

John Curtin Institute of Public Policy – Curtin Business School

Attention Deficit Hyperactivity Disorder Policy, Practice and Regulatory  
Capture in Australia 1992–2012

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## **Declaration**

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

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## **Abstract**

Like many first world nations, Australia has demonstrated an increasingly pharmaceuticalized response to Attention Deficit Hyperactivity Disorder (ADHD). Per capita rates of prescriptions of ADHD medications grew 277 percent between 1995 and 2010. However, there have been large and inconsistent intertemporal variations between state jurisdictions (shifting over time in relative terms). Most notably, in Western Australia (WA) in 2002 the child Pharmaceutical Benefits Scheme (PBS) per capita prescribing rate was 142 percent above the national average. However, after 2003, while in other states prescribing rates grew, they fell by 50 percent in WA, and by 2011 they were 11 percent below the national average.

There has been significant academic, public and media interest not only about the growing and inconsistent prescribing rates, but also about concerns that conflicts of interests and 'regulatory capture' may have affected significant policy development and regulatory processes in relation to ADHD. Regulatory capture occurs if an entity that is supposed to advance the public interest instead acts to benefit commercial or industry interests in ways that are contrary to the public interest.

The thesis draws heavily on the work of British sociologist John Abraham, who contends that regulatory capture is the most significant explanation of the process of pharmaceuticalization for many health conditions, including ADHD. Here key ADHD policy development processes are analysed to evaluate the extent of regulatory capture in Australian national and state jurisdictions. These include the development of national treatment guidelines and state-specific reviews of WA and New South Wales (NSW) prescribing practices.

For the purposes of this thesis, the term 'regulatory capture' is taken to have a broad scope, encompassing capture of any or all of the actors, both government and non-government, which have the declared intention of protecting and enhancing the public good. Examples of non-government actors include professional organisations, researchers, and patient advocacy groups.

The history of ADHD policy and regulation nationally from 1992 to 2012, in WA from 1993 to 2011 and in NSW from 2007 to 2011 is that regulatory capture occurred in the majority of policy development and regulatory processes. These 'captured' processes have been associated with subsequent ADHD child pharmaceuticalization. Conversely the only ADHD-critic dominated process identified occurred in WA in 2002 and was associated with subsequent ADHD child de-pharmaceuticalization. The findings of this thesis are consistent with Abraham's assertion that regulatory capture is a significant driver of pharmaceuticalization.

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## Preface

From 2001 until 2013 I was a member of the Western Australian Parliament. A significant amount of my energies during this time were expended trying to influence both State and Commonwealth Government responses - and ultimately clinical practice - in relation to diagnosis and treatment of Attention Deficit Hyperactivity Disorder (ADHD). In my inaugural speech I identified that my activism stemmed from my time as a teacher at a Perth all boys' high school (1995-2001) where I experienced:

students on AD[H]D medication sitting compliantly in class. They were not hyperactive or impulsive, but they were far from switched on. Their medication had not made them more attentive but it had made them more compliant and easier to manage.<sup>1</sup>

At the time of my inaugural speech (2001), I accepted the validity of the 'disorder' for children 'carefully diagnosed' but expressed concern that 'misdiagnosis and the resultant over-prescription of amphetamines is a threat to the health and happiness of many Western Australian children'.<sup>2</sup> As I became more immersed in the debate my position hardened so that by 2006 I stated that:

I did argue that ADHD is over-diagnosed and over-prescribed. I now say ADHD is a fraud – this is how my position has changed, not because kids do not have real things going on in their lives, but simply because the bar for diagnosing the condition is far too low.<sup>3</sup>

Much of my criticism of ADHD prescribing stems from the fact that the diagnostic criteria for ADHD include normal childhood behaviours like fidgeting, disliking homework and playing too loudly. However, I acknowledge some children do exhibit extreme behaviours that warrant investigation and support. I believe in such cases it is essential to identify the underlying cause of these problematic behaviours. Potential causes of ADHD-type behaviours include sleep deprivation, bullying or abuse, dietary problems, neurotoxin exposure, immaturity,

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<sup>1</sup> Martin Whitely MLA (2001), 'Inaugural speech', *Hansard*, Parliament of Western Australia, Thursday 3 May, pp. 152b–179a.

<sup>2</sup> Martin Whitely MLA (2001), 'Inaugural speech'.

<sup>3</sup> Martin Whitely, *Western Australian Parliamentary Debates*, Legislative Assembly, 8 March 2006, pp 138b–176b /2

dysfunctional teaching or parenting, sight or hearing problems or any of a multitude of environmental, social, educational or medical circumstances.

I contend that the often promoted concept that ADHD is caused by a biochemical brain imbalance is at best an unproven hypothesis. Furthermore, when this unproven hypothesis is assumed to be the cause of attention and hyperactivity problems of an individual child, and used as the rationale for drugging the child with amphetamines, this constitutes a dangerous fraud. In a book I wrote in 2010 titled *Speed Up and Sit Still- the controversies of ADHD diagnosis and treatment* I concluded:

The whole [ADHD] fraud hangs on the unsupported assumption of a biochemical brain imbalance and the generalised [almost universal] temporary behaviour-altering qualities of low-dose amphetamines. Stimulant medication acts in precisely the way it is intended to. It stimulates. This does not mean that it is treating a problem or fixing a chemical imbalance. Stimulants are simply acting as temporary behaviour modifiers, with compelling evidence of long-term educational disadvantage and cardiovascular damage.<sup>4</sup>

I am therefore obviously not a neutral observer in regards to the science of ADHD. I have been active in many of the policy processes described within this thesis with the aim of lowering ADHD child prescribing rates. However, this thesis does not seek to examine the legitimacy of the condition or the issue of whether rising or falling ADHD child prescribing rates are 'good outcomes'. Instead it identifies the effect of regulatory capture on prescribing rates.

My strong views and history of public advocacy have presented a challenge in objectively and dispassionately analysing processes that I have significantly influenced. I have attempted to present the viewpoints and actions of those that I identify as 'ADHD proponents' accurately and respectfully in this thesis, even though at times in other forums the debate has been passionate and personalised.

In summary, the merit of opposing views on the contentious issues of ADHD diagnosis and treatment is not the subject of this thesis. The focus is evaluating the relative impact of

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<sup>4</sup> Martin Whitely (2010), *Speed Up & Sit Still: The Controversies of ADHD Diagnosis and Treatment*, Perth, UWA Publishing, p. 145

ADHD proponents and critics on policy and regulatory processes and identifying any consequent impact on child prescribing rates.

# Chapter 1. Introduction: Regulatory Capture and Australian ADHD Child Prescribing

## 1.1 The significance of and need for the Study

Attention Deficit Hyperactivity Disorder (ADHD) is the most commonly diagnosed and medicated childhood psychiatric disorder in the world.<sup>5 6</sup> There are large variations in international, state and localised ADHD medication prescribing rates.<sup>7</sup> Both the diagnosis and treatment of ADHD are controversial and the subject of considerable debate within the psychiatric, paediatric and general medical professions, the media, and the public.

The controversy centres primarily around three key issues:

1. The validity of the diagnosis
2. The safety and efficacy of the medications used to treat the disorder
3. The relationship between ADHD and drug abuse.

Extensive research effort has been expended in regard to these issues. There is also widespread interest in ADHD prescribing rates, particularly for children, resulting from concerns about the safety and efficacy of ADHD medications.

The process and effect of public policy development, particularly in relation to government approved diagnosis and treatment guidelines of ADHD, and the regulatory frameworks in regard to the prescription of psychotropic drugs used to treat ADHD in Australia, have been little studied. Similarly, the extent to which commercial and private professional interests have influenced Australian ADHD policy and regulation has not been extensively studied.

This thesis examines the relationship between Australian State and Commonwealth Government policies and their implementation in relation to ADHD and national, inter-state

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<sup>5</sup> Inyang Takon (2011), 'Clinical use of a modified release methylphenidate in the treatment of childhood attention deficit hyperactivity disorder', *Annals of General Psychiatry*, 10:25. Available at <http://www.annals-general-psychiatry.com/content/10/1/25>; US National Library of Medicine, 'Attention Deficit Hyperactivity Disorder', *Medline Plus*, 11 April 2011. Available at <http://www.nlm.nih.gov/medlineplus/ency/article/001551.htm> (accessed 13 December 2011).

<sup>6</sup> Sung V, Hiscock H, Sciberras E, Efron D. (2008), 'Sleep problems in children with attention-deficit/hyperactivity disorder: Prevalence and the effect on the child and family', *Archives of Pediatrics and Adolescent Medicine*, 162(4): pp. 336-342.

<sup>7</sup> Philip Hazell (1995), 'Stimulant treatment for attention deficit hyperactivity disorder', *Australian Prescriber: an independent review*, 18:60-3; Available: <http://www.australianprescriber.com/magazine/18/3/60/3/> (accessed 13 December 2011); I McKenzie, C Wurr (2004), 'Diagnosing and treating attentional difficulties: a nationwide survey', *Archives of Disease in Childhood*, Vol 89;10 :pp. 913-916.

and inter-temporal ADHD medication prescribing rates for children. It focuses on the commercial, professional and political influences upon changes in policies and regulatory practice and identifies associated changes in ADHD prescribing rates.

ADHD diagnosis and treatment makes a significant call upon the public purse. Through the Pharmaceutical Benefits Scheme (PBS) - which subsidises the cost of many prescription medications - the Commonwealth Government subsidises ADHD drugs: dexamphetamine (brand names Adderall, Dexedrine, Dexostat), methylphenidate (Ritalin, Ritalin LA and Concerta) and atomoxetine (Strattera). In 2011 Australia-wide 80,647 people - of whom 62,834 (approximately 78 percent) were children<sup>8</sup> - were dispensed a total of 539,875 prescriptions of PBS subsidised ADHD medications at a cost to taxpayers of \$23,842,437.<sup>9</sup> A small proportion of these prescriptions were for conditions other than ADHD,<sup>10</sup> but these figures do not include non-PBS subsidised prescriptions. Although it is not possible to identify the quantum, the Commonwealth Government also subsidises, via Medicare co-payments, the fees of psychiatrists, paediatricians and general practitioners involved in the diagnosis and treatment of ADHD.

In addition to Commonwealth expenditures, state governments spend an indeterminate amount giving free medications via public health services and providing child and adolescent health and mental health services that diagnose and treat ADHD. They also expend resources monitoring the prescribing and dispensing of ADHD psychostimulants because of concerns about their diversion for illicit use.

Although there has been a consistent pattern of increasing national ADHD child prescribing rates across Australia, there are large and inconsistent intertemporal variations between States (shifting over time in relative terms). For example Western Australian per capita PBS prescribing rates throughout the 1990s and early 2000s were multiples of those in other

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<sup>8</sup> These statistics were provided to Martin Whitely, upon request, from the Australian Government, Department of Health and Ageing (2012), *Letter to Martin Whitely dated 21 April 2012*, PBS Information Management Section, Pharmaceutical Benefits Division, Canberra.

<sup>9</sup> Australian Government, Department of Health and Ageing, *Medicare Australia*. PBS information is available from the Medicare Australia website via self-generated reports. Available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-stats.htm-copy3>

<sup>10</sup> In 2011 4.6% of those dispensed psycho-stimulants in Western Australia were for the treatment of conditions other than ADHD (Brain Damage 0.2%, Depression 2.1%, Narcolepsy 2.3%) Department of Health (2012), *Western Australian Stimulant Regulatory Scheme 2011 Annual Report*, Pharmaceutical Services Branch, Health Protection Group, Department of Health, Perth: p. 20.

states. In 2002 WA's child per capita PBS prescribing rate of dexamphetamine (at the time the only PBS subsidised ADHD drug) was approximately 2.8 times the national average (excluding WA). Of the 31,738 Australian children who received a PBS dexamphetamine prescription, 7,500 (24 percent) lived in WA, despite WA having approximately 10 percent of the total population. The 2002 figures were even more startling for Western Australian adults where the rate was 7.1 times the national average (excluding WA) and 44 percent of Australian adults who received a PBS dexamphetamine prescription lived in WA.<sup>11</sup>

However after 2003, while in other Australian states child prescribing per capita rates grew, they fell in Western Australia by 50 percent and by 2011 were 11 percent below the national average (see Figure 5 at 4.4.1). There is considerable media and public interest in these geographical and inter-temporal variations in child prescribing rates and speculation as to the reasons for these variations.

Rapid growth in the prescribing of mental health medications in Australia is not limited to ADHD medications. From 2000 to 2011 there was a 58.2 percent increase in the dispensing of psychotropic drugs in Australia, driven by large increases in per capita prescribing rates of antidepressants (up 95.3 percent), atypical antipsychotics (up 217.7 percent) and ADHD medications (up 72.9 percent).<sup>12</sup> Understanding the drivers of increasing rates of prescribing ADHD medications may offer insights into similar increases for other psychotropic medications.

Controversy in regard to the diagnosis and treatment of ADHD is not a uniquely Australian experience. Worldwide, but particularly in many developed nations, there is a highly polarised debate about these issues, with competing commercial, medical-professional, community and ideological interests seeking to influence policy and regulatory processes in relation to ADHD.

Therefore the integrity and effectiveness of policy development and regulatory processes, including the development of government-endorsed policy in relation to the diagnosis and

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<sup>11</sup> Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*

<sup>12</sup> Stephenson CP, Karanges E, McGregor IS, (2013) 'Trends in the utilisation of psychotropic medications in Australia from 2000 to 2011', *Australian and New Zealand Journal of Psychiatry*, 47(1), pp.74-87

treatment of ADHD, and their effects on child prescribing rates, is of significant interest to many stakeholders.

Additionally many of the Australian regulatory and policy development processes relating to ADHD are similar to processes conducted by the same government and non-government agencies for other physical health and mental health disorders. Therefore the rigour of these processes is a significant public policy issue.

## **1.2 The Research Questions**

The motivation for this thesis is to understand why there has been a significant increase in Australian ADHD child prescribing rates over the last twenty years with large and inconsistent intertemporal variations between state per capita rates.

Most notably, WA ADHD child prescribing per capita rates have been outliers. As outlined in section 1.1, in 2002 Western Australia's per capita rates PBS child prescribing rates were approximately 180 percent higher than the national average and by 2011 were 11 percent below the national average. Two central questions in this thesis are: why has WA been an outlier and why has it dramatically changed its relative position?

In addition to concerns about inconsistent geographical and intertemporal prescribing rates there has been significant media coverage of concerns that conflicts of interests and 'regulatory capture' have affected significant policy development and regulatory processes in relation to ADHD. This thesis will identify relevant conflicts of interest in these processes and address the question: What is the relationship between regulatory capture in regulatory and policy development processes and ADHD per capita child prescribing rates?

## **1.3 Working Hypothesis**

The central hypothesis of this research is as follows: The occurrence or absence of regulatory capture of the development and implementation of ADHD policy has contributed significantly to variations in Australian national and state ADHD medication child prescribing rates between 1992 and 2012.



Implicit in this hypothesis are the assertions that:

1. There are alternative viewpoints as to the validity of the disorder and the safety and efficacy of pharmaceutical treatments; and
2. Supporters of, and beneficiaries from, these divergent viewpoints coalesce and compete to influence policy development and the regulation of the diagnosis and treatment of ADHD.

The thesis draws heavily on the work of British sociologist John Abraham. Abraham contends regulatory capture is the most significant explanation of the process of pharmaceuticalization – the increasing per capita rates of prescribing pharmaceutical interventions for health and mental health conditions including ADHD.<sup>13</sup> Abraham bases his theory on British and U.S. experience.<sup>14 15</sup> This thesis addresses the question of whether Abraham’s explanation of pharmaceuticalization is applicable to ADHD in Australia.

#### **1.4 Methodology**

The basic task of this thesis is to test the proposition that regulatory capture explains rising child ADHD per capita prescribing rates within Australia from 1992 to 2012.

Regulatory capture occurs if an entity that is supposed to advance the public interest instead acts to benefit commercial or industry interests in ways that are contrary to the public interest. For the purposes of this thesis the term ‘regulatory capture’ is taken to have a broad scope encompassing capture of any or all of the actors, both government and non-government, which have the declared intention of protecting and enhancing the public good. In regard to ADHD examples of these non-government actors include professional organisations such as the Royal Australian College of Physicians, researchers and patient advocacy groups.

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<sup>13</sup> John Abraham (2010), ‘The Sociological Concomitants of the Pharmaceutical Industry and Medications’ in Chloe E. Bird, Peter Conrad, et al (eds.), *Handbook of Medical Sociology*, 6<sup>th</sup> edn, Nashville: pp.304-305

<sup>14</sup> John Abraham (2010), ‘Pharmaceuticalization of Society in Context: Theoretical, Empirical and Health Dimensions’, *Sociology*, Vol. 44:4, pp.603-622.

<sup>15</sup> John Abraham (2003), ‘Learning from Drug Disasters and Reforming Medicines Regulation’, *Critical public health*, 13;3, pp.269-279.

Within this thesis a number of ADHD policy development processes are analysed to evaluate the incidence of regulatory capture in Australian national and state jurisdictions. These include the development of national ADHD treatment guidelines and state specific reviews of Western Australian and New South Wales ADHD prescribing practices.

There is no single objective method of identifying regulatory capture. A common method used throughout the thesis is to identify any potential conflicts of interest of participants in policy development and regulatory processes. For the purpose of this thesis 'conflicts of interest' are broadly defined to include 'commercial conflict of interest' and/or 'professional conflict of interest' and/or 'ideological bias' in regard to ADHD.

'Commercial conflicts of interest' are evidenced by financial ties to entities with a commercial interest in ADHD diagnosis and treatment. A common example is a member of a regulatory process receiving payment from ADHD drug manufacturers. An example of a 'professional conflict of interest' would be a frequent prescriber of ADHD medications reviewing the appropriateness of current and past ADHD prescribing practices. 'Ideological bias' is defined as when a person or organisation involved in a policy development or regulatory process has expressed a strong inflexible view about the appropriateness of ADHD diagnosis or treatment.

Regulatory capture occurs when, as a result of bias, outcomes favour the interests of industry over the public. Important evidence of whether regulatory capture exists includes identifying who is involved in the process. In the case of ADHD a process dominated by ADHD proponents is likely to be 'captured'. However, the outcomes of the process must advantage commercial interests at the expense of the public benefit.

Although it is less obvious a process can still be 'captured' if the participants in the process are not biased. For example, an independent objective committee could still come up with captured outcomes if they relied on data or research that was not scientifically rigorous and produced policy outcomes that benefited industry but disadvantaged patients. Evidence of policy outcomes that are based on poor quality biased data or research is also evidence of regulatory capture. Therefore in addition to identifying bias amongst participants the

‘rigour’ of evidence used to support policy and regulatory processes is identified throughout the thesis.

It is impossible to quantify or grade the extent to which a policy or regulatory process has been ‘captured’. There is far from perfect information. In some cases the identity of participants is not publicly disclosed or there is no disclosure of potential conflicts of interests. In other processes there is no disclosure of the evidence and the deliberative processes undertaken to develop a policy or make regulatory decisions. Considerable effort has been made to discover relevant information. However, for the reasons described above, beyond identifying processes as captured, balanced, neutral or critic dominated, there is no attempt to grade or rank the relative degree of capture of the processes analysed in the thesis.

There are three commonly expressed views as to the appropriateness of ADHD diagnosis or treatment practices and all are critical of current diagnosing and prescribing rates but for different reasons. One view is that ADHD is an under-diagnosed, under-medicated, inherited, biochemical imbalance in the brain that is best treated with safe, ‘effective’ medication.<sup>16</sup> Throughout the thesis those promoting this view are described as ADHD proponents.

At the other end of the spectrum are those who believe ADHD is not a valid psychiatric diagnosis and that the medications used to treat people diagnosed with ADHD cause significantly more harms than benefits.<sup>17</sup> A third view is that ADHD is a real but rare psychiatric disorder that is frequently misdiagnosed and the medications used to treat it are grossly over-prescribed.<sup>18</sup> Throughout the thesis I categorise people holding either of these two views as ADHD critics.

ADHD proponents generally regard rising child prescribing rates as a ‘good outcome’, arguing more children’s needs are being identified and appropriately treated. In contrast some ADHD critics believe it is a legitimate but over-diagnosed disorder and argue that ADHD medication is often prescribed carelessly and without clear indication of the

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<sup>16</sup> David Hay, ‘Why is ADHD so under-diagnosed and treated?’, *ABC News: The Drum*, 4 September 2008. Available at <http://www.abc.net.au/news/2008-08-29/why-is-adhd-so-under-diagnosed-and-treated/491866> (accessed 8 January 2013)

<sup>17</sup> Baugham Jr. Fred A., and Craig Hovey (2006), *The ADHD Fraud: How Psychiatry Makes ‘Patients’ of Normal Children*, Trafford Publishing, Victoria BC

<sup>18</sup> Allen Frances (March 2012), ‘Attention Deficit Disorder is Over-Diagnosed and Over-Treated’, *Huffington Post*, 5 March 2012. Available at [http://www.huffingtonpost.com/allen-frances/attention-deficit-disorder\\_b\\_1206381.html](http://www.huffingtonpost.com/allen-frances/attention-deficit-disorder_b_1206381.html) (accessed 9 January 2013)

condition. They regard falling ADHD child prescribing rates as a ‘good outcome’, arguing fewer children are likely to be damaged by inappropriate, harmful ‘labelling’ and ‘drugging’.<sup>19</sup> Other ADHD critics argue ADHD is not a legitimate diagnosis and no child should be prescribed ADHD medications.<sup>20</sup> Although I have a long and public history as an ADHD critic this thesis will not address the issue of whether rising or falling prescribing are ‘good outcomes’. Rather it will try to identify the effect of regulatory capture on prescribing rates.

The theory of ‘regulatory capture’ is described in detail at 2.5 below. In regards to ADHD, commercial regulatory capture would occur if the interests of pharmaceutical companies, who manufacture ADHD drugs, or other commercial interests that benefit from diagnosing and treating ADHD, dominate public interest. ADHD critics are seeking to either reduce or eliminate its diagnosis and treatment with pharmaceuticals. ADHD policy development and regulatory processes can become dominated by either ADHD proponents or critics. However domination by ADHD critics does not constitute the widely accepted definition of ‘regulatory capture’ as it would likely result in diminishing or destroying commercial interests in ADHD.

Therefore any process (including policy development processes) dominated by ADHD critics is throughout this thesis referred to as ‘critic dominated’. Alternatively where there is no influence by either proponents or critics, regulatory processes are classified as ‘neutral’ and where there is significant input from both proponents and critics they are classified as ‘balanced’. In summary throughout the thesis regulatory and policy processes will be classified as being either ‘proponent captured’, ‘critic dominated’, ‘neutral’ or ‘balanced’.

There are three primary public interest purposes for the regulation of ADHD. First the Commonwealth and State governments and professional bodies like the Royal Australian College of Physicians have an interest in, or responsibility for, ensuring patient welfare through the development of appropriate diagnosis and treatment guidelines. Second, the Commonwealth Governments subsidises, and State Governments directly deliver, diagnostic services and treatments. Third, State Governments also regulate the prescribing and

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<sup>19</sup> Frances, ‘Attention Deficit Disorder is Over-Diagnosed and Over-Treated’.

<sup>20</sup> Baughman and Hovey, *The ADHD Fraud*.

dispensing of ADHD medications in order to prevent their illicit use as the most commonly prescribed pharmaceuticals for the treatment of ADHD are either an amphetamine (dexamphetamine) or classed as a near amphetamine (methylphenidate).<sup>21</sup>

Assessing the success of an ADHD regulatory regime and conversely any adverse public interest outcomes of regulatory capture would ideally involve evaluating both patient outcomes and diversion rates of prescribed ADHD medications. A fall in medication diversion and abuse rates is widely regarded as a desirable outcome by most proponents and critics. WA data about inter-temporal patterns of the diversion and abuse of ADHD medications allows some assessment of the effectiveness of regulation designed to restrict diversion and illicit use. Where available this information will be identified.

It is, however, beyond the scope of this thesis to evaluate patient outcomes. Without the ability to identify and evaluate patient outcomes the best measure of the outcome of regulatory capture is to collate information about regulatory processes and child ADHD per capita prescribing rates.

There is no single data source that provides accurate statistics of state ADHD child prescribing rates for the entire study period 1992 to 2012. Accurate statistical data of ADHD PBS funded by state specific child patient numbers is available from the Australia Department of Health and Ageing for the period 2002 to 2011.

However, it was not until July 2007 that all ADHD medications were subsidised via the PBS. The first drug subsidised via the PBS was dexamphetamine in 1992. Ritalin, although commonly prescribed, was not subsidised until 1 August 2005. Ritalin LA (long acting), Concerta and Strattera were added in 2007. As these medications became subsidised the Commonwealth Government data source became more comprehensive and useful for this analysis.

There has been significant unsubsidised prescribing of ADHD medications, particularly prior to 2007. The Commonwealth Department of Health and Ageing (DoHA) has produced a

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<sup>21</sup> DSM IV recognises the abuse and addiction to amphetamines (both methamphetamine and dexamphetamine) and methylphenidate in a common class of 'Amphetamine or Amphetamine-Like – Related Disorders'. American Psychiatric Association (2000), *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision, American Psychiatric Association, Washington DC, p. 223.

series of reports titled 'Australian Statistics on Medicines' that identify the annual national total of both PBS subsidised and unsubsidised ADHD prescriptions from 1995 to 2010. These reports do not identify individual state rates or patient numbers or ages. This data is therefore only useful for identifying national trends in prescribing.

It was not until 2002 that age specific, state specific patient numbers were collected. This data however was not reported until, upon my request, DoHA provided me with age specific, drug specific, state based data in April 2012. Between 1992 and 2002 Commonwealth Government state specific prescribing data was limited to total PBS prescription numbers and there is no reliable estimate of patient numbers or their ages.

Nonetheless several sources provide data that allows estimation of state prescribing rates, particularly for Western Australia and to a lesser extent New South Wales. The availability of these state based statistics along with the availability of significant historical data on policy and regulatory processes in these states are the reasons these states were chosen for a detailed analysis.

The methodology used to establish these state based estimates is discussed in detail in chapters 4 and 6. These estimates, together with the data from the Department of Health and Ageing, form the basis for evaluating the relationship between regulatory processes and child prescribing rates.

WA was chosen for detailed analysis between 1994 and 2012 because it has the most comprehensive and detailed historical data about both ADHD prescribing rates and regulation and policy development practices of all Australian jurisdictions. In addition it has historically been an outlier with per capita prescribing rates showing a considerably different pattern in Western Australia compared to other Australian jurisdictions.

Data for NSW is not as comprehensive. However in recent years, namely from 2007 to 2012, NSW per capita child prescribing rates have grown significantly and are now the highest in Australia. This followed a significant regulatory and policy process in 2007.

In summary, the methodology involves identifying regulatory capture in relevant policy development and regulatory processes and identifying corresponding movements in ADHD child prescribing per capita rates.

## **1.5 Structure of the Thesis**

Thus far **Chapter 1: Introduction** has provided a justification for the research question and established the main exploratory arguments. Chapter 1 has also described the methodology and introduced some key concepts used in the rest of the thesis.

**Chapter 2: Background Information and the Theoretical Framework** provides background information about the controversial aspects of ADHD, namely the validity of the diagnosis, the safety and efficacy of its treatments and its relationship to illicit drug use.

The chapter then outlines the competing explanations for the pharmaceuticalization of ADHD, i.e. increased ADHD child prescribing rates. The first viewpoint is the biomedicalized viewpoint whereby ADHD proponents contend that ADHD pharmaceuticalization is a consequence of scientific breakthroughs and better recognition of a neurobiological condition. The competing medicalization view of ADHD critics is that diagnosing ADHD is an inappropriate application of the medical model and results in the harmful use of psychotropic drugs.

Finally the chapter outlines the theoretical basis of the concept of regulatory capture. In effect this chapter identifies the competing viewpoints seeking to influence the development and regulation of ADHD policy and practice both internationally, and within Australia, and provides a theoretical framework against which to analyse the conflict.

**Chapter 3: Imported Regulatory Capture** explores the effect of imported, primarily American, 'regulatory capture' on Australian ADHD diagnosis and treatment practice.

**Chapter 4: Statistics on Australian National and Western Australian and New South Wales ADHD prescribing rates** presents relevant statistical data about national, WA and NSW child and adult prescribing per capita rates from 1992 to 2011. This data is referred to extensively in subsequent chapters.

**Chapter 5: Australian National ADHD policy and Regulatory Capture** explores the relationship between regulatory capture and changes in national ADHD child prescribing rates identified in chapter 4.

**Chapter 6: Western Australian and New South Wales ADHD policy and Regulatory Capture** explores the relationship between the degree and direction of regulatory capture and changes in WA and NSW ADHD child and adult prescribing rates as identified in chapter 4.

**Chapter 7: Discussion, Conclusions and Recommendations** finishes the thesis by testing the working hypothesis and discussing the theoretical and policy implications for Australia and similar jurisdictions.



## **Chapter 2. Literature Review - Competing perspectives on ADHD Pharmaceuticalization, Biomedicalism versus Medicalization and Regulatory Capture**

Chapter 1 described the methodology and introduced some key concepts used in the rest of the thesis. This chapter identifies the competing viewpoints of people and organisations seeking to influence the development and regulation of ADHD and outlines the theoretical basis of the concept of 'regulatory capture'.

### **2.1 The Controversies about ADHD**

The three major controversies contested by ADHD proponents and ADHD critics are:

1. The validity of the diagnosis.
2. The safety and efficacy of the pharmaceuticals used to treat it.
3. The relationship between ADHD and drug addiction and abuse.

These are discussed in turn below.

#### **2.1.1 The validity of the diagnosis**

ADHD is a psychiatric disorder characterised by dysfunctional levels of inattention and/or impulsive/hyperactive behaviour. It is defined in the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV), the American Psychiatric Association's catalogue of mental illness.<sup>22</sup> DSM-IV was first published in 1994 and revised in 2000 however, there were no changes to the diagnostic criteria for ADHD in the revision. Earlier editions of the *Diagnostic and Statistical Manual of Mental Disorders* had included ADHD's predecessors, Attention Deficit Disorder (DSM-III 1980) and Hyperactive Disorder of Children (DSM-II 1968).

Although it is the most commonly diagnosed and medicated childhood psychiatric disorder in the world, there is a range of professional opinions as to the validity of ADHD as a psychiatric disorder. Proponents believe ADHD is a common genetically determined neurobiological disorder - that is, a 'biochemical brain imbalance' - which is under-diagnosed and under-medicated. Leading international ADHD proponent US psychologist Dr Russell Barkley<sup>23</sup> describes the disorder as 'a developmental failure in brain circuitry that underlies inhibition and

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<sup>22</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn.

<sup>23</sup> Dr Russell Barkley is a Research Professor in the Department of Psychiatry at the State University of New York Upstate Medical University and author of numerous works on ADHD.

self-control. This loss of self-control in turn impairs other important brain functions crucial for maintaining attention.<sup>24</sup> At the other end of the spectrum some ADHD critics argue ADHD is a fraudulent construct.<sup>25</sup> A third, middle view, is that ADHD is a rare but real condition that is frequently misdiagnosed and over-prescribed.

Much of the controversy stems from the fact that the diagnosis of ADHD is based on observations of behaviour, as 'there are no laboratory tests, neurobiological assessments, or attentional assessments that have been established as diagnostic in the clinical assessment of Attention Deficit/Hyperactivity Disorder'.<sup>26</sup> These behaviours include making careless mistakes, not seeming to listen, not following through on instructions, disliking homework, losing things, being forgetful in daily activities, fidgeting, climbing excessively, having difficulty playing quietly, talking excessively and interrupting.<sup>27</sup> Box 1 contains the full DSM-IV ADHD diagnostic criteria.

**Box 1 - Extract from DSM-IV: ADHD Diagnostic Criteria**

A. Diagnostic Criteria for Attention Deficit/Hyperactivity Disorder:

Either (1) or (2):

1. six (or more) of the following symptoms of inattention have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

*Inattention*

- a. often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities
- b. often has difficulty sustaining attention in tasks or play activities
- c. often does not seem to listen when spoken to directly
- d. often does not follow through on instructions and fails to finish schoolwork, chores, or duties in the workplace  
(not due to oppositional behavior or failure to understand instructions)
- e. often has difficulty organizing tasks and activities
- f. often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as schoolwork or homework)
- g. often loses things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools)

<sup>24</sup> Dr Russel Barkley quoted in Alistair Smith (2004), *The Brains Behind It: New Knowledge about the Brain and Learning*, revised edn, Network Educational Press Limited, Stafford, p.121. Available at <http://books.google.com.au/books?id=Zd7527QgM6AC&printsec=frontcover&dq=The+Brains+Behind+It&source=bl&ots=4qoiomiVwG&sig=dG-dvEA-0E7Y9hK1sVGDBAlu2u4&hl=en#v=onepage&q=The%20Brains%20Behind%20It&f=false>

<sup>25</sup> Baughman and Hovey, *The ADHD Fraud*.

<sup>26</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, pp.88-89.

<sup>27</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, pp.88-89.

- h. is often easily distracted by extraneous stimuli
  - i. is often forgetful in daily activities
2. six (or more) of the following symptoms of hyperactivity-impulsivity have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

*Hyperactivity*

- a. often fidgets with hands or feet or squirms in seat
- b. often leaves seat in classroom or in other situations in which remaining seated is expected
- c. often runs about or climbs excessively in situations in which it is inappropriate (in adolescents or adults, may be limited to subjective feelings of restlessness)
- d. often has difficulty playing or engaging in leisure activities quietly
- e. is often “on the go” or often acts as if “driven by a motor”
- f. often talks excessively

*Impulsivity*

- g. often blurts out answers before questions have been completed
  - h. often has difficulty awaiting turn
  - i. often interrupts or intrudes on others (e.g., butts into conversations or games)
- B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.
- C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).
- D. There must be clear evidence of clinically significant impairment in social, academic, or occupational functioning.
- E. The symptoms do not occur exclusively during the course of a Pervasive Developmental Disorder, Schizophrenia, or other Psychotic Disorder and are not better accounted for by another mental disorder (e.g., Mood Disorder, Anxiety Disorder, Dissociative Disorder, or a Personality Disorder).

ADHD critics contend these are all normal behaviours, particularly for children and especially boys. ADHD proponents counter this assertion by arguing that all psychiatric disorders - many of which are also treated with medication - are diagnosed using behavioural criteria. However, ADHD critics contend that at least conditions like schizophrenia involve extreme behaviours such as delusions or catatonia. In response, proponents acknowledge that while many people without ADHD are occasionally impulsive and/or hyperactive, what distinguishes ADHD sufferers from the rest of the population is their level of behavioural impairment or dysfunction. Specifically, ‘there must be clear evidence of clinically significant impairment in social, academic

or occupational functioning' and 'some impairment from the symptoms...[must be] present in two or more settings (e.g. at school or work and at home)'.<sup>28</sup> All eighteen behavioural criteria include the word often. How 'often' a child 'fidgets or squirms in their seat', or 'interrupts' or 'avoids homework' or 'fails to remain seated when remaining seated is expected' or 'is distracted by external stimuli' etc. so that they exhibit 'some impairment', is not defined in DSM-IV. The DSM-IV diagnostic criteria do not specify age-appropriate levels of attention or impulsivity control. The same eighteen behavioural diagnostic criteria are applied whether the child is two or seventeen.

The diagnosing clinician does not have to observe any of the symptoms or any impairment. He or she may base their diagnosis on third-party accounts of a child's behaviour. The child's parents and teachers usually provide these and are typically asked to fill in a questionnaire detailing if their child always, often, sometimes or never displays behaviour like avoiding homework and chores, losing toys, not listening, fidgeting, butting in, talking excessively or being easily distracted or forgetful. The most commonly used questionnaire is the Connors rating scale which basically formats the 18 diagnostic ADHD criteria in a tickbox questionnaire format.

'There are three Connors rating scales. One is designed for parents, another is for teachers, and a third Connors test asks adolescents to rate their own behavior.

Completing an ADHD Connors test takes from 5 to 30 minutes, depending on whether you're given the short or long version of the test. Long versions of the Connors ratings scales have about 60 to 90 questions, while short versions have less than 30 questions'<sup>29</sup>

DSM-IV states: 'Signs of the disorder may be minimal or absent when the person is receiving frequent rewards for appropriate behaviour, is under close supervision, is in a novel setting, is engaged in especially interesting activities, or is in a one-to-one situation (e.g., the clinician's office.)'<sup>30</sup> Therefore, according to the American Psychiatric Association's DSM-IV and other proponents, children with ADHD may behave appropriately and not display ADHD symptoms when they are rewarded, when people pay attention to them (close supervision) and when they

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<sup>28</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, pp.92-93.

<sup>29</sup> 'ADHD Connors Test', *The ADD/ADHD Support Site*. Available at <http://www.attentiondeficit-add-adhd.com/adhd-connors-test.htm> (accessed 7 May 2013).

<sup>30</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, pp.86-87.

are having new experiences. Conversely, children with ADHD may be inattentive, easily distracted and display ADHD symptoms when their good behaviour goes unrewarded, no one pays any attention to them, or they are bored.

Critics contend that the diagnostic process is unreliable, subjective and unscientific. They argue that this results in normal childhood behaviours being pathologised as the symptoms of disease and that on occasions labelling a child with ADHD hampers the identification of real disease and/or abuse or other problems. ADHD critic, prominent social and political historian Francis Fukuyama, considers part of the reason for the explosion in ADHD diagnosis rates is that modern time-poor societies are impatient with difference:

ADHD isn't a disease at all but rather just the tail of the bell curve describing the distribution of perfectly normal behaviour. Young human beings, and particularly young boys, were not designed by evolution to sit around at a desk for hours at a time paying attention to a teacher, but rather to run and play and do other physically active things. The fact that we increasingly demand they sit still in classrooms, or that parents and teachers have less time to spend with them on interesting tasks, is what creates the impression that there is a growing disease.<sup>31</sup>

The diagnostic criteria for ADHD are defined in terms most applicable to children and require 'some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years'.<sup>32</sup> In recent years considerable energy has been put into promoting the recognition of 'Adult ADHD'. (Refer to 6.4.2) However, as children, unlike adults, do not have the capacity for informed consent, and there are additional concerns about the effects of ADHD drugs on the developing brains and bodies of children, the issue of child ADHD is more controversial than adult ADHD.

Although ADHD diagnostic criteria are set by the APA, it is not only psychiatrists who use them. Paediatricians and even in some cases general practitioners diagnose and prescribe for the disorder and are frequently involved in research and developing policies in regard to its

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<sup>31</sup> Francis Fukuyama, Professor of International Political Economy at John Hopkins University, cited in Baughman and Hovey, *The ADHD Fraud*, p.17.

<sup>32</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, pp.92-93.

diagnosis and treatment.

### 2.1.2 The safety and efficacy of the pharmaceuticals used to treat ADHD

Although the behavioural basis of the diagnosis is controversial, the use of pharmaceutical interventions to treat the disorder is the primary source of controversy.

While many ADHD proponents acknowledge the aetiology of ADHD is uncertain they act on the assumption that ADHD is a neurobiological disorder caused by a biochemical brain imbalance. The assumption of a biochemical imbalance invites a biochemical, i.e. pharmaceutical, treatment. The most commonly used drugs to treat ADHD are the amphetamine-based psychostimulants dexamphetamine (current brand names Adderall, Dexedrine, Dexostat) and methylphenidate (Ritalin, Concerta, Attenta).<sup>33</sup> Another ADHD drug, Strattera, the brand name for atomoxetine hydrochloride, is not amphetamine-based and was prescribed to approximately 8.7 percent (7,054) of the 80,647 Australians who received PBS subsidised ADHD medications in 2011.<sup>34</sup>

#### 2.1.2.1 ADHD Stimulants

Proponents of ADHD medications argue that 'stimulants like dexamphetamine and methylphenidate (such as Ritalin) work by acting on the neurotransmitters that release the chemical dopamine. Greater amounts of dopamine help to curb the hyperactive and impulsive behaviours typical of the child with ADHD.'<sup>35</sup> They contend that the temporary sharpening (narrowing) of focus resulting from the use of stimulants makes children more available for learning, enabling them to achieve better academic results in the long run.<sup>36</sup>

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<sup>33</sup> Other less commonly used brand names for methylphenidate include Methylin, Daytrana, Rubifen, Equasym and Metadate.

<sup>34</sup> Note: Some patients (3,320 in 2011) receive Pharmaceutical Benefits Scheme sponsored prescriptions for a combination of ADHD drugs. While 7,054 Australians received PBS subsidised Strattera it is very likely that a significant number also received other PBS ADHD drugs as Strattera is only supposed to be prescribed as a second line treatment when stimulants prove ineffective or have unacceptable side effects. Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.

<sup>35</sup> 'Attention deficit hyperactivity disorder - drug therapy', *Better Health Channel*, nd. Available at [http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/attention\\_deficit\\_hyperactivity\\_disorder\\_-\\_drug\\_therapy?open](http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/attention_deficit_hyperactivity_disorder_-_drug_therapy?open) (accessed 28 December, 2011)

<sup>36</sup> Government of Western Australia (2010), Raine ADHD Study: Long-term outcomes associated with stimulant medication in the treatment of ADHD in children, Department of Health, Perth, p.30.  
The short term studies referred to in the Raine Study are Howard B. Abikoff, et al. (2007), 'Methylphenidate effects on Functional Outcomes in the Preschoolers with Attention-Deficit/Hyperactivity Disorder Treatment

Critics counter this contention by arguing that when taken orally in low doses psycho-stimulants will temporarily sharpen focus in most people regardless of their ADHD status.<sup>37</sup> The stimulant effects are very short, lasting a matter of hours with ‘no evidence that the medications promote or cause psychological, social, or emotional growth’ in the long term.<sup>38</sup> Critics also contend that ‘there is a paucity of evidence on the long-term effects of psycho-stimulant medication on children’<sup>39</sup> and that the little long term evidence there is indicates no lasting benefits, and significant risks from sustained use (see 6.7). Established potential adverse effects of psychostimulants include common and relatively mild short term side effects like insomnia and headaches and rare, life threatening side effects such as psychosis, strokes and suicide. These potential side effects are outlined in a comprehensive extract from the U.S FDA-approved prescribing information made available to clinicians for Dexedrine (a brand of dexamphetamine) provided at Appendix 1.<sup>40</sup> It is very similar to the US prescribing information for Ritalin (a brand of methylphenidate).<sup>41</sup>

### 2.1.2.2 Atomoxetine (Brand name Strattera)

Strattera is manufacturer Eli Lilly’s brand name for atomoxetine hydrochloride, a noradrenaline reuptake inhibitor. Unlike dexamphetamine and methylphenidate, Strattera is not amphetamine based and is considered to be non-addictive and unsuitable for illicit use. It was first trialled in 1982 as an antidepressant branded Tomoxetine but was found to be ineffective.<sup>42</sup>

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Study (PATS)’, *Journal of Child and Adolescent Psychopharmacology*, 17(5), pp. 581–92; C. L. Carlson & M. R. Bunner (1993), ‘Effects of Methylphenidate on the Academic Performance of Children with Attention-Deficit Hyperactivity Disorder and Learning Disabilities’, *School Psychology Review*, 22(2), pp. 184–98; Irene M. Loe & Heidi M. Feldman (2007), ‘Academic and educational outcomes of children with ADHD’, *Journal of Pediatric Psychology*, 32(6), pp. 643–54.

<sup>37</sup> Lori Jeanne Peloquin and Rafael Klorman (1986), ‘Effects of Methylphenidate on Normal Children’s Mood, Event-Related Potentials, and Performance in Memory, Scanning and Vigilance’, *Journal of Abnormal Psychology*, Vol. 95, No. 1, pp.88-98.

<sup>38</sup> Lydia Furman (2005), ‘What is Attention-Deficit Hyperactivity Disorder (ADHD)?’ *Journal of Child Neurology*, Vol. 20 No. 12, p.998.

<sup>39</sup> Western Australia Legislative Assembly (2004), *Attention Deficit Hyperactivity Disorder in Western Australia*, Education and Health Standing Committee, Report No. 8, p. 42.

<sup>40</sup> Extract from U.S. Prescribing Information for Dexedrine produced by Glaxo Smith Kline. Available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2006/017078s040lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/017078s040lbl.pdf) (accessed 21 March 2013)

<sup>41</sup> Extract from U.S. Prescribing Information for Ritalin (methylphenidate hydrochloride) produced by Novartis Pharmaceuticals. Available at [http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pi/pdf/ritalin\\_ritalin-sr.pdf](http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pi/pdf/ritalin_ritalin-sr.pdf) (accessed 31 March 2013)

<sup>42</sup> G. Chouinard, L. Annable, and J. Bradwejn (1984), ‘An early phase II clinical trial of tomoxetine (LY139603) in the treatment of newly admitted depressed patients’, *Psychopharmacology*, 83, p.126.

Strattera came onto the Australian market in early 2004. Strattera is only supposed to be prescribed as a second line treatment when stimulants prove ineffective or have unacceptable side effects. Despite claims of it being a milder ADHD drug than psychostimulants, concerns soon emerged about its safety. On 17 December 2004 the US FDA issued a talk paper, *'New Warning for Strattera'*, which stated:

The drug's labeling is being updated with a bolded warning about the potential for severe liver injury in patients taking Strattera. The label warns that severe liver injury can progress to liver failure in a small percentage of patients. It cautions clinicians to discontinue the drug in patients who develop jaundice or laboratory evidence of liver injury. It also notes that the actual number of cases of severe liver injury from the drug is not known because of under-reporting.<sup>43</sup>

Less than a year later, on 29 September 2005, the FDA issued a public health advisory announcing they had put the highest possible black box warning on Strattera for suicidal ideation:

Strattera increases the risk of suicidal thinking in children and adolescents with ADHD. Patients who are started on therapy should be observed closely for clinical worsening, suicidal thinking or behaviours, or unusual changes in behaviour. Families and caregivers should be advised to closely observe the patient and to communicate changes or concerning behaviours with the prescriber.<sup>44</sup>

In March 2006 the Australian Therapeutic Goods Administration (TGA) followed the FDA's lead and issued an equivalent 'suicidality' warning. In November 2011 the TGA added a

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<sup>43</sup> Food and Drug Administration (March 2005), *Warning on Liver Injury from Strattera: FDA Patient Safety News: Show #37*. Available at <http://www.accessdata.fda.gov/psn/prnter.cfm?id=302> (accessed 18 July 2007).

<sup>44</sup> Food and Drug Administration (29 September 2005), *Public Health Advisory: Suicidal Thinking in Children and Adolescents Being Treated with Strattera (Atomoxetine)*. Available <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm051733.htm> (accessed 13 September 2009); 'In review of 2,200 patients, 1, 357 of whom were taking Strattera, researchers found that 0.4 per cent of the children taking the drug reported suicidal thinking, compared to no cases in children taking a placebo. There was also one suicide attempt in the Strattera group.' Amanda Gardner (2005), 'FDA Issues Alert on ADHD Drug Strattera', *Healthday Reporter*, 29 September 2005.



warning about ‘clinically significant increases in heart rate and blood pressure’. The safety advisory warns ‘Atomoxetine [Strattera] is contraindicated in patients with symptomatic cardiovascular diseases, moderate to severe hypertension or severe cardiovascular disorders, whose condition would be expected to deteriorate if they experienced increases in blood pressure or in heart rate that could be clinically important.’<sup>45</sup> It followed new data obtained from clinical trials sponsored by Eli Lilly.

An extract of the Prescribing Information for Strattera is contained in Appendix 2.

### 2.1.3 ADHD and Drug Abuse

Proponents contend that the ‘under-recognition’ of ADHD is a cause of illicit drug abuse. They argue that early identification of ADHD and subsequent medication prevents undiagnosed individuals using illicit drugs to self-medicate.<sup>46</sup> ADHD critics counter that the amphetamine and amphetamine-like drugs most commonly used to treat ADHD are often diverted for illicit use or abused.

The effects of ADHD stimulants are similar to illicit amphetamines. In the US prescription methamphetamine (brand name Desoxyn) is used as an ADHD treatment.

Methamphetamine and cocaine, when taken orally in low doses, have temporary ‘focus narrowing’ effects similar to dexamphetamine and Ritalin. With a therapeutic dose of stimulants in their system most people become more narrowly focussed.<sup>47</sup>

Dr Peter Breggin contends;

The big difference (between ADHD stimulants and cocaine) appears to be the time it takes for the drug to reach the brain. Inhaled or injected cocaine hits the brain in seconds, while pills of Ritalin (and other ADHD stimulants) normally consumed take about an hour to reach the brain. Like cocaine,

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<sup>45</sup> Department of Health and Ageing (2011), *Therapeutic Goods Administration*, ‘Atomoxetine (Strattera) - risk of increased blood pressure and/or heart rate’, 2 November 2011. Available at <http://www.tga.gov.au/safety/alerts-medicine-atomoxetine-111102.htm> (accessed 5 June 2012).

<sup>46</sup> For instance, see Dave Coghill (2005), ‘Attention-deficit hyperactivity disorder: should we believe the mass media or peer-reviewed literature?’, *The Psychiatrist*, 29, pp.288–91; Dr Ken Whiting (2003), *Fact Sheet: Attention Deficit/Hyperactivity Disorder 2003 Update*, Learning and Attentional Disorders Society of WA, Perth.

<sup>47</sup> Peter R. Breggin M.D. (1998), *Talking back to Ritalin: What doctors aren't telling you about stimulants for children*, Common Courage Press, Monroe, p.73.

chronic use of Ritalin produces psychomotor stimulant toxicity, including aggression, agitation, disruption of food intake, weight loss, stereotypic movements and death.<sup>48</sup>

The American Psychiatric Association recognises that amphetamines, methylphenidate and cocaine are 'neuro-pharmacologically alike'.<sup>49</sup> DSM-IV recognises the abuse and addiction of these drugs in a common class of 'Amphetamine or Amphetamine-Like – Related Disorders'. It states: 'Prescribed stimulants have sometimes been diverted into the illegal market...Most of the effects of amphetamines and amphetamine-like drugs are similar to those of cocaine.'<sup>50</sup> Furthermore, the diagnostic criteria for 'Amphetamine Intoxication' include 'recent use of amphetamine or a related substance (e.g. methylphenidate)' and many of their potential side effects, including impaired social or occupational functioning, tachycardia, elevated blood pressure, nausea or vomiting, weight loss dyskinesia and dystonia, are common to both illicit amphetamines and prescribed psychostimulants.<sup>51</sup> All ADHD stimulants are addictive and carry similar warnings for abuse as the following warning in Box 2 for Dexedrine (a brand of dexamphetamine).<sup>52</sup>

**Box 2 - Extract from Prescribing Information for Dexedrine (a brand of dexamphetamine)**

**AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY. MISUSE OF AMPHETAMINES MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIO-VASCULAR ADVERSE EVENTS.**

The potential for illicit diversion is recognised in laws enacted by all Australian states and territories which make it illegal to possess, sell or use them without a prescription. In WA for

<sup>48</sup> Breggin, *Talking back to Ritalin*, p.73.

<sup>49</sup> American Psychiatric Association, *Treatments of Psychiatric Disorders: a task force report of the American Psychiatric Association*, Vol. 2, American Psychiatric Association, Washington DC (1989), p.1221.

<sup>50</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, p.223.

<sup>51</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, p.225.

<sup>52</sup> GlaxoSmithKline, *Prescribing Information – Dexedrine (dextroamphetamine sulphate)*. Available at [http://www.gskus.com/products/assets/us\\_dexedrine.pdf](http://www.gskus.com/products/assets/us_dexedrine.pdf) (accessed 28 July 2009).

example anyone found in possession of, or using, dexamphetamine or methylphenidate without a prescription may be fined up to \$2000 and/or receive a prison term of up to two years. Anyone convicted of selling or intent to sell dexamphetamine or methylphenidate illegally may receive a fine of up to \$100,000 and/or a prison term of up to twenty-five years.<sup>53</sup>

Nonetheless, ADHD proponents contend that in the absence of controlled doses of prescription stimulants, adolescents and adults with ADHD will seek and take illicit drugs in uncontrolled doses. There is also considerable support amongst ADHD proponents for the use of prescription stimulants as a substitution therapy for those addicted to illicitly obtained amphetamines.<sup>54</sup>

## 2.2 Pharmaceuticalization

Abraham coined the term 'pharmaceuticalization' to describe the process by which 'social, behavioral, or bodily conditions are treated, or deemed to be in need of treatment/intervention, with pharmaceuticals by doctors, patients, or both.'<sup>55</sup>

Pharmaceuticalization is a statistical reality for ADHD in Australia as prescribing rates have grown enormously during the period analysed in this thesis.

Abraham contends that pharmaceuticalization is frequently an inappropriate result of 'making the social medical'. However he believes that 'not all pharmaceuticalization involves making the social medical.' He cites the treatment of bacterial infections, previously without effective drug remedies, with new antibiotics as an example of pharmaceuticalization that benefits consumers.<sup>56</sup> In similar cases of genuine technological advancement he acknowledges that 'pharmaceuticalization' is in the public interest.

ADHD prescribing in Australia is just one example, of many, of pharmaceuticalization. The disputed questions around ADHD pharmaceuticalization are not if it is occurring, but rather why it is happening and is it appropriate?

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<sup>53</sup> Drug and Alcohol Office (2002), *Dexamphetamine: Facts*, Prevention Branch, Drug and Alcohol Office, Perth, p.3.

<sup>54</sup> Australian Government, National Amphetamine-Type Stimulant Strategy Background Paper: Monograph Series No. 69, *National Drug Strategy*. Available at <http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/mono69-1~mono69-1-ch5~mono69-1-ch5.6> (accessed 1 September 2012).

<sup>55</sup> Abraham, 'The Sociological Concomitants', p.290.

<sup>56</sup> Abraham, 'The Sociological Concomitants', p.291.

### 2.2.1 Competing Explanations for ADHD Pharmaceuticalization

Abraham has identified two competing explanations for the process of pharmaceuticalization: 'biomedicalism' which endorses pharmaceuticalization, and 'medicalization' which criticises it. He contends that the validity of the two explanations depends upon the condition or disorder being 'treated'. ADHD proponents typically subscribe to a biomedicalized explanation that encourages increased treatment with 'medications'. In contrast ADHD critics typically subscribe to a medicalization explanation of ADHD that either opposes any use of ADHD medication or seeks to reduce the number of children prescribed ADHD drugs.

#### 2.2.1.1 The Biomedicalized Viewpoint of ADHD Proponents

Abraham defines those who 'assert or give the impression that the expansion of pharmaceutical markets and prescribing over the last few decades is best understood as the innovative responses of biomedical science to growing and new health needs' as subscribing to the 'biomedicalization thesis'.<sup>57</sup> Many, including WA Professor of Psychology David Hay, argue that ADHD pharmaceuticalization has not gone far enough. Hay contends ADHD is an under-diagnosed, under-medicated, inherited, biochemical imbalance in the brain that is best treated with safe, effective medication.<sup>58</sup>

Proponents of ADHD contend it is a legitimate medical neurobiological condition treatable with safe effective medications. Abraham refers to this approach to ADHD as an example of the 'biomedicalism thesis' and identifies it as being in direct opposition to the 'medicalization thesis' of ADHD that he expressly supports.<sup>59</sup>

Some ADHD proponents acknowledge the proposal that it is caused by a biochemical brain imbalance as a hypothesis or theory. For example in DSM-5 the American Psychiatric Association classifies ADHD as a neurodevelopment disorder, whilst as was the case with DSM-IV, acknowledging the aetiology is uncertain.<sup>60 61</sup> Many other ADHD proponents are

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<sup>57</sup> Abraham, 'The Sociological Concomitants', p.290.

<sup>58</sup> Hay, 'Why is ADHD so under-diagnosed and treated?'

<sup>59</sup> Abraham, 'The Sociological Concomitants', p.290.

<sup>60</sup> John M. Grohol, 'DSM-5 Changes: Attention Deficit Hyperactivity Disorder (ADHD)' available at <http://pro.psychcentral.com/2013/dsm-5-changes-attention-deficit-hyperactivity-disorder-adhd/004321.html> (accessed 2 September 2013).

less restrained and treat this theory as fact by declaring ADHD a ‘genetic, neurobiological disorder’ or a ‘biochemical brain imbalance.’<sup>62</sup>

The major developments in successive editions of the DSM definition of ADHD and in the professional understanding of ADHD have been the result of medico-political processes such as committee consensus or votes rather than scientific discovery. For example, in 2002, a self-described ‘independent consortium’ of eighty-four ‘leading scientists’ signed the ‘International Consensus Statement on ADHD’ contained in box 3 below.<sup>63</sup> The first signatory was prominent ADHD proponent, American psychologist Dr Russell Barkley.

**Box 3 - International Consensus Statement on ADHD**

*Clinical Child and Family Psychology Review, Vol. 5, No. 2, June 2002 ( C ° 2002)  
January 2002*

We, the undersigned consortium of international scientists, are deeply concerned about the periodic inaccurate portrayal of attention deficit hyperactivity disorder (ADHD) in media reports. This is a disorder with which we are all very familiar and toward which many of us have dedicated scientific studies if not entire careers. We fear that inaccurate stories rendering ADHD as myth, fraud, or benign condition may cause thousands of sufferers not to seek treatment for their disorder. It also leaves the public with a general sense that this disorder is not valid or real or consists of a rather trivial affliction.

We have created this consensus statement on ADHD as a reference on the status of the scientific findings concerning this disorder, its validity, and its adverse impact on the lives of those diagnosed with the disorder as of this writing (January 2002). Occasional coverage of the disorder casts the story in the form of a sporting event with evenly matched competitors. The views of a handful of non-expert doctors that ADHD does not exist are contrasted against mainstream scientific views that it does, as if both views had equal merit. Such attempts at balance give the public the impression that there is substantial scientific disagreement over whether ADHD is a real medical condition.

In fact, there is no such disagreement—at least no more so than there is over whether smoking causes cancer, for example, or whether a virus causes HIV/AIDS. The U.S. Surgeon General, the American Medical Association, the American Psychiatric Association, the American Academy of Child and Adolescent Psychiatry, the American Psychological Association, and the American Academy of

<sup>61</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, pp.85-93.

<sup>62</sup> For some examples of this theory, see Nora D. Volkow, MD; Gene-Jack Wang, MD, et al, (2007), ‘Depressed Dopamine Activity in Caudate and Preliminary Evidence of Limbic Involvement in Adults With Attention-Deficit/Hyperactivity Disorder’, *JAMA Psychiatry, Arch Gen Psychiatry*; 64(8), pp.932-940; Philip Shaw, MD; Jason Lerch, PhD, et al, (2006), ‘Longitudinal Mapping of Cortical Thickness and Clinical Outcome in Children and Adolescents With Attention-Deficit/Hyperactivity Disorder’ *Arch Gen Psychiatry*. 63(5), pp.540-549.

<sup>63</sup> Russell A. Barkley, et al. (2002), ‘International Consensus Statement on ADHD’, *Clinical Child and Family Psychology Review*, Vol 5, No. 2, p.89. Available at <http://www.russellbarkley.org/factsheets/Consensus2002.pdf> 9 (accessed 28 March 2013)

Pediatrics, among others, all recognize ADHD as a valid disorder. Although some of these organizations have issued guidelines for evaluation and management of the disorder for their membership, this is the first consensus statement issued by an independent consortium of leading scientists concerning the status of the disorder.

Among scientists who have devoted years, if not entire careers, to the study of this disorder there is no controversy regarding its existence.

### **ADHD and Science**

We cannot overemphasize the point that, as a matter of science, the notion that ADHD does not exist is simply wrong. All of the major medical associations and government health agencies recognize ADHD as a genuine disorder because the scientific evidence indicating it is so overwhelming.

Various approaches have been used to establish whether a condition rises to the level of a valid medical or psychiatric disorder. A very useful one stipulates that there must be scientifically established evidence that those suffering the condition have a serious deficiency in or failure of a physical or psychological mechanism that is universal to humans. That is, all humans normally would be expected, regardless of culture, to have developed that mental ability.

And there must be equally incontrovertible scientific evidence that this serious deficiency leads to harm to the individual. Harm is established through evidence of increased mortality, morbidity, or impairment in the major life activities required of one's developmental stage in life. Major life activities are those domains of functioning such as education, social relationships, family functioning, independence and self-sufficiency, and occupational functioning that all humans of that developmental level are expected to perform.

As attested to by the numerous scientists signing this document, there is no question among the world's leading clinical researchers that ADHD involves a serious deficiency in a set of psychological abilities and that these deficiencies pose serious harm to most individuals possessing the disorder. Current evidence indicates that deficits in behavioral inhibition and sustained attention are central to this disorder—facts demonstrated through hundreds of scientific studies. And there is no doubt that ADHD leads to impairments in major life activities, including social relations, education, family functioning, occupational functioning, self-sufficiency, and adherence to social rules, norms, and laws. Evidence also indicates that those with ADHD are more prone to physical injury and accidental poisonings. This is why no professional medical, psychological, or scientific organization doubts the existence of ADHD as a legitimate disorder.

The central psychological deficits in those with ADHD have now been linked through numerous studies using various scientific methods to several specific brain regions (the frontal lobe, its connections to the basal ganglia, and their relationship to the central aspects of the cerebellum). Most neurological studies find that as a group those with ADHD have less brain electrical activity and show less reactivity to stimulation in one or more of these regions. And neuro-imaging studies of groups of those with ADHD also demonstrate relatively smaller areas of brain matter and less metabolic activity of this brain matter than is the case in control groups used in these studies.

These same psychological deficits in inhibition and attention have been found in numerous studies of identical and fraternal twins conducted across various countries (US, Great Britain, Norway, Australia etc.) to be primarily inherited. The genetic contribution to these traits is routinely found to be among the highest for any psychiatric disorder (70–95% of trait variation in the population), nearly approaching the genetic contribution to human height. One gene has recently been reliably

demonstrated to be associated with this disorder and the search for more is underway by more than 12 different scientific teams worldwide at this time.

Numerous studies of twins demonstrate that family environment makes no significant separate contribution to these traits. This is not to say that the home environment, parental management abilities, stressful life events, or deviant peer relationships are unimportant or have no influence on individuals having this disorder, as they certainly do. Genetic tendencies are expressed in interaction with the environment.

Also, those having ADHD often have other associated disorders and problems, some of which are clearly related to their social environments. But it is to say that the underlying psychological deficits that comprise ADHD itself are not solely or primarily the result of these environmental factors.

This is why leading international scientists, such as the signers below, recognize the mounting evidence of neurological and genetic contributions to this disorder. This evidence, coupled with countless studies on the harm posed by the disorder and hundreds of studies on the effectiveness of medication, buttresses the need in many, though by no means all, cases for management of the disorder with multiple therapies. These include medication combined with educational, family, and other social accommodations.

This is in striking contrast to the wholly unscientific views of some social critics in periodic media accounts that ADHD constitutes a fraud, that medicating those afflicted is questionable if not reprehensible, and that any behavior problems associated with ADHD are merely the result of problems in the home, excessive viewing of TV or playing of video games, diet, lack of love and attention, or teacher/school intolerance.

ADHD is not a benign disorder. For those it afflicts, ADHD can cause devastating problems. Follow-up studies of clinical samples suggest that sufferers are far more likely than normal people to drop out of school (32–40%), to rarely complete college (5–10%), to have few or no friends (50–70%), to underperform at work (70–80%), to engage in antisocial activities (40–50%), and to use tobacco or illicit drugs more than normal. Moreover, children growing up with ADHD are more likely to experience teen pregnancy (40%) and sexually transmitted diseases (16%), to speed excessively and have multiple car accidents, to experience depression (20–30%) and personality disorders (18–25%) as adults, and in hundreds of other ways mismanage and endanger their lives.

Yet despite these serious consequences, studies indicate that less than half of those with the disorder are receiving treatment. The media can help substantially to improve these circumstances. It can do so by portraying ADHD and the science about it as accurately and responsibly as possible while not purveying the propaganda of some social critics and fringe doctors whose political agenda would have you and the public believe there is no real disorder here.

To publish stories that ADHD is a fictitious disorder or merely a conflict between today's Huckleberry Finns and their caregivers is tantamount to declaring the earth flat, the laws of gravity debatable, and the periodic table in chemistry a fraud. ADHD should be depicted in the media as realistically and accurately as it is depicted in science—as a valid disorder having varied and substantial adverse impact on those who may suffer from it through no fault of their own or their parents and teachers.

As evidenced in the consensus statements ADHD proponents consider it is a valid psychiatric disorder because 'those suffering the condition have a serious deficiency [that] leads to harm to

the individual'. This includes harm 'in the major life activities...such as education, social relationships, family functioning, independence and self-sufficiency, and occupational functioning'. Critics respond that ADHD is a collection of loosely defined mildly dysfunctional behavioural symptoms, which is mistakenly regarded as the biological cause. They contend diagnosing ADHD involves identifying dysfunction in what is already identified as a dysfunctional population. Psychologist and Professor Emeritus at California State University, David Keirse, criticises the circularity of the argument stating, 'It's preposterous to say that the symptoms of attention deficit cause the deficit of attention.'<sup>64</sup>

The claim in the consensus statement that the signatories were an 'independent consortium' is contested by ADHD critics on a number of grounds. First, there is the obvious personal motivation in validating the authenticity of a controversial disorder for those 'who have devoted years, if not entire careers' to its study. In addition, many of the consortium of 'leading scientists' earn their incomes either through diagnosing and prescribing for ADHD or conducting drug-company funded research into the 'disorder'.

In the International Consensus Statement the legitimacy of ADHD is stated as an indisputable truth. Critics are dismissed as 'flat earthers' with the level of certainty around ADHD deemed to be equivalent to that supporting, 'the laws of gravity' and the 'periodic table'. The ADHD critic view that 'behavior problems associated with ADHD' result from a variety of causes including 'diet' is dismissed as 'wholly unscientific'. However, there is significant evidence that diet can contribute to inattentive and hyperactive behaviour in children.<sup>65 66</sup>

British psychiatrist and ADHD critic Sami Timimi believes the Consensus Statement was a response to the authors being 'shaken by criticism' of ADHD diagnosing and prescribing.<sup>67</sup> Timimi is highly critical of the Consensus Statement and sees it as an attempt to shut down debate:

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<sup>64</sup> David Keirse, 'The Great A.D.D. Hoax' at Keirse.com. Available at [http://www.keirse.com/add\\_hoax.aspx](http://www.keirse.com/add_hoax.aspx) (accessed 20 March 2008).

<sup>65</sup> Rowe KS, Rowe KJ, (1994) Synthetic food coloring and behavior: a dose response effect in a double-blind, placebo-controlled, repeated-measures study. *Journal of Pediatrics*, November, 125, pp. 691-8.

<sup>66</sup> McCann D et al (2007), Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial, *The Lancet* - 3 November Vol. 370, Issue 9598, Pages 1560-1567

<sup>67</sup> Sami Timimi, et al (2004), 'A Critique of the International Consensus Statement on ADHD', *Clinical Child and Family Psychology Review*, Vol. 7, No. 1, p.59.



Not only is it completely counter to the spirit and practice of science to cease questioning the validity of ADHD as proposed by the consensus statement, there is an ethical and moral responsibility to do so. It is regrettable that they wish to close down debate prematurely and in a way not becoming of academics. The evidence shows that the debate is far from over.<sup>68</sup>

According to Timimi, the authors of the Consensus Statement 'are well-known advocates of drug treatment for children with ADHD' who in the statement did 'not declare their financial interests and/or their links with pharmaceutical companies.'<sup>69</sup> Despite Timimi's concerns and the obvious false circularity of quoting consensus as evidence the *International Consensus Statement* is sometimes cited as evidence of the validity of ADHD diagnosis and treatment. One example is in the *2007 Clinical Excellence Commission Prescribing Review of ADHD in Children and Adolescents in New South Wales* commissioned by the New South Wales Government (outlined at 6.2).

Consensus amongst ADHD medication advocates has also driven significant Australian ADHD policy processes. The *Australian Draft Guidelines on ADHD* document was completed in 2009 by a committee, the majority of whom had commercial connections to ADHD drug manufacturers. Two thirds of the 203 draft recommendations of the guidelines committee were made without any supporting scientific evidence. They were based entirely on reference group consensus and justified as 'best practice based on clinical experience and expert opinion'. In particular, key recommendations in the draft guidelines promoting the widespread use of a range of psychotropic drugs were based upon the consensus opinion of the guidelines committee. (Refer to 5.3.2 for full details)

Other claims in the consensus statement about differences in brain structure and activity and genetic differences in ADHD patients are contested by critics and are discussed in greater detail below.

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<sup>68</sup> Timimi, et al, 'A Critique of the International Consensus Statement', p.59.

<sup>69</sup> Timimi, et al, 'A Critique of the International Consensus Statement', p.60.

