Sleep Disorders Australia
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REGISTERED CHARITY
acnc.gov.au/charityregister

HYPERSOMNOLENCE AUSTRALIA
ABN 19 662 120 036

13th Feburary 2019

Standing Committee on Health, Aged Care and Sport
Sleep health awareness in Australia

Dear Mr Zimmerman

On 11th Feburary the committee heard that access to affordable medication for people with sleep disorders is limited and that this extends beyond Xyrem. Modafinil is only PBS listed as a second line treatment option for narcolepsy. Currently there are no medications on the PBS for idiopathic hypersomnia. Also, people with idiopathic hypersomnia cannot access schedule 8 medications, eg: Dexamphetamine (which is the first line treatment option for narcolepsy) without a narcolepsy diagnosis. Doctors get around this for people with idiopathic hypersomnia because there is a possibility that idiopathic hypersomnia is on a spectrum with narcolepsy. Therefore, people diagnosed with idiopathic hypersomnia are prescribed medication as if they have narcolepsy, providing, like those with narcolepsy, they meet the other PBS criteria for Modafinil which includes a Multiple Sleep Latency Test (MSLT) of <10mins, hence the necessity for onsite sleep studies.

Narcolepsy and idiopathic hypersomnia are rare diseases. The numbers in Australia should be relatively small, however Narcolepsy Australia has a fairly big membership of approx. 1300. Hypersomnolence Australia has a patient registry of people diagnosed with idiopathic hypersomnia in Australia and the number of people on it is edging towards 500. We have had 35 people added to it in the last 5 weeks. This is an entirely voluntary survey that people fill in if they find out about it (doctors do not refer patients to it) so this is a conservative estimate of the number of people diagnosed with idiopathic hypersomnia in Australia.

I gave a presentation at a short course at the Australasian Sleep Association conference in October 2018. The short course was “Assessment and Treatment of Excessive Daytime Sleepiness: Risk, Rewards and Patient Perspectives on Stimulant Use”. My presentation was titled “Challenges from the perspective of advocacy and support groups”. I would like to share parts of it, modified for relevance with the committee because I think it is important that the inquiry knows that when medications are not made available to patients on the PBS some doctors will do what they can to get around it and there are consequences of that. It is important to note that it shouldn’t be necessary for doctors to do that. There is Australian research to support the use of modafinil in mild to moderate sleep apnea. Ron Grunstein’s team at the Woolcock has done a few trials including “Modafinil improves daytime sleepiness in patients with mild to moderate obstructive sleep apnoea not using standard treatments”. So, we know that modafinil/armodafinil are useful medications for the excessive daytime sleepiness in people with sleep apnea either on its own or in conjunction with CPAP however people with sleep apnea do not have access to it on the PBS unless they are overdiagnosed with idiopathic hypersomnia, which in turn goes on the record as a narcolepsy diagnosis.

At the hearing Prof David Hillman said, "…in the case of modafinil, some years ago we went to the PBS to get it as a first-line medication for treatment of hypersomnolence disorders. We were told, on cost effectiveness grounds, no—that amphetamines were cheap and cheerful, and that's your first line. Amphetamines are a problematic drug. For my own family, my choice would be modafinil before amphetamines. That's one example of the sort of difficulty we've had." That difficulty shouldn't exist but I think it is time for the ASA to approach the PBAC again. Perhaps a recommendation from the Sleep Health Inquiry would help?

October 2018 - Assessment and Treatment of Excessive Daytime Sleepiness: Risk, Rewards and Patient Perspectives on Stimulant Use – Challenges from the perspective of advocacy and support groups. *Modified*.

I founded Hypersomnolence Australia (HA) 6 years ago because there were no organisations anywhere in the world that catered specifically to Idiopathic Hypersomnia. It was clearly necessary. HA has an idiopathic hypersomnia patient registry of people diagnosed with idiopathic hypersomnia in Australia, it has had nearly 500 people provide their details to it so far. I have been overwhelmed by the number of people that have been diagnosed with idiopathic hypersomnia in Australia. For a rare disease, those numbers definitely don't add up. As a result of what I found I later joined the board of Sleep Disorders Australia (SDA). Apart from a marketing and publications role I am also the coordinator for narcolepsy, disorders of hypersomnolence and circadian rhythm disorders. I speak to a lot of people prescribed stimulate medication and a lot of people who are "tired all the time".

