To the Committee Secretary, Senate Finance and Public Administration References Committee
14th July, 2011

Regarding the Inquiry on the Government's administration of the Pharmaceutical Benefits Scheme
Particularly regarding the Medicare and Pharmaceutical Benefits Schemes for hyperhidrosis axillaris with Botulinum Toxin (Botox)

To the Honourable Senators

I write this submission on behalf of the Surgical Subcommittee of the Australasian College of Dermatologists and the Australasian College of Dermatologists as a whole. My credentials in this area relate to being a published author in this field[1,2] and presenting on this subject at the World Congress of Dermatology in 2007. I helped establish the first clinic in Australia devoted to this disease entity at the Skin and Cancer Foundation of Victoria in 2009. I have presented in Canberra at PBAC on 30th May, 2006 on this topic when they were looking to list this treatment for this troublesome disease.

(A) Deferral of Listing of Medicines: (Botulinum Toxin) on the PBS

Botulinum toxin was recommended for PBS listing by the PBAC for severe primary hyperhidrosis of the axillae in March 2010 but deferred indefinitely from PBS listing in February 2011. The PBAC's recommendation recognized the seriousness of this disease, its impact on the lives of patients and the clinical need for botulinum toxin. There is no alternative PBS listed medication for severe primary hyperhidrosis of the axillae.

(B) Consequences for patients of this deferral

Section 1- Introduction: Epidemiology and burden of disease

The burden of hyperhidrosis runs deep as it is not just a problem with some mildly increased sweating, it is a disease pattern affecting 2-3% of the population to some degree[3] and that degree ranges from inconvenient to completely disabling. The totally disabling picture is given in many patient testimonials and I refer you to Chey-Anne

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[1] Goodman G. Diffusion and short-term efficacy of botulinum toxin A after the addition of hyaluronidase and its possible application for the treatment of axillary hyperhidrosis. Dermatol Surg. 2003 May;29(5):533-8; discussion 538.
[2] Marcella S, Goodman G, Cumming S, Foley P, Morgan V. Thirty-five units of botulinum toxin type A for treatment of axillary hyperhidrosis in female patients. Australas J Dermatol. 2011 May;52(2):123-6.
[3] Lear W, Kessler E, Solish N, Glaser D. An epidemiological study of hyperhidrosis. Dermato Surg 2007;33:569-575

Ellsum's poignant article in the Herald Sun last week and I will enclose a copy of this at the end of this submission.

Hyperhidrosis affects the axillae (armpits), which is the subject of this application but can also affect the palms, soles, face and other body areas. When the patient suffers a significant degree of hyperhidrosis, grades 3 or 4 on the National Hyperhidrosis Scale of Severity, this affects and disables their everyday life and is suggested to be as problematic to handle in their daily life as any chronic disease.

Hyperhidrosis Disease Severity Scale

☐ My (underarm) sweating is never noticeable and never interferes with my daily activities	Score 1
☐ My (underarm) sweating is tolerable but sometimes interferes with my daily activities	Score 2
☐ My (underarm) sweating is barely tolerable and frequently interferes with my daily activities	Score 3
☐ My (underarm) sweating is intolerable and always interferes with my daily activities	Score 4

The extent of the disease pattern in the palmar/plantar situation will literally cause the hands and feet to drip the entire day, making social interaction impossible and personal interaction and relationships problematic.

Axillary hyperhidrosis requires frequent changes of clothing and wearing of certain colours (usually black) to disguise the hyperhidrosis as well as placing paper and other towels in the axillae and visiting washrooms many times a day to utilise the dryers to temporarily camouflage their problem.

This type of sweating is not adequately allayed by antiperspirants and is not usually responsive to oral medications. The degree of hyperhidrosis, in studies has been shown to be at least 5 times the maximum output of a normal patient during exercise or stimulation.

Of the 3% of the population who suffer this condition, 50-75% of these patients exhibit axillary hyperhidrosis. The axillary hyperhidrotic patient tends to present around puberty, later than those with palmar/plantar hyperhidrosis and in about 40-

50% cases, there is a family history of this condition. One's sense of self is being formed at this time and the forging of interpersonal relationships this affliction will adversely influence a person's ability to develop and become a happy productive adult.

This could be considered a hidden problem as 38% of patients in one study had sought health care advice but most had not[4] as it is such a poorly understood disease by the public and medical practitioners alike often labelling these patients as anxious or depressed when it is their disease that is causing these symptoms not visa versa. Although this may be caused by other conditions such as diabetes and thyroid disease, this is a primary focal hyperhidrosis with the aetiology or cause unknown.