### 2.2.1.2 The 'Medicalization' perspective of ADHD critics

The term 'medical model' was described by Scottish psychiatrist R. D. Laing in 1971 as a 'set of procedures in which all doctors are trained'.<sup>70</sup> Laing described the process of the medical model as a sequential process whereby doctors:

1. are told of a problem and complaint;
2. determine the patient's history;
3. conduct a physical examination and if required ancillary tests;
4. then diagnose and treat;
5. and describe the patient's prognosis with and without treatment.

According to Laing the medical model aims 'to find medical treatments for diagnosed symptoms and syndromes and treats the human body as a very complex mechanism.'<sup>71</sup>

Laing was critical of the application of the medical model to psychiatry, arguing that 'because the diagnosis of a mental illness was based on conduct or patient behavior and not on physical pathology, such a "diagnosis" essentially contravened standard medical procedure and hence the medical model.'<sup>72</sup> Although he is associated with the anti-psychiatry movement, Laing practiced as a psychiatrist and accepted the existence of mental illness. Laing contended that mental illness is most often transitory and often not a damaging experience and its pattern of onset and recovery is very different from the pathway of physical illness.

The term 'medicalization' is often used by critics of aspects of psychiatric practice (including ADHD critics) as a shorthand description for the incomplete and therefore inappropriate application of the 'medical model'. Incomplete because, as Laing described, in the absence of the third step - objective scientific evidence from a physical examination, blood test, brain scan for example - flimsy evidence is inappropriately regarded as sufficient proof of a medical/biological condition.

Abraham described those (himself included) who are critical of medicalization as a means of achieving social control and compliance as adherents to the 'medicalization thesis'. The

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<sup>70</sup> R.D. Laing (1971), *The Politics of the Family and Other Essays*, Penguin Books, Middlesex, p.35

<sup>71</sup> Laing, *The Politics of the Family*, p.35.

<sup>72</sup> Laing, *The Politics of the Family*, p.35.

medicalization thesis asserts 'that the growth in medical conditions partly reflects medical dominance in society and the significance of the "sick role" in redefining social deviance or dysfunctionality'.<sup>73</sup> ADHD critics typically regard the increasing reliance on medications to treat ADHD - the pharmaceuticalization of ADHD - as an inappropriate medicalization of childhood behaviours.

Abraham contends that until recently medicalization theorists 'focused primarily on interactions between the medical professions, patients, and health-care organizations'. He argues medicalization theorists had largely 'overlooked the influence of the pharmaceutical industry, the drug regulatory state, or patients as organized interests.'<sup>74</sup> In his view the pharmaceutical industry and allied interests have been central drivers in the growth of a number of psychiatric disorders, including ADHD and depression, and other disorders like erectile dysfunction. Furthermore he believes that, along with patient support groups, key opinion leaders, usually academics or high profile medical experts, are key to the process of pharmaceuticalization:

Subtle aspects of drug promotion include the integration of senior members of the medical profession and medical science into pharmaceutical marketing strategies by first paying them through grants or consultancies to be involved in the development of company products and then funding them to act as "opinion leaders" who speak favorably about the drug at various symposia attended by doctors.<sup>75</sup>

Although Abraham acknowledges that in some cases pharmaceuticalization may be the result of scientific advancement and improvement in patient care, he argues that most often the massive rapid worldwide increases in pharmaceutical markets is primarily a product of economic and sociological factors:

The biomedicalism thesis, popular among many scientists and media discourses, that growing pharmaceuticalization simply reflects discoveries in biomedical science that correspond to health needs, is not plausible. Some

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<sup>73</sup> Abraham, 'The Sociological Concomitants', p.290.

<sup>74</sup> Abraham, 'The Sociological Concomitants', p.290.

<sup>75</sup> Abraham, 'The Sociological Concomitants', p.293

pharmaceuticalization may fall into this category, but there is no good reason to support the thesis that most of it can be explained in this way. Indeed, there is evidence to suggest that, while pharmaceuticalization has increased the number of medications needed by patients and public health is actually decreasing, along with pharmaceutical innovation. Growing pharmaceuticalization seems to be best explained by sociological factors such as the political economy of the pharmaceutical industry and associated medicalisation (especially promotion and advertising activities involving physicians and clinicians), deregulatory ideology toward drug development and innovation, and access-oriented collaborative consumerism, which outweighs the countervailing effects of adversarial consumerism.<sup>76</sup>

As evidence of the primacy of medicalization rather than biomedicalism as an explanation for pharmaceuticalization, Abraham argues that pharmaceutical advertising and promotion expenditures are 'growing at a much faster rate than are pharmaceutical research and development (R&D) in most Western industrialized countries...if the major drivers of pharmaceuticalization were scientific discoveries that meet new medical needs, rather than socioeconomic forces, then one would expect clearer evidence of growth in R&D relative to marketing activities.'<sup>77</sup>

This appears to be a relatively weak, derivative argument as it measures the cost of inputs into research as compared to marketing. Other industries also have similar pattern of relative expenditure on research and marketing. For example the mobile phone industry expends huge sums on marketing yet it has experienced rapid improvements in technology, function and price which in part at least accounts for the massive increase in sales volumes.

Stronger evidence of inappropriate pharmaceuticalization would come from evidence of commercial and professional conflicts of interests, or from evidence of poor quality research resulting in pharmaceuticalized policy outcomes. This thesis concentrates on identifying the prevalence of such occurrences, rather than comparing relative expenditure on marketing and research.

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<sup>76</sup> Abraham, 'The Sociological Concomitants', p.304

<sup>77</sup> Abraham, 'The Sociological Concomitants', p.308

In 2010 Abraham wrote that ‘over the last forty years, the diagnostic criteria for ADHD have been consistently widened, making it virtually impossible to disentangle increased identification of ADHD sufferers from increased medicalization, and leading to concern that the threshold between normal behavior and ADHD has been set too low.’<sup>78</sup> He cited two studies. One ‘estimated that the official diagnostic criteria for ADHD apply to almost 20 percent of school-age children in the United States.’<sup>79</sup> The second, ‘a large-scale epidemiological study found that nearly 50 percent of U.S. children satisfied the symptom-criteria for official ADHD diagnosis’.<sup>80</sup> Abraham concluded that ‘fundamentally, the diagnostic criteria are problematic because of their overlap with normal experience or other psychiatric diagnoses’.<sup>81</sup>

Abraham also contends that marketing a disorder, in this case ADHD, to create a need for the pharmaceutical is a common international experience: ‘Disease-awareness campaigns, involving an alliance between pharmaceutical manufacturers and the medical establishment, are vital to the process of pharmaceuticalization.’ He cites examples of ‘industry-sponsored disease-awareness campaigns aimed at doctors’ prior to ADHD that ‘have exaggerated the benefits and neglected serious adverse effects of tranquilizers in the 1970s and 1980s, and of antidepressants since the early 1990s.’<sup>82</sup> Abraham specifically identifies ADHD diagnosis and prescribing as a product of a ‘pharmaceuticalization-medicalization complex’ and rejects the hypothesis that it is legitimately explained via the biomedicalization model. He dismisses the claim that ADHD is ‘an organic brain dysfunction - either due to reduced metabolism and inhibition in regions of the brain associated with

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<sup>78</sup> Abraham, ‘The Sociological Concomitants’, p.292.

<sup>79</sup> Goldman LS, M Genel, and RJ Bezman (1998), ‘Diagnosis and Treatment of ADHD in Children and Adolescents’, *Journal of the American Medical Association*, 279, pp.1100-1107.

<sup>80</sup> Bird, H., TJ Yager, B Staghezza, and MS Gould (1990), ‘Impairment in the Epidemiological Measurement of Childhood Psychopathology in the Community’, *Journal of the American Academy of Childhood and Adolescent Psychiatry*, 29, pp.796-803.

<sup>81</sup> Abraham, ‘The Sociological Concomitants’, p.292.

<sup>82</sup> Abraham, ‘The Sociological Concomitants’, p.291. See also John Abraham and Julie Sheppard (1999), *The Therapeutic Nightmare: The Battle over the World’s Most Controversial Sleeping Pill*, Earthscan, London ; David Healy (2004), *Let Them Eat Prozac: The Unhealthy Relationship between the Pharmaceutical Industry and Depression*, New York University Press, New York; HCHC [House of Commons Health Committee] (2005), *Inquiry into the Influence of the Pharmaceutical Industry: Health Select Committee Report*, TSO, London , 69–70; Charles Medawar (1992), *Power and Dependence: Social Audit on the Safety of Medicines*, Social Audit Ltd, London; Charles Medawar and Anita Hardon (2004) *Medicines out of Control? Antidepressants and the Conspiracy of Goodwill*, Askant, Amsterdam .

attention and motor activity’ as an unjustified application of the biomedical model. Abraham cites a number of technical limitations in the evidence supporting this claim.<sup>83</sup>

American neurologist and author of *The ADHD Fraud*, Fred Baughman is scathing in his criticisms of the Diagnostic and Statistical Manual approach to diagnosing all psychiatric disorders, including ADHD. He condemns the psychiatric diagnostic process as contrary to the process of defining and diagnosing legitimate disease:

Normally, as a condition is studied and more is learned about it, the diagnostic signs (signs = objective abnormalities) are narrowed down to a specific set of objective criteria that can be reliably applied. With ADHD the opposite happened.<sup>84</sup>

Other ADHD critics, including Queensland psychologist Dr Bob Jacobs, are less concerned about the inability to objectively identify abnormalities or difference but are more concerned with the medicalization of difference:

Even if researchers found a consistent difference between children who act a certain way (‘ADHD’) and children who don’t, and even if they could somehow prove that the difference caused the behaviours, there is no reason to believe there is any ‘disorder’. There may be physiological differences between people who are right-handed and left-handed, or people who prefer the colour red over the colour blue. But it doesn’t make either group ‘sick’. We know that people have individual physical differences, but it is dangerous ground to say that those differences are a ‘disorder’, just because they are in the minority, or because they cause problems with fitting into society’s rigid structures (like school).<sup>85</sup>

Despite Jacobs’ contention that difference does not constitute disease, much of the scientific argument about ADHD has been on the grounds contested by Baughman- that is, debating the existence of neurological and/or genetic difference between ADHD children and ‘normal’ children. ADHD proponents have sought to prove the validity of ADHD by

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<sup>83</sup> Abraham, ‘The Sociological Concomitants’, p.291.

<sup>84</sup> Baughman and Hovey (2006), *The ADHD Fraud*, p.58.

<sup>85</sup> Bob Jacobs (2005), Youth Affairs Network of Queensland, *Being an Educated Consumer of ‘ADHD’ Research*, Youth Affairs Network of Queensland.

establishing the existence of such differences. Critics contend the many claims of new research purporting to prove this difference however, have been shown to be false.

The 'Holy Grail' for many proponents of ADHD is establishing its 'genetic basis', the logic being that this would validate it as a psychiatric disorder. In September 2010 British researchers claimed to have proven the genetic basis of ADHD.<sup>86</sup> A psychiatrist who was a co-author of the study, Cardiff University Professor Anita Thapar, proclaimed 'now we can say with confidence that ADHD is a genetic disease.'<sup>87</sup>

The study that Professor Thapar claimed established that ADHD is a 'genetic disease' involved the comparison of the genetic codes of 366 children 'with ADHD' with that of 1047 'non-ADHD' control children. Researchers found 13.9 percent (51) of children with ADHD had short lengths of their genetic code that were either duplicated or missing. This compared with 7.4 percent (78) of the 'control children'.<sup>88</sup> The average recorded IQ of the 366 children 'with ADHD' was 86, fourteen points below the general population average of 100. Whilst the IQ of the 1047 'non ADHD children' was not specified, presumably they were as intelligent as the general population (average IQ of 100). Furthermore when 33 intellectually impaired 'ADHD children' (IQ lower than 70) were excluded from the ADHD cohort only 11 percent of the remaining 333 had the hypothesised ADHD genetic abnormality.<sup>89</sup> Even with the intellectually impaired children removed the average IQ (89) of the 333 remaining in the ADHD group was significantly lower than the human average of 100.<sup>90</sup> This evidence is more suggestive of a relationship between the identified genetic

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<sup>86</sup> Examples include Kate Kelland (2010), 'Study finds first evidence that ADHD is genetic', *Reuters*, 30 September 2010. Available at <http://www.reuters.com/article/2010/09/30/us-adhd-genes-idUSTRE68S5UD20100930> (accessed 22 November 2012); Elizabeth Landau (2010), 'ADHD is a genetic condition, study says', *CNN Health*, 29 September 2010. Available at <http://thechart.blogs.cnn.com/2010/09/29/adhd-is-a-genetic-condition-study-says/> (accessed 14 November 2012); 'Study finds genetic link to ADHD', *ABC Online News*, 30 September 2010. Available at <http://www.abc.net.au/news/2010-09-30/study-finds-genetic-link-to-adhd/2280292> (accessed 22 November 2012)

<sup>87</sup> 'Study finds genetic link to ADHD', *ABC Online News*, 30 September 2010. Available at <http://www.abc.net.au/news/2010-09-30/study-finds-genetic-link-to-adhd/2280292>

<sup>88</sup> Williams, Dr N.M. & Thapar, Prof. A., et al (2010), 'Rare chromosomal deletions and duplications in attention-deficit hyperactivity disorder: a genome-wide analysis', *The Lancet*, Vol. 376:9750, pp.1401-1408. Available at <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2810%2961109-9/abstract> (accessed 24 October 2012).

<sup>89</sup> Williams, et al, 'Rare chromosomal deletions'.

<sup>90</sup> Note: Whilst there is considerable anecdotal evidence of bright but under-stimulated and bored children being diagnosed with ADHD it could be for the geographical population of this study (at least) that having a low IQ increases a child's chances of being diagnosed with ADHD.

abnormality and intellectual disadvantage than it is of ADHD. Nonetheless the claims of proof of ADHD's genetic basis were reported internationally in mainstream media with little critical analysis.<sup>91</sup>

ADHD is a collection of behaviours, with children diagnosed being on average less attentive and/or more impulsive/hyperactive than their peers. Finding a genetic basis for ADHD would therefore mean finding a genetic basis for inattentive and/or impulsive/hyperactive behaviour. It is entirely reasonable to think behaviour is a combination of nature and nurture. However, as Jacobs concluded, conceding that ADHD may be in part a 'genetic difference' is vastly different from accepting it is a 'genetic disease'.

US psychiatrist and ADHD critic Peter Breggin argues that many of the studies that claim to show differences in 'ADHD brains' are similarly flawed. He claims these studies compared brains that had never been medicated with brains that had been exposed to psycho-stimulants. Psycho-stimulants, Breggin contends, 'routinely cause gross malfunctions in the brain of the child' and 'can cause shrinkage (atrophy) or other permanent physical abnormalities'.<sup>92</sup>

In 2000 American psychopharmacology researcher Dr Gahan Pandina identified that most of the supposed breakthroughs relate to brain-imaging using Positron Emission Tomography (PET) scanners or Magnetic Resonance Imaging (MRI) technology. Pandina contends that none of the claims have been sustained and all mainstream medical authorities recognize that the technologies have no role in the diagnosis of ADHD. He argued that even the more optimistic of assessments recognize brain-imaging technologies as having no diagnostic value, merely unfulfilled potential.<sup>93</sup> A year later in 2001 American researchers confirmed neuro-imaging can do little more than assess the shape and size of the brain:

Although gross differences in size or symmetry of brain structures can be quantified, individual cells and cell layers cannot yet be visualized. This means that, although

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<sup>91</sup> Examples include Kelland, 'Study finds first evidence that ADHD is genetic'; Landau, 'ADHD is a genetic condition'.

<sup>92</sup> Breggin, *Talking Back to Ritalin*, p.358.

<sup>93</sup> Gahan J. Pandina (2000), 'Review of Neuroimaging Studies of Child Adolescent Psychiatric Disorders from the past 10 years (Statistical Data Included)', *Journal of the American Academy of Child & Adolescent Psychiatry*, Vol. 39 No. 7, pp.815–28.



the volume and shape of brain structures may be determined, the underlying cause of any differences cannot.’<sup>94</sup>

This remains the case despite numerous media reports about imminent breakthroughs in the science of diagnosing ADHD. One recent example was in October 2012 when a radio program ran a piece promoting claims that neuroimaging and genetic tests for ADHD are ‘just around the corner’. The enthusiastic researcher was quoted as saying ‘neuroimaging and genetics are extremely exciting research tools’, although he conceded in relation to a scientific test for ADHD ‘We’re just not quite there yet’ and it was likely to take another 15 to 20 years.<sup>95</sup>

In summary some critics like Baughman oppose ADHD diagnosis because they believe it is as Laing identified - a misapplication of the medical model. They believe the third step identified by Laing, conducting a physical examination and if required ancillary tests to identify objective abnormality, is missing. Other ADHD critics like Jacobs are critical of the lack of acceptance of difference irrespective of whether it has been objectively verified via the rigorous application of the medical model described by Laing.

The diagnostic criteria of ADHD – in particular making careless mistakes, not ‘seeming to’ listen, failing to finish school work, being disorganised, disliking schoolwork or homework, blurting out answers and leaving a seat when remaining seated is expected – are all evidence of a child’s failure to comply in a school environment. Numerous ADHD critics contend that ADHD medications are used as a means of achieving control and compliance and minimising social deviance in classrooms. Although teachers do not diagnose children with ADHD, they, along with parents, provide the critical behavioural evidence for the doctors who make the diagnosis. In 2003 US research demonstrated that ‘in the majority of cases teachers are the first to suggest a diagnosis of ADHD’.<sup>96</sup> Even if teachers are not the first to suggest a diagnosis they still play a central role in the process.

Dr Linda Graham, an Australian academic researcher in the education field, contends that a

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<sup>94</sup> Sarah Durston, E. Hilleke, et al (2001), ‘Anatomical MRI of the Developing Human Brain: What Have We Learned?’, *Journal of the American Academy of Child & Adolescent Psychiatry*, Vol. 40 Issue 9, pp.1012–20.

<sup>95</sup> ‘Brain scans and genetic tests for ADHD diagnoses’, *AM*, 3 October 2012. Available at <http://www.abc.net.au/am/content/2012/s3602551.htm> (accessed 8 October 2012).

<sup>96</sup> Linda Graham (2006), ‘The Politics of ADHD’, in *Proceedings of the Australian Association for Research in Education (AARE) Annual Conference*, Adelaide, p.14.

diagnosis of ADHD removes responsibility from the school and shifts 'the focus away from what might be wrong with schooling to centre only on what is 'wrong' with the child.'<sup>97</sup> She argues the environment is not modified to fit the child; instead the child is modified (medicated) to fit the environment.

These are not new concerns. In 1970, in response to the relatively uncommon but emerging practice of 'medicating' to alleviate hyperactivity, American author and educator John Holt, when testifying about the US education system before a United States House of Representatives' committee said:

We consider it [hyperactivity] a disease because it makes it difficult to run our schools as we do, like maximum security prisons, for the comfort and the convenience of the teachers and administrators who work in them. The energy of children is 'bad' because it is a nuisance to the exhausted and overburdened adults who do not want to or know how to and are not able to keep up with it. Given the fact that some children are more energetic and active than others, might it not be easier, more healthy, and more humane to deal with this fact by giving them more time and scope to make use of and work off their energy?...Everyone is taken care of, except, of course, the child himself, who wears a label which to him reads clearly enough 'freak,' and who is denied from those closest to him, however much sympathy he may get, what he and all children most need – respect, faith, hope, and trust.<sup>98</sup>

In January 2007, *The Sunday Mail* reported that ADHD diagnosed students whose parents were refusing to allow them to be medicated were being excluded from Queensland schools, even though it was illegal to do so. The article reported the case of Denise, a Northside Brisbane mother and her son John, who had been branded a 'bad' child all through pre-school. 'This came to a head when he had only been in Grade 1 for approximately four months when the

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<sup>97</sup> Linda J. Graham (2008), 'Drugs, labels and (p)ill-fitting boxes: ADHD and children who are hard to teach', in *Discourse: Studies in the Cultural Politics of Education*, Vol. 29, No. 1, p.94.

<sup>98</sup> Ronald Lipman (1970), 'Federal involvement in the use of behaviour modification drugs on grammar school children of the right to privacy inquiry. Hearing before a Subcommittee of the Committee on Government Operations House of Representatives, Ninety-First Congress, Second Session, 29 September 1970, p. 33. Available at <http://www.fredsworld02.com/pdf/federal%20involvement.pdf> (accessed 9 April 2008).

principal came to me and told me I either put my son on medication or he would be expelled.’<sup>99</sup>

Linda Graham made similar claims: ‘Parents of children who can be described as “hyperactive” or “distractible” are under pressure to medicate their children so they can fit into an overwrought, under-funded public education system.’<sup>100</sup> In Australia this practice is not limited to Queensland. In 2006, a public primary school located in a disadvantaged area of Sydney made headlines by threatening to formally exclude an eight-year-old girl unless her mother medicated her for suspected ADHD.<sup>101</sup> I have heard of similar exclusions and threats of exclusion in Western Australia.<sup>102</sup>

The practice of excluding un-medicated ADHD diagnosed children from schools became so common in the US that some states took action to protect children and their parents from state-enforced medicating. In 1999, Colorado legislated to prevent school personnel from recommending psychotropic drugs to students, with other states following. However, the legislation does not stop teachers and other school employees recommending to parents that their child should be assessed by a doctor.<sup>103</sup> ADHD critics contend that the threat of school exclusions unless medicated is evidence of inappropriate medicalization and pharmaceuticalization.

### **2.3 Injury versus Access Orientated Consumerism**

Abraham identifies two potentially conflicting forms of consumer-driven pressure on government: one aims to enable, the other to restrict, access to pharmaceuticals. What he terms ‘injury orientated consumerism’ is pressure generated by reports of iatrogenic harm from the nominally therapeutic use of pharmaceuticals. This pressure can result in decisions to either restrict or remove the access to, or subsidy of, a particular pharmaceutical product or class of products. ‘Access orientated consumerism’ refers to the pressure brought on government to license and subsidise pharmaceutical products to fill or better serve perceived unmet medical need.

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<sup>99</sup> Daryl Passmore (2007), ‘Here, now be a good little child’, *The Sunday Mail*, 14 January 2007.

<sup>100</sup> Daryl Passmore (2007), ‘Out of Control’, *Courier Mail*, 14 January 2007. Available at <http://www.couriermail.com.au/news/sunday-mail/out-of-control/story-e6frep2o-1111112825767> (accessed 24 June 2009).

<sup>101</sup> Graham, ‘Drugs, labels and (p)ill-fitting boxes’, p.95.

<sup>102</sup> Martin Whitely (2010), *Speed Up & Sit Still: The Controversies of ADHD Diagnosis and Treatment*, Perth, UWA Publishing, p.82.

<sup>103</sup> Whitely, *Speed Up & Sit Still* p. 82

Abraham considers that, from a utilitarian public benefit perspective, injury orientated consumerism has generally been ineffective in protecting consumers from iatrogenic harm. Conversely, he believes access orientated consumerism has over-achieved in that ineffective, unnecessarily costly, or worse still, harmful medications have been licensed for market or subsidised.<sup>104</sup>

An Australian example of competition between ADHD proponent driven access orientated consumerism and ADHD critic driven injury orientated consumerism in regards to the subsidisation of Strattera via the PBS is discussed at 4.6.

## **2.4 Summary of ADHD proponent's and ADHD critic's positions**

### **ADHD Proponents**

Proponents typically contend that ADHD is a neurobiological condition with at least in part a genetic/biological cause that can be treated with safe effective medications and that it is underdiagnosed and under-treated. They also contend that individuals with undiagnosed and untreated ADHD frequently self-medicate with alcohol and illicit drugs.

They proffer a biomedicalized explanation of ADHD pharmaceuticalization. Specifically they argue that improvements in diagnostic criteria, and greater access to appropriate pharmaceutical treatments, accounts for the increase in ADHD per capita child prescribing rates. They have led access orientated consumer lobbying to facilitate greater access to subsidised pharmaceutical treatments.

### **ADHD Critics**

ADHD critics include two subgroups: those who believe it is a real but rare, over-diagnosed and over-medicated condition; and those who believe that ADHD is not a valid psychiatric disorder and the drugs used to treat it are unsafe and ineffective in the long term.<sup>105</sup> Both subgroups contend that the psycho-stimulants most commonly used to treat ADHD are addictive and frequently abused or diverted for illicit use.

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<sup>104</sup> Abraham, 'The Sociological Concomitants', p.295.

<sup>105</sup> The situation is further complicated by a subset of ADHD critics who believe that ADHD is real but caused by some other single factor. They tend to promote the use of a single alternative treatment as being the appropriate universal response to ADHD. In terms of the 'contest' to influence Australian policy, regulation and practice there is little evidence that they have been significant.

Critics also contend inappropriate medicalization accounts for increased ADHD pharmaceuticalization. They point to the lack of objective ‘scientific’ tests and the broadening of diagnostic criteria as evidence of unjustified pharmaceuticalization. They have led injury orientated consumer lobbying efforts to restrict access to ADHD pharmaceuticals.

Table 1 below summarises the most commonly argued perspectives of ADHD Proponents and ADHD Critics.

| Issue                | ADHD Proponents contend:                                                                                                                                                                                                                                                                                                                                                                            | ADHD Critics contend:                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What is ADHD?        | ADHD is a psychiatric disorder/disease characterised by extreme levels of dysfunctional inattentive and/or hyperactive/impulsive behaviour that effects a significant minority (estimates vary between 3 and 11% and even higher) of children and in many cases (60%) continues into adulthood. Leaving ADHD untreated destines an ADHD child to a future of academic, economic and social failure. | There are two different views amongst ADHD critics: <ul style="list-style-type: none"> <li>• ADHD is a real but rare condition affecting a tiny minority of children that is over-diagnosed and over-medicated, or</li> <li>• ADHD is not a valid psychiatric disorder. It a label inappropriately applied to children whose behaviour is distressing and/or inconvenient to adults.</li> </ul>                  |
| How is it diagnosed? | ADHD is diagnosed using behavioural diagnostic criteria developed by the American Psychiatric Association and outlined in DSM-IV. Specialist clinicians, usually paediatricians or child psychiatrists, expert in the diagnosis of the disorder assess the behaviour of the child against age appropriate norms and exclude other potential causes of aberrant behaviour.                           | The diagnosis of ADHD is unscientific. It involves the subjective application of vague behavioural diagnostic criteria. Furthermore the behaviours are part of the normal range of childhood behaviours. Where children do have significant behavioural issues the label ‘ADHD child’ dumbs down an individual child’s often complex circumstances and prevents a full understanding of any underlying problems. |

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What causes ADHD?                        | <p>Proponents acknowledge that the aetiology of ADHD is uncertain. However they describe it as a neurobiological condition. They contend that there is strong evidence that it occurs as a result of a genetically determined chemical imbalance in the brain.</p> <p>They contend that children with ADHD often have comorbid conditions that require separate but concurrent treatment.</p>                                                                                                              | <p>Critics contend there are multiple potential causes of behaviours characterised as ADHD including:</p> <ul style="list-style-type: none"> <li>• Intolerance of boisterous or day-dreamy children, particularly boys.</li> <li>• Trauma from bullying or physical, emotional or even sexual abuse.</li> <li>• Bright children being bored or dull children failing to keep up.</li> <li>• Inadequate teaching or parenting.</li> <li>• Exposure to neurotoxins, sleep deprivation, poor diet etc.</li> </ul>                                                              |
| Are ADHD medications safe and effective? | <p>The use of psycho-stimulants (and where stimulants are ineffective atomoxetine), balance an ADHD child's brain chemistry. This makes the child better able to focus and learn. It helps the child modify their dysfunctional impulsive and hyperactive behaviour prevents self-medication with illicit drugs and improves relationships with others. All medications carry risks. However psycho-stimulants are comparatively safe having been used to treat hyperactive behaviour since the 1930s.</p> | <p>The oral administration of psycho-stimulants increase focus in most people irrespective of their ADHD status. The increased focus resulting from the administration of psycho-stimulants to ADHD children is mistakenly regarded as the drugs addressing the child's biochemical imbalance. Furthermore although ADHD medications often modify behaviour in the short term they have no sustained benefits involve considerable short term risk and psycho-stimulants are addictive and frequently cause long term educational, psychiatric and cardiovascular harm.</p> |
| What accounts for increased ADHD         | <p>Increased awareness of the long under-recognised condition has resulted in increased ADHD pharmaceutical prescribing rates.</p>                                                                                                                                                                                                                                                                                                                                                                         | <p>The pharmaceutical driven marketing of the contrived 'disorder' to time-poor parents desperate for quick fixes that address annoying and inconvenient</p>                                                                                                                                                                                                                                                                                                                                                                                                                |

|                    |                                                                                                                          |                                                                                                                                                                                                    |
|--------------------|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| prescribing rates? | However the disorder remains under-recognised with ADHD prescribing rates considerably lower than ADHD prevalence rates. | childhood behaviours has created the demand for ADHD drugs. This marketing has been supplemented by pharmaceutical company controlled biased research and a lack of rigorous scientific oversight. |
|--------------------|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2.5 The Theory of Regulatory Capture

In 2005 European economic researcher Marianne Ojo identified two competing theories of regulation. The first, Ojo describes as the 'Public interest theory of Regulation' which holds that 'regulation is seen as catering for the interests of the public.' The second, the 'Private interest theory of Regulation', holds that 'parties affected by regulation...try to influence such regulations in such a way that it gives them favorable outcomes.' This theory holds that 'regulatory capture' by 'private interests of those being regulated overwhelm those interests of the public'.<sup>106</sup>

One of the prominent early theorists in regard to the concept of regulatory capture was George J Stigler, a Chicago economist and close colleague of the leader of the Chicago School of Economics and father of monetarism, Milton Friedman. In 1971 Stigler wrote:

The state - the machinery and power of the state - is a potential resource or threat to every industry in the society. With its power to prohibit or compel, to take or give money, the state can, and does electively help or hurt a vast number of industries.<sup>107</sup>

Stigler argued 'as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit.'<sup>108</sup> The basis of Stigler's theory is that industry has a

<sup>106</sup> Ojo Marianne (2005), 'The External Auditor's Role in Bank Regulation and Supervision : Helping the Regulator Avoid Regulatory Capture', Munich Personal RePEc Archive (MPRA) Paper No. 1293. Available at <http://mpa.ub.uni-muenchen.de/1293/> (accessed 15 January 2012).

<sup>107</sup> George J. Stigler (1971), 'The Theory of Economic Regulation', *Bell Journal of Economics and Management Science*, p.3.

<sup>108</sup> Stigler, 'The Theory of Economic Regulation', p.3.

greater stake in, and capacity to, control regulation than individual disaggregated consumers and that 'profit maximisation' is the key driver.

Specifically Stigler contends regulatory capture occurs because entities, most often commercial enterprises, with a significant interest in the outcome of a policy or regulatory decision, focus attention and resources on influencing the outcome. In contrast the public, who are less immediately and foreseeably affected by the outcome, are far less inclined to seek to influence the outcome. This imbalance in lobbying resources results in a skewing of policy and regulatory outcomes from the 'captured' agency that favour the organized, vested interests of the entity whose activities is at face value being regulated.<sup>109</sup>

In 1974 US economist and jurist Richard A Posner expanded on Stigler's work. Posner argued that 'regulation is not about the public interest at all, but is a process, by which interest groups seek to promote their (private) interest.'<sup>110</sup> Posner identified three different classes of proponents of regulatory capture. The first class, the 'Marxists and the Muckrakers', were summarily dismissed. Posner wrote that the theory 'put forward by Marxists and by Ralph Nader-type muckrakers, can be summarized in the following syllogism. Big business – the capitalists- control the institutions of our society. Among those institutions is regulation. The capitalists must therefore control regulation.'<sup>111</sup> Posner dismisses this perspective, citing examples of beneficial regulation and examples of regulation favouring the interests of small business.

The second class of proponents of a theory of regulatory capture identified by Posner were political scientists, whose theory he also considered unsatisfactory because, like the 'Marxist and Muckrackers', he believes it is unable to explain the complexity and variety of regulatory outcomes.

Posner's third category of 'regulatory capture' theorists include himself and others like Stigler from the Chicago Neo-classical economic tradition. Posner believes the outcomes of regulatory capture and the 'political process' involved are best explained by the 'general

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<sup>109</sup> George J. Stigler (1961), 'The Economics of Information,' *Journal of Political Economy*, 69(3), pp.213-225.

<sup>110</sup> R. Posner (1974), 'Theories of Economic Regulation', *Bell Journal of Economics and Management Science*, Vol 5, No. 2, p.341.

<sup>111</sup> Posner, 'Theories of Economic Regulation', p. 41.



assumption that human behaviour can be best understood as the response of rational self-interested beings to their environment.<sup>112</sup>

Other proponents of the theory of regulatory capture, including Bernstein,<sup>113</sup> Huntington,<sup>114</sup> Laffont and Tirole,<sup>115</sup> and Levine and Forrence<sup>116</sup> agree that the notion that government agencies and regulators typically act to enhance the public good is naïve. They argue therefore that regulatory agencies should, where possible, be protected from outside influence. In circumstances where this is not achievable it may be preferable not to have a designated regulatory agency, as the existence of the agency may create the mistaken belief that proper oversight and regulation is occurring.

Grabosky and Braithwaite argue that regulatory capture is more likely where the following preconditions exist:

1. only one industry is being regulated
2. the regulator is part of a larger organisation
3. there is conflict between the regulator and the regulated,
4. regular contact occurs between the regulator and the regulated, and/or where significant personnel interchange occurs between the regulator and the regulated.<sup>117</sup>

They also consider that, historically, regulatory agencies in Australia demonstrate fairly low levels of punitive enforcement.<sup>118</sup> Furthermore they argue that Australian regulatory agencies tend not to use their extensive powers to their fullest extent. The extent to

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<sup>112</sup> Posner, 'Theories of Economic Regulation', p.356; Stigler, 'The theory of economic regulation', pp.3-21; Jean-Jacques Laffont and Jean Tirole (November 1991), 'The Politics of Government Decision Making : A Theory of Regulatory Capture', *The Quarterly Journal of Economics*, Vol. 106, No. 4, pp.1089-1127.

<sup>113</sup> Marver Bernstein (1955), *Regulating Business by Independent Commission*, Princeton, N.J, Princeton University Press.

<sup>114</sup> Samuel P. Huntington (1953), 'The Marasmus of the ICC: The Commission, the Railroads, and the Public Interest', *Yale Law Journal* 61, pp.467-509.

<sup>115</sup> Laffont and Tirole, 'The Politics of Government Decision Making', pp.1089-1127.

<sup>116</sup> Michael E. Levine, & Jennifer L. Forrence (1990), 'Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis', *Journal of Law Economics & Organization*, Vol. 6, Issue 0, pp.167-198.

<sup>117</sup> Grabosky, P. & J. Braithwaite (1986), *Of Manners Gentle: Enforcement strategies of Australian business regulatory agencies*, Oxford University Press, Melbourne.

<sup>118</sup> Grabosky & J. Braithwaite, J, *Of Manners Gentle*.

which these conditions apply to the regulation of ADHD within Australia is identified in later chapters.<sup>119</sup>

Australian economist Greg McMahon defines regulatory capture in two steps. 'Capture' is described as 'behaviours, active and passive, by responsible authorities, which... protect the... illegal, unethical, immoral or anti-public interest practices that those authorities are charged with "policing"'.<sup>120</sup> Regulators are defined as the 'widest class of professionals and authorities within corporations, organisations or jurisdictions holding formal administrative cum legislative cum ethical responsibilities for maintaining accountability within those units of society, community and government.'<sup>121</sup>

McMahon contends regulatory capture occurs when a government or non-government agency created to act in the public interest instead advances the commercial or special interests that dominate the industry or sector it is charged with regulating, at the expense of the public interest. Specific examples of regulators identified by McMahon 'include auditors and accountants, lawyers and police, clergy and ethicists, medical practitioners and nurses, government and private industry 'watchdog' authorities, the professional-at-arms, and researchers and scientists'.<sup>122</sup>

Regulatory capture occurs when policy and regulatory outcomes from the 'captured' agency favour the organized, vested interests of the entity whose activities are at face value being regulated. For the purposes of this thesis McMahon's broad scope definition of regulatory capture is used, which encompasses capture of all of the agencies both government and non-government which have the declared intention of protecting and enhancing the public good.

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<sup>119</sup> Gary Adams, Sharon Hayes, Stuart Weiarter & John Boyd (2007), *Regulatory Capture: Managing the Risk*. A paper supporting a presentation within the stream *Government regulators – the environment and the corruption risks it presents*, Australian Public Sector Anti-Corruption Conference, 24 October 2007, Sydney. Available [http://www.apsac.com.au/2011conference/pdf/papers07/day1\\_24oct07/StreamA2/RegulatoryCaptureManagingTheRisks\\_JohnBoyd.pdf](http://www.apsac.com.au/2011conference/pdf/papers07/day1_24oct07/StreamA2/RegulatoryCaptureManagingTheRisks_JohnBoyd.pdf) (accessed 7 July 2012).

<sup>120</sup> G. McMahon (2002), *Regulatory Capture: Causes and Effects*, International Institute for Public Ethics, Brisbane, 4 October 2002, p.1.

<sup>121</sup> McMahon, *Regulatory Capture: Causes and Effects*, p.1.

<sup>122</sup> McMahon, *Regulatory Capture: Causes and Effects*, p.1.

Dominance of a process by ADHD proponents is not the only evidence of regulatory capture. A process can be captured even if participants are attempting to act in the public interest. Outcomes that favour industry's interests over the public's interest are the ultimate evidence of regulatory capture. For example, regulatory committees that have no particular bias in their membership can still be captured if they rely primarily on corrupted and biased evidence.

Hanson and Yosifon agree with McMahon that the phenomenon of 'capture' goes beyond government agencies and regulators in that vested interests have an incentive to control any entity, including non-government agencies, that has influence on their self-interest. Hanson and Yosifon refer to the successful capturing of these broader processes as 'deep capture'.<sup>123</sup> The potential for regulatory capture, even Hanson and Yosifon's deep capture, in medical settings is considerable. Doctors, nurses and other health professionals, researchers, patient advocacy groups, elected representatives, professional associations, medical standard setters and government regulators responsible for licensing and subsidising pharmaceuticals, all have the potential to be diverted from pure public interest considerations by external influence.

There is growing recognition that the scientific process does not simply steadily advance 'the certainty of our knowledge and control of the natural world'.<sup>124</sup> Rather it is a process whereby key decisions about methodology and the interpretation of information produced through research are influenced by political, cultural and economic drivers.<sup>125</sup> This presents challenges for those interpreting research and evaluating the risks and benefits of potential treatments and increases the potential for regulatory capture.

McMahon identifies a broad scope of potential beneficiaries from regulatory capture. The beneficiaries, 'the captors...include organisations or coalitions or classes/networks of individuals who would be the focus of the accountability regime but for their success in

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<sup>123</sup> Jon D. Hanson and David G. Yosifon (November 2003), 'The Situation: An Introduction to the Situational Character, Critical Realism, Power Economics, and Deep Capture', *University of Pennsylvania Law Review*, Vol. 152, No. 1, pp.129-346.

<sup>124</sup> Funtowicz S & Ravetz J (1993), *Science in the Post-Normal Age*, Futures 25, S pp. 739-755

<sup>125</sup> Millstone E. and Van Zwanenberg P. et al (2004), *Science in Trade Disputes Related to Potential Risks: Comparative Case Studies*, Institute for Prospective Technological Studies, Seville, Spain, EUR number 21301EN, August 2004 <http://ftp.jrc.es/EURdoc/eur21301en.pdf>

capturing that regime'. Examples can include major industries, corrupt officials, important customers, large corporations, political associations, professional elites, community leaders, and in-house wrongdoers.'<sup>126</sup> In the case of ADHD, individual clinicians, researchers, pharmaceutical companies, academics and paid opinion leaders, patient support groups and professional associations have an interest in both policy development and implementation.

McMahon identifies three 'levels' of regulatory capture.

At a first level of capture, the regulator allows the regulated to breach the law, ethic, good practice rule, moral principle or public interest duty that the regulator is responsible for upholding. At a second level, the regulator assists the regulated to avoid the regulatory consequences after the fact. At a deepest level of development, the 'capture' is so complete that the regulator may assist the regulated to defeat the regulatory regime before the fact.<sup>127</sup>

In contrast to McMahon and Yosifon's three levels of regulatory capture Australian academics Michael Briody and Tim Prenzler identify two degrees of regulatory capture.<sup>128</sup> The first, 'systemic capture', involves the 'procurement of an entire regulatory system by the regulated industry'. The second, less direct form of regulatory capture identified is 'undue influence', which involves 'personnel exchange, identification with values through frequent contact and direct corruption'.<sup>129</sup> These distinctions between McMahon's three levels, Briody and Prenzler's two degrees, and Hanson's moderate and deep capture are somewhat arbitrary and not indicative of any inconsistencies between their basic contentions.

For the purpose of this thesis patterns of regulatory capture is defined using the criteria outlined at 1.4. Regulatory (as in regulatory capture) is taken to include all agents, both government and non-government, that are supposed to be, or purport to be, acting in the

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<sup>126</sup> McMahon, *Regulatory Capture: Causes and Effects*, p.1.

<sup>127</sup> McMahon, *Regulatory Capture: Causes and Effects*, p.1.

<sup>128</sup> Briody M. & Prenzler, T. (1998), 'The enforcement of environmental protection laws in Queensland: a case of regulatory capture?', *Environmental and Planning Law Journal* 15(1), pp.54-71.

<sup>129</sup> McMahon, *Regulatory Capture: Causes and Effects*, p.10.

public interest. For instance it includes non-government organisations such as patient support groups and professional associations such as the Royal Australian College of Physicians. Although these organisations are not ‘regulators’ they do have professed aims of acting to promote patient welfare. Furthermore government agencies have for significant processes delegated their responsibility for policy development and regulation to non-government agencies as was the case for the 2009 NHMRC ADHD Draft Guidelines. (Refer to 5.3.2)

## **2.6 Abraham on Regulatory Capture and Pharmaceuticalization**

John Abraham argues the sociological foundations of the medicalization thesis are frequently valid. He believes that these factors, in combination with the commercial interests and political influence of the pharmaceutical industry, which he terms ‘socioinstitutional processes involving the marketing strategies of the pharmaceutical industry’, have caused increased diagnosis and treatment rates for a range of diseases and disorders. Abraham describes this interaction of the ‘pharmaceuticalization-medicalisation complex’ as being ‘one aspect of the medical-industrial complex.’<sup>130</sup>

As discussed at 2.4, Abraham contends ‘the biomedicalism thesis... is a weak explanatory factor because a significant amount of growth in pharmaceuticalization is inconsistent with scientific evidence.’<sup>131</sup> In 2010 he wrote that there are ‘five main biosociological explanatory factors’ that contribute to pharmaceuticalization: biomedicalism, medicalization, pharmaceutical industry promotion and marketing, consumerism, and regulatory-state ideology or policy.

Abraham contends that of these factors, regulatory capture is the most significant driver of pharmaceuticalization:

industry promotion, medicalization, and consumerism can all encourage the growth of pharmaceuticalization, such growth is substantially, though not entirely, dependent on a regulatory state that is willing to grant marketing approval to drugs that offer no therapeutic advance, to lower regulatory

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<sup>130</sup> Abraham, ‘The Sociological Concomitants’, p.292.

<sup>131</sup> John Abraham (2010), ‘Pharmaceuticalization of society in context: theoretical, empirical and health dimensions’, *Sociology*, Vol. 44:4, pp.603-622.

standards of efficacy in order to accelerate more NMEs [new molecular entities] on to the market, and indeed to relax restrictions or prohibitions on DTCA [direct to consumer advertising] of prescription medications.<sup>132</sup>

According to Abraham:

regulatory capture is especially important because the risk-benefit assessment of drugs has a high degree of technical uncertainty, which is inherent in toxicology, clinical trials, and epidemiology. Therefore, it is crucial to know how far regulators are willing to give the manufacturer the benefit of scientific doubt about safety and efficacy of their product. Indeed, regulators too often consistently award industry the benefit of scientific doubt when reviewing products.<sup>133</sup>

Abraham bases his theory of 'neo-liberal corporate bias' on 150 years of pharmaceutical regulation history in the United Kingdom supplemented by an analysis of U.S trends.<sup>134</sup> By neo-liberal Abraham means that the 'state should be minimal and subject to the tests of the market'.<sup>135</sup> This laissez-faire, self-regulatory philosophy, combined with a pro commercial interest bias, heavily favours the interests of the pharmaceutical industry often at the expense of consumer interests. While Abraham draws predominantly on British experience, the United Kingdom's regulatory environment is similar to Australia's in that government is central to the provision of health services and direct to consumer advertising of prescription medications is outlawed.

In 2007 Abraham was criticised by Alison Edgley, who wrote: 'contrary to Abraham's theory, medicines regulation is a more complex process than simply being neo-liberal and always "industry-friendly"'.<sup>136</sup> Edgley argued that 'in the current UK political environment where health care is still largely organized through state provision, the state, rather than being subject to a form of 'regulatory capture', is also able to employ regulatory processes in ways

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<sup>132</sup> Abraham, 'The Sociological Concomitants', pp.304-305

<sup>133</sup> Abraham, 'The Sociological Concomitants', pp.304-305.

<sup>134</sup> John Abraham (2007), 'From Evidence to Theory: Neo-Liberal Corporate Bias as a Framework for Understanding UK Pharmaceuticals Regulation – Response to Alison Edgley', *Social Theory & Health*, 5, p.173.

<sup>135</sup> Abraham, 'From Evidence to Theory', p.168.

<sup>136</sup> Alison Edgley (2007), "'A Spoonful of Regulation Helps the Medicine Go Down": The Changing Face of Medicine Regulation', *Social Theory & Health*, 5, p.153.

that promote its own interests – interests that one could suggest are neither clearly in the interests of industry, nor the public.’

In response Abraham countered:

The theory of corporate bias does not imply that the state has no interests of its own. On the contrary, unlike pluralist theory, it recognizes that the state has its own interests...As to the nature of the British state’s own interests when taking regulatory action against industry, I found overwhelmingly that, throughout history, the primary motive seems to have been budgetary savings, rather than patients’ interests per se’.<sup>137</sup>

He added that:

‘any major social theory is also necessarily complex, rather than absolutist...No sensible social theory would ever claim that there has never been and never will be a regulatory development introduced independently of industry interests... [but nonetheless] the most significant driver of regulatory change is industry interest, but... the role of other interests, especially those of the state [are] the second most important influence.’<sup>138</sup>

The relevant question for this thesis is whether Abraham’s neo liberal corporate bias theory on pharmaceuticalization and regulatory capture applies in an Australian context. Specifically have corporate interests and, to a lesser degree government interests - in the form of reduced costs and political acceptability - dominated the public interest in regard to the regulation of ADHD?

## **2.7 What policies have been proposed regarding regulatory capture and the pharmaceutical industry?**

Abraham has recommended reforming the way medical and psychiatric research is conducted, in order to contend with undue influence by the pharmaceutical industry. He has proposed having regulatory agencies conduct key safety research (animal carcinogenetic tests for example) on new drugs. He proposed the pharmaceutical companies would pay regulators for

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<sup>137</sup> Abraham, ‘From Evidence to Theory’, p.166.

<sup>138</sup> Abraham, ‘From Evidence to Theory’, p.173.

conducting the research. Abraham suggests this would be best done on an international co-operative cross jurisdictional basis, with sharing of results and responsibility between nations. He also believes this would be enhanced by the coordinated publication of a research journal.<sup>139</sup>

Abraham had the opportunity to influence UK national policy in 2004-5 when he was a 'special advisor' to a House of Commons Committee.<sup>140</sup> In response to concerns about the impact of inappropriate pharmaceutical industry influence on medical and psychiatric practice, the Committee conducted an inquiry titled *The Influence of the Pharmaceutical Industry Fourth Report of Session 2004–05*.<sup>141</sup>

The Committee concluded that:

- 'Our over-riding concerns are about the volume, extent and intensity of the industry's influence, not only on clinical medicine and research but also on patients, regulators, the media, civil servants and politicians...
- The regulatory system, the medical profession and Government have all failed to ensure that industry's activities are more clearly allied to the interests of patients and the National Health Service.
- The influence of the pharmaceutical industry is such that it dominates clinical practice, to an extent that deprives it of independent and constructively critical feedback; this is a discipline it needs and which can help it to improve.
- The traditional secrecy in the drug regulatory process has insulated regulators from the feedback that would otherwise check, test and stimulate their policies and performance.
- The closeness that has developed between regulators and companies has deprived the industry of rigorous quality control and audit.
- Other bodies are in a position to provide feedback and quality control. They include academic, research, clinical and professional institutions, as well as the media and patient groups. However, representatives of these interests have had only limited

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<sup>139</sup> Abraham, 'Learning from drug disasters'. pp.269-279.

<sup>140</sup> House of Commons Health Committee (2005), *The Influence of the Pharmaceutical Industry: Fourth Report of Session 2004-05*, Vol. 1, London, The Stationery Office, p.10. Available at <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf> (accessed 23 May 2013).

<sup>141</sup> House of Commons Health Committee, *The Influence of the Pharmaceutical Industry*, pp.97-109.



success in containing excessive industry influence. This can be partly attributed to lack of transparency, limited resources, significant dependency on industry funding, and some conflicts of interest.’<sup>142</sup>

The report detailed ‘problems with SSRIs antidepressants, notably Seroxat, and the COX-2 inhibitors, Vioxx and Celebrex’. It found unethical behaviour by drug manufacturers in failing to disclose adverse information when applying to licence new drugs. However, it also found that ‘prescribers must take their share of the blame for the problems that have resulted’ as some ‘medicines have been indiscriminately prescribed on a grand scale’. It attributed this reckless prescribing to ‘intensive promotional activity’ and ‘data secrecy and uncritical acceptance of drug company views’.<sup>143</sup>

The Committee concluded that the consequences of the above-mentioned failings were the ‘unsafe use of drugs’ and ‘increasing medicalization of society’. They also found that the ‘drift towards medicalization is a global phenomenon’, and despite the problems identified above the ‘UK may have a better record than many others [countries]’.

The Committee made a number of specific recommendations to tackle what it termed a ‘pill for every ill’ culture ‘compounded by an excessive reliance on results from premarketing clinical trials, together with a failing system of pharmacovigilance’. The recommendations included:

- A ‘clinical trials register be maintained by an independent body and the results of all clinical trials data, containing full trials information, be put on the register at launch as a condition of the marketing licence’.
- Limitations on, and health regulator’s approval of, promotional materials sent to and promotional visits to potential prescribers.
- ‘When companies are found to be in breach of advertising regulations or to have published misleading findings, the allowance for promotion and research, respectively, provided under the [National Health] Scheme should be reduced’.
- Full public disclosure of information used by pharmaceutical companies to apply to license and otherwise regulate drugs.

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<sup>142</sup> House of Commons Health Committee, *The Influence of the Pharmaceutical Industry*, pp.97-109.

<sup>143</sup> House of Commons Health Committee, *The Influence of the Pharmaceutical Industry*, pp.97-109.

- Systemic random audits of raw data used in research supporting licensing etc.
- Greater follow up of adverse reactions within research trials that prevented ongoing participation.
- Establishing 5 year post market surveillance of the safety and efficacy of newly licenced medicines.
- Improved post marketing reporting of adverse events by healthcare professionals.
- Restrictions on what professions can prescribe new medications for two years post licensing (for example only psychiatrists to prescribe new psychotropic medications)
- A 'public inquiry whenever a drug is withdrawn on health grounds' in order to prevent similar occurrences.
- Improved training of medical students on 'how to judge clinical trial results effectively, recognise adverse drug reactions and deal with drug company representatives'.
- 'Mandatory post-graduate training for all prescribers to keep up-to-date with prescribing changes'.
- 'Stricter regulation of individual prescriber's practices'.
- Establishment of a publicly available 'register of interests' of 'all substantial gifts, hospitality and honoraria' received by prescribers and researchers.
- Public disclosure of industry sponsorship of 'disease awareness campaigns' and 'patient [support] groups'.

Given the cultural and institutional similarities between Australia and the United Kingdom, the House of Commons Committee conclusions and recommendations may have relevance in Australia. Chapters 5 and 6 detail the extent of regulatory capture in Australia in relation to ADHD and the applicability of the Committee's recommendations to Australian policy is discussed at Chapter 7 (see 7.10).

## **2.8 Summary**

The competition between ADHD critics and proponents is part of a broader contest to determine the direction of psychiatric practice. Breggin, who supports non-pharmaceutical [environmental] psychiatric practice, argues: 'psychiatry is more like a two-party political

system with the biological [biomedicalized] and environmental parties constantly vying for power. Biological psychiatry is now the party in power.<sup>144</sup>

Opponents of biological psychiatry like Breggin and Abraham contend that greater access to resources and stronger economic incentives account for its dominance. Supporters see it as a result of technological and societal progress.

Both ADHD proponents and critics acknowledge the reality of ADHD pharmaceuticalization. Proponents consider this outcome is in the public interest. They contend it is a result of better diagnostic practices, a wider range of pharmaceutical treatments and greater awareness of a previously under-recognised condition.

ADHD critics reject this biomedicalization theory. They contend that ADHD pharmaceuticalization is contrary to the public interest and is a result of the aggressive, inaccurate promotion of both the consequences of ‘untreated ADHD’ and the benefits and safety of the pharmaceuticals used to treat it. They also contend that the dominance of regulatory and policy process by ADHD proponents and the pharmaceutical industry has supported the marketing of ADHD and its treatments. Critics further argue that ADHD proponents and ADHD drug manufacturers have greater access to resources and stronger economic incentives and this has resulted in regulatory capture of ADHD policy and regulatory processes.

ADHD proponents counter that critics are a vocal and populist fringe that ignore the overwhelming scientific evidence supporting the validity of the disorder and the safety and efficacy of ‘medications’ used to treat it. They argue that ‘major medical associations and government health agencies recognize ADHD as a genuine disorder because the scientific evidence indicating it is so overwhelming.’<sup>145</sup>

The debate is further complicated by some ADHD critics like Frances believing ADHD is a valid but massively over-diagnosed and over-hyped psychiatric disorder and others like Baughman believing it is an entirely fraudulent construct.

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<sup>144</sup> Breggin, *Talking Back to Ritalin*, p.286.

<sup>145</sup> Barkley, et al, ‘International Consensus Statement on ADHD’.

Subsequent chapters detail how the competition between proponents and critics has played out internationally and locally in regards to the regulation of ADHD in Australia.

## Chapter 3. ADHD and Imported Regulatory Capture

This chapter explores the influence of processes in the United States of America on Australian ADHD policy and practice. The Diagnostic and Statistical Manual of Mental Disorders which defines ADHD was developed by the American Psychiatric Association. In addition much of the research used as evidence in the development of Australian ADHD diagnosis and treatment guidelines and policies originates in the USA. The chapter identifies and analyses issues in regard to regulatory capture of US processes and the imported effects on Australia.

### 3.1 Defining ADHD

Internationally there are two alternative frameworks for diagnosing mental illness: the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), produced by the American Psychiatric Association (APA); and chapter five of the *International Classification of Diseases 10* (ICD-10), produced by the World Health Organization (WHO).

Unlike the DSM which deals only with mental illness, ICD covers the complete range of medical conditions and physical illness. In regard to mental illness, both systems outline diagnostic criteria and provide a numerical code that can be used to identify a disorder when clinicians claim payment from health insurers and government authorities. When the APA developed DSM-IV (in 1994), it endeavoured to standardise the codes to the ICD although minor differences remain. It is standard practice in the USA to use the diagnostic criteria of the DSM and claim payment using the ICD code.<sup>146</sup>

The ICD-10 numerical coding system is often used in the Australian health system by clinicians and hospitals to obtain Medicare co-payment entitlements, however DSM-IV is the most commonly used diagnostic system.<sup>147</sup> This is despite the fact that Australia is a member of the WHO and not the APA.

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<sup>146</sup> American Psychiatric Association (2012), *DSM-ICD Coding Crosswalk*. Available at <http://www.psychiatry.org/practice/dsm/dsm-icd-coding-crosswalk> (accessed 18 May 2013).

<sup>147</sup> Rosemary F. Roberts, Kerry C. Innes & Susan M. Walker (1998), 'Introducing ICD-10-AM in Australian hospitals', *Medical Journal of Australia*, Medical Journal Australia, 169;8, pp.32-35. Available at <https://www.mja.com.au/journal/1998/169/8/introducing-icd-10-am-australian-hospitals> (accessed 2 May 2013).

Although ICD-10 is the official classification system for mental illness in Australia, most psychiatrists use the DSM.<sup>148</sup> In contrast ICD-10 is the predominant diagnostic system in Europe.<sup>149</sup> The eighteen behavioural diagnostic criteria for 'Hyperkinetic Disorder' outlined in ICD-10 are virtually identical to those for ADHD in DSM-IV. There are, however, two subtle but important distinctions. First, for a diagnosis of hyperkinetic disorder under ICD-10, an individual is required to display at least six of nine of the inattentive *and* three of five of the hyperactive *and* one of four of the impulsive behaviours. For a DSM-IV diagnosis of ADHD, six of nine of the inattentive behaviours *or* six of nine of the hyperactive/impulsive behaviours are sufficient. Second, unlike the DSM definition of ADHD, ICD-10 states hyperkinetic disorder should not be diagnosed if another condition that may explain the behaviour is diagnosed.<sup>150</sup>

Although many of the criticisms of subjectivity of assessment of behaviours are common to both the DSM-IV and ICD-10, historical data indicates that fewer children are diagnosed using ICD-10. It has been found by two separate parliamentary inquiries - one in Western Australia and the other in South Australia - that as a likely consequence, the rates of psycho-stimulant use per head in the USA, Canada and Australia (using DSM-IV) between 1994 and 2000 were multiples of the UK rate (predominantly using ICD-10).<sup>151</sup> The Western Australian Parliamentary Inquiry in 2004 found that 'The use of different diagnostic tools may explain the variation in ADHD prevalence rates between Australia (DSM-IV) and the United Kingdom (ICD-10).'<sup>152</sup> A South Australian Parliamentary Inquiry two years earlier made a similar finding: 'The DSM-IV allows for multiple diagnosis with co-morbid conditions such as conduct disorder, while ICD-10 does not...As a result, prevalence studies from other countries using the ICD-10 (e.g. UK) indicate much lower ADHD rates than those from Australia and the USA.'<sup>153</sup>

<sup>148</sup> Andrews et al (1999), *The Mental Health of Australians*, Mental Health Branch, Commonwealth Department of Health and Aged Care, p.2. Available at [http://www.health.gov.au/internet/main/publishing.nsf/Content/78CA239BC007B0ADCA2572880002E508/\\$File/mhaust.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/78CA239BC007B0ADCA2572880002E508/$File/mhaust.pdf) (accessed 12 September 2013).

<sup>149</sup> M. Rosendal et al. (2007), 'Improving the Classification of Medically Unexplained Symptoms in Primary Care', *The European Journal of Psychiatry*, Vol. 21;1. Available at [http://scielo.isciii.es/scielo.php?script=sci\\_arttext&pid=S0213-61632007000100004](http://scielo.isciii.es/scielo.php?script=sci_arttext&pid=S0213-61632007000100004) (accessed 22 May 2013).

<sup>150</sup> Western Australia Legislative Assembly, *Attention Deficit Hyperactivity Disorder*, p.12.

<sup>151</sup> Constantine G. Berbatis, V. Bruce Sunderland et al. (2002), 'Licit psychostimulant consumption in Australia, 1984-2000: international and jurisdictional comparison', *Medical Journal of Australia*, 177; 10, p.540.

<sup>152</sup> Western Australia Legislative Assembly, *Attention Deficit Hyperactivity Disorder in WA*, p.14.

<sup>153</sup> Parliament of South Australia (2002), *Inquiry into Attention Deficit Hyperactivity Disorder: Sixteenth Report*

This is true not only for ADHD. DSM-IV generally contains broader, diagnostic criteria than ICD-10. A 2005 study compared diagnosis rates for a range of childhood psychiatric disorders using the diagnostic criteria in DSM-IV and the equivalent disorder in ICD-10. For the majority of disorders, including ADHD, rates of diagnosis were higher using DSM-IV, possibly because of the looser criteria.<sup>154</sup>

Rather than being developed as competing diagnostic systems, the ICD and DSM have had different development pathways that have converged over time. The first edition of the DSM was published by the APA in 1952. As the name indicates it is restricted exclusively to outlining the diagnostic criteria of mental illness. The ICD included a section on mental disorders for the first time in its sixth edition (ICD-6) in 1949.<sup>155</sup>

The ICD's origins can be traced to the 18<sup>th</sup> Century. It was developed as an attempt to systematically identify all potential 'causes of death' and so it is related to general medicine rather than mental disorders. The current version of ICD still performs this broad function.

The development of the DSM has reflected the shift within psychiatry from a psychoanalytic dominated approach, emphasising personal historical circumstances and later consequences, to a system of defining behavioural symptoms of an increasing number of discreet although often comorbid (co-existing) disorders. The development of ICD has lagged the DSM in following this trend. According to the American Psychological Association, the peak body for US psychologists:

Before 1980, psychiatric diagnostic systems reflected the dominant psychoanalytic ideas of the time, emphasizing the role of experience, downplaying biology.

"The American Psychiatric Association can really be credited with a revolution in psychiatric nosology with the publication of DSM-III by introducing a descriptive

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<sup>154</sup> of the Social Development Committee, Legislative Council, p.12.  
<sup>154</sup> Merete Juul Sorenson, Ole Mors and Per Hove Thomsen (September 2005), 'DSM-IV or ICD-10-DCR diagnoses in child and adolescent psychiatry: does it matter?', *European Journal of Child and Adolescent Psychiatry*, 14; 6, p.339.  
<sup>155</sup> Johannes Hebebrand & Jan K. Buitelaar (February 2011), 'On the way to DSM-V', *European Child and Adolescent Psychiatry*, 20; 2, pp.57-60. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038228/> (accessed 3 May 2012)

nosological system based on co-occurring clusters of symptoms", said WHO psychologist Geoffrey Reed, PhD.

There was very little international participation in the DSM-III, but at the time it may have been impossible to make such a big shift at the international level, he explained. As a result, DSM-III and ICD-8 (the version in effect at the time) were quite different from one another but as the descriptive phenomenological approach to diagnose mental disorders became dominant, the DSM and ICD have become very similar, partly because of collaborative agreements between the two organizations [The American Psychiatric Association and The World Health Organisation].<sup>156</sup>

Despite the gradual convergence, as previously discussed significant but subtle differences exist in the diagnostic criteria for ADHD and other disorders that are associated with lower rates of prescribing in jurisdictions using ICD-10 rather than DSM-IV.

In the USA ICD and the DSM are often used in a complementary manner. DSM is used as the dominant diagnostic criteria and ICD codes are used for administrative purposes in order to receive payment.<sup>157</sup> The situation is similar in Australia. The dominant role of the DSM-IV diagnostic criteria in Australia in recent decades means that the deliberations of the APA have had a significant influence on Australian psychiatric practice.

The reasons that DSM-IV has been more frequently used than ICD-10 in Australia are unclear. It appears unlikely that the rationale is based on any objective assessment of patient welfare in jurisdictions using the DSM-IV criteria compared to those using ICD-10's definition of Hyperkinetic Disorder. In relation to ADHD the USA has the highest child prescribing rate in the world with at least 2.7 million children currently taking ADHD 'medications'<sup>158</sup> ADHD critic American psychologist Dr Leonard Sax contends that as many

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<sup>156</sup> American Psychological Association, 'ICD vs DSM', *Monitor on Psychology*, Vol. 40;9 (October 2009). Available at <http://www.apa.org/monitor/2009/10/icd-dsm.aspx> (accessed 4 September 2012)

<sup>157</sup> U.S. Department of Health & Human Services, 'HHS Proposes Adoption of ICD-10 Code Sets and Updated Electronic Transaction Standards', *News Release*, 15 August 2008. Available at <http://www.hhs.gov/news/press/2008pres/08/20080815a.html> (accessed 22 October 2008)

<sup>158</sup> *In total, (in 2007) 4.8% of all children aged 4–17 years (2.7 million) were taking medication for ADHD*. Note: since 2007 US prescription rates have continued to grow. (2010), 'Increasing Prevalence of Parent-reported Attention-deficit/Hyperactivity Disorder Among Children – United States, 2003 and 2007', *Morbidity & Mortality Weekly Report, Centers for Disease Control and Prevention*, 59;44, pp.1439-



of the supposed benefits of medication for ADHD children relate to education, ‘you would expect American children to be racing ahead in their school work’, but as it is, ‘France, Germany, and Japan continue to maintain their traditional lead over the United States in tests of math and reading ability.’<sup>159</sup> Although Sax’s analysis ignores the complexity of the factors determining relative national education outcomes, it does raise obvious questions about the appropriateness of following the lead of the US in identifying and responding to perceived educational disadvantage without comparing outcomes associated with alternate approaches. Regardless of the record of the USA in terms of children’s wellbeing, Australian guidelines developed in 1997 and 2009 have recommended the use of the DSM-IV in preference to ICD-10 without providing a comprehensive rationale (refer to 5.3).

### 3.2 The American Psychiatric Association and Regulatory Capture

The APA is the dominant professional organisation of psychiatrists in the USA, and the largest psychiatric organisation in the world, with approximately 36,000 members.<sup>160</sup> It is self-regulated and is led by its President and a Board of Trustees with an Executive Committee. Along with the DSM – over which it has total editorial control - it publishes for sale journals and other material.

In the lead up to DSM-IV’s publication in 1994 a subcommittee of the American Psychiatric Association was tasked with developing and amending the diagnostic criteria for ‘Disorders Usually First Diagnosed in Infancy, Childhood and Adolescence’. The subcommittee decided by consensus to loosen the diagnostic criteria for ADHD. In 2006 US research revealed that the majority (61.9 percent) of members of that 1994 sub-committee had ties to the pharmaceutical industry.<sup>161</sup>

Commercial ties to the pharmaceutical industry within the APA subcommittees that developed

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1443. Available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5944a3.htm?s\\_cid=mm5944a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5944a3.htm?s_cid=mm5944a3_w) (accessed 18 January 2011).

<sup>159</sup> Leonard Sax, MD, ‘Ritalin: Better Living Through Chemistry?’ Sax quotes these statistics from Jodie Morse, ‘Summertime and School Isn’t Easy’, *Time*, 31 July 2000, p.20. French students scored 23 points above the international average; Japanese students, 94 points above. German students on average were 5 points below the international average; American students, 39 points below.

<sup>160</sup> American Psychiatry Association, (2012), ‘About APA & Psychiatry’. Available at <http://www.psychiatry.org/about-apa--psychiatry> (accessed 5 June 2012)

<sup>161</sup> Lisa Cosgrove, Sheldon Krinsky and Manisha Vijayaraghavan, (2006), ‘Financial Ties between DSM-IV Panel Members and the Pharmaceutical Industry’, *Psychotherapy and Psychosomatics*, 75, p. 54.

DSM-IV were not limited to members of the sub-committee responsible for ADHD.

Of the 170 DSM panel members 95 (56%) had one or more financial associations with companies in the pharmaceutical industry. One hundred percent of the members of the panels on 'Mood Disorders' and 'Schizophrenia and Other Psychotic Disorders' had financial ties to drug companies. The leading categories of financial interest held by panel members were research funding (42%), consultancies (22%) and speakers bureau (16%).<sup>162</sup>

The researchers concluded that 'there are strong financial ties between the industry and those who are responsible for developing and modifying the diagnostic criteria for mental illness. The connections are especially strong in those diagnostic areas where drugs are the first line of treatment for mental disorders.'<sup>163</sup>

Even within the APA questions have long been asked about the appropriateness of their relationship with the pharmaceutical industry. In 1985 Fred Gottlieb, APA Speaker of the House, told the APA:

I do not suggest that either they [the drug companies] or we [the American Psychiatric Association] are evil folks. But I continue to believe that accepting such money is, in the long run, inimical to our independent functioning. We have evolved a somewhat casual and quite cordial relationship with the drug houses, taking their money readily...We seem to discount available data that drug advertising promotes irrational prescribing practices. We seem to think that we as psychiatrists are immune from the kinds of unconscious emotional bias in favour of those who are overtly friendly toward us...We persist in ignoring an inherent conflict of interest.<sup>164</sup>

More recently in 2008 the US Senate Finance Committee, driven by Iowa Republican Senator Charles Grassley, began an investigation into the APA because of its financial ties to the pharmaceutical industry.<sup>165</sup> Grassley's probing led to revelations that the pharmaceutical

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<sup>162</sup> Cosgrove, Krinsky and Vijayaraghavan, 'Financial Ties between DSM-IV Panel Members', p.154.

