the contractual issue. Of course we would always like to improve the way in which we deal with complaints. Unfortunately, no company gets everything that they do right, and we recognise there are things that we can do a lot better. The reality is, however, that we do give training to our staff; we make sure that they clearly explain to people what they are committing to. Either they are committing to an upfront payment of a set amount or, if there is a stage payment, it is not just that they are told you are paying X dollars a month; it is that you are paying this amount in total. It is very clearly explained to patients. We monitor that regularly to make sure that people are not misled.

In terms of the issue of the outcome, the reality is that people do change their mind. The vast majority of complaints relate to people who simply change their mind. We have a voluntary cooling-off policy so that if people change their mind within a set period of time, they are simply refunded.

ACTING CHAIR—What is that period?

Mr Doyle—Forty-eight hours. There is no requirement at law at all for us to have a cooling-off period. We adopted that policy several years ago because we felt that it was appropriate. People are saying we are pressuring people into doing things. We do not cold-call. The only people who contact us are people who want to contact us, and we have a voluntary cooling-off period. If someone says, 'Look, I have thought about it and actually I have changed my mind; I want to go and do something different,' we give them that option. I think that that is entirely appropriate. But I can tell you that if you go to any other health professional in this area and you change your mind you do not get your money back.

Ms RISHWORTH—But how often are those health professionals signing you up for 12 months? There is a difference.

Mr Doyle—When you talk about 12 months, people sign up to all manner of different lengths of contracts. The reality is that if someone goes to Chris's practice they are charged $150 for a 15-minute consultation. Then they have to pay for the medication on top of that. It is extremely expensive. Medications in this area are not cheap.

Ms RISHWORTH—I understand that. I understand people go into mobile phone contracts and all the rest, but there are very few medical services where you would be signing up for 12 months.

Mr Doyle—People can always do things in a different way. They can charge a large up-front fee, which is what most other people do, and that just makes medicine less accessible in a different way. There seems to be some perception out here that we simply take consumers' money and do not refund it and that we deal with them inappropriately. That is just not correct. We routinely return funds to consumers. We routinely write off debts which are owed to us and which we are completely entitled to recover. We think the way in which we act is appropriate. Yes, there are a range of complaints. There will always be a range of complaints. Part of that is because the cost of medicine is high. Again, I refer to the article in yesterday's paper. We are not the only organisation in medicine that is complained about. There are complaints about skin clinics and plastic surgeons. There are a multiplicity of doctors who are complained about, and that is because medical costs are extremely high. And part of the reason they are extremely high is the shortage of doctors. The professional bodies in Australia do not want more doctors. They want to limit the number of people who are able to practise medicine. That is fundamentally the problem.

ACTING CHAIR—Just going back to some of your statements about providing alternative sources of medicine, you mentioned that Professor McMahon did not provide any alternatives. Do you think—

Mr Doyle—No. I was at pains to say that Dr McMahon mentioned a range of alternative treatments. So that is not correct.

ACTING CHAIR—Okay. Would the treatments that he was recommending have been TGA approved products?

Mr Doyle—Dr McMahon gave two consultations. One of those consultations was in the area of erectile dysfunction, and in that case he recommended TGA approved products. The other consultation was in the area of premature ejaculation, which is one of his other specialisations. What he prescribed then was Aropax. Aropax is registered with the TGA, but there are no medications registered for premature ejaculation. If you go to an urologist or anyone else to talk about medicines for premature ejaculation, you can only ever talk about off-label use. In fact, a number of the practitioners in our survey prescribed Cialis for premature ejaculation. Cialis is not indicated for premature ejaculation. It is not recognised in that field. It is indicated for erectile dysfunction, and is a well-recognised medication for that purpose.

ACTING CHAIR—The mood in the room seems to be towards greater regulation. In your situation, you are providing a service. That is what you stated not so long ago. You are not providing a medical solution; you are providing a service. Would increased regulation of the medical industry be any threat to the operation of your business and, if so, would you change tack again, as you did in the situation where you used the nasal passage as way of delivering your medicine? If we moved towards further regulation, would that affect your commerciality?

