The Route To Academic Success:

No Longer Just

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"It is a pity that doing one's best does not always answer."

— Charlotte Brontë, Jane Eyre

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CONTENTS:

ABREVIATIONS:

ADHD	Attention Deficit Hyperactivity Disorder
BZP	Benzylpiperazine
DMAA	1,3-dimethylamylamine
DMBA	4-methyl-2-pentanamine citrate
FDA	United States of America Food and Drug Administration
HSDD	Hypoactive Sexual Desire Disorder
LSD	Lysergic acid diethylamide
MAAC	Medicines Assessment Advisory Committee
MCC	Medicines Classification Committee
MODA	Misuse of Drugs Act 1975
NMA	New Medicine Application
OSAHS	Obstructive Sleep Apnoea Hypopnoea Syndrome
PESAC	Psychoactive Substances Expert Advisory Committee
PSA	Psychoactive Substances Act 2013
PSRA	Psychoactive Substances Regulatory Authority
SWDS	Sleep Work Shift Disorder
TDCN	Temporary drug class notices (under the Misuse of Drugs Act 1975)
The Convention	The United Nations Convention on Psychotropic Substances
US	The United States of America

INTRODUCTION:

"It is in vain to say human beings ought to be satisfied with tranquillity: they must have action; and they will make it if they cannot find it."
— Charlotte Brontë, Jane Eyre

A cup of coffee in the morning or two or six, a fish oil tablet with tea—the use of various substances to enhance one's performance is commonplace. The recent addition of synthetic compounds to this stimulant squad, however, is a relatively new phenomenon with the growing potential of making its way into the mainstream zeitgeist.[1]

Momentum for these engineered substances began in the 1960s with the discovery of piracetam, a substance synthesized in Belgium and intended for use as a sleep inducer.[2] Corneliu E. Giurgea, a Romanian professor of neurophysiology, saw the commercial potential in this experimental failure and began marketing piracetam in the early 1970s as a nootropic. The term 'nootropic' is derived from the Greek words 'noos' (mind) and 'tropos' (to bend) and used correctly, describes substances that:

1. enhance learning and memory;
2. facilitate the flow of information between cerebral hemispheres;
3. enhance resistance towards chemical and physical injuries;
4. lack the usual pharmacology of other psychotropic drugs;
5. have low toxicity; and
6. possess very few side effects.[3]

The term is now more colloquially used to describe any substance used for its neuro-enhancing properties and because of their increasing use by students, they are widely known as 'study drugs' or 'smart drugs'. When deadlines loom or as the library packs out for exam preparation, students pop these psychoactive pills in a similar fashion to downing a triple shot trim latte. There is a smorgasbord of study drugs already available on the market ranging from caffeine pills and green tea extracts, to racetams (for example, piracetam), modafinil (for example, Provigil), methylphenidate (for example, Ritalin) and dextroamphetamine (for

[1] Carole Cadwalladr "Students used to take drugs to get high, now they take them to get higher grades" *The Guardian* (15 February 2015) <http://www.theguardian.com/society/2015/feb/15/students-smart-drugs-higher-grades-adderall-modafinil>.
[2] Doru G Margineanu "A Weird Concept with Unusual Fate: Nootropic Drug" (2011) 182 Revue des Questions Scientifiques 33.
[3] At 36.

example, Dexedrine). Study drugs target cognitive functions including concentration and memory as well as non-cognitive functions such as mood, motivation and sleep.[4] Users of these drugs aim to amplify core capacities so as to more efficiently or effectively complete the task at hand.

While the risks and challenges of party pills have been deliberated for decades, study drugs have been kept under the regulatory radar. Students and young graduates, desperate to gain admission into the pinstriped prison,[5] are placing themselves under immense pressure to perform and as a result, the use of study drugs is on the rise. Because the risks and side effects of these substances are not well understood, an appropriate and durable set of regulatory controls is imperative. Importantly, the unresolved ethical challenges of neuro-enhancers mean that any rules or regulations must be flexible and able to accommodate attitude change when necessary. Postponing discussion until a consensus has been reached is inappropriate and the law must be forward thinking—proactive not reactive.

Chapter I seeks to examine the nature of study drugs and how they can be distinguished from treatment drugs and recreational drugs. Can a meaningful and logical line be drawn between coffee, No Doz tablets[6] and a prescription stimulant? If cheating is embodied by dishonesty, is the free and frank consumption of study drugs unfair? Do students feel pressured to take these substances? How can we weigh the risks and benefits of these drugs when their safety profiles are so unclear? These questions will be addressed with reference to both current and hypothetical enhancers.

Chapter II considers the legal landscape for drug use in New Zealand at both an international and domestic level. With our hands tied by the United Nations Convention on Psychotropic Substances 1971, changing the regulation of methylphenidate and dextroamphetamine (two common cotemporary study drugs controlled by the Misuse of Drugs Act 1975 (MODA)) is not recommended. The current regulation of other study drugs is split between the Medicines Act 1981 and the Psychoactive Substances Act 2013 (PSA). Amending either of these Acts is unnecessary, but an understanding of the differences between recreational drug use and academic drug use is important. Such an understanding allows one to appreciate that the rigid regulation of study drugs under the PSA may be inappropriate.

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[4] NF Wagner, J Robinson and C Wiebking "The Ethics of Neuroenhancement: Smart Drugs, Competition and Society" (2015) 6 International Journal of Technoethics 1.

[5] This phrase was coined by Lisa Pryor in her book *The Pin Striped Prison* (Picador Australia, 2008).

[6] No-Doz tablets contain 100mg of caffeine or approximately the same amount as a cup of coffee according to its promotional material: No Doz "Extend your Waking day with No Doz" No Doz <http://www.nodoz.com.au/more_about_nodoz.php>.

Chapter III investigates the imprecise interface and perhaps unanticipated interaction between the PSA and the Medicines Act. The reasons why the regulation of study drugs under the latter is more appropriate will be explored with particular reference to a hypothetical study drug ‘A-Plus’.

CHAPTER I:

What are study drugs and what ethical challenges do they pose?

"Conventionality is not morality."
— Charlotte Brontë, Jane Eyre

A. Enhancement vs treatment:

With prescription-only medications being among the most commonly used study drugs, the distinction between their treatment uses and their use by healthy adults as neuro-enhancements is an important one. A well-known example of this is the stimulant methylphenidate, which is prescribed in New Zealand for the treatment of 'attention deficit hyperactivity disorder' (ADHD)[7] or narcolepsy.[8,9,10] There is neither specific nor conclusive evidence on how methylphenidate produces its mental and behavioural effects but in its stimulation of the central nervous system, it may help increase attentiveness and decrease impulsivity.[11,12] Although there is some evidence suggesting its effects are limited when the user does not suffer from ADHD,[13,14] methylphenidate is increasingly being used as a focus enhancer by healthy adults. Another prescription-only stimulant and common study drug is modafinil, a wakefulness-promoting agent used for the treatment of 'sleep work shift disorder' (SWSD), 'obstructive sleep apnoea hypopnoea syndrome' (OSAHS) and narcolepsy. In the military, modafinil can be used to sustain performance in long operations.[15] Used in an academic setting, modafinil can help students fight fatigue and study for longer.

The line between enhancement and treatment is undoubtedly an elusive (if not impossible) one, in part because 'normal', 'healthy' and 'disease' are predominantly social rather than

[7] The argument that the medicalisation of a poor attention span (attention deficit hyperactive disorder) is a societal symptom of an over-diagnosis epidemic will not be looked at in much detail. 'Medicalisation' as a concept is briefly assessed in Chapter III.
[8] Novartis New Zealand Limited "Data sheet: Ritalin (methylphenidate hydrochloride)" Medsafe NZ <http://www.medsafe.govt.nz/profs/datasheet/r/RitalintabSRtabLAtab.pdf>.
[9] Novartis New Zealand Limited "Data sheet: Rubifen (methylphenidate hydrochloride)" Medsafe NZ <http://www.medsafe.govt.nz/profs/datasheet/r/rubifentabsrtab.pdf>.
[10] Janssen "Data sheet: Concerta (methlyphenidate hydrochloride)" Medsafe NZ <http://www.concerta.net/sites/default/files/pdf/Prescribing_Info-short.pdf#PAGE=30>.
[11] Novartis New Zealand Limited, above n 9.
[12] Janssen, above n 10.
[13] For example: CL Bray and others "Methylphenidate Does Not Improve Cognitive Function in Healthy Sleep-Deprived Young Adults" (2004) 52 J Investig Med 192.
[14] For example: AMW Linssen and others "Cognitive effects of methylphenidate in healthy volunteers: a review of single dose studies" (2014) 17 Int J Neuropsychopharmacol 961.
[15] Arthur Estrada and others "Modafinil as a replacement for dextroamphetamine for sustaining alertness in military helicopter pilots" (2012) 83 Aviat Space Environ Med 556.

scientific concepts. Regardless of the philosophical merits of this debate however, we live in a society whose health system often relies upon such a distinction. Take, for example, botulinum toxin type A (Botox), which is cosmetically used to prevent or reduce natural wrinkles but is also used as a treatment for haemorrhoids, irritable bladder and muscle contractures in cerebral palsy.[16] While the former would be considered unnecessary enhancement and attracts no government funding, the latter indications are examples of treatment. If certain criteria are met, botulinum toxin type A can be obtained for treatment at a low cost or for free under New Zealand's public healthcare system.[17]

Treatment implies restoration to some base line functioning whereas enhancement implies augmentation beyond what would be considered species-typical or normal for that particular individual.[18] Applying this oversimplified definition to the case of modafinil, taking the substance to manage sudden uncontrollable sleep episodes, blurred vision, sleep paralysis and hallucinations (symptoms of narcolepsy) would be considered treatment but a healthy student taking it to facilitate a 24 hour study day would be considered enhancement.

B. Do study drugs actually exist?

The excitable chatter surrounding study drug advantages must be kept in check in light of the emerging consensus that the measureable benefits of existing neuro-enhancing drugs are modest at most.[19] With regards to modafinil, the presiding Wolf of Wall Street,[20,21,22,23] a consensus on the value of its enhancement capabilities is yet to be reached.[24,25] In spite of this,

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[16] Botox "Data Sheet: Botulinum Toxin Type A" (December 2013) Medsafe NZ <http://www.medsafe.govt.nz/profs/datasheet/b/Botoxinj.pdf>.

[17] Ministry of Health "Publicly funded health and disability services" Ministry of Health NZ <http://www.health.govt.nz/new-zealand-health-system/publicly-funded-health-and-disability-services>.

[18] Fabrice Jotterand, Jennifer McCurdy and Bernice Elger "Chapter 11: Cognitive Enhancers and Mental Impairment: Emerging Ethical Issues" in *Rosenberg's Molecular and Genetic Basis of Neurological and Psychiatric Disease* (5th ed, Elsevier Inc, 2015) at 2.

[19] Irena P Ilieva and Martha J Farah "Enhancement stimulants: perceived motivational and cognitive advantages" (2013) 7 Front Neurosci.

[20] This is a reference to former stockbroker Jordan Belfort and his non-fiction memoir *Wolf of Wall Street* (Bantam Books, 2007).

[21] Robert Kolker "The Real Limitless Drug Isn't Just for Lifehackers Anymore" (31 March 2003) NYMag.com <http://nymag.com/news/intelligencer/modafinil-2013-4/>.

[22] Ruth Brown "Meet the Drug That's Powering Wall Street" (7 April 2013) Newser <http://www.newser.com/story/165490/meet-the-drug-thats-powering-wall-street.html>.

[23] Comstock Courtney "Wall Street's Favourite Drugs" (11 May 2011) Business Insider Australia <http://www.businessinsider.com.au/wall-streets-favorite-drugs-2011-5>.

[24] Ahmed Dahir Mohamed and Chris Roberts Lewis "Modafinil Increases the Latency of Response in the Hayling Sentence Completion Test in Healthy Volunteers: A Randomised Controlled Trial" (2014) 9 PLoS One e110639.

[25] Ahmed Dahir Mohamed "The Effects of Modafinil on Convergent and Divergent Thinking of Creativity: A Randomized Controlled Trial" [2014] J Creat Behav n/a.

modafinil's ability to promote wakefulness means its value as a performance maintaining study-aid[26] cannot be dismissed. Doubts over dextroamphetamine[27] and methylphenidate[28] as neuro-enhancers also exist, with research suggesting their effects may fade in healthy adults with normal baseline functioning.