<sup>163</sup> Cosgrove, Krinsky and Vijayaraghavan, (2006), 'Financial Ties between DSM-IV Panel Members' p. 154

<sup>164</sup> Cited in Breggin, *Talking Back to Ritalin*, p. 215

<sup>165</sup> Senator Chuck Grassley of Iowa, (December 2009), '*Grassley works for disclosure of drug company payments*

industry contributed approximately 30 per cent of the APA's \$US62.5 million in funding in 2006. Approximately half that money was from drug advertisements in APA journals and exhibits at the APA annual meeting. The other half was for sponsorship of 'fellowships, conferences and industry symposiums at the annual meeting.'<sup>166</sup>

There has been relatively recent recognition of the problem from the top level of the APA by retiring President, Dr Steven S. Sharfstein. In 2008 Sharfstein wrote a commentary piece on the relationship between psychiatry and the pharmaceutical industry entitled 'Big Pharma and American Psychiatry: the Good, the Bad, and the Ugly':

There is widespread concern of the over-medicalization of mental disorders and the overuse of medications. Financial incentives and managed care have contributed to the notion of a 'quick fix' by taking a pill and reducing the emphasis on psychotherapy and psychosocial treatments. There is much evidence that there is less psychotherapy provided by psychiatrists than 10 years ago. This is true despite the strong evidence base that many psychotherapies are effective used alone or in combination with medications...In a time of economic constraint, a 'pill and an appointment' has dominated treatment.

...There are examples of the 'ugly' practices that undermine the credibility of our profession. Drug company representatives will be the first to say that it is the doctors who request the fancy dinners, cruises, tickets to athletic events, and so on. But can we really be surprised that several states have passed laws to force disclosure of these gifts?

So-called 'preceptorships' are another example of the 'ugly'; that is, drug companies who pay physicians to allow company reps to sit in on patient sessions allegedly to learn more about care for patients and then advise the doctor on appropriate prescribing. Drug company representatives bearing gifts are frequent visitors to psychiatrists' offices and consulting rooms. We should have the wisdom

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to medical groups'. Available at [http://www.grassley.senate.gov/news/Article.cfm?customel\\_dataPageID\\_1502=24413](http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=24413) (accessed 28 March 2010).

<sup>166</sup> Gardiner Harris and Benedict Carey, 'Psychiatric Group Faces Scrutiny Over Drug Industry Ties,' *The New York Times*, 12 July 2008.

and distance to call these gifts what they are—kickbacks and bribes.<sup>167</sup>

Despite Sharfstein's criticisms his replacement as President of the APA, Alan Schatzberg had a serious conflict of interest. As a result of probing by Senator Grassley it was revealed that Schatzberg was the principal investigator in a US Federal Government sponsored study conducted into a drug, mifepristone, as a possible treatment for depression. Mifepristone was being developed by a company Schatzberg had set up and in which he owned US\$4.8 million worth of shares.<sup>168 169</sup> Schatzberg countered that he had complied with his employer's (Stanford University) disclosure policies and US federal guidelines that pertained to his research. He also argued that constraining researchers from trying to bring medications to market would result in 'less opportunities to help patients with severe illnesses'.<sup>170</sup> However, what is not in dispute is that the APA elected as President, a researcher who took US taxpayer funds to research a drug he has a substantial personal financial interest in, at a time when the retiring APA President criticised American psychiatry for failing to manage pharmaceutical industry conflict of interests.

The co-dependent relationship between the APA and pharmaceutical companies is attributed to declining incomes for both the APA and individual American psychiatrists in the 1970s. Critics contend that, partly in response to increasing competition from non-medical mental health practitioners, psychiatry has increasingly become dominated by the 'pill for every ill' biomedicalized model.<sup>171 172</sup> Psychologists, counsellors and social workers are all able to offer professional talking therapies as alternatives to psychiatry. The licence to medically intervene either pharmacologically or through surgery is psychiatry's major marketing edge. Breggin contends:

'In the early 1980s, the APA made a decision that changed its history and that of our society. It decided to create an economic and political partnership with the drug

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<sup>167</sup> Steven S. Sharfstein, (August 2008), 'Big Pharma and American Psychiatry', *Psychiatric News*, Vol. 40, No. 16, p.3.

<sup>168</sup> Letter from Charles E. Grassley, United States Senate, Committee on Finance to Dr. John L. Hennessy, President, Stanford University, 23 June 2008. Available at <http://pogoarchives.org/m/ph/grassley-letter-to-stanford-20080623.pdf> (accessed 28 March 2010).

<sup>169</sup> Cary and Harris, 'Psychiatric Group Faces Scrutiny'.

<sup>170</sup> Cary and Harris, 'Psychiatric Group Faces Scrutiny'.

<sup>171</sup> Breggin, *Talking Back to Ritalin*, p.216.

<sup>172</sup> Robert Whitaker (2010), *Anatomy of an Epidemic: Magic Bullets, Psychiatric Drugs, and the Astonishing Rise of Mental Illness in America*, Crown Publishing Group, New York, pp.276–278.

companies. The partnership would enable psychiatry to use drug company funds to promote the medical model, psychopharmacology, and the authority and influence of psychiatry...Psychiatry's decision to save itself by going into partnership with the drug companies was an openly discussed survival plan.'<sup>173</sup>

Elements of the co-operative relationship include that in 1982 the pharmaceutical industry funded the establishment of a Washington based APA Political Action Committee to lobby Congress. The pharmaceutical industry also partly paid for the APA's media training workshops. Prominent psychiatrists were paid by pharmaceutical companies to deliver rehearsed speeches and became 'thought leaders' frequently quoted in the media.<sup>174</sup> One US psychiatrist, Stefan Kruszewski, who delivered paid speeches for Pfizer, Glaxo-Smith Kline and Johnson and Johnson, claimed he was pressured to lie in presentations.<sup>175</sup>

Some of these thought leaders have agreed to be listed as authors of ghostwritten articles written by pharmaceutical company employees that promote their products in return for gifts 'and trips to luxurious settings'. In addition, supposedly 'independent' researchers served as 'consultants to companies whose products they are studying, join advisory boards and speakers' bureaus, enter into patent and royalty arrangements'.<sup>176</sup>

As well as the abovementioned changes there was a significant move away from research at American academic medical centres to American commercial research facilities during the 1990s. Part of the explanation is likely to be that the commercial research sector completes drug trials faster and at lower cost than academic medical centers.<sup>177</sup> Given that universities are at least not notionally profit motivated, there is arguably a greater potential for commercial researchers to tailor their results to suit the needs of their potential ongoing

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<sup>173</sup> Breggin, *Talking Back to Ritalin*, p.216.

<sup>174</sup> Whitaker, *Anatomy of an Epidemic*, pp.276–278.

<sup>175</sup> Duff Wilson, 'Side Effects May Include Lawsuits', *The New York Times*, 2 October 2010. Available at [http://www.nytimes.com/2010/10/03/business/03psych.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2010/10/03/business/03psych.html?pagewanted=all&_r=0) (accessed 10 October 2010)

<sup>176</sup> Marcia Angell (May 2000), 'Is Academic Medicine for Sale?', *The New England Journal of Medicine*, 343, pp.508-510. Available at <http://www.nejm.org/doi/full/10.1056/NEJM200008173430712> (accessed 23 May 2013)

<sup>177</sup> Thomas Bodenheimer (May 2000), 'Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry', *The New England Journal of Medicine*, Vol. 32;20, pp.1539-44. Available at <http://155.97.32.9/~bbenham/Phil%207570%20Website/aBodenNEJM00.pdf> (accessed 24 August 2011).

client particularly if the client represents a significant proportion of their potential revenue base.

The close commercial relationship between the APA and the pharmaceutical industry that emerged in the 1970s and 1980s coincided with the shift from a psychoanalytical focus in DSM-II published in 1968 to a biological focus in DSM-III published in 1980.<sup>178</sup> The biological focus of DSM-III, and the later DSM-IV, aligned with the interests of pharmaceutical manufacturers producing products that treat perceived biochemical imbalances.

In a very short period of time, mental illnesses were transformed from broad, etiologically defined entities that were continuous with normality to symptom-based, categorical diseases. The third edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-III) was responsible for this change...Its symptom-based diagnoses reflect a growing standardization of psychiatric diagnoses. This standardization was the product of many factors, including: (1) professional politics within the mental health community, (2) increased government involvement in mental health research and policymaking, (3) mounting pressure on psychiatrists from health insurers to demonstrate the effectiveness of their practices, and (4) the necessity of pharmaceutical companies to market their products to treat specific diseases.<sup>179</sup>

Many of the concerns discussed in this section of the chapter relate to commercial relations dealings between the APA and the pharmaceutical industry. However, the Chairperson of DSM-IV development taskforce, Dr Allen Frances, believes that financial conflicts of interest are not necessarily as important as what he terms 'intellectual conflicts of interest'. He contends 'experts always overvalue their pet area and want to expand its purview, until the point that everyday problems come to be mislabelled as mental disorders.'<sup>180</sup> There is little systemic evidence to support or refute Frances' contention, but if true it supplements rather than refutes concerns about the scientific validity of the diagnostic criteria in the DSM.

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<sup>178</sup> American Psychological Association, 'ICD vs DSM'.

<sup>179</sup> R. Mayes and AV Horwitz (2007), 'DSM-III and the revolution in the classification of mental illness', *Journal of the History of the Behavioral Sciences*, Vol. 43;4, p.419.

<sup>180</sup> Allen Frances, 'Diagnosing the D.S.M.', *New York Times*, 11 May 2012. Available at [http://www.nytimes.com/2012/05/12/opinion/break-up-the-psychiatric-monopoly.html?\\_r=0](http://www.nytimes.com/2012/05/12/opinion/break-up-the-psychiatric-monopoly.html?_r=0) (accessed 3 July 2012).

### 3.3 History of ADHD: the broadening of the diagnostic criteria

As discussed above and identified by Abraham (refer to 2.5), since the 1970s there has been a progressive broadening in the diagnostic criteria for ADHD and the conditions that predated ADHD. The history of the forerunners of ADHD begins in 1902 when Dr Fredric Still documented cases involving impulsiveness, labeling it a 'defect of moral control'. It was later renamed 'minimal brain damage'. In 1922 the symptoms were further defined and given the name 'post encephalitic behaviour disorder'.<sup>181</sup>

The use of stimulants to modify behaviour began in 1937 when American doctor Charles Bradley was the first to recommend stimulants to treat hyperactive children.

...[Bradley] observed the 'calming' effect of stimulants on children when he gave Benzedrine (trademark for amphetamine) to a group of 30 children in order to treat headaches that resulted from spinal taps they were given. The Benzedrine did not do anything for the headaches, but it did make the children less active and more compliant, in a fashion he called 'spectacular'.<sup>182</sup>

Bradley had identified the effects of amphetamines on 'normal' children but proposed amphetamines as a treatment for hyperactive children. In 1950 he undertook a study of 275 hyperactive children given amphetamines. He reported 'between 60 per cent and 70 per cent to be much improved while on the drugs'.<sup>183</sup>

In 1956 the stimulant Ritalin was first used as a treatment for hyperactive children. During the 1960s the use of stimulant medication to treat hyperactive children became more common. However it was not until the 1990s that, facilitated by the loosening of the DSM-IV diagnostic criteria, prescribing rates exploded in North America (and Australia).<sup>184</sup>

Except for Still's 'defects of moral control', early emphasis was on aetiology-based descriptions of the disorder's predecessors. This is despite the fact that the cause or causes had never been

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<sup>181</sup> Baughman and Hovey, *The ADHD Fraud*, pp.52–53.

<sup>182</sup> Baughman and Hovey, *The ADHD Fraud*, pp.52–53.

<sup>183</sup> Baughman and Hovey, *The ADHD Fraud*, p.54.

<sup>184</sup> In 1991 in Australia, less than 10,000 prescriptions were dispensed for dexamphetamine sulphate. In 1998, nearly 250,000 prescriptions were dispensed for the same drug, an increase of 2400 per cent. Paul Mackey and Andrew Kopras, *Medication for Attention Deficit Hyperactivity Disorder (ADHD): An Analysis by Federal Electorate*, Parliament of Australia, Canberra, 2001, p.4.

established. The term 'minimal brain dysfunction' used in the early 1960s was altered in the late 1970s to 'hyperactive disorder of childhood'. During the 1970s, further symptoms such as a lack of focus and daydreaming were added to the diagnostic list. Impulsiveness was also expanded at this time to include verbal, cognitive and motor impulsiveness. In 1980 the APA voted to change the name of the disorder to 'attention deficit disorder' (ADD) and its definition was again expanded. The new definition was based on the assumption that attention difficulties are sometimes independent of impulse problems and hyperactivity – the disorder was redefined as primarily a problem of inattention, rather than of hyperactivity. In keeping with this approach, two subtypes of ADD were presented in DSM-III (APA 1980): ADD/H, with hyperactivity, and ADD/WO, without hyperactivity or passive ADD. The recognition of passive ADD has been the subject of debate ever since.

With DSM-III-R (APA 1987), the revised version of DSM-III, the name of the condition was changed to the one used today, Attention Deficit Hyperactivity Disorder (ADHD), and the symptoms were again merged into a single disorder without any subtypes. Specifically, DSM-III-R required a child to display six of nine inattentive behaviours *and* six of nine impulsive/hyperactive behaviours.<sup>185</sup> This diagnostic requirement did away with the possibility that an individual could have the disorder without being hyperactive. A child had to display both inattentive and hyperactive/impulsive behaviours. This change went against the long term trend of loosening the diagnostic criteria.

Subsequent to the release of DSM-III-R a number of studies were published justifying the existence of passive or inattentive ADD without the hyperactivity element. In response to this backlash, the definition was changed yet again in the fourth edition of the manual published in 1994 (DSM-IV). The 1987 decision was effectively reversed as the criteria were broadened so that a 'patient' needed to display six of nine inattentive *or* six of nine hyperactive/impulsive behaviours.

The APA did not change the name ADHD, but the symptoms were divided into two categories: inattentive and hyperactive/impulsive. Three subtypes of the disorder were also defined: 'ADHD – Primarily Inattentive', 'ADHD – Primarily Hyperactive/Impulsive', and 'ADHD –

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<sup>185</sup> American Psychiatric Association (1987), *Diagnostic and statistical manual of mental disorders*, 3<sup>rd</sup> edn, revised, Washington, DC, American Psychiatric Association.



Combined Type (both inattentive and impulsive)'. Not surprisingly, this created some confusion. Sometimes when the term Attention Deficit Disorder (ADD) is used today it is used in its original generic sense – interchangeably with ADHD. On other occasions it is used as a specific descriptor of passive ADHD without the H for Hyperactivity.

ADHD now applies to a broad spectrum of child behaviour. Children who are considered too active (hyperactive) and children who are considered too inactive (hypoactive) are included. In addition to the ADHD hyperactive and inattentive subtypes, DSM-IV-TR<sup>186</sup>, the version of DSM-IV updated in 2000 contains yet another category, 'Attention Deficit/Hyperactivity Disorder – Not otherwise specified', which further broadens the criteria to include 'individuals whose symptom pattern does not meet the full criteria for the disorder'.<sup>187</sup>

DSM-IV Chairperson Allen Frances later acknowledged the role of expanded DSM-IV criteria in triggering a 'false epidemic for ADHD', however he believes this was part of a greater process of commercially driven pharmaceuticalization:

It is no coincidence that rates began skyrocketing immediately after two unrelated events that occurred almost simultaneously in the late 1990s. First, new drugs for ADD were brought to market that were no better than the old drugs, but they were lots more expensive and provided a rich profit incentive for aggressive marketing. Second, FDA deregulation freed drug companies to pursue unrestrained direct-to-consumer multimedia advertising. The companies quickly determined that peddling the ADD ill was the royal road to expanding the market for their new expensive pills... The epidemic started precisely when aggressive drug company marketing succeeded in 'educating' and sensitizing doctors, parents, and teachers to spot ADD in kids previously considered to be on the normal side of the spectrum's boundary... The drug company cause has been furthered by heavily subsidized thought leaders (usually psychiatrists), by physicians (especially in primary care) who are too free in diagnosis and treatment, and

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<sup>186</sup> TR stands for Text revised.

<sup>187</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th edn, p93.

by harried parents and teachers trying to figure out how best to help and manage their difficult children.<sup>188</sup>

In contrast to the assertions of Dr Frances and other critics, ADHD proponents contend that better education of clinicians, improved diagnostic procedures and increased public awareness of the condition account for increased prescribing rates internationally. For example the Canadian Attention Deficit Hyperactivity Disorder Resource Alliance, a Canadian ADHD patient support group contends: 'ADHD may seem to be more common today than in the past but this is largely due to the increase in research and media scrutiny. Research has encouraged awareness within the professional community, leading to better diagnoses. Media coverage, although not always accurate, has heightened public awareness of the condition.'<sup>189</sup> Other ADHD proponents agree, arguing that greater knowledge and awareness of the disorder has 'empowered physicians and parents' resulting in higher diagnosis and prescribing rates.<sup>190</sup>

### 3.4 Further broadening of ADHD criteria in DSM-5

The latest edition of the APA's DSM, DSM-5, was released in May 2013. Frances regrets changes in DSM-IV as helping 'trigger three false epidemics..for Autistic Disorder...[the] childhood diagnosis of Bi-Polar Disorder and the... the wild over-diagnosis of Attention Deficit Disorder.'<sup>191</sup> Dr Frances warned of similar problems with DSM-5. After reviewing an early draft of DSM-5 he predicted further 'false epidemics' and 'unnecessary, expensive and often horrible treatments for conditions that really are made up by the people doing the

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<sup>188</sup> Frances, 'Attention Deficit Disorder is Over-Diagnosed and Over-Treated'.

<sup>189</sup> *Attention Deficit Hyperactivity Disorder*, Canadian Attention Deficit Hyperactivity Disorder Resource Alliance. Available at [http://www.caddra.ca/cms4/index.php?option=com\\_content&view=article&id=22&Itemid=233&lang=en](http://www.caddra.ca/cms4/index.php?option=com_content&view=article&id=22&Itemid=233&lang=en) (accessed 12 November 2012).

<sup>190</sup> Dr. Tanya Froehlich, an American developmental and behavioral pediatric specialist was quoted in Alan Mozes, HealthDay, 'Study: Nearly 1 in 10 U.S. kids diagnosed with ADHD', *USA Today*, (18 August 2011). "In 2001 the American Academy of Pediatrics put out clinical practice guidelines on the assessment and treatment of children with ADHD. And a tool kit was also put out giving physicians actual measures to use to assess ADHD. All of this has really empowered physicians and parents. So given that, I would not really be surprised if that's why more and more kids have been diagnosed." Available at <http://usatoday30.usatoday.com/news/health/wellness/special-needs/story/2011/08/Study-Nearly-1-in-10-US-kids-diagnosed-with-ADHD/50057050/1> (accessed 18 May 2013).

<sup>191</sup> Dr Allen Frances, 'Psychiatrists Propose Revisions to Diagnosis Manual', PBS Newshour, 10 February 2010. Available at [http://www.pbs.org/newshour/bb/health/jan-june10/mentalillness\\_02-10.html](http://www.pbs.org/newshour/bb/health/jan-june10/mentalillness_02-10.html) (accessed 26 February 2010).

manual (DSM5)'.<sup>192</sup> A draft released for public comment attracted considerable critical attention that resulted in significant back-downs by the DSM-5 development committee, including abandoning most of the changes proposed for ADHD diagnostic criteria.

The most obvious of the abandoned proposed changes was the inclusion of four extra ways of exhibiting ADHD. For a diagnosis of the primarily hyperactive subtype, instead of children having to display 6 of 9 (67 percent) impulsive/hyperactive diagnostic criteria, it was proposed that 6 of 13 (47 percent) would be sufficient. The four additional criteria proposed were:

1. Tends to *act without thinking*, such as starting tasks without adequate preparation or avoiding reading or listening to instructions. May speak out without considering consequences or make important decisions on the spur of the moment, such as impulsively buying items, suddenly quitting a job, or breaking up with a friend.
2. Is often *impatient*, as shown by feeling restless when waiting for others and wanting to move faster than others, wanting people to get to the point, speeding while driving, and cutting into traffic to go faster than others.
3. Is *uncomfortable doing things slowly and systematically* and often rushes through activities or tasks.
4. Finds it *difficult to resist temptations or opportunities*, even if it means taking risks (A child may grab toys off a store shelf or play with dangerous objects; adults may commit to a relationship after only a brief acquaintance or take a job or enter into a business arrangement without doing due diligence).<sup>193</sup>

For anyone aged 17 or older the ADHD diagnostic threshold was proposed to be lowered even further. If the proposed changes were adopted it would be sufficient to meet as little as 4 (down from 6) of either the 9 inattentive or 4 of the expanded 13 impulsive/hyperactive

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<sup>192</sup> Frances, 'Psychiatrists Propose Revisions'.

<sup>193</sup> American Psychiatric Association, 'DSM-5 Development, Proposed Revision', *Attention Deficit/Hyperactivity Disorder*. Available at <http://www.dsm5.org/ProposedRevision/Pages/proposedrevision.aspx?rid=383> (accessed 25 July 2011).

criteria.<sup>194</sup> These proposed changes would have continued the long term trend of lowering the bar for a diagnosis of ADHD. DSM-III (APA 1980) required six of nine inattentive behaviours and six of nine impulsive/hyperactive behaviours. The bar was lowered significantly in DSM-IV (APA1994) when the requirement was reduced to six of nine inattentive or six of nine hyperactive/impulsive behaviours<sup>195</sup> Effectively any patient was required to display at least 12 of 18 (67 percent) behaviours in DSM-III, however for DSM-5 it was proposed that as few as 4 of 22 (17 percent) would qualify for a diagnosis for anyone aged seventeen or older.

Other more subtle but nonetheless significant proposed changes included:

1. The relaxation of the DSM-IV expectation that teachers independently provide evidence. DSM-IV states; 'The clinician should therefore gather information from multiple sources (e.g. parents, teachers) and inquire about the individual's behavior in a variety of situations within each setting.'<sup>196</sup> The wording proposed for DSM5 was: 'In children and young adolescents, the diagnosis should be based on information obtained from parents and teachers. When direct teacher reports cannot be obtained, weight should be given to information provided to parents by teachers that describe the child's behavior and performance at school'.<sup>197</sup>
2. Replacing hyperactive actions in the wording of criteria to feelings or perceptions of 'restlessness'. One of the hyperactive/impulsive diagnostic criteria in DSM-IV states; 'often leaves seat in classroom or in other situations in which remaining seated is expected.'<sup>198</sup> The wording proposed to replace this in DSM5 was: often *restless* during activities when others are seated (may leave his or her place in

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<sup>194</sup> American Psychiatric Association, 'DSM-5 Development, Proposed Revision'.

<sup>195</sup> For a full description of the history of how the diagnostic criteria for ADHD have evolved see Whitely, *Speed Up & Sit Still*, p.16.

<sup>196</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, p.87.

<sup>197</sup> American Psychiatric Association, 'DSM-5 Development, Proposed Revision'.

<sup>198</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, p.92.

the classroom, office or other workplace, or in other situations that require remaining seated).<sup>199</sup>

3. Pathologising the normal phenomena that ADHD behaviours are *‘typically more marked during times when the person is studying or working’* than *‘during vacation’*.<sup>200</sup>
4. The inclusion of adult relevant examples in most of the diagnostic criteria which had previously been primarily orientated to children in a school setting.<sup>201</sup>
5. The change in the requirement that signs of the behaviour should be displayed before age seven to age twelve.<sup>202</sup>

All the DSM-5 proposed changes if implemented were likely to increase ADHD patient numbers and ADHD pharmaceuticalization.

In August 2011 Frances criticized the proposed changes:

We are already in the midst of a false epidemic of ADD...In part this came from changes in DSM-IV, but most of the inflation was caused by a marketing blitz to practitioners that accompanied new on-patent drugs by new regulations that also allowed direct to consumer advertising to parents and teachers. In a sensible world, DSM5 would now offer much tighter criteria for ADD and much clearer advice on the steps needed in its differential diagnosis. This would push back, however feebly, against the skilled and well financed drug company sell. DSM5 should work hard to improve its text, not play carelessly with the ADD criteria in a way that may unleash a whole set of dreadful unintended consequences – unneeded medication, stigma, lowered expectations, misallocation of resources, and

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<sup>199</sup> American Psychiatric Association, ‘DSM-5 Development, Proposed Revision’.

<sup>200</sup> American Psychiatric Association, ‘DSM-5 Development, Proposed Revision’.

<sup>201</sup> American Psychiatric Association, ‘DSM-5 Development, Proposed Revision’.

<sup>202</sup> American Psychiatric Association, ‘DSM-5 Development, Proposed Revision’.

contribution to the illegal secondary market peddling stimulants for recreation or performance enhancement.<sup>203</sup>

After widespread criticisms similar to those made by Frances the APA backed down on many of its proposed changes for ADHD in DSM5. It abandoned the proposal to include the abovementioned four additional criteria and reduced the number of criteria for people aged 17 and over to five, not four, as was originally proposed. However, the existing 18 diagnostic criteria have been reworded to be applicable to adults as well as children, reflecting the ADHD industry's persistent and successful efforts to expand the adult market.<sup>204</sup>

Another remaining concern for ADHD critics was the inclusion of an ADHD category titled *Attention Deficit/Hyperactivity Disorder Not Elsewhere Classified*. This additional category reads:

Attention Deficit/Hyperactivity Disorder (ADHD) Not Elsewhere Classified may be coded in cases in which the individuals are below threshold for ADHD or for whom there is insufficient opportunity to verify all criteria. However, ADHD-related symptoms should be associated with impairment, and they are not better explained by any other mental disorder.<sup>205</sup>

The inclusion of this additional category effectively enables clinicians to diagnose and prescribe without even the protection offered by the already extremely broad DSM-IV diagnostic criteria.

The APA only modified its original proposals after significant past users of the DSM, including the British Psychological Association and chapters of the American Psychological Association, threatened a boycott of DSM5.<sup>206</sup> This supports the contention that the APA's

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<sup>203</sup> Allen Frances, 'DSM-5 Will Further Inflate the ADD bubble', *Psychology Today*, 1 August 2011. Available at <http://www.psychologytoday.com/blog/dsm5-in-distress/201108/dsm-5-will-further-inflate-the-add-bubble> (accessed 21 January 2013)

<sup>204</sup> see American Psychiatric Association, 'DSM-5 Development, Proposed Revision'.

<sup>205</sup> see American Psychiatric Association, 'DSM-5 Development, Proposed Revision'.

<sup>206</sup> For further detail refer to Martin Whitely, 'Boycott DSM5- it is dangerous and scientifically unsound', *Speed Up & Sit Still: The truth about ADHD and other mental health controversies from Australia*, 28 March 2013. Available online at <http://speedupsitstill.com/sign-on-line-petition-proposed-dsm5> (accessed 6 May 2013); and Martin Whitely, 'Dr Allen Frances, the lead author of DSM-IV, and the British

DSM development process is driven by politics, pressure, and money, rather than science and patient welfare.

### 3.5 Regulatory Capture and International Drug Research

The ADHD drug manufacturers are multinational companies that sell the pharmacologically identical products around the globe. The decision whether to licence and subsidise the drugs is made by each individual nation's regulatory authorities. However, these individual decisions are often substantially based on submissions from the drug manufacturers which use the same research in different national jurisdictions.

In 2012 Canadian researcher Professor Marc-André Gagnon concluded that the 'dominant business model' of the pharmaceutical sector is to promote drugs that often don't offer any significant 'therapeutic advance'. He contends research is conducted by the pharmaceutical industry 'like a promotional campaign'.

Data obtained from clinical research are primarily used to boost and support sales rather than to improve prescribing behaviour... Ghostwriters are employed to inflate the number of publications showing the drug in a positive light; results that would harm sales are not published (publication bias); and negative data are suppressed... Pharmaceutical companies consider that private-sector clinical research produces private, confidential results that are their own intellectual property... And they are not compelled by political and health authorities to make public the data obtained in clinical trials.<sup>207</sup>

As evidence of these assertions Gagnon highlighted that:

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Psychological Association, lead the chorus of opposition to disease mongering proposals in DSM5', *Speed Up & Sit Still: The truth about ADHD and other mental health controversies from Australia*, 17 August 2011. Available online at

<http://speedupsitstill.com/dr-allen-frances-lead-author-dsmiv-british-psychological-association-lead-chorus-opposition-disease-mongering-proposals-dsm5>.

<sup>207</sup> Marc-Andre Gagnon, 'Corporate influence over clinical research: considering the alternatives', Translated from *Rev Prescrire*, April 2012: Vol 32:342, p.311. Available at <http://english.prescrire.org/en/81/168/47752/0/NewsDetails.aspx?page=7> (accessed 5 May 2013).

- 'The [world's] 15 biggest drug companies... spend about twice as much on promotion as on research.'<sup>208</sup>
- 'In 2009, *Prescrire* analysed 109 new [to the French market] drugs or indications (excluding generics): 3 were considered a minor therapeutic breakthrough, 76 added nothing new to the existing pharmacopoeia, while 19 were deemed to represent a possible public health risk.'<sup>209</sup>
- In 2004 after causing an estimated 60,000 deaths worldwide primarily from heart attacks and strokes Merck pharmaceuticals bestselling arthritis drug Vioxx was withdrawn from sale worldwide. Prior to that 'Merck mounted a ghostwriting campaign [to promote Vioxx]... 96 articles were published, some of which omitted to mention the deaths of patients who participated in clinical trials of the drug.'<sup>210</sup> ...Merck had 'drawn up a hit list of "rogue" researchers who had criticised Vioxx [who] had to be discredited and 'neutralized'.<sup>211 212</sup>

Gagnon concludes 'as long as pharmaceutical companies hold the purse strings of biomedical research, medical knowledge will be selectively constructed for the purpose of marketing drugs rather than improving public health.'<sup>213</sup> Gagnon's criticisms of the French and Canadian systems are similar to those of critics of the USA drug licencing system administered by the Food and Drug Administration (FDA). In the USA, pharmaceutical companies are free to determine who conducts their studies, which studies they publish and

<sup>208</sup> Marc-Andre Gagnon & Joel Lexchin, 'The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States, *PLoS Med* 5(1). Available at <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050001> (accessed 4 May 2013).

<sup>209</sup> *Prescrire Int* 2010; 19 (106), pp.89-94. Available at <http://www.ncbi.nlm.nih.gov/pubmed/20568499> (accessed 6 May 2013).

<sup>210</sup> Joseph S. Ross et al, 'Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation', *Journal of American Medical Association*, 299: 15 (2008).

<sup>211</sup> M Rout, "Vioxx maker Merck and Co drew up doctor hit list" *The Australian* 1 April 2009.

<sup>212</sup> Vioxx was an arthritis and acute pain medication that was launched in the United States in 1999 by Merck & Co and was marketed in over eighty countries. Sales in 2003 were worth \$2.5 billion. In March 2000 the results of a study, the Vioxx Gastrointestinal Outcomes Research (VIGOR), indicated an increased risk of cardiovascular events. This trial found that there was an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, 18 months after treatment began. 'Merck Announces Voluntary Worldwide Withdrawal of VIOXX®', available at [http://www.merck.com/newsroom/vioxx/pdf/vioxx\\_press\\_release\\_final.pdf](http://www.merck.com/newsroom/vioxx/pdf/vioxx_press_release_final.pdf) (accessed 7 February 2007). Merck failed to warn treating doctors or patients about the results of the VIGOR study (2000). No information, let alone warnings, about the risks were given, until some two years later. Even then the information that was finally given was unclear. Consequently, doctors and patients continued prescribing and using Vioxx until its withdrawal. As a result, thousands of people may have suffered serious injury or died as a result.

<sup>213</sup> Gagnon, 'Corporate influence over clinical research'.



which they keep private. Some pharmaceutical companies use two methods to deny the FDA and the American public full information. The first is to ignore unfavourable studies. The second is to spin the results of unfavourable findings for the 'primary outcome' – the main question the study was designed to answer – and highlight a favourable 'secondary outcome'.<sup>214</sup> Pfizer, the manufacturer of antidepressant Zoloft, conducted five studies for presentation to the FDA:

The drug seemed to work better than the placebo in two of them. In three other trials, the placebo did just as well at reducing indications of depression. Only the two favorable trials were published, researchers found, and Pfizer discusses only the positive results in Zoloft's literature for doctors.<sup>215</sup>

These tactics are not limited to Pfizer. In 2008 the *Wall Street Journal* highlighted that in the case of 74 pharmaceutical company sponsored studies into antidepressants, 37 of 38 favourable studies were published, but the majority of unfavourable (22 of 36) studies were not. Of the fourteen unfavourable studies that were published, 'at least 11 of those studies mischaracterized the results and presented a negative study as positive... In nine (of 11) of the negative studies that were published, the authors simply omitted any mention of the (negative) primary outcome.'<sup>216</sup>

### **3.6 Oregon Health and Science University ADHD Drug Effectiveness Review Project**

Both Gagnon's analysis and the American experience demonstrate the capacity for regulatory capture of research and licencing in Western democracies. Research directly related to ADHD and drugs marketed in Australia was conducted by the Oregon Health and Science University in 2005. The *ADHD Drug Effectiveness Review Project* was commissioned by fifteen US states in order to determine which drugs were the safest and most cost effective.<sup>217</sup> The 731-page review analysed 2287 studies, 'virtually every investigation ever

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<sup>214</sup> David Armstrong and Keith J. Winstein, 'Antidepressants Under Scrutiny Over Efficacy', *The Wall Street Journal*, 17 January (2008).

<sup>215</sup> Armstrong and Winstein, 'Antidepressants Under Scrutiny'.

<sup>216</sup> Armstrong and Winstein, 'Antidepressants Under Scrutiny'.

<sup>217</sup> Marian S. McDonagh, Kim Petersen, et al (2007), *Drug Class Review on Pharmacologic Treatments for ADHD: Final Report Update 2*, Portland, Oregon Health & Science University. Available at [http://www.ohsu.edu/ohsuedu/research/policycenter/customcf/derp/product/ADHD\\_Final%20Report%20Update%20Evidence%20Tables.pdf](http://www.ohsu.edu/ohsuedu/research/policycenter/customcf/derp/product/ADHD_Final%20Report%20Update%20Evidence%20Tables.pdf) (accessed 13 February 2009).

done on ADHD drugs anywhere in the world'.<sup>218</sup> Of the studies analysed, 'The group rejected 2,107 investigations as being unreliable, and reviewed the remaining 180 to find superior drugs'.<sup>219</sup> Instead of being able to make objective comparisons of the safety and effectiveness of the different drugs, the review was 'severely limited' by a lack of studies measuring 'functional or long-term outcomes'.<sup>220</sup>

The review concluded that 'evidence on the effectiveness of pharmacotherapy for ADHD in young children is seriously lacking',<sup>221</sup> and that there was 'no evidence on long-term safety of drugs used to treat ADHD in adolescents'.<sup>222</sup> The review also found that 'good quality evidence on the use of drugs to affect outcomes relating to global academic performance, consequences of risky behaviours, social achievements, etc. is lacking'.<sup>223</sup> It was also critical of the lack of research into the possibility that some ADHD drugs could stunt growth.<sup>224</sup> In addition it found that the evidence that ADHD drugs help adults was 'not compelling'.<sup>225</sup> Overall, the report ascertained that the quality of evidence was very often 'poor'.<sup>226</sup>

### 3.7 Imported Regulatory Capture Summary

In Australia the appearance of new ADHD drugs on the market and government subsidisation of the drugs has followed the US experience generally, lagging by a few years (refer Chapter 4). One significant difference is that direct to consumer marketing has remained illegal. Therefore US experience is not identical to Australia's.

However, the official endorsement by Australian authorities, most notably the professional associations and the National Health and Medical Research Council, of the DSM-IV diagnostic criteria over which the Australian medical profession has no control, results in Australian psychiatric practice being influenced by the same forces that influence American

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<sup>218</sup> Alexander Otto (2005), 'Are ADHD drugs safe? Report finds little proof', *The News Tribune*, 13 September 2005. Available at <http://www.playattention.com/attention-deficit/articles/are-adhd-drugs-safe-report-finds-little-proof> (accessed 12 May 2007).

<sup>219</sup> Otto, 'Are ADHD drugs safe?'.

<sup>220</sup> Otto, 'Are ADHD drugs safe?'.

<sup>221</sup> Oregon Health & Science University, *Drug Class Review*, p.24.

<sup>222</sup> Oregon Health & Science University, *Drug Class Review*, p.20.

<sup>223</sup> Oregon Health & Science University, *Drug Class Review*, p.16.

<sup>224</sup> Oregon Health & Science University, *Drug Class Review*, p.19.

<sup>225</sup> Oregon Health & Science University, *Drug Class Review*, p.21.

<sup>226</sup> Oregon Health & Science University, *Drug Class Review*, pp.77-81.

psychiatric practice. Regulatory capture in the US of the APA has therefore become imported regulatory capture in Australia.

Similarly Australian regulatory authorities have no direct control over much of the research that is used to evaluate the safety and efficacy of ADHD medications. Australia is effectively an importer of this evidence with limited capacity to ensure its integrity. The effect of this imported research on Australian policy development and regulatory processes is described in greater detail in chapter 5 (particularly 5.3.2, 5.4.1 and 5.4.2). But first, Chapter 4 provides statistical information on the prescription of ADHD medications in Australia.

## **Chapter 4. Statistics on Australian National and Western Australian and New South Wales ADHD prescribing rates**

This chapter presents and analyses relevant statistical data about national, Western Australian (WA) and New South Wales (NSW) child and adult ADHD drug prescribing per capita rates from 1992 to 2011. These data are referred to extensively in subsequent chapters.

### **4.1 Sources of Data**

*Commonwealth Government Sources:* There is no single data source that provides accurate statistics of Australian national and state ADHD child prescribing rates for the entire study period 1992 to 2011. Between 1992 and 2002 Commonwealth Government state-specific prescribing data are limited to total Pharmaceutical Benefits Scheme (PBS) subsidised prescription numbers and there is no reliable estimate of patient numbers or their ages. Accurate statistical data of ADHD PBS funded state-specific child patient numbers is available from the Australia Department of Health and Ageing (DoHA) for the period 2002 to 2011. However, it was not until July 2007 that all ADHD medications were subsidised via the Pharmaceutical Benefits Scheme.

For the years 1995 to 2010 DoHA has identified the annual national total of both PBS subsidised and unsubsidised ADHD prescriptions.<sup>227</sup> However, the DoHA data does not identify individual state rates or patient numbers or ages and are therefore only useful for identifying national trends in prescribing.

*WA and NSW State Government Sources:* Several sources provide data that allows estimation of state prescribing rates, particularly for WA and to a lesser extent NSW. The availability of these state-based statistics and significant historical data on policy and regulatory processes in these states are the reasons these states were chosen for a detailed analysis.

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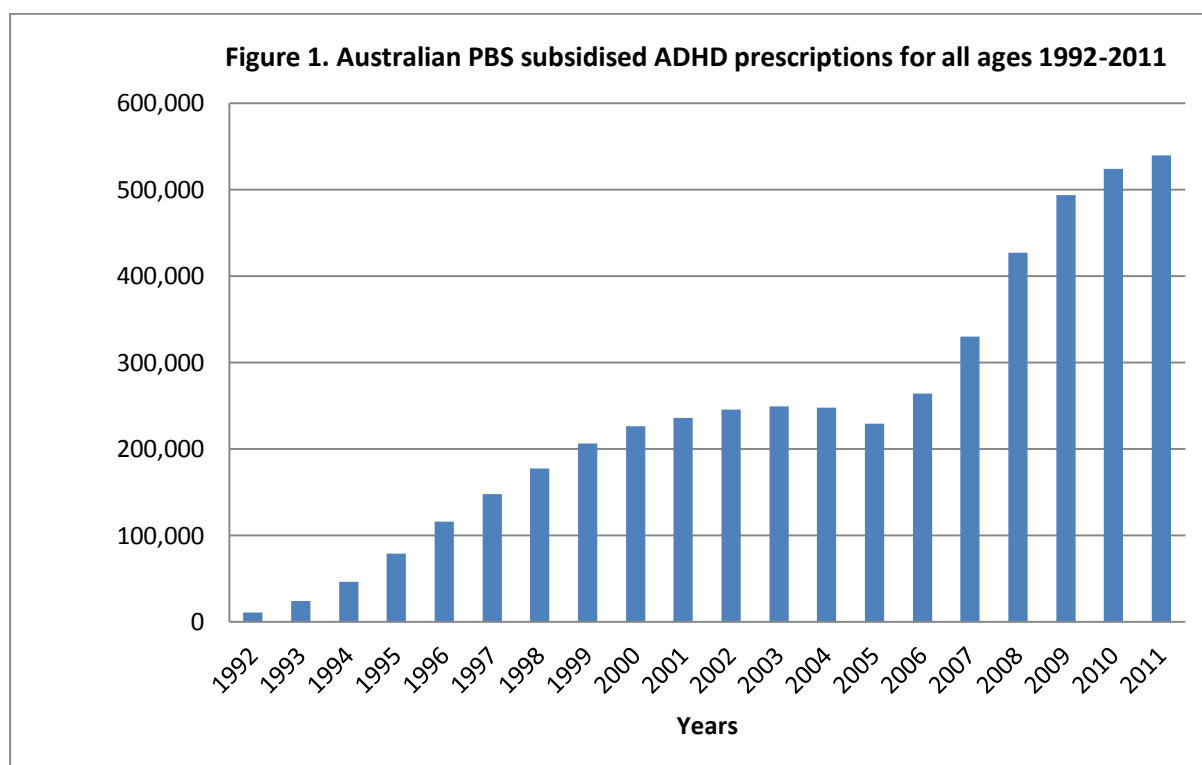
<sup>227</sup> The Commonwealth Department of Health and Ageing has produced a series of annual reports titled 'Australian Statistics on Medicines' covering the period 1995 to 2010. These reports are available at <http://www.pbs.gov.au/info/browse/statistics#ASM> (accessed 31 August 2013).

Of all Australian states WA has the most comprehensive and detailed historical data about both ADHD prescribing rates and regulation and policy development practices. In addition it has historically been an outlier with per capita prescribing rates showing a considerably different pattern in WA compared with other Australian jurisdictions.

Data for NSW is not as comprehensive. However in recent years, namely between 2007 and 2012, NSW per capita child prescribing rates have grown significantly and are now the highest in Australia. This followed a significant regulatory and policy process in 2007, the Clinical Excellence Commission Prescribing Review, discussed in section 6.10.1.

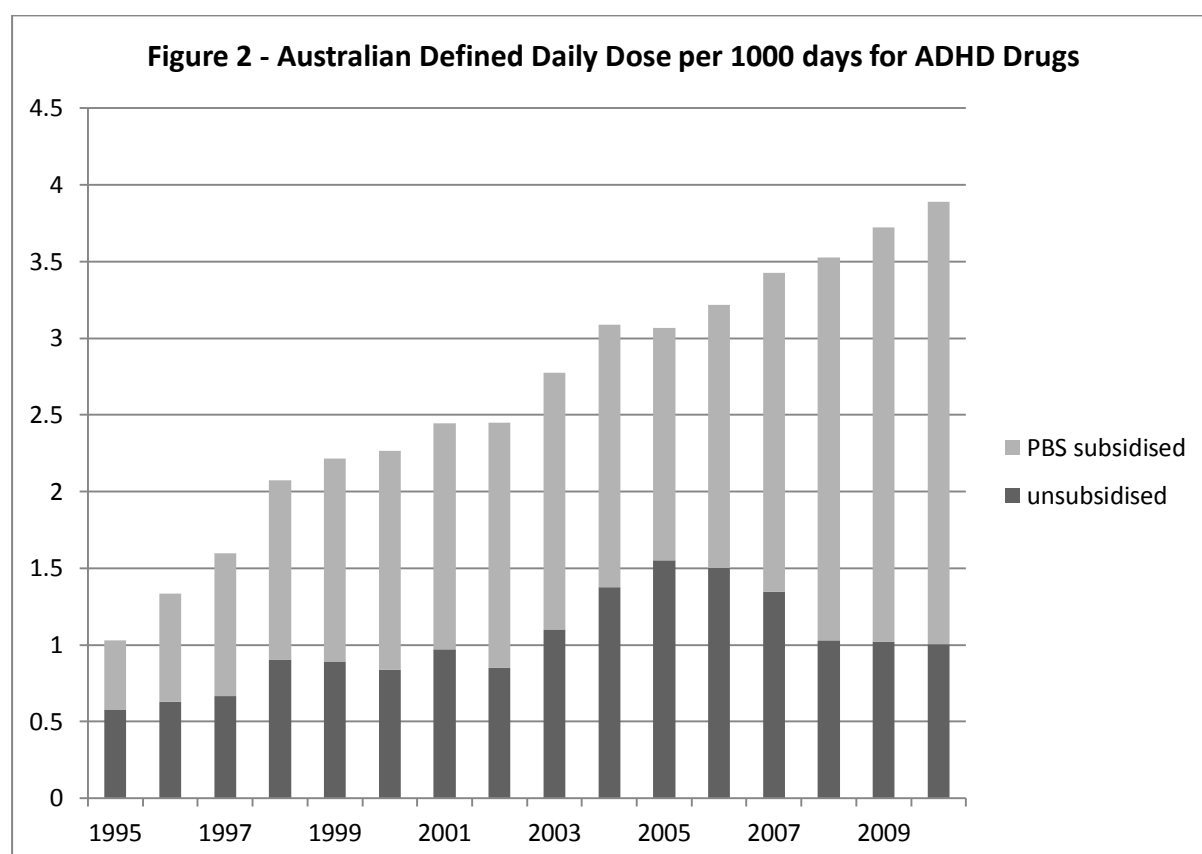
#### 4.2 National prescribing rates for ADHD medications 1992-2011

Information about the pattern of national ADHD prescribing in the study period is presented in three figures below. Each covers different time periods and has limitations resulting from the data source. Although chapters 5 and 6 of this thesis later analyse policy processes in the 2012 year, significant statistical data were not available at the time of writing for the 2012 calendar year.



Source: Department of Health and Ageing, *Medicare Australia*. Self-generated report available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-stats.htm-copy3> (accessed 5 August 2013)

In Figure 1 Australian national rates are shown using data sourced from the PBS. This information first became available in 1992 when dexamphetamine was added to the PBS hence Figure 1 above commences in 1992. The major limitations of these data are that they do not include non-PBS prescriptions and or provide information about the number of patients or breakdown by age. Another limitation is that it does not take account of the 27.7 percent increase in Australia's population between 1992 (estimated 17,581,000) and 2011 (estimated 22,447,000).<sup>228</sup>

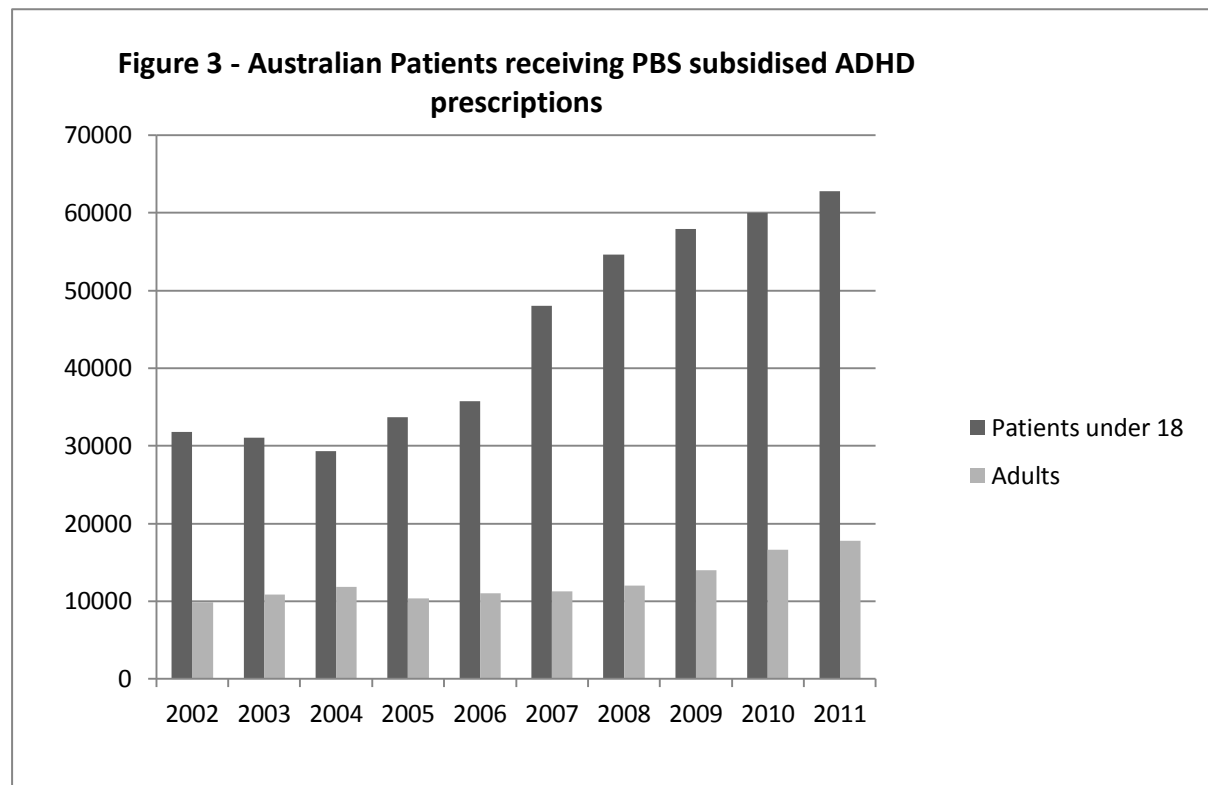


Source: Department of Health and Ageing *Australian Statistics on Medicines* Available at <http://www.pbs.gov.au/info/browse/statistics#ASM> (accessed 31 August 2013)

Figure 2 is far more comprehensive than Figure 1 although it covers a shorter timeframe (1995 to 2010). It incorporates both PBS-subsidised and unsubsidised prescriptions, and presents the information as the Australian defined daily dose (DDD) per 1000 days between 1995 (1.031 per 1000) and 2010 (3.888 per 1000 days). The World Health Organisation definition of DDD is the 'assumed average maintenance dose per day for a drug used for its

<sup>228</sup> ChartsBin statistics collector team (2010), *Historical Population of Australia, 1788 to Future*, ChartsBin.com. Available at <http://chartsbin.com/view/eoo> (accessed 30 August 2013).

main indication in adults.<sup>229</sup> The most significant limitation for the purpose of this thesis is that it does not identify patient numbers or differentiate between prescriptions to adults or children. In addition as the DDD refers to ‘assumed average dose used for adults’ and children on typically lower doses are the majority of ADHD medication users, it is likely that the measure underestimates the actual Australian average daily dose per 1000 days.



Source: Department of Health and Ageing (2012), *Letter to Martin Whitely dated 21 April 2012*.

Figure 3 covers the period 2002 to 2012 and provides an accurate breakdown of the age demographic of patients receiving PBS subsidised ADHD drugs. This information was not collected by DoHA before 2002. As in Figure 1 the most significant limitation is that it does not include non-PBS prescriptions. The first ADHD drug subsidised via the PBS was dexamphetamine in 1992. Ritalin, although commonly prescribed, was not subsidised until 1 August 2005. Ritalin LA, Concerta and Strattera were added in 2007.<sup>230</sup> As these medications became subsidised the Commonwealth Government data source became more comprehensive and useful for this analysis. For instance in the 1999/2000 financial year

<sup>229</sup> ‘Definition and general considerations’, *World Health Organisation Collaborating Centre for Drug Statistics Methodology*. Available at [http://www.whocc.no/ddd/definition\\_and\\_general\\_considera/](http://www.whocc.no/ddd/definition_and_general_considera/) (accessed 31 August 2013).

<sup>230</sup> Whitely, *Speed Up & Sit Still*, p.123.

‘around 96 000 prescriptions for Ritalin were dispensed in Australia’. This was roughly 30 percent of the total prescribed in 2000.<sup>231</sup> Another limitation of Figure 3 is that like Figure 1 it does not take account of population change. Between 2002 and 2011 the Australian population increased 13.5 percent.<sup>232</sup>

Regardless of the distorting factors identified above, the trend in the three figures above is so strong that they provide compelling evidence of an explosion in ADHD prescribing for the period 1992 to 2011. Figure 2 provides the most compelling evidence of rapid pharmaceuticalization for ADHD during the study period. Accounting both for population changes and unsubsidised prescription it indicates a 277 percent growth in per capita prescribing rates between 1995 and 2010.

Figure 1 shows an even more dramatic increase however this is in part due to the substitution of subsidised prescriptions for unsubsidised prescriptions as more medications were added to the PBS. As demonstrated in Figure 2 the proportion of subsidised scripts of total prescriptions rose from 49.5 to 74.2 percent between 2005 and 2010. Nonetheless Figure 1 provides evidence that the process of pharmaceuticalization occurred in the periods not covered in the data presented in Figure 2. Specifically between 1993 (the first full year of PBS subsidisation) and 1995 and between 2010 and 2011 the numbers of ADHD PBS subsidised prescriptions increased 220 percent and 3 percent respectively.

Despite the limitations identified above and the shorter timeframe (2002-2010) Figure 2 is very significant. It demonstrates the rapid pharmaceuticalization of the treatment of ADHD in Australia, particularly for children over this period with the total number of children receiving PBS subsidised prescriptions growing 98 percent between 2002 and 2010.

It is notable that there was a small fall in the number of scripts between 2004 and 2005 (see Figure 1 and Figure 2), and a small fall in the number of child patients between 2002 and 2004 (see Figure 3). The reasons for the small timing discrepancy are unclear. However, these small downturns are inconsistent with the long-term trend of rapidly increasing

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<sup>231</sup> Australian Parliament, *Medication for Attention Deficit/Hyperactivity Disorder (ADHD): an analysis by Federal Electorate (200103)*, Research Brief No. 2. 200405, 16 November 2004. Available <http://www.aph.gov.au/library/pubs/RB/2004-05/05rb02.htm#Exec>

<sup>232</sup> ChartistBin, *Historical Population of Australia*.



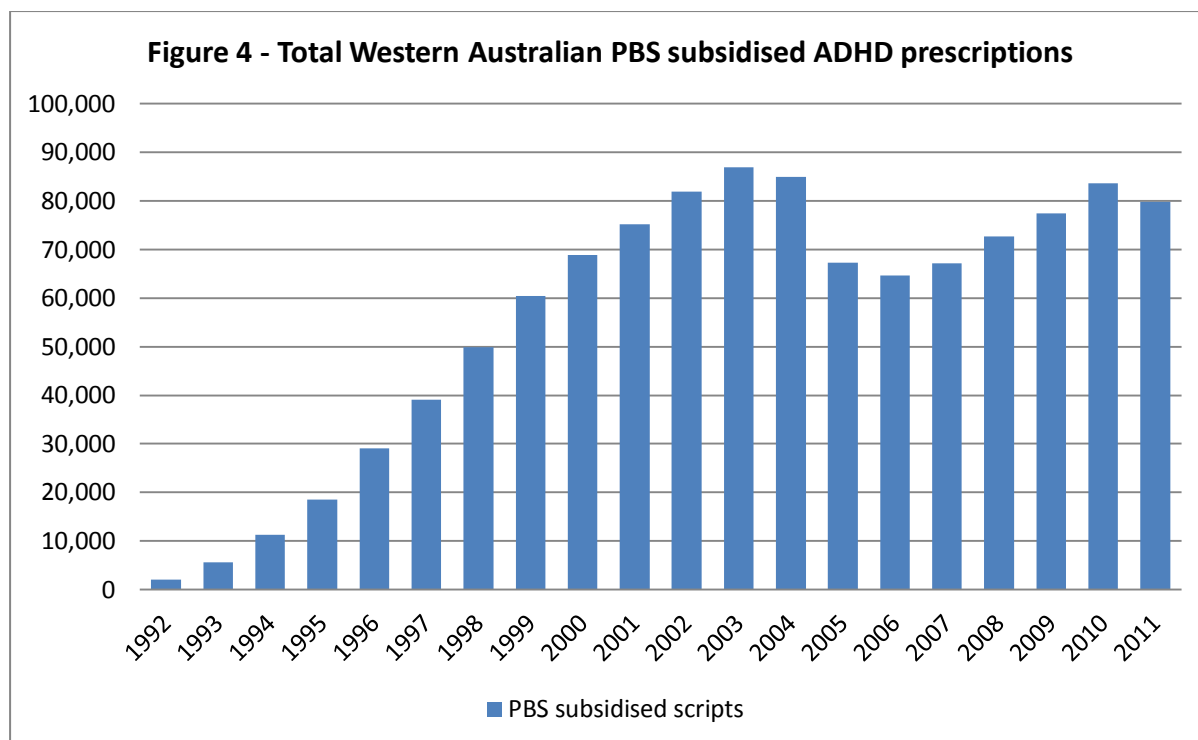
pharmaceuticalization. It is likely that a significant part of the explanation of these small falls is the fall in WA prescribing rates since 2003 that is demonstrated in Figure 4.

#### **4.3 Western Australian inter-temporal statistics on ADHD child prescribing**

The WA Government collects data about the rates of prescribing of ADHD medications. Neither WA data nor Australian Commonwealth data are individually sufficient to properly evaluate inter-temporal trends in WA prescribing between 1992 and 2011. In combination, however, they do provide sufficient information to identify significant trends in prescribing patterns.

*Commonwealth Government data sources on WA prescribing numbers:* Commonwealth Government data on state-specific prescribing are limited to those collected or derived from the PBS. The most significant limitation is that data regarding prescriptions that are privately funded or funded via state public health systems (primarily WA Government hospitals, child development clinics and child and adolescent mental health services) are not captured by this system. This limitation was particularly significant before all ADHD medications were subsidised via the PBS.

In addition, as previously identified it was not until 2002 that age-specific patient numbers were collected for each state. Furthermore, these data were not reported until, upon my request, DoHA provided me with age-specific, drug-specific, state-based data in April 2012. Therefore from 1992 to 2002 Commonwealth Government prescribing data for WA are limited to total prescription numbers and there are no reliable estimates of patient numbers. Prior to 1992 there is no Commonwealth data and only very limited state-based data.



Source: Department of Health and Ageing, *Medicare Australia*. Self-generated report available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-stats.htm-copy3> (accessed 5 August 2012)

*WA Government data sources:* In August 2003 the WA Health Department began collecting detailed data identifying the number of patients by age, gender, health district, prescriber and dosage for all ADHD stimulants via the WA Stimulants Regulatory Scheme. This has provided detailed calendar-year data for analysis. However, for the purposes of this thesis, it has three significant limitations:

1. Most significantly, it does not provide detailed demographic data (patient age, diagnosis, dose etc.) about the period prior to the introduction of this system which occurred simultaneously to the abolition of 'block authorisation' (see 6.4.1). Hence it is insufficient, in isolation, to determine the statistical results of the abolition of Block Authorisation and tighter prescribing accountability procedures. In other words, it enables the analysis of the 'after' period of prescribing accountability changes but does not alone provide an accurate 'before' baseline estimate of child prescribing numbers.
2. The Stimulants Regulatory Scheme does not provide data about prescriptions of atomoxetine hydrochloride (brand name Strattera) which was approved as a second line treatment for ADHD (when stimulants failed or had unacceptable side effects) in

2004, and was subsidised via the PBS from 1 July 2007. However, Commonwealth PBS data on an aged, per state-basis are available for Strattera, which indicates that it constitutes a relatively small proportion of the total number of patients who receive subsidised ADHD medications.<sup>233</sup> Nonetheless, as for all ADHD medications, it cannot be assumed that all Strattera prescriptions are subsidised via the PBS as individuals may obtain them free via state health services or pay for scripts without subsidisation.

3. Teething issues with the introduction of the Stimulants Regulatory Scheme, including ensuring all prescribers completed all notifications, limits the reliability of prescribing numbers reported, particularly for the early years (2003-2006) after the system's introduction in August 2003. This is likely to result in an underestimation of the number of patients prescribed psychostimulants in the WA Department of Health estimates in the early years of the introduction of the system.

Prior to the introduction of the WA Stimulants Regulatory Scheme the WA Health Department published estimates of the numbers, including age breakdowns, of Western Australian patients using ADHD medications for 2000 and 1994. There are significant limitations as to the accuracy and reliability of these estimates which will be identified when they are quoted.

In order to provide more reliable information, in October 2012 the WA Department of Health produced a retrospective analysis of the number of patients dispensed ADHD psychostimulants from 1998 to 2011. However, the analysis states 'the pre-2003 data should be viewed as a crude measure of stimulant use and only data from 2003 onwards should be relied upon to give an accurate picture of stimulant prescribing in Western Australia'.<sup>234</sup>

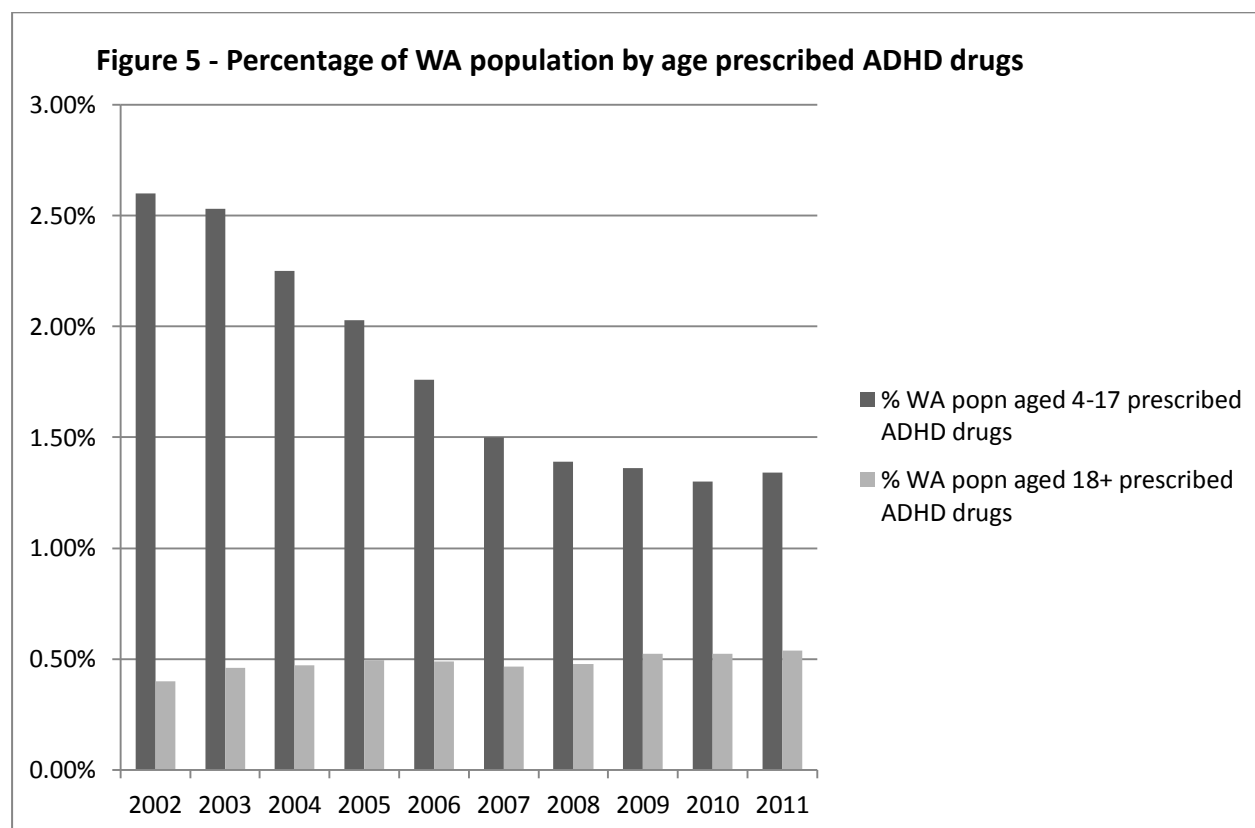
Nonetheless, when used in combination with Commonwealth Government data, the WA data enables the estimation of child and adult ADHD prescribing rates for the 2002 and 2003

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<sup>233</sup> Less than 7% of Western Australian child patients in 2011 took Strattera. As Strattera is a second line treatment to be trialled if psycho-stimulants are ineffective or cause unacceptable side effects it is likely that a significant proportion of children who took Strattera had also taken a psychostimulant in the same calendar year. Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.

<sup>234</sup> Department of Health, *Western Australia Stimulant Regulatory Scheme 2011 Annual Report*, p.15.

calendar years, covering the period just prior to the abolition of the block authorisation and the introduction of Stimulants Regulatory Scheme in August 2003.



Sources: Department of Health (2012), *Western Australia Stimulant Regulatory Scheme 2011 Annual Report*. And, Department of Health and Ageing (2012), *Letter to Martin Whitely dated 21 April 2012*.

Most of the data in Figure 5 are sourced from the WA Health Department *Stimulant Regulatory Scheme 2011 Annual Report*. The exceptions are the estimate of the population for each year which were sourced from the Australian Bureau of Statistics and the breakdown between child (4-17) and adult figures for the 2002 and 2003 years. For these years the WA Health Department provided an estimate of the total ADHD cohort number but not the breakdown between children and adults. However DoHA data provides detailed information about the numbers of adult and child PBS patient numbers for 2002, 2003 and 2004.

Unlike WA Health Department figures these Commonwealth PBS figures for 2002 to 2004 do not include non-PBS funded scripts, for Ritalin sold at full price or Ritalin and dexamphetamine dispensed for free in state government clinics. However, they cover the majority of patients and indicate a significant shift in the age composition of the WA ADHD

PBS cohort between 2002 (63.3 percent children) and 2004 (54.9 percent).<sup>235</sup> The 2004 WA Health Department proportion (58.4 percent)<sup>236</sup> was used as the starting point and the 2002 and 2003 child and adults figures were estimated by interpolating the same pattern of relative movement as demonstrated in the commonwealth figures. As a result it was estimated that 66.1 percent were aged 0-17 in 2002, and 62.1 percent were aged 0-17 in 2003.

There are many possible reasons for the small (3.5 percent) difference in the proportion of children in the Commonwealth and State data for 2004 including:

- Different age classifications for the state and commonwealth systems.
- Differences in the date of prescribing (the time of age information capture for the state based system) and dispensing of the drugs (the time of age information capture for the commonwealth based system).
- The dispensing of free sample packs as the first dose for newly diagnosed patients.
- The tendency for a higher proportion of adults to use dexamphetamine, with relatively more children using Ritalin. As only dexamphetamine was PBS subsidised from 1992 until 2005, this would lead to the proportion of children in the Commonwealth PBS data source being lower than the state based WA figure.

Irrespective of the reason the difference is modest. The more complete state based data are the data used in Figure 6 for 2004-11 and the basis of the estimate for 2002 and 2003 years.

#### **4.3.1 Patient numbers growth from 1992 to 2002**

Because of the absence of reliable data on the relative child to adult patient breakdown from either Commonwealth or state data sources it is impossible to reliably estimate the number of child and adult ADHD patients for the years prior to 2002. However, WA Health Department estimates of the total number of Western Australians prescribed psycho-stimulants for all purposes grew by over twenty-one-fold (from 880 to 18,715) from 1989<sup>237</sup>

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<sup>235</sup> Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.

<sup>236</sup> Department of Health, *Western Australia Stimulant Regulatory Scheme 2011 Annual Report*, p15.

<sup>237</sup> 'In 1989 in WA, 880 people were prescribed stimulant medication.' Government of Western Australia (2002), Department of Health, *Attentional Problems in Children: Diagnosis and Management of Attention*

to 2002. Of the 18,715 estimated to be on stimulants in 2002 an estimated 17,237 (92.1 percent) were diagnosed with ADHD.<sup>238</sup> Commonwealth Government figures reveal a similar trend. In 2002 WA's child per capita PBS prescribing rate of dexamphetamine (at the time the only PBS-subsidised ADHD drug) was approximately 2.8 times the national average (excluding WA). 7,500 of the 31,738 (24 percent) Australian children who received a PBS dexamphetamine prescription lived in WA despite WA having about 10 percent of the total population.

Despite the lack of detailed data, there was clearly a massive increase in patient numbers, consistent with the increase in PBS prescription numbers between 1993 and 2002 displayed in Figure 4. Between 1993 (the first full year of PBS subsidisation) and 2002 the number of PBS subsidised prescriptions of dexamphetamine (the only PBS subsidised psycho-stimulant sponsored in this period) grew over fourteen-fold (from 5623 to 81892).<sup>239</sup>

#### **4.3.2 Analysis of inter-temporal trends in WA prescribing**

Figure 4 shows that the number of PBS subsidised scripts peaked in 2003 and then declined, with the largest fall in 2005. This significant fall occurred even though Ritalin was added to the PBS in 2005 and, all other things being equal, it would be expected that PBS prescribing rates would increase as a result. Although Figure 4 shows that the number of prescriptions peaked in 2003, Figure 5 shows the per capita prescribing rate for children peaked in 2002 (although 2003 numbers are similar). The small difference in the timing of the peaks may be a consequence of the rapid shift in the age profile of the WA ADHD cohort. In 2002 Commonwealth PBS data revealed that the proportion of children of the total number of patients receiving PBS subsidised dexamphetamine fell from 63.3 percent in 2002 to 54.9 percent in 2004.<sup>240</sup>

Collectively Figure 4 and Figure 5 show there was a massive and consistent increase in ADHD child prescribing between 1992 and 2002, and a large (50 percent) decrease in the proportion of 4 to 17 year olds prescribed between 2002 and 2010, with the major decline

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*Deficit Hyperactivity Disorder (ADHD) and Associated Disorders*, Office of Mental Health, Department of Health, Perth, p.21.