Mr Doyle—AMI is part of a publicly listed group. We are at pains to comply with all laws and regulations that adhere to us. If the law is changed, we will change our business to comply with the law and be an appropriate corporate citizen. In terms of the level of regulation, there is already quite a lot of regulation in this area, some of which has been talked about and some of which has not. The reality is that all doctors are subject to professional review. They are required to go through registration, be appropriately qualified and have appropriate experience. If they

make mistakes in their practice, there are medical boards to deal with those issues—and they routinely deal with those issues and remove doctors from practice. I am less well qualified to comment on the pharmaceutical area; but, again, it is a matter that is subject to extensive regulation.

There seems to be some pretence in this room that off-label prescription is not standard medicine and is not done as a matter of course. In fact, it is done as a matter of course across a broad range of industries. Part of the written submission that we will be giving in due course will cover some of those issues. It is a well-recognised matter that people provide off-label medications, and there are a variety of reasons for that. One of the core reasons is that a clinical trial costs tens and even hundreds of millions of dollars per formulation. The only people who are prepared to go through that expense are those who can get patent protection for their products and who have a monopoly. In having a monopoly, as I am sure all of you are aware, it means that you can charge above market prices for your products. When we talk about medications being used for an alternative use for an extended period of time, that type of protection is not there. The real reason that these medications are not registered with the TGA has nothing to do with efficacy and nothing to do with safety. All the ingredients in the medications have been fully tested for those types of issues. The real reason is that the cost vastly outweighs the benefit.

ACTING CHAIR—I might open up the questioning and focus on trying to find some suggestions that we can make as recommendations to the minister.

Dr Pinskier—Just listening to Mr Doyle's comments, there are a number of issues that need to be addressed. He raised the issue that these things are required because there is a gap in the marketplace and patients do not have access to general practitioners or they do not have access to primary care clinics. That may be true in some instances, but it is not universally true. He then went on to suggest, on the basis of his limited, and dare I say biased, sampling of 30, 'We do it well, we do it better, but we do it better than general practitioners.' He is actually saying he knows more about the way general practice operates than the general practice industry! He made that claim quite unashamedly. If that is the case, I welcome him to come and join the college and teach us how to do it better. I think we are at odds here. He made a subsequent claim about the MBS. He said, 'If this was regulated under some sort of MBS or Medicare arrangement, taxpayers wouldn't want that.' I will run the thin edge of the wedge argument here and say, 'Let's just remove the MBS, because that will save taxpayers lots of money.' It is an illogical argument.

The final point I want to make is the one of holistic continuity of care. Patients and the system have clearly demonstrated that where you have a gatekeeper model and a primary care general practitioner or family physician, it provides better care. Barbara Starfield's work in the USA is incontrovertible on this, and I ask the committee to look up her work around the provision of primary care services and specialist services. Her evidence is incontrovertible that primary care physicians provide effective, cost-effective, safe, high-quality care and, in the long term, achieve results that have lower morbidity and lower mortality. This is a specialist service and should be treated as a specialist service. And if it is going to be a specialist service, then the doctors working in that service that should come under the requirements of the specialist board and they should require specialist registration. They should be required to undergo continuing professional development, they should be required to undergo continuing accreditation

framework and there should be a process that make these doctors accountable. At the moment, any doctor who is registered can go and work there. I asked a question about where the evidence is surrounding the education they are providing. We did not get that response, and it leaves quite an unsavoury taste in the mouths of general practitioners.

Prof. McMahon—Richard Doyle's suggestion that you can predict the treatment patterns of general practitioners from a sample size of 30 is really drawing the longest of longbows. The notion that an approved drug in one particular form, such as a tablet, will work in a different form—that is, a nasal spray—is just ridiculous. It flies totally in the face of one of the basic disciplines of evidence based medicine—that is, that a clinical trial must be done to confirm safety and efficacy. I take heart in the fact that AMI are keen to save the Australian taxpayer a dollar, but frankly I think most legislators in this country would rather save a life than save a dollar. I believe at this stage that, with their current standard of care, AMI does not have a place as a health care provider in this country.