Irrespective of such deliberations however, the general discussion on study drugs is not futile, as efficacy problems are likely to be soon solved by either new evidence or by the emergence of new substances.

C. Recreational setting vs academic setting:

The social context of drug use is an essential consideration when determining a drug's risk of harm.[29] This harm includes short and long term health risks as well as social harms, including the effects on public safety, productivity, personal relationships and general wellbeing.[30] Typical assessments of the repercussion of drug use routinely refer to users exhibiting aggressive and dysfunctional behaviour.[31] Descriptions of health harms often lead to further articulations of community breakdown, family violence, impaired productivity and a general reduction in the quality of life.[32] A salient feature of these assessments is that they commence on the assumption that non-medical drug use is (or begins as) a source of recreation. This assumption may have been appropriate in days bygone but with stimulants increasingly being used to check-in rather than check-out, these social implications need revisiting.

Conventional motivations for recreational drug use among students are relaxation, social lubrication and fun.[33] Because use is often characterised by patterns of poly-drug use (using a number of different substances simultaneously), consumption frequently leads to acute intoxication, a condition resulting in disturbed levels of consciousness, perception, judgement, behaviour, functions and responses.[34] In this way, and because feelings of

[26] Hazem Zohny "The Myth of Cognitive Enhancement Drugs" [2015] Neuroethics 1.
[27] Irena Ilieva, Joseph Boland and Martha J Farah "Objective and subjective cognitive enhancing effects of mixed amphetamine salts in healthy people" [2012] Neuropharmacology 496.
[28] Bray and others, above n 13.
[29] Ministerial Committee on Drug Policy *National Drug Policy 2007-2012* (Ministry of Health, 2007) at 60.
[30] At 60.
[31] JP Smith *The Social Impact of Drug Abuse* (United Nations International Drug Control Programme, 1995).
[32] At 16.
[33] Katherine Hammond "Recreational Drug Using Behaviour and Legal Benzylpiperazine Party Pills" (Victoria University of Wellington, 2008) at 7.
[34] World Health Organisation "Acute intoxication" (2015) World Health Organisation <http://www.who.int/substance_abuse/terminology/acute_intox/en/>.

intoxication are in fact what is sought, recreational drug users are highly susceptible to dependency and abuse.[35]

Motivations for study drugs are quite different. While the accuracy of the data available is likely to be distorted by inhibitions students may have regarding drug legality, common incentives for use include increasing concentration, prolonging productivity and improving efficiency.[36,37] Study drugs in an academic setting are a means to an end and could be seen as a manifestation of a student's demanding syllabus. This is aggravated by the immense pressure put on them by their parents and the competitive job market awaiting them. Study drugs are not about fun, they are about work.

The primary benefit of party pills is the facilitation of recreation itself. While this does have some inherent value, the potential benefits of study drugs are much greater. Safe, effective and enabling study drugs may facilitate the development of more skilled, knowledgeable and prolific communities. If study drugs have features that render them the pharmaceutical antithesis of party pills, the cost-benefit analysis we engage in for these drugs must tolerate a higher level of risk.

D. Common objections to neuro-enhancers:

1. Authenticity

A standard objection to study drugs is that they pose a threat to the authenticity of our achievements. Some shortcuts (such as calculators) are well tolerated in academia and others (such as plagiarism) are not. A formula sheet in a physics exam does not threaten the integrity of the examination but simply encourages students to redirect their time from memorising formulas to applying them. Both mental skills have merit and it is up to the examiner to determine what is being tested. Can this reasoning be extended to study drugs?

In entertaining this objection it is important to consider the analogy to doping in sport. Can a logical moral distinction be drawn between a marathon runner breaking the world record under the influence of steroids and a scientist solving the mystery of dark energy under the influence of stimulants? Perhaps the importance of process in academia is outweighed by the

[35] Hammond, above n 33, at 7.

[36] Christian J Teter and others "Illicit Use of Specific Prescription Stimulants Among College Students: Prevalence, Motives, and Routes of Administration" (2006) 26 Pharmacotherapy 1501.

[37] K Graff Low and AE Gendaszek "Illicit use of psychostimulants among college students: a preliminary study" (2002) 7 Psychology, Health & Medicine 283.

importance of the product?[38] Perhaps not. Nevertheless, society ceased celebrating Lance Armstrong when allegations of drugs use were confirmed but no one seems to care that Paul Erdos, a distinguished Hungarian mathematician of the 20th century, spent much of his adult life taking amphetamines.[39]

It would seem a consensus has been reached that bio-pharmaceutical enhancers in sport are undesirable. Such a consensus has not been reached for neuro-enhancers. Since their potential uses are widespread—from memory enhancers for exam preparation to focus enhancers in 11-hour surgical operations to wakefulness promoters in long-haul flights—when and where they are accepted may differ. It is the responsibility of educational institutes themselves to determine whether study drugs are tolerable but before they become conventional in any setting, it is imperative that an appropriate regulatory framework is in place.

2. Justice:

(i) Cheating:

Whether an action can be considered cheating depends on the rules of the game and the setting in which the game is being played. While picking up the ball is permitted in basketball, it is generally prohibited in football and while acetazolamide is prescribed by travel doctors for altitude sickness,[40,41,42] it is prohibited in sport.[43] In a similar fashion, internet access is permitted during study but generally prohibited during exams, and perhaps neuro-enhancers could be approved for late night essay writing but banned in spelling bee competitions. The value judgements necessarily required to set such parameters of a 'legal but limited' status should be made by the educational institutes themselves (as the World Anti-Doping Agency does for sport) and the role of regulators should be to minimise harm until such an ethical consensus is reached.

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[38] Rob Goodman "Cognitive enhancement, cheating, and accomplishment" (2010) 20 Kennedy Inst Ethics J 145.

[39] Paul Hoffman *The Man Who Loved Only Numbers: The Story of Paul Erdos and the Search for Mathematical Truth* (Hyperion Books, 1998) at ch 1.

[40] Samantha van der Sande "Staying Healthy at High Altitude - A Step Higher" (1 March 2013) University of Waikato <http://www.waikato.ac.nz/news-events/step-higher/2013/03/the-challenges-at-high-altitud.shtml>.

[41] Pharmacy Retailing (NZ) Limited "Data Sheet: Diamox (Acetazolamide)" (15 February 2010) Medsafe NZ <http://www.medsafe.govt.nz/profs/datasheet/d/Diamoxtabinj.pdf>.

[42] Family Doctor Editorial Team "Altitude Sickness - A Patient's Guide" <http://www.familydoctor.co.nz/index.asp?U=conditions&A=4420>.

[43] World Anti-Doping Agency *The Revised 2014 Prohibited List-International Standard Version 20* (The World Anti-Doping Agency, 2014).

(ii) Positional vs absolute goods:

The value of a positional good depends on limited access and if study drugs were only used to gain a positional advantage, their social utility would not offset the costs they may put on society.[44] Used instead for their intrinsic social value, study drugs can be likened to laptops, private tuition or even synthetic sunshine.[45] Before candlelight or lamplight, people worked and slept according to day light hours. The ability to remain productive at night is advantageous to the individual user and does create pressures on those who are not using it, but the intrinsic value also benefits the community collectively. The appropriate social response to synthetic sunshine was not to prohibit it, but rather to regulate it and improve access.[46]

The intrinsic social value in a better memory or an improved understanding of difficult concepts supports controlled access to study drugs. The competitive pressures they carry must be acknowledged, but provided they are not used purely for a positional advantage, they should not be automatically dismissed.

(iii) Distributive justice:

Distributive justice is problematic when the good in question is scarce and access depends on wealth. This would be the case if the study drug was used as a positional good as discussed above. For drugs that augment capacity in all individuals, limited access may instead serve to heighten the self-amplifying inequalities already faced by lower socio-economic groups. Alternatively, drugs that exhibit an inverted-U-shaped relationship between baseline functioning and effect[47] may in fact operate to level the distorted intellectual playing field, enabling those who were unlucky in the genetic lottery to become academically competitive.

Either way, until pharmaceutical patents expire and cheap generic equivalents become available, cost barriers are likely to exist. If prohibition or extensive restriction is to be justified by unequal access, the hypocrisy of permitting laptops, wireless internet or private tuition would need to be addressed.

[44] N Bostrom and A Sandberg "Cognitive Enhancement: Methods, Ethics, Regulatory Challenges" [2009] Sci Eng Ethics 311 at 328.

[45] John Harris "Chapter 16: Chemical Cognitive Enhancement: Is It Unfair, Unjust, Discriminatory, or Cheating for Healthy Adults to Use Smart Drugs?" in *Oxford Handbook of Neuroethics* (OUP Oxford, 2011) 265 at 268.

[46] At 268.

[47] Some studies indicate that this may be the case for methylphenidate: Bray and others, above n 13.

3. Coercion:

Intervention to improve neurological performance is nothing new. Caffeine, regular exercise and a balanced diet are all well-known and widespread examples of neuro-enhancing strategies for which negligible concerns as to coercion exist. Coercion with respect to study drugs requires certain fundamental criteria to be met.

First, the study drugs must confer a substantial academic advantage such that those who do not take them are at a noticeable disadvantage.[48] If a drug temporarily gave a student photographic memory, its value to that student for last minute essay memorisation would be substantial. If another drug enabled a student to stay awake and alert for 24 hours while simultaneously countering the effects of fatigue, its value would also be substantial. Unlike those who abstain from caffeinated drinks, the advantages conferred by these hypothetical study drugs are such that those who are not taking them may be at a substantial academic disadvantage. The application of evolution's 'Red Queen Principle' fittingly describes such a situation, as individuals would need to use study drugs in order to maintain their position relative to their competitors.[49] In Lewis Carroll's looking-glass land, the Red Queen exclaims, "here, you see, it takes all the running you can do, to keep in the same place".[50]

Second, a large proportion of students must be perceived to be taking them in order to perpetrate the perception that 'everyone' is using them. Note that hard evidence as to this widespread use is not actually necessary. No studies have touted results that a majority of students are currently using study drugs yet some students are already reporting a pressure to take them.[51]

Finally, the most successful students would need to be taking them in order to validate the concern than one cannot succeed unless they conform. Coffee, for example, is an extensively used nootropic on campus but because it is still possible for students to succeed without, coercion is not widespread.

An added difficulty in addressing study drugs is that substances could be unsafe and individuals may be coerced into adopting risk-taking behaviours in order to stay in the game.

[48] V Cakic "Smart drugs for cognitive enhancement: ethical and pragmatic considerations in the era of cosmetic neurology" (2009) 35 J Med Ethics 611 at 612.
[49] At 612.
[50] Lewis Carroll *Through the Looking Glass and What Alice Found There* (London: Oxford University Press, 1971) at ch 2.
[51] Catrin Einhorn, Jon Huang and Marc Lavallee/The New York Times "In Their Own Words: 'Study Drugs'" (9 June 2012) The New York Times <http://www.nytimes.com/interactive/2012/06/10/education/stimulants-student-voices.html?_r=0#/#1>.

The risk profile and the extent to which a substance in question improves performance will thus be the most crucial considerations in the ongoing ethical debate as to whether study drugs should be acceptable and if so, which ones.

4. Safety:

Neuro-enhancing drugs actively interfere with our central nervous system but there is limited research available on their side effects and virtually no research available on their long-term health implications. It is largely in light of this limited knowledge that the ethical seesaw swings. Are occasional consumers of methylphenidate at an increased risk of cognitive decline in their old age? Will serial users of modafinil face hypothalamic dysfunction? How does aniracetam use affect healthy Caucasian vegans in their second trimester?

While unknown side effects are always a risk of drug use, the risks are particularly high with study drugs as they are the subjects of very limited clinical trials and statements as to their long-term effects are speculative at best.

Of the limited clinical trials that have occurred or are being conducted, most are concerned with the effects of neuro-enhancing pharmaceuticals as treatment options for the cognitively impaired. While some studies have been conducted to explore the effects of neuro-enhancers on healthy non-sleep deprived individuals,[52,53] data from healthy users in the community cannot be accurately collected. Widely used contemporary study drugs such as methylphenidate, dextroamphetamine and modafinil have a prescription-only classification status and in prescribing these substances, doctors operate under strict guidelines and regulations. Because they cannot be freely distributed and because a social stigma might exist around their use, individuals may exaggerate or confabulate symptoms in order to obtain these substances under the guise of a recognised medical disorder.[54,55] This not only contaminates the data sets of other disorders like ADHD, SWSD and OSAHS, but it prevents the collection of meaningful enhancement data. Without this data, no reliable conclusions about the use of neuro-enhancing pharmaceuticals in healthy individuals can be drawn.