Section 2 - Quality of life and (non-PBS) alternatives to Bolulinum Toxin.

In quality of life studies[5,6], this has been found to cause less confidence in daily activities, a feeling of depression or unhappiness in almost 50% of patients. Close to 50% also had a change in leisure activities due to this condition, 1/3 experienced frustration with daily activities, 25% missed outings or events with family or friends, 60% were limited at work and in 40% of cases, it prevented a particular career path. Effectiveness at work was also limited in 38% of patients with almost 25% of patients stating they worked less carefully and accurately due to their excess sweating. Thus, if one was to perform an economic analysis, which is not my province, it would have to be said that these patients could be far more productively employed if this condition was adequately addressed.

I note the Honorable Nicola Roxon's response in Hansard to this issue, where she suggested there are other good alternatives available on the Government support schemes such as axillary excision and sympathectomy. There are medical options but these are not effective in most cases and are not supported by pharmaceutical benefits. Surgical options consist of excision of sweat glands in various forms, which are highly skilled procedures performed by a limited number of surgeons in Australia. When these are performed here, they are often not performed optimally as they are so uncommonly performed. It also has the morbidity and sequela of a scarred armpit, which, for an adolescent female, is not a desirable outcome and incurs potential complications and morbidities such as abscess formation, seromas (collections of fluid) and wound breakdown.

Endoscopic transthoracic sympathectomy is the other option that Minister Roxon has suggested as an alternative to the use of botulinum toxin for the treatment of

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[4] Strutton DR et al.
US prevalence of HH and impact on individuals with axillary HH.
Results of a national survey.
J Am Acad 2004;51:241-8.
[5] H Hamm, MK Naumann, NJ Lowe. Effect of Botulinum Toxin Type A on Quality of life Measures in Hyperhidrosis Patients, JEADV (2001) 15 (Suppl 2): p132
[6] Naumann, M.K., Hamm, H. & Lowe, N.J. Effect of botulinum toxin type A on quality of life measures in patients with excessive axillary sweating: a randomized controlled trial. British Journal of Dermatology 147,1218-1226..

hyperhidrosis but is problematic when performed for the axillae. There is a 65% recurrence rate, in one study[7], of axillary hyperhidrosis with compensatory hyperhidrosis (intractable and incurable sweating elsewhere in the patient), which can be embarrassing or disabling in up to 40% of patients,. It is a flawed operation for this area and is not recommended by most practitioners as a first line treatment, if at all for axillary hyperhidrosis. Palmar/plantar hyperhidrosis is better treated with this operation but it is certainly not considered as useful or safe for axillary hyperhidrsosis. I would note that this operation has been banned in Sweden, the country where it was first described and also Taiwan. Other countries are also considering its utility. I would suggest that it is not to be recommended as an alternative for patients as it is a morbid operation with many potential complications and side effects.

Section 3 – The Use of Botulinum toxin for hyperhidrosis

The use of botulinum toxin has been explored in many studies[1289]. It is a simple procedure but not one that a patient would undertake lightly.

It involves many injections of botulinum toxin, on approximately a 6 monthly basis, in to the axillae and no one would reasonably undergo 20 or more injections in to the axillae to resolve a slight sweating problem. It is a procedure that is performed for significant hyperhidrosis only.

The quality of life changes with this treatment have been studied and not only does it improve hyperhidrosis[10], but also bromhidrosis (or odour) in the axillae improves. The improvement is quite extraordinary in its efficacy and anhidrosis or virtually no sweating is found in many patients with a low chance of side effects and morbidity. All adverse events in the European study of hyperhidrosis were virtually the same as the placebo.

In a study[11] that involved a 16 month review of the number of treatments required, 38.6% required only 1 treatment, 44.9% required 2 treatments and 14.3% required 3 treatments. No patient required the maximum of 4 treatments in this study. Therefore I feel that it is probable that even 6-8 months, as suggested by the protocol would be the most that patients would require and there would be a subgroup that wouldn't

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[7] Long term results of ETS for upper limb hyperhidrosis. Grossot et al. Ann Thorac Surg 2003;75:1075-9.
[8] Martí N, Ramón D, Gámez L, Reig I, García-Pérez MA, Alonso V, Jordá E. Botulinum toxin type A for the treatment of primary hyperhidrosis: a prospective study of 52 patients. Actas Dermosifiliogr. 2010 Sep;101(7):614-21.
[9] Bhidayasiri R, Truong DD.J Neural Transm. 2008;115(4):641-5. Epub 2007 Sep 21.Evidence for effectiveness of botulinum toxin for hyperhidrosis.
[10] Skroza N, Bernardini N, La Torre G, La Viola G, Potenza C. Correlation between Dermatology Life Quality Index and Minor test and differences in their levels over time in patients with axillary hyperhidrosis treated with botulinum toxin type A. Acta Dermatovenerol Croat. 2011 Mar;19(1):16-20.
[11] Naumann M, Lowe NJ. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomised, parallel group, double blind, placebo controlled trial. BMJ. 2001 Sep 15;323(7313):596-9.

even require this. It is an extremely efficacious, useful and according to the PBAC's evaluation, cost effective therapy.