ACTING CHAIR—Is it just AMI, or other businesses as well?

Prof. McMahon—People who have the same model as AMI. I would like to go two steps further and make some suggestions as to how this can be corrected and their role reappraised. I believe that all patients with ED must have a physical examination and that telemedicine in that group has no place. I believe that in patients with premature ejaculation, the treating doctor must have an opportunity to physically examine a patient—he may choose not to do so—and again in that situation telemedicine is not appropriate. I believe that all off-label medications must satisfy a minimum standard of evidence. We have different levels of evidence that can be assigned to clinical trials, and that clinical trials be done so that we can assign this level of evidence. Without that level of evidence, those medications should not be used. That is going to require that the current legislation is radically changed.

Prof. Handelsman—I would reflect a little bit on the issue about whether AMI in its current form is a pharmaceutical manufacturer. I go back to the fact that in the nineties the On clinics, run by exactly the same people, had all of the same problems but simply slipped around and changed the names a bit. But in reality, the idea that they advertise a service is a carefully constructed legal fiction. It is like a bottom of the harbour scheme for responsibility. What they do is they have a service, but they have a very clearly stipulated preference for nasal medications, which they have contracted out to a compounding pharmacist.

Most large pharmaceutical companies will actually do similar sorts of arrangements, but they come under the one roof. They have their development components and they have their manufacturing components. Sometimes they are not part of the same plant necessarily. But in this case, this is a service and a recommended therapy. They really belong as one but they are conveniently constructed as a legal fiction with a Chinese Wall between them to evade any responsibility of proving safety and efficacy.

It is not true that you need a patent to market drugs. Generic manufacturers market drugs and they do not have to go through the extraordinarily high costs of a patent medicine going through primary evaluations. Nevertheless, somebody has to take responsibility for a pharmaceutical product put on the market in a context where every other company, including generic

manufacturers, have to prove a degree of efficacy and safety. They evade that by this carefully constructed legal fiction.

I noticed, for example, earlier in the day—perhaps in an inadvertent comment—Mr Doyle said that they actually give subtherapeutic doses of some medications. Obviously that will avoid side effects. It will also avoid all effects, including efficacy effects. The point is that they have never proven that these medications actually work. That is because they have avoided that responsibility—evaded it in this case. I think that it is now high time—it is more than 10 years since complaints came to the notice of the state government because of the volume of complaints. All the slipping and sliding around does not change the fact that they function as a pharmaceutical manufacturer. If the laws do not work at the moment, then they should be changed sufficiently so that the reality of working as a pharmaceutical manufacturer is brought into the proper regulatory framework to protect the public.

Prof. Lording—Moving forward and given that, from of a consumer point of view, contracting seems to be a really substantial cause of concern, perhaps through you, I could ask Robert Doyle in a moment to answer this question: if it is not just all about money and maximising the amount of money that is extracted from patients—and I might suggest that the major adverse outcome of treatment at AMI is in the hip pocket—why is there a need to continue the contracting arrangement? Why cannot AMI simply dispense their medications? After all, we have heard that this is a very successful treatment program with high support from its patients. If it is very good, why can't a month's supply of medication be obtained at a time with a small payment? If it does not work, there is no obligation to stay in the program—just like all the other drugs we prescribe in medicine, whether they are on private or PBS based subscriptions. Most of the things that we prescribe, even if they are relatively high-cost private drugs, will be prescribed and paid for in small amounts. It can be tried. There is no obligation to stay on it if there is no efficacy. I would ask Mr Doyle in this model moving forward in good faith to answer the question: why is there a need for AMI to continue this contracting arrangement, which is a pernicious, nasty and I think somewhat unethical means of extracting money from patients?

Mr Doyle—I am very happy to answer the question. People have commented that we have not answered all questions. Unfortunately, there are time limitations here. It is not that we are avoiding questions, but there are a number of people who need to be given the opportunity to speak.

