Australian Custom Pharmaceuticals Pty Ltd

Submission to House Standing Committee Roundtable Forum into Impotence Medicines

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I have been a practicing compounding pharmacist since 1987. I am a member of the Pharmaceutical Society of Australia, the Australian Society of Cosmetic Chemists, and the Board of Australasian Academy of Antiaging Medicine. I am a Life Fellow of the Pharmacy Practice Foundation (University of Sydney) and I am the owner of Australian Custom Pharmaceuticals Pty Ltd (ACP), the largest compounding pharmacy in Australia. I am a member of Australasian Compounders Association. I am also one of few individuals who have made submissions to the TGA NCCTG Review into Extemporaneous dispensing.

After reading the full transcript and other submissions to the House Standing Committee's Roundtable Forum into Impotence medicine I would like to contribute the following facts about the practice of compounding as carried out at ACP.

ACP has produced over 15 million individual doses of compounded medicines in individual dose forms to patients of AMI clinics and over 2,500 other medical practitioners with no major adverse drug reactions. ACP compounds medicines that use ingredients that are listed in the Standard for the Uniform Scheduling of Drugs and Poisons . Inclusion in the standard is subject to a decision of the National Drugs and Poisons Schedule Committee. Decisions made by this Committee to include drugs and poisons into these Schedules are only made after comprehensive research and tests regarding safety and efficacy are undertaken.

ACP does not develop or use new molecular moieties or trial new drug entities that are undergoing registrations in its compounding activities. All compounded formulas supplied to AMI Clinics are fully tested for stability, dose distribution and any other dose form specific requirement in state of the art analytical labs owned by NxGen Pharmaceuticals Pty Ltd. NxGen is a product research and development company which creates data packs for TGA and APVMA listed and registered products. I would go as far to say that the AMI compounded medicines are amongst the most tested extemporaneously produced formulas in Australia. It is reprehensible that Professor Handelsman suggests that compounding is a "pre-thalidomide industry" which puts patient welfare at risk. I remind Professor Handelsman that thalidomide was a new drug entity with TGA approval and was not an established medicine with decades of safety data created by a compounding pharmacy. The Australian experience with thalidomide demonstrates that listing on the TGA's ARTG does not guarantee public safety. The repeated use of the thalidomide name by Professor Handelsman is a scare tactic which must be refuted.

Neither ACP nor NxGen has any financial or pecuniary interest in AMI. AMI has no financial or pecuniary interest in ACP or NxGen.

I am the 100% owner of ACP. ACP has no written contracts with AMI or any of the doctors who work with AMI. Having worked closely with AMI for the last 2 years I do not believe that AMI is an unlicensed pharmaceutical manufacturer nor am I aware of any evidence of unlicensed manufacture.

I do however agree with Professor Handelsman that compounders cannot draw any information on a compounded product by referring to the ARTG listing of another product using the same ingredient in a different dose form. The ARTG is irrelevant to compounding except in instances where I would refer to it to check on the availability of a commercially produced product. I would be extremely happy if the debate shifted away from the ARTG to the more appropriate SUSDP listing which refers to the safety and efficacy of raw ingredients. All the ingredients that I use in compounded medicines for impotence are listed on the SUSDP listing with appropriate scheduling and warnings if required and the efficacy and safety of all of the ingredients used by AMI are well known and recorded on this listing.

Professor Handelsman's ill informed and extremely misleading comments with respect to the medication delivery process to AMI patients unfortunately displays his lack of knowledge in the area of pharmaceutical formulation , development, and regulation. I would respectfully suggest that he should concentrate on his area of expertise and refrain from making comments with respect to the area of pharmaceutical regulation and the extemporaneous pharmaceutical industry. In respect to the rules that govern compounding. There are guidelines as described by Mr Mackey from the Pharmaceutical Society of Australia (PSA) but they are just that, and have no basis in legislation. One point I wish to clarify however, contrary to Mr Mackey's comments, is that there are in the NSW Pharmacy Practice Act clear rules for the supply of medicines through the mail or internet. These include provision of a local call cost phone number to allow patients to call and have immediate access to a pharmacist. I have up to 7 pharmacists on staff at any time available to deal with any such queries or concerns. Also, Mr Gerry McInerney a member of the Pharmacy Board of NSW subcommittee on Compounding has stated to me that it is the Boards opinion that every compounded medication should have supplied with it a Consumer Medicine Information Sheet (CMI). AMI products have extensive patient information in the form of instructional CD's and DVD's and 20 page booklets outlining details of the medicines and their safe use. This material accompanies every prescription dispensed by ACP. It is also law under the NSW Poison Schedule and APF 21 Practice Guidlines that an extemporaneous product must have listed on its label all of the active ingredients and their strengths including its preservative. In the circumstances I do not understand Dr Malouf's difficulty in finding out the active ingredients of AMI's medications. He could have also used the usual method of enquiry when asking about medications and call the pharmacist directly by using the phone number which is on the medication packaging.