[52] For example: Bray and others, above n 13.

[53] For example: RM Battleday and AK Brem "Modafinil for cognitive neuroenhancement in healthy non-sleep-deprived subjects: a systematic review" [2015] European Neuropsychopharmacology.

[54] Myriam J Sollam, John D Ranseen and David T Berry "Detection of Feigned ADHD in College Students" (2010) 2 Psychological Assessment 325.

[55] Randy A Sansone and Lori A Sansone "Faking Attention Deficit Hyperactivity Disorder" (2011) 8 Innov Clin Neurosci 10.

Society does readily allow individual autonomy to override risk, for example the risk of almost certain death following a parachute malfunction while skydiving. The risks inherent in adventure sports are, however, quite discernible and limited to the health and safety of the individual. Conversely, the risks of study drugs are largely unknown and because of abuse potential and behavioural side effects, they may cause wider community harms. Another important distinction here is the differing benefits that the two activities pose. While the benefit of skydiving is recreational enjoyment, the benefit of taking study drugs may be academic advancement and, by extension, employment. While most sane individuals would not unwillingly succumb to skydiving peer pressure, many may risk their health if a job or scholarship opportunity is on the cards.

In order to determine which study drugs should be permitted and how widespread their availability should be, the safety profile of the drug in question will be determinative. Importantly, while safety concerns may justify the prohibition or heavy restriction of one drug, it may not justify the prohibition or heavy restriction of another. In the interim, while these safety profiles are being explored and understood, unknown risks justify substantial regulation and it is in line with New Zealand's harm-minimisation policy on drug use[56] to promote supervised and safe access to such substances.

As the self-proclaimed guinea pig generation, regulation of study drugs needs to be ongoing, evidence-based and the result of a continuing dialogue between the medical profession, educational providers, policy makers and the general public.[57]

[56] Ministerial Committee on Drug Policy, above n 29.

[57] Barbara Sahakian and Sharon Morein-Zamir "Professor's little helper" (2007) 450 Nature 1157.

CHAPTER II:

Does New Zealand's current legal regime appropriately regulate study drugs?

"Laws and principles are not for the times when there is no temptation."

–Charlotte Brontë, Jane Eyre

A. Introduction:

While the jury may still be out as to whether study drugs are compatible with society's ethical standpoint, the need for appropriate regulation is unequivocal. Even if educational institutes were in unanimous agreement that pharmaceutical enhancements are undesirable, a legal framework is nonetheless necessary in the event of an attitude change. Further, reasons for condemning their use in an educational setting may not be applicable to their wider use in settings such as aviation or late night surgical operations.

There are a number of Acts in New Zealand that regulate substances intended for human consumption. Most notable for this discussion are:

- The Misuse of Drugs Act 1975 (and the Misuse of Drugs Regulations 1977)
- The Food Act 1985 (and the Dietary Supplements Regulations 1985)
- The Psychoactive Substances Act 2013
- The Medicines Act 1981

Together these target a number of different types of substances and a number of different settings for their use but an examination as to whether our existing regime adequately addresses the unique challenges of study drugs is needed given that 'study drugs' does not seem to have been a widely contemplated concept among New Zealand lawmakers.

In order to properly analyse whether we have an appropriate regulatory regime, it is important to look at both contemporary and future study drugs. The variety of study drugs that will be contemplated can be distinguished depending on how they are regulated and specific examples will be used to add colour to the description of our current legal framework. Examples of study drugs that will be considered include:

- Controlled drugs—methylphenidate and dextroamphetamine
- Prescription-only approved drugs—for example, modafinil
- Prescription-only unapproved drugs—for example, piracetam (a nootropic racetam)
- Illegal drugs—for example, sunifiram
- Next generation drugs

The regulation of all study drugs under one regime may not be practical given that these substances vary significantly in risk and areas of application. As demonstrated by the regulation of other health products, the legal distinctions made between higher and lower risk substances enable regulatory bodies to engage in review processes that are proportional to risk. Methylphenidate, dextroamphetamine and modafinil all have recognised therapeutic uses but are regulated according to risk. All are regulated as medicines under the Medicines Act[58] but because of their higher risk profiles, methylphenidate and dextroamphetamine face additional regulations as controlled drugs under the MODA.[59] All nootropic racetams that Medsafe[60] are aware of (such as piracetam and aniracetam) are now scheduled as 'prescription-only' medicines, although no medicines containing these substances are currently approved. Sunifiram is a new kid on the nootropic block and is unclassified under the Medicines Act and therefore illegal under the PSA.[61]

An examination of this range of substances will enable us to determine whether our patchwork system is watertight and able to appropriately deal with new psychoactive study drugs.

B. United Nations Convention on Psychotropic Substances 1971:

Before turning to examine New Zealand domestic law, regard must be given to our international obligations and the constraints they put on our legislative liberties.

New Zealand signed the United Nations Convention on Psychotropic Substances (the Convention) on 13 September 1971. The Convention is one of three main international drug control conventions and was signed in response to the inadequacy of the Single Convention on Narcotic Drugs 1961 to control the diversifying and expanding number of psychotropic drugs. Parties to the Convention recognise that public health and social problems result from the abuse of certain psychotropic substances and agree that the use of such substances should be limited to legitimate medical purposes.[62] Classification of substances is risk dependant with restrictions on use determined accordingly.

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[58] Medicines Regulations 1984, Schedule 1.

[59] Misuse of Drugs Act 1975, Schedule 2.

[60] Medsafe is New Zealand's medicines and medical devices safety authority. They are responsible for the regulation of medicines and medical devices in New Zealand.

[61] Sunifiram is not a controlled drug or a medicine but falls within the ambit of the Psychoactive Substances Act 2013 because of its stimulant effects. It is not necessary for the Psychoactive Substances Regulatory Authority to expressly acknowledge sunifiram for it to be caught.

[62] Convention on Psychotropic Substances 1971, Preamble, retrieved from <https://www.unodc.org/unodc/en/treaties/psychotropics.html?ref=menuside>.

Schedule I drugs are considered highly dangerous with grave risks to public health and negligible or disputed therapeutic value (for example lysergic acid diethylamide (LSD)).[63] Schedule II drugs are also dangerous but given they have some recognised therapeutic value, their distribution and use is more widely tolerated (for example, methylphenidate). Schedule III and IV drugs are generally considered to be therapeutically valuable and these substances are divided based on their risk of abuse and dependency.[64] New psychotropic substances can be added to the Convention by the Commission on Narcotic Drugs on recommendation of the World Health Organisation according to the provisions laid out in Article 2. Movement between schedules in light of new evidence is also permitted.

Article 2 – Scope of control of substances

1. *If a Party or the World Health Organisation has information relating to a substance not yet under international control, which in its opinion may require the addition of that substance to any of the Schedules of this Convention, it shall notify the Secretary-General and furnish him with the information in support of that notification. The foregoing procedure shall also apply when a Party or the World Health Organisation has information justifying the transfer of a substance from one Schedule to another among those Schedules, or the deletion of a substance from the schedules.*

   ...

4. *If the World Health Organisation finds:*

   (a) That the substance has the capacity to produce

   (i) 1. A state of dependence, and

   2. Central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood, or

   (ii) Similar abuse and similar ill effects as a substance in Schedule I, II, III or IV, and

   (b) That there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control, the World Health Organisation shall communicate to the Commission an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy, together with recommendations on control measures, if any, that would be appropriate in the light of its assessment

[63] Mark AR Kleiman and James E Hawdon *Encyclopedia of Drug Policy* (SAGE Publications, 2011) at 169.
[64] At 169.

5. *The Commission, taking into account the communication from the World Health Organisation, whose assessments shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may add the substance to Schedule I, II, III or IV. The Commission may seek further information from the World Health Organisation or from other appropriate sources.*

6. *If a notification under paragraph 1 relates to a substance already listed in one of the Schedules, the World Health Organisation shall communicate to the Commission its new findings, any new assessment of the substance it may make in accordance with paragraph 4 and any new recommendations on control measures it may find appropriate in the light of that assessment. The Commission, taking into account the communication from the World Health Organisation as under paragraph 5 and bearing in mind the factors referred to in that paragraph, may decide to transfer the substance from one Schedule to another or to delete it from the Schedules.*

Efficacy aside, dextroamphetamine and methylphenidate are common study drugs[65,66,67] and both substances are currently listed in Schedule II of the Convention; dangerous but with some recognised therapeutic value. Schedule II Convention drugs can only be used, dispensed or administered in the authorised exercise of therapeutic or scientific functions and can only be supplied or dispensed for individual use pursuant to a medical prescription.[68] Prescriptions must be issued in accordance with sound medical practice and subject to strict regulations so as to protect public health and welfare.[69]

It is highly unlikely that either of these substances will be removed from the Convention as their side effects when misused are not well investigated, their therapeutic value is considered limited and their risk of harm may be increasing with consumption on the rise.

1. Spotlight: Dextroamphetamine

Dextroamphetamine is a stereoisomer of the amphetamine molecule, and like all amphetamines, it stimulates the central nervous system by increasing the levels of dopamine

[65] Shaheen E Lakhan and Annette Kirchgessner "Prescription stimulants in individuals with and without attention deficit hyperactivity disorder: misuse, cognitive impact, and adverse effects" (2012) 2 Brain Behav 661.
[66] Kari Benson and others "Misuse of Stimulant Medication Among College Students: A Comprehensive Review and Meta-analysis" (2015) 18 Clinical Child and Family Psychology Review 50.
[67] Elaine A Moore *The Amphetamine Debate* (McFarland, 2010) at 163.
[68] UN Convention on Psychotropic Substances 1971, Article 9(1).
[69] UN Convention on Psychotropic Substances 1971, Article 9(2).

and norepinephrine in the brain.[70] The sought after 'high' of illicit amphetamine use includes feelings of wakefulness, hyperactivity, arousal, elation and euphoria.[71] Although dextroamphetamine is not as potent as methamphetamine (which has undergone an additional methylation and is thus processed more quickly and powerfully by the body), very high doses of amphetamines can produce similar effects.[72] The adverse side effects of amphetamine use include increased heart rate, irregular heart beat, palpitations, shortness of breath, headaches, paranoia and hallucinations—to name a few.[73]

As a prescription medication, dextroamphetamine is used to treat ADHD, bringing the focus and impulsivity control of those suffering from below average to normal. As a study drug, students hope that dextroamphetamine will increase their attention span, alertness and enjoyment of work to a level that enables them to sustain or increase productive study for longer than normal. The substantial overlap between medical use and academic use is obvious.

While low and controlled doses of dextroamphetamine do not pose a serious risk of abuse, prolonged use in high euphoria-inducing doses (most likely from recreational abuse) can lead to tolerance,[74] psychological dependence[75] and the possible development of toxic psychosis.[76] The temptation of recreational drug users to mix dextroamphetamine with other amphetamines and amphetamine-type stimulants (poly-drug use) is also of serious concern and unsurprisingly, there is very little reliable information available on the side effects of such concoctions.[77]

Due to its addictive potential and the risks it poses if used improperly, it is highly unlikely that dextroamphetamine will be removed or rescheduled under the Convention.

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[70] Stephen Maisto, Mark Galizio and Gerard Connors *Drug Use and Abuse* (Cengage Learning, 2014) at 142.
[71] SM Berman and others "Potential adverse effects of amphetamine treatment on brain and behavior: a review" (2008) 14 Mol Psychiatry 123.
[72] Michael Larson "Amphetamine-Related Psychiatric Disorders: Background, Pathophysiology, Epidemiology" (23 July 2013) <http://emedicine.medscape.com/article/289973-overview>.
[73] New Zealand Drug Foundation "Methamphetamine Health Effects" (2015) New Zealand Drug Foundation <https://www.drugfoundation.org.nz/methamphetamine/health-effects>.
[74] MM Glatt *A Guide to Addiction and Its Treatment* (Springer Science & Business Media, 2012) at 129.
[75] At 129.
[76] At 129.
[77] Gregory Snodgrass and Loyd S Wright "Alcohol and Poly-drug Use among College Undergraduates" (1983) 21 NASPA Journal 26.