<sup>238</sup> Department of Health, *Western Australia Stimulant Regulatory Scheme 2011 Annual Report*, p.15.

<sup>239</sup> Australian Government, *Medicare Australia*.

<sup>240</sup> Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.

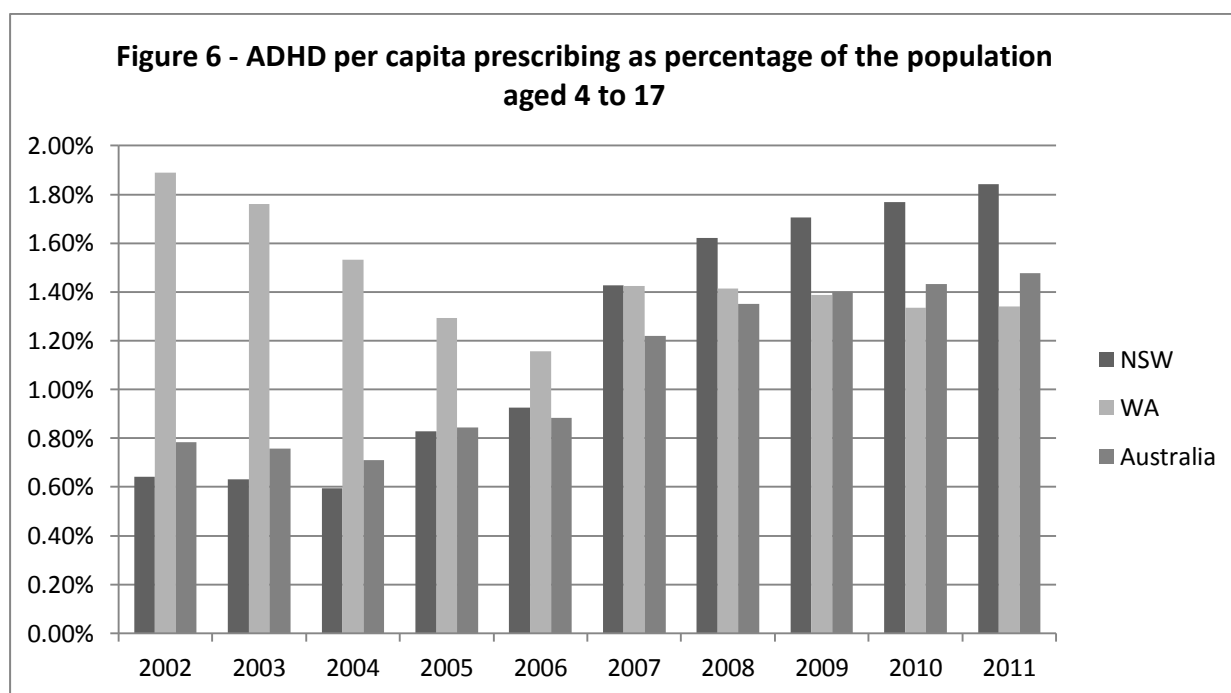
occurring between 2003 and 2007. WA adult patient per capita numbers increased 35 percent (from 0.4 to 0.54 percent) between 2002 and 2011. Clearly the factors influencing WA child and adult prescribing rates are significantly different.

#### 4.4 A comparison of NSW and WA inter-temporal statistics on ADHD prescribing

Commonwealth PBS prescribing data allows a comparison of both child and adult prescribing rates between 2002 and 2011.

##### 4.4.1 WA versus NSW Child Prescribing Rates

Figure 6 below compares NSW, WA and National, ADHD child prescribing per capita rates from 2002 to 2011. The primary source of the data below is statistics provided to me by DoHA. At my request DoHA collated the number of patients by age-group receiving PBS subsidised ADHD medication between 2002 and 2011.



Source: Department of Health and Ageing (2012), *Letter to Martin Whitely dated 21 April 2012*.

Figure 6 significantly under-estimates prescribing rates until 2007 – particularly before 2005 when dexamphetamine was the only ADHD drug subsidised via the PBS. The spike in NSW PBS prescribing rates in 2005 and 2007 in Figure 6 was most likely to have been caused by the addition of Ritalin (2005) and Concerta and Strattera (2007) to the PBS. WA experienced

a similar spike in 2007 however in 2005 WA rates fell significantly despite Ritalin being added.

The difference in the statistics and pattern of WA prescribing in Figure 6 (showing a spike in 2007) and Figure 5 (showing a decline) is also likely to be a result of the addition of Concerta and Strattera to the PBS in 2007. Figure 5 is likely a more accurate representation of total WA child ADHD per capita prescribing rates as it is based on WA Health Department data that includes all prescriptions not just PBS scripts.

Nonetheless Figure 6 allows a comparison of NSW, WA and National rates as all information is collected on the same basis, that is, prescriptions of PBS ADHD drugs by jurisdiction. However, NSW has consistently had a higher proportion of its ADHD cohort prescribed Ritalin than WA. Therefore caution needs to be exercised in comparisons of the above data, particularly prior to 2005. However, other state based data sources (discussed below) confirm the trend of significantly rising NSW rates relative to WA rates over the period 2000 to 2011.

Although it does not produce annual figures the NSW Health Department estimated that on 1 December 2000, 15,927 NSW children were treated with stimulant medication.<sup>241</sup> In 2002 the number of WA children on stimulants is estimated at 11,399 (refer to Appendix 1) and between 2000 and 2002 the number of WA PBS subsidised prescriptions of stimulants grew 19 percent from 68,869 to 81,892 (see Figure 3). Ignoring the ageing trend of the WA ADHD cohort (and therefore probably underestimating) the number of WA children receiving stimulants in 2000 is estimated at 9,600.<sup>242</sup> Using the estimates of 15,927 for NSW and 9,600 for WA and the relative populations in 2000 a WA child was approximately twice as likely as a NSW child to be treated with stimulants.

In 2007 NSW and WA per capita child prescribing rates were almost identical (refer to Figure 6). Subsequently NSW rates grew substantially (13.5 percent from 2008 the first full year of total PBS coverage to 2011) while WA's fell slightly (5.5 percent). By 2011 NSW per capita

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<sup>241</sup> P. Salmelainen (2002), *Trends in the prescribing of stimulant medication for the treatment of attention deficit hyperactivity disorder in children and adolescents in New South Wales*, Sydney, NSW Department of Health. Available at <http://www0.health.nsw.gov.au/pubs/2002/adhd2002sup.html> (accessed 2 May 2013).

<sup>242</sup> Year 2000 estimate was calculated by applying a discount of 19% on the 2002 estimate.



PBS child prescribing rates were 25 percent above the national rate, while WA rates were 11 percent below.

The figures for the period 2007 to 2011 in Figure 6 are relatively reliable as they are collected for all states on the same basis and since 2007 all ADHD drugs have been subsidised via the PBS. However, the raw PBS data does not include non-PBS prescriptions and there may be some variability in the use of non-PBS stimulants between states.

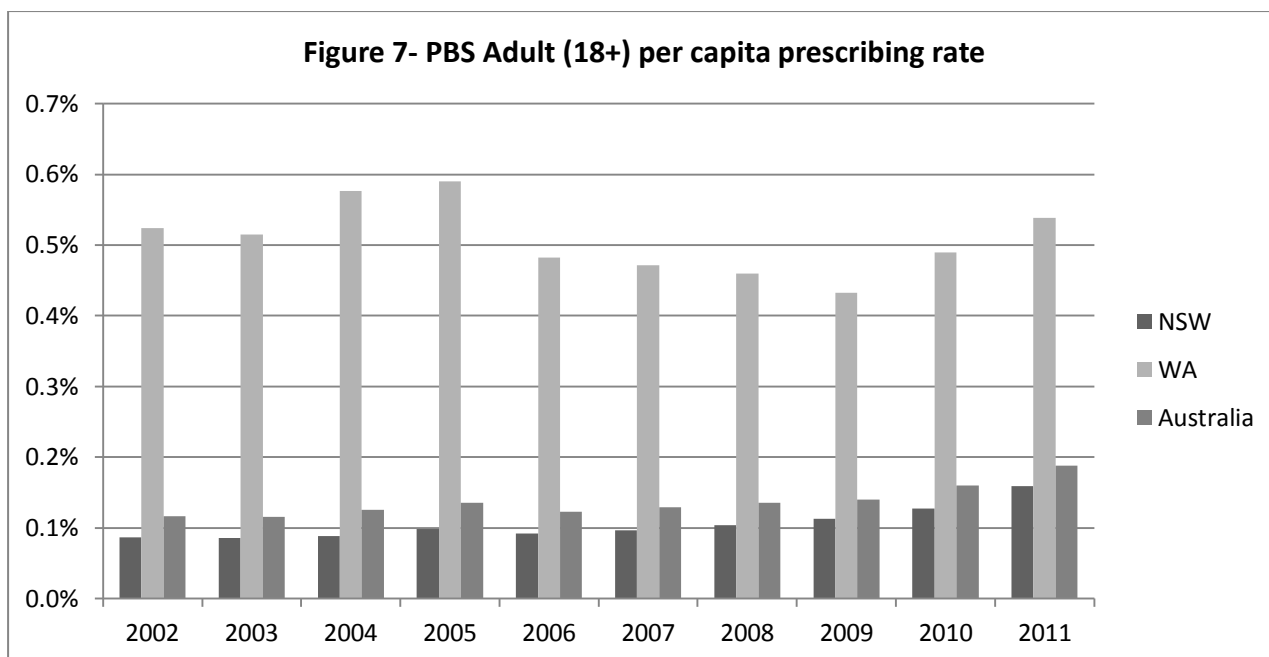
#### **4.4.2 WA versus NSW Adult Prescribing Rates**

Figure 7 below compares NSW, WA and National, ADHD adult prescribing per capita rates from 2002 to 2011. The source of the data is the same as that for children in Figure 6. Therefore the same limitations and concerns about distortion and comparison with Figure 5 apply.

Although Figure 7 indicates NSW adult rates are below the Australian average, NSW has had the highest per capita rate in 2010 and 2011 of all Australian States excluding WA. The extremely high rates in WA drag up the national average. The only Australian jurisdiction that at any time had during the review period in had adult prescribing rates similar to WA was the Australian Capital Territory. In 2011 they were 82 percent of WA per capita rate and were rising quickly.<sup>243</sup>

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<sup>243</sup> Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.



Source: Department of Health and Ageing (2012), *Letter to Martin Whitely dated 21 April 2012*.

The pattern of comparative prescribing rates for adults in NSW, WA and Australia is very different from that for children. As for children the WA per capita adult rate of prescribing in 2002 was much higher than the NSW or national rate. In 2002 Western Australian adults were prescribed PBS subsidised dexamphetamine at 7.1 times the national average (excluding WA) and 44 percent of Australian adults who received a PBS dexamphetamine prescription lived in WA.<sup>244</sup> It is likely the differential in all ADHD drugs prescribed to adults is somewhat less dramatic as other states appear likely to have used proportionately more methylphenidate.

Although there has been a modest closing of the gap WA rates were still a multiple of the national (3.3 times) and NSW rates in 2011. It is however worthy of note that despite the addition of Ritalin (2005) and Concerta and Strattera (2007) to the PBS there was a sharp fall in WA adult prescribing rates between 2005 and 2009 with the major fall occurring in 2006. It is also noteworthy that rates have risen in both WA and NSW in 2010 and 2011.

#### 4.5 Summary of ADHD prescribing statistics 1992-2011

Australian ADHD prescribing rates grew very rapidly between 1992 and 2011, with WA per capita rates growing much faster than the other states. By 2000, WA child prescribing rates

<sup>244</sup> Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.

were at least double the national average and adult prescribing rates were over four times the national rate. However, beginning in 2003, WA prescribing rates for children began to fall and by 2010 were approximately half of what they were in 2002.

Child prescribing rates, however, rose in all other states so that by 2011 WA rates were (approximately 11 percent) below the national average. In contrast NSW child prescribing rates, which were significantly below WA rates in 2000, have grown rapidly and are now significantly higher than WA rates. Other states have also demonstrated a pattern of increasing prescribing rates although South Australian and Victorian child prescribing rates both remain lower than WA rates.<sup>245</sup>

WA's adult ADHD prescribing experience has been significantly different from that for WA child prescribing. While there was a modest fall in the mid-2000s the rates have remained consistently much higher than all other Australian states.

This information is used in subsequent chapters to evaluate the impact of policy and regulatory processes both nationally (Chapter 5) and in WA and NSW (Chapter 6).

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<sup>245</sup> Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.

## Chapter 5. National ADHD Policy and Regulation

The previous chapter presented relevant statistical data about national ADHD child prescribing rates from 1992 to 2011. This chapter outlines the history of Australian national ADHD policy and regulation. It provides information for the analysis of the relationship between regulatory capture and pharmaceuticalization discussed in detail in Chapter 7.

### 5.1 Commonwealth Government Responsibilities in Regard to ADHD

In Australia public sector responsibility for ADHD is split between the Commonwealth and State governments. State governments provide public health services that diagnose and treat ADHD. They are also responsible for regulating the dispensing of prescription drugs, like dexamphetamine and methylphenidate, which are potentially divertible for illicit use. Chapter 6 discusses the regulation of ADHD by the West Australian and New South Wales Governments respectively.

The Australian Commonwealth Government has primary responsibility for the:

1. development of standard treatment guidelines through the National Health and Medical Research Council (NHMRC);
2. licencing of and approval for market, and the after-market monitoring of the safety of ADHD medications through the Therapeutic Goods Administration (TGA);
3. subsidisation of these medications through the Pharmaceutical Benefits Scheme (PBS); and
4. subsidising via Medicare of the diagnosis and ongoing treatment by private sector clinicians - primarily paediatricians, psychiatrists and less frequently general practitioners.<sup>246</sup>

Decisions by the Commonwealth Government therefore have a significant impact on ADHD diagnosis and prescribing rates. These decisions determine which medications are allowed to be marketed, give guidance as to the circumstances for their use, determine the price to patients, and pay the clinicians who diagnose ADHD.

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<sup>246</sup> In most Australian States only psychiatrists and paediatricians can initially prescribe psycho-stimulants. Although in a number of States general practitioners can be co-prescribers and be involved in the ongoing management of ADHD and issue repeat prescriptions. In Queensland general practitioners can initiate treatment with psychostimulants.

The remainder of this chapter identifies and analyses the involvement of the various Commonwealth Government agencies involved in the policy formulation and regulation of ADHD. Box 4 below is a timeline of significant events regarding the Commonwealth Government's response to ADHD across all Commonwealth Government agencies. Events that are described in detail in this chapter are *italicised* below in Box 4.

**Box 4 - Timeline of significant events regarding the Commonwealth Government's response to ADHD**

1992- Dexamphetamine was the first drug to be sponsored via the PBS for the treatment of ADHD.

*1993- Ritalin was licenced by the TGA for the treatment of ADHD.*

*1997- The first national guidelines for the treatment of ADHD were developed by a committee appointed by the NHMRC.*

*1998- The Commonwealth Department of Health and Family Services Health Special Programs Branch sponsored research on the prevalence of mental illness amongst young people in Australia which estimated 11.2% of Australian children had ADHD.*

*2002- Ritalin LA was licenced for use by the TGA.*

*2004- Strattera was licenced for the treatment of ADHD.*

2005- Ritalin was subsidised via the PBS.

*2006- The first national guidelines on ADHD were rescinded by the NHMRC and the Royal Australian College of Physicians (RACP) was commissioned to develop new national guidelines for the treatment of ADHD. This committee was chaired by Victorian paediatrician Doctor Daryl Efron.*

*2007- Concerta, Ritalin LA and Strattera were subsidised via the PBS.*

*2007- Doctor Daryl Efron stood down as chairperson of the National ADHD Guidelines Development Committee over conflict of interest concerns.*

*2009- The NHMRC announced that because of extensive undisclosed conflict of interest concerns with research relied upon to develop the draft national guidelines on ADHD the draft guidelines would not be adopted.*

*2011- A committee was appointed to develop Clinical Practice Points (CPP) to provide national guidance on the diagnosis and treatment of ADHD.*

*2012- The Clinical Practice Points were released and approved by the NHMRC and Australian Minister for Mental Health Mark Butler.*

## 5.2 Department of Health and Aged Care commissioned research into the prevalence of ADHD

In 1998 the Department of Health and Ageing, Mental Health and Special Programs Branch commissioned research into the prevalence of mental illness in Australian children as part of a broader National Survey of Mental Health and Wellbeing.<sup>247</sup> The results were published as, *The Mental Health of Young People in Australia*.<sup>248</sup>

Prevalence rates are estimates of the percentage of a population with a disease or disorder. A prevalence rate is different from a diagnosis rate, which is the percentage of the population diagnosed with a condition.<sup>249</sup> For diseases with definitive scientific diagnoses, if prevalence rates exceed diagnosis rates then real disease is going undiagnosed and therefore maybe untreated.

In spite of the contention of critics that it is impossible to objectively diagnose ADHD, estimates of prevalence rates are frequently quoted by proponents to defend against critics' allegations that it is over-diagnosed and over-medicated. A common claim of ADHD proponents is that prevalence rates exceed diagnosis and prescribing rates and that ADHD is in fact under-diagnosed and under-medicated. One example is the 1997 guidelines (see 5.3.1) which noted that ADHD prescribing rates were below prevalence rates and therefore ADHD is not over-diagnosed and over-medicated. The guidelines stated that 'Current overall prescribing rates are 0.7 percent for 0 to 19 year olds. Overall prescribing rates in Australia are less than 1 percent of school age children (lower than the 2 to 5 percent incidence of ADHD). The rhetoric of over prescribing is not supported.'<sup>250</sup>

There have been numerous studies to determine prevalence rates for ADHD. Estimates of ADHD prevalence vary widely. An American study conducted in 1998 found that prevalence

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<sup>247</sup> The Department of Health and Ageing was called the Department of Health and Community Services until October 1998. For the sake of simplicity it is referred to the Department of Health and Ageing (DoHA) throughout the thesis.  
<http://web.archive.org/web/20131109190520/http://www.health.gov.au/internet/main/publishing.nsf/Content/health-history.htm#summary>

<sup>248</sup> M. G. Sawyer, F. M. Arney et al (2000), *The Mental Health of Young People in Australia*, Mental Health and Special Programs Branch, Commonwealth Department of Health and Aged Care, Canberra.

<sup>249</sup> 'Prevalence rates do not equate to diagnostic rates, as they are drawn from surveys and questionnaires rather than actual clinical figures. In this respect, the Committee questions their accuracy.' Western Australia Legislative Assembly, *Attention Deficit Hyperactivity Disorder*, p.11.

<sup>250</sup> National Health and Medical Research Council (1997), *Attention Deficit Hyperactivity Disorder (ADHD)*, Canberra, Australia, p.38.

estimates vary between 1.7 per cent and 16 per cent.<sup>251</sup> Estimates of prevalence rates also vary across cultures, possibly influenced by cultural norms with the highest reported (29 per cent) being in India.<sup>252</sup>

Published in 2000 and based on data collected in 1998, the research commissioned by the Department of Health and Ageing estimated that 11.2 per cent of Australian children age 6 to 17 had ADHD.<sup>253</sup> The lead author of the study, Professor Michael Sawyer, was a member of an advisory board for Eli Lilly and received payments from Eli Lilly to attend an international conference (see appendix 3).<sup>254</sup>

The study involved the parents of 2737 children completing a checklist on the behaviour of their child.<sup>255</sup> Parents rated their child on each of eighteen ADHD behavioural symptoms as displaying the behaviours rarely, sometimes, often or very often. Children who recorded 6 of 9 often or very often in either the inattentive or hyperactive/impulsive behaviours were classified as having ADHD. The survey did not attempt to ensure the child met the full criteria for the diagnosis of ADHD. There was no measure for impairment or attempt to establish that the child displayed the behaviours in at least two settings as required by the DSM-IV (refer to box 1 at 2.1.1). Neither was the possibility of other explanations for the ADHD type behaviours explored.

The 11.2 percent estimate was therefore likely to be an overestimate of the percentage of Australian children who would qualify for a thorough application of the DSM-IV criteria. Nonetheless, this overestimate has been frequently used to support the argument that ADHD is under-diagnosed and under-medicated. A prevalence rate of 11.2 percent equates to more than one in nine Australian children having ADHD. It is widely accepted that ADHD

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<sup>251</sup> Goldman, et al, 'Diagnosis and treatment of attention-deficit/hyperactivity disorder'.

<sup>252</sup> Department of Health, Government of Western Australia, *Inquiry into Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder in Western Australia*, Legislative Assembly, Transcript of evidence taken on 26 November 2003 (Professor Stephen Houghton, Psychologist/University Professor, Graduate School of Education, University of Western Australia).

<sup>253</sup> Sawyer, et al, *The Mental Health of Young People in Australia*, p.809.

<sup>254</sup> Royal Australasian College of Physicians (RACP) (2009), *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder (ADHD)*, Melbourne. Available at [http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/adhd\\_draft\\_appendices.pdf](http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/adhd_draft_appendices.pdf) (accessed 2 December 2012).

<sup>255</sup> 'The mental disorders were assessed using the parent-version of the Diagnostic Interview Schedule for Children Version IV. Parents completed the Child Behaviour Checklist to identify mental health problems and standard questionnaires to assess health-related quality of life and service use. The Youth Risk Behaviour Questionnaire completed by adolescents was employed to identify health-risk behaviours.' M. G. Sawyer, R. J. Kosky et al (2000), 'The National Survey of Mental Health and Wellbeing: the child and adolescent component' in *Australian and New Zealand Journal of Psychiatry*, 34, p.215.

is far more prevalent in boys than in girls, at a ratio of approximately three to one.<sup>256</sup> Given that ratio, and assuming a prevalence rate of 11.2 percent, approximately one in six boys aged 6 to 17, and one in 18 girls aged 6 to 17 would have ADHD.

The study identified the following rates of prevalence for children for a number of psychiatric disorders.<sup>257</sup>

| Percentage of children and young people with specific disorders: data from the Child and Adolescent Component of the National Survey of Mental Health and Wellbeing |              |            |         |             |         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|---------|-------------|---------|
| Disorder                                                                                                                                                            | All Children | 6-12 years |         | 13-17 years |         |
|                                                                                                                                                                     |              | Males      | Females | Males       | Females |
| Depressive disorder                                                                                                                                                 | 3.7%         | 3.7%       | 2.1%    | 4.8%        | 4.9%    |
| Conduct disorder                                                                                                                                                    | 3.0%         | 4.8%       | 1.9%    | 3.8%        | 1.0%    |
| ADHD                                                                                                                                                                | 11.2%        | 19.3%      | 8.8%    | 10.0%       | 3.8%    |

The gender differential and the finding that nearly one in five boys aged 6 to 12 had ADHD, but that nearly half of them would 'recover' in their teenage years, supports the assertion by ADHD critics that ADHD type behaviours are both masculine and immature behaviours. Evidence of the importance of immaturity in the diagnosis of ADHD came from a 2012 review of the medical records of 937,943 Canadian children. The review showed that children born in December, the last month of their school year intake, were much more likely to be diagnosed and medicated (boys 41 percent and girls 77 percent) for ADHD than their classmates born in January.<sup>258</sup> This study confirmed the late birthday effect demonstrated in two earlier smaller US studies.<sup>259</sup>

<sup>256</sup> Salynn Boyles (2009), 'Study confirms ADHD is more common in boys', *WebMD Health News*, 15 September 2004. Available at <http://www.webmd.com/add-adhd/news/20040915/study-confirms-adhd-is-more-common-in-boys> (accessed 4 October 2009).

<sup>257</sup> Sawyer, et al, *The Mental Health of Young People in Australia*.

<sup>258</sup> The eleven year study of 937,943 children aged six to twelve in the Canadian province of British Columbia, titled *Influence of relative age on diagnosis and treatment of attention-deficit/hyperactivity disorder in children*, Richard L. Morrow MA. et al (2012), 'Influence of relative age on diagnosis and treatment of attention-deficit/hyperactivity disorder in children' *CMAJ*, March 5, 2012. Available at <http://www.cmaj.ca/content/early/2012/03/05/cmaj.111619.full.pdf+html> (accessed 10 March 2011).

<sup>259</sup> The Canadian study confirms the ADHD late birthdate effect found in two recent smaller US studies. Elder, T.E (2010), 'The importance of relative standards in ADHD diagnoses: Evidence based on exact birth dates', *Michigan State University*, June 2010; WN Evans, MS Morrill, & ST Parente (2010), 'Measuring Inappropriate Medical Diagnosis and Treatment in Survey Data: The Case of ADHD among



Putting aside these and other concerns about the inadequacies of the DSM-IV diagnostic criteria, accurately estimating the prevalence rate of ADHD as defined in DSM-IV requires a far more thorough process. It would involve sampling a significant number of the target population (4-17 year olds) and identifying which of those 'often' exhibit ADHD behaviours (avoiding homework, fidgeting, interrupting, squirming etc.) in the required combinations (all subtypes)

1. in two or more settings,
2. to the level of significant impairment.
3. and do not have other conditions that could better explain their behaviour.

Therefore to accurately determine ADHD prevalence rates the following three steps would be required:

Step 1- Every sample's (child's) parents in the study would need a complete a checklist of the child's behaviour to identify if they exhibit sufficient behaviours at home "often" enough to meet the criteria for an ADHD subtype

Step 2- The teachers of those children who do exhibit sufficient behaviours at home should then complete a similar checklist to identify if they exhibit sufficient ADHD behaviours in a school (second) setting.

Step 3- Those children who exhibit sufficient behaviours at home and at school would then need an intensive audit of their behaviour and familial, social and environmental circumstances to determine if they are "significantly impaired" and if the behaviour was not caused by non-ADHD factors.

Following the above steps would not diminish ADHD critics' fundamental concern about the subjectivity of the individual behavioural criteria. Neither would it offer any evidence of prevalence of a biochemical brain imbalance, or of the likely effectiveness of psycho-stimulants. It would, however, give a more accurate estimate of the proportion of the

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School-Age Children', *J Health Econ.* 2010 Sep;29(5), pp.657-73. Epub 2010 August 4. Available at <<http://www.ncbi.nlm.nih.gov/pubmed/20739076>>(accessed 12 February 2013).

target population that exhibit behaviours consistent with a diagnosis of ADHD as defined in DSM-IV.

The Department of Health and Ageing's sponsored study was methodologically flawed in that it missed steps 2 and 3. That is the 11.2 percent estimate of prevalence ignored the requirements that the behaviours occur in at least two settings to a degree that impairs effective functioning, and are not due to other factors. Regardless of the questions on the accuracy of the prevalence rate, on numerous occasions commentators have ignored this fundamental flaw and used this 11.2 percent prevalence estimate to counter criticism of misdiagnosis/over-prescription and argue that, to the contrary, ADHD is under-diagnosed and under-medicated.

One of these claims was a statement in 2001 by Perth paediatrician Dr Ken Whiting who, in responding to concerns about Western Australia's high ADHD prescribing rates, claimed

'A recent Federal Government report had put the number of Australian children with ADHD at 11 per cent, but the more widely accepted estimate was 5 per cent to 7 per cent. Yet, only about 4 per cent of children were given drugs to treat the condition. Even that 4 per cent is a bit suspect and it may actually be less because that number would include children who only received one prescription but never continued with the medication.'<sup>260</sup>

On other occasions Whiting was less cautious. When interviewed for a television programme in 2002, Whiting said 'if you look at the Federal Government mental health study on youth mental health, which was completed in [19]99 under Michael Woolridge that showed that 11.2 per cent of children in Australia have ADHD.'<sup>261</sup>

Another example of the use of this misleading statistic was by the then State President of the Western Australian branch of the Australian Medical Association (AMA), Dr Bernard Pearn-Rowe. He was quoted in an article titled 'AMA backs drug complaints' in *The Australian* in 2002 as saying '(in Western Australia) local specialists were leading the way in diagnosing and treating the condition...a 1999 review by the National Health and Medical

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<sup>260</sup> Kristen Watts (2001), 'More ill than get treatment', *The West Australian*, 8 June 2001.

<sup>261</sup> Alison Wright (2002), 'The abuse of ADHD drugs in WA', *7.30 Report*, ABC Television, 1 October 2002.

Research Council found 11 per cent of the population aged 4 to 17 years had ADHD, but that less than 2 per cent of cases were treated.’<sup>262</sup>

Of greater significance is that in November 2009, nearly a decade after the flawed estimate was produced, the Federal Health Minister Roxon, the Royal Australian College of Psychiatry (RACP) and the National Health and Medical Research Council (NHMRC) used the 11.2 percent estimate, in a joint press release promoting the 2009 Draft ADHD Guidelines, to claim there were 350,000+ Australian children and adolescents with ADHD.<sup>263</sup> This was over seven times the number (47,127) of children on Pharmaceutical Benefits Scheme sponsored ADHD medications in 2007.<sup>264</sup> Yet the NHMRC 2009 guidelines chairperson Dr Forbes, in the same statement, is quoted as saying, ‘what’s important is that it is likely fewer children will be prescribed medication.’<sup>265</sup>

In summary the Commonwealth Government relied on and financially supported methodologically flawed research that erroneously supported the contention that ADHD was massively under-treated.

### 5.3 The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is an independent statutory agency funded by the Commonwealth government to develop recommendations for best health policy and practice. It ‘brings together within a single national organisation the functions of research funding and development of advice.’ Its objectives include fostering ‘the development of consistent health standards between the various States and Territories’ and ‘medical research and training and public health research and training throughout Australia.’<sup>266</sup>

The NHMRC either produces the guidelines internally or externally by outsourcing the development of treatment guidelines to individuals and organisations with the relevant

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<sup>262</sup> Belinda Hickman (2002), ‘AMA backs drug complaints’, *The Australian*, 20 December 2002, p.4.

<sup>263</sup> The Hon Nicola Roxon MP, Minister for Health and Ageing (2009), National Health and Medical Research Council, and Royal Australasian College of Physicians, ‘Draft ADHD Guidelines Released’, *Joint Media Release*, 30 November 2009.

<sup>264</sup> Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.

<sup>265</sup> The Hon Nicola Roxon MP, ‘Draft ADHD Guidelines Released’.

<sup>266</sup> National Health and Medical Research Council (NHMRC), ‘How NHMRC develops its guidelines’, Australian Government. Available at <http://www.nhmrc.gov.au/guidelines/how-nhmrc-develops-its-guidelines> (accessed 3 July 2013).

expertise. The NHMRC's practice of commissioning research and guidelines development means that its primary responsibility is to ensure the competence and independence of those they appoint to conduct this research. Box 5 below contains an excerpt from the NHMRC website that details how it develops guidelines.<sup>267</sup>

**Box 5- Excerpt from the NHMRC Website on Developing Treatment Guidelines**  
(available at <http://www.nhmrc.gov.au/guidelines/how-nhmrc-develops-its-guidelines> )

'[The] NHMRC may oversee the entire guideline development process itself (internal development). Alternatively, it may partner with another organisation such as a professional college, which then carries out much of the development up to and including step 5 below (external development). Either way, the process is substantially the same...Guidelines are developed by teams of specialists following a rigorous evidence-based approach. The specialists include:

- Members of working committees that are set up to develop guidelines. Members are high-level experts nominated by NHMRC's CEO and Council as well as relevant organisations such as government agencies, peak professional bodies, advocacy groups and educational institutions
- specialists in evaluating evidence
- professional technical and scientific writers.'

They are developed...using a 9-step process, parts of which are specified in the *NHMRC Act*

1. A working committee is established consistent with the *NHMRC Act*. The committee provides expert advice to NHMRC during the guideline development process.
2. Specialists in evaluating medical evidence carry out a systematic literature review. This is arguably the most important step in the process because one of the main principles of guideline development is that they should be based on the best available evidence.
3. Professional technical and scientific writers turn the literature review into a set of draft guidelines.
4. The draft guidelines are put out for public consultation, as required by the *NHMRC Act*.
5. NHMRC considers all submissions arising from the public consultations and advises if the guidelines need to be redrafted due to new evidence or concerns raised by stakeholders. If so, the working committee advises the technical and scientific writers about the best way to do this.
6. NHMRC subjects the draft (or redrafted) guidelines to review by an independent reviewer who ensures that all the necessary processes have been followed during the guidelines' development.
7. NHMRC may choose to have a peer review of the guidelines. If so, they are sent to a number of experts in the subject area for their opinion, primarily on the evidence base used for the guidelines.
8. The guidelines go to NHMRC's Council for its consideration. Council can send the guidelines back for further work if, for example, it feels more evidence is required in a particular area. When it is satisfied with the final draft, Council makes a recommendation to NHMRC's CEO, who makes the decision to issue internally-developed guidelines or approve externally-developed ones.

<sup>267</sup> NHMRC, 'How NHMRC develops its guidelines'.

9. The guidelines are published and disseminated.

The entire process typically takes around 18 months to two years, although it can take less or more time depending on the complexity of the issues being addressed and the number of submissions received during consultation.

Since 1997 the NHMRC has commissioned the development of three separate processes to provide guidance to clinicians and others on the diagnosis and treatment of ADHD. Each of these processes is described below in order to identify the outcome and degree of regulatory capture.

### **5.3.1 - The 1997 National Health and Medical Research Council (NHMRC) National ADHD Treatment Guidelines**

In 1997 the NHMRC produced guidelines designed to advise clinicians on the diagnosis and treatment of ADHD. These 1997 guidelines were rescinded on the 31<sup>st</sup> of December 2005 (for details of why they were rescinded refer to 5.3.2).

Although the names of the members of the guidelines development panel were disclosed there was no information about potential conflicts of interest. The panel that developed the guidelines consisted of three paediatricians, one child psychiatrist, a general practitioner, a psychologist and a consumer representative.<sup>268</sup> The child psychiatrist on the NHMRC panel was Dr Florence Levy from New South Wales.<sup>269</sup> Later, Dr Levy (in 2002) was one of the signatories of the ADHD International Consensus Statement (see 2.2.1.1) and remains a prominent ADHD proponent. One of the three paediatricians was prominent ADHD proponent Dr Paul Hutchins (see 6.10.1). It was later disclosed that Dr Hutchins has served as adviser to manufacturers of ADHD drugs although it is not known if this predated 1997.<sup>270</sup> There is insufficient information on the ADHD related views and associations of the other guidelines panel members.

<sup>268</sup> The Membership of the NHMRC ADHD study Working Party was: Professor Allan Carmichael (Prof of Paediatrics), Dr Paul Hutchins (paediatrician), Professor Frank Oberklaid (paediatrician) and Dr Florence Levy (Child Psychiatrist). Also included were Dr Peter Adkins (General Practitioner), Mr Ivan Gall (consumer representative) and Mr John McCormack (Educational Psychologist).

<sup>269</sup> Dr Florence Levy was described as Child Psychiatrist, Head, Avoca Clinic, Royal South Sydney Hospital, New South Wales.

<sup>270</sup> Clinical Excellence Commission (CEC) (2007), *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales – 2007: Final Report of the Special Review*, Sydney, p.64.

The process invited public input in two stages. The first stage invited input on six broad terms of reference and received 54 submissions. The second stage invited comments on the draft guidelines and received 90 submissions that were described as ‘overall supportive of the draft guidelines’.<sup>271</sup> The submissions were not made public so it is impossible to determine how much influence they had on the final guidelines.

A key finding of the 1997 guidelines report was that ‘stimulant medication has been shown to be effective in the short term in modifying disruptive behaviour and improving performance in both children and adolescents with ADHD.’<sup>272</sup> The guidelines therefore recommended that ‘the use of stimulant medication should be considered for treatment of most children with ADHD.’<sup>273</sup> The guidelines committee claimed generalised benefits for the ‘ADHD population’, regardless of age, stating that ‘stimulants, dexamphetamine or methylphenidate, have the same proven benefits for adolescents as for younger children’ and ‘stimulant response of adults with childhood ADHD resembles that of children.’<sup>274</sup> The fact that low dose orally administered stimulants modify behaviour and enhance focus in the majority of people, regardless of their ADHD status, was not mentioned.<sup>275</sup>

The 1997 guidelines report emphasised that medicating with ADHD drugs has benefits for other family members. ‘Family functioning improves on stimulants with enhanced parental warmth and approval, less criticism, less sibling conflict.’<sup>276</sup> ADHD type behaviours as defined in the DSM diagnostic criteria - fidgeting, interrupting, playing loudly, avoiding chores and being disorganised - can all be frustrating and annoying for parents and siblings and lead to family disharmony. However, ethical issues arise from the use of ‘psychotropic drugs’ in part at least to enhance family harmony.

The 1997 guidelines discussed the differences between the American Psychiatric Association’s DSM-IV and the World Health Organisation’s ICD-10 diagnostic criteria. The guidelines acknowledged that DSM-IV outlines a broader definition of ADHD and that a child

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<sup>271</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, pp.99-100.

<sup>272</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.v.

<sup>273</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.vii.

<sup>274</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, pp.57-59.

<sup>275</sup> Lori Jeanne Peloquin and Rafael Klorman (1986), ‘Effects of Methylphenidate on Normal Children’s Mood, Event-Related Potentials, and Performance in Memory, Scanning and Vigilance,’ *Journal of Abnormal Psychology*, Vol. 95, No. 1, pp.88-98.

<sup>276</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.26.

is more likely to be diagnosed using DSM-IV. Without directly providing a rationale, the guidelines recommended DSM-IV as the 'minimum criteria necessary for a diagnosis'.<sup>277</sup> In choosing, without explanation, DSM-IV in preference to ICD-10, the committee opted for the criteria associated with higher prescribing rates (see 3.1). The closest the 1997 guidelines came to addressing the reasons for its choice was the implied criticism of ICD-10 in the statement: 'Insistence on a single diagnosis, simplistic management or on whether the problem is primary or secondary can bedevil understanding, compliance and professional collaboration.'<sup>278</sup> The more rigorous ICD-10 precludes co-morbidity, and insists on a single primary diagnosis, that must be treated before the secondary ADHD condition (i.e.: symptom) is specifically treated.

The committee not only opted for the already loose ADHD criteria by choosing DSM-IV, it further loosened the requirements by inviting practitioners to diagnose and prescribe stimulants when the full criteria of DSM-IV were not met. A specific example is the statement: 'It is essential that the assessment utilize multiple sources of information, preferably from multiple settings.'<sup>279</sup> The statement on casual reading sounds thorough. However, multiple sources could be as narrow as a teacher's behavioural checklist along with a school report. The failure to insist on multiple settings violates one of the criteria of DSM-IV that the behaviours must be displayed in at least two settings.<sup>280</sup>

The 1997 guidelines panel made comprehensive and emphatic pro-medication recommendations despite acknowledging the cause/s of ADHD are unknown:

The aetiology of ADHD is essentially unknown..... It is likely that a variety of contributing factors may operate in a vulnerable child to result in the behaviours of ADHD.<sup>281</sup> ...Genetic traits, parents' responses and the behaviour models observed by the child contribute to uninhibited aggressive and anti-social behaviour, causing and compounding economic, social and health disadvantage. These strong adverse intrinsic and environmental influences may all contribute to ADHD, as well as compromise its

<sup>277</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.xi.

<sup>278</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.v.

<sup>279</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.v.

<sup>280</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, p.92.

<sup>281</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.9.

management, but medication still may have powerful benefits.<sup>282</sup>

So despite a lack of understanding of what was causing a child to be inattentive and/or impulsive, the authors recommended medication. Even if poor parenting and inappropriate role models, or even poverty, were significantly contributing to problematic ADHD type behaviours, pharmaceutical interventions were still recommended.

The 1997 guidelines encouraged clinicians to diagnose and medicate very capable children even if they did not exhibit the symptoms of ADHD before the age of 7 as required by DSM-IV:

Attention deficits and language learning difficulties are often more subtle in individuals of high ability whose other strengths may allow them to compensate and escape detection by functioning appropriately for their age but not their ability. Able individuals more often exhibit the inattentive ADHD type, presenting later in high school or even in adulthood, as their abilities and compensatory strategies are overwhelmed by the complexity and extent of cognitive and performance demands, and the added anxiety of formal examinations, life planning and employment.<sup>283</sup>

Problems caused 'by the complexity and extent of cognitive and performance demands, and the added anxiety of formal examinations, life planning and employment' are related to the individual's environment and the stresses of modern life. Just as not all individuals are gifted with extraordinary intellect, not everybody, even the very bright, are suited to coping with high stress situations like examinations. Nonetheless the guidelines recommended medicating an individual to suit their environment, rather than altering an environment to suit the individual (or removing them from the environment).

Another clear message to clinicians in the guidelines was that parents seeking non- drug alternatives are motivated by ignorance and irrational prejudices:

Many parents who seek alternate [non-drug] treatments for their child's problems are more ideologically attuned to a 'natural' solution, or are

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<sup>282</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.32.

<sup>283</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.31.



seduced by the promise of a rapid improvement. Others are attracted by a relatively simple and straightforward explanation for their child's problems, while others are uncomfortable about the use of medications in their child.<sup>284</sup>

In contrast, critics of ADHD prescribing contend the appeal of stimulants over drug free alternatives is that stimulants offer the 'simple and straightforward explanation', that they balance a biochemical imbalance, leading to a 'rapid improvement' in behavior.<sup>285</sup>

Whilst acknowledging that 'children with ADHD represent a complex set of problems for parents and professionals alike,' the 1997 guidelines simplified the options for clinicians, to 'interventions with demonstrated benefits', in other words, medication.<sup>286</sup> Non-drug interventions were not only represented as costly and time wasting, but also as a violation of the rights of the child:

Quite apart from the cost of these programs, which are often considerable, there are a number of ways in which they can have adverse effects on the child and family. First, such interventions may take up valuable time, both in postponing the introduction of an accepted intervention that has been shown to be of benefit in children with ADHD, as well as allowing the child less time for more fruitful and constructive pursuits. Second, the child with ADHD may be made to feel even worse by claims that his/her eyes are not working properly or there is something wrong with his/her brain, or in the way he/she handles food.<sup>287</sup>

The 1997 guidelines statement that pursuing non-drug treatments may make 'the child with ADHD...feel even worse by claims that...there is something wrong with his/her brain' appears contradictory given that the rationale for ADHD prescribing is that children have chemically imbalanced brains i.e. have something 'wrong' with their brains. In addition,

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<sup>284</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.47.

<sup>285</sup> Steve Edelman and John Breeding, 'A Few Simple Truths About ADHD and Stimulant Drugs: Responses to Common Professional Statements Made to Parents About Their Children', *The Wildest Colts Make The Best Horses*. Available at [http://www.wildestcolts.com/psych\\_opp/b-psychiatric\\_drugs/1-stimulants.html](http://www.wildestcolts.com/psych_opp/b-psychiatric_drugs/1-stimulants.html) (accessed 3 June 2013).

<sup>286</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, pp.51-52.

<sup>287</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, pp.51-52.

presenting non-drug treatments as unnecessarily postponing ‘accepted interventions’, (meaning stimulants), is further evidence of the pro-medication emphasis of the 1997 guidelines.

Additionally, the 1997 guidelines encouraged clinicians to diagnosis outside DSM-IV criteria and prescribe ‘off label’, that is, outside approved guidelines for the use of medications. They state: ‘Use of medication outside officially listed indications and drug evaluation mechanisms is proper if it complies with reasonable theory, expert practice and or controlled scientific studies.’<sup>288</sup> What constitutes ‘reasonable theory’ is not specified, it was left to the clinician to determine. Any behaviour that could be caused by a biochemical imbalance, or even just modified by ‘medication’, clearly in the mind of some clinicians constitutes reasonable theory. The statement, ‘Guidelines encourage caution and evidence based practice, though clinical experience may precede research’ further encourages clinicians to prescribe ahead of research.<sup>289</sup> ‘Off label’ prescribers are offered the justification that their clinical experience qualifies them to do so.

While the 1997 guidelines clearly identified stimulants as being the first-line drug for treatment of ADHD, they encouraged the use of other drugs either as complementary or second-line treatments. They even encouraged the use of drugs like Clonidine to manage the adverse upper effects of stimulants stating, ‘they may be useful, however, for children for whom stimulants are ineffective, have unacceptable side effects, or who have significant co-morbid anxiety, depression or tic disorder or may potentially abuse prescribed stimulants.’<sup>290</sup> There was no cautionary note to highlight the then current concerns with the combination of Clonidine with methylphenidate, following the report of three deaths in children whose treatment included this combination.<sup>291</sup>

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<sup>288</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.34.

<sup>289</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.38.

<sup>290</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.33.

<sup>291</sup> JM Swanson, et al (1995), ‘Clonidine in the Treatment of ADHD: Questions about Safety and Efficacy’, [letter to the editor], *Journal of Child and Adolescent Psychopharmacology* 5, p.301.

There were at least five references in the 1997 guidelines that were critical of controls by state government health authorities on prescribing stimulants including:

The monitoring process only has jurisdiction over stimulants and is a laborious and confusing process for many prescribers. This encourages the use of many other psycho-tropics with little scientific evidence for efficacy in children, limited clinical experience, potentially serious adverse effects, no statutory control and no restriction to specialists.<sup>292</sup>

Although the point that these controls may encourage the substitution of other psychotropic drugs is valid, the suggestion was to relax controls on stimulants, rather than to tighten control on other drugs.

The report was also critical of restrictions that prevent paediatricians continuing to treat ADHD adolescent patients into adulthood. 'At present, the recognition and understanding of adult ADHD is rudimentary. Initial prescribing in adulthood after the age of 18 years, according to statutory Australian guidelines, requires opinion from a psychiatrist. More flexibility, allowing paediatricians to continue management into early adulthood would be constructive.'<sup>293</sup> Clearly, the paediatricians on the panel that developed the guidelines opposed restrictions on their profession's ability to diagnose and prescribe for ADHD in young adults.

The main message from the 1997 guidelines, and therefore from the NHMRC to clinicians, was clear: 'medication can work similarly across the range of cognitive ability and age.'<sup>294</sup> If a patient was young or old, bright or dull, if they had difficulty organising their life and/or are inclined to act on impulse or are inattentive, stimulants were the recommended first line response. The imprimatur of the NHMRC gave this report legitimacy. It gave official sanction to potential prescribers to prescribe off label stimulants and a range of psychotropic drugs for ADHD, based on reasonable theory, without placing any practical limitations on what constitutes reasonable theory.

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<sup>292</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p. 39.

<sup>293</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.58.

<sup>294</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.32.

It is impossible to isolate the impact of these guidelines as many factors contributed to the pharmaceuticalized response to ADHD in Australia. However, it is notable that the number of PBS subsidised prescriptions of dexamphetamine the only ADHD drug subsidised through from 1997 until 2002, grew 66 percent (refer to Figure 1 at 4.2).

There was a subsequent fall in this rate between 2002 and when the guidelines were officially rescinded in 2005. This was probably due to a significant fall in Western Australian prescribing rates over this period from 87,103 prescriptions in 2002 to 67,104 in 2005 (refer to Figure 4 at 4.3 and 6.4).

### **5.3.2 The 2009 NHMRC Draft National ADHD Treatment Guidelines**

In line with the NHMRC policy of reviewing its publications after five to ten years, the NHMRC 1997 ADHD guidelines were reviewed by the Publications Review Working Party a subcommittee (with additional members) of the NHMRC Health Advisory Committee. The Working Party was tasked with reviewing NHMRC publications and guidelines to see if they were up to date with recent research.<sup>295</sup> It decided that the 1997 guidelines were not sufficiently evidence based and had not addressed the issue of co-morbidity. Consequently they were rescinded on 31 December 2005. The Working Party recommended that the new guidelines required a full literature review, an inter-disciplinary approach from Paediatrics and Psychiatry, and needed to consider new medications (Strattera, Ritalin LA and Concerta).<sup>296</sup>

The development of replacement guidelines was outsourced by the NHMRC to the Royal Australasian College of Physicians (RACP).<sup>297</sup> No specific rationale for the choice of the RACP was offered by the NHMRC. However, the RACP is a prominent organisation with approximately 9,000 members and is responsible for the training of physicians and paediatricians. It is unclear whether individual members were invited or applied to become members of the RACP committee.

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<sup>295</sup> NHMRC, *Attention Deficit Hyperactivity Disorder*, p.78.

<sup>296</sup> Information provided by Christine Bengier, Assistant Director, Evidence Translation, *National Health and Medical Research Council*, 27 February 2008.

<sup>297</sup> Health Minister Tony Abbott MHR (2007), 'ADHD Review', *Media release*, 2 May 2007.

An obvious alternative organisation to develop the guidelines would have been the Royal Australian and New Zealand College of Psychiatry (RANZCP). There is no public history of competition between the RACP and the RANZCP and there is no reason to believe the RANZCP opposed the RACP developing the guidelines. However a 2004 Western Australian parliamentary inquiry into ADHD found that although both professions use DSM-IV, seeing a paediatrician as opposed to a psychiatrist was more likely to result in a child being prescribed stimulants for ADHD.<sup>298</sup> Whether this is unique to Western Australian is unclear.

The draft guidelines were dogged by controversy primarily because of allegations of bias amongst the guidelines reference group members, and the reliance on research by ADHD experts with undisclosed commercial ties to ADHD drug manufacturers. As a result of the controversy the Guidelines were not finally approved by the NHMRC, despite being completed by November 2009. A substitute process began in 2011 when another panel was convened to develop the Australian Clinical Practice Points. These were completed and published in September 2012.

The following section summarises in chronological order the major events in relation to the 2009 NHMRC Draft National ADHD Treatment Guidelines and Clinical Practice Points.

### **5.3.2.1 Timeline of controversy around the 2009 NHMRC Draft National ADHD Treatment Guidelines and Clinical Practice Points**

**31 December 2005-** After the 1997 Guidelines were rescinded on 31 December 2005, the development of replacement guidelines was outsourced by the NHMRC, at a cost of \$135,000, to the Royal Australasian College of Physicians.<sup>299</sup> At the time the RACP benefited from considerable sponsorship from drug manufacturers. For example, the RACP 2009 Annual Physicians Week Conference was sponsored by ADHD drug manufacturer Jansen-Cilag and included paid exhibitions by Eli Lilly (manufacturer of ADHD Drug Strattera) and Novartis (manufacturer of ADHD Drug Ritalin). On the RACP website, potential sponsors and exhibitors were encouraged to fund the RACP Conference with comments like, 'Sponsorship and Exhibition opportunities allow you to align the needs of your company to specific

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<sup>298</sup> Western Australia Legislative Assembly, *Attention Deficit Hyperactivity Disorder in WA*, p.23.

<sup>299</sup> Abbott, 'ADHD Review'.

Congress events, whilst exposing your staff directly to your captive target markets [i.e. potential prescribers].<sup>300</sup>

**April /May 2007-** The RACP guidelines reference group was initially chaired by Melbourne paediatrician and academic Dr Daryl Efron who had been on the advisory boards of ADHD drug manufacturer Novartis and Eli Lilly. Dr Efron resigned as chairperson (but remained a reference group member) after his ADHD pharmaceutical company ties were publicised by the *Daily Telegraph* in April 2007. When asked by the newspaper about these ties, Dr Efron argued his pharmaceutical company ties were irrelevant, stating, 'the important thing is we declare our potential conflicts of interest'.<sup>301</sup> However, the names of guidelines reference group members and their pharmaceutical company ties were not made public until Freedom of Information processes revealed them (see 17 November 2008 below). In the same *Daily Telegraph* article Dr Efron declared he supported the use of Ritalin by children under the age of six despite the manufacturer recommending against it.<sup>302</sup>

Media exposure of Dr Efron's pharmaceutical company ties prompted then Howard Government Health Minister Tony Abbott's intervention and Efron's resignation as chair. Abbott said he 'instinctively questioned' the long-term use of drugs for non-life-threatening conditions.<sup>303</sup> This followed comments the previous week by then Prime Minister John Howard who said, 'I am very worried about reports of the over-prescription of Ritalin.'<sup>304</sup> Despite the Prime Minister expressing these sentiments, Health Minister Tony Abbott stated: 'I want to see new clinical guidelines but I stress it is up to the experts to carefully weigh all the issues.'<sup>305</sup>

The then Opposition Health Spokesperson, (later Rudd Government Health Minister) Nicola

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<sup>300</sup> The Royal Australasian College of Physicians (2009), 'Trade Exhibition and Sponsorship', *Physicians Week 2009*. Available at <http://www.physiciansweek.com/sponex.asp> (accessed 12 August 2009).

<sup>301</sup> Janet Fife-Yeomans (2007), 'ADHD reviewer double-up', *The Daily Telegraph*, 30 April 2007. Available at <http://www.dailytelegraph.com.au/news/sydney-news/adhd-reviewer-double-up/story-e6freuzi-111113435833> (accessed 21 September 2008).

<sup>302</sup> Fife-Yeomans, 'ADHD reviewer double-up'.

<sup>303</sup> Janet Fife-Yeomans (2007), 'ADHD guru quits over Ritalin link', *The Daily Telegraph*, 5 May 2007. Available at <http://www.dailytelegraph.com.au/news/sydney-news/adhd-guru-quits-over-ritalin-link/story-e6freuzi-111113472188> (accessed 29 October 2011).

<sup>304</sup> Janet Fife-Yeomans and Bruce McDougall (2007), 'As one boy enjoys life without medication, experts ask – Why do we drug our children?', *The Daily Telegraph*, 27 April 2007.

<sup>305</sup> Fife-Yeomans, 'ADHD guru quits over Ritalin link'.

Roxon, expressed the desire to protect children from unnecessary prescribing.<sup>306</sup> Roxon called for the names and drug company connections of the guidelines reference group to be made public, saying ‘these guidelines are incredibly important and it is important there is public confidence in them. Given the controversy surrounding ADHD, releasing the names is the sensible option to help restore public confidence in the process.’<sup>307</sup> The Australian Medical Association’s responded to Roxon’s call by defending prescribing practices, rejecting a ‘full-blown inquiry’ and insisting the RACP committee complete its work.<sup>308</sup> Minister Abbott rejected Shadow Minister Roxon’s call for full disclosure.

**November 2007-** Rudd Labor won the federal election and Nicola Roxon became Minister of Health. Despite her previous call for full disclosure of reference group members’ names and conflicts of interest, she refused to disclose the names of the committee or their drug company connections.<sup>309</sup>

In addition November 2007 was the deadline for the first of two opportunities for public input into the guidelines. Interested parties were able to make submissions into the scope of the guidelines and literature and other evidence that should be considered in the guidelines development process.

**July 2008-** The second opportunity for public input occurred in July 2008 when interested parties were able to comment on the first draft of the guidelines. In a submission to the RACP guidelines committee I highlighted that the most frequently cited author in the first draft, Harvard University Professor Dr Joseph Biederman, was under investigation for undisclosed pharmaceutical company payments. Dr Biederman was cited as the principal author or co-author 83 times in the Draft Guidelines. My submission stated: ‘on June 8 2008 the New York Times exposed how Dr Biederman was paid US\$1.6 million in consulting fees from drug makers between 2000 and 2007 but did not disclose this income to his employer Harvard University.’<sup>310</sup> Biederman received research funds from fifteen pharmaceutical companies and serves as a paid

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<sup>306</sup> ‘Call for policy on ADHD drugs’, *Courier-Mail*, 27 April 2007. Available at <http://www.couriermail.com.au/news/national-old/call-for-policy-on-adhd-drugs/story-e6freooo-1111113419496> (accessed 29 October 2011).

<sup>307</sup> Janet Fife-Yeomans (2007), ‘Secrecy for ADHD doctors’, *Daily Telegraph*, 30 June 2007.

<sup>308</sup> Fife-Yeomans and McDougall, ‘As one boy enjoys life without medication’.

<sup>309</sup> Whitely, *Speed Up & Sit Still*, p.114.

<sup>310</sup> Gardiner Harris and Benedict Carey, ‘Researchers Fail to Reveal Full Drug Pay’ *New York Times*, 8 June 2008.

speaker or adviser to at least seven drug companies.’<sup>311</sup>

Dr Biederman was not the only Harvard University researcher, cited in the draft guidelines, under investigation for undisclosed drug company payments. Two other Harvard researchers under investigation, Drs Timothy Wilens and Thomas Spencer, were cited thirty-two and forty-six times respectively.<sup>312</sup> At least two other researchers cited in the guidelines, Drs Karen Wagner and Augustus John Rush of the University of Texas, were also under investigation for similar misconduct.<sup>313</sup>

Other researchers cited in the 2009 Draft Guidelines on numerous occasions include:

- Dr Christopher Gillberg of the Department of Child and Adolescent Psychiatry, University of Gothenburg, Sweden. In 2005 he was convicted of fraud, for failing to disclose when required by a court research he claimed proved the existence of an invented disorder ‘DAMP’ (Deficits in Attention, Motor control and Perception).<sup>314</sup> Gillberg received a suspended sentence and appealed to the Supreme Court, with his last appeal failing in April 2006. Three of his co-workers also received suspended sentences for destroying data from the study and not making it available.
- Russell Barkley PhD, is a key advisor to the U.S. ADHD support group, Children and Adults with Attention Deficit Hyperactivity Disorder (CHADD). CHADD was exposed in 2006 for its conflicts of interest with the pharmaceutical industry. Specifically CHADD did not publish critical information about ADHD drugs, including an FDA warning in 2005 that the ADHD drug, Strattera, caused suicidal ideation. Eli Lilly, the maker of Strattera is one of CHADD’s biggest donors.<sup>315</sup> In 2010 Dr. Barkley received

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<sup>311</sup> Dr. Joseph Biederman (2006), ‘The Evolving Face of ADHD: From Adolescence to Adulthood—Clinical Implications’. Available at <https://itunes.apple.com/us/podcast/evolving-face-adhd-from-adolescence/id210821748> (accessed 29 October 2012).

<sup>312</sup> Gardiner Harris (2009), ‘3 Researchers at Harvard are named in subpoena’, *The New York Times*, 27 March 2009.

<sup>313</sup> Emily Ramshaw (2009), ‘University of Texas officials vow to strengthen ethics rules for researchers’, *The Dallas Morning News*, 11 February 2009.

<sup>314</sup> Douglas J. Keenan, ‘The Gillberg Affair’. Available at [www.informath.org/apprise/a6400.htm](http://www.informath.org/apprise/a6400.htm) (accessed 1 October 2012).

<sup>315</sup> Thomas Ginsberg (2006), ‘Donations tie drug firms and non-profits; Many patient groups reveal few, if any, details on relationships with pharmaceutical donors’, *The Philadelphia Enquirer*, 28 May 2006. Available at <http://www.intenex.net/pipermail/mindfreedom-news/2006-May/000034.html> (accessed 25 July 2008).



funding as a Speaker/Consultant for Eli Lilly, Shire, McNeil, Janssen-Cilag and Novartis.<sup>316</sup>

- Dr. Laurence Greenhill - co-authored a number of the cited studies. He is a frequent paid speaker for ADHD drug manufacturers.<sup>317</sup> Dr. Greenhill has worked as a paid consultant to Alza Corp., Bristol-Myers Squibb, Richwood and GlaxoSmithKline, Eli Lilly, McNeil Pharmaceutical, Novartis Pharmaceuticals, and Solvay.<sup>318</sup> He has been a paid speaker for Eli Lilly, Janssen Pharmaceuticals and Novartis Pharmaceuticals. I was in the audience at the International Association for Child and Adolescent Psychiatry and Allied Professions conference in Melbourne in September 2006 when Dr Greenhill, whilst addressing an international audience of 300 psychiatrists, misrepresented the FDA deliberations on the black box warning debate on stimulants. In July 2005, reports of adverse cardiovascular and psychiatric events prompted the FDA to convene a Drug Safety Advisory Panel consisting of sixteen of America's top drug safety experts. The experts were provided with details of the adverse event reports and given the brief of designing further research to establish the safety of ADHD drugs. The Drug Safety Advisory Panel voted to recommend a 'black box warning' for cardiovascular risks on all ADHD stimulant drugs. A black box warning is the strongest form of warning issued by the FDA about a drug, the step taken just short of removing it from the market.<sup>319</sup> Greenhill portrayed the call for a black box warning for stimulants as coming from isolated clinicians rather than from the specially appointed FDA Drug Safety Advisory Panel. Doctor Greenhill only revealed his extensive drug company connections to attendees at the conference when I asked him specifically at the end of his presentation.<sup>320</sup>

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<sup>316</sup> This information is available at National Association for Continuing Education, *Attention Deficit Hyperactivity Disorder in Adults: The latest assessment and treatment strategies* (2010). Available at <http://www.naceonline.com/NCC14.php> (accessed 14 November 2012).

<sup>317</sup> 'New study warns of side effects for Pre-Schoolers' *Lubbock Avalanche Journal*, AJ Media, 20 October 2006. Available at [http://lubbockonline.com/stories/102006/med\\_102006080.shtml](http://lubbockonline.com/stories/102006/med_102006080.shtml) (accessed 25 July 2008).

<sup>318</sup> Greg Birnbaum and Douglas Montaro (1999), 'Shrinks for Sale. Analyze This: Docs get Drug Co. \$\$', *New York Sunday Post*, 28 February 1999.

<sup>319</sup> Trisha Torrey (2008), 'Black Box Warning (From the FDA)'. Available at <http://patients.about.com/od/glossary/g/blackboxwarning.htm> (accessed 18 March 2010).

<sup>320</sup> Whitely, *Speed Up & Sit Still*, p.120.

**19 August 2008-** The first draft of the guidelines included the recommendation that ‘Federal, State and Territory funding allocations to schools need to be revised to enable schools to access funding for students diagnosed with ADHD’.<sup>321</sup> Critics contended this would, if implemented, have provided an economic incentive to schools to encourage the diagnosis of ADHD in students.

<sup>322</sup> This criticism was based on the experience in the US where there has been an explosion in ADHD diagnosis and prescribing rates partly attributed to schools seeking desperately needed general purpose funds.<sup>323</sup> In 1991 the US Department of Education issued a memorandum setting guidelines for schools with children diagnosed ADHD to be made eligible for a special subsidy of approximately US\$420 per child per year, under the health impaired category. Children ‘may get little more than the services of a nurse or clerk handing out a dose of Ritalin while the money goes into a general purpose fund’.<sup>324</sup> After a letter to the Rudd Government from a group of fourteen Australian researchers in education, disabilities and ADHD (led by Dr Linda Graham) to the Rudd government gained media coverage, this recommendation was dropped. The letter criticised ‘moves to instruct teachers to look out for ADHD and to allocate special funding to schools for students with the disorder’.<sup>325</sup>

**17 November 2008-** Freedom of Information processes revealed the vast majority, at least seven, but probably eight of the original ten guidelines reference group members, including doctors, have ‘declared receiving grants and air fares, hotels and overseas trips from companies making drugs to treat the disorder... [Adelaide Now] has obtained the conflict of interest declarations made by nine of the 10 original working group members. The 10th has demanded details remain secret.’<sup>326</sup> When this de-identified information was reported in the media, it was reported that ‘the publicly-funded committee had threatened to quit if their names were revealed.’<sup>327</sup> Appendix 3 is an extract from the draft guidelines where members declared their dualities and potential conflicts of interest.<sup>328</sup> This information was not made publicly available until November 2009.

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<sup>321</sup> Royal Australasian College of Physicians, *Draft Australian Guidelines*, p.122.

<sup>322</sup> Justine Ferrari (2008), ‘Alert over ADHD guidelines in schools’, *The Australian*, 19 August 2008.

<sup>323</sup> Breggin, *Talking Back to Ritalin*, p.264.

<sup>324</sup> Breggin, *Talking Back to Ritalin*, p.252.

<sup>325</sup> Justine Ferrari (2008), ‘Alert over ADHD guidelines in schools’, *The Australian*, 19 August 2008.

<sup>326</sup> Janet Fife-Yeomans (2008), ‘Guidelines panel linked to drug firms’, *Adelaide Now*, 17 November 2008. Available at <http://www.adelaidenow.com.au/news/guidelines-panel-linked-to-drug-firms/story-e6freo8c-111118054187> (accessed 4 October 2009).

<sup>327</sup> Fife-Yeomans, ‘Guidelines panel linked to drug firms’.

<sup>328</sup> RACP, *Draft Australian Guidelines*.

The General Practitioner representative on the review group was Geraldton GP Dr Kim Pedlow. In 2004 Geraldton was identified, by a spokesperson for the pharmaceutical industry sponsored ADHD patient support group the Learning and Attention Disorders Society (LADS), Michele Toner, as being an excellent model for regional service delivery. In 2004, in response to a question from the then Member for Geraldton, Shane Hill, Toner said:

Geraldton would be the exception [to the poor provision of ADHD diagnosis and treatment services in regional WA], because there is an excellent sharecare program with a Dr Kim Pedlow who works there. Geraldton would be the exception and services are fairly accessible and doctors travel up there fairly regularly, but we get phone calls from isolated areas where there are just no services available.<sup>329</sup>

In 2004 Geraldton was one of three districts out of a total of 31 to have a prescription rate higher than 10 patients per 1000 population of the total population.<sup>330</sup> In 2006 Geraldton had the second highest child prescription rate compared with the other 31 Health Districts, with a rate of 25.7 children per 1000 children aged 2 to 17.<sup>331</sup> This pattern has continued through to 2011 with Geraldton having both the highest childhood (25.3 children per 1000 2 to 17 year olds) and the second highest adult prescribing (10.0 children per 1000).<sup>332</sup>

**27 November 2008-** Following up from the media coverage of the conflict of interest issues (which did not provide the detail of individual conflicts listed above), independent South Australian Senator Nick Xenophon asked for details of potential conflicts of interest in a question in the Australian Senate. The requested details were not provided and the response was limited to: 'Minister [Roxon] has been advised that the conflicts of interest declared by

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<sup>329</sup> Department of Health (2003), Government of Western Australia, *Inquiry into Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder in Western Australia*, Legislative Assembly, Transcript of evidence taken on 27 October 2003, p.2 (Michelle Toner).

<sup>330</sup> Department of Health (2005), *'Stimulant Prescribing and Usage Patterns for the Treatment of ADHD in Western Australia'*, 1 August 2003 – 31 December 2004, Pharmaceutical Services Branch, Department of Health, Western Australia.

<sup>331</sup> Western Australian Government (2007). Department of Health, *Western Australian Stimulant Regulatory Scheme 2006 Annual Report*, Pharmaceutical Services Branch, Health Protection Group, Department of Health, Perth.

<sup>332</sup> Department of Health, *Western Australian Stimulant Regulatory Scheme 2011 Annual Report*, p.27 and p. 42

working party members are consistent with the normal range associated with clinician review committees of this nature.<sup>333</sup>

**June 2009-** The draft guidelines document was completed with ‘the majority of the identified studies on ADHD medications being sponsored, at least in part, by the manufacturers of the medications’.<sup>334</sup> In addition, two thirds of the 203 draft recommendations were made without any supporting scientific evidence. They were based entirely on reference group consensus and justified as ‘best practice based on clinical experience and expert opinion’.<sup>335</sup>

The key recommendations of the draft guidelines encourage the use of stimulants, either methylphenidate or dexamphetamine, with the substitution of one for the other in the case of adverse side effects or ineffectiveness. If children do ‘not respond to or are intolerant of stimulant medication’, the non-stimulant drug Strattera is recommended.<sup>336</sup> If both stimulants and Strattera fail to result in a ‘clinical response’ Clonidine can be ‘trialed’.<sup>337</sup>

Another example of this pharmaceuticals-first approach is the recommendation that if, as is common, ADHD stimulants cause tics or pre-existing tics become worse, the following treatment options are recommended:

- continue the ADHD medication alone;
- add an anti-tic medication; or
- trial another ADHD medication.<sup>338</sup>

The guidelines also encourage polypharmacy, by recommending concurrent prescribing of a range of psychotropic drugs to children with ‘comorbid’ depression and bipolar disorder along with ADHD. This is despite the TGA insisting manufacturers of all selective serotonin reuptake inhibitors (SSRI) antidepressants include advice that their use by under-twenty-four-year-olds

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<sup>333</sup> Commonwealth of Australia, Parliamentary Debates, Senate, 27 November 2008, p.7540 (Senator Joe Ludwig on behalf of Hon Nicola Roxon, Minister for Health and Ageing).

<sup>334</sup> Royal Australasian College of Physicians, *Draft Australian Guidelines*, p.82.

<sup>335</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.x – xxix.

<sup>336</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.xviii.

<sup>337</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.xviii.