In terms of the particular issue that has been raised about contractual arrangements, how we choose to structure our business is really a matter for us. We are a commercial enterprise and we are entitled to do whatever we wish to as long as we comply with the laws. We can always move to a model where we charge market fees for doctor consultations upfront—the same as everyone else in the medical industry—and we can charge people separately for medication. We can move to that model at any stage. It does not really matter. The reality is that there are a number of reasons why we have long-term contracts, one of which is that it actually takes some period of time before a medication becomes effective. Everyone seems to think that you can take a pill and you are going to have an overnight impact on your health. The reality is that that is bollocks—it is not correct. People need to take treatment for a period of time before it has a therapeutic effect. It is not just a matter of taking medication; it is also a matter of patient behaviour. There are a number of reasons why we structure our arrangements the way that we do and we do not

see anything that is improper in the way that we do them. We are quite happy to discuss that formally or informally with anyone at any time.

Mr Fitzsimons—I would like to just state a few things with respect to the regulation of prescription medicines. Certainly as part of registering a product here in Australia we need to provide phase 1, phase 2 and phase 3 trials to establish whether it is safe, efficacious and efficacious in that particular formulation. As was rightly said before, that does cost a lot of money. Patent protection allows for innovation to occur, and the person taking the financial risk in bringing that innovation to market does need some protection in order to protect their investment. So patent protection is an essential part of innovative research and bringing innovations to market.

Certainly as part of the registration process and evaluation in our indication we know how long a patient will need to take a medication for until it is effective. A lot of those issues around when it is effective, how it is effective and how long it will take to have an effect are already known. So there is a reason for that regulation and marketing registration to occur. Also, certainly looking at manufacturing, all our products have to comply with good manufacturing practice. We have audits by the Therapeutic Goods Administration. That may be done in-house by the company, and even the contractors to those companies have to have certification. As part of the good manufacturing process all companies have to keep an audit trail of all their batches and batch numbers, all the tests that have been done and certainly the quality control undertaken in that manufacturing process.

At the end of the day, all this regulation ensures safe and effective treatment for patients. With compounded medications certainly back in the early 1900s and early part of the 20th century pharmacists did make up a lot of medications. But they also had formularies—either the *Australian Pharmaceutical Formulary and Handbook*, the *United States Pharmacopeia Dispensing Information*, the *British Pharmacopoeia* or *Martindale*. They had standard treatments that did have a body of evidence behind them. So the issue around compounding is that at the present moment if a person is changing a formulation or making a different formulation out of an already proprietary product then there are a lot of unknowns in translating that from the current dosage form—say, a tablet—to a novel form, whether it be a skin application, an inhalation or whatever you choose to do.

So certainly from our side of things we find that there is a bit of an unlevel playing field in relation to this. There is a high expectation and a requirement for us to bring a product to market yet there seems to be an anomaly where a compounded medicine, whether it be out of a formulary or a change in dose, does not need that same sort of scrutiny. There is probably a role for it where the current treatments are not appropriate however in most cases proprietary products will treat the majority of patients. On the issue of advertising, we are covered under the Therapeutic Goods Act. Also Medicines Australia members, which represent virtually all the innovative companies, abide by that code as well. That does outline the sorts of claims we can make to consumers, the claims that can be made about those treatments and what we can actually advertise to doctors as well.

Companies have to actually audit their education events to doctors to Medicines Australia and to the Medicines Australia code of conduct on what they have actually spent on education events. So there is a lot of transparency there. The regulations are there for a good reason. At the

end of the day that sort of level of regulation is there to provide safe and efficacious medicine to the community. That is why we have been advocating for quite a while to have that sort of level playing field in other areas of therapy as well.

Dr Malouf—First of all, I would just like to make the observation that Mr Doyle, presumably inadvertently, has misled the committee. In the 2004 AUA guidelines there is a direct reference to the use of PDE5 inhibitors or Cialis type medications for the use of premature ejaculation, and there are studies which validate that approach. The statement that Mr Doyle made earlier on is actually incorrect.