2. Spotlight: Methylphenidate

Methylphenidate also increases the levels of dopamine and norepinephrine in the brain and its prescription uses and study drug allure are largely comparable.[78] Taken orally and in the correct dosage, methylphenidate does not pose a high risk of addiction but as with dextroamphetamine, if taken in high doses or administered improperly (insufflated[79] or injected), it can be addictive and dangerous.[80]

The United Nations International Narcotics Control Board is responsible for the implementation of the Convention and has recently explored the high abuse potential for methylphenidate. In their 2014 Annual Report,[81] they expressed a growing concern for skyrocketing consumption levels which reached roughly 71.8 tonnes in 2013, approximately a 66% increase from the previous year.[82] This increase was attributed to a number of possible causes including the increased number of patients diagnosed with ADHD, misdiagnosis of ADHD, lack of appropriate guidelines around methylphenidate prescriptions and the increased use of the substance among young adults. In its report, the Board urged Governments to limit consumption of methylphenidate to "actual medical needs"[83] and to "exercise vigilance to prevent possible misdiagnosis of ADHD and inappropriate prescribing".[84] The report also expressly acknowledges the increasing tendency of students to use methylphenidate while studying despite limited evidence that it is effective and despite them knowing very little about health risks and appropriate dosage.[85]

In light of the growing threat of abuse, it is also highly unlikely that methylphenidate will be removed or rescheduled under the Convention.

C. Misuse of Drugs Act 1975:

New Zealand's obligations under the Convention are translated into domestic law by the MODA, New Zealand's primary tool for regulating illegal drug use. The MODA classifies moderate to high-risk drugs into three tiers, much like the Convention, "according to the risk

[78] R Kuczenski and DS Segal "Effects of methylphenidate on extracellular dopamine, serotonin, and norepinephrine: comparison with amphetamine" (1997) 68 J Neurochem 2032 at 2032.
[79] Insufflation describes the act of blowing a powder, gas or vapour drug into a body cavity: Merriam-Webster Online Dictionary "Insufflation" (1 Oct 2015) <http://www.merriam-webster.com/dictionary/insufflation>.
[80] University of Utah Health Sciences "Ritalin and Cocaine: The Connection and the Controversy" Genetic Science Learning Centre <http://learn.genetics.utah.edu/content/addiction/ritalin/>.
[81] International Narcotics Control Board *Report of the International Narcotics Control Board for 2014* (United Nations Publication 2015).
[82] At 38.
[83] At 39.
[84] At 39.
[85] At 39.

of harm the drug poses to individuals, or to society, by its misuse".[86] Criminal sanctions vary in severity according to the classification.

Section 4(B)(2) sets out a range of matters to which the Minister (on advice of the Expert Advisory Committee on Drugs) must give regard when classifying or reclassifying a drug.

> *Section 4(B)(2)*
>
> *(a) the likelihood or evidence of drug abuse, including such matters as the prevalence of the drug, levels of consumption, drug seizure trends, and the potential appeal to vulnerable populations; and*
> *(b) the specific effects of the drug, including pharmacological, psychoactive, and toxicological effects; and*
> *(c) the risks, if any, to public health; and*
> *(d) the therapeutic value of the drug, if any; and*
> *(e) the potential for use of the drug to cause death; and*
> *(f) the ability of the drug to create physical or psychological dependence; and*
> *(g) the international classification and experience of the drug in other jurisdictions; and*
> *(h) any other matters that the Minister considers relevant.*

The inclusion of "international classification and the experience of the drug in other jurisdictions"[87] as a determinative factor has been criticised as irrelevant for the determination of an appropriate maximum penalty for misuse.[88] Importantly, however, these same factors determine the way in which the drug is regulated and directly acknowledging the significance of our international obligations indicates that the legislature does not intend to deviate from the standards and classifications under the Convention.

The most important application of the MODA to study drugs is the controls it places on dextroamphetamine and methylphenidate. While it could be applied to other popular study drugs in the future, only its application to these substances will be looked at in any depth.

1. Dextroamphetamine and methylphenidate:

Corresponding to their Schedule II classification under the Convention, dextroamphetamine and methylphenidate are both listed as Class B 'high-risk' substances under the MODA and are subject to strict controls. While s 25 of the Medicines Act does permit off-label

[86] Misuse of Drugs Act 1975, s 3A.
[87] Misuse of Drugs Act 1975, s 4B(2)(g).
[88] Law Commission *Controlling and Regulating Drugs : A Review of the Misuse of Drugs Act 1975* (NZLC R122 2011).

prescribing of an approved medicine (even if it is a controlled drug), provided that the health professional complies with all restrictions in the Misuse of Drugs Regulations 1977, reg 22[89] sets further prescribing parameters for certain controlled drugs that are particularly liable to abuse. Under reg 22, the supply or administration of certain drugs to any person except in the circumstances approved by the Minister of Health is strictly prohibited.[90] Similar restrictions for these controlled substances operate in Australia.[91,92]

Both dextroamphetamine and methylphenidate are affected by reg 22 due to their high susceptibility to abuse. In New Zealand, the prescription of dextroamphetamine is strictly limited to the treatment of narcolepsy and ADHD.[93] Methylphenidate is similarly restricted but with the added approved use in palliative care.[94] The natural implication of these restrictions is that neither dextroamphetamine nor methylphenidate can be legally prescribed in New Zealand for their off-label use as neuro-enhancers.

Restrictions on the use of dextroamphetamine and methylphenidate in New Zealand are unlikely to change in the near future. Experts have recommended that regulations remain strict as the known risks of harm outweigh the potential benefits of making these substances more widely available.

2. Are the MODA restrictions being adhered to?

For a student to obtain dextroamphetamine or methylphenidate in New Zealand for use as a study drug they would either have to acquire it from someone with a lawful prescription or they would have to confabulate symptoms in order to obtain a false clinical ADHD diagnosis.

Although authorisation for a prescription must come from a specialist psychiatrist or paediatrician,[95] the diagnostic criteria used by these professionals[96] is extraordinarily ambiguous and is naturally contingent on the honest word of the patient or parent. Such

[89] Amended by the Misuse of Drugs Amendment Regulations 2001.
[90] Misuse of Drugs Regulations 1997, s 22.
[91] Drugs and Poisons Regulation Group *Schedule 8: permit requirements plus notification requirements* (Victoria Department of Health, 2010).
[92] Department of Health "Prescribe a psychostimulant medication - Medical Practitioners" (9 June 2015) NSW Government <http://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/prescribe-psychostimulant.aspx>.
[93] Medsafe "Medicines with Restrictions" (17 February 2015) Medsafe NZ <http://www.medsafe.govt.nz/profs/riss/restrict.asp#Dexamphetamine>.
[94] Medsafe, above n 93.
[95] Ministry of Health *New Zealand Guidelines for the Assessment and Treatment of Attention-Deficit/Hyperactivity Disorder* (Ministry of Health, 2001).
[96] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (4th edition) (Washington DC: American Psychiatric Association, 1994).

criteria include things like "often does not seem to listen when spoken to"[97] and "dislikes engaging in tasks that require sustained mental effort".[98] Due to the lack of any objective tests to validate a diagnosis, it is likely that prescriptions for ADHD medication are frequently given to individuals whose base line functioning does not actually deviate very significantly, if at all, from 'normal'.[99,100] Due to the legality issues of obtaining controlled drugs off-label, ample evidence to substantiate this claim is understandably lacking.

If the ADHD diagnostic criteria were more strictly enforced, the trending tendency to 'doctor shop'[101] is likely to worsen, as users would visit a larger number of clinics until they successfully obtained an ADHD diagnosis. The resulting erosion of patient-doctor trust is a largely unavoidable consequence of such strict regulation but reform is not desirable for these two substances. A public health campaign to inform and educate individuals about the legal and health consequences may effectively deter some users but confabulation tendencies are likely to continue until an objective neurological test is available. Liberalising the availability of methylphenidate or dextroamphetamine would be at odds with the tenor of our international obligations but the repercussions of such strict regulation can inform our discussion going forward. If healthcare professionals are to be involved in the provision of study drugs, individuals must be honest about their reasons for requesting them.

Dextroamphetamine and methylphenidate are two controlled substances that are widely used as neuro-enhancements. But what of new study drugs that are yet to enter the market?

3. Application of the MODA to other study drugs:

Study drugs should only be considered for scheduling under the MODA if they pose a moderate to high risk of harm to the individual and society. This is not and will not be the case for all study drugs. Further, the MODA's application to new substances has been well considered in New Zealand and the conclusion was reached that for new substances, it lacks teeth.

If a new substance can be shown to have chemical similarity to a controlled drug then it is classified as a controlled drug analogue and is treated as a Class C drug. While this prima

[97] Ministry of Health, above n 95, at 57.
[98] At 57.
[99] Sollam, Ranseen and Berry, above n 54.
[100] Sansone and Sansone, above n 55.
[101] M Soledad Cepeda and others "Doctor shopping for medications used in the treatment of attention deficit hyperactivity disorder: shoppers often pay in cash and cross state lines" (2015) 41 Am J Drug Alcohol Abuse 226.

facie addresses the problem of new synthetic drugs being created with slight molecular differences to controlled drugs, it is in reality a feeble mechanism of control. Not only does it overlook the fact that the new substance may have an entirely distinct impact on the central nervous system, but there is also a great deal of uncertainty with respect to the degree of structural similarity necessary. As such, classification as a controlled drug analogue can be both an inaccurate representation of the risk of harm that the substance poses and also necessarily involves the subjective judgement of the chemical analyst.

For drugs that are chemically distinct, the MODA is inapplicable unless it is explicitly brought within one of the MODA schedules. The case of the recreational drug benzylpiperazine (BZP) illustrates the inevitable time lag between a harmful drug entering the market and it being brought within the ambit of the MODA. BZP started appearing in the New Zealand party scene in about 2000[102] but it was not until June 2005 that it was classified as a 'restricted substance' under the MODA[103] and it was not until March 2008 that it was reclassified as a Class C drug under the same Act.

In 2011, amendments to the MODA[104] were made to enable the Minister of Health to pass temporary drug class notices (TDCN) for any substance believed to pose a risk of harm to individuals or society. The issuing of a TDCN meant any substance could be treated as a Class C controlled drug for 12 months while the risk of harm was assessed and appropriate classification, if any, was determined. This was an effective method of control once regulators became aware of the substance in question, but there was still ample room for a problematic time lag between market release and Ministry realisation. The TDCN scheme has now been repealed by the PSA.

D. Psychoactive Substances Act 2013:

The PSA was enacted to end the Tom and Jerry[105] between regulators and producers of new psychoactive substances. Its purpose is to "regulate the availability of psychoactive substances in New Zealand to protect the health of, and minimise harm to, individuals who use psychoactive substances".[106] The PSA achieves this purpose by establishing a pre-market

[102] New Zealand Drug Foundation "Benzylpiperazine (BZP)" (2015) New Zealand Drug Foundation <https://www.drugfoundation.org.nz/party-pills/what-it-is>.
[103] Misuse of Drugs Amendment Act 2005, Part 3: repealed, on 18 July 2013, by section 110 of the Psychoactive Substances Act 2013.
[104] Misuse of Drugs Act 1975 s 4 C: repealed, on 18 July 2013, by section 110(1) of the Psychoactive Substances Act 2013.
[105] This is a reference to the cartoon of the same name: Joseph Barbera and William Hanna *Tom and Jerry* (Cartoon, Warner Bros Animation, 1940). Tom is a cat and Jerry is a mouse.
[106] Psychoactive Substances Act 2013.

approval system for psychoactive products, similar to that of medicines under the Medicines Act, so that proof of no more than low-risk of harm is required before they can be sold. Higher-risk substances continue to be controlled by the Expert Advisory Committee on Drugs under the MODA.

Although the PSA's purpose does not refer to any setting in which the substance is used, there are strong indications that the legislature considers new psychoactive substances to be broadly synonymous with recreational drugs. One such indication of this is an online publication updated in June 2015 where the PSRA states that with respect to new psychoactive substances, "you might know such drugs as herbal highs, legal highs, synthetic cannabis, legal recreational drugs".[107] This suggests that the use of these substances in an academic setting is not being considered by the regulator and may not have even been properly considered by the legislature.

1. Meaning of 'psychoactive substance':

The meaning of 'psychoactive substance' under the PSA is circular, defined "as a substance, mixture, preparation, article, device, or thing that is capable of inducing a psychoactive effect"[108]. 'Psychoactive effect' is defined as "the effect of the substance on the individual's mind".[109] The court in *Mihinui v Police*[110] acknowledged this circularity but held that the intended meaning was clear; whether a substance is psychoactive depends on the effect it has on the mind of the individual and this is deliberately broad and encompassing.[111]

(i) Claiming a psychoactive effect:

According to the January 2015 Draft Product Approval Guidelines, the PSRA noted that any product sold or promoted as being able to induce a psychoactive effect would meet the statutory definition of a 'psychoactive substance', irrespective of ingredients. The natural consequence of such broad classification is that any substance that promotes itself as a study drug will be caught.