<sup>338</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.xxi.

increases the risk of suicidality.<sup>339</sup>

Similar evidence of a pro-pharmaceutical approach is the recommendation that methylphenidate be used as a second line treatment in children under six years of age, despite the manufacturers' prescribing information for all stimulants stating they should not be used in children under 6 years. Ritalin prescribing information which is available to clinicians says 'Ritalin should not be used in children under 6 years, since safety and efficacy in this age group have not been established'.<sup>340</sup> Concerta's says 'safety and efficacy has not been established in children less than six years old or elderly patients greater than 65 years of age'.<sup>341</sup> Dexedrine's (a brand of dexamphetamine) says 'long-term effects of amphetamines in pediatric patients have not been well established. Dexedrine is not recommended for use in pediatric patients younger than 6 years of age with Attention Deficit Disorder with Hyperactivity'.<sup>342</sup>

The draft guidelines included numerous statements about the possible biological and genetic underpinnings of ADHD like:

'the dominant current paradigm suggests that disordered fronto-striato-cerebellar brain circuitry underpins the executive function deficits at the core of this condition. Twin studies have established a strong genetic component. This appears to involve polymorphisms in a number of genes, including those coding for dopamine transporters.'<sup>343</sup>

These 'suggestions' and 'appearances' were apparently sufficient in the view of the RACP committee to justify the use of amphetamines as the first line of treatment for ADHD.

Like the superseded 1998 guidelines the 2009 draft guidelines recommended that stimulants can be prescribed 'off label' to pre-schoolers if ADHD symptoms are having a severe impact on 'family/carers'.<sup>344</sup> This raises ethical issues about the use of 'psychotropic drugs' in part at least to enhance the welfare of family or carers.

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<sup>339</sup> Julie-Anne Davies (2008), 'Probe into anti-depressants being conducted "in secret"', *The Australian*, 1 November 2008.

<sup>340</sup> Ritalin's prescribing information is available at [http://www.pharma.us.novartis.com/product/pi/pdf/ritalin\\_ritalin-sr.pdf](http://www.pharma.us.novartis.com/product/pi/pdf/ritalin_ritalin-sr.pdf).

<sup>341</sup> Concerta's prescribing information is available at [http://www.concerta.net/sites/default/files/pdf/Prescribing\\_Info-short.pdf#zoom=56](http://www.concerta.net/sites/default/files/pdf/Prescribing_Info-short.pdf#zoom=56).

<sup>342</sup> Dexedrine's prescribing information is available at [http://www.dexedrine.com/docs/dexedrine\\_PI.pdf](http://www.dexedrine.com/docs/dexedrine_PI.pdf).

<sup>343</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.8.

<sup>344</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.87.

Another controversial recommendation in the final draft guidelines was that ‘as ADHD and ADHD symptoms are common in individuals entering the justice system, screening for ADHD may be indicated in this population’.<sup>345</sup> Similarly controversial is the conclusion that ‘the use of stimulant medication to treat people with ADHD does not increase the risk of developing substance use disorder’.<sup>346</sup> As discussed at 2.2 critics contend that providing ADHD stimulants facilitates drug abuse and that supplying prisoners with divertible ADHD amphetamines may result in amphetamine abuse. Like the majority of the 203 recommendations, the prisoner screening recommendation was based entirely on the consensus of the RACP panel with no supporting evidence. The admission in the guidelines that ‘more research is needed to determine whether treatment of ADHD can reduce the risk of crime and recidivism’ further fuelled concerns that hypothesis and bias, rather than evidence, is the basis of many of these draft guidelines.<sup>347</sup>

Another recommendation without any supporting evidence was that ‘given the high rate of suicide in Australia’s Indigenous population and the association of impulsivity with suicidal ideation among Indigenous youth...there is an urgent need for culturally appropriate assessment of ADHD’.<sup>348</sup> Similarly the recommendation that ‘in people with intellectual disability and ADHD, use of stimulant medication should be considered’ is also controversial. Inherent in this recommendation is the assumption that it is possible to distinguish between the diagnostic criteria of ADHD and the consequences of intellectual disability.<sup>349</sup>

**October 2009-** The National Health and Medical Research Council (NHMRC) announced that because of an investigation involving undisclosed drug company payments to US researcher Dr Joseph Biederman, who was cited 82 times in the draft guidelines, the guidelines had not been approved and remain in draft format.<sup>350</sup>

<sup>345</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.xxviii.

<sup>346</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.xxiii.

<sup>347</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.xxviii.

<sup>348</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.54.

<sup>349</sup> RACP, *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, p.xxi.

<sup>350</sup> NHMRC (2009), ‘Draft Australian Guidelines on ADHD – NHMRC consideration deferred pending outcome of USA investigation’, Research Notices, Australian Government, Canberra, ACT. Available at <http://www.nhmrc.gov.au/media/notices/2009/draft-australian-guidelines-adhd-%E2%80%94-nhmrc-consideration-deferred-pending-outcome-u> (accessed 30 January 2013).

**23 November 2009-** The NHMRC issued a press release stating that ‘If the US investigation remains unresolved by mid-2010, NHMRC will move to redevelop the draft guidelines’.<sup>351</sup> The *Sydney Daily Telegraph* reported the NHMRC decision to redevelop the guidelines and quoted a RACP spokesperson asserting that ‘the College was not aware of the US investigation (into Biederman) when drafting the guidelines’.<sup>352</sup>

**24 November 2009-** *The Australian* reported that contrary to the RACP spokesperson’s statement sixteen months earlier ‘(Martin Whitely) wrote to the [RACP] panel in July last year, warning that its work had been tainted by Dr Biederman’s research’ and ‘raised similar concerns with Ms Roxon’s advisers in August last year’.<sup>353</sup>

In addition to relying on compromised researchers and pharmaceutical company controlled research, significant evidence that there was little quality long term evidence on the safety and effectiveness of ADHD psychostimulants was either ignored or downplayed. Despite me personally handing a copy of the *Oregon Health and Science University, Drug Class Review on Pharmacologic Treatments for ADHD* to committee chairperson Dr David Forbes, and including a summary of it in my submission, the valuable detailed analysis of over 2000 studies into the safety and efficacy of ADHD drugs was ignored.<sup>354</sup> The reference group had the opportunity to cross reference the detailed analysis in the *Oregon Health and Science University, Drug Class Review on Pharmacologic Treatments for ADHD* to the research they relied on, but did not. (For detail of the Oregon Health and Science University, Drug Class Review on Pharmacologic Treatments for ADHD refer to 3.5)

**30 November 2009-** Throughout 2009, Minister Roxon came under pressure from both sides of the ADHD debate. ADHD critics concerned about the potential of the new guidelines to further accelerate the growth in child prescribing rates lobbied Roxon to abandon the draft guidelines and seek advice from psychiatrists without ties to the pharmaceutical industry. ADHD proponents, including members of the RACP guidelines reference group, wanted the guidelines to be released. The NHMRC had effectively offered Health Minister Roxon a circuit breaker (see 23 November 2009); however she rejected the opportunity to put the redevelopment of the

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<sup>351</sup> NHMRC, ‘Draft Australian Guidelines on ADHD – NHMRC’.

<sup>352</sup> Kate Sikora (2009), ‘ADHD guidelines pulled after payment scandal’, *The Daily Telegraph*, 23 November 2009.

<sup>353</sup> Nicola Berkovic (2009), ‘Review of “tainted” ADHD guidelines’, *The Australian*, 24 November 2009.

<sup>354</sup> McDonagh et al, *Drug Class Review on Pharmacologic Treatments for ADHD*.

guidelines in the hands of clinicians without commercial ties to the pharmaceutical industry. Minister Roxon, the NHMRC and the RACP issued a joint press release with Roxon praising the draft guidelines stating 'I am pleased that we can finally provide this more up-to-date information on ways to identify and care for those in our community who may be suffering from ADHD.' Despite all the previously highlighted problems, the joint statement also said 'The RACP has conducted a thorough and careful process to develop these draft Guidelines. They utilised a panel of independent experts to review the scientific evidence, and an independent scientific writer to prepare the draft document, with the work overseen by an expert working group.'<sup>355</sup> The guidelines replacement chairperson Dr David Forbes mirrored Roxon's position stating; 'There's been a hiccup that's emerged but we think that practitioners and children in Australia should have the benefit of these while we're awaiting clarification (from the US).'<sup>356</sup> The public and the medical profession were left with the mixed message that according to the NHMRC, the guidelines were draft and subject to withdrawal, but that Roxon was pleased they finally offered 'more up-to-date information'.

**September 2010-** The Honourable Mark Butler was appointed Australia's first Mental Health Minister and assumed shared responsibility with the Minister for Health the Hon Nicola Roxon for the issue of ADHD. Minister Butler was responsible for mental health related issues; however the NHMRC remained the responsibility of the Health Minister.

**July 2011-** Mental Health Minister Mark Butler announced that 2009 Draft ADHD Guidelines would not be approved and an alternative process the *Australian Clinical Practice Points for the Diagnosis and Treatment of ADHD in Children* would be initiated. The membership of the committee responsible for developing the *Clinical Practice Points* was made public along with their conflict of interest declarations.

**May 2013-** Despite the publication of the Clinical Practice Points, and the concerns with the 2009 draft Guidelines, the latter were still published on the NHMRC website along with the explanation in box 6 below.<sup>357</sup>

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<sup>355</sup> The Hon Nicola Roxon MP, 'Draft ADHD Guidelines Released'.

<sup>356</sup> Julian Drape (2009), 'Drugs shouldn't be first port of call for ADHD kids: report', *Australian Associated Press General News*, 30 November 2009.

<sup>357</sup> National Health and Medical Research Council (2009), *Draft Australian Guidelines on ADHD: Summary Information*, Canberra, NHMRC. Available at <http://www.nhmrc.gov.au/guidelines/publications/ch54> (accessed 13 March 2012).



**Box 6 - NHMRC Statement - Draft Australian Guidelines on ADHD Summary information**

The *Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder*, 2009 (the Draft Guidelines) were developed by the Royal Australasian College of Physicians. The Draft Guidelines aim to provide health professionals with a guide to assessment, management and care of preschoolers, children, adolescents and adults with ADHD.

The Draft Guidelines have been available on the NHMRC's website since late 2009 pending the outcomes of conflict of interest investigations against three Harvard Medical School researchers whose work is heavily cited throughout the Draft Guidelines.

In July 2011 Harvard Medical School and Massachusetts General Hospital sanctioned Professor Biederman and Drs. Spencer and Wilens for failing to report their industry sponsored activities and subsequently violating their organisations' conflict of interest policies. This announcement did not reveal the extent to which the conflicts impacted on the integrity of their research.

Despite repeated inquiries to Harvard Medical School, the Council of NHMRC has not been able to determine whether these undisclosed sponsorships affected the findings underpinning the Draft Guidelines. Hence, the Council of NHMRC has not recommended the Draft Guidelines for approval.

NHMRC has released *Clinical Practice Points on the Diagnosis, Assessment and Management of ADHD in Children and Adolescents* (the CPPs). Clinical Practice Points are a resource that outlines good clinical practice based on the consensus of an expert working group. These CPPs do not replace the draft Guidelines as they have a narrower focus and do not cover the management of adults with ADHD. Instead they aim to provide clarity to clinicians on one of the most controversial areas in ADHD - the use of medication, in particular stimulants, in managing children and adolescents with ADHD symptoms. The CPPs were developed while the above conflict of interest allegation was being investigated by Harvard University.

The Draft Guidelines will continue to be available on NHMRC website for a limited time only.

In summary despite acknowledging the cause or causes of ADHD are unknown, and despite having been made aware of issues in relation to the integrity and rigor of evidence supporting the use of pharmaceutical interventions, the guidelines committee made recommendations promoting the first line use of medications even outside the manufacturer's guidelines. They promoted pharmaceutical use on the basis of 'reasonable theory' even if there was little or no supporting evidence. However, the use of non-drug treatments was strongly discouraged because of a lack of supporting evidence.

The guidelines development process was 'internally' captured. ADHD proponents developing the guidelines in part at least relied on research conducted by other ADHD proponents with

significant undisclosed conflict of interests and produced pharmaceuticalized recommendations. However, after the event, as a result of persistent public advocacy by ADHD critics and sustained media coverage of the conflict of interest issues, the guidelines were not officially endorsed and remained in draft format. The contest between ADHD proponents and critics was external to the formal 'captured' process. However, it demonstrates that total dominance by ADHD proponents is not inevitable. These issues are discussed in greater detail at 7.4.2.1.

### **5.3.3 The 2012 Australian Clinical Practice Points for the Diagnosis and Treatment of ADHD in Children**

Unlike the 2009 guidelines process, from the beginning the names of the Australian Clinical Practice Points for the Diagnosis and Treatment of ADHD in Children (Clinical Practice Points) development committee were made public as were the details of their conflict of interest declarations.

Also in contrast to the previous ADHD Guidelines development processes the Clinical Practice Point development process was balanced in that it included a broad range of views and interests. Although the Clinical Practice Points are described as being 'based on expert consensus' it may have been more accurate if they were described as being 'based on expert compromise'.<sup>358</sup> Neither ADHD proponents nor critics were entirely happy with the compromise outcome. Perhaps this was an inevitable product of a committee which contained members with diametrically opposed views like ADHD sceptic, Professor Jon Jureidini (a psychiatrist), and ADHD prescribing enthusiast, Professor Michael Kohn (a paediatrician).

Of the ten members invited to participate two members, Professor Kohn<sup>359</sup> and notional consumer representative, Learning and Attentional Disorders Society (LADS)<sup>360 361</sup> member

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<sup>358</sup> National Health and Medical Research Council (2012), *Clinical Practice Points on the Diagnosis, Assessment and Management of Attention Deficit Hyperactivity Disorder in Children and Adolescents*, Commonwealth of Australia. Available at [http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/mh26\\_adhd\\_cpp\\_2012\\_120903.pdf](http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/mh26_adhd_cpp_2012_120903.pdf) (accessed 2 august 2013).

<sup>359</sup> Professor Kohn has significant financial connections to ADHD drug manufacturers Eli Lilly and Janssen Cilag. He was a member of Strattera Advisory Board for Eli Lilly and is currently undertaking publicly funded research on Strattera. He has received other financial support from both Janssen Cilag and Eli Lilly and been paid to prepare and deliver educational materials by Janssen Cilag. He has also received research

Margaret Vikingur had commercial ties to ADHD drug manufacturers. In addition both Professor Kohn and LADS had demonstrated a strong ideological ‘biomedicalized’ ADHD proponent bias. Professor Michael Kohn’s 2009 description of an article in Sydney’s *Daily Telegraph* detailing extreme reactions to ADHD medications reported to the TGA, such as psychotic episodes and suicidal ideation as ‘blaspheming the use of Ritalin’ indicates a near religious fervour for prescribing amphetamines like drugs to children.<sup>362</sup> LADS encouraged the illegal use of ADHD amphetamines. Specifically in 1998 LADS was warned twice not to recommend the illegal use of a child’s ADHD stimulants by parents if they thought they had adult ADHD.<sup>363</sup>

The chairperson of the group Professor of Psychiatry Bruce Tonge had previously conducted research on ADHD and endorsed the validity of the disorder. However, unlike Kohn or LADS, Tonge had not specialised in the disorder or been a frequent proponent.<sup>364</sup> Some other members of the Clinical Practice Points process including Tonge had commercial ties to pharmaceutical companies but none related directly to ADHD. In contrast to Michael Kohn and Margaret Vikingur, psychiatrist Professor Jon Jureidini had been a frequent critic of

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support for ADHD studies from Brain Resource Ltd which has received funding from at least 13 different pharmaceutical companies. For details see M. Williams et al (2010), ‘An “integrative neuroscience” perspective on ADHD: linking cognition, emotion, brain and genetic measures with implications for clinical support’, *Expert Review of Neurotherapeutics*, 10:10.

<sup>360</sup> LADS is partially funded by drug companies and has a long history of marketing of ADHD as having a biological cause best treated with ‘safe, effective medication’. ‘LADS has accepted limited unrestricted grants from pharmaceutical companies’ including Eli Lilly and Novartis. See <http://www.ladswa.com.au/page.php?id=6> (accessed 26 June 2009) and <http://www.nhmrc.gov.au/guidelines/adhd-conflicts-interest> (accessed 13 July 2011).

<sup>361</sup> LADS have also publicly endorsed ADHD drugs in press releases prepared by public relations business in order to promote ADHD drugs. Last Say Communications, ADHD – A Day of Calm – Dawn to Dusk: Long Lasting Medication to Provide Relief for Kids with ADHD, *Media Release*, 27 March 2007

<sup>362</sup> ‘Medicating our children’, *Reportage Online: Magazine of the Australian Centre for Independent Journalism*, 22 December 2009. Available at <http://www.reportageonline.com/2009/12/medicating-our-children/>. Kohn’s comment was in response to Kate Sikora (2009), ‘We’re turning our children psychotic with ADHD medication’, *The Daily Telegraph*, 13 October, 2009. Available at <http://www.dailytelegraph.com.au/lifestyle/body-soul/were-turning-our-children-psychotic/story-e6frf01r-1225786025127> ↩. This is not an isolated comment from Professor Kohn. For further information see Martin Whitely (June 2011), ‘Where is the evidence to support ‘ADHD expert’ Prof Kohn’s claim that amphetamines aid brain development?’, *Speed Up & Sit Still*. Available at <http://speedupsitstill.com/evidence-support-adhd-expert-prof-kohns-claim-amphetamines-aid-brain-development>.

<sup>363</sup> WA Stimulant Committee, *Minutes of Meeting held on 4 August, 1998*, obtained under Freedom of Information Act 1992.

<sup>364</sup> Monash University, *Emeritus Prof. Bruce Tonge – Researcher Profile*, Melbourne. Available at <http://www.monash.edu.au/research/people/profiles/profile.html?sid=691403&pid=7507> (accessed 18 June 2013)

ADHD diagnosis and prescribing.<sup>365</sup> Another member psychiatrist Professor Helen Milroy, although not as critical as Jureidini, had also previously expressed concern about misdiagnosis and over-prescription.<sup>366</sup>

There was significant opportunity for public input with approximately 140 submissions spanning the divergent range of views on ADHD and resulting in significant differences between draft and final guidelines.<sup>367</sup> One of the more notable changes from the draft was the removal of the statement that ‘as with any medical intervention, the inability of parents to implement strategies may raise child protection concerns’.<sup>368</sup> This statement attracted widespread media attention and condemnation as it was interpreted as a threat to remove children from parents who refused to allow their children to be ‘medicated’ for ADHD.<sup>369</sup> On 23 November 2011 the NHMRC issued a media release denying that a failure to medicate may result in the intervention of child protection authorities.<sup>370</sup> This statement was removed from the final Clinical Practice Points which were released in September 2012.

The final Clinical Practice Points were significantly different to the 2009 Draft Australian Guidelines. Table 2 below lists both features of the Clinical Practice Points that ADHD critics support and statements that they contest.

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<sup>365</sup> Penelope DeBelle (2011), ‘Festival of Ideas: All in the mind’, *Adelaide Advertiser*, 1 October 2011. Available at <http://www.adelaidenow.com.au/ipad/festival-of-ideas-all-in-the-mind/story-fn3o6wog-1226151737735> and Sue Dunlevy (2012), Safety fears over ADHD drug, *The Sunday Telegraph*, September 09, 2012. Available at <http://www.news.com.au/national-news/nsw-act/safety-fears-over-adhd-drug/story-fndo4bst-1226468000702>.

<sup>366</sup> Sarah Ferguson and Nick Rushworth (2006), ‘ADHD – The Quick Fix’, *The Sunday Program*, Channel 9, 14 May 2006. Interview previously available at [http://sunday.ninemsn.com.au/sunday/cover\\_stories/article\\_1983.asp?s=1](http://sunday.ninemsn.com.au/sunday/cover_stories/article_1983.asp?s=1) (accessed 2 April 2008).

<sup>367</sup> For details of the effect of the submissions on the final ADHD Clinical Practice Points see appendix D page 16 available at [http://www.nhmrc.gov.au/files\\_nhmrc/publications/attachments/mh26\\_adhd\\_cpp\\_appendices\\_120903\\_0.pdf](http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/mh26_adhd_cpp_appendices_120903_0.pdf).

<sup>368</sup> National Health and Medical Research Council (2011), *Public Consultation on the Draft Clinical Practice Points on the Diagnosis, Assessment and Management of Attention Deficit Hyperactivity Disorder in Children and Adolescents*, Australian Government, p.15. Available at [http://consultations.nhmrc.gov.au/open\\_public\\_consultations/a-d-h-d](http://consultations.nhmrc.gov.au/open_public_consultations/a-d-h-d)

<sup>369</sup> Sue Dunlevy (2011), ‘medicate ADHD kids or else, parents told’, *The Australian*, 21 November 2011. Available at <http://www.theaustralian.com.au/national-affairs/medicate-adhd-kids-or-else-parents-told/story-fn59niix-1226200652633> ↵ (accessed 30 November 2011).

<sup>370</sup> See National Health and Medical Research Council, ‘Reassuring parents new draft ADHD clinical practice points do not mandate medication’, *Media Release*, 23 November 2011. Available at <http://www.nhmrc.gov.au/media/releases/2011/reassuring-parents-new-draft-adhd-clinical-practice-points-do-not-mandate-medica> ↵ <http://www.nhmrc.gov.au/media/releases/2011/reassuring-parents-new-draft-adhd-clinical-practice-points-do-not-mandate-medica> (accessed 24 November 2011).

Table 2 - **ADHD Clinical Practice Points statements supported and contested by ADHD critics.**

| ADHD Clinical Practice Points statements <u>supported</u> by ADHD critics.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ADHD Clinical Practice Points statements <u>opposed</u> by ADHD critics.                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p style="text-align: center;"><b>DIAGNOSIS</b></p> <ul style="list-style-type: none"> <li>• ‘The clinician should always be mindful of seeking a more meaningful explanation of the child/adolescent’s behaviour than simply labelling it as ADHD because it meets diagnostic criteria.’ (Page 14)</li> <li>• ‘ADHD is a description rather than an explanation of a pervasive, persistent, disabling pattern of inattentiveness, overactivity and/or impulsivity. A child/adolescent who meets diagnostic criteria for ADHD may not be always best served by making that diagnosis. For example, their behaviour could be understood as a reaction to specific cognitive difficulties or family/environmental circumstances.’ (Page 6)</li> <li>• ‘All children and adolescents can display active, impulsive and inattentive behaviour as part of normal development. This does not mean that they have a disorder, and important controversies exist about the use of ADHD as a diagnosis for children and adolescents.’ (Page 10)</li> </ul> | <p style="text-align: center;"><b>DIAGNOSIS</b></p> <ul style="list-style-type: none"> <li>• ‘The risk of not making a diagnosis is that the child/adolescent may not receive appropriate management and care.’ (Page 12)</li> </ul>                                                                |
| <p style="text-align: center;"><b>TREATMENT</b></p> <ul style="list-style-type: none"> <li>• ‘Parents/carers must be given information on the diagnosis and management plan, including any potential adverse effects of treatment in order to fully inform them and to have them make a decision regarding the</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p style="text-align: center;"><b>TREATMENT</b></p> <ul style="list-style-type: none"> <li>• ‘Regardless of whether the cause is explicable or not these symptoms impact so adversely on the child or adolescent and their family that the symptoms cannot be left untreated.’ (Page 11)</li> </ul> |

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>treatment that is offered to their child.’ (Page 16)</p> <ul style="list-style-type: none"> <li>Potential ‘adverse-effects’ of stimulants identified in the CPPS include sleep disturbance, reduced appetite, abdominal pain, headaches, crying spells, repetitive movements, slowed growth (height and weight), restlessness, dizziness, anxiety, irritability cardiovascular effects such as tachycardia, palpitations and minor increases in blood pressure and psychosis or mania. In addition the ADHD CPPS say where to report side-effects in Australia (to the TGA) and acknowledge that stimulants are Schedule 8 drugs because they can be addictive and are abused. (Page 20)</li> <li>‘Children/adolescents on stimulant medication require 3-6 monthly clinical assessment and review to ensure the management strategies remain appropriate and effective. Monitoring should include assessment of side effects and particularly psychological symptoms and plotting of growth parameters, pubertal development, heart rate and blood pressure.’ (Page 8)</li> <li>‘Practical supports for families, such as respite care, parenting education and guidance and counselling, may be helpful or even a sufficient intervention perhaps obviating the need for specific treatment and psychological management of the child.’ (Page 17)</li> </ul> | <ul style="list-style-type: none"> <li>‘Use of stimulant medications (methylphenidate and dexamphetamine sulphate) can reduce core ADHD symptoms and improve social skills and peer relations in children and adolescents diagnosed with ADHD in the short term (up to 3 years).’ (Page 8)</li> <li>‘Both medication and combined medication and behavioural treatment have been shown to be more effective in treating ADHD symptoms than psychosocial or behavioural interventions alone.’ (p.19)</li> <li>‘For young children (under 7 years) psychological, environmental and family interventions should, if possible, be trialed and evaluated before initiating pharmacological treatment. If all these other interventions have not been effective then stimulants might be considered for this age group in consultation with the parents or guardians and including when appropriate teachers or other carers.’ (p. 9) Note: The manufacturers prescribing information for all stimulants state stimulants should not be used in children under 6 years, since safety and efficacy in this age group have not been established.<sup>371</sup></li> </ul> |
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<sup>371</sup> Ritalin prescribing information says “Ritalin should not be used in children under 6 years, since safety and efficacy in this age group have not been established”. See Novartis Pharmaceuticals Corporation, *Ritalin Prescribing Information*, December 2010. Available at [http://www.pharma.us.novartis.com/product/pi/pdf/ritalin\\_ritalin-sr.pdf](http://www.pharma.us.novartis.com/product/pi/pdf/ritalin_ritalin-sr.pdf). Concerta’s says “safety and efficacy has not been established in children less than six years old or elderly patients greater than 65 years of age”. See McNeil Pediatrics (2010), *Concerta Highlights of Prescribing Information*. Available at [http://www.concerta.net/sites/default/files/pdf/Prescribing\\_Info-short.pdf#zoom=56](http://www.concerta.net/sites/default/files/pdf/Prescribing_Info-short.pdf#zoom=56). Dexedrine’s (a brand of dexamphetamine) says “Long-term effects of amphetamines in pediatric patients have not been well established. DEXEDRINE is not recommended for use in pediatric patients younger than 6 years of age with Attention Deficit Disorder with Hyperactivity”. See Amedra Pharmaceuticals (2010), *Dexedrine Prescribing Information*. Available at [http://www.dexedrine.com/docs/dexedrine\\_PL.pdf](http://www.dexedrine.com/docs/dexedrine_PL.pdf).

| OTHER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | OTHER                                                                                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• 'There is no one single known cause of ADHD....' (Page 10).</li> <li>• '...the effect of medication and behavioural or educational interventions on long-term outcomes such as academic and social and emotional outcomes, has not been established....' (Page 11) AND 'Considering that there is insufficient evidence on the long-term outcomes and long-term adverse effects following use of stimulants, the continuing benefit from, and need for medication should be regularly assessed.' (Page 21)</li> </ul> | <ul style="list-style-type: none"> <li>• 'Heredity, genetic, neuro-imaging and neuro-psychological studies provide evidence for a biological basis for inattention and impulsiveness.' (p. 10)</li> <li>• 'Data from 2000 indicates the prevalence rate of ADHD symptoms among 6–17 year-olds in Australia is around 11%.' (p. 11) (Refer to 4.4.1)</li> </ul> |

Obviously any impact of the publication and official endorsement of the Clinical Practice Points will occur outside the period (1993-2011) for which prescribing data is analysed in this thesis. Nonetheless the Clinical Practice Points process demonstrates that when ADHD critics compete with proponents within the formal process, NHMRC ADHD regulatory processes are not always 'captured'.

#### 5.3.4 Summary of the NHMRC's involvement in ADHD policy processes

As outlined in Box 5 the NHMRC processes for the development of treatment guidelines is based on selecting 'experts' and 'evaluating medical evidence [by] carry[ing] out a systematic literature review'.<sup>372</sup> Through the two guidelines' development processes the NHMRC has consistently selected ADHD proponents or outsourced to an organisation that has in turn selected ADHD proponents.

As identified by the NHMRC the 'systematic literature review' is 'arguably the most important step in the process'.<sup>373</sup> However, the research relied on in the 2009 guidelines process (at least) was clouded by extensive undisclosed conflicts of interest issues.

<sup>372</sup> NHMRC, 'How NHMRC develops its guidelines'.  
<sup>373</sup> NHMRC, 'How NHMRC develops its guidelines'.

Furthermore, the NHMRC and the Commonwealth Government failed to respond when these issues were raised with them privately and only responded slowly when there was adverse publicity.

These observations invite the question as to whether selecting ‘experts’ in a particular condition predisposes outcomes that match their particular perspective and agenda. It also raises issues about how it is best to ensure the independence and ‘rigour’ of evidence used to generate guidelines. These issues are discussed in greater detail at 7.4.2.1.

#### **5.4 The Therapeutic Goods Authority**

The Therapeutic Goods Authority (TGA) is a Division of the Australian Department of Health and Ageing established under the *Therapeutic Goods Act 1989*. The TGA has primary responsibility for the approval for market and the after-market monitoring of the safety of all medications and medical devices.

The Australian Drug Evaluation Committee (ADEC) was appointed to provide advice to the Minister and the Secretary of the Commonwealth Department of Health and Ageing and the TGA on the quality, risk-benefit, and effectiveness of any drug referred to it for evaluation. In 2010, ADEC was replaced by the Advisory Committee on Prescription Medicines which performs a similar function but has more supporting subcommittees to deal with the increasing workload.<sup>374</sup> The members ‘are appointed by the Minister and must have expertise in relevant clinical or scientific fields or appropriate consumer issues’.<sup>375</sup> They generally work elsewhere and attend regular scheduled committee meetings.

The TGA acknowledges that ‘from time-to-time committee members will have an interest in matters being considered by the advisory committee. This is because of the nature of the professional expertise of committee members, and the limited number of people with

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<sup>374</sup> See Department of Health and Ageing (2002), ‘A history of the Australian Drug Evaluation Committee’, Australian Government. Available at <http://www.tga.gov.au/archive/committees-adec-history.htm>

<sup>375</sup> Department of Health and Ageing (DoHA), (2011), *TGA committee members must declare conflict of interest*, Commonwealth of Australia. Available at <http://www.tga.gov.au/newsroom/btn-committee-coi.htm> (accessed 3 July 2013).



expertise and experience in relevant fields in Australia'.<sup>376</sup> In response the TGA has rigorous conflict of interest declarations that require declarations:

- prior to appointment on a committee
- at the time of appointment
- annually
- on an ad hoc basis when they arise or become apparent
- at any meeting at which they might be relevant.

It is unclear what requirements existed when the events described below occurred.

#### **5.4.1 Licencing of Ritalin and Ritalin LA via the TGA**

Ritalin, produced by Novartis, is the brand name for the most commonly prescribed form of methylphenidate. Ritalin LA (long acting) is a slow release form of Ritalin developed to allow 'once a day' use to prevent the need for 'patients' to take the drug more regularly. Ritalin LA contains a higher dose of the active ingredient methylphenidate hydrochloride which is released more slowly through a less permeable membrane.

In 1993 the TGA approved Ritalin for the treatment of ADHD despite advice from the ADEC that was critical of the data in relation to safety and adverse side effects. ADEC commented:

The data to support the use of methylphenidate in the treatment of ADHD have not been generated as a result of a co-ordinated, structured drug development program but rather in a somewhat haphazard manner by the various research groups in various locations over a long period of time. As a result the data package to support this application is deficient in certain areas when compared with that usually required by ADEC and the Department...The data on safety are the most deficient. No evaluable data on laboratory testing has been provided. Data on the incidence of adverse reactions was provided in only four of the short-term placebo-controlled trials. Long-term incidence data is confined only to the retrospective analysis of 250 children.<sup>377</sup>

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<sup>376</sup> DoHA, *TGA committee members must declare conflict of interest.*

<sup>377</sup> Australian Drug Evaluation Committee, *Evaluation of Clinical Data, Part IV*, Meeting No. 1993/2, 10 March

Nine years later, in 2002, the TGA relied on similarly deficient information when it approved the heavier dosage drug Ritalin LA (long-acting). ADEC's comments on the submission supporting Ritalin LA included the following:

The clinical evaluator draws attention to the increased risk of overdose posed by the Ritalin LA capsule compared with Ritalin immediate release tablets due to the increased strength of the LA formulation. There is also no safety data on Ritalin LA for longer than 12 weeks.<sup>378</sup>

When later questioned in the Australian Parliament the TGA justified their decision to licence Ritalin LA by arguing that 'bioequivalence of the registered Ritalin tablet and the proposed Ritalin LA capsule has been satisfactorily demonstrated indicating that significant safety difference between 2 products would be unlikely.'<sup>379</sup> The United States Food and Drug Administration has defined bioequivalence as 'the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study'.<sup>380</sup> In other words the TGA determined that Ritalin and Ritalin LA delivered equivalent doses. This is in direct contradiction to the clinical evaluator's finding that Ritalin LA posed a greater threat of overdose. Without public disclosure of the deliberative material it is impossible to know why the TGA dismissed the concerns raised by ADEC.

Furthermore, in the absence of data for Ritalin LA the TGA relied on the 'deficient' safety data from the original 1993 Ritalin application. The concern raised by the clinical evaluator about the 'increased risk of overdose' for Ritalin LA over Ritalin and the deficiencies in the original Ritalin data might have, but did not, result in the requirement of a rigorous safety analysis of Ritalin LA by the TGA.

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1993. Obtained through *Freedom of Information Act 1992*.

<sup>378</sup> Australian Government, Written Question on Notice, *Ritalin*, Budget Estimates 2006-2007, 31 May–1 June 2006.

<sup>379</sup> Australian Government, Written Question on Notice, *Ritalin*.

<sup>380</sup> United States Food and Drug Administration (2012), *CFR – Code of Federal Regulations, Title 21*, Revised 1 April 2012. Available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=320.1> (accessed 30 October 2012).

#### 5.4.2 Licencing of Strattera by the Therapeutic Goods Administration

One of the two studies that supported Eli Lilly's successful application for approval for marketing in Australia in 2004 was chosen at random by me to analyse its independence. The study '*Atomoxetine in the Treatment of Children and Adolescents with Attention-Deficit/Hyperactivity Disorder: A Randomized, Placebo-Controlled, Dose-Response Study*' was published in 2001.<sup>381</sup> All eighteen authors had pre-existing financial ties to Eli Lilly, with five being shareholders and/or employees. The study was not blind rated. Many of the raters were paid by Eli Lilly and significant potential raters, teachers, in the most relevant setting, schools, were excluded from the study.

The study is attributed to eighteen authors, David Michelson, Douglas Faries, PhD; Joachim Wernicke, MD, PhD, Douglas Kelsey, MD, PhD, Katherine Kendrick, BS, F. Randy Sallee, MD, PhD, Thomas Spencer, MD and eleven members (mostly MDs) of the Atomoxetine ADHD Study Group. Drs Sallee and Spencer (see chapter 4.3.3.1) and all eleven members of the study group 'have acted as paid consultants and/or investigators for studies sponsored by Eli Lilly and Company'.<sup>382</sup> The other five individually identified authors, Drs Michelson, Faries, Wernicke, Kelsey and Ms Kendrick are employees and shareholders of Eli Lilly and Company'.<sup>383</sup>

The rationale for the study was that 'several reports have provided evidence that atomoxetine is superior to placebo in reducing symptoms of ADHD in children and adults. However, the relative efficacy and the relative safety and tolerability of different doses have not been assessed.' Given that Eli Lilly funded the study, and all eighteen authors had financial ties to the company, it is hardly surprising that the results supported the use of Strattera concluding:

The data reported here provide additional evidence of the efficacy and safety of atomoxetine in older children and adolescents with ADHD and that successful treatment with atomoxetine is associated with both symptomatic

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<sup>381</sup> David Michelson, Douglas Faries, et al (2001), 'Atomoxetine in the Treatment of Children and Adolescents with Attention-Deficit/Hyperactivity Disorder: A Randomized, Placebo-controlled, Dose-response study', *Pediatrics*, Vol. 108, No. 5. Available at <http://pediatrics.aappublications.org/cgi/content/full/108/5/e83> (accessed 13 January 2008).

<sup>382</sup> Michelson et al, 'Atomoxetine in the Treatment of Children'.

<sup>383</sup> Michelson et al, 'Atomoxetine in the Treatment of Children'.

and functional improvement.<sup>384</sup>

The study assessed ADHD symptoms, affective symptoms, and social and family functioning using parent and investigator rating scales. It included 297 eight- to eighteen-year-olds diagnosed with ADHD and concluded: 'Social and family functioning also were improved in the atomoxetine groups compared with placebo with statistically significant improvements in measures of children's ability to meet psychosocial role expectations and parental impact.'<sup>385</sup> There was an obvious bias in that one source of ratings, the investigators, received payment from Eli Lilly. Additionally the study was not blinded and parents knew whether the child was medicated or un-medicated, therefore parent ratings must be viewed with caution. Even if parents noticed children were more compliant, this benefit is external to the child. The children were not asked how the medication affected them.

Another notable aspect of the study was the decision to exclude teacher ratings and the performance of children in an educational setting. The rationale offered was that:

This study did not include teacher evaluation.....Although some large studies have had success in getting teacher ratings, our experience in multicenter trials has been unsatisfactory. In 2 previous studies, we had extreme difficulty getting baseline and endpoint teacher evaluations returned consistently. This probably was because these large multisite studies involved several hundred different schools and teachers, as well as a variety of attitudes toward participation. We believed that this problem would have been compounded in the study reported here, because it was a year-round study and included adolescents in junior high and high school with multiple teachers seeing students for limited periods.<sup>386</sup>

Most of the 18 diagnostic criteria are either classroom specific or most easily applied to a classroom setting. Claims that the study provides 'additional evidence of the efficacy and

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<sup>384</sup> Michelson et al, 'Atomoxetine in the Treatment of Children'.

<sup>385</sup> Michelson et al, 'Atomoxetine in the Treatment of Children'.

<sup>386</sup> Michelson et al, 'Atomoxetine in the Treatment of Children'.

safety of atomoxetine in older children and adolescents with ADHD',<sup>387</sup> when the main setting in which ADHD supposedly impacts is ignored, are clearly questionable.

In summary, Eli Lilly was required by the TGA to provide two studies supporting the use of Strattera. Eli Lilly was free to determine who conducted their studies. For the one study I reviewed, they chose paid employees and shareholders to conduct the study. Eli Lilly were also free to choose the design of and controlled the dissemination of results.

#### **5.4.3 Post licencing monitoring of Strattera by the Therapeutic Goods Administration**

Soon after Strattera came on the market concerns emerged about its safety. On 17 December 2004 the US Food and Drug Administration (FDA) issued a statement titled 'New Warning for Strattera', which stated:

The drug's labelling is being updated with a bolded warning about the potential for severe liver injury in patients taking Strattera. The label warns that severe liver injury can progress to liver failure in a small percentage of patients. It cautions clinicians to discontinue the drug in patients who develop jaundice or laboratory evidence of liver injury. It also notes that the actual number of cases of severe liver injury from the drug is not known because of under-reporting.<sup>388</sup>

Soon after the FDA warning, the Australian Therapeutic Goods Administration (TGA) altered the Consumer Medicine Information for Strattera, but made no public announcement.

Less than a year after the information about potentially fatal liver damage came to light, and less than two years after Strattera came on to the Australian market, more safety concerns emerged. On 29 September 2005 the FDA issued a public health advisory announcing they had put the highest possible black box warning on Strattera for suicidal ideation:

Strattera increases the risk of suicidal thinking in children and adolescents with ADHD. Patients who are started on therapy should be observed closely for clinical worsening, suicidal thinking or behaviours, or unusual changes in behaviour. Families and caregivers should be advised to closely observe the patient and to

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<sup>387</sup> Michelson et al, 'Atomoxetine in the Treatment of Children'.

<sup>388</sup> Food and Drug Administration, *Warning on Liver Injury from Strattera*.

communicate changes or concerning behaviours with the prescriber.<sup>389</sup>

This health advisory was well publicised in the US and attracted considerable media attention in outlets such as *The New York Times* and *NBC News*.<sup>390</sup> As well as publicising the warning, the FDA insisted that specific information about these dangers be provided to consumers with every new prescription of Strattera.<sup>391</sup> In contrast, the TGA made little effort to publicise this disturbing information. While six months later (on 19 March 2006) they did put a boxed warning for suicidal ideation on the product information made available to prescribers, they did not issue a press release to ensure parents were informed. The decision about whether to inform parents and/or patients for suicidality was left with individual prescribers. The TGA did not alert Australian media about the warnings or any subsequent adverse event reports of suicidal behaviour.

It was not until November 2006, when I became aware of the warnings and reports and I raised the issue of the TGA's extremely low-key response in the WA Parliament, that the suicidality warning got significant media coverage.<sup>392</sup> I stated:

Although it [the TGA] put a black-box warning of suicide on Strattera on 19 March 2006, it did almost nothing to inform the public of this. Even the term 'black-box warning' is extremely misleading. Until recently, I mistakenly assumed that it was a prominent warning written in black on the outside of drug packaging. However, I was mistaken. In reality, it is the warning on the product information sheet that is available only to doctors, not patients or parents. Apart from the inadequate,

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<sup>389</sup> US Food and Drug Administration, *Public Health Advisory: Suicidal Thinking*. 'In the review of 2,200 patients, 1,357 of whom were taking Strattera, researchers found that 0.4 percent of the children taking the drug reported suicidal thinking, compared to no cases in children taking a placebo. There was also one suicide attempt in the Strattera group.' Amanda Gardner (2005), 'FDA Issues Alert on ADHD Drug Strattera', *Healthday Reporter*, September 29 2005. Available at <http://psychdata.blogspot.com.au/2005/10/fda-issues-alert-on-adhd-drug.html> (accessed 19 May 2010).

<sup>390</sup> See Benedict Carey (2005), 'F.D.A orders new warning on an Attention-Deficit drug', *The New York Times*, 30 September 2005. Available at [http://www.nytimes.com/2005/09/30/health/30drug.html?pagewanted=print&\\_r=0](http://www.nytimes.com/2005/09/30/health/30drug.html?pagewanted=print&_r=0) (accessed 1 December 2012); Associated Press (2005), 'Strattera associated with suicide risks in kids', *NBC News*, 29 September 2005. Available at [http://www.msnbc.msn.com/id/9529101/ns/health-mental\\_health/t/strattera-associated-suicide-risks-kids/#.ULoE.4Z5L1I](http://www.msnbc.msn.com/id/9529101/ns/health-mental_health/t/strattera-associated-suicide-risks-kids/#.ULoE.4Z5L1I) (accessed 1 December 2012); John J. Lumpkin (2005), 'ADHD drug may cause suicidal thoughts in kids', *Associated Press*, 29 September 2005. Available at <http://www.seattlepi.com/lifestyle/health/article/ADHD-drug-may-cause-suicidal-thoughts-in-kids-1184026.php> (accessed 1 December 2012).

<sup>391</sup> US Food and Drug Administration (2004), *New Warning for Strattera*, Talk Paper, 17 December 2004. Available at <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01335.html> (accessed 11 April 2009)

<sup>392</sup> Clara Pirani (2006), 'The Dark Side of a Wonder Drug', *The Australian*, 28 March 2006.

hard-to-find, softly worded information in consumer medicine information, there is no mechanism for ensuring that parents and patients are informed. The TGA had no excuse for its half-baked response...The TGA has done almost nothing to warn parents that Strattera could cause their children's liver to fail or cause their children to want to kill themselves.<sup>393</sup>

When my comments and the information about adverse events were eventually reported, Eli Lilly issued a press release:

Eli Lilly stands by the safety profile of Strattera. It is an important treatment option for people diagnosed with ADHD. We also stand by the rigorous processes put into place by the TGA to ensure patient safety. As Mr Whitely pointed out, following the emergence of new safety-related data, we reported it immediately to the TGA and action was undertaken to update public safety information. Eli Lilly worked closely with the TGA to actively inform prescribing specialists, GPs and pharmacists of the new precautions in the product information to ensure they are able to monitor patients accordingly. All relevant ADHD patient support groups were informed at the time of the Product Information update. An update was posted on the Eli Lilly website.<sup>394</sup>

Eli Lilly's assurance that all relevant ADHD patient support groups were informed was revealing. In Western Australia the Learning and Attentional Disorders Society (LADS), who Eli Lilly supports and which promotes its products, was informed. However the group Drug Free Attention Difficulties Support (DFADS) incorporated, which I founded, which promotes drug free approaches for children with attentional difficulties, was not informed.<sup>395</sup> At no point did Eli Lilly dispute the facts contained in my parliamentary speech. Their press release added little except to emphasise how 'Eli Lilly worked closely with the TGA' and that they praised the 'rigorous process put in place by the TGA'.

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<sup>393</sup> Western Australia (2006), *Parliamentary Debates*, Legislative Assembly, 23 November, p.8772 (Martin Whitely).

<sup>394</sup> Cited in WA 36th Parliament, Mr. M. P. Whitely [9.39 am] Thursday, 23 November 2006.

<sup>395</sup> In 2003 I was instrumental in helping to establish *Drug Free Attention Difficulties Support (DFADS)* designed to achieve two objectives. First to influence public policy as it relates to ADHD and second to provide support to parents and patients who wish to try drug-free approaches.

A very favourable article on Strattera called ‘Drug to cut schoolyard trade’ had previously appeared in the *West Australian* newspaper on 16 April 2004. It featured both Dr Whiting and LADS promoting the drug:

A new non-stimulant drug to treat attention deficit hyperactivity disorder released in Australia this week could help cut the school playground trade in ‘kiddy speed’, a Perth paediatrician has claimed. Ken Whiting said atomoxetine hydrochloride, sold as Strattera, was a once-daily drug which did not contain the stimulants amphetamine or methylphenidate. Excluding stimulants also eliminated the possibility of addiction. Substance abuse is known to be higher in people with ADHD, although that risk can be reduced by up to 50 per cent with treatment. WA support group The Learning and Attentional Disorders Society (LADS) of WA (spokeswoman Michelle Toner) said families would welcome new, clinically proved options for better ADHD management.<sup>396</sup>

Dr Ken Whiting was a key member of LADS and is currently listed as its patron.

However there was no media coverage when the black box warning for suicidality was issued. Several months later when I generated an article in the *West Australian* highlighting the suicide warning Dr Whiting responded: ‘the drug company is trying to make practitioners aware of it so that we can watch patients and ensure there’s no problems. It’s important that patients don’t stop taking the drug suddenly but see their doctor.’<sup>397</sup>

In November 2011 the TGA added a warning about ‘clinically significant increases in heart rate and blood pressure’. The safety advisory warned:

Atomoxetine [Strattera] is contraindicated in patients with symptomatic cardiovascular diseases, moderate to severe hypertension or severe cardiovascular disorders, whose condition would be expected to deteriorate if they experienced increases in blood pressure or in heart rate that could be

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<sup>396</sup> Liz Tickner (2004), ‘Drug to cut schoolyard trade’, *The West Australian*, 16 April.

<sup>397</sup> Cathy O’Leary (2005), ‘WA kids still biggest users of ADHD pills’, *The West Australian*, 1 October.



clinically important'. It followed new data obtained from clinical trials sponsored by Eli Lilly.<sup>398</sup>

From 2004, when Strattera first came on to the market, until March 2012, there were one hundred and six voluntary adverse event reports made to the Australian Therapeutic Goods Administration, including over fifty of self-harm or suicidal ideation for Strattera.<sup>399</sup> It is impossible to know the true number of actual events, as the voluntary nature of the reporting system means only a fraction of the actual incidents gets reported. A 2008 study by Curtin University pharmacologist Con Berbatis identified that for the prescription of all drugs by Australian General Practitioners only two percent of adverse events are reported.<sup>400</sup>

A sample from the Adverse Drug Reactions Committee (ADRAC) adverse event reports for Atomoxetine Hydrochloride (Strattera) is available in Appendix 4. The TGA made adverse event reports available upon request but did not publish them either through the media or the internet. Without requesting the adverse event reports there was no way of the public accessing this information.

In November 2010, the Gillard Government announced a review of the way the TGA communicates 'to ensure that the Australian public is better informed about the benefits and risks of therapeutic goods...and to address community concerns that have been raised about the lack of information made available by the TGA.'<sup>401</sup> In June 2011 the 'Review to Improve the Transparency of the TGA Final Report' recommended the 'TGA make its Adverse Events Database available to, and searchable by, the public in a manner that supports the quality use of therapeutic goods'.<sup>402</sup> However when the change was implemented only summaries of the total number of adverse events were made available online, individual de-identified case

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<sup>398</sup> See Therapeutic Goods Administration (2011), 'Atomoxetine (STRATTERA) – risk of increased blood pressure and/or heart rate', 2 November. Available at <http://www.tga.gov.au/safety/alerts-medicine-atomoxetine-111102.htm> (accessed 10 December 2011).

<sup>399</sup> Adverse events information related to Strattera obtained from the Therapeutic Goods Administration's Public Case Detail reports.

<sup>400</sup> Con Berbatis (2008), 'Primary care and Pharmacy: 4. Large contributions to national adverse reaction reporting by pharmacists in Australia', *i2P E-Magazine*, Issue 72, June 2008.

<sup>401</sup> Department of Health and Ageing, 'Call for input: Review to improve transparency of the Therapeutic Goods Administration', 11 February 2011. Available at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101-call-for-input-101222.htm> (accessed 25 December 2013).

<sup>402</sup> Panel to Review the Transparency of the Therapeutic Goods Administration, 'Review to improve the transparency of the Therapeutic Goods Administration Final Report June 2011.' Available at <http://www.tga.gov.au/pdf/consult/review-tga-transparency-1101-final-report.pdf> (accessed 25 December 2013).

reports like those summarised at appendix 4 were no longer available on request. This followed significant media and online coverage of the details of these de-identified individual reports.

The handling of Ritalin, Ritalin LA and Strattera are not the only examples of questionable regulatory practices by the TGA. From January to September 2005 the US FDA issued twenty black box warnings (see chapter 3) for prescription drugs sold in both the US and Australia. However, the Australian TGA issued warnings for only five of these twenty.<sup>403</sup> In response to a question on notice in the Senate, the TGA admitted that it did not monitor the FDA's drug warnings stating: 'The TGA does not record which drugs sold in the US, with black box warnings in the US approved prescribing information document, do not carry black box warnings in the Australian prescribing information (P1) document'.<sup>404</sup>

While this example does not relate to ADHD medications the willingness of the TGA to accept 'deficient' foreign safety data as demonstrated in the case of Strattera to approve drugs, yet ignore emerging overseas evidence of the dangers of these drugs, as demonstrated by the application of boxed warnings, is consistent with the assertion that the TGA has demonstrated a neo-liberal corporate bias.

#### **5.4.4 Off Label Prescribing and the TGA**

Pharmaceutical companies receive approvals from the FDA or TGA for the treatment of conditions within specified guidelines. However, in both the US and Australia, once a drug has been approved doctors are free to prescribe it as they see fit, even in contravention to the manufacturer's recommendations (off label). The individual clinicians are legally liable for any harm that may arise from their unapproved speculative prescribing.

However off label prescribing occurs so regularly that it has, in many cases, become the norm. A 2009 study found that 62 percent of U.S. pediatric office visits included off-label prescribing, with younger children at higher risk of receiving off-label prescriptions.<sup>405</sup> In 2003 an Australian nationwide survey of 435 general paediatricians and 187 child and adolescent psychiatrists 40

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<sup>403</sup> Australian Government (2006), *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005*, Community Affairs Legislation Committee, 3 February.

<sup>404</sup> Australian Government, Written Question on Notice, *Black Box Warnings*, Budget Estimates 2006–2007, 31 May–1 June 2006.

<sup>405</sup> Alicia Bazzano MD MPH, Rita Mangione-Smith MD et al (2009), 'Off-label Prescribing to Children in the United States Outpatient Setting', *Academic Pediatrics*, Vol 9;2, pp.81-88.

percent reported off-label prescribing of psychotropic medications.<sup>406</sup>

Pharmaceutical companies profit but are immune to liability for any damage caused by this 'off label' use. Many children are prescribed drugs either at doses above the approved dosage, or in combination with contraindicated medications, because of the clinical judgement of prescribers.

Methylphenidate, for example, is not approved for the treatment of children younger than six.

In 1995 the 'off label' prescribing of Ritalin was so widespread in the US that the Drug Enforcement Agency (DEA) expressed concern 'that children under the age of six are being treated with methylphenidate contrary to labelling guidelines in the absence of controlled studies suggesting that this is appropriate'. The DEA entered the debate because they considered Ritalin use a possible 'risk factor for substance abuse'.<sup>407</sup>

Whatever protection is provided to Australian consumers by the Therapeutic Goods Authority licensing system is weakened by 'off label' prescribing. However, the drug companies benefit from increased sales with no liability for the clinical judgement of individual practitioners. Drug companies obviously deserve protection from liability due to individual rogue prescribers, but the practice of using psychotropic drugs 'off label' is so common that it represents normal practice and the drug companies must be aware that this is the case.

Both the 1998 and 2009 NHMRC guidelines processes recommended 'off label' prescribing of psychotropic drugs. For instance the 2009 draft guidelines recommendation that SSRI antidepressant medication (fluoxetine/Prozac) 'may be considered for adolescents with ADHD and comorbid moderate to severe depression' is in direct contravention of the manufacturer's prescribing guidelines which state 'Prozac is not recommended for use in children and adolescents under 18 years of age'.<sup>408</sup> Similarly as with the draft guidelines the recommendation that Methylphenidate be used as a second line treatment in children under six years of age directly contravenes the manufacturer's guidelines that state 'Ritalin should not be used in children under 6 years, since safety and efficacy in this age group have

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<sup>406</sup> D Efron, H Hiscock, JR Sewell et al (2003), 'Prescribing of psychotropic medications for children by Australian paediatricians and child psychiatrists', cited in Royal College of Psychiatrists London (2007), 'Use of licensed medicines for unlicensed applications in psychiatric practice: College Report CR142 Available at <http://www.rcpsych.ac.uk/files/pdfversion/cr142.pdf> (accessed 5 May 2013).

<sup>407</sup> Breggin, *Talking back to Ritalin*, p.186.

<sup>408</sup> Eli Lilly Australia Pty Limited, *Prozac: Consumer Medicine Information*, (June 2010). Available at [http://www.betterhealth.vic.gov.au/bhcv2/bhcmcd.nsf/pages/lycprozc/\\$file/lycprozc.pdf](http://www.betterhealth.vic.gov.au/bhcv2/bhcmcd.nsf/pages/lycprozc/$file/lycprozc.pdf) (accessed 3 February 2012)

not been established'.<sup>409</sup> This government endorsement of off label prescribing gives official endorsement to speculative prescribing against the recommendation of commercial interests that have the most economically to gain. From a profit maximisation perspective this works to enhance the interests of the ADHD drug manufacturers by boosting their sales and externalising any legal risks from potential harms from 'off label' use to either clinicians who prescribes or the government who endorses the practice.

## 5.5 The Pharmaceutical Benefits Scheme

The Commonwealth Government currently subsidises dexamphetamine (since 1992), Ritalin (2005), Ritalin LA, Concerta and Strattera (2007). The subsidisation significantly reduces the cost to consumers of the drugs. Before Concerta was added to the PBS, it was \$150 a script, but after subsidisation it cost \$31.30.<sup>410</sup> Subsidising drugs through the Pharmaceutical Benefits Scheme removes a financial barrier to their use.

Decisions to subsidise pharmaceuticals via the PBS are ultimately made by the Commonwealth Minister for Health or in the case of decisions above \$10million per annum the full cabinet. The Minister for Health and the Cabinet almost always follows the recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC).

The PBAC is an 'independent expert body appointed by the Australian Government. Members include doctors, health professionals, health economists and consumer representatives [whose] primary role is to recommend new medicines for listing on the Pharmaceutical Benefits Scheme. No new medicine can be listed unless the committee makes a positive recommendation.'<sup>411</sup> In determining whether to recommend a medicine for listing, the PBAC is supposed to consider 'the medical conditions for which the medicine was registered for use in Australia, its clinical effectiveness, safety and cost-effectiveness...compared with other treatments.'<sup>412</sup> The PBAC has two advisory sub-committees to assist with analysis and advice in these areas, the Drug Utilisation Sub

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<sup>409</sup> *Ritalin Prescribing Information* (revised June 2013) available at [http://www.pharma.us.novartis.com/product/pi/pdf/ritalin\\_ritalin-sr.pdf](http://www.pharma.us.novartis.com/product/pi/pdf/ritalin_ritalin-sr.pdf) (accessed 24 July 2013)

<sup>410</sup> Louise Hall, 'New front opens in ADHD war', *Sydney Morning Herald*, 10 February 2008.

<sup>411</sup> Department of Health and Ageing, Pharmaceutical Benefits Advisory Committee (PBAC), Australian Government. Available at <http://www.pbs.gov.au/info/industry/listing/participants/pbac> (accessed 29 October 2012)

<sup>412</sup> Department of Health and Ageing, Pharmaceutical Benefits Advisory Committee (PBAC)

Committee and the Economics Sub Committee. The Drug Utilization Sub Committee assesses estimates on projected usage and financial cost and analyses data on actual use. The Economics Sub Committee assesses clinical and economic evaluations of medicines submitted to the PBAC for listing.<sup>413</sup> The current membership includes health economists, pharmacologists, epidemiologists, a pharmacist, pharmacologists, general practitioners and industry representatives.<sup>414</sup>

The following is a detailed analysis of the events relevant to the subsidisation of Strattera via the PBS in 2007.

### **5.5.1 Case Study: The marketing of Strattera and subsidisation via the Pharmaceutical Benefits Scheme**

Strattera is pharmaceutical company Eli Lilly's brand name for atomoxetine hydrochloride, a noradrenaline reuptake inhibitor. Unlike the most commonly prescribed ADHD drugs dexamphetamine and methylphenidate, Strattera is not amphetamine based and has the advantage of being non-addictive and unsuitable for illicit use. It is the only non-stimulant drug approved for the treatment of ADHD in Australia.

Atomoxetine hydrochloride was first trialled in 1982 as an antidepressant branded Tomoxetine but was found to be ineffective.<sup>415</sup> Eli Lilly refused a request by me to release results of trials of Tomoxetine as an antidepressant arguing:

It is important to note that the population in these trials is different from the population in which atomoxetine hydrochloride is approved for use by the TGA in Australia. As a result, the relevance of the trials for current clinical practice is significantly diminished.<sup>416</sup>

Strattera's now established propensity to cause suicidal ideation may explain why atomoxetine hydrochloride was unsuitable as an antidepressant. Eli Lilly re-branded Tomoxetine as Strattera,

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<sup>413</sup> Department of Health and Ageing, Pharmaceutical Benefits Advisory Committee (PBAC)

<sup>414</sup> Department of Health and Ageing, *Economics Sub Committee (ESC)*, Commonwealth of Australia. Available at <http://www.pbs.gov.au/info/industry/listing/participants/economics-subcommittee-esc> (accessed 23 June 2013)

<sup>415</sup> Chouinard, 'An early phase II clinical trial, p. 126.

<sup>416</sup> *Letter to Martin Whitely MLA*, from Eli Lilly Australia Pty Ltd, 1 December 2009.

a revolutionary non-stimulant ADHD drug. In 2002 the US FDA approved Strattera for the treatment of ADHD. It was approved in Australia in early 2004.

Prior to Strattera, Eli Lilly had not marketed an ADHD medication. When Strattera was first marketed in Australia Eli Lilly's Australian website on Strattera contained a section entitled 'What Is ADHD?' It stated, 'Attention-Deficit/Hyperactivity Disorder is a neurological condition related, in part, to the brain's chemistry and anatomy' which 'manifests itself as a persistent pattern of inattention and/or hyperactivity-impulsivity' and that 'While some children outgrow ADHD, about 60 per cent continue to have symptoms into adulthood.'<sup>417</sup> It presented the hypothesis that the aetiology is 'neurological', related to 'brain chemistry and anatomy', and that in most cases ADHD is a life-long condition, as if it were a certainty.

This is a clear example of biomedicalism with a profit motive and similar to Eli Lilly's aggressive approach to marketing Strattera in the US. Eli Lilly marketed Strattera for adult ADHD in a way that blurs the lines between the stresses of modern life and disease in advertisement for Strattera in the *US News & World Report*.

Distracted? Disorganized? Frustrated? Modern Life or Adult ADD? Many adults have been living with Adult attention deficit disorder and don't recognize it. Why? Because its symptoms are often mistaken for stressful life.<sup>418</sup>

Eli Lilly attracted the attention of the US Food and Drug Administration (FDA) for making unsubstantiated claims about Strattera. In June 2005 an American TV advertisement attracted the ire of the FDA, which issued a warning letter stating 'The TV ad is false or misleading because it inadequately communicates the indication for Strattera and minimizes the risks associated with Strattera.'<sup>419</sup>

In Australia Eli Lilly publicised Strattera's non-addictive properties in an environment of growing concern about the safety of stimulants and their illicit use. In Western Australia Strattera was promoted through a very favourable article 'Drug to cut schoolyard trade' in the *West*

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<sup>417</sup> Eli Lilly Website, [http://www.strattera.com/1\\_3\\_childhood\\_adhd/1\\_3\\_1\\_1\\_what\\_is.jsp](http://www.strattera.com/1_3_childhood_adhd/1_3_1_1_what_is.jsp) (accessed 14 January 2008, now removed from site).

<sup>418</sup> Eli Lilly advertisement for Strattera, appeared in *US News & World Report*, 26 April 2004, p.65.

<sup>419</sup> Food and Drug Administration (2005), *Letter to Eli Lilly and Company*, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration, Maryland. Available at <http://www.pharmcast.com/WarningLetters/Yr2005/Jun2005/EliLilly0605.htm> (accessed 23 September 2008).

*Australian* newspaper on 16 April 2004:

A new non-stimulant drug to treat attention deficit hyperactivity disorder released in Australia this week could help cut the school playground trade in 'kiddy speed', a Perth paediatrician has claimed. Ken Whiting said atomoxetine hydrochloride, sold as Strattera, was a once-daily drug which did not contain the stimulants amphetamine or methylphenidate. Excluding stimulants also eliminated the possibility of addiction. Substance abuse is known to be higher in people with ADHD, although that risk can be reduced by up to 50 per cent with treatment. WA support group The Learning and Attentional Disorders Society (LADS) of WA (spokeswoman Michelle Toner) said families would welcome new, clinically proved options for better ADHD management.<sup>420</sup>

The following day another favourable article entitled 'Aid for new ADHD drug sought' appeared in the *West Australian* lobbying for Strattera to be subsidised via the Pharmaceutical Benefits Scheme. The article quoted Western Australian Secondary School Executives' Association president Ray Maher as saying 'the drug could be a boon to schools and particularly principals ultimately responsible for ensuring the security and correct administration of dexamphetamine – sometimes referred to as kiddie speed'.<sup>421</sup>

At the same time more articles promoting Strattera's non-addictive advantage appeared in other Australian newspapers. Page 3 of the Brisbane *Courier Mail* carried an article titled 'New drug combats child addiction fears'. It quoted Dr Michael McDowell, a developmental pediatrician from the Child Development Network at Brisbane's Mater Hospital, who conducted the Australian clinical trials of Strattera, as saying: 'The fear parents have of amphetamines...is the possibility of addiction and abuse, whereas this current medication doesn't come with that risk.'<sup>422</sup> Page 3 of the *Sydney Morning Herald* carried an article titled 'Milder new drug hailed for attention disorder'. It also quoted McDowell:

There is no risk they will take too much for a psychological high...there's no risk they will sell it on to other children in the playground because it can't be taken as a

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<sup>420</sup> Liz Tickner (2004), 'Drug to cut schoolyard trade', *The West Australian*, 16 April.

<sup>421</sup> Charlie Wilson-Clark (2004), 'Aid for new ADHD drug sought', *The West Australian*, 17 April.

<sup>422</sup> Kylie Walker (2004), 'New drug combats child addiction fears', *Courier-Mail*, 15 April.

recreational drug. But it does have similar side effects to the other drugs including abdominal pain, decreased appetite, increased blood pressure and vomiting. There are side effects, but overall they're milder and I suspect the likelihood that parents would stop the medication because of side effects is less than existing medications.<sup>423</sup>

Comments like McDowell's, and the fact that Strattera was non-addictive, gave the appearance that it was a safer option than stimulants. The co-operation between the pharmaceutical company, the patient support group they sponsor (LADS), researchers they pay, and educators, to obtain pharmaceutical benefits scheme subsidisation of Strattera is a clear demonstration of biomedicalized access orientated consumerism.

Subsequent to this lobbying, significant evidence of potential significant harms, particularly suicidality and potentially fatal liver damage emerged. Lobbying efforts by ADHD critics to restrict access to Strattera attracted media coverage but were unsuccessful.<sup>424</sup>

In addition I wrote a letter on 22 December 2006 to the then Health Minister, the Hon. Tony Abbot expressing my concern that Strattera had been recommended for inclusion in the Pharmaceutical Benefits Scheme.<sup>425</sup> The response received from the assistant Minister for Health, Christopher Pyne, was dismissive of my concerns concluding;

All medicines have potential risks. The balance between the benefits offered by the medicine and the potential risks associated with its use, need to be considered when these products are prescribed. The decision to use a particular medicine should be made between the prescribing medical practitioner and the patient, and should entail informed consent.<sup>426</sup>

On 5 June 2008 following the change of government and the election of the Rudd Labor

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<sup>423</sup> Ben Wyld (2004), 'Milder new drug hailed for attention disorder', *The Sydney Morning Herald*, 15 April.

<sup>424</sup> For example, see media articles on Strattera: Amanda Banks (2006), 'Drug risk warning inadequate: MP', *The West Australian*, 28 November; Cath Hart (2007), 'ADHD treatment skips curbs', *The Australian*, 16 April; Stephen Lunn & Julie-Anne Davies (2009), 'MP wants ADHD drug ban', *The Australian*, 12 January.

<sup>425</sup> *Letter from Martin Whitely MLA to the Hon Tony Abbott, Minister for Health and Ageing*, 22 December 2006.

<sup>426</sup> *Letter from Chris Pyne Assistant Minister for Health and Ageing to Martin Whitely MLA*, 14 February 2007.



government, I also wrote to the Minister for Health and Ageing, the Hon. Nicola Roxon, outlining numerous adverse event reports reported to the TGA, including suicide ideation.<sup>427</sup> I asked the Health Minister to reverse the decision to subsidise Strattera via the PBS, but this request was rejected. Ultimately the lobbying to prevent the Pharmaceutical Benefits Scheme subsidisation was unsuccessful as Strattera was listed on the PBS on 1 July 2007 and remains so.

Despite its warning for suicidal ideation and potentially fatal liver damage, Strattera was placed on the Pharmaceutical Benefits Scheme (PBS) on 1 July 2007 at an anticipated cost to taxpayers of \$101.2 million over four years.<sup>428</sup>

Eli Lilly had applied unsuccessfully on at least three previous occasions to have Strattera subsidised via the PBS. In November 2008 I requested, via Freedom of Information, copies of all documents relating to the decision of the Pharmaceutical Benefits Advisory Committee (PBAC) to recommend Strattera's listing on the PBS. I was particularly interested in what consideration had been given by the PBAC to Strattera's black box warning for suicidal ideation and the numerous adverse event reports. The Department of Health and Ageing (DoHA) refused to release all but a tiny percentage of heavily censored and irrelevant documents.

The Administrative Appeals Tribunal heard my appeal against DoHA's refusal to release the documents in April 2010. The DoHA argued successfully that they had erred in giving me any documents because the Health Act 1953 prevented anyone working for the Commonwealth revealing information relating to the affairs of a (legal) person (in this case Eli Lilly).

The net effect is that this has created a precedent and the public has no legal right to know why the PBAC recommends taxpayers subsidising any drug. In essence Eli Lilly benefited from a price subsidy worth an estimated \$101.2 million over four years funded by Australian taxpayers but the public is not allowed to know why.

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<sup>427</sup> Letter from Martin Whitely MLA to the Hon Nicola Roxon, Minister for Health and Ageing, 5 June 2008.

<sup>428</sup> Cath Hart (2007), ADHD drug earns subsidy despite suicidal side effects, *The Australian* April 13 <http://www.theaustralian.com.au/news/health-science/adhd-drug-earns-subsidy-despite-suicidal-side-effects/story-e6frg8y6-111113333953>

### 5.5.2 Other evidence of Pharmaceutical Benefits Scheme Regulatory Capture

A 2013 review by the Grattan Institute of the cost to the Australian Government of subsidising PBS drugs provided evidence of regulatory capture of PBS process and concluded both Australian citizens and the Commonwealth Government pay far too much for prescription drugs.<sup>429</sup> In contrast to New Zealand, where a total budget figure is set for all subsidised drugs, in Australia there is no upper limit on expenditure on PBS drugs.