I feel this deserves further consideration and the Senate Committee should proceed with further consideration of what a severe, disabling, crippling and life changing disease this condition is and how simple, effective and relatively cheap to the community a therapy such as botulinum toxin is as a treatment.

(I) Any other matters

Section 1 - The place of Dermatologists in the provision of services.

It is probably worth noting that Dermatologists have authored most of the articles regarding the use of botulinum toxin for axillary hyperhidrosis, run specialist clinics, devoted societies, organise devoted meetings and have established guidelines of therapy. Dermatologists are the natural caregivers in this condition as exemplified by the hyperhidrosis clinic at the Skin and Cancer Foundation.

We note in the schedule that there is an item number for the provision of hyperhidrosis and has been on the Medicare schedule for many years. It has never had any approved providers who are able to issue this treatment. Dermatologists have rather bewilderingly not had access to it for these patients.

As a College we are perplexed that Government has not approved Dermatologists as the natural providers for this item number and this seem be an expeditious way to allow treatment fort some of these patients An item number that is not able to be utilised would seem to be a waste of an item number. It should be also noted that the PBAC, when recommending the PBS listing of BOTOX in March 2010, also recommended that Dermatologists be added to the Botulinum Toxin Program in recognition of the importance of their role in treating this disease.

Herald Sun
07/07/2011

Section 2 – Article on Chey-Anne Ellsum' s battle with this disease

Chey-Anne Ellsum has had botox injections under her armpits to stop her severe sweating condition. Picture: Ellen Smith Source: Herald Sun

TEENAGER Chey-Anne Ellsum can hold her boyfriend's hand and hug loved ones after being treated for a debilitating medical condition.

The 17-year-old's life has been turned around after her grandparents stepped in to fund Botox injections to stop her severe sweating, a condition called hyperhidrosis.

Now the Bairnsdale schoolgirl is bravely taking on Health Minister Nicola Roxon for refusing to publicly fund the injections, after dismissing her condition as "not life-threatening".

It is one of seven drugs Ms Roxon has deferred funding on the Pharmaceuticals Benefits Scheme, and the only one for which no alternative treatment is available.

Miss Ellsum and her mother, Elizabeth Trapani, are taking their fight all the way to Canberra to help thousands of Australians with the condition who can't afford the treatment.

"It's terrible to think I'm getting this when there are people out there suffering because they can't afford it. Not everyone has grandparents like me," Miss Ellsum said.

She has been cruelly taunted and bullied at school, knocked back on jobs, suffered depression, and been forced to wear several layers, even in the summer, to hide the sweat stains.

Ms Trapani said her daughter's condition, which had no known cause or cure, was "life-altering in the extreme".

"Chey-Anne could shower and scrub and by the time she'd towelled off, she'd smell like she'd been doing a full training run with a footy team," Ms Trapani said.

Miss Ellsum said: "It really controlled my life, but it's like a rock has been lifted off my shoulders, I can be a normal kid.

"My boyfriend and I have grown a lot closer, we've been together for a year and a half ... now for the first time I'll hold his hand for a whole day, and I'll hug my friends."

She had 30 botox injections in each armpit, at $2700, which would stop her sweating for six to 18 months. She was also using an experimental lotion, which cost $170 for 20ml, and lasted a month.

Miss Ellsum developed severely sweaty feet and hands at three, and by 13 it also affected her armpits.

Skin and Cancer Foundation Victoria head of surgery Assoc Prof Greg Goodman said: "It's a completely disabling disease. It's not the trifling little problem Nicola Roxon thinks it is."

Section 3 - Conclusion

Patients need access to both PBS subsidized Botox and to the MBS code for the procedure and Dermatologists being the natural providers for this item number and the experts in this area and should be added to the Botulinum toxin program to appropriately facilitate access. I would urge the Senate Committee and the Government in general to communicate with the Australasian College of Dermatologists regarding the future provision of these item numbers.

Yours sincerely

Associate Professor Greg Goodman

Dr Cathy Reid (secretary of the Australasian College of Dermatologists)

On behalf of the Australasian College of Dermatologists