Mr Doyle—If that is the case then that is not to my knowledge.

Dr Malouf—Secondly, in this forum of openness, I wonder if Mr Doyle or Dr Vaisman might like to make available a selection of the names of doctors in New South Wales who are working for AMI, because under the New South Wales Medical Practice Act there is mandatory reporting of clinical practice which lies outside a minimum standard of care. It is my opinion that the prescribing of unproven and inappropriate medications constitutes an inappropriate standard of care, and as a result there is an obligation upon me to make a representation to the New South Wales Medical Board on that matter. I would direct the inquiries to the organisation accordingly. Thirdly, I would ask whether Mr Doyle would like to comment on reports, which I have been made aware of, that Australian based doctors employed by AMI have been providing prescriptions or may have in the past provided prescriptions to New Zealand patients. To my understanding, that lies outside the jurisdiction of their registration and may constitute an illegal practice.

Mr Doyle—In terms of the question as to whether an Australian registered doctor has provided New Zealand prescriptions, that is false. Earlier there was a comment about how doctors based in New South Wales can treat Adelaide based patients. In fact the doctors are registered for practice in South Australia, and in fact all Australian states and territories. So they are acting within their rights. In terms of other threats and so on about doctors, I do not think it is appropriate for me to comment about matters which are really not appropriate to deal with in this forum.

Ms RISHWORTH—I have a question on the doctors. Obviously you do the in-house training. We are talking about doctors whose predominant role is to prescribe medication, effectively, as well as doing the assessments. So they do the assessment and then prescribe medication or refer patients on. There was some comment about people in this room feeling that they should be specialists in the area. What level of official training do the doctors have who work within your organisation? Does that vary?

Mr Doyle—I am very happy to comment on training issues. All our doctors are qualified general practitioners. They are not required to be registered as specialists. There are many general practitioners, not just in the impotence field but in a wide variety of fields, who concentrate on a particular area of medicine. That is standard practice; it is not confined to this particular area of medicine. In terms of training, every week a training session is held in AMI for all of its doctors. Any suggestion that there is not ongoing training and regular discussion of these issues is completely inaccurate. We are at pains to ensure that the doctors who are working in this area have a very detailed knowledge and understanding of this area. You said that their

job is one of prescription. Their job is a medical practice job. They are there to treat patients and to deal with patients. As part of patient care in this particular area medication is often prescribed. But, as I indicated, one-third of the patients who contact us are actually not suitable for any form of treatment at all. I am talking here about a medicated treatment. Yes, they can have counselling and, yes, there is a range of other things that they can do, but we do not provide medication to people who should not be provided with medication.

Ms RISHWORTH—But ultimately, your service then does not go on to treat that one-third. Your service then refers them on somewhere else.

Mr Doyle—Correct.

Ms RISHWORTH—I take your point that it is not just about your not dispensing medication to everyone. Ultimately your service is not a comprehensive service that then follows up that counselling and provides that—

Mr Doyle—If someone wants us to provide counselling to them on an ongoing basis for a commercial fee—and there is obviously a cost in providing advice and treatment to patients—we are delighted to provide them with that service. We have no issue in providing it. But the reality is that often when people hear that there is not a medication available for them that inhibits their view as to what they should or should not do.

ACTING CHAIR—Mr Maskell-Knight has offered to clarify something for us.

Mr Maskell-Knight—When Mr Doyle earlier made the comment that he understood the compounding pharmacy used by AMI is inspected by the TGA if it is Australian Custom Pharmaceuticals, that is not correct. They are not audited by the TGA and they do not hold a manufacturing licence. I understand that our regulatory compliance inspectors may have visited the premises but that was to ensure compliance with the act rather than to ensure quality.

Mr Doyle—That is correct. First of all, I indicated quite clearly to the committee that I did not know whether they held a licence or did not hold a licence. All I indicated to the committee was that the TGA regularly inspects the premises.