‘For Australia’s PBS... decisions on drug pricing are opaque and unconstrained by a budget. Key decisions are made by a committee inside the Department of Health and Ageing that includes among its six members two representatives of drug companies. They have little interest in keeping prices low.’<sup>430</sup>

The committee referred to in the quote above is the Pharmaceutical Benefits Pricing Authority (PBPA). After a drug has been licenced by the TGA and recommended for PBS listing by the PBAC the PBPA recommends the maximum price that can be charged. It also recommends the extent of the Government payment to manufacturers through the PBS. The PBPA is established at the direction of the Minister for Health. Two of the six members on the committee ‘are industry lobbyists from Medicines Australia and the Generic Medicines Industry Association’ and its recommendations remain private.<sup>431</sup> Having significant industry representation in a process that is closed, and has no budgetary constraints on its recommendations for the expenditure of taxpayer funds, is consistent with the existence of regulatory capture.

### 5.6 The effects of other Commonwealth Government policies on the economics of diagnosing and treating ADHD

In addition to the PBS the Australian Government also affects the diagnosis and treatment of ADHD through other economic incentives. Un-timed Medicare co-payments mean that

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<sup>429</sup> The Grattan Institute is a think tank established to develop Australian public policy. It was formed in 2008 and is funded by the Australian and Victorian Governments and the private sector including BHP and charitable foundations. For further information see <http://grattan.edu.au/about-us>.

<sup>430</sup> Duckett, S.J., P. Bredon et al (2013), *Australia’s bad drug deal: high pharmaceutical prices*, Grattan Institute, Melbourne, p.2. Available at [http://grattan.edu.au/static/files/assets/5a6efeca/Australias\\_Bad\\_Drug\\_Deal\\_FINAL.pdf](http://grattan.edu.au/static/files/assets/5a6efeca/Australias_Bad_Drug_Deal_FINAL.pdf) (accessed 25 June 2013).

<sup>431</sup> Duckett, *Australia’s bad drug deal*.

paediatricians receive the same financial reward for a rushed or comprehensive consultation. Along with significant patient 'out of pocket costs' for allied health treatment (for example speech and occupational therapy), this may encourage the speedy diagnosis of ADHD rather than a full assessment of a child's medical and social needs.

In some Australian states extra in-class support is provided to students with a range of diagnosed disabilities. While a diagnosis of ADHD does not qualify for extra in-class support in state government schools, parents of a child diagnosed with ADHD may be entitled to a fortnightly Commonwealth carer allowance of \$87.30 (in 2008). Australian Government welfare agency Centrelink advised 'An ADHD diagnosis is usually sufficient but does not automatically guarantee the allowance. Parents must show the child has a physical, intellectual or psychiatric disability (that impacts on the family) and is likely to suffer from the disability permanently or for an extended period (that is, for 12 months or more)'.<sup>432</sup>

By contrast, in Finland 'diagnoses' do not fulfil the gate-keeping function...every student who needs it is entitled to additional assistance. There, results indicating poor academic achievement acts as a barometer indicating the need for additional support.<sup>433</sup> Finnish schools concentrate their resources on students whose failure to thrive is evidenced by poor results compared to their peers, rather than via subjective notions of 'disability'.

The Australian Government's approach is to respond to a child's diagnosis of ADHD rather than the individual circumstances of the child. It is consistent with a case management neo-liberal rationalist approach to public sector service delivery which Abraham contends – along with regulatory capture – is part of the explanation for the pharmaceuticalization of ADHD (refer to 2.9).

## **5.7 Summary of the Australian Government experience of Pharmaceuticalization and Regulatory Capture**

Despite the incomplete nature of records prior to 2008 the magnitude of the increase in ADHD prescribing shown in Figures 1,2 and 3 provide strong evidence of the pharmaceuticalized response within Australia to ADHD. The evidence in this chapter

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<sup>432</sup> Source: Email response to Martin Whitely received from Centrelink on 5 February 2008.

<sup>433</sup> Graham, 'Drugs, labels and (p)ill-fitting boxes', p.97.

indicates that from the period 1993 to 2010 the development of ADHD policy and regulation at a Commonwealth level has been captured by ADHD proponents. The rapid growth in National ADHD prescribing rates from 1993 to 2011 coincided with this period of ADHD proponent regulatory capture.

Although the Clinical Practice Point Process began in 2011, the Clinical Practice Points were not published until September 2012, so any effect on diagnosing and prescribing practices will be outside the period covered in this thesis. The Clinical Practice Points, however, indicate that while regulatory capture by ADHD proponents of Commonwealth Government regulatory agency processes may be the 'norm', it is not inevitable.

In addition all of the following events outlined in this chapter are evidence of significant regulatory capture by the pharmaceutical industry of the operation of government agencies notionally established to protect the public interest:

- Licencing of Ritalin, Ritalin LA and Strattera via the TGA showed that the licencing process for new ADHD drugs was far from rigorous and that the benefit of any doubt is given to pharmaceutical companies seeking to licence a product for market.
- Reluctance of the TGA to publish information about adverse effects risks of ADHD drugs.
- Failure of the TGA to monitor and act upon the FDA's imposition of significant safety warnings on drugs marketed in Australia with TGA approval.
- Tacit endorsement of off label prescribing through PBS sponsorship.
- Department of Health and Ageing actively seeking to prevent public access to information (by opposing Freedom of Information access) used to justify significant expenditure of public funds via the PBS.
- Direct involvement of the pharmaceutical industry in determining Pharmaceutical Benefits Pricing Authority recommendations on the pricing and level of government subsidy of PBS drugs.

A more comprehensive analysis of the evidence in this chapter in regards to the relationship between ADHD pharmaceuticalization and regulatory capture is presented in Chapter 7.

## **Chapter 6. Western Australian and New South Wales ADHD policy and Regulatory Capture**

Chapter 4 presented relevant statistical data about WA and NSW ADHD child prescribing rates from 1992 to 2011. This chapter outlines the history of WA and NSW ADHD policy and regulation. It provides information for the analysis of the relationship between regulatory capture and pharmaceuticalization discussed in detail in Chapter 7.

### **6.1 Western Australian State Government Responsibilities in Regard to ADHD**

The Western Australian (WA) State Government has several responsibilities in regard to ADHD including:

- Educating students diagnosed or at risk of diagnosis of ADHD.
- Running health and mental health services that potentially diagnose (and treat) children with ADHD.
- Regulating the prescribing and dispensing of pharmaceuticals, including dexamphetamine and methylphenidate, with a high potential for diversion for illicit use.

WA State Government schools educate the majority of children in Western Australia. Given that many of the symptoms relate to behaviours demonstrated in a classroom setting, schools, or more specifically their teachers, play a central role in providing information that forms the basis of the diagnosis. They also are responsible for the administration of medication within school hours.

The WA State Government also run health services including public hospitals, Child and Adolescents Mental Health Services and State Child Development Services which diagnose and treat children.

However, the WA State Government responsibility that has attracted the greatest attention is its role in regulating the prescribing of ADHD psycho-stimulants. The potential for illicit diversion, rather than the controversial nature of ADHD and the potential side effects of the drugs, is the primary reason most extra accountability controls over the prescription of ADHD stimulants were initially established.

State Governments have primary responsibility for monitoring Schedule 8 drugs and poisons, otherwise known as Controlled Drugs. However all states have agreed to a standardised approach where the classification of drugs is recommended by the National Drugs and Poisons Schedule Committee, a committee of the TGA which has representation from state health authorities.<sup>434</sup>

Schedule 8 drugs are substances and preparations for therapeutic use which have high potential for abuse and addiction. They are called Schedule 8 drugs because they are listed on Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons, which is published under the Commonwealth Therapeutic Goods Act. All drugs on Schedule 8 require a doctor to have a Schedule 8 permit before prescribing treatment. Individual state governments can restrict which clinicians can prescribe schedule 8 drugs and place other regulatory controls - for example reporting requirements - on the prescribing and dispensing of Schedule 8 drugs.<sup>435 436</sup>

Despite Strattera having the highest possible 'black box' warning for suicidal ideation and a record of serious adverse event reports that, at least superficially, appears worse than stimulants, it is not subject to the same level of prescription controls.<sup>437</sup> This is because Strattera is a Schedule 4 prescription drugs because it does not have the same risks of addiction and abuse.

Schedule 4 drugs are drugs and poisons (otherwise known as prescription only drugs) which can only be prescribed by a doctor, but do not need to be authorised by the WA State Health Department. Neither Schedule 8 nor Schedule 4 drugs can be advertised directly to the public and are often subsidised via the Commonwealth Government's Pharmaceutical

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<sup>434</sup> Department of Health and Ageing (2011), *National Drugs and Poisons Schedule Committee (NDPSC)*, Commonwealth of Australia. Available at <http://www.tga.gov.au/archive/committees-ndpsc.htm> (accessed 4 July 2013).

<sup>435</sup> Department of Health, (2012), *Schedule 8 Medicines Prescribing Code*, Pharmaceutical Services Branch, Public Health and Clinical Services Division, Department of Health, Perth, Western Australia. Available at <http://www.public.health.wa.gov.au/cproot/4947/2/S8-medicines-prescribing-code-C20121121AG-2.pdf> (accessed 19 May 2013).

<sup>436</sup> Pharmacy Guild of Australia. See [http://www.5cpa.com.au/iwov-resources/documents/The\\_Guild/PDFs/News%20and%20Events/Publications/Fact%20Sheets/scheduling\\_system.pdf](http://www.5cpa.com.au/iwov-resources/documents/The_Guild/PDFs/News%20and%20Events/Publications/Fact%20Sheets/scheduling_system.pdf) (accessed 19 may 2013).

<sup>437</sup> Martin Whitely, 'Strattera's sad story – (Warning, it may make you want to kill yourself)', *Speed Up & Sit Still*, 30 August 2012. Available at <http://speedupsitstill.com/strattera>

Benefits Scheme, with phone authority needed from the Commonwealth Department of Human Services for increased amounts or multiple repeats.

## **6.2 Timeline of significant events regarding the Western Australian Government's response to ADHD**

The events detailed in this chapter occurred during the terms of the Court liberal Government (1993-2001), the Gallop and Carpenter Labor Governments (2001-2008), and the Barnett Liberal Government (2008 to present).

The majority of this chapter identifies and analyses the history of WA policy formulation and regulation in regards to ADHD. Box 7 below is a timeline of significant events.

### **Box 7 - Timeline of significant events regarding the Western Australian Government's response to ADHD**

The following is a timeline of significant events regarding the Western Australian State Government's response to ADHD. I have *italicised* events that are described in this chapter.

1989- An estimated 880 Western Australians receive stimulant medication.

1997- *The Report of the Technical Working Party on Attention Deficit Disorder to the Cabinet Sub-Committee is published.*

1997- *The Stimulants Committee was established.*

1998- *The International Panel on the Diagnosis and Treatment of ADHD meets and prepares the Report of the International Panel on Attention Deficit Hyperactivity Disorder to the Mental Health Division of Western Australia (1999).*

2001- Gallop Labor Government elected in February.

2002- *The report Attentional Problems in Children: Diagnosis and Management of Attention Deficit Hyperactivity Disorder (ADHD) and Associated Disorders was published by the Western Australian Mental Health Division.*

2003- *The Western Australian Government establishes the Stimulants Regulatory Scheme and abolishes 'Block Authorisation' and the Stimulants Committee is replaced by the Stimulants Panel.*

2004- *Western Australian Legislative Assembly Education and Health Standing Committee conducted a Parliamentary Inquiry into ADHD.*

2005- *Western Australian Minister for Health, Jim McGinty, appointed a Ministerial Implementation Committee (MICADHD) to implement the recommendations of the Western Australian Legislative*

*Assembly Education and Health Committee 2004 Parliamentary Inquiry into ADHD.*

2005- *The Australian Secondary School Alcohol and Drug Survey (ASSAD) indicated 9,492 (5.5%) of 12-17 year olds had abused ADHD stimulants in the last year.*

2005- Poisons regulations were enacted to prevent pharmacy shopping for ADHD drugs.

2007- *The Western Australian Government conducts the Amphetamine (Ice) Summit.*

2008- The Carpenter Labor Government narrowly lost office to the Barnett Liberal/National Government.

2009-2010- *Two State Government multidisciplinary ADHD clinics were opened.*

2010- *The Raine ADHD Study, Long-term outcomes associated with stimulant medication in the treatment of ADHD in children was published by the Western Australian Department of Health.*

### **6.3 WA ADHD policy and politics 1994 -2001**

The history of WA ADHD policy and practice will be discussed in two distinct periods. The first is the period 1994 to 2001 when policy development and implementation was dominated by the biomedicalized view of ADHD proponents. The second is the period 2001 to 2011 when policy development was contested by ADHD proponents and ADHD critics – including myself as a State Labor Party MP elected in 2001 - who adhere to the ‘medicalization thesis’ of ADHD.

Concerns about WA rates of prescription and the diagnostic practices of some unnamed Perth paediatricians first emerged in the mid-1990s. In 1995 the Court Liberal State Government set up the Technical Working Party on Attention Deficit Disorder ‘to report to government on the incidence of ADHD in Western Australia and to seek expert opinion on the appropriate diagnosis and treatment for the condition’.<sup>438</sup> Published in 1997 *The Report of the Technical Working Party on Attention Deficit Disorder to the Cabinet Sub-Committee* highlighted that, in 1994, Western Australian child (5-14) prescription rates were between two to two and a half times the national average, and that there had been a massive (forty-

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<sup>438</sup> *The Report of the Technical Working Party on Attention Deficit Disorder to the Cabinet Sub-Committee*, Parliament House Western Australia, 1996, p.2.



three-fold) growth in the prescription of dexamphetamine to five- to fourteen-year-olds between 1989 and 1994.<sup>439</sup>

*The Report of the Technical Working Party* identified two ADHD hotspots: one in Perth's affluent western suburbs and the other in Perth's economically disadvantaged south-east corridor. The report concluded this patchy geographical distribution was probably 'more reflective of the prescribing patterns of paediatricians servicing the various areas than it is of social or other factors'.<sup>440</sup> The report raised concerns about the rigour of diagnostic practices of some clinicians. 'The parent is frequently the sole source of information and often educational and behavioural information is not sought. When information is sought from the school, the questions asked are frequently inappropriate. Behavioural observations are rarely obtained.'<sup>441</sup>

To address the inconsistency in prescribing rates identified in the Technical Working Party's 1997 report, it recommended 'random audits into the use of Block Authorisations, and that paediatricians and psychiatrists found to be failing to abide by the appropriate criteria have their Block Authorisation capacity removed'.<sup>442</sup>

### **6.3.1 Block Authorisation**

Block Authorisation exempted frequently prescribing clinicians from the requirement to get authorisation for each individual prescription. With Block Authorisation 'a practitioner was able to apply to the (WA) Department of Health and be granted blanket approval to treat any number of patients with stimulant medication, without further notifying of changes to individual patient details or dosage,' provided the dose was within the manufacturers prescribing guidelines.<sup>443</sup>

When prescribers with Block Authorisation prescribed within dosage limits they were not required to request authorisation for each patient. In contrast, a clinician who prescribed infrequently was accountable for every individual script. The rationale for the policy of 'Block Authorisation' was the assumption that those who prescribed frequently were

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<sup>439</sup> *The Report of the Technical Working Party*, p.5.

<sup>440</sup> *The Report of the Technical Working Party*, p.6.

<sup>441</sup> *The Report of the Technical Working Party*, p.8.

<sup>442</sup> *The Report of the Technical Working Party*, p.20.

<sup>443</sup> Western Australia Legislative Assembly, *Attention Deficit Hyperactivity Disorder in WA*, p.27.

considered to be ‘familiar with the guidelines for prescribing stimulants’.<sup>444</sup> Effectively the heaviest prescribers were the least accountable.

### 6.3.2 Western Australian Stimulants Committee

In response to the *Report of the Technical Working Party* recommendations the WA Stimulants Committee was established by the Western Australian Department of Health in 1997. The Stimulants Committee was supposed to monitor the prescription of psycho-stimulants to ensure appropriate prescribing. The Committee included some of Perth’s most prominent prescribers, who themselves had block authorisation, and were therefore exempt from oversight. The recommended audits of Block Authorisations never happened.

Drs Trevor Parry and Ken Whiting were members of the Stimulants Committee from its inception in 1997 until it was abolished in 2003. Both had Block Authorisation and were therefore exempt from prescribing accountability requirements.<sup>445</sup> Stimulants Committee meeting minutes from 20 February 2002 recorded:

As there were a number of applications outside the mg/kg range, Dr Oleh Kay, enquired if it would be possible to have en-bloc authorisation for doses outside the mg/kg<sup>446</sup> ...Dr Whiting said he would be pleased to be exempt in this case and he advised that Dr Parry would be also...Dr Harris advised that the Department could not be put in a position where members of the Committee had en-bloc authorisation to prescribe outside the mg/kg range, as this would understandably be seen to be bias.<sup>447</sup>

Drs Whiting and Parry were part of the committee tasked with ensuring the safe and responsible prescription of amphetamines in Western Australia. According to Dr Whiting, they were happy to extend their personal accountability exemptions to allow them to prescribe outside the manufacturers’ prescribing guidelines. Further, Stimulant Committee meeting minutes below show Dr Ken Whiting’s relaxed attitude to prescribing ‘off label’ and monitoring

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<sup>444</sup> *The Report of the Technical Working Party*, p.20.

<sup>445</sup> WA Stimulant Committee, *Minutes of Meeting held on 20 February 2002*, obtained under Freedom of Information Act 1992

<sup>446</sup> The term mg/kg refers to recommended dose in milligrams of medication per kilogram of body weight.

<sup>447</sup> WA Stimulant Committee, *Minutes of Meeting held on 20 February 2002*

individual clinician's prescribing patterns.

20 February 2002- It was raised by Ms Arrigo the issue of co-prescribing methylphenidate and dexamphetamine and requested advice from the Committee with the aim of incorporating this advice into the Guidelines.<sup>448</sup> Dr Whiting advised that the Department is being excessively bureaucratic and that it really has nothing to do with the Department if a medical practitioner co-prescribes the two drugs together. He advised it comes down to a clinical issue to be determined by the patient's medical practitioner...Ms Arrigo advised that the Department would like some guidance in being able to process the applications that come through, and the Committee agreed that children being prescribed both drugs together should not exceed the milligram per kilo range of each drug. For adults the dose should not exceed 12 tablets of each drug per day. Anything outside this should be submitted to the Committee.<sup>449</sup>

21 August 2002- Dr McLaughlin<sup>450</sup> raised the issue again of co-prescribing of methylphenidate and dexamphetamine and advised that the Department has still not found supportive evidence for prescribing both the drugs together...Dr Whiting enquired why the Department should be concerned. He advised that he has quite a few patients on both drugs together. Dr McLaughlin asked if there was any documentation to support the prescribing of both drugs together because we would be unable to support co-prescribing of both drugs until there was documentation to support the practice. Dr Whiting advised that the Interest Group for ADHD will come back with advice to the Department.<sup>451</sup>

Other Stimulants Committee minutes obtained through Freedom of Information (FOI) revealed that the Committee took a hands-off approach to the most reckless prescribers, even when their prescribing resulted in children being hospitalised. The names of the doctors with the questionable prescribing practices were not disclosed in the FOI documents. The minutes refer

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<sup>448</sup> Ms Rosemary Arrigo, was a public servant from the WA Department of Health who was the Assistant Secretary to the Stimulants Committee in January 2001 and from September 2001 to May 2003

<sup>449</sup> WA Stimulant Committee, *Minutes of Meeting held on 20 February 2002*.

<sup>450</sup> Dr Virginia McLaughlin from the WA Department of Health was Chairperson of the Stimulants Committee the from July 2001 to August 2002 and February 2003 to May 2003.

<sup>451</sup> WA Stimulant Committee, *Minutes of Meeting held on 21 August 2002*.

to an unnamed doctor (Dr Z) whose child patient was hospitalised because of ‘abnormal limb movements, slurred speech and unusual behaviour’ after being prescribed Ritalin at an extraordinarily high dose in combination with ‘several’ other drugs. The 6mg/kg dose was three times the recommended maximum dose. The term mg/kg refers to recommended dose in milligrams of medication per kilogram of body weight. In patients under the age of 18 years, doses are not to exceed 1mg/kg/day for dexamphetamine up to a maximum of 60mg per day; or not to exceed 2mg/kg/day for methylphenidate up to a maximum of 120mg per day.<sup>452</sup> Although Dr Z had block authorisation, he still needed to apply for special authority to prescribe at that level – therefore his actions were illegal. The Stimulants Committee took no formal action except for organising a meeting with Dr Z which was ‘felt to be fruitful’. Perhaps the most revealing comment minuted was ‘that although the stimulant dose was high these were inherently safe drugs and yet there was no prescribing restrictions of other far more dangerous drugs’. These minutes demonstrate that the Committee was not prepared to act after an illegally prescribed overdose of amphetamine saw a child hospitalised to detox.<sup>453</sup>

In 1999 there were concerns about another doctor (Dr H) which prompted an advisory meeting between members of the Stimulants Committee and Dr H. At the meeting Dr H ‘acknowledged that some of his patients were on up to 25 tablets daily but they seemed to be doing well...[and]...he was aware of the possible problem of patients selling tablets’. Although the Stimulants Committee sent an advisory letter and organised two ‘fruitful’ meetings, it took no decisive action. This did not significantly change Dr H’s prescribing practices. While they did discuss the prospect of curtailing his Block Authorisation capacity and making him accountable for every script, change only occurred because Dr H left the state.<sup>454</sup>

The Stimulants Committee did not take action against other illegal prescribers. Dr X was neither a paediatrician nor a psychiatrist and was therefore not able to initiate a patient on stimulant medication. Dr X prescribed a patient with dexamphetamine even though it was ‘contraindicated in this patient’ as he had ‘psychotic symptoms with emerging schizophrenia’. The Committee considered two options: recommending to the WA Health Department that

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<sup>452</sup> Information obtained from Government of Western Australia, Department of Health, *Stimulant Prescribing Code: Explanatory Notes*, September 2012, Public Health and Clinical Services, Perth 2012, p.4.

<sup>453</sup> WA Stimulant Committee, *Minutes of Meeting held on 10 November 1998*.

<sup>454</sup> WA Stimulant Committee, *Minutes of Meeting held on 2 November 1999*.

‘action be taken against Dr X as it is illegal what he has allegedly done’, or that the Department write to Dr X advising him not to ‘prescribe dexamphetamine or supply it without authorisation from the Commissioner of Health’. The Committee initially decided on the second softer option and then failed to follow through. The draft letter was never sent but ‘retained on file and if another allegation comes forward then the Department will have more weight in which to write to him’.<sup>455</sup>

Further minutes disclose the Committee’s enthusiasm for even fewer restrictions on prescribing. The Committee discussed the option of dropping ‘the age for stimulant prescribing from 4 years of age down to 3 years of age’, and ‘members agreed that earlier intervention is the best way’.<sup>456</sup> The Committee also approved two applications for dexamphetamine to be used outside guidelines during pregnancy. Committee members, notably Dr Trevor Parry, argued that for paediatricians, ‘provided they [did] not initiate treatment for [people] over 18 years of age, there should be the freedom for continuity of care and [this] should not be seen as a problem’.<sup>457</sup> Other minutes record that the ‘Stimulant Treatment Guidelines have been amended to indicate that extended periods between specialist review were allowable at the discretion of the specialist, provided that adequate feedback from the GP was ensured’.<sup>458</sup>

In August 2002, four months before the announcement that the Stimulants Committee would be replaced and prescribing accountability measures would be tightened, Committee minutes recorded: ‘Dr Parry advised that the Committee would rarely query an application outside the guidelines. He advised that the Committee’s time would be more usefully spent with ongoing monitoring and adaptation of the stimulant guidelines’.<sup>459</sup>

These minutes collectively demonstrate that the Stimulants Committee was basically not interested in doing the task it was established to do. That is, it was not interested in ensuring responsible practice by individual prescribing clinicians. Instead, ADHD proponents on the committee sought to influence clinical practice by promoting further prescribing.

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<sup>455</sup> WA Stimulant Committee, *Minutes of Meeting held on 26 September 2001*, and *Minutes of Meeting held on 20 February 2002*.

<sup>456</sup> WA Stimulant Committee, *Minutes of Meeting held on 20 February 2002*.

<sup>457</sup> WA Stimulant Committee, *Minutes of Meeting held on 21 August 2002*.

<sup>458</sup> WA Stimulant Committee, *Minutes of Meeting held on 10 May 2000*.

<sup>459</sup> WA Stimulant Committee, *Minutes of Meeting held on 21 August 2002*.

### **6.3.3 The 1998 WA Health Department convened International Panel on the Diagnosis and Treatment of ADHD**

In May 1998, at my request, the WA (Labor) Opposition Health Spokesperson Jim McGinty asked a WA Legislative Assembly parliamentary question on notice. It referred to 'the report of the Government Working Party on Attention Deficit Disorder' of the Minister for Health and asked, 'Is Western Australia mis-diagnosing and/or over-prescribing ADHD stimulant medication...at a disproportionately higher rate than the other States?'

The reply from the then Minister for Health the Hon Kevin Prince acknowledged the controversy regarding the use of stimulants and announced that an international expert panel would review the issue:

As there was very limited psychiatric input to the Government working party on Attention Deficit Disorder I have asked Prof. George Lipton (General Manager, Mental Health Division) to arrange for a panel of Nationally and Internationally recognised psychiatrists to meet in Perth later this year, to consider the reports, and to provide a supplementary report.<sup>460</sup>

Later, in response to advocacy by ADHD proponents led by Sandy Moran (see 6.3.4), Minister Prince advised a parliamentary committee that:

The eminent experts would visit Perth in August/September 1998 and undertake consultative forums to discuss the local prevalence, diagnosis and treatment of ADHD. They would then spend another 2 days analysing the information gained from the forums and the Western Australian and Australian literature. Based on this evidence they would prepare their report which would come to the Minister and the Cabinet Sub-Committee on ADHD for consideration. The report would provide advice on sound

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<sup>460</sup> Legislative Assembly - *Questions on Notice*, Tuesday 19 May 1998, McGinty; Prince, Attention Deficit Disorder Page 2768 / 3.

modern clinical practice in the diagnosis, treatment and care of people with ADHD.<sup>461</sup>

McGinty's question was prompted by my ADHD critic activism within the Labor Party (prior to my entering parliament) for action to address what I perceived as the misdiagnosis and over-prescription of ADHD psycho-stimulants. It, along with Sandy Moran's ADHD proponent advocacy, helped build momentum for Minister Prince's 'international expert panel' response to ADHD policy development.

In September 1998 the WA Department of Mental Health convened a three-day symposium to address concerns '*about the number of WA children diagnosed with attention deficit disorder and the use of amphetamine-like medication to treat them*'.<sup>462</sup> The Department invited 'international expert' Professor Larry Greenhill of New York's Columbia University. Professor Greenhill has received payment from fifteen pharmaceutical companies and is an advocate of ADHD prescribing. He has worked as a paid consultant to Alza Corp., Bristol-Myers Squibb, Richwood and GlaxoSmithKline, Eli Lilly, McNeil Pharmaceutical, Novartis Pharmaceuticals and Solvay.<sup>463</sup> He has been a paid speaker for ADHD drug manufacturers Eli Lilly, Janssen Pharmaceuticals and Novartis Pharmaceuticals.<sup>464</sup>

The International Panel also included the following members:

- Associate Professor Brian Barnett, School of Psychiatry, University of New South Wales
- Dr Brian Greenfield, Associate Professor of Psychiatry, McGill University School of Medicine, Montreal Children's Hospital, Quebec
- A/Professor Florence Levy, School of Psychiatry, University of New South Wales;

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<sup>461</sup> Western Australian Parliament, n.d, *Report of the Standing Committee on Constitutional Affairs in Relation to a Petition Regarding Attention Deficit Hyperactivity Disorder*, Report 47, Legislative Council, p.6. Available at [http://www.parliament.wa.gov.au/parliament/commit.nsf/\(Report+Lookup+by+Com+ID\)/CFD83DAF6BB3264D48257831003E9414/\\$file/ca047.pdf](http://www.parliament.wa.gov.au/parliament/commit.nsf/(Report+Lookup+by+Com+ID)/CFD83DAF6BB3264D48257831003E9414/$file/ca047.pdf).

<sup>462</sup> Wendy Pryer (1999), 'Dismay at child attention disorder figures', *The West Australian*, 1 September.

<sup>463</sup> Greg Birnbaum and Douglas Montaro (1999), 'Shrinks for Sale. Analyze This: Docs get Drug Co. \$\$', *New York Sunday Post*, 28 February.

<sup>464</sup> Associated Press (2006), 'Study Warns of Ritalin Side Effects in Preschoolers', 19 October. Available at <http://www.foxnews.com/story/0,2933,222559,00.html> (accessed 25 July 2008).

- Professor Robert McKelvey, Professor and Director, Division of Child and Adolescent Psychiatry, Oregon Health Sciences University, Oregon, USA
- Professor Barry Nurcombe, School of Psychiatry, University of Queensland.<sup>465</sup>

Conflict of Interest declarations for participants, if collected, were not made public.

The panel of 'international experts' prepared a report entitled *Attention Deficit Hyperactivity Disorder (ADHD) in Western Australia - Report of the International Panel on the Diagnosis and Treatment of ADHD* ('the International Panel Report') which was presented to the Mental Health Division of the Health Department of Western Australia.<sup>466</sup>

The International Panel Report encouraged polypharmacy by recommending concurrent prescribing of a range of psychotropic drugs to children with 'comorbid' disorders. The report acknowledged the debate but did not address the issue of whether ADHD was over or under-medicated in WA. Rather it concluded 'since the effectiveness of stimulants in the treatment of ADHD is beyond dispute, the first stage of medication intervention inevitably involves their use.'<sup>467</sup>

### 6.3.4 The 1999 Parliamentary Inquiry into a petition concerning ADHD

In April 1998 the Hon. Ray Halligan, a Liberal Party (Court Government) Member of The Legislative Council, tabled a petition concerning ADHD.<sup>468</sup> The petition requested the Legislative Council to:

1. In line with the World Health Organisation, National Health and Medical Research Councils and Commonwealth Government Policies, acknowledge the existence of Attention Deficit Hyperactivity Disorder (including ADD and

<sup>465</sup> WA Parliament, *Report of the Standing Committee on Constitutional Affairs*, pp.8-9.

<sup>466</sup> *Attention Deficit Hyperactivity Disorder (ADHD) in Western Australia: Report of the International Panel on the Diagnosis and Treatment of ADHD*, Mental Health Division, Health Department of Western Australia, Perth (n.d.)

<sup>467</sup> *Attention Deficit Hyperactivity Disorder (ADHD) in Western Australia: Report of the International Panel*, p.20.

<sup>468</sup> Hon. Ray Halligan (1998), Western Australian Legislative Council, *Minutes of Proceedings: Tabled Paper # 1561*, 29 April. Available at [http://www.parliament.wa.gov.au/Parliament/sitsched.nsf/0/0AB78F62652E97FA48256CE60033AAB7/\\$file/cm350172.pdf](http://www.parliament.wa.gov.au/Parliament/sitsched.nsf/0/0AB78F62652E97FA48256CE60033AAB7/$file/cm350172.pdf).



Associated Learning Disabilities) as affecting an unknown but significant number of children, youth and adults in Western Australia.

2. Ascertain the services and facilities available to those disadvantaged in this way within the Ministries of Health, Education, Disabilities, Youth, Children and Family Services, Justice and Employment and Training.
3. Encourage a program of public and professional education and awareness to allow the facilitation of early identification and appropriate remediation for sufferers of this neurobiological disorder.
4. Encourage the establishment of a professional advisory board to advise Government of the appropriate remediation and protocols within Government agencies.

The petition was re-tabled by Hon Ray Halligan MLC in September 1998 and again in September 1999 requesting that the Legislative Council consider the matters in the petition.<sup>469</sup> The lead petitioner was Sandy Moran, an active member of the Learning and Attention Disorders Society (see 6.8). Moran contended that many of the problems experienced by Aboriginal youth were caused by undiagnosed and un-medicated ADHD.<sup>470</sup> As well as being the principal petitioner in May 1998 Sandy Moran wrote a letter stating:

There are little or no services for ADHD sufferers in any Government Services. Children with ADHD are only treated at Western Australia's sole children's hospital if they have a co-existing medical problem, which requires attention. A diagnosis of ADHD does not allow services to be made available. Some children are seen at the Child Development Centre (Rheola Street) but the majority of children are serviced through the private sector, scattered scant regional facilities and the Attention Deficit Society in

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<sup>469</sup> Hon. Ray Halligan (1998), Western Australian Legislative Council, *Attention Hyperactivity Disorder: Petition*, 8 September 1998. Available at <http://www.parliament.wa.gov.au/48256603002A13E1/0/95B62C65477FFA4A48256691001E2FBC?Open&Highlight=2,sitesearchyes>; Hon. Ray Halligan, Western Australian Legislative Council, *Attention Hyperactivity Disorder: Petition*, 7 September 1999. Available at <http://www.parliament.wa.gov.au/48256603002A13E1/0/8CDFE11450ADA3BB482567E8001BFBC3?Open&Highlight=2,sitesearchyes>.

<sup>470</sup> WA Parliament, *Report of the Standing Committee on Constitutional Affairs*, pp.2-3.

Mosman Park which is a benevolent society with little or no government funding...Parents who have ADHD children and who have the financial means will have access to appropriate medical assistance. There is [sic] absolutely no facilities at all for Aboriginal children, many of whom suffer from ADD/ADHD...There exists no Government education or direction in the wider community to protect these vulnerable children and their families from the prejudice generated by a misinformed media...A professional body of appropriately credentialed personnel with a substantial degree of clinical practice could assist Government policies in being more targeted and as a rule more effective in remediating such tragedies in our community.<sup>471</sup>

In a subsequent letter to the Committee dated July 23 1998, Sandy Moran wrote that: 'one of the tragedies of our Mental Health System is that ADHD/ADD clients are being diagnosed with an exotic array of psychiatric disorders and are subsequently being 'warehoused' at facilities like Graylands Hospital'.<sup>472</sup> In 1999 the persistence of Sandy Moran, and her fellow petitioners, was rewarded when a committee of the WA Legislative Council conducted an Inquiry titled *Report of the Standing Committee on Constitutional Affairs in relation to a Petition regarding Attention Deficit Hyperactivity Disorder*. The Legislative Council parliamentary committee validated the diagnosis of ADHD but avoided expressing an opinion on the safety and efficacy of ADHD medications. It concluded that ADHD is a 'recognisable condition which affects a significant number of children, youth and adults in Western Australia' but acknowledged there is a 'range of attitudes...about the prevalence... and how those suffering from it should be treated.'<sup>473</sup>

Despite avoiding the issue of medication use, the committee endorsed the approach requested by the petitioners, concluding:

The Committee agrees with the petitioners that there should be a program of public and professional education and awareness to assist in the early identification of the condition and to facilitate the remediation of people affected by ADHD. The Committee believes that the professional

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<sup>471</sup> WA Parliament, *Report of the Standing Committee on Constitutional Affairs*.

<sup>472</sup> WA Parliament, *Report of the Standing Committee on Constitutional Affairs*.

<sup>473</sup> WA Parliament, *Report of the Standing Committee on Constitutional Affairs*.

development of those involved in the diagnosis and treatment of people with ADHD is integral to ensuring a best practice standard for treating the condition...The Committee is aware of anecdotal evidence that suggests that many of the problems associated with crime, in all sectors of our community, could in some way be attributable to ADHD. Should further research confirm this anecdotal evidence, early intervention could provide considerable long term financial savings and benefits to those suffering from ADHD, their families, and the community in general.<sup>474</sup>

In line with these conclusions the committee recommended establishing a:

- Professional Advisory Body to develop policies and guidelines ‘to overcome apparent existing deficiencies’ in diagnosis and treatment of ADHD.
- Program of public and professional education and awareness be established to assist in the early identification of ADHD and to facilitate the treatment of people affected by the condition.<sup>475</sup>

When the committee report was debated in the Legislative Council a number of members who were not on the committee - the Hon Barbara Scott (Liberal), the Hon Greg Smith (Liberal), the Hon Chrissy Sharp (Greens) and the Hon Murray Nixon (Liberal)– spoke in support of its findings and recommendations. They were all supportive of the validity of the disorder, with Greg Smith identifying that two of his three children took ADHD medications and in his views benefited. All spoke in complimentary terms about the advocacy of Sandy Moran and/or the Learning and Attentional Disorders Society (LADS), although Nixon identified that the Education Department ‘was aware that there were no reliable tests for ADHD and was concerned that some children might be labelled inappropriately’.<sup>476</sup>

<sup>474</sup> WA Parliament, *Report of the Standing Committee on Constitutional Affairs*,. p.31.

<sup>475</sup> WA Parliament, *Report of the Standing Committee on Constitutional Affairs*, p.33.

<sup>476</sup> Hon. Murray Nixon (2000), ‘Standing Committee on Constitutional Affairs – In Relation to a Petition Regarding Attention Deficit Hyperactivity Disorder’, *Hansard*, Parliament of Western Australia, Thursday 16 March 2000, p5090 /1. Available at <http://www.parliament.wa.gov.au/hansard/hans35.nsf/16ab30a0303e54f448256bf7002049e8/cc1211c4fa7c0c6b482568d9000cd448?OpenDocument> (accessed 1 June 2013).

Direct ADHD proponent parliamentary activism during the period of the Court Liberal State Government (1993 to 2001) was undertaken by the Member for Dawesville Arthur Marshall. In 2003, in a speech in the Western Australian Legislative Assembly, Marshall summarised his contribution during this period.

Sometime in 1994-95 I introduced this problem to the Legislative Assembly. At the time it was an estimates debate and I was incensed that the education gurus would not recognise that attention deficit hyperactivity disorder actually existed. The education system was not allocating money to deal with the problem. After a lot of debate, I got funding to the tune of \$100 000, which was a needle in a haystack but at least it recognised that there was a problem. I subsequently made many speeches to improve the public awareness of the problem. I went to meetings in Mandurah. I saw family split-ups because of the emotional aspect of this problem with which families must deal. My daughter Dixie Marshall, who works for Channel Nine, made a documentary that was aired nationally to increase awareness. Finally, everybody is starting to recognise that there is a problem that needs to be addressed. ...Reports have identified that Western Australia has the highest incidence of the use of dexamphetamines, and the medical profession has been criticised for this. However, I believe that diagnosis of this problem in this State is much better than in other States, which should follow suit.<sup>477</sup>

During the period 1992 to 2001 the available evidence indicates that a number of WA State politicians were sympathetic with the views of ADHD proponents. This may have helped facilitate dominance of ADHD policy and regulation in WA by ADHD proponents.

### **6.3.5 Training of Western Australian Paediatricians**

Both ADHD proponents and critics accept that differences in the training of paediatricians account for differences in state prescribing rates. In 2006 Perth paediatrician and University of Western Australia Professor of Paediatrics and Child Health, Dr Trevor Parry, acknowledged on Channel Nine's *Sunday* program, that the prescribing practices of paediatricians he trained contributed significantly to WA's disproportionately high prescribing

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<sup>477</sup> Arthur Marshall MLA, (2003), *Hansard*, Parliament of Western Australia, Wednesday, 16 April, p.6844b-6848a.

rates (see Box 8 below).<sup>478</sup> Parry argued rates were historically higher because WA prescribers were better at recognising and diagnosing ADHD than those of other states. Parry's proud acceptance of his leading role in Western Australia's high child prescribing rates occurred when child prescribing rates were in sharp decline.

**Box 8 - Excerpt from transcript of TV program 'ADHD – the Quick Fix', Sunday, 14 May 2006**

Reporter: One very influential WA paediatrician Trevor Parry says there's no problem with the state's prescription rates.

Dr Trevor Parry: I have always been happy with that, despite what the critics have said about WA being the drug capital of Australia.

Reporter: Parry has had a lot to do with the rates of prescription...since he trained many of those practising in the field...You may be practising less but those people you trained are out there following your lead.

Dr Trevor Parry: I can only hope so!

Reporter: Western Australia also sits apart from the rest of Australia because doctors here prescribed the medication for ADHD in higher doses...

Dr Trevor Parry: People are comfortable that up to ten or twelve tablets a day for a certain weight of children...we don't faint and beat our breasts about that if four a day...for high school children is higher than the other states are using then I would hope that for some children other states might become a bit more confident.

Four years earlier (in 2002) Parry had referred to Victoria's prescribing rates, when he said '[Victorian rates] have been the lowest...because they have not strongly believed in the existence of ADHD nor have they trained their paediatricians accordingly until quite recently'.<sup>479</sup> In 2002 there were 7,500 Western Australian and only 5,060 Victorian children who received a Pharmaceutical Benefits Scheme sponsored prescription of dexamphetamine (see Table 5 at 6.1). This is despite the population of Victoria being 4,902,920, approximately two and a half times that of Western Australia's 1,940,485.<sup>480</sup>

<sup>478</sup> Sarah Ferguson and Nick Rushworth (2006), 'Part 1: ADHD – the quick fix', *Sunday*, 14 May. Available at [http://sgp1.paddington.ninemsn.com.au/sunday/cover\\_stories/article\\_1983.asp?s=1](http://sgp1.paddington.ninemsn.com.au/sunday/cover_stories/article_1983.asp?s=1) (accessed 10 August 2009).

<sup>479</sup> Dr Trevor Parry, quoted in George Halasz, et al (2002), 'Smartening up or dumbing down?: A Look Behind the Symptoms, Overprescribing and Reconceptualizing ADHD', *Cries unheard: a new look at attention deficit hyperactivity disorder*, Altona Vic, Common Ground Publishing, p.80.

<sup>480</sup> Australian Bureau of Statistics (2003), 3239.0.55.001 - *Population, Australian States and Territories - Electronic delivery*, Dec 2002, Commonwealth of Australia, 27 May.. Available at

Victorian psychiatrist ADHD critic, Dr George Halasz, agrees with Parry that differences in training and medical culture accounted for the difference between WA and Victorian prescription rates. However, Halasz was highly critical of Western Australian practice. Halasz believes the increase in ADHD prescription was a consequence of the 'dumbing down' of child mental health assessment, diagnosis and treatment, stating 'the art and science of the assessment of child behaviour had become merely the chronicling of a set of symptoms'.<sup>481</sup> In his opinion this erosion was in part due to the way new doctors were trained. Halasz believed the training provided little opportunity to impart an understanding of the importance of a 'development perspective'. ADHD proponent Victorian Paediatrician Dr Daryl Efron (refer to 4.4.3.1) also agrees that the attitudes of those training clinicians is a significant determinant of prescribing rates.

Often it comes down to small numbers of high profile, often academic individuals at a teaching hospital who maybe believe strongly in the benefits of medication, and teaching the trainees for a generation in that particular town that stimulants are good and therefore you get lots of children being prescribed; whereas, you might have in another town more psychologically based clinicians who are less inclined to use medication.<sup>482</sup>

A 2004 WA parliamentary inquiry into ADHD heard evidence of Western Australian children being diagnosed and prescribed by a private sector paediatrician after a fifteen-minute (and sometimes even shorter) consultation. Dr Halasz who also gave evidence to the Inquiry pointed to reduced time for patient care and argued that even fifty to sixty minutes were inadequate to assess the development of a child's symptoms.

The Inquiry found that the shortage in Perth of appropriately trained child psychiatrists to perform time-intensive diagnoses and treatments left a vacuum filled by a relatively small number of inadequately trained paediatricians who diagnosed and prescribed quickly. 'During their training, paediatricians have not been adequately informed about the extent of alternative diagnoses and treatment methods, and are therefore more likely to use drug

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<http://www.abs.gov.au/ausstats/abs@.nsf/ProductsbyReleaseDate/41DF4C7B03A8A820CA256EA00079B23F?OpenDocument> (accessed 14 April 2013).

<sup>481</sup> Halasz, et al, 'Smartening up or dumbing down?', p.80

<sup>482</sup> Dr D. Efron, Paediatrician, Royal Children's Hospital, Melbourne, interviewed on The Health Report, *ABC Radio*, 23 October 2000.

therapy in the first instance in the management of ADHD.<sup>483</sup> The inquiry was influenced by a submission that contended that seeing a paediatrician as opposed to a mental health professional (i.e. a psychiatrist) was a 'risk factor in the use of stimulant medication'.<sup>484</sup> The submission stated, 'by virtue of their training and workload it is also possible that paediatricians may be more prone to use drug therapy than the other therapies recommended for the management of ADHD.'<sup>485</sup>

#### 6.4 WA ADHD policy and politics 2002-2012

The suggestion to audit Block Authorisation prescribing was first made by the Technical Working Party in 1996. Five years later in 2001, when I was elected as the Member for Roleystone as part of the new Gallop Labor government, the total number of Pharmaceutical Benefits Scheme subsidised dexamphetamine scripts were more than two and a half times higher.<sup>486</sup> I raised the issue of Block Authorisation in my inaugural speech in May 2001 stating, 'the problem of Block Authorisation continues. I believe making doctors accountable on a case-by-case basis for the prescription of stimulant medication is essential to dealing with the problem of over prescription'.<sup>487</sup> The change of government, my election and the appointment of the Honourable Bob Kucera as WA's Health Minister, provided the opportunity for the direction of policy to be reversed. Minister Kucera, a former senior policeman, told me he had seen the problems caused by the diversion of amphetamines prescribed for ADHD.

In 2002 the report *Attentional Problems in Children and Young People* was published by the Western Australian Mental Health Division ultimately overseen by Minister Kucera. An earlier draft was developed by the WA Department of Health with guidance by an ADHD Policy Reference Group which consisted of ADHD proponents and some members with a more critical perspective.

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<sup>483</sup> WA Legislative Assembly, *Attention Deficit Hyperactivity Disorder in Western Australia*, p.24.

<sup>484</sup> WA Legislative Assembly, *Attention Deficit Hyperactivity Disorder in Western Australia*, p.23.

<sup>485</sup> WA Legislative Assembly, *Attention Deficit Hyperactivity Disorder in Western Australia*, p.24.

<sup>486</sup> Statistics obtained from the Medicare Australia website, relating to the prescription of stimulant medications, show that in WA 29,009 prescriptions for stimulant medication were subsidised by the PBS in 1996. By 2001, this figure had risen to 75,185. Medicare Australia, Pharmaceutical Benefits Schedule Item Reports. Available at [https://www.medicareaustralia.gov.au/statistics/pbs\\_item.shtml](https://www.medicareaustralia.gov.au/statistics/pbs_item.shtml) (accessed 15 September 2012).

<sup>487</sup> Martin Whitely MLA (2001), 'Inaugural speech', *Hansard*, Parliament of Western Australia, Thursday 3 May, pp. 152b–179a.

Although the makeup of the committee was arguably balanced, this early draft of the report emphasised developing a tiered approach, with teachers and childcare workers referring suspected ADHD children for diagnosis by specialist clinicians. The draft report also stated 'ADHD is the most common childhood developmental disorder with the prevalence levels estimated to be between 3 to 9 percent'<sup>488</sup> and 'the efficacy of stimulant medication in treating many of the symptoms of ADHD is not in question'.<sup>489</sup> Soon after I was elected I wrote to the Minister for Health that 'the result of accepting the two statements highlighted above is to legitimise, without objective scientific evidence, the prescription of amphetamines to children because they are perceived to be behaving in an unacceptable manner'.<sup>490</sup>

The draft report was, with my input (as an ADHD critic), significantly altered by Minister Kucera's office. The final draft abandoned the tiered referral approach and recommended the abolition of Block Authorisation, as well as the establishment of multidisciplinary clinics to diagnose and treat children with behavioural and learning problems. Minister Kucera announced the decision to end Block Authorisation in December 2002 and the practice was stopped in August 2003. The Stimulants Committee was replaced by the Stimulants Assessment Panel and although Dr Trevor Parry was initially invited onto the Stimulants Assessment Panel,<sup>491</sup> it had a significantly different membership. After Block Authorisation was abolished all authorised prescribers were equally accountable for each prescription.<sup>492</sup>

The WA Chief Psychiatrist, Dr Rowan Davidson, later told a West Australian Parliamentary committee 'The work of the stimulants panel...is very much directed at trying to provide a degree of control and support for issues such as accuracy of diagnosis and monitoring, so that we monitor not just the overall patterns but also individual clinician prescribing

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<sup>488</sup> Mental Health Division, *Draft: Attention Problems in Children and Young People: Diagnosis and Management of ADHD and Associated Disorders*, Department of Health, August 2001, p.2.

<sup>489</sup> Mental Health Division, *Draft: Attention Problems*, p.19.

<sup>490</sup> *Letter from Martin Whitely to the Hon Bob Kucera, Minister for Health*, 28 February 2001.

<sup>491</sup> WA Stimulant Committee (2003), *Minutes of Meeting held on 14 May 2003*. Dr Parry advised that he has been invited to be a member of the new Stimulants Assessment Panel.

<sup>492</sup> Every prescriber was compelled to 'apply to the (West Australian) Department of Health and obtain a unique Stimulant Prescriber Number (SPN) to initiate stimulant treatment in any patient. The practitioner must provide individual patient details, including age, gender and dose required, thus enabling the collection of data for future analysis of stimulant use in WA'. WA Legislative Assembly, *Attention Deficit Hyperactivity Disorder*, p.27.



patterns, and can then ask an individual clinician for appropriate explanations about prescribing patterns'.<sup>493</sup>

This represented a significant change in the purpose of the stimulants monitoring process. The stimulants committee had previously been a rubber stamp which paid limited attention to the issue of psychostimulant diversion and very little to the appropriateness of diagnosis and prescribing practices.

The decision to establish the Stimulants Assessments Panel and abolish Block Authorisation was announced in December 2002. Block Authorisation was abolished and the Stimulants Panel began to meet and the Stimulant Regulatory Scheme began collecting information in August 2003. The first annual report (which covered 17 months of operation from August 2003 to December 2004) was published in 2005.

Minister Kucera's and my own enthusiasm for the end of Block Authorisation, and for the new accountability measures, was not shared by the then president of the Western Australian branch of the Australian Medical Association Dr Bernard Pearn-Rowe, who said: 'Families should have no doubt that the Health Minister is trying to take away the ability of a doctor to make clinical decisions in consultation with parents...I hope the Minister will tell individual parents that his policy is responsible for the refusal of treatment, even when recommended as appropriate by a qualified medical practitioner.'<sup>494</sup> Pearn-Rowe denied that WA clinicians were misdiagnosing and overprescribing and claimed that 'other States and Territories under-prescribe dexamphetamine because they do not have as many paediatricians who specialise in treating ADHD.'<sup>495</sup>

#### **6.4.1 Child Prescribing**

Figure 5 in Chapter 4 shows there was a large (50 percent) decrease in the proportion of 4 to 17 year olds prescribed between 2002 and 2010 with the major decline occurring between 2003 and 2007. It appears very likely the abolition of Block Authorisation, the appointment of the Stimulants Panel, and the implementation of the Stimulant Regulatory

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<sup>493</sup> Dr Rohan Davidson, *Inquiry into Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder in Western Australia*, Transcript of Evidence taken at Perth, 15 September 2004, Education and Health Standing Committee.

<sup>494</sup> Amanda James (2002), 'WA top State for "Dexies"', *The West Australian*, 24 September.

<sup>495</sup> The West Australian (2002), 'ADHD drug linked to poverty: report', September 25, p.5.

Scheme were responsible for this fall. These innovations were supported by a sympathetic Minister for Health and driven by me, an ADHD critic who believes ADHD is an inappropriate application of the medical model. Clearly a policy process 'dominated' by an ADHD critic resulted in a significant and sustained decline in child prescribing rates.

#### **6.4.2 Why did Western Australian adult prescribing rates continue to grow when child prescribing rates fell?**

In contrast to the decline in WA child prescribing rates, the proportion of adults receiving ADHD medications has risen from 0.40 percent in 2002 to 0.54 percent in 2011, an increase of 35 percent. Clearly the factors influencing child and adult prescribing rates are significantly different. There is no obvious single reason for the disparity between the post-2003 decline in child prescribing rates and the increase in adult rates.

Possible explanations include:

1. *The natural ageing of the ADHD cohort with carryover childhood patients turning 18 and continuing stimulant medication.*

An obvious explanation is that this may be a result of the ageing in the cohort of ADHD children who were first diagnosed in the 1990s and early 2000s who have become adults and maintained the diagnosis and remain on prescription ADHD medications. This may have contributed to the 35 percent rise in the per capita rate of adult patients between 2002 and 2011. However, the 2011 Stimulants Monitoring System Annual Report showed that 80 percent of adult patients are first diagnosed and prescribed stimulants as adults.<sup>496</sup> Therefore the ageing of the child ADHD cohort is unlikely to be the dominant reason.

2. *The marketing of ADHD as an under-recognised, under-diagnosed, adult psychiatric disorder by Western Australian ADHD support group the Learning and Attentional Disorders Society.*

DSM-IV states: 'Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.'<sup>497</sup> Despite this and the fact that the

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<sup>496</sup> Department of Health, *Western Australia Stimulant Regulatory Scheme 2011 Annual Report*, p.40.

<sup>497</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> edn, p.92.

diagnostic criteria are defined in terms most applicable to children in a classroom setting, in recent years considerable energy has been put into promoting 'Adult ADHD'. ADHD Proponents contend that ADHD is an under-diagnosed and under-medicated adult condition, arguing 60 percent of those with ADHD as children continue to have the disorder in to adulthood.<sup>498</sup>

As well as promoting the disorders recognition in Western Australian children (see 6.6) the Learning and Attentional Disorders Society (LADS) has put considerable effort into 'raising awareness' of adult ADHD. In 2003 LADS produced an ADHD facts sheet that attributed a variety of adult problems, including car crashes, divorce and even bad manners, to undiagnosed Adult ADHD:

The symptoms of ADHD can cause severe disruptions in the lives of adults: Concentration difficulties may result in people becoming procrastinators, and earning a reputation for laziness and a lack of motivation. They may be embarrassed in social situations as their concentration drifts during conversations. They may have a tendency to interrupt others or to make tactless comments. Physically, they may engage in high-risk activities. People with ADHD receive more traffic infringements and licence suspensions, particularly for speeding. They are involved in more motor vehicle accidents. Intimate relationships may be more difficult to sustain, with higher rates of separation and divorce occurring in this group. Educational and professional under-achievement is common, and causes great frustration. Adults with ADHD often find it difficult to manage their ADHD children...Dexamphetamine and Methylphenidate improve symptoms in up to 78 per cent of adults with ADHD.<sup>499</sup>

In 2004, in verbal evidence given on behalf of LADS to the 2004 WA parliamentary inquiry into ADHD, Michelle Toner even attributed criminality and drug abuse to undiagnosed, and therefore un-medicated, ADHD.

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<sup>498</sup> 'While some children outgrow ADHD, about 60 per cent continue to have symptoms into adulthood.' Eli Lilly Website, [http://www.strattera.com/1\\_3\\_childhood\\_adhd/1\\_3\\_1\\_1\\_what\\_is.jsp](http://www.strattera.com/1_3_childhood_adhd/1_3_1_1_what_is.jsp) (accessed 14 January 2008).

<sup>499</sup> Michelle Toner (2003), *Fact Sheet: ADHD in Adults*, Learning and Attentional Disorders Society of WA Inc, Perth.

The research shows that people with ADHD are six times more likely to develop a substance abuse problem. However, if they are treated with stimulant medication, the risk is reduced to the same as someone without ADHD...Some excellent work has been done by Dr Tony Mastrioni on the New South Wales prison system. He estimates that 30 per cent of the prison population in NSW has ADHD, either diagnosed or undiagnosed.<sup>500</sup>

Critics contend that criminal and drug-taking behaviour are in themselves dysfunctional and most often impulsive acts. They counter the argument that ADHD, when left un-medicated, causes criminal behaviour or drug abuse as a confusion of cause and effect. They argue that attributing undiagnosed ADHD as the cause of dysfunction in a population that is already identified as a dysfunctional population is the 'equivalent of being able to bet on a horse after the race has finished.'<sup>501</sup>

Regardless of the merits of the two perspectives, it is likely that the marketing (or awareness raising) of Adult ADHD as an underdiagnosed psychiatric disorder by LADS in WA contributed to the growth in WA adult prescribing rates.

### *3. A culture of 'doctor shopping' for dexamphetamine by young Western Australian Adults*

Critics including Curtin University Professor of Public Health Bruce Maycock contend there is a group of young adult WA 'dexie' abusers, who 'doctor shop' for dexamphetamine in preference to methylphenidate and have learned how to tick the right ADHD boxes and say the right things to a small number of high prescribing Perth psychiatrists.<sup>502</sup> While there is no quantitative research on the extent of doctor shopping for ADHD dexamphetamine by

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<sup>500</sup> West Australian Parliament, *Inquiry into Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder in Western Australia*, Legislative Assembly, Transcript of evidence taken on 27 October 2003, p.2 (Michelle Toner).

<sup>501</sup> Whitely, *Speed Up & Sit Still*, p.20.

<sup>502</sup> Bruce Maycock et al (2005), 'Issues for consideration relating to the illicit diversion and use of dexamphetamine' Western Australian Centre for Health Promotion Research. Available at [http://espace.library.curtin.edu.au/R/?func=dbin-jump-full&object\\_id=160712&local\\_base=GEN01-ERA02](http://espace.library.curtin.edu.au/R/?func=dbin-jump-full&object_id=160712&local_base=GEN01-ERA02).

WA adults, U.S. research published in 2011 revealed nearly a quarter of all adults seeking treatment for ADHD feigned symptoms to get a cheap supply of amphetamines.<sup>503</sup>

Doctor shopping occurs when in order to secure a supply of federal government subsidised amphetamines drug abusers go to a sympathetic doctor and fake the symptoms of ADHD and receive prescriptions for dexamphetamine. They then go to a pharmacist and get the original prescription filled and take the repeat prescriptions to another pharmacist shortly after, despite the fact that they have just been dispensed with a month's supply. They will then get the repeat prescriptions filled in an extraordinarily short period by simply going from one pharmacist to another. The pharmacists are unaware that the 'patient' is a drug abuser, and, in some cases, minor drug trafficker and is filling the prescriptions very quickly so that the drugs can be either abused shared or sold.

A 2005 survey of WA 12 to 17 year olds revealed that the vast majority of high school students (84 percent) who have abused amphetamines had abused prescription ADHD amphetamines<sup>504</sup> (for more detail see 6.5). The age range of these drug abusers would in 2011 have been 18 to 23. It is possible that for some their habit of abusing dexamphetamine has transformed into doctor shopping. Faking the symptoms of ADHD to obtain a supply of dexamphetamine seems far more likely amongst adult 'patients' than children (or their parents). For adults, the diagnosis relies heavily on self-reports of behaviour, but for children third party reports of teachers and parents are the central evidence. The Stimulants Regulatory System may therefore have been more effective as a drug abuse prevention strategy for children than adults.

A number of statistics are consistent with the contention that young adult Western Australians abuse prescription dexamphetamine:

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<sup>503</sup> Meredith Melnick (2011), 'Faking It: Why nearly 1 in 4 adults who seek treatment don't have ADHD', *Time Healthland*, 28 April. Available at <http://healthland.time.com/2011/04/28/faking-it-why-nearly-1-in-4-adults-who-see-treatment-dont-have-adhd/> (accessed 24 May 2011).

<sup>504</sup> A 2005 survey of Western Australian secondary school students (*the Australian School Students Alcohol and Drug Survey or ASSAD*) found that 84 per cent of those who had abused amphetamines in the last year had abused prescription amphetamines. Drug and Alcohol Office WA (2007), *ASSAD Drug Report 2005*, Mt Lawley, pp.30-32.

- During 2011, 137 patients had their authority to receive psychostimulants withdrawn because they had abused prescription drugs.<sup>505</sup>
- Despite the fact that methylphenidate (Ritalin, Concerta) is the most commonly prescribed ADHD stimulant in Australia, (73 percent of all scripts in 2010)<sup>506</sup> in 2011 the vast majority (81.3 percent) of WA adults who received stimulants were prescribed dexamphetamine. In contrast only 22.3 percent of WA children who received stimulants for ADHD were prescribed dexamphetamine.<sup>507</sup>
- The majority (53 percent) of those diagnosed as adults are first diagnosed between ages 18 and 29.<sup>508</sup>
- In 2011 one WA clinician (a psychiatrist) alone was responsible for prescribing to 1473 patients (1346 adults and 127 children).<sup>509</sup>

These facts are consistent with the contention that these confirmed 137 prescription drug abusers may be the tip of the iceberg and that a significant proportion of these young Western Australians are targeting doctors with a reputation for being easy targets in order to get a taxpayer subsidized supply of dexamphetamine.

In summary, there is insufficient empirical evidence to determine the relative importance of the above three factors and other factors. However, it seems likely that the ageing of the ADHD cohort, the marketing of Adult ADHD and doctor shopping for 'dexies' have all contributed to rising adult prescribing rates. Clearly different factors drove the decrease in child prescribing rates. This indicates that different policy responses are required for adults and children if the intention is to decrease prescription rates. This may be particularly true if doctor shopping by adults is prevalent.

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<sup>505</sup> Department of Health, *Western Australian Stimulant Regulatory Scheme 2011 Annual Report*, p.19.

<sup>506</sup> Statistics relate to 2010 calendar year and were obtained from the Medicare Australia website, Available at [https://www.medicareaustralia.gov.au/statistics/pbs\\_item.shtml](https://www.medicareaustralia.gov.au/statistics/pbs_item.shtml)

<sup>507</sup> Department of Health, *Western Australian Stimulant Regulatory Scheme 2011 Annual Report*, pp.28 & 43.

<sup>508</sup> Department of Health, *Western Australian Stimulant Regulatory Scheme 2011 Annual Report*, p.41.

<sup>509</sup> Department of Health, *Western Australian Stimulant Regulatory Scheme 2011 Annual Report*, pp.21 & 37.

### 6.4.3 Limitations on Stimulant Dispensing

The abolition of Block Authorisation and the establishment of the Stimulants Panel were not the only measures designed to curtail ADHD amphetamine use. In the Government Gazette of Tuesday, 15 November 2005, the Poisons Amendment Regulations 2005 were published. The regulations came into effect on 1 January 2006.<sup>510</sup> The new regulations were designed to limit the incentives to engage in doctor shopping.

The changes to stimulant dispensing regulations required repeat scripts to be held by the pharmacist who issued the first script. The changes were made in response to a recommendation of the WA Legislative Assembly Education and Health Standing Committee 2004 Inquiry into ADHD. Recommendation 9 of the Inquiry stated: 'The Committee recommends that Western Australian legislation be amended in line with New South Wales, to restrict the frequency with which repeat Schedule 8 medication prescriptions may be dispensed.'<sup>511</sup>

The Committee was influenced by evidence of amphetamine abusers going from pharmacy to pharmacy and getting months' worth of repeat scripts filled in days. The parliamentary inquiry was told of a teenager receiving 175 days' worth of repeat scripts in 13 days and an adult patient receiving 125 days' worth of repeat scripts in 40 days. All repeat scripts for a 'patients' psycho-stimulants are now held by one pharmacist and can only be filled as required for prescribed dose usage. Implementation of this initiative post-dated the fall in teenage amphetamine in W.A. teenage abuse rates between 2002 and 2005. Therefore, unlike the end to Block Authorisation, it cannot be viewed as a likely cause of this initial decline.

### 6.4.4 The 2004 WA Legislative Assembly Education and Health Standing Committee into ADHD

In 2004 a second WA Parliamentary Inquiry was held into ADHD. This was conducted by the Education and Health Standing Committee of the Legislative Assembly. The committee included six parliamentarians, three from the Labor Party (including me as a co-opted, non-voting

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<sup>510</sup> Western Australian Government Gazette of Tuesday, 15 November 2005, the *Poisons Amendment Regulations* 2005.

<sup>511</sup> WA Legislative Assembly, *Attention Deficit Hyperactivity Disorder in Western Australia*, p.70.

member), one from the Liberal Party and one from the National Party, none of whom had any commercial interest in ADHD.

Opposition Health Spokesperson Mike Board suggested the Inquiry to Health Minister Bob Kucera. On Minister Kucera's suggestion Board and I negotiated the terms of reference for the Inquiry. The Inquiry was conducted in a co-operative bi-partisan manner and reached unanimous conclusions. The terms of reference of the Inquiry were to inquire into:

- the extent of the incidence, diagnosis and use of stimulant medication for the treatment of attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD) in WA, taking into account all previous reports and inquiries;
- an analysis of those figures compared to other States of Australia and other countries;
- the analysis of emerging medical opinion and varying medical and behavioural approaches for the treatment of ADD and ADHD;
- the divergence of public opinion and the need for a more defined state policy;
- the relationship, if any, between those diagnosed with and/or medicated for, ADD or ADHD and drug addiction; and
- the relationship, if any, between ADD or ADHD and the educational, economic and social wellbeing of individuals, and that the committee report to the Assembly by 30 June 2004.<sup>512</sup>

Of the committee members I had a predetermined ADHD critic position and one other member Paul Andrews MLA, like me a former high school teacher, had expressed concern about ADHD prescribing. None of the other four members had publicly expressed concern about ADHD prescribing. However, in introducing the motion to establish the Inquiry Board said:

‘The incidence of attention deficit disorder and attention deficit hyperactivity disorder in Western Australia is significant; it is something like 400 per cent higher

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<sup>512</sup> MF Board (2003), *Hansard*, Parliament of Western Australia, Wednesday 16 April, pp.6844b-6848a. Available at [http://www.parliament.wa.gov.au/Hansard/hansard.nsf/0/0955f38e4cc755dec8257570007f6abc/\\$FILE/A36%20S2%2020030416%20p6844b-6848a.pdf](http://www.parliament.wa.gov.au/Hansard/hansard.nsf/0/0955f38e4cc755dec8257570007f6abc/$FILE/A36%20S2%2020030416%20p6844b-6848a.pdf) (accessed 12 June 2013).



than the national average. It is a massive and major issue...People are confused about the issue; they do not know whether the prescription of drugs to settle down children is in the interests of those children...The jury is out to some degree about the extent of long-term addiction or non-addiction and whether the prescription of drugs to deal with ADD and ADHD may have long-term effects on young people.’<sup>513</sup>

Board was prominent through the process, chairing many of the hearings. When the committee reported its findings to the Western Australian Parliament all members who spoke expressed similar views including:

Hon Michael Board MLA- The committee found that in most instances the medical profession errs on the side of caution, saying that as something has not been proved it will take a slow, cautious approach. However, the opposite seems to occur with ADHD.

MR Paul Andrews MLA- The first rule of medicine is to do no harm. There is a huge debate about whether the use of medication for the treatment of ADHD is effective. There is a huge debate about the very biological existence of ADHD. There is so much doubt about it that we must question whether the first rule of medicine has been understood by the medical profession and the wider community.

MR Ross Ainsworth MLA- There is a problem but it is very loosely defined because there is no clear evidence of a physical condition around which a boundary can be put to indicate that it is ADHD and that everything outside it is something else. The edges are very blurred; there is a range of behaviours that would fit some of the criteria for assessment as ADHD, but in many cases the behaviours are brought about by a range of other conditions that have nothing to do with what is described as ADHD.<sup>514</sup>

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<sup>513</sup> Board, *Hansard*, 16 April 2003, pp.6844b-6848a.

<sup>514</sup> Ross Ainsworth MLA (2004), *Hansard*, Parliament of Western Australia, Thursday 11 November, pp.8024c-8030a. Available at [http://www.parliament.wa.gov.au/Hansard/hansard.nsf/0/4d630a272cef0e46c82575700016f766/\\$FILE/A36%20S2%2020041111%20p8024c-8030a.pdf](http://www.parliament.wa.gov.au/Hansard/hansard.nsf/0/4d630a272cef0e46c82575700016f766/$FILE/A36%20S2%2020041111%20p8024c-8030a.pdf) (accessed 12 June 2013).

Box 9 below includes the most significant findings and recommendations in relation to the core controversies of ADHD.<sup>515</sup>

**Box 9 - Excerpt from the Findings of the 2004 WA Legislative Assembly Education and Health Standing Committee into ADHD**

Finding 3- The consumption of dexamphetamine in Western Australia is disproportionately high in comparison with other Australian and international jurisdictions. Prescriptions for dexamphetamine were almost four times the national average in the period 1999 to 2003.

Finding 4- During their training, paediatricians have not been adequately informed about the extent of alternative diagnoses and treatment methods, and are therefore more likely to use drug therapy in the first instance in the management of ADHD.

Finding 10- The behavioural symptoms underlying the diagnosis of ADHD are a key factor in the controversy surrounding the condition as many are within the range of 'normal' childhood behaviour.