[107] Psychoactive Substances Regulatory Authority "Home Page" (5 June 2015) Psychoactive Substances Regulatory Authority <http://psychoactives.health.govt.nz/>.
[108] Psychoactive Substances Act 2013 s 9.
[109] Psychoactive Substances Act 2013, s 8.
[110] Mihinui v Police [2015] NZHC 1127.
[111] At [49].

(ii) Medicines are not 'psychoactive substances':

A number of exclusions apply to this broad definition in order to avoid legislative inconsistencies including a 'medicine'.[112] Pursuant to its legal definition in s 3 of the Medicines Act, a medicine is any substance supplied to a human being for a 'therapeutic purpose'.

> *Section 4— Meaning of therapeutic purpose*
>
> *In this Act, unless the context otherwise requires, therapeutic purpose means any of the following purposes, or a purpose in connection with any of the following purposes:*
>
> *(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or*
> *(b) influencing, inhibiting, or modifying a physiological process; or*
> *(c) testing the susceptibility of persons to a disease or ailment; or*
> *(d) influencing, controlling, or preventing conception; or*
> *(e) testing for pregnancy; or*
> *(f) investigating, replacing, or modifying parts of the human anatomy.*

A study drug could come under the Medicines Act if it contained an ingredient classified as a medicine or if it makes a therapeutic claim. No new medicine can be sold, distributed or advertised in any way until the consent of the Minister of Health has been obtained.[113] Pre-market approval processes for medicines are costly and time consuming.

(iii) Dietary supplements are not 'psychoactive substances':

Dietary supplements within the meaning of regulation 2A of the Dietary Supplements Regulations 1985 are also excluded from the meaning of a 'psychoactive substance'.[114]

L-tyrosine for example, is an essential amino acid with a psychoactive effect that is openly marketed as a dietary supplement for those with low motivation and stamina.[115] Although the long-term effects of l-tyrosine supplements have not been studied, there are no clinically significant reports of negative side effects when taken in controlled doses. If concerns arose that the product was more than low-risk, the active substance could be scheduled as a controlled drug under the MODA or a medicine under the Medicines Act.

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[112] Psychoactive Substances Act 2013, s 9(3)(c).
[113] Medicines Act 1981, s 20.
[114] Psychoactive Substances Act 2013, s 9(3)(e).
[115] Solgar "L-Tyrosine 500mg" (2015) Health Post NZ <http://www.healthpost.co.nz/solgar-l-tyrosine-500mg-sgtyr.html>.

Provided the product contains no ingredient classified under the MODA or Medicines Act and makes no therapeutic claim, manufacturers can avoid the pre-market approval process by advertising their product as a dietary supplement. Unsurprisingly, this is an attractive marketing option.

Pursuant to the Dietary Supplements Regulations at reg 2A(6) a dietary supplement must be intended to supplement the amount of the substance normally derived from food. Regulation 3 specifies the maximum daily doses for certain vitamins and minerals suggesting that the legislature intended supplements to only contain quantities of the food derivative that could be found in a healthy and balanced diet. Since maximum daily intake values are not listed for every supplement however, the question remains as to whether unnaturally high quantities of an unspecified substance would be permitted.

An example of a product that recently attempted to meet the dietary supplement criterion (and failed) is the pre-workout stimulant powder 'Frenzy' by Driven Sports.[116] This product contained 4-methyl-2-pentanamine citrate (DMBA), which the manufacturer claimed was a natural extract from Pouchong tea.[117] Evidence (of questionable reliability) shows that in reality, only traceable quantities of DMBA actually exist in this tea and approximately 1000kg of the tea would be required to derive 12mg of DMBA.[118] Each serving of Frenzy contains 120mg of DMBA,[119] a quantity that clearly exceeds any amount that could ever be normally derived from food. The PSRA stated in May 2015 that products containing DMBA did not meet the definition of a dietary supplement because "the ingredients are clearly not intended to supplement the amount normally derived from food".[120] It is clear that the PSRA has interpreted this section to mean that the quantities must not far surpass what could normally be acquired from a natural diet. This interpretation does not resolve the ambiguity entirely but does rule out substances that exist in foods in only negligible quantities.

An obvious limitation to this process is that it requires regulators to keep a close eye on new products that enter the market as dietary supplements. Since there is no pre-market approval

[116] Driven Sports "The Official Driven Sports Website" (2010) <http://drivensports.com/>.
[117] Driven Sports "Image of Frenzy Nutritional Information" (2015) SuppsRUs <http://staging.suppsrus.com.au/media/wysiwyg/nutrition/DRIVFRENZY00_NI.jpg>.
[118] Y.S. Chen, A.S.M. Ou. "Changes in volatile components of Pouchung teas during storage". J. Chin. Agric. Chem. Soc. 1998, 36, 630 [in Chinese] cited in Pieter A Cohen, John C Travis and Bastiaan J Venhuis "A synthetic stimulant never tested in humans, 1,3-dimethylbutylamine (DMBA), is identified in multiple dietary supplements" (2015) 7 Drug Test Analysis 83.
[119] Cohen, Travis and Venhuis, above n 118.
[120] Psychoactive Substances Regulatory Authority "Products containing 1,3-dimethylbutylamine (DMBA)" (13 May 2015) Psychoactive Substances Regulatory Authority <http://psychoactives.health.govt.nz/compliance>.

process and since only the principal ingredients need to be listed on the label,[121] the identification of harmful psychoactive substances can be like searching for a white cat in a snowstorm, with the added setback that the person searching has no idea what a cat looks like. Luckily, once a potential cat has been located, the PSRA requires only a very low standard of proof to verify that what you have is in fact a furry feline. Nonetheless, this inefficient process of pursuit is likely to put undesirable time and monetary strains on the regulators.

(iv) Only a low standard of proof is required for a 'psychoactive substance' classification:

In addition to their finding that DMBA did not meet the statutory criteria for a dietary supplement, the PSRA declared DMBA to be a 'psychoactive substance' within the meaning of Director-General of the PSA. Because DMBA has not been approved under the PSA, it is illegal.

DMBA was declared psychoactive on the basis that it is a close chemical cousin of the banned party pill ingredient 1,3-dimethylamylamine (DMAA). Interestingly, the PSA does not actually have an analogue provision like the MODA that allows a substance to be banned based on chemical similarity to an already banned substance. Preliminary testing shows that DMBA has some blood pressure effects that are similar to those induced by DMAA. This limited evidence was at the core of the conclusion that DMBA is functionally similar to DMAA and therefore capable of producing a psychoactive effect. Concerns that nothing was known about the side effects of the substance in humans motivated swift action and it would seem that very little substantive evidence is required before the PSRA can declare a substance psychoactive for the purposes of the PSA.

If the Natural Health and Supplementary Products Bill is passed, a requirement to notify a Natural Health and Supplements Authority of any new ingredients in a product (i.e. those not already listed in the Act as permitted or prohibited ingredients) would resolve this problem. Once this Authority has been alerted of a new ingredient, a safety assessment can be commenced.[122]

2. Meaning of 'low-risk':

Under s 37(2), the PSRA (upon consultation with the Psychoactive Substances Expert Advisory Committee (PESAC)) must refuse to approve a product if it is unable to satisfy

[121] Dietary Supplements Regulations 1985, s 5.

[122] "Natural Health and Supplementary Products Bill 324-2 (2011), Government Bill – New Zealand Legislation" <http://www.legislation.govt.nz/bill/government/2011/0324/latest/whole.html#DLM3984689> at s 23.

itself that the degree of harm poses no more than a low-risk of harm to the individual. The meaning of 'low-risk' is decidedly unclear.

Criteria that the PSRA considers when evaluating psychoactive products include:

> *Section 11(3)*
>
> *(a) The specific effects of the product, including pharmacological, psychoactive, and toxicological effects; and*
> *(a) The risks, if any, to public health; and*
> *(b) The potential for use of the product to cause death; and*
> *(c) The potential for the product to create physical or psychological dependence; and*
> *(d) The likelihood of misuse of the product; and*
> *(e) The potential appeal of the product to vulnerable populations; and*
> *(f) Any other matters that the Authority considers relevant.*

Pursuant to s 12 of the PSA, PSEAC must not have regard to the results of any trials involving animals when considering whether or not to deem a product low-risk.[123] Curiously, such results can be considered to substantiate a decision that the product is more than low-risk.[124] The PSRA has indicated in the Draft Product Approval Guidelines that they are currently unaware of any appropriate non-animal alternatives for the suitable assessment of pharmacokinetics, metabolism, reproductive toxicity or addiction potential of a substance.[125] All these factors are essential considerations in assessing risk. While some indications of effect can be adequately assessed in vitro,[126] they cannot at present replace all necessary in vivo trials. The likely implication of the animal trials restriction is that manufacturers will have to wait to compile data from in-human trials with volunteer participants.

Approval from the Director-General of Health pursuant to s 30 of the Medicines Act is not required for applicants of psychoactive substances, but all human research trials must be carried out in accordance with the 'good clinical practice' requirements laid out in Part 11 of the 'Guidelines on the Regulation of Therapeutic Products in New Zealand'. These requirements include the reporting of any adverse events to Medsafe.[127] Any reporting of a

[123] Psychoactive Substances Act 2013, s 12.
[124] Psychoactive Substances Act 2013, s 12(2).
[125] Psychoactive Substances Regulatory Authority *Draft Psychoactive Substances Product Approval Guidelines* (Ministry of Health, 2015) at [92].
[126] Organisation for Economic Co-operation and Development "OECD Guidelines for the Testing of Chemicals, Section 4 Health Effects" [2015] OECD Publishing.
[127] Medsafe *Guideline on the Regulation of Therapeutic Products in New Zealand - Part 11 - Edition 14* (Ministry of Heath, 2015) at 22.

serious adverse event, which very broadly includes anything considered to be a "medically important reaction",[128] is sufficient evidence for the PSRA to conclude that the product poses more than a low-risk of harm to users.[129]

An application for review by the regional Health and Disability Ethics Committee (HDEC) would also be needed which would require adherence to the ethical guidelines set out for 'intervention studies' by the National Ethics Advisory Committee.[130] According to these guidelines, an intervention can include "a study with no therapeutic value to the subject, conducted with healthy volunteers, giving them an intervention previously untested in humans to evaluate its safety".[131] The risks associated with such trials may be high but it is generally accepted that the level of acceptable risk is a determination for the participants.[132]

When a product has sufficient evidence to submit an application and if the PSRA is satisfied that the study drug in question poses no more than a low-risk of harm, then the granting of a licence enabling them to import, research, manufacture, wholesale and retail these products[133] is not problematic. Under the PSA, if evidence shows that a 'psychoactive substance' is low-risk, a three year licence can be granted. Only 'fit and proper' individuals and body corporates of 'good repute' can apply for a licence and the PSRA retains the right to revoke these at any time.[134] Unless society reaches the ethical consensus that the use of neuro-enhancers is undesirable, sale from licensed premises in accordance with the statutory limitations regarding age[135] is acceptable.

E. How do study drugs fit within this regime?

A drug will be regulated as a 'psychoactive substance' under the PSA if it induces or claims to induce a psychoactive effect.[136,137] A substance is excluded from this definition if it meets the legal definition of a medicine.[138] A 'medicine' includes any substance that has a 'therapeutic purpose', which broadly includes "influencing, inhibiting, or modifying a

[128] Psychoactive Substances Regulatory Authority, above n 125.
[129] Psychoactive Substances Regulatory Authority, above n 125.
[130] National Ethics Advisory Committee *Ethical Guidelines for Intervention Studies: Revised edition* (Ministry of Health, 2012) at [2.4].
[131] At [2.5].
[132] At [3.8].
[133] Psychoactive Substances Regulatory Authority "The Psychoactive Substances Act 2013" (5 June 2015) The Psychoactive Substances Regulatory Authority <http://psychoactives.health.govt.nz/psychoactive-substances-act-2013>.
[134] Psychoactive Substances Act 2013 s 19(b).
[135] Psychoactive Substances Act 2013, s 48.
[136] Psychoactive Substances Act 2013, s 9.
[137] Psychoactive Substances Regulatory Authority, above n 125.
[138] Psychoactive Substances Act 2013, s 9(3)(c).

physiological process".[139] Interestingly, this legal definition is different to the orthodox bio-ethical definition of 'therapy' considered in Chapter I. Bio-ethicists conventionally use 'therapy' and 'treatment' interchangeably in reference to a restoration of health to a normal level. This ethical definition of 'therapy' excludes substances used recreationally or for enhancement. The legal definition of 'therapeutic purpose' does not.