Hypersomnolence Australia conducted a survey, Sleep Health in Patients with Sleep Disorders. 305 people responded to our survey. 57% of all responders had an idiopathic hypersomnia diagnosis - 32% of those have also been diagnosed with at least one other sleep disorder*. Of those 57% with an idiopathic hypersomnia diagnosis the majority do not have hypersomnia, that is, they do not report sleeping excessively. They do not regularly sleep any more than 7-8 hours per night. They do not nap regularly, and those that do nap, the length and frequency of the naps generally still doesn't make total sleep time in a 24 hour period exceed 7-8 hours. In fact only 7.5% said that they sleep for 10 hours and only 7% said that they sleep for more than 10 hours. These numbers are reduced when considering some of these people also report regularly waking up during the night. This means that the majority of people diagnosed with idiopathic hypersomnia do not fit the clinical definition of it. **Note: for an idiopathic hypersomnia diagnosis to be considered the excessive daytime sleepiness (EDS), hypersomnolence and/or MSLT findings are not better explained by another sleep disorder, other medical or psychiatric disorder, or the use of drugs or medications.*

Unfortunately, I was not surprised by our survey results. They are indicative of what we see. I receive a lot of correspondence from people diagnosed with idiopathic hypersomnia and it is not uncommon to find that a likely cause for the persons symptoms has not been ruled out and in some cases that the likely cause is rather obvious. In fact it is not unusual for someone to be diagnosed with sleep apnea and sometime later they are diagnosed with idiopathic hypersomnia despite not sleeping excessively (hypersomnia is excessive sleep), indeed despite having disturbed sleep (which should rule an idiopathic hypersomnia diagnosis out). In some cases this would be due to ignorance. Many Australian sleep specialists just don't know enough about non respiratory sleep disorders. However, we also know (I have had doctors tell me this) that in some cases this is done to enable doctors to prescribe stimulant medication that would either not ordinarily be available to them at all, for example in the case of schedule 8 medications, Dexamphetamine or Ritalin and in the case of Modafinil and Armodafinil would not be available to them under the PBS.

Whether doctors are labelling the EDS in sleep apnea or difficult to classify cases of EDS as idiopathic hypersomnia which end up on the record as narcolepsy or genuine cases of idiopathic hypersomnia are being 'coded' as narcolepsy, it creates many problems. It perpetuates ignorance in relation to the "genuine" diagnosis and it also renders any epidemiological study 'flawed'.

Australian government authorities (including the Therapeutic Goods Administration) rely on statistics from Australia's PBS and MBS yet these records do not reflect the true prevalence of idiopathic hypersomnia and narcolepsy. Therefore, one could get a false impression of an epidemic of "narcolepsy" when in fact if you were to isolate the true narcoleptics the number would be quite small. This also causes a number of problems for patient support and advocacy groups too. It creates problems when trying to advocate for medications to treat idiopathic hypersomnia and narcolepsy (narcolepsy cannot be considered an orphan disease when there are thousands and thousands of people diagnosed with it). Officially there are no medications on the PBS for idiopathic hypersomnia and people with idiopathic hypersomnia cannot access schedule 8 medications without a narcolepsy diagnosis. This needs to change and there is no reason it shouldn't. It also creates problems when trying to raise awareness of EDS in other medical conditions, and also the importance of CPAP compliance. If people are diagnosed with idiopathic hypersomnia to gain access to medications (rather than because they actually have the condition) they naturally attribute all of their daytime symptoms ie: excessive daytime sleepiness and cognitive dysfunction to that rather than the medical condition and/or lifestyle choices that are more likely to be causing those symptoms. Untreated moderate to severe sleep apnea can kill, yet I hear from people with sleep apnea who have stopped using their CPAP because they now believe they have idiopathic hypersomnia and that it's the idiopathic hypersomnia that is causing their EDS so they focus on 'treating' that.