Prof. Marshall—One thing—and it is not so much a matter of going forward but something that concerns me as the discussion has unfolded—is that there does appear to be a system here where we have the development of a contract between a patient and company, as I understand it, as between a patient and medical practitioner. If this individual is acting, as I would see it, as a medical practitioner, it should be a consultation and this consultation should be in the best interests of the patient not necessarily in the best interests of that individual's employer. As I understand it, a contract is then signed between the patient and the company and not between the patient and the doctor, so in that sense it could be construed that the doctor is actually acting as an agent or a salesperson for a particular product. That may not be inappropriate but certainly in terms of clinical practice, and indeed in the sort of context of informed consent and independence of clinical opinion, this surely must be compromised under these circumstances. So it would seem to me that one of the things that might need to be looked at in regulation is whether a product, if it is being sold by a company, is then actually having doctors who are then selling that product, in essence, on behalf of that company. There ought to be a regulatory

framework which looks at whether these doctors are at arm's length from a company in terms of their opinion. It is true, and it has been indicated, that they say that some of them are not. However that tends to then end up with the patient moving onto the product that is provided by the company. A very dangerous situation is developing where we actually have medical practitioners who, I would say, are de facto agents for a pharmaceutical product.

Ms Varrto—In trying to understand the extent of the erectile dysfunction industry, I looked at a number of websites and noted that on the Advanced Medical Institute website it indicated that you saw about 45,000 clients a year. That seemed to be an enormous number. You indicated earlier that about 50 per cent of those clients are seen face to face and presumably the other 50 per cent are not. I would like to understand whether for those clients that are seen face to face Medicare is involved in the payment for the consultation.

Mr Doyle—There is no Medicare involved.

Ms Varrto—Thank you.

Dr Pinskier—Just picking up on the point made earlier around autonomy of care, the RACGP stands for accreditation of a very strong position in relation to general practice, general practitioner autonomy of care. In other words, the GP, whilst they may or may not be working for an employer in a master-servant relationship or whatever, must have complete autonomy in how they practise from a clinical perspective, who they refer to and who they do not refer to, and how they manage the patient. We cannot as an employer direct a practitioner to prescribe product X or product Y, or to refer to specialist Y, or use pathology X or Y, and it is a breach of the accreditation standards and probably a breach of general peer standards.

It seems to me that the point you made here earlier is that what is happening is that these doctors have been contracted or conscripted by a particular service and then they have a choice of either engaging the patient into the program or not engaging. So they are in or out. Once you are in, then you follow the script. I would strongly argue that there is no autonomy of care under that arrangement and that supports my previous premise around the requirement to have an accredited framework under which these clinics operate.

The second point is a point of order around the use of the term 'general practitioner'—and I will state this very clearly. A general practitioner is a doctor who has gone for the RACGP training program, is a fellow of the college, or who otherwise was grandfathered onto the Vocational Register prior to December 1996 and, as a condition of being on the Vocational Register is required to undergo ongoing continuing professional development through either the College of General Practitioners or the Royal Australian College of Rural and Remote Medicine. Any doctor who is registered can claim the title notionally of general practitioner but they are not required, unless they are on the Vocational Register, to undergo continuing professional development. I would be curious to know how many of these doctors are actually general practitioners as defined by the act. If they are not, then how does one monitor them in terms of their ongoing CPD?

Mr Doyle—I cannot comment on the number of doctors, but I have already spoken about the nature of training. If someone is concerned about the nature of training, I do not know how much more training you can give than every single week.

Dr Pinskier—I am talking about general practice training, not specialist training. If you want to treat them as specialists then they should come under the specialist requirement of the act.

ACTING CHAIR—I think that Dr Pinskier has made his point. Mrs Spierings, would you like to make a contribution?

Mrs Spierings—I think my concerns have been discussed.

Mr McCann—Again, just focusing on consumers, regardless of what the regulations are, consumers are expecting the government to act on protecting them where they believe they need to be protected, and at this point of time it is clear they feel they are not being protected.