Because s 4 defines 'therapeutic purpose' so broadly, the definitions of 'psychoactive substance' and 'medicine' are prima facie incompatible.

All substances that induce a psychoactive effect fulfil the statutory criteria of a 'medicine' because all these substances influence a physiological process in their stimulation of the central nervous system. If a strict reading of the legislation is taken, party pills and study drugs both meet the definition of a 'medicine'. Because the Medicines Act takes precedence,[140] if Medsafe interpreted their remit as widely as the statutory definition of 'therapeutic purpose' permits, the definition of 'psychoactive substance' under the PSA would be rendered virtually redundant. This clearly cannot have been the intent of Parliament.

Deconstructing legislative definitions and rebuilding them so as to prevent overlap may be possible but it is not necessary. With study drugs on our doorsteps, if not already in our desk drawers, a pragmatic response that requires only minimal change is desirable. Such a response is easily conceivable and can be achieved with little more than a reclarification of the policy positions of Medsafe and the PSRA. If these two regulatory bodies worked in partnership to synchronise their legislative scope, drugs used for treatment, enhancement or recreation could all be regulated according to the nature of the substance and the risks it poses.

[139] Medicines Act 1981, s 4(b).
[140] Psychoactive Substances Act 2013, s 9.

CHAPTER III:

Should study drugs be regulated as medicines?

"It is thoughtless to condemn them, or laugh at them, if they seek to do more or learn more than custom has pronounced necessary for [them]."
— Charlotte Brontë, Jane Eyre

A. What is the problem?

In order to illustrate the blurred boundary between the PSA and the Medicines Act, consider a hypothetical drug 'A-Plus'. The drug is manufactured by AP Ltd and its active ingredient Chemical A is a new chemical entity that operates by increasing the levels of dopamine in the brain to promote wakefulness and enjoyment of the task at hand.

1. How will a hypothetical drug 'A-Plus' be regulated?

Recall that a substance classified as a 'medicine' is excluded from the definition of a 'psychoactive substance'.[141] Recall again that all 'psychoactive substances' in fact meet the statutory definition of 'medicines' because they all influence or claim to influence a physiological process.[142] If Medsafe were to interpret their remit by taking a strict and literal construction of the legislation, study drugs and party pills would all be regulated as medicines. By reflecting on how recreational drugs have been regulated in the past (i.e. unregulated until classified under the MODA), AP Ltd concludes that in some cases, Medsafe must have been limiting 'therapeutic purpose' to substances that are conventionally used for treatment. While this does not strictly adhere to the black letter definition of a 'therapeutic purpose', it explains why drugs such as BZP were not considered to be medicines. Will the same approach be taken for study drugs? Or will Medsafe decide that, analogous to cosmetic botulinum toxin type A (Botox) or hair loss medication, some substances are best administered by healthcare professionals despite not being used to treat a condition of poor health?

As a medicine, A-Plus cannot be sold, distributed or advertised until approval of a New Medicine Application (NMA) has been granted from the Minster of Health.[143] Given A-Plus is a new substance and only a few in-human trials have been conducted, approval will be a long and arduous process. If A-Plus cannot market itself directly to students, it will have to rely on word of mouth and the discretion of health practitioners to prescribe it off-label as an

[141] Psychoactive Substances Act 2013, s 9(3)(c).
[142] Medicines Act 1981, s 4(b).
[143] Medicines Act 1981, s 20 or s 23.

unapproved medicine.[144] Because the ethical opinion on neuro-enhancers is still divided, not all doctors will feel comfortable obtaining the drug and not all students will feel comfortable requesting it as part of a formal medical consultation.

AP Ltd thinks that because A-Plus is not intended to treat a disease, it will be likened to a recreational drug and the Medicines Classification Committee (MCC) will not consider it to be intended for a 'therapeutic purpose' despite the broad statutory definition. Furthermore, the pre-market approval process is off putting so AP Ltd does not purposefully try and market A-Plus as a medicine.

Evidence of structural similarity to an already banned psychoactive substance DMBA[145] is deemed sufficient evidence that A-Plus is capable of inducing a psychoactive effect despite no analogue provision. Further, because A-Plus is marketed as a study drug, the Product Approval Guidelines (still currently in draft)[146] state that irrespective of ingredients, the definition of 'psychoactive substance' is met.[147]

AP Ltd thinks that A-Plus is an excellent product with great potential to help students reach their educational goals. A-Plus does not directly make students smarter but it enhances their focus, enabling each hour spent in front of a laptop or lab report, to be more productive and more valuable. The drug may also have important benefits in settings such as long haul flights or for late night road users. AP Ltd applies for approval under s 37 of the PSA at a cost of $175,000.[148] According to the [Draft] Product Approval Guidelines, applicants for 'psychoactive substances' are not required to obtain approval from the Director-General of Health to conduct clinical trials under s 30 of the Medicines Act.[149] Because data from animal trials cannot be used, AP Ltd conducts a number of small in-human trials with healthy volunteers, eager to offer their weekend (and wellbeing) to participate in a trial with such promise. Most participants have given the drug excellent reviews but there were a few reported side effects including headaches, insomnia, heart palpitations and dehydration. One girl who claimed she suffered from an almond allergy also broke out in boils but it is unclear whether this had anything to do with Chemical A.

[144] This is permitted under section 29 Medicines Act 1981 and will be discussed in more detail in Chapter 3.
[145] Psychoactive Substances Regulatory Authority, above n 120.
[146] Psychoactive Substances Regulatory Authority, above n 125.
[147] At [6].
[148] Psychoactive Substances (Fees and Levies) Regulations 2014, Schedule 1 Part 2.
[149] Psychoactive Substances Regulatory Authority, above n 125, at [93].

The PSRA, on advice of the PSEAC, decides that since Chemical A's stimulation of the central nervous system is strong but there is limited information about the side effects and no information about the long-term consequences of use, the product cannot be considered low-risk. Additionally, the palpitations reported by trial participants are deemed 'medically important' and therefore constitute a 'serious adverse reaction'. Any such reaction is sufficient grounds for the PSRA to hold that the product is more than low-risk.[150] AP Ltd's application is rejected.

2. Would this be the right decision?

The decision made by the PSRA is a sensible one. Very little is known about A-Plus and it would be undesirable to have such a substance available in general sale stores. It does not necessarily follow, however, that the availability of A-Plus should be nil.

Regulation and prohibition restrict freedom of choice and must therefore be based on an overriding need to protect others from harm and reduce the costs to society. Generally, as the social value of a product or activity increases, the level of tolerated risk should also rise. Compared to recreational drugs of a similar risk profile, the social value of A-Plus is arguably higher. This is not reflected in the law.

If the law responds to this disconnect adequately, the use of study drugs could be supervised and scrutinised as necessary. This would ensure that individuals understand the risks they are undertaking and use the novel drugs in a carefully controlled manner. Failure to respond as such, or imposing disproportionately heavy restrictions may effectively deter some users but is also likely to encourage the proliferation of a nootropics black market. Further, if their availability is not widespread, the ethical issues of distributive justice will be exacerbated.

Pragmatic regulatory compromise to ensure that risks are proportional to benefits is the most appropriate response to emerging neuro-enhancers. Dramatic amendments or enactments are unnecessary as New Zealand's array of existing drug laws already have the capacity to effectively address study drugs provided that the purposes, parameters and powers conferred by these Acts are well understood by all parties.

Substances that are controlled under the MODA or gain approval as low-risk psychoactive substances under the PSA do not warrant much worthwhile objection. The same holds for prescription drugs that are used off-label for neuro-enhancing purposes (such as modafinil).

[150] At [9.3].

The availability of these drugs is already proportional to the risks they pose i.e. they pose more than a low level of risk so availability is limited and closely monitored by health care professionals. It is the emerging study drugs that pose the biggest regulatory challenge. If not classified under the Medicines Act, all emerging study drugs will be caught by the PSA.

Who should be responsible for the regulation of study drugs? Should study drugs be considered to have a 'therapeutic purpose'? How can the definition of 'medicine' and 'psychoactive substance' be reconciled so that the latter is not an empty set? Who should undertake the risk assessment of study drugs? Once determined, how should this risk be managed so as to mitigate adversity?

B. Classification as a 'medicine' under the Medicines Act 1981:

Classification of new psychoactive substances as prescription-only medicines under the Medicines Act is not unprecedented. Before the enactment of the PSA, medicinal classification was the timeliest way to ensure that substances with risk potential were not being freely distributed. Now that the PSA is operative, the classification as a medicine of an otherwise unapproved psychoactive substance serves to loosen restrictions so that the substance is available in limited circumstances under close medical supervision.

1. How is a substance classified as a 'medicine'?

The MCC was established under s 8 of the Medicines Act and operates to advise the Minister of Health on all matters regarding drug classification.[151] Once a substance has been categorised as a medicine it can fall within one of three classification categories:

1. Prescription-only medicines;
2. Restricted medicines; or
3. Pharmacy only medicines.[152]

Medicines that do not fall into one of these three categories[153] are considered by default to be 'general sale' medicines and can be sold from any outlet.[154]

If a study drug makes a therapeutic claim within the meaning of s 4 of the Medicines Act, it meets the definition of a 'medicine' but it cannot be sold, distributed or advertised until consent from the Minister of Health under s 20 or s 23 has been obtained. Study drugs that

[151] Medicines Act 1981, s 9.
[152] Medicines Act 1981, s 9.
[153] Medicines Regulations 1984, Schedule 1.
[154] Medsafe "Classification Categories and Criteria" (16 August 2013) Medsafe NZ <http://www.medsafe.govt.nz/profs/class/classificationCategoriesAndCriteria.asp>.

are not classified as medicines (such as sunifiram) fall unambiguously within the ambit of the PSA where they will remain illegal unless an application for approval by the PSRA is submitted and approved.

2. Before the PSA:

Before the PSA was enacted, classification of a psychoactive substance as a 'medicine' changed the legal status of that substance from unregulated to restricted.

In 2001 the Medicines Assessment Advisory Committee (MAAC) notified the MCC of a number of new chemical entities including piracetam and modafinil. On the basis that very little was known about them, they were classified as prescription-only medicines.[155]

In 2005, adrafinil was also scheduled as a prescription-only medicine following Medsafe's reported concerns about potential abuse of the substance as a party drug.[156] Adrafinil is a pro-drug of modafinil, meaning it is metabolised into modafinil in vivo.[157] While modafinil has supposedly on occasion been used as a party pill, its use to enhance mental performance in an educational or professional setting is far more prevalent.[158] Medsafe's failure to acknowledge the use of adrafinil in an academic or professional setting may indicate that Medsafe was unaware of the study drug phenomenon at the time of classification.

3. After the PSA:

After the PSA was enacted, the classification of a psychoactive substance as a 'medicine' changes the legal status of that substance from illegal (unless the substance is deemed low-risk and approved by the PSRA) to restricted.

In March 2015, the legal status of DMAA was changed from an illegal 'psychoactive substance' under the PSA to a 'medicine' under the Medicines Act. Because a classification decision for DMAA has not yet been made, it is a 'general sale medicine' by default. The submission for classification as a 'prescription-only medicine' will be reviewed at the 54th

[155] Medicines Classification Committee "Minutes of the 25th Meeting" (23 May 2013) Medsafe NZ <http://www.medsafe.govt.nz/profs/class/mccMin25May01.htm>.

[156] Medicines Classification Committee *Out-of-Session Consultation Agenda 34A* (Medsafe, Ministry of Heath, 2005).

[157] A Beotra and others "A novel study of screening and confirmation of modafinil, adrafinil and their metabolite modafinilic acid under EI-GC-MS and ESI-LC-MS-MS ionization" (2009) 41 Indian Journal of Pharmacology 278.

[158] Sydney Lupkin "Users Say the 'Smart Drug' Modafinil Is the New Adderall — Only Better" (31 August 2015) VICE News <https://news.vice.com/article/users-say-the-smart-drug-modafinil-is-the-new-adderall-only-better>.

meeting of the MCC on 24 November 2015 and in this submission, Medsafe justifies classification on the basis that DMAA was originally synthesized as a medicine and is structurally and functionally similar to a substance that is already a medicine in New Zealand. Submissions from the Ministry of Health[159] to have DMAA scheduled under the MODA were rejected by the Expert Advisory Committee on Drugs on the basis that the appropriate harm threshold was not reached.