Finding 11- The clinical diagnosis of ADHD is most often based on reported behavioural observations made by parents and/or teachers. There are no tests that identify the existence of ADHD in a biological sense. This is one of the reasons for the divergent views on the existence of ADHD as a clinical entity.

Finding 12- Comorbidities or coexisting conditions may be misdiagnosed as ADHD due to the similarity in behavioural symptoms.

Finding 13- There is a paucity of evidence on the long-term effects of psychostimulant medication on children.

Finding 14- Individuals who are prescribed psychostimulant medication may also be prescribed other medications to alleviate side effects.

Finding 15- There have been cases in Western Australia of prescribed stimulant medication levels exceeding the recommended dosage, which have resulted in some children requiring hospital admission for detoxification and reported episodes of psychotic behaviour.

Finding 21- The greater use of dexamphetamine in Western Australia for the treatment of ADHD is inconsistent with practice in all other Australian States and Territories.

Finding 23- There are divergent opinions in relation to a connection between ADHD, stimulant medication and later substance misuse. The Committee found that there have been no conclusive results from the studies undertaken on the connection between ADHD, stimulant medication and later substance abuse. Further, no science-based evidence was provided to the Committee of a causal link between undiagnosed ADHD and illicit substance misuse.

Finding 24- There is a growing body of evidence to suggest that stimulant medication is sometimes diverted for illicit use.

Finding 26- There is evidence that repeat prescriptions for stimulant medication are on occasions dispensed too frequently in Western Australia, creating the opportunity for abuse. Currently there

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<sup>515</sup> WA Legislative Assembly, *Attention Deficit Hyperactivity Disorder in Western Australia*.

are no restrictions on dispensing repeat prescriptions of Schedule 8 medication in Western Australia.

Finding 28- The practices and attitudes of individual teachers and schools may influence the rate at which students are diagnosed and possibly medicated for ADHD.

Finding 35- Some parents and/or carers of children suspected to have ADHD experience pressure to have their child formally diagnosed and medicated before that child is included in academic and social activities.

Finding 37- Whilst there is evidence of a correlation between the diagnosis of ADHD and family social and economic dysfunction, whether ADHD is the cause of the dysfunction or ADHD behaviours are the result of the dysfunction is not clear.

The committee had received 83 written submissions and met with 37 witnesses with the full range of views on ADHD. Arguably my, along with Paul Andrews, membership of the committee resulted in it making findings and recommendations in the main consistent with the mild ADHD critic view; that is, ADHD is frequently misdiagnosed and the medications are over-prescribed. The report and individual hearings attracted media coverage that may have contributed to public awareness of concerns about over-prescription that may have contributed to the fall in WA child prescribing rates demonstrated in Figure 5.

The Parliamentary Inquiry and advocacy of individual politicians after the February 2001 State Election clearly favoured an ADHD critic perspective in comparison to the period before 2001. While this coincided with a change of government from Liberal/National to Labor this was never a partisan issue. Rather than party affiliations, attitudes of individual politicians influenced their advocacy and policy outcomes.

## **6.5 Amphetamine Abuse and ADHD Prescribing In Western Australia**

Throughout the 1990s and early 2000s there had been considerable media reporting of the diversion of ADHD amphetamines amongst teenagers and young adults.<sup>516</sup> When data on teenage abuse rates first became available through the 2005 Australian Secondary Students' Alcohol and Drug Survey (ASSAD) it confirmed there was considerable diversion of dexamphetamine for illicit use. Even though prescription rates had begun to drop by 2005 the ASSAD survey estimated that 9,492 (being 5.5 percent) of WA secondary school students

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<sup>516</sup> James, 'WA top State for "Dexies"'.

who had abused prescription amphetamines.<sup>517</sup> This represented 84 percent of the total number of students who had self-reported abusing amphetamines in the previous 12 months. Some may have abused both diverted ADHD amphetamines and illegally produced Methamphetamine but clearly diverted dexamphetamine and Ritalin represented a very significant portion of the problem.

The same survey found that 27 percent of twelve to seventeen year-olds who had been prescribed stimulant medication either gave it away or sold it.<sup>518</sup> Of these, 67 percent had done so in the last year and 30 percent in the last week.<sup>519</sup> The ASSAD survey also showed that 45 percent of WA high school students who had ever taken dexamphetamine or methylphenidate were not prescribed the drugs by a doctor.<sup>520</sup>

Students were also asked how many dexamphetamine tablets or Ritalin they usually have at one time and where or from whom they usually get dexamphetamine or Ritalin. Most students (53 percent) had only one or two dexamphetamine or Ritalin at one time, 26 percent reported taking three to four and 21 percent reported having 5 or more at one time. Students who were not prescribed dexamphetamine or Ritalin by their doctor reported they were given them by someone who is prescribed them (24 percent) or given them by someone who doesn't have a prescription for them (17.2 percent). Fourteen percent bought dexamphetamine either from someone who was prescribed them (9 percent) or someone who did not have a prescription for them (5 percent). Four percent reported trading or swapping something for dexamphetamine or Ritalin and two percent got them from other means or sources.<sup>521</sup>

Specific data about the abuse of prescription ADHD drugs was not collected until the 2005 ASSAD survey. However, from the 2002 ASSAD Survey to the 2005 ASSAD Survey there was a reduction in 'last 12 month amphetamine abuse' by Western Australian 12-17 year olds from 10.3 percent to 6.5 percent.<sup>522</sup> Subsequent ASSAD surveys showed that between 2005 and 2008 as prescribing rates continued to fall so did teenage amphetamine abuse rates. In

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<sup>517</sup> Drug and Alcohol Office WA, *ASSAD Drug Report 2005*, pp 30–32.

<sup>518</sup> Drug and Alcohol Office WA, *ASSAD Drug Report 2005*, p.33.

<sup>519</sup> Drug and Alcohol Office WA, *ASSAD Drug Report 2005*, p.33.

<sup>520</sup> Drug and Alcohol Office WA, *ASSAD Drug Report 2005*, p.33.

<sup>521</sup> Drug and Alcohol Office WA, *ASSAD Drug Report 2005*, p.33.

<sup>522</sup> P. Griffiths, R. Kalic, & A. Gunnell (2009), *Australian School Student Survey 2008: Western Australian Results (excluding tobacco)*, Brief Communication no. 2, Drug and Alcohol Office, Perth.

total between 2002 and 2008 there was a massive 51 percent decline in teenage (last 12 months) amphetamine abuse rates.<sup>523</sup> Over the same time period, 2002 to 2008, the proportion of WA children prescribed ADHD medications fell from 2.6 percent to 1.39 percent - a drop of 47 percent. Rates continued to fall until 2010 bottoming out at 1.3 percent before rising marginally to 1.34 percent in 2011 (see Figure 5 at 4.3).

Interstate comparisons of dexamphetamine prescription rates and amphetamine abuse rates confirm that high prescribing rates are associated with high amphetamine abuse rates. In the 2003 Commonwealth Department of Health and Aged Care Survey the national average of dexamphetamine prescriptions was 11.3 per 1000 population, Victoria reported the lowest rate of 6.7, while WA was clearly the highest with a rate of 43.2.<sup>524</sup> In 2004 WA had the highest level of amphetamine abuse of all states, with a rate of 4.5 percent of the population aged 14 years and over having abused amphetamines in the past year. This was well above the national average of 3.2 percent. Victoria had one of the lowest rates of just 2.8 percent.<sup>525</sup> The proportion of people presenting for treatment with amphetamine abuse as the principal drug of concern in 2005/6 also confirmed this trend. The Australian average was 11 percent of all treatment episodes with amphetamines identified as the principal drug of concern, while WA reported the highest rate of 24.6 percent and Victoria the lowest with a rate of 6.3 percent.<sup>526</sup>

Far from supporting the commonly made assertion that medicating for ADHD prevents illicit drug abuse by self-medicating untreated ADHD sufferers, all the above evidence supports the assertion that prescribing amphetamines facilitates their abuse. It also supports the contention that the abolition of Block Authorisation and change in personnel between the Stimulants Committee (1997-2003) and the stimulants panel (2003 onwards) not only reduced child prescribing rates but also reduced teenage amphetamine abuse rates. Given that the rationale for state government controls on stimulant prescribing is to prevent diversion these reforms achieved their intended purpose at least in regard to those under

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<sup>523</sup> P. Griffiths, R. Kalic, & A. Gunnell, *Australian School Student Survey 2008*.

<sup>524</sup> Commonwealth Department of Health and Aged Care (2000); Australian Bureau of Statistics, *Population by Age and Sex*, (ABS 3201.0).

<sup>525</sup> Australian Institute of Health and Welfare (2005), *2004 National Drug Strategy Household Survey: State and territory supplement*, AIHW cat. No. PHE 61, Canberra, AIHW, p.7.

<sup>526</sup> Australian Institute of Health and Welfare (2007), *Alcohol and other drug treatment services in Australia, 2005-06*, p.14.

18 years of age.

## **6.6 Learning and Attentional Disorders Society: a Western Australian ADHD Patient Support Group**

A 2004 survey revealed that, 'two-thirds of global health charities and patient groups now accept support from drug or device manufacturers.'<sup>527</sup> Australian investigative health journalist Ray Moynihan contends these groups are not simply puppets of the drug companies. Rather he asserts they are motivated by a desire to help, arguing pharmaceutical manufacturers sponsor these groups as a means of 'helping to paint a picture of an under-diagnosed medical disorder best treated with drugs'.<sup>528</sup>

Moynihan considers that prominent US ADHD support group Children and Adults with Attention Deficit Hyperactivity Disorder (CHADD) is no mere 'advocacy group' but more like a 'highly energised political or religious organisation'.<sup>529</sup> In 2003 CHADD Chief Executive Officer E. Clark Ross admitted that the 'science' to support the validity of ADHD 'really is a matter of belief'.<sup>530</sup>

CHADD honours high-profile ADHD proponents in the 'ADHD Hall of Fame'. Inductees include Distinguished Professor of Psychiatry at the University of Utah School of Medicine, Paul Wender.<sup>531</sup> In 1995 Wender claimed to have found a reliable biological marker, foot tapping.

Fidgeting and foot movements (known in our research setting as 'Wender's sign') are very common signs of hyperactivity in adult ADHD patients – so much so that such patients can usually be diagnosed in the waiting room by a knowledgeable receptionist...I seriously entertain the possibility that this foot movement may be a biological marker for ADHD<sup>532</sup> ...The reduction of the foot sign in ADHD patients may also

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<sup>527</sup> Quoted in Ray Moynihan and Alan Cassels (2005), *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning us all into Patients*, Nation Books, New York, p. 62.

<sup>528</sup> Moynihan and Cassels, *Selling Sickness*, pp. 66–67.

<sup>529</sup> Moynihan and Cassels, *Selling Sickness*, p. 67.

<sup>530</sup> Kelly Patricia O'Meara (2003), 'Putting Power Back in Parental Hands; legislation being considered that would allow parents not schools to decide whether their children need to be medicated as a prerequisite for attending classes', *Washington Post's Insight Magazine*, 26 May.

<sup>531</sup> Breggin, *Talking back to Ritalin*, p.236.

<sup>532</sup> Paul H. Wender (1995), *Attention-Deficit Hyperactivity Disorder in Adults*, Oxford University Press, New York, p.20.

be an indicator of stimulant [drug] response.<sup>533</sup>

CHADD has been influential in the US where drug companies can advertise directly to consumers. However, in Australia this is not the case, which potentially makes pharmaceutical companies potentially more reliant on ADHD support groups to help them maximise patient numbers and profits. Like CHADD, Western Australian ADHD support group the Learning and Attentional Disorders Society (LADS) is partially funded by ADHD drug manufacturers and has a long history of promoting the biomedicalized thesis that ADHD has a biological cause that is best treated with 'safe', 'effective' medication.<sup>534</sup> In a 2004 paid community newspaper advertisement for LADS, executive officer Michelle Toner was quoted as saying:

[ADHD was] caused by an imbalance of the chemical dopamine in the brain...it was as inheritable as height and could create problems with inattention, impulsiveness, memory, organisation, time management and hyperactivity...not all people diagnosed with ADHD were hyperactive and the extreme behaviours often associated with it were uncharacteristic...ADHD medication had been used since 1937 and the 'hysteria' sometimes associated with it was often unfounded and uninformed.<sup>535</sup>

In a similar vein LADS has reassured parents that they are not a cause of their child's behaviour. A LADS ADHD fact sheet produced by Perth Clinical Psychologist Derek Cohen begins:

If I had to select one fundamental issue to comment on in the therapy of ADHD children it would be the erroneous conclusion drawn by many parents and professionals alike that ADHD children have behaviour problems that simply require more discipline. While ADHD children present with problem behaviours, these are due to underlying neuropsychological factors.<sup>536</sup>

On occasions LADS have presented completely inaccurate information. In 2003, on a Perth community television program *Face the Facts*, speaking on behalf of LADS, Michelle Toner and

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<sup>533</sup> Wender, *Attention-Deficit Hyperactivity Disorder in Adults*, pp.139–49.

<sup>534</sup> 'LADS has accepted limited unrestricted grants from pharmaceutical companies.' (Including Eli Lilly and Novartis.) See <http://www.ladswa.com.au/page.php?id=6> (accessed 26 June 2009).

<sup>535</sup> 'Help for ADHD sufferers', *Medical & Healthy Living, Community Newspaper*, Perth, 20 September 2004.

<sup>536</sup> Derek Cohen, ed., *Fact Sheet: Parenting a Child with ADHD*, Learning and Attentional Disorders Society of WA Inc, Perth, n.d.

psychiatrist Dr Roger Patterson made some noteworthy statements. Dr Patterson said:

Dexamphetamine has the amphetamine name in it and this is what people are starting to worry about because they are giving them to children – or they are taking them themselves...let me dispel that, they are taking a medicinal form of amphetamine...this is not addictive stuff. In fact, I wish it was a little more addictive so that my younger patients would remember to take it rather than having to be reminded by their long-suffering parents.<sup>537</sup>

Toner's statements on the same TV program were even more notable. 'In order to get a high equivalent to what people are taking [as] street speed, you would have to take close to 200 tablets. Children take 1 or 6 tablets a day and it is not addictive at all.'<sup>538</sup> Two hundred of the standard 5 milligram dexamphetamine tablets would deliver a dose of 1 gram which would kill most people.<sup>539</sup>

Also obviously ignorant of the effects of 1 gram of dexamphetamine, the interviewer went on to ask Toner: 'Right, but if you do have ADHD and you take the medication, is it successful?' Toner replied, 'Oh yes...a lot of people discovered they had ADHD by accident. For example, truckies who needed uppers to keep them awake while they were driving across the Nullarbor suddenly found that they were driving a whole lot better...when they were taking dexies.'<sup>540</sup> As for Michelle Toner's claim about truckies driving 'a whole lot better', she was presumably unaware that driving with non-prescription dexamphetamine is illegal and carries penalties including disqualification from driving, fines and/or imprisonment. Research has found that rather than 'driving a whole lot better' people who use dexamphetamine illicitly or for ADHD make more mistakes while driving, probably because the drug causes tunnel vision which stops them seeing

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<sup>537</sup> Dr Roger Patterson interviewed on *Face the Facts*, video recording taken from Channel 31 Perth, 27 January 2003.

<sup>538</sup> Michelle Toner interviewed on, *Face the Facts*, video recording taken from Channel 31 Perth, 27 January 2003. This information is also referred to in Ferguson and Rushworth, 'ADHD – The Quick Fix'.

<sup>539</sup> 'Individual patient response to amphetamines varies widely. While toxic symptoms occasionally occur as an idiosyncrasy at doses as low as 2mg, they are rare with doses of less than 15mg; 30mg can produce severe reactions, yet doses of 400 to 500mg are not necessarily fatal.' GlaxoSmithKline's *Prescribing Information for Dexedrine (dextroamphetamine sulphate)*. Available at [http://www.dexedrine.com/docs/dexedrine\\_PI.pdf](http://www.dexedrine.com/docs/dexedrine_PI.pdf) (accessed 26 October 2012).

<sup>540</sup> Toner, *Face the Facts*. This information is also referred to in Ferguson and Rushworth, 'ADHD – The Quick Fix'.



peripheral information like red lights.<sup>541</sup>

In the 1990s LADS was warned twice not to recommend the illegal use of a child's stimulant by parents. Minutes from meetings of the WA Stimulants Committee (formed to monitor the prescription of psychostimulants, see chapter 5) revealed that in August 1998 the Committee wrote to LADS asking it to stop advising parents to take their child's medication if they thought they had adult ADHD.<sup>542</sup>

An example of direct scripted cooperation between LADS and an ADHD drug manufacturer is the press release in box 10 below, prepared by public relations business Last Say Communications on behalf of the manufacturer of Concerta, Janssen Pharmaceuticals.<sup>543</sup> LADS provided the human face for the Concerta story helping to create an emotionally charged sense of urgency about the need for this long-acting form of methylphenidate:

**Box 10 – ADHD: A Day of Calm – Dawn to Dusk Long Lasting Medication to Provide Relief for Kids with ADHD**

From April 1<sup>st</sup> 2007, an effective way of delivering medication over a 12-hour period will be available on the PBS and help children with ADHD normalise their lives. This long acting form of methylphenidate (Concerta) will overcome the stigma of taking their daily medication during school hours, an issue faced by many children with ADHD.

'School can be hell for kids with ADHD,' says Michelle Toner of the Learning and Attentional Disorders Society (LADS), an organisation supporting children with Attention Deficit Hyperactivity Disorder (ADHD) and their parents. 'We always have a box of tissues handy at the LADS office for mums who drop their kids off at school and then come in for a cry.

'Often, the worst problem faced by these kids is the attitude of other children, and the stigma of carrying the ADHD label. Parents work long and hard with teachers to put strategies in place which help their children cope with the demands of the classroom and playground.'

'Medication is often a valuable part of their treatment plan, but the vast majority can only afford short-acting versions, which require a lunchtime dose to be taken at school.'

'Young people hate being singled out like that and many schools don't like the responsibility of medicating children. As a result lots of kids refuse to take their lunchtime dose. For them schoolwork becomes harder, the playground becomes a minefield, and bullying often occurs.'

<sup>541</sup> Beata Silber, Katherine Papafotiou et al (2005), 'The effects of dexamphetamine on simulated driving performance', *Psychopharmacology*, 179, 2005, pp.541–42.

<sup>542</sup> WA Stimulant Committee, *Minutes of Meeting held on 4 August, 1998*, obtained under *Freedom of Information Act 1992*.

<sup>543</sup> Last Say Communications (2007), *ADHD – A Day of Calm – Dawn to Dusk: Long Lasting Medication to Provide Relief for Kids with ADHD*, Media Release, 27 March.

As with LADS 'access orientated' advocacy in regards to the listing of Strattera on the PBS (refer to 5.5.1) LADS willingly allied itself with ADHD drug manufacturers in promoting Concerta.

### **6.7 The Raine Study: a unique Western Australian long-term data review of the safety and efficacy of ADHD psychostimulant use by children**

In January 2005 the Western Australian Minister for Health Jim McGinty, appointed a Ministerial Implementation Committee (MICADHD) to implement the recommendations of the WA Legislative Assembly Education and Health Committee 2004 Parliamentary Inquiry into ADHD. The committee included both members who were ADHD proponents and critics. A number of ADHD proponents on the committee suggested a review of the Raine Study data to see if it provided useful data on the long-term safety and effectiveness of ADHD stimulants.

The Raine Study started in 1989, when 2900 pregnant women were recruited into this comprehensive health and wellbeing research study at King Edward Memorial Hospital in Perth. The mothers were assessed during pregnancy. The children were assessed at birth, and at one year, then two, three, five, eight, ten, fourteen, seventeen and twenty years of age. At each follow up information was collected from the parents and the child. Information on the child's height, weight, eating, walking, talking, eating, behaviour, educational performance any medical conditions or illness etc. was collected.<sup>544</sup>

By age fourteen 'of the 1785 adolescents (remaining) in the sample, 131 (7.3 per cent) had received a diagnosis of ADHD'. At age five none of the 131 had taken ADHD stimulants. By age fourteen, twenty-nine had never taken stimulants, forty-one had been on prescription stimulants in the past but were not taking them, and sixty-one were on ADHD stimulants. This gave three groups for comparison, the 'never medicated', 'previously medicated' and the 'currently medicated' groups. In addition analysis of the effect of the duration of stimulant treatment was undertaken.<sup>545</sup>

Published in February 2010, the data showed significant evidence of long-term harm from the

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<sup>544</sup> Information on the *Raine Study* is available at <http://www.rainestudy.org.au/about/what> (accessed 7 May 2010).

<sup>545</sup> Government of Western Australia (2010), *Raine ADHD Study: Long-term outcomes associated with stimulant medication in the treatment of ADHD in children*, Department of Health, Perth. Available at [http://www.health.wa.gov.au/publications/subject\\_index/a/adhd.cfm](http://www.health.wa.gov.au/publications/subject_index/a/adhd.cfm) (accessed 20 May 2013)

sustained use of stimulants by children to treat ADHD. The review provided the world's first independent data on the long-term effects (eight years) of psycho-stimulant medication.<sup>546</sup> The statistically significant differences that existed at age fourteen occurred between age five and fourteen, after some of the children were medicated. To the extent that (non-statistically significant differences) existed at age five these were 'controlled for by using the "propensity for medication" score, the symptom severity before commencement of medication treatment, and a number of sociodemographic measures'.

The two most significant findings of the MICADHD Raine Study Review were:

1. Long-term cardiovascular changes: 'The most noteworthy finding in the study was the association between stimulant medication and diastolic blood pressure. Compared to not receiving medication, the consistent use of stimulant medication was associated with a significantly higher diastolic blood pressure (of over 10mmHg). This effect did not appear to be solely attributable to any short-term effects of stimulant medication, as when comparing groups who were currently receiving medication, it was found that those who had consistently received medication at all time points had a significantly higher mean diastolic blood pressure than those who had not consistently received medication in the past (difference of 7mmHg). These findings indicate there may be a lasting longer term effect of stimulant medication on diastolic blood pressure above and beyond the immediate short-term side effects.'<sup>547</sup>
2. School performance: 'In children with ADHD, ever receiving stimulant medication was found to increase the odds of being identified as performing below age-level by a classroom teacher by a factor of 10.5 times.'<sup>548</sup>

In addition the report indicated that there was a marginally negative outcome for both ADHD symptoms (inattention and hyperactivity) and depression with the long-term use of stimulant medication.<sup>549</sup>

The finding that amphetamine use may permanently raise diastolic blood pressure was of great

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<sup>546</sup> Government of Western Australia, *Raine ADHD Study*.

<sup>547</sup> Government of Western Australia, *Raine ADHD Study*, p.52.

<sup>548</sup> Government of Western Australia, *Raine ADHD Study*, p.6.

<sup>549</sup> Government of Western Australia, *Raine ADHD Study*, p.5.

significance. It had been previously recognised that while stimulants were in the patient's system, heart rate and blood pressure were elevated, leading to the associated risks of heart attacks and strokes. But it was assumed that when the short-term stimulant effects wore off the cardiovascular system returned to normal.

The finding that past stimulant use increased the probability of an ADHD diagnosed child 'being identified as performing below age-level by a classroom teacher by a factor of 10.5 times' undermines the hypothetical basis of medicating for ADHD. As stated in the MICADHD report the basis for the belief that amphetamines have long-term educational benefits are short-term studies which 'indicate that immediate management of ADHD symptoms allows children to function more effectively within a classroom. It is hypothesised that this makes children more available for learning and allows children to learn skills and concepts which are necessary to function well within a classroom in the future.'<sup>550</sup> The analysis of the Raine Study data was the first time this hypothesis had been tested.

The suggestion that the Raine Study would be a possible source of long-term data on stimulant medication was first made by MICADHD members who were ADHD proponents with a long history of prescribing and advocating the use of stimulants. They were obviously expecting very different results. I expected the results to show no long-term educational benefits or some adverse educational outcome from stimulants, but even I was surprised by the strength of the negative outcomes.

Initially, the ADHD proponents on MICADHD tried to claim that the outcomes for the medicated children were most probably worse than those for un-medicated children, because the medicated children had more severe ADHD. As a member of the committee, however, I insisted on a comparison of the groups at age five, which was prior to any of the children having been medicated. This analysis established that there were no statistically significant differences in developmental, behavioural and health measures before the children were medicated.

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<sup>550</sup> Government of Western Australia, *Raine ADHD Study*, p.30. The short term studies referred to in the Raine Study are Howard B. Abikoff, et al (2007), 'Methylphenidate effects on Functional Outcomes in the Preschoolers with Attention-Deficit/Hyperactivity Disorder Treatment Study (PATs)', *Journal of Child and Adolescent Psychopharmacology*, 17(5), pp. 581–92; C. L. Carlson & M. R. Bunner (1993), 'Effects of Methylphenidate on the Academic Performance of Children with Attention-Deficit Hyperactivity Disorder and Learning Disabilities', *School Psychology Review*, 22(2), pp. 184–98; Irene M. Loe & Heidi M. Feldman (2007), 'Academic and educational outcomes of children with ADHD', *Journal of Pediatric Psychology*, 32(6), pp. 643–54.

Subsequently ADHD proponent members of MICADHD sought to prevent the publication of the data in relation to the long-term safety and efficacy of psycho-stimulants claiming methodological weaknesses despite having approving the design of the study before the results were known. Instead they sought to design and publish the results of a second study which found that social and educational outcomes of children diagnosed with ADHD were worse than those in the general population.<sup>551</sup> This is similar to the behaviour outlined in the *Wall Street Journal* in relation to research controlled by pharmaceutical companies on mental health drugs that 'spin the results of negative findings for the primary outcome – the main question the study was designed to answer – and highlight a positive secondary outcome'.<sup>552</sup>

The chairperson of MICADHD paediatrician Prof Lou Landau resisted the efforts to suppress the long-term medication research and the results were published and received considerable publicity in Australia in February 2010. When published, Professor Ian Hickie from the Brain and Mind Research Institute, dismissed the poor educational outcomes saying, 'typically those kids who go on the medication are considerably worse to start with'.<sup>553</sup> Professor Hickie had not been involved in the research and was presumably unaware of the comparison of the never medicated and medicated groups at age five. Professor Hickie is a very prominent psychiatrist and media commentator on a range of mental health issues who was later embroiled in controversy because of allegations by the editor of *The Lancet* that he exaggerated the benefits and understated the risks of an antidepressant (Agolomatine) he was paid to promote by its manufacturer Servier.<sup>554</sup> Professor Hickie's online 2009 CV acknowledged receipt of \$411,000 from four different pharmaceutical companies, mostly for research on psychotropic medications for depression, psychosis and bipolar disorder.<sup>555</sup>

As with all studies there are limitations with the MICADHD study. While the sample size (131)

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<sup>551</sup> Martin Whitely (2010), *Speed Up & Sit Still: The Controversies of ADHD Diagnosis and Treatment*, Perth, UWA Publishing, p.56.

<sup>552</sup> Armstrong and Winstein, 'Antidepressants Under Scrutiny'

<sup>553</sup> Interview with Professor Ian Hickie on ABC PM program with Mark Colvin, 'New Research Reignites Debate over ADHD', 17 February 2002. Available at <http://www.abc.net.au/pm/content/2010/s2822748.htm> (accessed 15 March 2010).

<sup>554</sup> Sue Dunlevy (2012), 'Campaign targets depression guru Ian Hickie', *The Australian*, 13 February. Available at <http://www.theaustralian.com.au/news/health-science/campaign-targets-depression-guru/story-e6frg8y6-1226269135293> (accessed 7 May 2013).

<sup>555</sup> Professor Ian Hickie received the following grants totalling \$411,000 from pharmaceutical companies: \$10,000 from Roche Pharmaceuticals (1992); \$30,000 from Bristol-Myers Squibb (1997); \$40,000 from Bristol-Myers Squibb (1998–1999); \$250,000 from Pfizer Australia (2009); \$81,000 from Pfizer Australia (n.d.). Cited in Ian Hickie, *Curriculum Vitae*, last updated 23 August 2009.

was small, 'it was larger than those in many short-term studies that supported the use of stimulants as a safe and effective treatment for children with ADHD'.<sup>556</sup> The evidence from the Review does not prove that psycho-stimulants cause failure at school and permanent cardiovascular deterioration but it raises serious concerns. It is notable that despite the fact that the follow up data at age 17 and 20 has been available since 2010, promised follow up research is yet to be undertaken.

## **6.8 Summary of Western Australia's ADHD history**

WA's history is one of rapid growth in ADHD prescribing until 2003, followed by a significant contraction in child prescribing rates with a simultaneous increase in adult prescribing rates. This is a more complex pattern than the general national pattern of consistently increasing rates. It is also notable that WA rates grew much faster than national rates and by 2002 were 2.4 times the national rate for children (see Figure 6 at 4.4.1) and 5 times the national rate for adults (see Figure 7 at 4.4.2).

The downward turning point for child prescribing rates followed closely after an ADHD critic-dominated policy development process that resulted in the introduction of tighter prescribing accountability measures and more detailed prescribing reporting in late 2003. By 2011 WA child per capita prescribing rates were 11 percent below the national average. Adult rates initially fell slightly and then rose consistently and in 2011 were 3.3 times the per capita national average.

Throughout the period of rapidly increasing child and adult prescribing rates (1993 to 2002) policy development and regulatory processes were almost exclusively dominated by ADHD proponents with a 'biomedicalized' perspective. Most notably the Stimulants Committee tasked with ensuring clinicians prescribed responsibly showed little interest in their appointed task. They sought to remove already loose controls and advocated for further personal exemptions from accountability measures for themselves.

The Stimulants Committee was established in response to concerns about misdiagnosis and over-prescription however, it became dominated by ADHD proponents. The WA Health

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<sup>556</sup> Government of Western Australia (2010), Department of Health, 'Study raises questions about long-term effect of ADHD medication', *Media Release*, 17 February.

Department 2002 report *Attentional Problems in Children and Young People* contained a number of ADHD proponent friendly recommendations however these were ignored and reversed by ADHD critic political intervention.

This suggests change is not 'linear' or 'neutral' in that a contest between competing interests and ideologies in both policy formation and implementation has resulted in a series of 'wins' and 'losses' for ADHD proponents and critics in WA. In summary ADHD proponents captured processes and 'won' with rapidly increasing child prescribing rates until 2002/2003, however subsequently ADHD critics have had considerable success in reducing child (but not adult) prescribing rates. These issues are discussed in greater detail in Chapter 7.

## **6.9 New South Wales ADHD policy and regulatory history**

As outlined at 4.4.1 New South Wales (NSW) child prescribing per capita rates are now significantly above the national rate and have risen rapidly since 2007. Prior to 2007 WA had had much higher rates but NSW rates are now significantly higher (see Figure 6). The following section analyses policy and regulation in NSW of ADHD prescribing that occurred since 2007.

### **6.9.1 ADHD in Children and Adolescents in New South Wales – 2007 Clinical Excellence Commission Prescribing Review**

In April 2007 NSW District Court Judge Paul Conlon, when sentencing a twenty-year-old man for aggravated sexual assault, said that in his experience ADHD medications were causing significant criminality and drug abuse. 'I have huge concerns. The tide of cases is amazing...I am starting to lose count of [the number of] offenders coming before the courts who were diagnosed at a very young age with ADHD for which they were "medicated".'<sup>557</sup> Judge Conlon also said he had seen signs that children prescribed psychostimulant drugs like Ritalin went on to develop addiction to drugs like methamphetamine. He also expressed frustration at the failure of the medical profession to effectively self-regulate:

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<sup>557</sup> Janet Fife-Yeomans (2007), 'The Ritalin Generation – Top judge condemns the ADHD explosion', *The Daily Telegraph*, 26 April.

My own research indicates that ADHD is perhaps the most over-diagnosed condition in today's society...I think it's an absolute disgrace and those doctors and psychiatrists really need to look much more closely at the child and consider other methods of treatment other than putting them on these drugs and chemicals...In other words, they need to apply greater professional rigour.<sup>558</sup>

Then NSW Health Minister Reba Meagher responded to Judge Paul Conlon's comments by setting up a committee to review NSW ADHD diagnosing and prescribing. The purpose of the 'review was to:

- 1- Advise on the current development of clinical guidelines in Australia for the treatment of ADHD and on treatment via the prescription of the stimulant medications dexamphetamine and methylphenidate.
- 2- Assess current practice in the assessment and treatment of ADHD.
- 3- Undertake a clinical audit of a cross-section of medical practitioners approved under Section 29 of the Poisons and Therapeutic Goods Act 1966 to prescribe stimulant medication for ADHD, to assess whether current practice complies with the requirements of the Act and its regulations, which are referenced in the NSW Health Criteria for the Diagnosis and Management of Attention Deficit Hyperactivity Disorder in Children and Adolescents, Version 6, June 2004.

The focus of the review [was] on children and adolescents less than 18 years of age, but may also consider the 'impact of treatment and prescribing practice in adults.'<sup>559</sup>

The review was conducted without public input into either its membership or process, and was restricted to a literature review, a survey of prescribers outlining their prescribing practices and a review of the data from the NSW Stimulants Committee. The review chairperson Professor Philip Mitchell and two other committee members, Drs Patrick Concannon and Paul Hutchins, have served as advisers to manufacturers of ADHD drugs.<sup>560</sup> In addition, many of the members of the review committee were prescribers who were in effect reviewing their and their colleagues' practice. Professor Philip Mitchell and Doctors Patrick Concannon and Paul Hutchins

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<sup>558</sup> Fife-Yeomans, 'The Ritalin Generation'.

<sup>559</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p9.

<sup>560</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.64.



declared their connections to drug manufacturers, but claimed there were no conflicts of interest.<sup>561</sup> Dr Concannon later was also a member of the NHMRC 2009 ADHD Guidelines Reference Group and Chairperson of the NSW Stimulants Committee (see 5.3.2). Dr Hutchins was a member of the NHMRC Committee that developed the 1997 National ADHD Guidelines (see 5.3.1).

The review report states as established fact the hypothetical proposition that ADHD is a brain dysfunction, specifically a 'neurodevelopmental condition'.<sup>562</sup> It also stated 'since their origin in 1989, the New South Wales guidelines have been regularly updated to reflect the current international consensus.'<sup>563</sup> It quoted the International Consensus statement on ADHD published in January 2002. One of the review panel members Doctor Florence Levy was one of 87 signatories of the International Consensus Statement. Along with Dr Hutchins she was a member of the NHMRC 1997 National ADHD Guidelines Committee.

The review concluded that, 'the overall impression was of conscientious doctors giving plenty of time trying to offer the best total management in these very complex situations'.<sup>564</sup> The review, however, was restricted to an audit of 137 of the 19,382 patients (0.7 per cent) and was a file review only. In other words only the clinician's file notes were reviewed. There was no fresh diagnosis of the children by interviewing parents and teachers. Participation in the audit and the practice survey by prescribers was voluntary, with only 207 of 367 prescribers co-operating.<sup>565</sup> The review described the 56 per cent response rate of prescribers as 'excellent', despite the potential bias that those who were confident in the rigour of their practices were more likely to participate and the tendency to overestimate one's own professional competence.<sup>566</sup>

Another notable aspect of the review was the willingness of clinicians to prescribe a range of psychotropic drugs in conjunction with stimulants. The proportion of other drugs prescribed by surveyed clinicians with stimulants was: Clonidine (75 per cent), atypical antipsychotics (71 per cent), SSRI antidepressants (66 per cent), anti-epileptic medications

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<sup>561</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, pp.64–65.

<sup>562</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.14.

<sup>563</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.10.

<sup>564</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.32.

<sup>565</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p. 20.

<sup>566</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.25.

(55 per cent), tricyclic antidepressants (27 per cent), other antidepressants (14 per cent) and conventional antipsychotics (12 per cent).<sup>567</sup> Some of these drugs are contraindicated for use with stimulants and/or are not recommended for use in children. For example no SSRI or any antidepressant is 'currently approved in Australia for the treatment of MDD [major depressive disorder] in children and adolescents (persons aged less than 18 years).'<sup>568</sup>

The prescribing patterns of clinicians were similar to those in Western Australia, with a minority of prescribers specialising in ADHD. 'For 7% of practices, patients with this condition (ADHD) comprised 51-90% of their patients and for one practice (0.5% of the sample) having patients with this condition accounted for more than 90% of their patients.'

<sup>569</sup> The review also confirmed that NSW paediatricians, like their WA colleagues, were far more likely to be frequent prescribers than a child psychiatrist with '34 percent of paediatricians, and only 5 percent of child psychiatrists, prescribing to 100 or more patients.'<sup>570</sup>

The review report also contained the common ADHD proponent claim that prescribing rates are less than prevalence rates. It quoted the flawed Commonwealth Government commissioned research that estimated an 11.2 percent prevalence estimate (refer to 4.4.1) without identifying the complete absence of measurement for dysfunction in that estimate and concluded that 'as the prevalence of ADHD in Australia is up to 11 percent of children and adolescents, we would consider that the rate of prescribing of stimulants for ADHD in NSW (0.5 percent to 1.5 percent) is conservative.'<sup>571</sup>

The review report also quoted the fourteen-month results of the Multimodal Treatment of Attention Deficit Hyperactivity Disorder (MTA) study which were supportive of the use of stimulants to treat ADHD.<sup>572</sup> However, the review did not reference the three-year follow-up results of the MTA. The three-year data indicated no long-term benefits and significant risks of

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<sup>567</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.24.

<sup>568</sup> Therapeutic Goods Administration (2004), *Use of SSRI Antidepressants in Children and Adolescents*, Department of Health and Ageing, Canberra, 15 October (updated May 2011). Available at <http://www.tga.gov.au/safety/committees-adrac-ssri-041015.htm> (accessed 13 February 2013).

<sup>569</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.20.

<sup>570</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.27.

<sup>571</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.12.

<sup>572</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.15; Allegra Stratton (2007), 'Questions raised about drugs as treatment for ADHD sufferers' *The Guardian*, 12 November.

stunted growth.<sup>573</sup>

The review report stated that;

‘many of the children and families were battling with very complex situations...many children had significant learning difficulties, social problems, and other developmental conditions and were living in dysfunctional and sometimes chaotic families, including changes in carers. Several children were being reared by grandparents and a number were in foster homes or experiencing multiple placements. Domestic violence and parental substance abuse were not uncommon.’<sup>574</sup>

Some of the other more notable features of the review were:

- ‘When conducting a routine review of a patient on stimulants 67% of prescribers normally assessed blood pressure.’<sup>575</sup> Given that the risks of cardiovascular adverse events, particularly strokes and heart attacks, are increased significantly by using stimulants, it is arguable all prescribing clinicians should routinely assess blood pressure.
- ‘The following details were recorded at review sessions, Weight (79%), Height (68%).’<sup>576</sup> Given that growth retardation is an established side effect of stimulants, it is arguable all prescribing clinicians should routinely measure weight and height.
- ‘When making the diagnosis of ADHD 76% of clinicians assess vision and hearing.’<sup>577</sup> This means that almost a quarter of clinicians don't check if a child's lack of attention may be caused by an inability to see or hear properly.
- When prescribing stimulants, only 70 percent of clinicians provide current Consumer Medicine Information.<sup>578</sup> Providing Consumer Medicine Information to parents and patients requires minimal effort and the failure to do so by 3 in 10 surveyed clinicians reflects a disregard for the principle of informed consent.

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<sup>573</sup> Whitely, *Speed Up & Sit Still*, p.175.

<sup>574</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p 32.

<sup>575</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.23.

<sup>576</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.31.

<sup>577</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.21.

<sup>578</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*, p.23.

It is noteworthy that the above figures were based on clinicians' self-reporting their practice habits and are therefore likely to overstate practice competence.

The catalyst for the review was Judge Conlon's comments. After the review was completed the *Daily Telegraph* reported (25 February 2008), that as a result of a complaint by an undisclosed ADHD support group, Judge Conlon was 'gagged' from making further comments on his experience of ADHD medications leading to drug abuse and criminality.<sup>579</sup> Judge Conlon had called on the medical profession to apply greater 'professional vigour'. The outcome was a review conducted by a group with extensive conflicts of interest who - on the basis of self-reporting by prescribing clinicians - concluded there was no problem while the catalyst for the study, Judge Conlon, was prevented from further comment.

The controls on clinicians prescribing ADHD stimulants in NSW are similar to those that existed in WA prior to the abolition of 'Block Authorisation' in August 2003. Provided that they prescribe within 'routine prescribing criteria' in relation to patient dosages and age restrictions 'Paediatricians and Child Psychiatrists who wish to prescribe stimulants may apply to the [Health] Department...for a general authority number (CNS Number) which allows the prescription of stimulants for patients under their care, without further application, provided that...

- All prescriptions issued using the CNS number are notified (using the Notification form) to the Department each month. [and]
- The prescriber participates in clinical audits concerning the prescription of stimulant medications as requested by the Department of Health.<sup>580</sup>

In other words, like those WA authorised prescribers who prior to August 2003 had block authorisation, NSW paediatricians and child psychiatrists with a general authority number (CNS Number) can prescribe for unlimited individual patients without requiring individual approvals. Again similar to the provision that existed in WA prior to August 2003 special case by case approval must be sought for dosages above the prescribing criteria or for very young patients.

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<sup>579</sup> Janet Fife-Yeomans (2008), 'Go sit in the corner – Judge who spoke out against Ritalin kids gagged', *The Daily Telegraph*, 25 February.

<sup>580</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*.

In NSW 'Other Designated Prescribers' doctors who are not psychiatrists and paediatricians, can prescribe to individual patients. However they 'must obtain an authority for each individual patient. Applications which fall outside the routine prescribing criteria will not be approved.'<sup>581</sup>

The pattern of total regulatory capture by ADHD proponents and rapidly rising prescribing rates for the period 2007 to 2011 is consistent with the national pattern for the period 1993 to 2011 outlined in Chapter 5. The relationship between regulatory capture and pharmaceuticalization in NSW is discussed in greater detail in Chapter 7.

### **6.10 WA and NSW comparative history of regulation and prescribing rates**

As highlighted at 4.4 WA and NSW inter-temporal prescribing rates have exhibited considerably different patterns most notably:

- From 1992 to 2002 WA and NSW per capita prescribing rates grew rapidly although WA rates were much higher throughout the whole period being at least twice as high for children and four times higher for adults.
- From 2003 WA child prescribing rates fell approximately 50 percent and NSW rose rapidly. By 2011 NSW per capita PBS child prescribing rates were 25 percent above the national rate, while WA rates were 11 percent below.
- WA adult rates in 2011 were similar to those in 2002. NSW rates have grown substantially (approximately 50 percent) from 2008 to 2011 however they were still less than a third of WA rates.

WA rates for children fell significantly after regulatory changes resulting from a critic dominated process. In contrast NSW child prescribing rates grew rapidly after a proponent 'captured' process. This is consistent with the contention that regulatory capture influences prescribing rates and is part of the explanation of ADHD pharmaceuticalization. These issues are discussed in greater detail in Chapter 7.

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<sup>581</sup> CEC, *Attention Deficit Hyperactivity Disorder in Children and Adolescents in New South Wales*.

## **Chapter 7. Discussion, Conclusions and Recommendations**

This chapter finishes the thesis by synthesising the contents of previous chapters and testing the working hypothesis and discussing the theoretical and policy implications for Australia and similar jurisdictions.

### **7.1 The Hypothesis**

The central hypothesis of this research is that regulatory capture of the development and implementation of ADHD policy has contributed to variations in Australian geographical and inter-temporal ADHD medication child prescribing rates.

### **7.2 Pharmaceuticalization for childhood ADHD in Australia**

As identified at various points in this thesis there are limitations in the Commonwealth Government data sources in regard to ADHD prescribing rates. However, irrespective of these limitations the trend in the available data is so strong that it provides ample evidence of an explosion in Australian ADHD child prescribing rates for the period 1993 to 2011. The clearest evidence of this pharmaceuticalization is presented in Figure 2. Specifically from 1995 to 2010 there was a 277 percent per capita increase in prescription rates. In addition Figure 3 demonstrates that between 2002 and 2011 the number of children receiving PBS subsidised ADHD medication grew 98 percent while Australia's population only grew 13.5 percent (see 4.2).

WA is an exception to this trend. From 2003 there has been a significant and sustained fall in child ADHD prescribing rates indicating a less pharmaceuticalized response to childhood ADHD in WA for that period. However, during the period 1993 to 2003 WA was an outlier with child ADHD per capita prescribing rates being multiples of the national average (see 4.4). Over the period 2003 to 2008 WA child prescribing rates fell sharply while in other states they rose and have continued to rise. Since 2008 there has been a further small fall so that in 2011 WA's per capita child prescribing rate was 11 percent below the national average (see 4.4.1).

The latest available state based data for 2011 and historical data indicates there is considerable variation between state per capita child prescribing rates indicating variations

in the degree of pharmaceuticalization across jurisdictions.<sup>582</sup> Furthermore the divergence in the pathway of child and adult prescribing rates in WA, with WA adult per capita prescribing rates remaining way above the national average, indicates that different factors influence different demographics within the same geographical jurisdiction. The review of NSW and WA policy development and regulatory processes indicates that the degree of capture correlates with prescribing rates. ADHD proponent domination of processes is associated with high and increasing prescribing rates whereas the one example of a critic dominated process has been associated with falling rate for children. However, the divergence in the pathway of child and adult prescribing rates in WA, with WA adult per capita prescribing rates remaining way above the national average, indicates that different factors can influence different demographics within the same geographical jurisdiction.

### **7.3 The contest to influence ADHD policy and regulation in Australia**

Although some ADHD proponents have sought to portray the validity of the diagnosis and appropriateness of the pharmaceutical treatments as incontrovertible (see 2.4) there is ample evidence presented throughout this thesis that ADHD diagnosis and treatment and related policy and regulation is very controversial. The controversy attracts considerable and sustained attention both within medical-psychiatric circles and the media and general public. However, the extent to which policy development and regulatory processes are contested between ADHD proponents and ADHD critics is highly variable.

American based processes, particularly the American Psychiatric Association's development of the Diagnostic and Statistical Manual of Mental Disorder, have been dominant in determining whether ADHD is recognised and how it is diagnosed and treated in Australia. These processes have not been influenced by Australian regulators or professional bodies. These processes have therefore have been 'uncontested' within Australia in their development, although there has been some media and professional criticism of their adoption in Australia (see Chapter 3).

The development of proposed and abandoned changes for ADHD diagnostic criteria in DSM5 published in 2013 demonstrates that the development of ADHD criteria is essentially

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<sup>582</sup> Department of Health and Ageing, *Letter to Martin Whitely dated 21 April 2012*.

a political rather than a scientific process. The proposed addition of four additional potential ways of displaying ADHD was abandoned in the face of criticism. This is evidence that the DSM outcomes are negotiated, rather than scientifically self-evident. Despite this the DSM outcomes have been exported to Australia with very little scrutiny within Australia (see 3.6).

Throughout this thesis there are several examples of processes within Australia in which ADHD proponents have set policy or applied regulations in an ‘uncontested internal process’. The meaning of ‘uncontested internal process’ in this context is where there are no ADHD critics, only ADHD proponents, involved in the formal policy development or regulatory process. These processes have also typically been closed with no or little opportunity for public input. Examples include the:

- NHMRC Australian ADHD Guidelines processes (1997 and 2009)
- WA Stimulants Committee (1997-2003)
- WA International Panel on ADHD (1999)
- NSW ADHD in Children and Adolescents Special Review (2007)

Some of these proponent dominated closed processes have attracted limited criticism and scrutiny after the event. However, only one process identified in this thesis, the 2009 draft ADHD guidelines, was subject to sustained external media scrutiny prompted by ADHD critics.

There are also a few examples of ‘balanced’ processes in which ADHD proponents and critics have contested the outcomes within the formal policy development process. These examples include the Australian ADHD Clinical Practice Points process, the WA Ministerial Implementation Committee on ADHD (MICADHD) process and the WA Technical Working Party on ADHD. However, while it is premature to assess the impact of the ADHD Clinical Practice Points process there is evidence that for the other two contested processes some of the implementation of recommendations from those processes have been ‘captured’ by ADHD proponents. This was particularly the case with the Technical Working Party on ADHD process in which the resulting Stimulants Committee was totally dominated by ADHD



proponents who sought to loosen controls on prescribing and promoted a heavily pharmaceuticalized approach to ADHD (see 6.3.2).

Throughout the period of this thesis and within the three jurisdictions analysed (Australian National, WA and NSW) there is only one example of an uncontested internal ADHD critic dominated process. That example is the redraft of the WA Mental Health Division *Attentional Problems in Children and Young People* report which resulted in the abolition of Block Authorisation and the establishment of the Stimulants Regulatory Regime in WA in 2003.

In summary most important local and imported policy development and regulatory processes, have been dominated by ADHD proponents. Some local processes have been contested by proponents and critics and only one dominated by ADHD critics.

## **7.4 Regulatory Capture**

Regulatory capture occurs if a government or non-government agency created to act in the public interest instead advances commercial or industry interests at the expense of the public interest. Theorists propose that regulatory capture is a result of a mismatch of resources and effort where commercial entities with a significant interest in a policy or regulatory process focus on influencing the outcome. The public, who are less immediately and foreseeably affected by the outcome and lack the resources of commercial entities, are far less likely to seek to influence the outcome (see 2.8).

### **7.4.1 Imported Regulatory Capture**

Despite a complete lack of Australian input and widespread concerns about improper pharmaceutical company influence upon the American Psychiatric Association, (see 3.2) Australian agencies, both Commonwealth and State Government and Non- Government, have endorsed and promoted the use of the ADHD DSM-IV diagnostic criteria. There have been some isolated calls to end the dominance of the DSM model on Australian psychiatric practice. However, they have been ineffective. The dominance by the American Psychiatric Association of the definition and diagnosis of ADHD has effectively become imported regulatory capture.

Alternative diagnostic criteria, the *International Classification of Diseases 10* (ICD-10) produced by the World Health Organisation (WHO), has been consistently ignored by Australian regulatory agencies despite Australia being a member of the WHO. DSM-IV criteria have been associated with increased prescribing rates as compared to jurisdictions relying on ICD-10. It is therefore likely that regulatory capture of the American Psychiatric Association has contributed significantly to Australia's increasingly pharmaceuticalized response to ADHD.

The decision to use DSM-IV, rather than ICD-10, has been made in several important Commonwealth Government ADHD policy processes, without providing a rationale (see 5.3). In addition in no process has there been any attempt to compare the educational, social and health outcomes of countries using ICD-10 criteria with those using DSM-IV. A cursory examination of the wellbeing of children using DSM-IV indicates both higher ADHD prescribing rates and reduced wellbeing (see 3.1). From a public interest perspective this observation at least invites proper examination of this issue before endorsing either the DSM-IV or the ICD-10 approach. Each of the processes that have recommended DSM-IV, rather than ICD-10, has been a captured process. It is therefore not surprising, that the criteria associated with higher prescribing rates, were preferred. However, it is noteworthy that there has been a convergence of the contents of the DSM and ICD over time.

Over time there has also been a progressive broadening of the DSM-IV diagnostic criteria for ADHD and the conditions that predated ADHD and increasing international prescription rates. This expansion of both the diagnostic criteria and pharmaceutical markets has happened without significant accompanying breakthroughs in the science of the diagnosis or treatments. It is notable that several unsubstantiated claims of scientific breakthroughs in the diagnosis and treatment of ADHD have received considerable media coverage (see 2.3.1.2).

Other examples of significant imported regulatory capture include the reliance on International 'experts' with significant and in some cases hidden commercial ties to ADHD drug manufacturers. Notable examples include the:

- Influence on the 2009 National Draft Guidelines by Harvard Professors Biederman, Spencer and Wilens (see 5.3.2.1).

- Western Australian International Panel on ADHD (see 6.3.3).
- International Consensus Statement that has been quoted in a number of Australian policy processes (see 2.4).

There has also been a pattern of selective attention to international research where research favourable to the perspective of ADHD proponents is promoted but research unfavourable to their perspective is ignored. Examples of significant unfavourable research which have had virtually no effect on Australian public policy include the:

- Oregon Health and Science University *ADHD Drug Effectiveness Review Project* – that critiqued unfavourably ‘virtually every investigation ever done on ADHD drugs anywhere in the world’ determining there is a dearth of research on the long term effects of medications (see 3.5).
- British Columbian Birthday Study titled *Influence of relative age on diagnosis and treatment of ADHD in children* – that revealed amongst the over 938,000 studied, children born in the last month of their school year were much more likely to be diagnosed and medicated for ADHD than their older classmates (see 5.3).

An example of the same phenomena is the MICADHD Raine Study ADHD Review. It provided unique and significant evidence in regards to the long term safety and efficacy of ADHD stimulants that attracted some media attention in Australia but has had little practical effect in Australia and has been virtually ignored internationally (see 6.7).

#### **7.4.2 Regulatory Capture of Australian Commonwealth Government Processes**

Decisions by the Commonwealth Government determine which medications are licenced for sale and which are subsidised via the Pharmaceutical Benefits Scheme. It also gives guidance as to the circumstances for their use and determines the price patients pay for the medications. The Commonwealth Government also subsidise the payments to clinicians who diagnose the ‘disorder’.

An early example of questionable but influential research sponsored by the Commonwealth Government was the 1998 prevalence estimate discussed at 4.4.1. The research was significantly methodologically flawed, resulting in a significant overestimate of the true

proportion of children who would qualify for a DSM-IV diagnosis. Despite this the 11.2 percent estimated prevalence rate remains frequently quoted by both ADHD proponents and even an Australian Government Health Minister to demonstrate the significance of the issue and the extent of under-diagnosis and under-treatment.

Analysing the relative influence of ADHD proponents with a 'biomedicalized' and ADHD critics with a 'medicalization' perspective on Commonwealth Government policy and regulatory processes is most logically done both on an inter-temporal and agency by agency basis. Chronological analysis enables the identification of cross agency inter-temporal trends. Agency analysis enables the identification of patterns of behaviour in regards to specific functions.

The following Table (Table 4) is a summary of the history of Commonwealth Government ADHD policy development and regulation in chronological order:

| <b>Agency, process and date</b>                                         | <b>Outcomes of Process</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Nature of process, captured, contested, neutral or critic dominated</b>                                                                                                                                        |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| TGA<br>licencing of Ritalin 1993<br>and licencing of Ritalin LA in 2002 | <p>The Therapeutic Goods Authority (TGA) licenced Ritalin for use in Australia despite being warned by the Australian Drug Evaluation Committee the safety and efficacy data to support the submission was 'deficient in certain areas when compared to that usually required by the Australian Drug Evaluation Committee and the Commonwealth Department of Health'. (see 4.5.1)</p> <p>.....</p> <p>Without any specific data for Ritalin LA the TGA used the 'deficient' safety data from the original 1993 Ritalin application to approve Ritalin LA for use to treat ADHD despite the fact that it contained a higher dose of methylphenidate with an increased risk of overdose. (see</p> | <p>There is insufficient information to determine if any conflicts of interest existed in either process however, the licencing processes were not rigorous and the outcome clearly favoured ADHD proponents.</p> |

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|                                                                                                                                                                      | 4.5.1)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                 |
| NHMRC<br>ADHD<br>Guidelines<br>1997                                                                                                                                  | The NHMRC established a working party to produce guidelines designed to advise clinicians on the diagnosis and treatment of ADHD. The guidelines working party made comprehensive and emphatic pro-medication recommendations despite acknowledging the cause/s of ADHD are unknown. Non-drug interventions were dismissed as costly and time wasting and a violation of the rights of the child to effective treatment. The guidelines encouraged clinicians to diagnose outside the already broad DSM-IV criteria and prescribe outside approved guidelines for the use of medications. The guidelines identified stimulants as being the first-line of treatment and encouraged the use of other drugs either as complementary or second-line treatments based on reasonable theory and clinical experience without placing any practical limitations on what constitutes reasonable theory. (see 4.4.2) | There was no conflict of interest information collected at the time the guidelines were developed. However, several members of the Guidelines development committee have subsequently declared commercial ties to the pharmaceutical industry or have been strong proponents of ADHD diagnosis and prescribing. |
| Department<br>of Health<br>and Ageing<br>sponsored<br>research on<br>the<br>prevalence<br>of mental<br>illness<br>amongst<br>Australian<br>children<br><br>1998-2000 | The Department of Health and Ageing commissioned research published in 2000 but based on data collected in 1998 that estimated that 11.2 percent of Australian children age 6 to 17 had ADHD. The research was methodologically flawed in that it ignored the requirements that ADHD behaviours occur in at least two settings to a degree that impairs effective functioning and are not due to other factors. As a result the research significantly overestimated the proportion of children that would qualify for a diagnosis using the full DSM-IV diagnostic criteria. This fundamental flaw has been ignored on numerous occasions - including by the Federal Health Minister - and used to counter criticism of misdiagnosis/over-prescription and argue that to the contrary ADHD is under-diagnosed and under-medicated.                                                                         | There is no publicly available information about potential conflicts of interest for the authors of the study.                                                                                                                                                                                                  |

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|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                   | (see 4.4.1)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                        |
| TGA<br>licencing of<br>Strattera<br>2004 and<br>post market<br>regulation<br>2006 | <p>The TGA licenced Strattera (atomoxetine) for use in Australia. The TGA relied on research funded by manufacturer Eli Lilly and run and designed by researchers chosen by Eli Lilly. The TGA does not consider previous research conducted by Eli Lilly that demonstrated Strattera is unsuitable as an antidepressant. For the one of the two studies used to support its licencing application for Strattera by Eli Lilly that I reviewed to analyse its independence Eli Lilly chose employees and shareholders to conduct the study and controlled the dissemination of results. (see 4.6.2)</p> <p>.....</p> <p>The TGA placed the highest possible boxed warning on Strattera for suicidal ideation. As is standard practice in Australia this boxed warning is placed on the product information made available to prescribers but not on Consumer Medicine Information sheets that are provided to patients, or parents of child patients, on request. The TGA did this six months after the US FDA took similar action however, the TGA did not issue a press release or seek any publicity to ensure patients or parents were informed. The TGA left the decision about whether to inform parents and/or patients for suicidality with individual prescribers. The TGA also issued similarly low key warnings for Strattera for potentially fatal liver damage (2005) and an increased risk of adverse cardiovascular events (2011). In addition the TGA did not publicise or alert Australian media about any of subsequent 113 voluntary adverse event reports – including more than fifty of suicidal/homicidal ideation - up until November 2010. All through this period the TGA made adverse event</p> | There is insufficient information to determine if any conflicts of interest existed in either process. However, the licencing processes and post market regulation were not rigorous and the outcome clearly favoured ADHD proponents. |

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|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                         | reports available upon request but did not publish them either through the media or the internet. (see 4.6.2)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                     |
| PBS listing for subsidy of Strattera 2007               | Despite the then current warnings for suicidal ideation and potentially fatal liver damage for Strattera the Pharmaceutical Benefits Scheme Advisory Committee (PBAC) recommended Strattera's inclusion on the PBS in November 2006. Because of the high estimated cost (an anticipated cost to taxpayers of \$101.2 million over four years) Howard Government cabinet approval was needed. This was obtained and Strattera was subsidised via the PBS beginning 1 July 2007. In 2010 the Department of Health and Ageing successfully defended my appeal against denial of access via Freedom of Information processes to the documents used by the PBAC to recommend the PBS listing of Strattera. The Department argued successfully that the Health Act 1953 afforded the same privacy rights to Eli Lilly as are afforded to the Commonwealth health records of individuals. This Administrative Affairs Tribunal determination created a precedent denying public access even via Freedom of Information processes to the records of dealings between Commonwealth Government agencies and pharmaceutical companies. | There is insufficient information to determine if any conflicts of interest existed in either process. However, the licencing processes were not rigorous and the outcome clearly favoured ADHD proponents including the manufacturer of Strattera. |
| NHMRC ADHD diagnosis and treatment guidelines 2005-2009 | The NHMRC outsourced the development of replacement (for the 1997) guidelines to the Royal Australasian College of Physicians (RACP) who receive significant sponsorship from ADHD pharmaceutical manufacturers. The guidelines development process was dogged by a series of controversies primarily because of allegations of conflicts of interest and bias amongst the guidelines committee members and the reliance on research by ADHD 'experts' with undisclosed commercial ties to ADHD drug manufacturers. As a result of the controversies the Guidelines were not                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | There were significant conflict of interests both with the guidelines development committee and the research they relied upon. This was a 'captured' process that produced outcomes that clearly favoured the perspective of ADHD                   |

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|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
|                                                                                  | <p>finally approved by the NHMRC despite being completed by November 2009. The recommendations contained within the draft guidelines strongly encouraged the use of stimulants as the first line treatment even outside manufacturer's prescribing guidelines. If drugs had severe adverse side effects or were ineffective substitute or complementary drugs were recommended. The basis of two thirds of the 203 recommendations was committee consensus and the majority of studies cited in the guidelines were <i>'sponsored, at least in part, by the manufacturers of the medications'</i>.<sup>583</sup> The guidelines also recommended prison screening for adult ADHD and special emphasis on identifying ADHD in indigenous populations without identifying any supporting evidence other than identifying high rates of dysfunctionality.</p> <p>Unfavourable media coverage of numerous conflict of interest issues culminating in scrutiny around the issues of undisclosed drug company payments to Harvard Professors Biederman, Wilens and Spencer prompted by ADHD critic scrutiny eventually resulted in the guidelines not being formally endorsed.</p> | proponents.                                                                                    |
| NHMRC and the Australian Mental Health Minister and the Clinical Practice Points | <p>In response to the conflict of interest issues with the Draft ADHD Guidelines - particularly those in relation to research by Professors Biederman, Spencer and Wilens - in July 2011 Mental Health Minister Mark Butler announced that a committee would develop National ADHD Clinical Practice Points. The Clinical Practice Points were intended to provide guidance on the diagnosis and treatment of ADHD in children. Unlike the Draft Guidelines process:</p> <ul style="list-style-type: none"> <li>the names of the development committee were</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | The process was a contested process with representation from critics, neutrals and proponents. |

<sup>583</sup> RACP, *Draft Australian Guidelines*, p.82.



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|  | <p>made public as were their ‘conflict of interest’ declarations.</p> <ul style="list-style-type: none"> <li>• ADHD proponents and critics were included on the development committee.</li> <li>• included significant opportunity for public input with approximately 140 submissions spanning the divergent range of views on ADHD.</li> </ul> |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

Any effect of the Clinical Practice Points on child prescribing rates will occur outside the period (1993-2011) for which data is analysed in this thesis. The Clinical Practice Points process however demonstrates that when contested by ADHD critics Commonwealth ADHD regulatory processes are not always ‘captured’ by ADHD proponents. However, despite the balanced nature of the Clinical Practice Point process, for all other significant processes there has been a consistent pattern of regulatory capture and outcomes that favoured the perspective of ADHD proponents.

#### **7.4.2.1 Regulatory Capture and the National Health and Medical Research Council**

The NHMRC’s practice of outsourcing research and guidelines development processes mean that in these cases its primary responsibility is to ensure the competence and independence of those they appoint to conduct these tasks. In relation to the two guidelines development processes (the 1997 guidelines and the draft 2009 guidelines) the NHMRC delegated the task to ‘expert’ clinicians and to a lesser extent non-expert consumer representatives with significant commercial ties to ADHD drug manufacturers and/or an ideological pro-ADHD medication bias. These processes were ‘proponent captured’ and promoted the use of pharmaceutical treatments based on ‘expert consensus’ (2009 draft guidelines), ‘reasonable theory’ (1997 guidelines) and ‘clinical experience’ (1997 guidelines), often without even poor quality supporting evidence and against manufacturers’ guidelines (1997 guidelines & 2009 draft guidelines).

As well as having been ADHD proponent captured, these processes were also ‘closed’ processes, meaning that the public were not entitled to know either the identity of those developing the guidelines or details of any conflicts of interest. In the case of the draft

guidelines the NHMRC effectively delegated the process to the Royal Australian College of Physicians that had significant commercial ties to the pharmaceutical industry. The Royal Australian College of Physicians in turn delegated the task to 'ADHD experts' with similar ties.

In the case of the 1997 guidelines the closed proponent captured process escaped scrutiny, even retrospective scrutiny. However, in the case of the 2009 draft guidelines a series of media disclosures facilitated by ADHD critics exposed the depth and breadth of the 'capture'. The information about the conflicts of interest were obtained through Freedom of Information (FOI) processes and other publicly available sources as earlier (non-FOI) requests for disclosure were refused.

The response of the NHMRC was to ignore the revelations or defend the 2009 draft guidelines as rigorous and independent. The initial media disclosure in 2007 that the majority of the guidelines development process had undisclosed commercial ties to ADHD drug manufacturers resulted in the original chairperson Doctor Daryl Efron stepping down but remaining on the committee.

An 'independent chairperson' without ADHD related commercial ties, Doctor David Forbes, was appointed as a replacement. The parliamentary response on behalf of the Minister for Health that she had been 'advised that the conflicts of interest declared by working party members are consistent with the normal range associated with clinician review committees of this nature'<sup>584</sup> supports the contention that regulatory capture of similar processes are the norm (see 4.4.3).

Subsequent private written disclosures of the 'corruption of research' issues surrounding Professors Biederman, Spencer and Wilens by ADHD critics to both the NHMRC and relevant Federal Minister were either inadvertently overlooked or deliberately ignored. It was national media disclosure in 2009 of the Biederman issue that was the trigger for the NHMRC's decision not to endorse the guidelines; however the 'draft guidelines' remain available to clinicians and the public and ADHD proponents frequently quote them to 'validate' their perspective.

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<sup>584</sup> Commonwealth of Australia, *Parliamentary Debates*, (Senator Joe Ludwig)

The NHMRC process for developing of guidelines is based on selecting ‘experts’ and ‘evaluating medical evidence’ via a ‘literature review’. This thesis demonstrates that at least in regard to ADHD, selecting those identified as ‘experts’ on a controversial issue facilitates regulatory capture. It also demonstrates that NHMRC evidence selection processes were inadequate. In summary, during the period 1997 to 2009, ADHD proponent ‘biomedicalization theorist’ capture of the NHMRC has been ‘closed and total. Notably throughout this period the total number of PBS subsidised ADHD drugs tripled (see 4.3).

#### **7.4.2.2 Regulatory Capture and the Therapeutic Goods Authority (TGA)**

Dexamphetamine was licensed for use in Australia prior to the timeframe of this thesis. Although used much earlier in the US, methylphenidate was licensed as a number of products (Ritalin 1993, Ritalin LA 2002) throughout the study period. Atomoxetine (Strattera) was licenced in 2004. As discussed at 4.6.1 the TGA licensed Ritalin and Ritalin LA in the absence of long-term data and using short term data that was ‘deficient in certain areas when compared to that usually required by the Australian Drug Evaluation Committee and the Commonwealth Department of Health’. This experience of the TGA’s licencing of Ritalin LA in 1993 closely parallels the experience in the USA of the Food and Drug Administration’s licencing of Ritalin SR in 1978 (see 3.5). Both processes - as Abraham identified are typical of regulatory capture - gave the ‘manufacturer the benefit of scientific doubt about the safety and efficacy of their product’ (see 2.9).

For the purpose of this thesis the analysis of the TGA approval of Strattera (atomoxetine) is limited to the examination of one (chosen at random) of the two studies chosen by Eli Lilly to support the application to licence Strattera for use in Australia. Eli Lilly funded the research, set the parameters, controlled the dissemination of the results and handpicked and paid the researchers. The total direct control by Eli Lilly, the manufacturer of Strattera, of this significant piece of evidence used by the TGA to determine if the product is licensed is consistent with the practices identified by Professor Marc-André Gagnon (see 3.5). It is compelling evidence of the regulatory capture in Australia by profit driven ‘ADHD proponents’. In addition the safety data held by Eli Lilly collected to examine the suitability of atomoxetine as an antidepressant, when branded Tomoxetine, was not considered by the TGA (see 4.6.1).

The TGA's responsibility as a government body extends to monitoring the after-market (after licensing) safety of therapeutic drugs. The TGA's 2006 admission that it does not monitor FDA black box warnings and its almost non-existent effort to publicise the black box warning for suicidality for Strattera demonstrate regulatory capture. Similarly the low key nature of warnings that are placed on product information sheets that are available to patients on request from pharmacists indicates that the TGA does not make informing patients a focus of their work. In addition, adverse event reports were only available upon request and were not publicly reported by the TGA until 2012. However, when summaries of the adverse event were made available online the TGA stopped making individual de-identified reports available on request. Irrespective the voluntary nature of the reports and the low proportion of events reported also meant there is no comprehensive database from which to assess the real world incidence of adverse reports. Neither the TGA or any other government or non-government agencies make any effort to monitor the safety and efficacy of 'off label' use of medications even though such use is common for many psychotropic drugs including Ritalin to children aged 5 and younger (see 4.7). These are all examples of the TGA, commonly through omission, acting in the interests of the pharmaceutical industry rather than consumers and the public interest.