ACTING CHAIR—Dr Weerakoon? Mr Mackey?

Dr Weerakoon—No, thank you.

Mr Mackey—No, thank you.

ACTING CHAIR—We have got a few more minutes so if anyone else wants to ask another question or make a statement—

Mr Doyle—I just want to make one further statement. There have been a number of comments about independence of doctors and so on, and I just want to be quite clear. Our doctors are not remunerated on the basis of how much medication or how many treatments are sold. We would consider that to be entirely inappropriate and we do not engage in any such practices. Doctors are free to make their own independent assessment as to whether a treatment is effective or is not effective, and I think the fact that they do that is validated by the fact that one-third of patients are found to be contra-indicated for treatment and are not provided with a treatment program. If we were there simply to make money, then the behaviour would be considerably different from that. So any such statement is simply not appropriate.

The second overriding statement that I would like to make is that we seem to have a lot of comments made about the fact that there is no clinical efficacy for the products. The reality is that there are trials which support the use of the products. The fact that people are not aware of them is not my responsibility; they should read more broadly. The reality is that there are studies out there that protect it.

The further statement I would like to make is in relation to patent protection. The reality is that patent protection is only available for products which have not already been commercially sold. All of these treatments have already been commercially sold. If there were a major health issue regarding their use, there would have been a lot of major adverse health outcomes, and there has not been. So there is not. It does not matter how many clinical tests you put them through, you cannot get patent protection for these particular products and any suggestion put by anyone here that that is ever going to be an outcome, is simply false.

Prof. Lording—I have done a literature search of apomorphine and phentolamine recently and both drugs have been used in clinical trials and there is some data of efficacy for these drugs used orally. It is marginal at best and the companies that ran those clinical trial programs chose

not to persist with them in a commercial sense for those indications. So they have marginal efficacy. I am a little surprised that given the high level of doctor education within these clinics and the concept of them being able to practise independently, that none of them prescribe the first-line medications which all other doctors would regard as the initial pharmaceutical agent—an oral PD5 inhibitor.

Prof. Handelsman—I will not take a lot of time, but I just want to pick up a point that Mr Doyle made in his last comment about the way in which doctors are remunerated. I will just mention in a very short precis what one of the former practice administrators of the same organisation under a different name said some years ago. He reported that doctors were paid a fixed percentage of the gross takings, that they had a thing called a 'conversion rate' which was the number of patients who were sold medication divided by the number of patients they saw. If doctors did fail to sell the right rate, they were counselled to bring this up to a certain level. I am glad to hear that the company has changed its practices so that it now totally disavows it. It did not in the past and I wonder whether in fact we are getting a complete picture.

Mr Fitzsimons—I have just another thing on patent protection. A number of these products are still under patent protection so therefore the intellectual property of the molecule, the formulation et cetera, is still under patent, which does not actually allow anyone else to do a clinical trial for that particular indication. We need to be just a bit clear why sometimes clinical trials cannot be done on particular molecules especially if a molecule itself is currently under a patent.

ACTING CHAIR—We do encourage all participants to make submissions to the inquiry and the committee would appreciate receiving any other submissions within the next two weeks. This will enable the committee to report sooner rather than later. This hearing concerns ED and men's health in the long-term. We will take the evidence that has been put forward today and any further submissions and make recommendations from this committee to the appropriate minister and regulatory authorities

I think that today has been a good roundtable forum. Unfortunately it probably has not been long enough for some of us, but the member for Kingston and I have enjoyed the time that we have had and we do appreciate that some of you have travelled to come here and to present to this roundtable forum. Thank you for your attendance today. I thank Hansard and Broadcasting, the secretariat staff and Heather for attending and helping out with the preparations. I hope that you have enjoyed the experience here today, thank you.

Resolved (on motion by **Ms Rishworth**):

That this committee authorises publication, including publication on the parliamentary database, of the transcript of the evidence given before it at public hearing this day.

Subcommittee adjourned at 2.14 pm