Submissions from PCCA (Professional Compounding Chemists of Australia Pty Ltd) , ACA (Australasian Compounders Association) and PSA to the Committee.

I feel that the committee should be aware of the financial interests and cross memberships of these three groups. I was disappointed at the omission of myself and my compounding operation from the list of invitees to the forum given that I am the largest supplier of impotence medicine in Australia.. Whilst I understand that the Pharmaceutical Society of Australia was of course invited to make a submission as one of the premier recognized pharmacy bodies in Australia I believe that compounding pharmacies with expertise in this field should have been included in the discussion. I note that the PSA's invited representative Mark Feldshue, who could not attend due to personal matters, is the l argest Australian

Shareholder in the predominantly American owned (86.88% US Ownership) franchise operation PCCA. PCCA provides membership to pharmacists after they pay a fee of approximately $20,000 (plus an annual ongoing fee) and attend a 4 day compounding course. This membership entitles members to a certificate, the right to be proclaimed a compounding pharmacist and the right to claim the title member of the Professional Compounding Chemists of Australia. **I have a concern for public safety arising from the operation of these compounding pharmacies.** Ironically these members are nearly always pharmacists and not chemists at all. I note that the PCCA has lodged a written submission to the Committee.

I also note that the Australasian Compounders Association (whose membership numbers 60 pharmacists out of a possible 300 modern compounders in Australia) ,has also lodged a written submission to the Committee. I note that the ACA's executive comprises Ms Jenny Giam , current technical officer of PCCA and author of the PCCA submission to the Committee , Ms Heidi Bova , ex technical officer of PCCA , Mr Bob Harrison , major shareholder of PCCA and Mr Mark Hickey, franchisee of PCCA.

Both PCCA and ACA are representing small compounders interests on the PMTWG a group advising the TGA on compounding regulation. There is no representation at all from proposed Class 3 compounders (largest compounders) on any of the advisory committee to the TGA thus bringing into serious doubt as to the balanced nature of any advice given to the TGA. They both claim that to the best of their knowledge their members do not supply compounded medicines to impotency clinics even though a quick look at the PCCA product catalogue shows that they have available all the products currently almost exclusively used for sexual dysfunction . They include clomipramine, prostaglandin E1, phentolamine, and apomorphine. In fact PCCA on their member formulary list have formulas to teach their members how to produce nasal sprays and other products for males and female sexual disorders such as "scream Cream" for women and Clomipramine Nasal Spray for Men to name a few. It also may come as a surprise to Ms Giam that one of her members, Australian Pharmacy Compounding (APC) is possibly the second largest supplier of compounded medicines to the Australian public through filling prescriptions from impotence clinics.

Further I would like to comment concerning the following statement on page three of PCCA's submission: "From documents available on the Australian Stock Exchange website relating to the proposed purchase by a public company of a company supplying compounded medicines to an impotence clinic in Australia. It appears that the clinic employing medical practitioners who prescribe impotence medicines may derive significant profit from the sales of those impotence medicines. "

The documents she refers to on the Stock Exchange Website in fact refer to the attempted takeover by Nusep Ltd, a publicly listed biotech company, of NxGen Pharmaceuticals Pty Ltd. (NxGen), a diverse product development and analytical company.

NxGen does not hold a pharmacy license or a TGA license to manufacture so it cannot and does not supply compounded medicines to an impotency clinic. Even though Ms Giam is not a fulltime practicing pharmacist she should be aware of the fact that it is illegal for a compounding pharmacy to supply compounded medicines to a doctor's clinic.

These facts were also misrepresented on the Channel 7 Today Tonight Show in exactly the same fashion earlier this year.

It is therefore my belief that the compounding industry in Australia is no longer comprised simply of the traditional compounders who mix the odd formula as supplied in the Australian Pharmaceutical Formulary. There is a new type of compounder being proliferated by American Franchise operators who use potent pharmaceutical chemicals and hazardous compounding techniques under the current regulations designed for traditional compounding. These modern compounders generally have no extra training in formulation and drug development and need a new set of regulations to guarantee availability and safe delivery of custom pharmaceuticals to the Australia general public. Currently TGA is considering the further regulation of the compounding industry based not on a quality, safety or good manufacturing practice basis but simply on number of prescriptions produced. With a suggested "cut off " number of 2000 prescription per month this would do absolutely nothing to assure public safety and guarantee the proliferation of small inexperienced operators operating under self regulation. The message being if you are inexperienced and compound medicines infrequently you don't need regulation but if you are experienced and compound hundreds of prescription a day you must be TGA licensed. If a number was to be used ,the number of prescriptions dispensed each month should be 250 after which the pharmacy premises should be licensed and the pharmacist undergoes some sort of formulation training. Compounders should be allowed to compound one month's anticipated supply so that they can batch test to assure safety of all compounds. This one simple concession, which is legal in the United States and the UK, would go along way to reducing all of the concerns of the Committee and the public in general about compounding.

If the Committee wishes any further information about the compounding practices of ACP I am very happy to help

Yours Sincerely

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