In August 2015, 23 racetam and racetam-like substances (and stereoisomers for 11 of these)[160] were classified as 'prescription-only medicines'. Prior to this classification, the psychoactive racetams (such as aniracetam) were illegal under the PSA. Reasons given for the proposed classification in this case were that their claimed nootropic effects fell within the definition of 'therapeutic claim' under the Medicines Act and that classification would be a mechanism for controlling and reducing the harm that may occur to consumers who use the substances inappropriately.[161]

> *"Medsafe considers it appropriate to similarly classify other racetams and racetam-like compounds that are emerging as having claimed nootropic or other effects on cognitive and central nervous system abilities…A prescription classification is considered appropriate as the risk profile of the substances has not been extensively studied…"*[162]

The reasoning given for classification suggests that Medsafe was unaware that the psychoactive racetams were already 'controlled' by the PSA. Regardless, the reclassification from 'psychoactive substances' to 'prescription-only medicines' is appropriate. The PSA was enacted to regulate low-risk recreational drugs but its domain of operation (perhaps unintentionally) extends beyond this. The rigid regulation of higher-risk, non-recreational substances with potentially high social value under the PSA is inappropriate and reclassifying these substances as 'medicines' allows for more tailored control.

The operation of the PSA adds an extra protective hurdle to New Zealand consumers wishing to obtain inherently risky psychoactive substances because classification as a 'medicine' is no longer necessary to protect consumers from the harms of such substances. Classification can now be used by Medsafe as a method of relocating substances with therapeutic potential

[159] In 2008 and again in 2014: Medsafe *Classification of 1,3-dimethylamylamine (DMAA) - Submission to the Medicines Classification Committee* (Medsafe, Ministry of Heath, 2015).
[160] An isomer has the same molecular formula but a different geometrical orientation: Merriam-Webster Online Dictionary "Isomer" (7 Oct 2015) <http://www.merriam-webster.com/dictionary/isomer>.
[161] Medsafe *Agenda for the 53rd MCC Meeting: Classification Status of Racetams* (Medsafe, Ministry of Heath, 2015).
[162] Medsafe, above n 161.

(which includes both treatment and enhancement) from the realm of the PSA, to the realm of the Medicines Act. The New Zealand legal landscape is unique in this way.

Recall that any study drug that makes a therapeutic claim will already be regulated as a 'medicine' under the Medicines Act. Such substances cannot be sold, distributed or advertised without the consent of the Minster of Health.[163]

C. Should a study drug be considered a medicine?

Pursuant to its legal definition in s 3 of the Medicines Act, a 'medicine' is any substance supplied to a human being for a therapeutic purpose. Recall that such a purpose is defined broadly in s 4 and includes "influencing, inhibiting, or modifying a physiological process".[164] This broad legal definition however, is not entirely consistent with society's long established understanding of a medicine as being a substance used to heal the sick.

So as not to conflict with this conventional interpretation, (and perhaps in some cases, to take full advantage of health funding) society has been quick to medicalise facets of what would have otherwise been considered the normal human experience. Is your child not listening to you? They may have Oppositional Defiance Disorder.[165] Are your siblings so annoying that you sometimes shout high volume profanities at them in an uncontrollable rage? Intermittent Explosive Disorder.[166] Does your partner display a frustratingly uninterested attitude toward sex? Medically manageable female Hypoactive Sexual Desire Disorder (HSDD)—it is not your fault after all.[167]

More well known examples of potentially controversial conditions for which pharmaceutical treatment plans already exist include hair loss, erectile dysfunction, anxiety and a child's inability to focus on menial tasks. For conditions that are not managed with drugs, recognition from legitimate sources (such as the Diagnostic and Statistical Manual for Mental Disorders[168]) facilitates the development of treatment plans and enables justification for drug use if and when it becomes available. But is such vindication really necessary? Should pharmaceuticals only be used to treat disease? Is classification of neuro-enhancers as 'medicines' necessarily inconsistent with society's existing perception of the medical profession?

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[163] Medicines Act 1981, s 20.
[164] Medicines Act 1981, s 4(b).
[165] American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders Fifth Edition DSM-5* (American Psychiatric Association Publishing) at s 313.81.
[166] At [312.34].
[167] At [302.72].
[168] American Psychiatric Association, above n 165.

While the invention and subsequent recognition of a 'Motivational Deficiency Disorder'[169] does not seem entirely implausible, access to substances that enhance neurological abilities need not be contingent on the recognition of a medical disease. The role of a doctor has long extended beyond treatment of the sick. In the modern day, doctors are charged as gatekeepers of many beneficial but inherently risky substances for which controlled access and monitored use is appropriate. A study drug, in a similar manner to cosmetic botulinum toxin type A (Botox), could be considered such a substance.

1. Spotlight: Sildenafil (Viagra)

The medicalisation of male impotence enabled society to justify medical intervention to manage a condition often accepted as an unfortunate consequence of aging. Rather than concede that medicine had extended beyond the treatment of the sick, and in order to avoid the labours of the enhancement debate, erectile dysfunction was recognised as a medical disorder and any attempts to manage it were considered to be 'treatment' rather than 'enhancement'. Sildenafil was initially approved for the treatment of pulmonary hypertension and coronary artery disease, but its desirable side effects led to United States Food and Drug Administration (FDA) approval for erectile dysfunction treatment in 1998.[170] Pfizher's little blue pill 'Viagra' was approved for use in New Zealand shortly after.[171]

2. Spotlight: Flibanserin (Addyi)

More recently, this little blue pill has been joined by a little pink pill. Flibanserin was originally trialled as an antidepressant but focus shifted when trial participants reported unexpected side effects of an increased sexual desire. Flibanserin gained FDA approval in August 2015 to treat acquired, generalised HSDD in premenopausal women.[172] No other indications are currently approved. Although flibanserin is promoted as treatment for HSDD, it enables us to better imagine a situation where a drug could gain approval as a new medicine despite its only indication being for the management of a condition widely accepted as a variation of normal. For study drugs this may be the inability to sustain productivity for long periods of time.

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[169] A fictitious disease that was used to illustrate medicalisation in: Ray Moynihan "Scientists Find New Disease: Motivational Deficiency Disorder" (2006) 332 BMJ 745.

[170] Letter from MD Temple "New Drug Application (Viagra (sildenafil citrate)) Approval Letter: from the Department of Health and Human Services to Pfizer Pharmeceuticals Production Corporation Limited" (27 March 1998).

[171] Medsafe *Prescriber Update No 21* (Medsafe, Ministry of Heath, 2001) at 8.

[172] US Food and Drug Administration "FDA approves first treatment for sexual desire disorder" (18 August 2015) US Departmnet of Health and Human Services <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm458734.htm>.

D. Obtaining prescription-only study drugs:

Once a substance has been classified as a prescription-only medicine, it can be placed in one of two distinct categories; approved medicines and unapproved medicines. Both approved and unapproved prescription-only medicines can be prescribed subject to certain restrictions (such as those imposed on some drugs controlled by the MODA). In order for the status of a prescription medicine to advance from unapproved to approved, the manufacturer must submit a NMA to the MAAC.[173]

1. Unapproved medicines:

An unapproved medicine is a medicine that has been classified by the MCC but has not received approval from the MAAC meaning it cannot be sold, distributed or advertised by the manufacturer in New Zealand.[174] The nootropic racetams, such as piracetam and aniracetam, fall into this category of study drugs.

Section 29 of the Medicines Act permits the sale or supply of unapproved medicines to medical practitioners. Section 25 then permits the practitioner to prescribe these medicines to any patient in their care.[175] In these circumstances, the person supplying the unapproved medicine must notify the Director-General of Health "in writing of the practitioner, patient, describing the medicine, and identifying the occasion when and the place where the medicine was so sold or supplied".[176] The 'Good Prescribing Practice' guidelines published by the Medical Council of New Zealand[177] emphasize that if a doctor is to prescribe an unapproved medicine, the doctor should assume responsibility for overseeing that patient's care.[178] The doctor should also inform the patient about any alternative options, of any risks or side effects and of the details that will be supplied to the Director-General of Health by the supplier.[179] Advertising or promotion of unapproved medicines to consumers or healthcare professionals is forbidden.[180]

This is likely to be a common method of procuring study drugs. Due to the ethical impediments that remain unresolved by society, the approval of a new medicine for use as a neuro-enhancer would be highly contentious (addressed below). Provided that the substance

[173] Medicines Act 1981, s 20 or s 23.
[174] Medicines Act 1981, s 20.
[175] Medicines Act 1981, s 25.
[176] Medicines Act 1981, s 29(2).
[177] Medical Council of New Zealand *Good Prescribing Practice* (Medical Council of New Zealand, 2010).
[178] At [11].
[179] At [11].
[180] Medicines New Zealand *Code of Practice Edition 16* (2014) at 27, 60.

has been scheduled as a prescription-only medicine, it will be legal to obtain by the exercise of a doctor's procuring rights under s 29 and prescribing rights under s 25.

2. Unapproved use of an approved medicine:

The Medicines Act permits authorised prescribers to "procure the sale or supply of any medicine" for patients in their care even for indications that have not been approved by Medsafe,[181] provided that they comply with the ethical and professional standards set out in the Code of Health and Disability Services Consumers' Rights.[182] If there is limited or equivocal documented support for the indication, then the use would be considered experimental[183] and written consent from the patient is needed.[184]

Prescribing an approved medicine for an unapproved indication is very common. A recent US study found that off-label prescriptions of modafinil increased 15-fold during the 2002 to 2009 study, with 89% of prescriptions being used for non-approved indications.[185] Of the off-label prescriptions, 30% were attributed to depression or multiple sclerosis.[186] This indicates that a significant number (perhaps up to 70%) of prescriptions could have been issued for neuro-enhancing purposes.

Any new medicine approved for the treatment of neurological dysfunction disorders can be legally prescribed off-label for nootropic effects on healthy individuals without notifying the Director-General of Health. Such prescriptions would of course be subject to the 'Good Prescribing Practice' guidelines[187] but since 'good practice' is principally subjective and anything but static, changes in social attitude towards the role of the doctor may mean that prescriptions for enhancements will not be considered a divergence from 'good practice'.

3. Approval of a new medicine or new indication:

In New Zealand, the pre-market approval process for a medicine involves the evaluation of applications to market the new medicine, approval of clinical trials and the issuing of licenses to import and distribute. Subject to the limited statutory exemptions in the Medicines Act, no

[181] Medicines Act 1981, s 25.
[182] Right 7 (6) Health and Disability Commissioner *The HDC Code of Health and Disability Services Consumers' Rights Regulation* (Health and Disability Commissioner, 1996).
[183] Medsafe "Use of Unapproved Medicines and Unapproved Use of Medicines" (22 October 2014) Medsafe NZ <http://www.medsafe.govt.nz/profs/riss/unapp.asp>.
[184] Right 7 (6) Health and Disability Commissioner, above n 182.
[185] Peñaloza RA and others "Trends in on-label and off-label modafinil use in a nationally representative sample" (2013) 173 JAMA Intern Med 704.
[186] At 704.
[187] Medical Council of New Zealand, above n 177.

new medicine can be sold, distributed or advertised until the consent of the Minister has been notified in the Gazette.[188, 189] Applications for the distribution of a new medicine are considered by Medsafe's MAAC who are then charged with providing advice to the Minister of Health as to the outcome of the application under s 22(2).

For a standard NMA, MAAC will conduct a full evaluation of the submitted dossier. For an abbreviated application the MAAC will base its assessment on the evaluation reports of recognised overseas regulatory authorities.[190] Only certain medicines would qualify for the abbreviated evaluation process and criteria include having the same formulation, dosage and indications as the equivalent product that has been approved overseas.[191]

Using an already approved medicine for neuro-enhancement would be considered a new indication of that medicine. While changes to the label or location of manufacture may only require the approval of the Director-General of Health,[192] officially recording a new indication of a medicine requires the approval of the Minster of Health. A Changed Medicines Notification referred to the Minister under s 24(5) is liable to the same eligibility requirements as an NMA.

(i) Clinical trials:

It is unlikely that pharmaceutical companies will inconvenience themselves with clinical trials in New Zealand. If such trials were conducted, however, then ethical and scientific endorsement from an HDEC and the Standing Committee on Therapeutic Trials (SCOTT) would be required.