#### **7.4.2.3 Regulatory capture and the Australian Drug Evaluation Committee (ADEC) and the Pharmaceutical Benefits Scheme Advisory Committee**

For the purpose of this thesis there is insufficient information in relation to the operation of the Australian Drug Evaluation Committee (now replaced by the Advisory Committee on Prescription Medicines) to assess the degree or nature of regulatory capture (if any). However, the licencing of Ritalin and Ritalin LA indicate that historically other Commonwealth Government agencies, in particular the TGA, have ignored or downplayed ADEC's negative advice and licenced ADHD drugs.

The decision made by the PBSAC to recommend Strattera for subsidy despite the after-market issuing of a black box suicidality warning, along with a liver damage warning and significant adverse event reports, is notable. The process of deciding to subsidise Strattera via the Pharmaceutical Benefits Scheme was a contested process between access orientated ADHD proponents and injury orientated ADHD critics. ADHD proponents clearly got the

outcome they desired. Furthermore, the denial to the public of access to any documentation referring to an application by a pharmaceutical manufacturer even via Freedom of Information processes is additional evidence of the primacy of commercial interest over the public interest.

Although not related specifically to ADHD drugs, the Grattan Institute review of the cost to the Australian Government of subsidising PBS drugs provides further evidence of regulatory capture of PBS processes by corporate interests (see 4.5.1).

#### **7.4.2.4 The Role of Commonwealth Parliamentarians**

Unlike in Western Australia, where there has been two parliamentary inquiries and activism by both ADHD proponent and ADHD critic politicians, (see chapter 6) there has been relatively little proactive interest in ADHD by Commonwealth politicians.

In 2007 the then Prime Minister John Howard expressed concern about ‘reports of the over-prescription of Ritalin’ but left the policy response to Health Minister Tony Abbott. Minister Abbott expressed similar concerns but dealt with conflict of interest issues amongst ADHD experts in the 2009 guidelines process by leaving it to the same ‘experts to carefully weigh all the issues’. Opposition spokesperson Nicola Roxon echoed ADHD critic concerns about the ADHD proponent captured 2009 guidelines process, calling for full public disclosure of the names and commercial ties of the guidelines committee. However she refused to release these details when she became the Health Minister. After she was replaced as Health Minister by Mark Butler, ADHD critic media pressure continued. Minister Butler responded by initiating the ‘balanced’ Clinical Practice Point process. Minister Butler however left the 2009 draft guidelines available for public access pleasing ADHD proponents who continue to refer to them for expert guidance (see 5.3.3).

The above indicates that the attitudes of Commonwealth politicians have not been influential in terms of ADHD policy development; rather they have responded to media coverage and lobbying from both ADHD proponents and critics. Whether this is a result of a lack of interest or a belief that the process of ADHD regulation should be depoliticised is unclear. At different times responsible Ministers Tony Abbott and Nicola Roxon have expressed the view that ADHD related policy outcomes should be determined by ‘experts’. The failure to ensure the

independence of the ‘experts’ has allowed these processes to be repeatedly captured.

In developed nations like Australia regulatory decisions about which products are approved for market are usually made after some form of risk assessment. Risk assessment inevitably involves decisions about what ‘evidence to include...how to interpret the available evidence [and]...respond to uncertainties, and how much of different kinds of evidence would be necessary or sufficient to sustain different types of judgements’.<sup>585</sup> These decisions are ‘routinely and inevitably influenced by the socio-economic and cultural contexts in which they are developed’.<sup>586</sup> However, as demonstrated by both Ministers Abbott and Roxon the influence of these factors is often understated. Outcomes of ‘expert’ processes are regarded as if they are the product of pure science.

At least in the case of ADHD a more interventionist approach, where Commonwealth politicians ensure, rather than assume, the independence from industry influence of ‘expert processes’ may have helped prevent their capture. This would go against the long term trend of Australian Governments, with both Labor and Conservative since the late 1980s, facilitating greater pharmaceutical industry involvement in decisions relating to the licencing and pricing of pharmaceuticals. This has been attributed to ‘the then Labor [Hawke] Government’s concern for the future of Australian high-technology manufacturing’, a concern shared by subsequent governments.<sup>587</sup> Perhaps rising ADHD prescribing rates have in part been a result of the pharmaceutical company friendly regulatory culture encouraged by successive Australian Governments.

#### **7.4.2.5 Summary of regulatory capture in regard to Commonwealth Government processes in relation to ADHD**

The evidence in Chapter 4 indicates that from the period 1993 to 2010 the development of ADHD policy and regulation at a Commonwealth level has been captured by ADHD proponents. The rapid growth in National ADHD prescribing rates from 1993 to 2011 coincided with this period of ADHD proponent regulatory capture. Although the Clinical

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<sup>585</sup> Millstone E. and Van Zwanenberg. P. et al (2004), Science in Trade Disputes Related to Potential Risks

<sup>586</sup> Millstone E. and Van Zwanenberg. P. et al (2004), Science in Trade Disputes Related to Potential Risks

<sup>587</sup> Lofgren H and de Boer R (2004) Pharmaceuticals in Australia: developments in regulation and governance. Social Science & medicine 58 pp. 2397-2407

Practice Point Process began in 2011 they were not published until September 2012. So any effect on diagnosing and prescribing practices is outside the period covered in this thesis. However the Clinical Practice Points indicate that although regulatory capture by ADHD proponents of Commonwealth Government regulatory agency processes may be the ‘norm’, it is not inevitable.

## 7.5 Western Australia the Outlier

Table 5 below briefly outlines in chronological order Western Australia’s history of regulation and policy development in relation to ADHD.

Table 5 – Summary of Western Australia’s history of regulation and policy development in relation to ADHD

| Agency, process and date                                                                                             | Outcomes of Process                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Nature of process, captured, contested, neutral or critic dominated                                                                      |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1995-1997</b><br>WA State Government establishes the <i>Technical Working Party on Attention Deficit Disorder</i> | The <i>Technical Working Party on Attention Deficit Disorder</i> task was ‘to report to government on the incidence of ADHD in WA and to seek expert opinion on the appropriate diagnosis and treatment for the condition’. <sup>588</sup> Published in 1997 <i>The Report of the Technical Working Party</i> highlighted that, in 1994, Western Australian ADHD prescribing rates had grown very rapidly between 1989 and 1994 and were much higher (approximately two and a half times) than the Australian national average. It also identified large differences in suburban prescribing rates within the Perth metropolitan area and recommended random audits of the prescribing practices of clinicians with ‘block authorisation’, to ensure | The committee was balanced, including both ADHD proponents and members who later expressed public concerns about ADHD over-prescription. |

<sup>588</sup> *The Report of the Technical Working Party*, p.2.

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|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                              | responsible prescribing. (see 6.2)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                   |
| <b>1997 - 2002</b><br>The WA Health Department establishes the Stimulants Committee                                          | In response to the <i>Technical Working Party on Attention Deficit Disorder</i> recommendations the WA Department of Health established the Stimulants Committee. The Committee included some of Perth's heaviest prescribers, who had block authorisation. It was tasked with monitoring the prescription of psycho-stimulants to ensure appropriate prescribing. The recommended audits of Block Authorisations never happened. Stimulants Committees minutes demonstrate that the committee made only token efforts to ensure responsible practice by individual prescribing clinicians and even effectively turned a blind eye to illegal prescribing. Instead the committee sought to influence clinical practice by promoting further prescribing. (see 6.2.2) | This was an example of complete regulatory capture by ADHD proponents of a process specifically intended to address concerns about inappropriate prescription by ADHD proponents. |
| <b>1998</b><br>The WA Minister for Health and the Health Department convened an International Panel on ADHD for a symposium. | The symposium was established to address concerns ' <i>about the number of WA children diagnosed with attention deficit disorder and the use of amphetamine-like medication to treat them</i> '. <sup>589</sup> The Department invited 'international expert' Professor Larry Greenhill of New York's Columbia University. Professor Greenhill has received payment from fifteen pharmaceutical companies and is a prominent advocate of ADHD prescribing. The other members of the International Panel were prominent ADHD proponents. The International Panel Report validated the 'effectiveness of stimulants' as 'beyond dispute' and encouraged polypharmacy.                                                                                                  | The symposium was captured by ADHD proponents.                                                                                                                                    |

<sup>589</sup> Pryer, 'Dismay at child attention disorder figures'.



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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>(published in 2002)</b></p> <p>WA Health Department commissioned a panel to prepare a report titled <i>Attentional Problems in Children and Young People</i></p> | <p>The draft of the report <i>Attentional Problems in Children and Young People</i> recommended developing a tiered approach, with teachers and childcare workers referring children suspected of having ADHD for diagnosis by specialist clinicians and validated the diagnosis of ADHD for '3 to 9 percent' of children. It also promoted the use of stimulant medication to treat ADHD.</p> <p>.....</p> <p>Before it was published by the WA Mental Health Division it was substantially rewritten (key recommendation were altered) by me with the co-operation of the Health Minister Bob Kucera. The final report abandoned the tiered referral approach and recommended the abolition of Block Authorisation. (see 6.3)</p> | <p>The initial development of the draft report was undertaken by a 'balanced' committee that included both ADHD proponents and members who later expressed public concerns about ADHD over-prescription.</p> <p>.....</p> <p>The final rewrite of key recommendations in this report became dominated by ADHD critics.</p> |
| <p><b>2003 - 2004</b></p> <p>WA Legislative Assembly Education and Health Standing Committee (EHSC) into ADHD</p>                                                      | <p>The committee made findings and recommendations broadly consistent with the view that ADHD is frequently misdiagnosed and the medications are over-prescribed. (see 6.5)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>The committee contained two (of six) parliamentarians who were ADHD critics.</p>                                                                                                                                                                                                                                        |
| <p><b>2005 – 2012</b></p> <p>Ministerial Implementation Committee on ADHD (MICADHD) established by State Government in order to</p>                                    | <p>One of the recommendations of the EHSC Parliamentary Inquiry was to facilitate research into the long-term safety and efficacy of ADHD medications. The idea to review Raine Study data to evaluate the long term safety and efficacy of ADHD stimulants was first suggested by ADHD proponents on the MICADHD committee. They had significant input to the design of the study. However, when the results showed that amongst</p>                                                                                                                                                                                                                                                                                               | <p>The Committee was a balanced process with both ADHD proponents and critics contesting the committee's outcomes.</p>                                                                                                                                                                                                     |

|                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |
|----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| implement the recommendations of the EHSC WA Parliamentary Inquiry into ADHD 2005-2010 | <p>ADHD diagnosed children taking stimulants long term was associated with significantly worse educational outcomes and raised diastolic blood pressure, they criticised the methodology and sought to retrospectively alter the methodology and prevent publication of the results.</p> <p>However, the MICADHD committee was balanced, with both ADHD proponents and critics, and the committee was informed as the research progressed ADHD proponents were unsuccessful in preventing the publication of the data. (see 6.7)</p> |  |
|----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

WA's ADHD history is one of rapid growth in prescribing until 2003, followed by a significant contraction in child prescribing rates and teenage amphetamine abuse rates, concurrent with a simultaneous increase in adult prescribing rates. This is a more complex pattern than the general national pattern of consistently increasing rates. It is also notable that WA rates grew much faster than national rates. By 2002, despite WA having less than 10 percent of the Australian population,<sup>590</sup> 24 percent of children and 44 percent of adults receiving Pharmaceutical Benefits Scheme sponsored ADHD drugs lived in Western Australia. (See Figure 5 at 4.3)

WA's ADHD history in the period of the rapid growth in child prescribing rates (1993-2002) followed a pattern of regulatory capture and pharmaceuticalization. The clearest example is the Stimulants Committee that was established in response to concerns about misdiagnosis and overprescribing raised in the 1997 *Technical Working Party Report*. The Stimulants Committee was dominated by ADHD proponents who were frequent prescribers. (Refer 5.4.2) Similarly the 1998 International Panel on ADHD was dominated by proponents with a biomedicalized viewpoint.

<sup>590</sup> Australian Bureau of Statistics (2003), 'Proportion in Working Ages Set to Decline', *Media Release*, 2 September. Available at <http://www.abs.gov.au/ausstats/abs@.nsf/mediareleasesbytitle/F4A2F9DD7183EE99CA256D9500046E75?OpenDocument> (accessed 8 September 2011).

However, the earlier 1997 *Technical Working Party Report* was a more balanced process with a greater diversity of views. Although it validated the diagnosis and drug treatment of ADHD it raised concerns about inappropriate prescribing and recommended audits of heavy prescribers with block authorisation. These recommendations were either not implemented or, as was the case with the Stimulants Committee, adjusted to a significantly more ADHD proponent friendly approach.

The downward turning point for child prescribing rates followed closely after the introduction of tighter prescribing accountability measures and more detailed prescribing reporting in late 2003. These policy changes occurred because of the direct intervention by myself - an activist ADHD critic politician - and a sympathetic Minister, both of whom were criticised by proponents who were 'shut out' of the process. This ADHD critic dominance of a policy process is unique in Australia for the period of this study and is the likely explanation for the significant downturn in WA's child prescribing rates. Subsequent WA ADHD policy processes were balanced with significant input from both ADHD critics and proponents.

The downturn in child prescribing rates occurred simultaneously with a similar decline in teenage amphetamine abuse rates. In contrast, adult per capita prescribing rates have continued to increase since the introduction of the prescribing accountability measures. Clearly different factors drove adult and child prescribing rates. Possible explanations for the increasing proportion of adults include the ageing of the ADHD cohort, the marketing of 'Adult ADHD' and doctor shopping for dexamphetamine by adult West Australians.

In summary the evidence of regulatory capture of WA Government processes up until 2001 is considerable. However, in 2002 ADHD critic dominance of a policy development process resulted in the tightening of prescribing controls including the abolition of Block Authorisation. The changes were not implemented until late 2003. During the period of regulatory capture child prescribing rates grew at a rapid rate. However, soon after the implementation of the ADHD critic dominated process child prescribing rates fell sharply.

## 7.6 New South Wales

In NSW in 2007 media coverage of comments by a judge expressing concerns in relation to potential harms resulting from the prescription of amphetamines for ADHD resulted in the State Government commissioning a review of diagnosing and prescribing practices. The NSW State Government invited 'ADHD experts', many of whom had commercial ties to the pharmaceutical industry and/or clinicians who were frequent prescribers, to review the prescribing practices of themselves and their peers.

This review found that there was no basis for concerns about possible harms and that rather than being over-diagnosed and over-prescribed, ADHD was under-diagnosed and the drugs used to treat it were consequently under-prescribed. Recommendations from this review encouraged the further diagnosis of, and prescription for, ADHD. The recommendations of the review were made based on the consensus of the 'experts' on the review committee and the self-reporting of prescribing practices by clinicians. The review was followed by a significant increase in ADHD child prescribing rates from 2007 to 2011. The catalyst for the review was comments by a judge based on his courtroom experience. However, he was 'gagged' from making further comments on his experience of ADHD medications leading to drug abuse and criminality (see 6.9.1).

The similarities between the ADHD history of NSW from 2007 until 2011 and Western Australia from 1993 to 2002 are considerable. NSW grants a General Authority Number - the equivalent of WA's now abolished 'Block Authorisation' - where frequent prescribers are exempt from the case-by-case monitoring requirements imposed on those who prescribe infrequently. In both periods respective State child prescribing rates rose rapidly. Like WA from 1993 to 2002, 'regulatory capture' by ADHD proponents in NSW appears almost absolute and this has been associated with a rapidly increasing pharmaceuticalized response. The notable difference is that in 2007 the voice of a prominent NSW ADHD critic was silenced. In contrast in WA in 2002 policy changes exclusively dominated by ADHD critics were implemented and child prescribing rates fell.

## 7.7 Non Government Processes

There are numerous not-for-profit and for-profit non-government agencies involved in the regulation or provision of services related to ADHD. The limited evidence that is available is consistent with the assertion that ADHD proponents dominate these agencies, a phenomenon that Hanson and Yosifon describe as deep capture (see 2.5). Possible explanations include economic incentives and ideological self-selection, where individuals with values and beliefs in line with a biomedicalized ADHD perspective chose to involve themselves in ADHD related policy processes and work in a co-operative manner with drug manufacturers.

The WA ADHD support group, the Learning and Attentional Disorders Society (LADS), have accepted funding from ADHD drug manufacturers and has openly co-operated with them to market their products. LADS has consistently promoted the biomedicalized thesis that ADHD has a biological cause that is best treated with 'safe', 'effective' medication. LADS have presented completely inaccurate information, particularly in relation to the addictive properties of stimulants to be diverted for illicit use. On two occasions in the late 1990s LADS was counselled about promoting the illegal non-prescription use of a child's stimulants by their parents. LADS have engaged in 'access orientated' advocacy in regards to the listing of ADHD drugs on the PBS (see 6.6).

Ideally researchers engage in unbiased scientific inquiry. It is questionable whether this is a realistic expectation when researchers are chosen and paid for by ADHD pharmaceutical manufacturers. The scandal involving high profile ADHD advocates, Harvard University's Biederman, Spencer and Wilens is a clear example of commercial conflicts of interest resulting in either the corruption of or the suspicion of the corruption of supposedly independent research. Despite disclosure of the issues around Biederman, Spencer and Wilens, to the Royal Australian College of Physicians draft guidelines development group during the public input process, it was only critical media coverage of the issue that eventually resulted in action by the NHMRC and the Commonwealth Government (see 5.3.2).

Many other researchers engaged in ADHD drug trials have pre-declared positions supporting the validity of the diagnosis and the safety and efficacy of ADHD drugs. They may be predisposed to finding results consistent with their beliefs and ignore or minimise the significance of those that are inconsistent. For example many of the International Consensus Statement signatories are researchers who in signing the consensus statement declare the validity of the disorder is beyond dispute. These include Australian ADHD experts such as Dr Florence Levy who have been involved in Australian consensus processes that have determined the 'official' Commonwealth and State Government responses to ADHD (refer to 5.3.1 and 6.9.1).

The dismissive response to the unexpected results produced in the *Raine Study ADHD Medication Review* by the ADHD proponents on MICADHD who first suggested the study and designed and conducted the research is significant. It was consistent with the contention that the effort that goes into validating and promoting research is frequently influenced by personal bias. However, as the MICADHD process was a contested process the attempt by ADHD proponents to ignore the research was unsuccessful. This supports the contention that open contested policy development, research and regulatory processes help to enhance the rigour of these processes.

Professional associations like the RACP in Australia and the APA in America presumably include professionals with a broad spectrum of views about ADHD amongst their membership. In April 2006 the WA magazine *Medical.WA Forum* conducted a poll of 245 Western Australian general practitioners. Fifty-six per cent of the GPs polled thought that ADHD drugs were over-prescribed to children in Western Australia and 16 per cent thought they were not. The other 28 per cent of GPs basically did not express an opinion.<sup>591</sup> However, the members of the RACP ADHD Guidelines Committee were almost exclusively ADHD proponents.

This mismatch between the range of professional views on ADHD and the narrow ADHD proponent dominance of the RACP process supports the contention that ADHD proponents seek to influence processes that they specialise in treating and hold strong views about and/or earn

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<sup>591</sup> Rob McEvoy (2006), 'Poll Results – General Practitioners May 2006', *Medical.WA Forum*, 2 May. Available at <http://www.medicalhub.com.au/view-editions> (accessed 17 June 2007).

income from treating. In contrast, it is difficult to make an income from specialising in 'not' diagnosing a condition and it is therefore very difficult to develop specialist expertise in ADHD for those who do not believe it is a valid psychiatric disorder. On the other hand, there are substantial incentives, both commercial and professional, for 'believers' in ADHD to become experts. This is consistent with Stigler's theory that 'regulatory capture' is a logical consequence of regulatory and policy processes being dominated by the most motivated and best resourced (see 2.5).

### **7.8 How does Australia's ADHD experience of Regulatory Capture relate to Abraham's theories?**

Abraham contends the medicalization thesis is the best explanation for the international pharmaceuticalization of ADHD. Abraham bases his theory on British and U.S. experience. This thesis addressed the question of whether Abraham's 'medicalization thesis' explanation of pharmaceuticalization is applicable to childhood ADHD in Australia.

For the massive growth in national child prescribing rates to be consistent with the alternate 'biomedicalization' thesis there would need to have been significant scientific breakthroughs validating the diagnosis and/or safety and efficacy of the drugs used to treat it. Despite many 'false dawns' where ADHD proponents have claimed to be on the verge of discovering the cause or causes of ADHD, the aetiology of the 'disorder' remains confused and uncertain. Although they attracted considerable international media attention, claims of finding the genetic basis of ADHD were shown on close examination to be unsubstantiated (see 2.6). In summary there have been no scientific breakthroughs in either the understanding of the aetiology, diagnosis or treatment of ADHD that support a biomedicalized explanation of the massive and continuing growth in ADHD prescribing rates from 1993 until 2012.

Although there have been no advances in the science of diagnosing ADHD there has been a pattern of the American Psychiatric Association (APA) broadening the behavioural diagnostic criteria for ADHD. This was a result of consensus during committee processes of the APA. The principal author of the DSM-IV, Professor Allen Frances, has criticised the subsequent explosion in international ADHD prescribing rates, offering an explanation

consistent with the medicalization thesis (see 3.3). Consensus amongst ADHD medication advocates has also driven significant Australian ADHD policy processes. The Australian 1997 guidelines and the 2009 draft guidelines were both the result of consensus amongst a committee, the majority of whom had commercial connections to ADHD drug manufacturers (see 5.3).

It is likely that there are many factors affecting ADHD child prescribing rates. Abraham contends there are multiple factors that contribute to medicalization and pharmaceuticalization but the most important factor is regulatory capture. It is impossible to quantify the relative effects of factors. Nonetheless, the Australian experience of regulatory capture being the norm and being associated with rapidly growing prescribing rates is consistent with Abraham's contention.

WA's history post 2003 is an outlier from this general pattern of regulatory capture. Abraham acknowledges that his theory of regulatory capture and pharmaceuticalization is not absolute and that in exceptional cases other outcomes may occur. The direct intervention of an activist ADHD critic parliamentarian and a sympathetic responsible minister are unusual circumstances that explain WA's deviation from the norm of regulatory capture and increasing pharmaceuticalization.

Abraham bases his theories on 150 years of United Kingdom's pharmaceutical regulation history supplemented by an analysis of U.S trends.<sup>592</sup> Abraham contends a primary driver of the cycle of regulatory capture and pharmaceuticalization is 'neo-liberal corporate bias'.<sup>593</sup> By 'neo-liberal' Abraham means the ideology that the 'state should be minimal and subject to the tests of the market'.<sup>594</sup> He contends this laissez-faire, self-regulatory philosophy combined with a pro commercial interest bias heavily favours the interests of the pharmaceutical industry often at the expense of consumer interests.

Abraham draws predominantly on British experience. The United Kingdom's regulatory environment is similar to Australia's in that government is central to the provision of health services and direct to consumer advertising of prescription medications is outlawed.

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<sup>592</sup> Abraham, 'From Evidence to Theory', p.173.

<sup>593</sup> Abraham, 'From Evidence to Theory', p.173.

<sup>594</sup> Abraham, 'From Evidence to Theory', p.168.



Abraham is particularly critical of the regulatory capture of drug regulators in the United Kingdom, concluding:

The present drug regulatory systems are insufficiently rigorous in their political relations with the pharmaceutical industry, because they prevent proper public accountability, are highly vulnerable to industrial capture, and permit the industry's scientific experts to have extensive conflicts of interest while providing their expert advice. A regulatory system capable of delivery of publicly defensible assessments, which are uncompromisingly in the interests of public health, is needed.<sup>595</sup>

Clearly the prevention of public disclosure via Freedom of Information processes of the documents relating to the approval of 'medications' for Pharmaceutical Benefits Scheme subsidisation in Australia is contrary to Abraham's recommendation that a 'regulatory system capable of delivery of publicly defensible assessments...is needed' (see 4.6.4).

As outlined at 7.4.2.2, other Australian examples of 'insufficiently rigorous' drug regulation processes include:

- The TGA licencing of Ritalin and Ritalin LA (see 5.4.1).
- The TGA licencing of new drugs relying on only two studies chosen by the applying drug manufacturer (see 5.4.2).
- The NHMRC recommending the 'off label' prescribing of Ritalin and other drugs in treatment guidelines (see 5.3.1 and 5.3.2).
- The TGA not publicising information about product warnings and adverse events (see 5.4.3).

Abraham considers that pharmaceuticalization is in part a result of a consistent pattern of 'failures of injury-oriented adversarial consumerism and the successes of access-oriented collaborative consumerism'.<sup>596</sup> Furthermore he contends the pharmaceutical industry:

encourages consumerism when it is about patients' access to medications but vigorously contests the relevance and expertise of consumerism when it condemns

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<sup>595</sup> Cited in Richard C. Horton (2003), *Second Opinion: Doctors, Diseases and Decisions in Modern Medicine*, Granta Publications, London, p.xv.

<sup>596</sup> Abraham, 'The Sociological Concomitants', p.297.

the safety problems of some pharmaceutical products...One may conclude that pharmaceuticalization has expanded largely because the drug industry has used its power to have a central influence on all the key sociological factors driving the phenomenon. Consequently, pharmaceuticalization has increased mainly in accordance with the commercial interests of the pharmaceutical industry.<sup>597</sup>

One clear Australian example of the dominance of access over injury-orientated consumerism relates to the decision to subsidise Strattera (atomoxetine) via the Pharmaceutical Benefits Scheme on 1 July 2007. Eli Lilly facilitated access orientated consumer pressure via an ADHD patient support group, LADS, which successfully counteracted injury orientated consumerism, resulting in taxpayer subsidized access to Strattera.

The post market regulation of Strattera by the Therapeutic Goods Administration and the processes of subsidisation via the Pharmaceutical Benefits Scheme by the relevant government agencies are consistent with Abraham's assertion that regulatory capture results in pharmaceuticalization, counter to the public interest, through the exaggeration of benefits and minimisation of risks in public benefit assessment processes (see 2.9). They are also consistent with the findings of the UK House of Commons Committee Inquiry into Pharmaceutical Company Influence, which detailed concerns that the 'regulatory system, the medical profession and Government have all failed to ensure that industry's activities are more clearly allied to the interests of patients and the National Health Service' (see 2.10).

## **7.9 The applicability of other regulatory capture theorists to Australia's experience**

An early theorist of the concept of regulatory capture, George J Stigler, contended regulatory capture is a logical outcome of economic incentives. Commercial enterprises - pharmaceutical companies and their allies in the case of ADHD - focus attention and resources on protecting their economic and professional interests. In contrast, those who are less immediately and foreseeably affected by the outcome don't try to influence the relevant policy and regulation. According to Stigler this regularly leads to policy and regulatory outcomes that favour the

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<sup>597</sup> Abraham, 'The Sociological Concomitants', p.305.

interests of those whose activities are at face value being regulated (see 2.5).

There are numerous examples in this thesis of policy committee processes being dominated by ADHD proponents who specialise in diagnosing and treating the condition and nominate for inclusion onto these committees. Examples include the:

- 1997 NHMRC Guidelines Development Committee (see 4.4.2)
- 2009 NHMRC RACP Guidelines Development Committee (see 4.4.3)
- 1997-2003 WA Stimulants Committee (see 5.4.2)
- 2007 NSW Child ADHD Review Committee (see 6.9)

With a few notable exceptions the competition between ADHD proponents and ADHD critics to influence policy and regulatory outcomes has been dominated by ADHD proponents. They have been better resourced, better organised and more strategic in their approach. ADHD proponents have had commercial, professional and ideological motivations for promoting the disorder and the drugs that treat it. In contrast ADHD sceptics do not have the same commercial or professional incentives (or resources) and are typically ideologically motivated.

There are numerous examples where the regulation of ADHD prescribing has become what Briody and Prenzler would describe as ‘systemically captured’ and McMahon would identify as the third and ‘deepest’ level of regulatory capture. In these cases the ADHD industry has effectively self-regulated, with only the superficial appearance of external independent oversight.

These examples include the operation of the:

- WA Stimulants Committee (1997-2003) where very heavy prescribers of ADHD medication oversighted their own prescribing and/or exempted themselves from accountability requirements. (refer to 6.3.2)
- The NHMRC ADHD guidelines development process, in which a group of ADHD industry insiders relied on consensus and commercially compromised research to develop guidelines that promoted ‘medication’ based responses. (refer to 5.3)
- The NSW Government commissioned ADHD prescribing review established in response to judicial concerns about ADHD prescribing related crime. The review

was conducted by a committee of prescribing clinicians with extensive ties to the pharmaceutical industry who found there was no evidence of over-prescribing and that in contrast ADHD was underdiagnosed and under-treated. (see 6.9)

None of the examples cited above involved direct, illegal corruption. Although the issues involving non-disclosure of millions of dollars in pharmaceutical company payments to prominent ADHD medication advocates Harvard University's Biederman, Spencer and Wilens were the catalyst for abandoning the draft ADHD guidelines (see 5.3.2) there are no known Australian examples of direct criminal corruption in regards to the regulation of ADHD. Obviously where total ADHD proponent dominance is effectively achieved there is little need for less direct forms of influence.

As noted at 2.8, Grabosky and Braithwaite argue regulatory capture is more likely where the following preconditions exist:

- 1- only one industry is being regulated
- 2- the regulator is part of a larger organisation
- 3- there is conflict between the regulator and the regulated,
- 4- regular contact occurs between the regulator and the regulated, and/or where significant personnel interchange occurs between the regulator and the regulated.

Although it is often argued it is comorbid with other psychiatric disorders ADHD is conceptualised as a discrete disorder. The regulatory responses and 'expert' committees and review panels processes set up to develop diagnosis and treatment guidelines by state and commonwealth government agencies are all specific to ADHD. This meets Grabosky and Braithwaite's first precondition and may contribute to the potential for regulatory capture by isolating expertise and interest in an issue to a relatively small number of motivated enthusiasts.

In relation to the second precondition, developing and implementing ADHD related policy is only a tiny fraction of the work of government regulatory agencies like the NHMRC and state and federal health departments and ministers. Even for non-government agencies like the RACP, ADHD represents a tiny fraction of their areas of interest.

In regards to the third precondition, there are few instances of direct conflict between the regulator and the regulated. Rather, it has been common for government departments and ministers to respond to public concern about ADHD prescribing by delegating the detail of their response to committees and review groups composed of ADHD industry insiders, typically using the rationale that they are experts.

With regards to the fourth precondition, regulators, especially the TGA, have come to rely on the regulated, the pharmaceutical industry, for the evidence used to determine whether the products should be licenced for market. In addition, state governments concerned about reports of indiscriminate prescribing have sought the advice of ADHD specialist clinicians, themselves frequent prescribers, for advice on the appropriateness of prescribing practices.

In summary, in Australia ADHD has effectively become a medical speciality with the majority of prescribing done by a tiny minority of prescribers. These ‘experts’ and their allies have typically dominated not only clinical practice and regulatory processes, but also the public debate, research and the development of diagnosis and treatment guidelines. On rare occasions ADHD critics have successfully competed to influence research and policy and regulatory outcomes. However, these incidents have been the exception rather than the rule. These outcomes are consistent with the theory of regulatory capture and its application to psychiatric practice in general and ADHD in particular as espoused by John Abraham.

### **7.10 Policy Recommendations**

The primary finding of this thesis is that regulatory capture of ADHD policy and regulatory processes is normal but not universal and that this is a consequence of unequal resourcing and motivation of proponents and critics. Consequently the most significant policy implication for the regulation of ADHD and similar conditions is that governments should facilitate robust contested policy and regulatory processes.

Specifically the following policy innovations could be taken by governments to ensure robust competition and prevent ‘capture’ of health and mental health processes by the pharmaceutical industry and allied interests:

**1. Ensuring diverse views are robustly represented in health and mental health policy and regulatory process.**

Rather than enabling a process of self-selection by like-minded ‘experts’ with the aim of achieving a consensus outcome, these processes should be open and contested, with a range of views competing to influence outcomes.

**2. Addressing the inequity of resourcing of competing perspectives on controversial mental health and health policy issues by direct government funding of independent non-government pharmaceutical and medical/psychiatric watchdogs.**

The pharmaceutical industry has demonstrated that it has sufficient resources to effectively organise, lobby and market to enhance its own economic interests. However, there is no significant counterbalancing economic interest that supports those concerned about the inappropriate and unsafe use of pharmacological interventions. Industry domination of notional consumer support groups further exacerbates this problem of regulatory capture by creating the false impression of independent consumer driven advocacy. Governments could address this imbalance by funding independent non-government watchdogs specifically tasked with critiquing research and clinical practice in the medical/psychiatric and pharmaceutical fields.

**3. Require full public disclosure of all relevant safety and efficacy data, and pre-registration of research, used to support the TGA licencing and PBS subsidisation of pharmaceutical products in Australia.**

Two methods employed by pharmaceutical companies for denying both regulators and the public adequate access to relevant research are:

- ignoring and not publishing results of negative studies
- spinning the results of negative findings for the ‘primary outcome’ – the main question the study was designed to answer – and highlighting a positive ‘secondary outcome’.<sup>598</sup>

Gagnon (refer 3.5) concludes ‘as long as pharmaceutical companies hold the purse strings of

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<sup>598</sup> Armstrong and Winstein, ‘Antidepressants Under Scrutiny’.

biomedical research, medical knowledge will be selectively constructed for the purpose of marketing drugs rather than improving public health.<sup>599</sup> However, it is unreasonable to expect pharmaceutical companies to expend significant resources developing new products and then relinquish control over the conduct of their research. The situation is further complicated by the globalised nature of pharmaceutical research as it would be impractical and wasteful to require national licencing and subsidisation of pharmaceutical products purely on intra-national research.

Therefore there must be a mechanism for ensuring the rigour and integrity of all research including foreign research relied on to support the licencing and subsidisation of products in Australia. A system that rewards pharmaceutical companies for innovation and invention by protecting legitimate 'commercial in confidence information' – such as chemical formulations and financial information - but prevents the selective disclosure of safety and efficacy data is required. Public registration of research (regardless of where it is conducted) that may be relied upon later by pharmaceutical companies applying for TGA licencing or PBS subsidisation could help achieve this. The purpose of the research and proposed methodology could be recorded in advance. Then the results of the research in terms of safety and efficacy could be recorded after the research is completed. This system would help prevent pharmaceutical companies hiding negative results or adjusting the purpose or methodology of research 'post hoc'.

Obviously this system would only work prospectively and not enable access to studies already concluded. To address this shortfall details of all research conducted on a particular drug should be provided to the relevant regulator for consideration and made available for public scrutiny. This would help to address the problem of a narrow base of selective research used to licence and subsidise drugs. Regulators would have access to all related research. This would prevent a repeat of the situation which happened with Strattera, where research conducted by the drug manufacturer Eli Lilly was not made publicly available or provided to the relevant regulator because without external scrutiny the manufacturer determined it was not relevant (refer to 4.5.1).

#### **4. Avoid direct capture of Australian psychiatric practice by the American Psychiatric Association over which Australian governments and the Australian medical/mental**

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<sup>599</sup> Gagnon, 'Corporate influence over clinical research'.

**health professions have no control by making the *International Classification of Diseases (ICD)* the only diagnostic criteria utilised in Australia.**

By only providing financial support (including Medicare co-payments and PBS drug subsidisation) for the treatment of mental health disorders diagnosed using the World Health Organisation's (WHO) ICD criteria, the dominance of the American Psychiatric Association's DSM could be ended. Australia is a member of the WHO but has no capacity to influence the APA. Alternatively, given that there are also concerns about capture of WHO processes Australia could develop its own diagnostic framework.

**5. Facilitate informed consent by Australian pharmaceutical consumers by improving public disclosure of adverse event risks.**

This could be achieved by:

- **Strengthening Consumer Medicine Information (CMI) requirements** so that every warning currently included in information to prescribers is also on the CMI. Prescribing doctors should also be obliged by law to hand patients or parents a CMI, and it should be compulsory to insert CMI sheets in medication packaging.
- **Putting black box warnings on the outside packaging of drugs** as with cigarette packaging so consumers are aware of very significant risks. Currently black box warnings are often only highlighted on information made available to prescribers and are not seen by consumers.
- **Make adverse drug event reporting for a specified range of serious reactions (suicidal ideation, strokes, psychosis etc.) mandatory** and regularly publish full details on the internet. Voluntary reporting means that only a tiny fraction of adverse events ever get reported. Arguably reckless prescribers may be less likely to report serious adverse events than cautious prescribers, because they may be concerned about acknowledging the consequences of their prescribing practices. The public has a right to know and policy makers need to know about the frequency of adverse events so they can make informed decisions about the risk benefit profile of medications.
- **Reforming Commonwealth Freedom of Information legislation to end the entitlement**



**of corporations to rely on privacy provisions** originally intended to protect the health records of individuals (refer to 4.6.4).

- 6. Require full public disclosure of pharmaceutical industry funding sources for clinicians, researchers, patient groups, advisory board members and members of committees involved in regulatory and policy development processes.**

Parents and patients are entitled to know what factors other than patient welfare might be motivating the doctors and patient support groups that are advising them. Likewise, government and the public are entitled to know about the commercial ties of researchers and advisers.

- 7. Prohibit pharmaceutical company donations to political parties and candidates and compensate if necessary through increased public funding of political parties.**

Governments are responsible for multi-million-dollar decisions about which drugs get approved and subsidised and must make these decisions without fear or favour. There is currently retrospective disclosure of political donations and there is no evidence of direct corruption. However, there has been very little scrutiny of pharmaceutical company operation by parliamentarians. Although a similar case could be made for a range of industries, the pharmaceutical industry is unique in that it produces mind and body altering chemicals that are ingested by children a particularly vulnerable consumer group. Many of these chemical interventions are lifesaving; most are warranted but as with ADHD some are highly questionable. Government must be free from improper influence of the pharmaceutical industry.

- 8. Research the extent and health impacts of 'off label' prescribing and if necessary enforce restrictions that limit PBS subsidisation to drugs that are prescribed 'on label'.**

Off label prescribing does not necessarily result in adverse outcomes. However it is unregulated and outside safety and efficacy parameters established through evidence based licencing processes. Although medications that are prescribed outside approved guidelines are not supposed to receive PBS subsidisation the extent to which medications prescribed 'off label' are subsidised is unknown. The net health benefit (or loss) of off label prescribing is also unknown

and warrants investigation.

Therefore the Commonwealth Government should commission or conduct research into the incidence and impact of 'off label' prescribing. The research should concentrate on the health impacts of off label prescribing and the extent of PBS subsidisation of the off label use of medications. Based on the outcome of this research the Commonwealth Government may consider if over time it is worth encouraging 'off label' prescribing to become 'on label'. This may be achieved in part by gradually enforcing restrictions that limit PBS subsidisation of medications to those prescribed within the approved guidelines. This may encourage pharmaceutical companies to apply to the TGA to expand the range of authorised uses of their products and would help ensure that prescribing practices are supported by robust evidence.

The abovementioned recommendations are primarily designed to ensure, open, contested regulatory and policy processes and clinical practice reliant on scientifically robust independent evidence. Many of the abovementioned recommendations are similar to those made by the UK House of Commons Committee, outlined at 2.7.

### **7.11 Conclusion**

The purpose of this thesis was to examine the relationship between regulatory capture of ADHD policy and regulatory processes and child ADHD prescribing rates in Australia nationally and within state jurisdictions. The history of ADHD policy and regulation nationally from 1992 to 2012, in Western Australia from 1993 to 2011 and in New South Wales from 2007 to 2011 indicates regulatory capture and corresponding pharmaceuticalization is highly probable, but not inevitable. With the exception of Western Australia post 2001 and the balanced national ADHD Clinical Practice Point process in 2011-2012, all the other State and Commonwealth Government processes examined have been captured by ADHD proponents in the policy development and/or implementation phase. Even WA's balanced 1997 *Technical Working Party* process was captured in the implementation phase when the Stimulants Committee set up as a result of the Working Party recommendations was captured by ADHD proponents.

All of these captured processes have been associated with subsequent ADHD child pharmaceuticalization, i.e. rapidly increasing per capita child prescribing rates. Conversely

the only ADHD critic dominated process was associated with subsequent ADHD child de-pharmaceuticalization, i.e. rapidly falling per capita child prescribing rates. In summary the evidence in relation to Government policy and regulation indicates that in relation to ADHD in Australia for the period 1993 to 2011, regulatory capture leading to pharmaceuticalization was normal but not inevitable.

Australian regulatory capture has been reinforced by ‘imported regulatory capture’. Specifically there has been a pattern of selective attention to international research and practices favourable to the perspective of ADHD proponents. Most notably despite significant and substantiated concerns about improper pharmaceutical company influence upon the American Psychiatric Association (APA), Australian agencies, both government and non- government, have endorsed and promoted the use of the ADHD DSM-IV diagnostic criteria. Alternative diagnostic criteria in the *International Classification of Diseases 10* (ICD-10) produced by the World Health Organisation (WHO), has been consistently ignored by Australian regulatory agencies and stakeholders, despite Australia being a member of the WHO. The use of DSM-IV criteria are associated with increased prescribing rates as compared to jurisdictions relying on ICD-10. It is therefore likely that regulatory capture of the American Psychiatric Association has contributed significantly to Australia’s increasingly pharmaceuticalized response to ADHD.

Caution needs to be displayed in generalising the findings of this thesis. It relates specifically to ADHD in Australia and it is impossible to quantify the relative importance of the many factors that may influence prescribing rates. However, the positive relationship between regulatory capture and pharmaceuticalization demonstrated in this thesis is consistent with Abraham’s contention that ‘regulatory capture’ is the most significant driver of pharmaceuticalization in general and ADHD pharmaceuticalization in particular. Further research is warranted on the relationship between ‘regulatory capture’ and pharmaceuticalization for ADHD and other controversial medical/psychiatric conditions in Australia and other jurisdictions.

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Appendix 1- Extract from U.S. Prescribing Information for Dexedrine produced by Glaxo Smith Kline

Full document available at  
[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2006/017078s040lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/017078s040lbl.pdf)  
(accessed 11 November 2013)

**WARNING**

**AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY. MISUSE OF AMPHETAMINES MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS...**

**WARNINGS**

**Serious Cardiovascular Events**

**Sudden Death in Patients with Pre-existing Structural Cardiac Abnormalities or**

**Other Serious Heart Problems: *Children and Adolescents:*** Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant drug.

**Adults:** Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS).

**Hypertension and Other Cardiovascular Conditions:** Stimulant medications cause a modest increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 bpm), and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g., those with pre-existing hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia (see CONTRAINDICATIONS)...

**Psychiatric Adverse Events**

**Pre-Existing Psychosis:** Administration of stimulants may exacerbate symptoms of behaviour disturbance and thought disorder in patients with a pre-existing psychotic disorder...

**Long-Term Suppression of Growth:** Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14

months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted

**Seizures:** There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

**Visual Disturbance:** Difficulties with accommodation and blurring of vision have been reported with stimulant treatment...

**Pediatric Use:** Long-term effects of amphetamines in pediatric patients have not been well established. Amphetamines are not recommended for use in pediatric patients under 3 years of age with Attention Deficit Disorder with Hyperactivity described under INDICATIONS AND USAGE.

Clinical experience suggests that in psychotic children, administration of amphetamines may exacerbate symptoms of behavior disturbance and thought disorder. Amphetamines have been reported to exacerbate motor and phonic tics and Tourette's syndrome. Therefore, clinical evaluation for tics and Tourette's syndrome in children and their families should precede use of stimulant medications...

## **ADVERSE REACTIONS**

**Cardiovascular:** Palpitations, tachycardia, elevation of blood pressure. There have been isolated reports of cardiomyopathy associated with chronic amphetamine use.

**Central Nervous System:** Psychotic episodes at recommended doses (rare), overstimulation, restlessness, dizziness, insomnia, euphoria, dyskinesia, dysphoria, tremor, headache, exacerbation of motor and phonic tics, and Tourette's syndrome.

**Gastrointestinal:** Dryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances. Anorexia and weight loss may occur as undesirable effects.

**Allergic:** Urticaria.

**Endocrine:** Impotence, changes in libido...

## **OVERDOSAGE**

Individual patient response to amphetamines varies widely. While toxic symptoms occasionally occur as an idiosyncrasy at doses as low as 2 mg, they are rare with doses of less than 15 mg; 30 mg can produce severe reactions, yet doses of 400 to 500 mg are not necessarily fatal...



Appendix 2 - Extract from Strattera Prescribing Information prepared by Eli Lilly

Available at

<http://www.fda.gov/ohrms/dockets/dockets/06p0209/06P-0209-EC3-Attach-1.pdf>

(accessed 11 November 2011)

**...WARNING: SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS STRATTERA (atomoxetine) increased the risk of suicidal ideation in short-term studies in children or adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). Anyone considering the use of STRATTERA in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber...**

All reactions occurred in children 12 years of age or younger. All reactions occurred during the first month of treatment. It is unknown whether the risk of suicidal ideation in pediatric patients extends to longer-term use. A similar analysis in adult patients treated with STRATTERA for either ADHD or major depressive disorder (MDD) did not reveal an increased risk of suicidal ideation or behavior in association with the use of STRATTERA...

The following symptoms have been reported with STRATTERA: anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania and mania...

## **5.2 Severe Liver Injury**

Postmarketing reports indicate that STRATTERA can cause severe liver injury. Although no evidence of liver injury was detected in clinical trials of about 6000 patients, there have been rare cases of clinically significant liver injury that were considered probably or possibly related to STRATTERA use in postmarketing experience. Because of probable underreporting, it is impossible to provide an accurate estimate of the true incidence of these reactions...

### **Serious Cardiovascular Events Sudden Death and Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems**

Children and Adolescents — Sudden death has been reported in association with atomoxetine treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems...

### **Effects on Blood Pressure and Heart Rate**

STRATTERA should be used with caution in patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease because it can increase blood pressure and heart rate. Peripheral vascular effects — There have been spontaneous postmarketing reports of Raynaud's phenomenon (new onset and exacerbation of preexisting condition).

### **Emergence of New Psychotic or Manic Symptoms**

Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without a prior history of psychotic illness or mania can be caused by atomoxetine at usual doses.

### **Aggressive Behavior or Hostility**

Patients beginning treatment for ADHD should be monitored for the appearance or worsening of aggressive behavior or hostility. Aggressive behavior or hostility is often observed in children and adolescents with ADHD. In short-term controlled clinical trials, 21/1308 (1.6%) of atomoxetine patients versus 9/806 (1.1%) of placebo-treated patients spontaneously reported treatment emergent hostility-related adverse events. Although this is not conclusive evidence that STRATTERA causes aggressive behavior or hostility, these behaviors were more frequently observed in clinical trials among children and adolescents treated with STRATTERA compared to placebo (overall risk ratio of 1.33 [95% C.I. 0.67–2.64– not statistically significant]).

### Allergic Events

Although uncommon, allergic reactions, including angioneurotic edema, urticaria, and rash, have been reported in patients taking STRATTERA...

Commonly observed adverse reactions in acute child and adolescent, placebo-controlled trials —

Commonly observed adverse reactions associated with the use of STRATTERA (incidence of 2% or greater) and not observed at an equivalent incidence among placebo-treated patients (STRATTERA incidence greater than placebo) are listed in Table 1...

Table 1: Common Treatment–Emergent Adverse Reactions Associated with the Use of STRATTERA in Acute (up to 18 weeks) Child and Adolescent Trials **Adverse Reaction\***

Percentage of Patients Reporting Reaction

|                                                             | STRATTERA<br>(N=1597) | Placebo<br>(N=934) |
|-------------------------------------------------------------|-----------------------|--------------------|
| <b>Gastrointestinal Disorders</b>                           |                       |                    |
| Abdominal pain†                                             | 18                    | 10                 |
| Vomiting                                                    | 11                    | 6                  |
| Nausea                                                      | 10                    | 5                  |
| <b>General Disorders and Administration Site Conditions</b> |                       |                    |
| Fatigue                                                     | 8                     | 3                  |
| Irritability                                                | 6                     | 3                  |
| Therapeutic response unexpected                             | 2                     | 1                  |
| <b>Investigations</b>                                       |                       |                    |
| Weight decreased                                            | 3                     | 0                  |
| <b>Metabolism and Nutritional Disorders</b>                 |                       |                    |
| Decreased appetite                                          | 16                    | 4                  |
| Anorexia                                                    | 3                     | 1                  |
| <b>Nervous System Disorders</b>                             |                       |                    |
| Headache                                                    | 19                    | 15                 |
| Somnolence‡                                                 | 11                    | 4                  |
| Dizziness                                                   | 5                     | 2                  |
| <b>Skin and Subcutaneous Tissue Disorders</b>               |                       |                    |
| Rash                                                        | 2                     | 1                  |

**What are possible side effects of STRATTERA?** See “**What is the most important information I should know about STRATTERA?**” for information on reported suicidal thoughts and actions, other mental problems, severe liver damage, and heart problems.

**Other serious side effects include:**

- serious allergic reactions (call your doctor if you see swelling, hives, or experience other allergic reactions)
- slowing of growth (height and weight) in children
- problems passing urine including
- trouble starting or keeping a urine stream
- cannot fully empty the bladder

**Common side effects in children and teenagers include:**

- upset stomach
- decreased appetite
- nausea or vomiting
- dizziness
- tiredness
- mood swings

**Common side effects in adults include:**

- constipation
- dry mouth
- nausea
- decreased appetite
- dizziness
- trouble sleeping
- sexual side effects
- menstrual cramps
- problems passing urine

This is not a complete list of possible side effects. Call your doctor for medical advice about side effects...

### **Appendix 3 – RACP 2009 ADHD Guidelines Reference Group Dualities and conflicts of interest summary**

Available at

[http://www.nhmrc.gov.au/files\\_nhmrc/publications/attachments/adhd\\_draft\\_appendices.pdf](http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/adhd_draft_appendices.pdf)

(accessed 11 November 2011)

#### **Professor David Forbes, WA**

In relation to ADHD I have a clinical and administrative role in the Child & Adolescent Health Service, Department of Health, WA Government. My role is not involved in service delivery to children with ADHD. I have no previous or current professional or personal pecuniary interest in any companies or other organisations involved in the development, manufacture or marketing and distribution and education of drugs and medicinal preparations.

#### **Members of the Reference Group**

##### **Dr Patrick Concannon, NSW**

As a health professional in this clinical area, I:

- am employed as Senior Staff Specialist at Royal North Shore Hospital;
- work part-time in private developmental paediatrics;
- have attended two Advisory Board meetings (Novartis Pharmaceuticals (2006) and Janssen-Cilag (2007)). The sitting fee was directed to a local charity;
- have lectured at a Janssen-Cilag sponsored clinical meeting. The fee was directed to a local charity;
- have been sponsored (Eli Lilly) to attend the 1999 annual conference of the American Academy of Child & Adolescent Psychiatry;
- participated as a principal investigator in international Metadate CD (Celltech) Study. The funds received were paid into a Royal North Shore Hospital Child & Family research fund and my involvement was approved by the RNSH ethics committee;
- have acted as a Medical Consultant to the NSW Board of Studies (1988 to present);
- am currently Chair of the NSW Health Department's Stimulant Committee; and
- was a member of the NSW ADHD Review (2007).

##### **Dr Daryl Efron, Vic**

As a health professional in this clinical area, I:

- am a senior Paediatrician at the Royal Children's Hospital (Vic) Centre for Community Child Health; The Centre for Community Child Health applied for and received educational grants for ADHD research from Novartis, Eli Lilly and Janssen-Cilag in 2004-2006. These funds have been used in accordance with the Hospital's ethical guidelines, to support research into various aspects of ADHD;
- have been an honorary (unpaid) member of ADHD advisory boards for Novartis and Eli Lilly in 2003-2004;
- am one of four Chief Investigators in a NHMRC-funded, multi-centre research study into the cognitive and behavioural effects of a medication (atomoxetine) for ADHD; and
- am a member of the ADHD Coalition of Victoria – a voluntary, multidisciplinary advocacy

group for ADHD in Victoria.

**Dr Brad Jongeling, WA**

As a health professional in this clinical area, I:

- am employed by the Western Australian Child and Adolescent Community Health Service as a senior paediatrician providing assessment to children with developmental disability, including ADHD;
- work in private paediatric practice assessing children with general and developmental paediatric issues including assessment of ADHD;
- have participated as a site (Joondalup CDC/State CDC) principal investigator in the international Metadate CD (Celltech) Study – concluded in 2005. This medication is not prescribed in Australia. Funds received from this study were paid into a Princess Margaret Hospital (PMH) research account and were used according to PMH ethical guidelines – principally for the employment of a research nurse. My involvement was approved by PMH ethics committee;
- am a member of the WA Health Department Implementation Committee (clinical guidelines subcommittees) on ADHD following a WA Parliamentary Inquiry into ADHD; and
- have until recently been the Chair RACP, Paediatric & Child Health Division – WA and have arranged local conferences which some pharmaceutical companies have sponsored.

**Dr John Wray, WA**

As a health professional in this clinical area, I:

- am employed by the Western Australian Child and Adolescent Community Health Service as a senior paediatrician providing assessment to children with developmental disability, including ADHD;
- am a member of the WA Health Department Implementation Committee and the Clinical Subcommittee of the WA Parliamentary Inquiry into ADHD;
- am the Western Australian representative of the Child Development and Behaviour Special Interest Group, of the Paediatrics & Child Health Division of the RACP;
- have received several competitive grants – no pharmaceutical research grants – to undertake research in the area of autism. One research project collaborates with an independent company that produces digestive enzymes for children with autism;
- have been a paid member of a global research team in a pharmaceutical company (Eli-Lilly) sponsored research program examining the long-term efficacy of atomoxetine in children with ADHD (2001 to 2008, now completed);
- have appeared before the Australian Pharmaceutical Benefits Advisory Committee in support of inclusion of risperidone on PBS for children with autism;
- attended two international conferences (American Academy of Child and Adolescent Psychiatry) sponsored by Eli-Lilly in 2001 and 2002 (airfare, accommodation and travel paid directly by pharmaceutical company, with approval from employer); and
- infrequently, deliver professional development lectures at meetings that have been partially or fully sponsored by pharmaceutical companies. I have never received payment for these lectures.

**Dr Mark Kneebone, NSW**

As a health professional in this clinical area, I:

- am a general psychiatrist in full-time private practice in NSW;
- have an interest in complementary treatment approaches with an evidence base;

- attended medical psychiatric meetings in November 2007 and March 2008 that were sponsored by Wyeth;
- attended three ADHD case presentation dinner meetings in 2007, sponsored by Eli-Lilly; and
- enrolled to participate in an Eli-Lilly sponsored clinical trial of Strattera in adults with ADHD. No financial reimbursement or inducement was offered or provided to participate.

**Dr Julian Trollor, NSW**

As a health professional in this clinical area, I:

- am a paid employee of the South Eastern Sydney Illawarra Area Health Service as a Senior Staff Specialist Neuropsychiatrist and the University of New South Wales as a Senior Research Fellow;
- have sought, on behalf of various conference organising committees, sponsorship from numerous drug companies;
- have received personal payments for consultancy and review work for Novartis, Eli-Lilly and Pfizer;
- have reviewed material and provided advice to Janssen-Cilag for which no remuneration was received; and
- have attended many pharmaceutical sponsored education sessions.

**Dr Peter Jenkins, Vic**

As a health professional in this clinical area, I:

- am a Consultant Child and Adolescent Psychiatrist and Clinical Director of Eastern Health Child & Adolescent Mental Health; and
- am a Fellow of the Royal Australasian and New Zealand College of Psychiatrists,
- am a member of the Faculty of Child and Adolescent Psychiatry of this College and a member of the Executive group of this Faculty.

**Associate Professor John Brennan, NSW**

As a health professional in this clinical area, I am employed as Director of the Child and Adolescent Mental Health Service at Sydney Children's Hospital (SCH).

**Professor Michael Sawyer, SA**

As a health professional in this clinical area, I:

- am employed by the Children, Youth and Women's Service of South Australia and the University of Adelaide. I also conduct a range of research activities for the South Australian Departments of Education and Children's Services;
- declined to participate as lead investigator in a 2002–2008 study investigating the relative impact of buprenorphine versus methadone maintenance therapy during pregnancy on children's outcomes. I remain on the study as a co-investigator providing methodological support for a colleague at Flinders University who subsequently undertook this study, and as a co-supervisor of a PhD student working on the study;
- was a member of the ADHD advisory board for Eli Lilly to advise on the introduction of atomoxetine into Australia; resigned from committee after attending initial meetings because of the desire to avoid conflicts of interest;
- was sponsored (Eli Lilly) to attend the 2002 annual conference of the American Academy of Child & Adolescent Psychiatry;
- am an author of the textbook *Medications for School-age Children* (Brown RT and Sawyer

MG. Guilford Press: New York. 1998); and

- am an author of the “Child and adolescent” chapter for *Therapeutic Guidelines.Psychotropic*. Version 6. 2008. Therapeutic Guidelines Limited: Melbourne.

#### **Associate Professor Geoff Mitchell, Qld**

As a health professional in this clinical area, I:

- am an Associate Professor of General Practice employed by the University of Queensland;
- currently hold an NHMRC grant to investigate the effects of methylphenidate (MPH) as a treatment for fatigue in palliative care;
- currently hold an NHMRC grant to investigate the effects of methylphenidate (MPH) as a treatment for inattention and higher brain function in children with traumatic brain injury;
- have previously held (1999–2006) funding from AHMAC, RACGP, PHCRED and Queensland Medical Laboratories investigating single patient trials of MPH and dexamphetamine (DEX).

#### **Dr Kim Pedlow, WA (see below)**

As a health professional in this clinical area, I:

- am a rural generalist medical practitioner with special interest in obstetrics, paediatrics and minor surgery;
- am a member of LADDs in Western Australia;
- was Medical Advisor to the Geraldton Network ADHD Project (1996);
- have published in the *Australian Family Physician* journal on the Geraldton network.

#### **Professor Vicki Anderson, Vic**

As a health professional in this clinical area, I:

- am Director of the Psychology Department at Royal Children’s Hospital (Vic);
- am Theme Director of Critical Care & Neurosciences at the Murdoch Children’s Research Institute;
- lead a research team, the Australian Centre for Child Neuropsychology Studies, which is currently involved in a clinical trial to test the effects of Omega-3 on attentional behaviours. The research project has been funded by Naturel, a Norwegian company. The trial has been approved by appropriate bodies in Australia, and our ethics approval gives us the right to publish data regardless of whether the trial is positive for the drug or not. I receive no direct, personal benefit from the company. [Trial subsequently cancelled]

#### **Professor David Hay, WA**

As an academic and research professional in this clinical area, I:

- am employed as a Professor of Psychology by Curtin University;
- undertake research work on ADHD that is, or has been funded by the US National Institute of Mental Health (NIMH), NHMRC and ARC (International Linkage);
- am a Member of the European Network for Hyperkinetic Disorders;
- am a Member of the NIMH, ADHD Molecular Genetics Network;
- am involved in both the Project Grants Scheme and the Training Awards Committee of the NHMRC;
- receive royalties from the sale of a 2001 book *Attention, Genes and ADHD* (Levy and Hay);
- attended a meeting of the International Collaboration on ADHD and Substance Abuse (ICASA) in Barcelona in September 2008. Curtin University paid for my airfare. My expenses in Barcelona were paid by grants to the Trimbos Institute, which administers ICASA, from

Janssen-Cilag, Eli Lilly, UCB Pharma and Shire. This sponsorship was provided under unrestricted conditions. The sponsors had no influence on who participated in ICASA, the topics discussed or any resultant activities, including research;

- was a main speaker at the Janssen-Cilag Sydney meeting “Continuities and Discontinuities of Youth Mental Health” in November 2007. I undertook this with the approval of my employer. The company organised my flight and hotel directly and I received no reimbursement. At the instruction of my University, I refused the honorarium;
- was funded by Shire Pharmaceuticals (who at the time and presently do not operate in Australia) to attend their International Planning Meeting in Amsterdam in 2005; and
- work as a consultant with organisations that may pertain to ADHD including the WA Departments of Health, Education and Training and Community Development. Also the Royal Australian and New Zealand College of Psychiatry (WA Branch). I receive no financial benefit from any of these.

#### **Professor Loretta Giorcelli, NSW**

As an academic and consultancy professional in this clinical area, I:

- undertake national and international consultancy work involving consultation to school systems, schools, universities and courts on matters related to the education and inclusion of learners with additional needs. Some of this work involves the examination of empirical evidence regarding best practice for the integration or inclusion of learners with ADHD and comorbid/overlapping conditions;
- have authored a chapter and assisted in the organisation of conferences and seminars about students with ADHD and overlapping conditions. I have also given numerous presentations on the educational implications of students with ADHD since 1996; and
- attended one meeting of Janssen-Cilag in 2005 as an educational adviser. Accommodation expenses for one night were paid. There was no honorarium.

#### **Dr Michelle Pearce, WA**

As an educationalist, I:

- have been employed by the NSW Department of Education as a school principal; the Association of Independent Schools in Western Australia as an educational consultant; and the University of Notre Dame and Curtin University as a sessional lecturer;
- offer advice, lectures, articles and professional development that focus on strategies teachers can use to support children with attentional, behavioural and learning difficulties, regardless of whether they have a diagnosis of ADHD or not; and
- have contributed strategies that have been successful with teenagers with ADHD to improve their concentration and organisation, to Novartis Pharmaceuticals Australia. Several of these strategies were published by Novartis in point form in a 2005 pamphlet.

#### **Ms Geraldine Moore, Vic**

I am a consumer advocate in this clinical area. I:

- provide my time voluntarily to The ADHD Coalition of Victoria;
- have published a book titled *ADHD Potatoes: A Journey from Darkness into Light*. This book was published by Hybrid Publishers of Melbourne. It told the story of my own family dealing with the challenge of ADHD in the 1990s, and the emergence of the support movement for ADHD in Victoria with which I was associated, throughout that period; and
- launched my book in Melbourne in November 2005. There was a subsidiary launch in Sydney in 2006 attended by about 15 people. The venue was donated by the Children’s Hospital and



the main speaker donated her services. Travel, accommodation, publicity and communication expenses were paid by myself. The cost of finger food and drinks for the attendees at the Sydney launch (around \$100) was paid by Eli Lilly.

**Ms Joy Toll OAM, NSW**

I am a consumer advocate in this clinical area and for the past 25 years have provided my time voluntarily to the Learning Difficulties (LD) Coalition of NSW Inc. I:

- am founder (1995) and currently Secretary of ADDults with ADHD (NSW) Inc. and previously founder (1988) and President for 10 years of the Learning Difficulties (LD) Coalition of NSW Inc.;
- was invited as President of the LD Coalition of NSW Inc to attend a 2003 international meeting of ADHD support organisations in Rome, representing parents of children with ADHD. Eli Lilly was a sponsor of this international meeting. Travel and accommodation for the two nights was provided by the conference organisers. I received no financial benefit from attending this meeting – in fact my employer required me to take time off without pay;
- as Secretary of ADDults with ADHD (NSW) Inc., in the absence of other sponsors, approached Eli Lilly to sponsor the cost of printing the organisation's information pamphlet;
- as Secretary of ADDults with ADHD (NSW) Inc., attended two consultation meetings with Janssen-Cilag during the development of a new Australian website: <http://www.livingwithadhd.com.au>. I received no financial reimbursement. The company provided taxi vouchers to cover my travel expenses; and
- as Secretary of ADDults with ADHD (NSW) Inc., since 2003 have attended annual consultation meetings with Eli Lilly who provide taxi vouchers to cover my travel expenses and coffee/sandwiches. I received no financial reimbursement.

**Appendix 4 - A Sample from the Adverse Drug Reactions Committee (ADRAC) adverse event reports for Atomoxetine Hydrochloride (Strattera)**

Source: Adverse events information related to Strattera obtained from the Therapeutic Goods Administration's Public Case Detail reports.

- 11 year old boy who *'threw a cricket stump javelin style at a school teacher' and 'threatened to kill himself'*
- 8 year old boy who *'hit his head against a wall' and had 'thoughts of suicide – stating that he wants to kill himself'*
- 18 year old male who suffered *'swollen, painful and tender testicles'*
- 25 year old woman who wanted to kill herself
- 12 year old girl who experienced; *'anorexia, weight loss, fidgeting and compulsive behaviour that included ripping out fingernails and toenails, picking and cutting clothing, and anger outbursts'*
- 7 year old girl who *'became very agitated while travelling in the family car and had explosive mood swings. She said that she intended to open the door and get out of the car, and she tried to open the car door'*
- 9 year old boy who *'developed abnormal behaviour, including strange facial expressions with bilateral eyelid ptosis and became very emotionally withdrawn'*
- 9 year old boy who displayed *'aggression, was totally irrational for three days and became violent, all of which was totally out of character'*
- 11 year old boy who *'became agitated, emotionally labile and experienced thoughts of self-harm'*
- 13 year old boy who *'experienced chest pains and hostile and aggressive behaviour, but the problems immediately disappeared with the cessation of Strattera'*
- 9 year old boy who slammed *'his head against walls, had extreme mood swings, violent outbursts' and was 'always angry, depressed or sad and said he wanted to kill himself'*
- 10 year old boy who *'experienced nausea, then became acutely depressed, aggressive and had suicidal thoughts'*
- 22 year old man who experienced suicidal and homicidal ideation
- 7 year old girl who experienced *'abdominal pain, nausea, severe right sided headache, shooting pains, white spots in visual fields, academic regression and faecal and urinary incontinence'*
- 7 year old boy who experienced *'suicidal ideation and mood changes' and suffered from 'increased aggression' and 'threats to self with knife, picking his skin, poking self with knife'*
- 12 year old boy experienced *'very strong suicidal ideation...talking about dead bodies and about hanging himself'*
- 11 year old boy who *'attempted suicide' and who experienced 'headache(s), stomach cramps, muscle rigidity and poor concentration'*
- 7 year old boy who experienced *'suicidal ideation'*
- 10 year old boy who developed *'psychotic symptoms' and began 'talking about suicide'*
- 11 year old boy who experienced *'a psychotic episode and took an overdose of his mother's thyroxine'*
- 9 year old boy who *'experienced suicidal thoughts'*
- 11 year old boy who became *'extremely agitated' and 'talked about wanting to die'*
- 13 year old boy who experienced *'suicidal ideation, physical and verbal aggression to family' and became 'angry, withdrawn, socially isolatory, impulsive, moody'*
- 15 year old boy who was *'expressing suicidal thoughts'*
- 11 year old boy who *'took Strattera for the treatment of ADHD to complement Ritalin, under*

*the influence of which he became suicidal and depressed'*

- 12 year old girl who *'ripped out her fingernails and toenails'*
- 9 year old girl who *'experienced self-harming'*
- 9 year old boy who expressed *'suicidal ideation', 'aggression' and 'self harm'* and made *'drawings of him hanging upside down from a tree, in (the) ocean'*
- 10 year old boy who was psychotic and experienced auditory hallucinations including *'hearing voices in his head to kill his sister'*
- 8 year old boy who lost his appetite and experienced homicidal ideation, lost weight and was angry and confused
- 15 year old girl who experienced suicidal ideation and started cutting herself to the extent that was *'life threatening'*
- another 15 year old girl who experienced suicidal ideation and started cutting herself with razors, scissors and knives
- 10 year old boy who experienced suicidal ideation
- another 10 year old boy who had abnormal thoughts about *'others jumping off buildings'*
- 8 year old boy who talked about killing himself *'in a boastful manner'*
- 17 year old male who *'was verbally and physically aggressive. These behaviours have never been seen in this man previously'*
- 8 year old boy who *'had lost appetite, was homicidal, losing weight, and lashing out/angry, patient had bruising'*
- 22 year old male who engaged in *'psychotic behaviour'*
- Two reports of a 14 year old girl who *'started cutting herself. It was reported that she felt compelled to start cutting herself and cut her arms with razors, scissors, knives. The patient had suicidal ideation while causing self-harm'*
- 10 year old boy who *'experienced suicidal thoughts'*
- 10 year old boy who *'had thoughts about others jumping off buildings'*
- 8 year old boy who was *'talking about killing himself/suicide. Patient was not depressed and discussed suicide in a boastful manner. Treating paediatrician continued atomoxetine and considered adding Risperidone. Past history included sexual abuse'*
- 7 year old girl had *'severe abdominal pain' which 'caused or prolonged inpatient hospitalisation'*
- 10 year old boy who had *'suicidal thoughts and threats, despair/depression... and violent outbursts'*
- 8 year old boy had *'suicidal tendencies'*
- 6 year old boy who had *'seizures'*
- 12 year old girl who was *'ripping their fingernails and toenails out.'*
- 17 year old male who had *'suicidal thoughts; paranoia'*
- 13 year old boy who experienced *'suicidal ideation'*
- 17 year old male who experienced *'suicidal ideation'*
- 13 year old boy who *'commenced on Strattera ... and was more agitated than usual and extremely strong suicidal ideation and urges – he climbed on a roof to jump off. Also had extremely strong ideation to seriously hurt and put in intensive care some of the other schoolchildren.'*