I joined Sleep Disorders Australia because I realised that excessive daytime sleepiness is a major problem in Australia and that an idiopathic hypersomnia diagnosis (that goes on record as a narcolepsy diagnosis) used to access affordable prescription stimulate medication is clearly not a solution. However, the problem is bigger than Sleep Disorders Australia and Hypersomnolence Australia can manage without the support of doctors and other medical professionals including the Australasian Sleep Association (ASA). When doctors do not provide sufficient or accurate information to patients it falls on advocacy and support groups to do the job. In a perfect world that wouldn't be so bad. Unfortunately, there is nothing perfect in the sleep health community. Patient focused organisations in Australia do not receive funding. Organisations like Narcolepsy Australia and Hypersomnolence Australia do not even charge membership – we have no income source. Yet the burden on patient focused organisations to provide the level of information that is required is enormous. This is exacerbated by the fact that we wouldn't need to provide so much information if patients were not overdiagnosed (particularly without their knowledge) with idiopathic hypersomnia simply so that their doctor can prescribe modafinil under the PBS or have access to schedule 8 medications.

EDS symptoms and causes need more awareness. We need to work together to better educate patients that present with EDS. People that have a sleep disorder that causes EDS need to understand and accept the limitations of treatments including that CPAP treatment may reduce the number of apneas to a safe level however it does not always eliminate any or all of the EDS. It is called residual sleepiness. People need to know what residual sleepiness is and understand that it isn't that uncommon. And of course, these people need to have access to modafinil under the PBS to help them manage the residual sleepiness without doctors having to overdiagnosis them with another medical condition, idiopathic hypersomnia/narcolepsy.

Stimulant medications however are not miracle pills. People need to understand that consistent poor sleep, whatever the cause, will result in daytime symptoms including EDS and cognitive dysfunction and that there is no magic pill that will resolve that. In fact in some cases there is nothing at all that will resolve it but that doesn't automatically mean the patient has idiopathic hypersomnia. Idiopathic hypersomnia is not EDS and 'you don't know why' or it can't be resolved. While it may be tempting for a doctor to diagnose Idiopathic hypersomnia in cases of excessive daytime sleepiness of unknown cause, particularly when it means they can access PBS listed medication, this does a gross disservice to the many patients that in fact do not meet the clinical definition of idiopathic hypersomnia.

Idiopathic hypersomnia is a neurological disorder diagnosed by identifying key clinical features and by a thorough exclusion process. Unfortunately, a lack of awareness and proper understanding of what these key clinical features are and a less than thorough exclusion process coupled with a flawed test, namely the MSLT, can result in misdiagnosis and unnecessary prescription of stimulant medications. It also results in the underlying cause remaining unidentified and/or untreated. It can also result in people ending up with a medical diagnosis for something that is actually quite normal. Some people need to regularly sleep 9 hours or more, and if they get the amount of sleep they require they feel fine during the day however patients are not advised nearly enough to try sleeping longer on a regular basis to see if that resolves their daytime symptoms. They have instead ended up on stimulant medication and it has made their daytime symptoms worse.

I believe one of the problems is that people with EDS often have cognitive problems that result in poor communication skills, that is, they are not communicating their symptoms and experiences adequately enough for their doctor to make an informed decision on referral, diagnosis and treatment. That combined with a medical community (GP's) that have little to no education in sleep and specialists that have little to no education in non respiratory sleep disorders creates issues with regards to misdiagnosis and extended time to diagnosis. I would like to work with the ASA to improve education and awareness about EDS and I would like to work with the ASA and RACP to improve doctor/patient communication.

I would like to see better education for GP's and sleep specialists so that misdiagnosis and time to diagnosis is reduced. I also hope that it is a recommendation of this inquiry that medications currently approved for narcolepsy eg: Dexamphetamine and Modafinil/Armodafinil are also approved for idiopathic hypersomnia, ie: in their own right, without being prescribed under a narcolepsy diagnosis. And, also that Modafinil for sleep apnea is added to the PBS.

References:

Modafinil improves daytime sleepiness in patients with mild to moderate obstructive sleep apnoea not using standard treatments: a randomised placebo-controlled crossover trial. https://thorax.bmj.com/content/69/3/274.short

Idiopathic Hypersomnia - A Comprehensive Review
https://www.hypersomnolenceaustralia.org.au/single-post/2017/12/29/Idiopathic-Hypersomnia---A-Comprehensive-Review

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