HDEC approval:

Ethics approval from an HDEC must be granted in accordance with the guidelines published by the National Ethics Advisory Committee.[193] These guidelines reference principles of

[188] Medicines Act 1981, s 20.
[189] The Gazette is New Zealand's official government newspaper.
[190] Medsafe recognises: Australian Therapeutic Goods Administration (TGA), United States Food and Drug Administration (FDA), Health Products and Food Branch of Health Canada, Medicines and Healthcare products Regulatory Agency (MHRA), European Medicines Agency (centralised procedure only), EU member states (decentralised or mutual recognition procedure only. Medsafe *NZ Regulatory Guidelines for Medicines Part C: Requirements for application types - Edition 6.17* (Ministry of Health, 2015) at 16.
[191] At 16.
[192] Medicines Act 1981, s 24.
[193] National Ethics Advisory Committee, above n 130.

beneficence and non-maleficence,[194] which draws to attention, the importance of balancing the desired benefits with the possible risks.

Non-therapeutic clinical studies will only gain ethical approval if "the importance of the objective outweighs the inherent risks and burdens to the participant, and participants are well informed of the possible risks".[195] Although effective study drugs may not be considered 'treatment',[196] they can still be considered therapeutic in the sense that they offer users a benefit by influencing or modifying a physiological process (pursuant to the legal definition of a 'therapeutic purpose' under s 4 of the Medicines Act).

For a medicine that has not been extensively tested in humans already, a manufacturer is likely to first apply for approval as a 'treatment' of a recognised disease such as Alzheimer's disease or ADHD. First-in-human trials for an enhancement rather than treatment purpose would likely face strong ethical opposition based on arguments of disproportionate risks to benefits. The same is true for trials of medicines that have not already been widely tested in humans under a different indication.

SCOTT approval:

Under s 30 of the Medicines Act, SCOTT makes recommendations to the Director-General of Health on whether or not these trials for new medicines should be permitted based on a scientific assessment of the application.

(ii) Spotlight: Modafinil (a new indication)

An analysis of modafinil's neuro-enhancing capabilities was recently conducted by the University of Oxford and Harvard Medical School. The report was published in August 2015 and reviews 24 studies on the substance, finding that modafinil does improve an individual's ability to complete tasks requiring planning, decision-making, flexibility, learning, memory and creativity.[197] In their concluding remarks, the researchers state that "more benefits are being associated with modafinil use rather than less, which suggests that modafinil may well deserve the title of the first well-validated pharmaceutical 'nootropic' agent".[198] While this does not mean that its use as a study drug is approved, the findings may encourage modafinil manufacturers to apply to have neuro-enhancement included as an approved indication.

[194] At [4.11].
[195] At [5.49].
[196] Yet!
[197] Battleday and Brem, above n 53.
[198] At 20.

To have an enhancement indication approved, the manufacturer would have to submit a NMA to the MAAC. Data on efficacy and safety from any previous trials would have to be submitted with the NMA and if any further clinical trials were to be carried out in New Zealand (unlikely) approval from an HDEC and SCOTT would be required. Importantly, the legality of direct-to-consumer advertising of therapeutic products in New Zealand[199] means that approval would enable manufacturers to perpetuate the mind-set that 'everyone is using them'. This is likely to exacerbate feelings of coercion.

E. How should the roles of Medsafe and the PSRA differ?

Study drugs that meet the low-risk threshold required for approval under the PSA could continue to be regulated as 'psychoactive substances'. If this were to result in confusion, however, all study drugs should be regulated as 'medicines'. This requires no legislative amendments, only a clarification of the policy positions and regulatory boundaries of Medsafe and the PSRA. Higher-risk study drugs should continue to be subject to additional restrictions under the MODA.

The PSA was crafted in response to a very specific social problem, namely the increasingly diverse market of emerging recreational party pills.[200] The PSA was passed almost unanimously, 119 votes to one, which reflects the general consensus in New Zealand that the costs of recreational drugs outweigh the benefits unless a sufficiently low level of harm can be proven. In such cases, if the approval of the PSRA is obtained, restricted sales from licensed premises enables regulators to strike the appropriate balance between individual autonomy and harm minimisation. Such a balance is not struck when this rigid regime is applied to study drugs.

The PSRA should interpret their remit of responsibility narrowly, limiting their role to the envisioned regulation of recreational drugs. For psychoactive drugs used to treat or enhance, the broad definition of 'therapeutic purpose' under the Medicines Act permits classification as a 'medicine'. While Medsafe may have traditionally interpreted 'therapeutic purpose' narrowly, the interpretation should be wide enough to capture study drugs, but not so wide as to capture recreational drugs and undermine the authority of the PSRA.

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[199] Medsafe *Guidelines on the Regulation of Therapeutic Products in New Zealand - Part 7 - Edition 10* (Medsafe, Ministry of Heath, 2011).

[200] Reporting Services House of Representatives "Psychoactive Substances Bill — First Reading" (9 April 2013) <http://www.parliament.nz/en-nz/pb/debates/debates/50HansD_20130409_00000028/psychoactive-substances-bill-%E2%80%94-first-reading>.

The medicinal classification status of the substance in question could reflect the level of harm that substance carries. As risks and side effects become better understood, the substance could be reclassified accordingly. Sildenafil, when sold as an erectile dysfunction medication, is a good example of a substance that was originally classified as a 'prescription-only medicine' but now, in light of thorough research, it has been reclassified as a 'restricted medicine'.[201] Restricted medicines can be obtained without a prescription from a licensed pharmacist.

Emerging study drug substances are likely to attract a prescription-only classification status, which is desirable until a thoroughly researched risk profile supports any other classification.

F. How would a student obtain study drugs under this regime?

Methylphenidate and dextroamphetamine aside, a student could obtain study drugs by openly requesting them during a consultation with their medical practitioner. Until enhancement indications for such drugs have been approved, neither the manufacturer nor the practitioner can advertise their availability so knowledge of their existence would have to be acquired through word of mouth.

Under Right 4 of the Code of Health and Disability Service Consumers' Rights, patients have the right to "services that comply with legal, professional, ethical and other relevant standards". 'Good Medicial Practice'[202] was created by the New Zealand Medical Council as a fundamental document for such standards. The Medical Council operates under the Health Practitioners Competence Assurance Act 2003 and their function is to "to set standards of clinical competence, cultural competence, and ethical conduct to be observed by health practitioners of the profession".[203]

If a patient requests prescription study drugs from their doctor, 'good medical practice' requires the doctor to first assess the patient's condition and be satisfied that the medicine is in the patient's best interests.[204] What constitutes 'best interests' necessarily requires subjective clinical judgement but it is likely that this would involve an examination into whether the patient is suffering from any other underlying medical condition, what their current study habits are like, and whether there are any less health-hazardous methods of managing their time and stress. All risks, side effects, costs and benefits should be discussed

[201] To males aged 35-70 years: Medicines Classification Committee "Database of Medicine Classifications: Sildenafil" (17 April 2012) Medsafe NZ <http://www.medsafe.govt.nz/profs/class/classification.asp>.
[202] Medical Council of New Zealand *Good Medical Practice* (Medical Council of New Zealand, 2013).
[203] Health Practitioners Competence Assurance Act 2003, s 118(i).
[204] Medical Council of New Zealand, above n 177, at 1.

with the patient[205] in a face-to-face consultation[206] and prescriptions should only be issued for small quantities of the drug to minimise the potential for misuse and abuse. Follow-up consultations should be encouraged so that the patient's experience of the substance can be monitored and any adverse side effects can be reported to Medsafe's Medicines Adverse Reactions Committee.

The World Anti-Doping Agency states that "doping is fundamentally contrary to the spirit of sport"[207] and if, in time, educational institutes similarly decide that study drugs are contrary to the perceived spirit of education, amendments to the 'Good Medical Practice' guidelines would be an effective way to limit their distribution to less controversial settings. Legislative changes to prohibit the use of study drugs may be an unnecessary use of resources, particularly when the ethical opinion on the issue is likely to oscillate. A set of guidelines like those that exist for sport enhancers[208] could detail when neuro-enhancing prescriptions would be considered appropriate. If a health practitioner does not act in accordance with these guidelines, they could be found guilty of professional misconduct and face disciplinary proceedings.[209]

[205] At [11].
[206] At [3].
[207] World Anti-Doping Agency *World Anti-Doping Code* (World Anti-Doping Agency, 2009) at 14.
[208] Medical Council of New Zealand *Prescribing Performance Enhancing Medicines in Sport* (Medical Council of New Zealand, 2010).
[209] Health Practitioners Competence Assurance Act 2003, s 100.

CONCLUSION:

"God has given us, in a measure, the power to make our own fate: and when our energies seem to demand a sustenance they cannot get—when our will strains after a path we may not follow—we need neither starve from inanition, not stand still in despair: we have but to seek another nourishment for the mind."

— Charlotte Brontë, Jane Eyre

Until society has reached an ethical accord on the multitude of moral dilemmas that neuro-enhancing substances pose, a panacea for the study drug problem is not possible. If study drugs are used as a positional good, the advantage to one user is offset by an external disadvantage of equal magnitude and the net gain to society would be nil.[210] If access was widespread, however, and study drugs were used to achieve personal excellence rather than just an edge to the detriment of another, their absolute benefits are compelling. Study drugs could serve to better the general health of the community and in this way their social value may be significantly higher than that of recreational drugs. The associated cost-benefit analysis that our lawmakers engage in must reflect this.

Prior to the enactment of the PSA, nootropic substances not already classified as 'medicines' under the Medicines Act or 'controlled drugs' under the MODA were largely unregulated, subject only to the requirements of consumer guarantees legislation or the Dietary Supplements Regulations if so marketed. The time lag caused by the cumbersome classification process under the MODA meant that emerging drugs could cause significant harm before adequate safety measures were put in place to control distribution and use. The enactment of the PSA in 2013 reversed the onus of proof for psychoactive substances and so ended this cat and mouse game between regulators and manufacturers.

Unless classified as 'medicines' or 'controlled drugs', study drugs fall within the catch all provisions of the PSA. Despite the wide-ranging scope of the PSA, is clear that study drug users have not actually been considered by Parliament in the same way that club drug crusaders have. Because the ethical repercussions and potential benefits of study drugs are so distinct from those posed by party pills, the same rigid regime does not appropriately accommodate both types of drugs.

[210] Bostrom and Sandberg, above n 44, at 328.

A regulatory body that is better equipped to engage in the delicate weighing of costs and benefits for study drugs is Medsafe. Because the Medicines Act takes precedence over the PSA, classification as a medicine allows for a more flexible approach to availability. The recent classification of the nootropic racetams in August 2015 indicates that Medsafe is perhaps already willing to undertake the regulation of neuro-enhancers.

Until the side effects of a particular study drug have been properly explored, access must be proportional to the risk potential it carries. Methylphenidate and dextroamphetamine should continue to be tightly regulated[211] with availability restricted to the treatment of ADHD and narcolepsy.[212] Liberalising their availability would not only be a divergence from our international obligations[213] but it would fail to reflect their high risks and disputed efficacy. The availability of other new generation study drugs should remain prescription-only until thoroughly researched risk profiles provide sufficient verification for alternative classifications.

Rigidly prohibiting study drugs that do not satisfy the low-risk threshold under the PSA does not adequately reflect the unique benefits that study drugs may offer. Users of study drugs are motivated by different goals and the supervised consumption of these substances by medical professionals will mitigate health harms as well as facilitating the collection of meaningful enhancement data.

Long gone are the days when students would deem a good nights sleep to be sufficient preparation for a productive day. Synthetic sunshine, copious caffeine consumption and a reliable internet connection are widely considered to be crucial study-aids and neuro-enhancing study drugs may soon join their ranks. Students are told, "You can be anything," but what they are hearing is, "You have to be everything". Deadlines must be met, friendships must be made, grades must be maintained and meaningful community connections must be established. A successful student is a global citizen, a social activist, a conscious consumer, a high achiever, a dreamer. They need a part time job to pay their rent and a full time graduate job to pay off their loan. If a pharmaceutical pill meant they could achieve it all and still stay afloat, it is easy to see how the use of such a substance could become the norm.

[211] Both these substances are regulated as controlled drugs under the MODA and are subject to prescribing restrictions under the Medicines Regulations 1984, reg 22.
[212] Medsafe, above n 93.
[213] UN Convention on Psychotropic Substances 1971.

To prepare for this looming reality, it is imperative that study drugs be brought into the legislative limelight. Practical compromise that clarifies the hazy interface between the ambits of Medsafe and the PSRA is advisable and the regulation of study drugs as ‘medicines’ is most appropriate.

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