

## **TAKE ACTION!**

### **New Federal ADHD Guidelines Could Cause Public Health Crisis with Increase of Children Prescribed Mind-Altering Drugs**

In response to federal government concerns about the number of children labelled with “Attention Deficit Hyperactivity Disorder” (ADHD) and prescribed Schedule 8 stimulants and amphetamines (likely to cause abuse or dependency), the Royal Australasian College of Physicians has issued Draft Guidelines on ADHD that will only increase the problem and by 2015, could see more than 335,000 Australian children prescribed potentially addictive drugs.

- **If adopted, the Guidelines could cost taxpayers an estimated \$373 million**, violate the informed consent rights of parents and increase the number of children prescribed stimulants that can cause hallucinations, psychosis, cardiac irregularities, stroke and sudden death.<sup>1</sup> The Guidelines also undermine workable non-drug alternatives to these drugs.
- **The RACP ADHD Committee and many of the studies cited in the report are rife with pharmaceutical company ties**, a conflict of interest that would prompt federal investigation were it in the United States, but apparently not here. One U.S. psychiatrist, Dr. Joseph Biederman, whose studies are cited more than 70 times, is currently under U.S. Congressional investigation for his undisclosed financial ties to the pharmaceutical industry that paid him US\$1.6 million to research and promote psychiatric drugs. Yet, federal regulators here seem unaware of this and the ADHD Committee conflicts.
- **—next to Canada and the United States Australia and New Zealand have the third highest rate of ADHD drug consumption in the world.**<sup>2</sup> University of Victoria researcher and author Alan Cassels says America has created a “medical epidemic” with the number of children prescribed stimulants.<sup>3</sup> The ADHD Guidelines could cause the same crisis here.
- The Guidelines claim that 6.8% of children have ADHD, of which 3-5% are currently identified and even less takes “medication.” Currently, there are an estimated 40,174 children 15 years of age and under (46,586 under the age of 18) taking stimulants, amphetamines and Strattera for ADHD.<sup>4</sup> If the Guideline recommendations are implemented— *adding teachers, GPs and juvenile justice workers as referrals to psychiatrists*—then the full quota of children and teens (278,800) labelled as ADHD could be reached. The number of kids prescribed powerful stimulants could increase nearly 700% and, based on child and adolescent population growth, could reach 335,500 kids by 2015.<sup>5</sup>
- **Under the Guidelines, Indigenous children are particularly targeted.** With an estimated 102,500 Indigenous children, 6.8% would mean 6,970 children could be labelled ADHD and drugged. According to the Guidelines, in North Queensland, only 0.19% of Indigenous children are diagnosed with ADHD compared to 3.5% non-Indigenous children in that area—an 18-fold difference the Guidelines would like to see balanced out.
- **Between 1985 and 2000, there was a 34-fold increase in two stimulants alone prescribed to children and adolescents; and a 12-fold increase in antidepressants and antipsychotics.** If all 6.8% of “ADHD” identified and labelled children were drugged, the costs to the Pharmaceutical Benefits Scheme (PBS) alone could increase five-fold, topping nearly **\$58 million** or **\$70 million** by 2015.<sup>6</sup>

- This doesn't include the estimated 13,000 (some as young as 6) children taking one antidepressant, Aropax.<sup>7</sup> The Guidelines also recommend use of antidepressants, including Strattera (sold as a non-stimulant ADHD drug) approved for PBS subsidy in July 2007 and predicted to be prescribed to 18,000 people within the first year and at a cost of **\$101.2 million** over 3 years to the PBS and RPBS. Concerta, a stimulant similar to Ritalin was approved in 2006 at a cost of **\$10 million** to the PBS for the first year and a predicted **\$30 million** in its fourth year.<sup>8</sup>
- **ADHD Clinics:** The Guidelines recommend that about 22 special "ADHD" clinics be established to meet the workload of what promises to be a *created* epidemic of "ADHD" children and which could cost taxpayers an estimated **\$25 million**.<sup>9</sup>
- **Teachers** would be co-opted into using subjective behavioural checklists based on the American Psychiatric Association's (APA) *Diagnostic and Statistical Manual for Mental Disorders* (DSM), with schools paid additional funds for any child labelled with ADHD or a behavioural "disorder." That could cost a potential **\$300 million** a year.<sup>10</sup> Teachers are already facing increasing school violence,<sup>11</sup> yet the Guidelines would place them at further risk, making them feeder lines to psychiatrists and others that would prescribe drugs known to cause **aggression, agitation, violence and suicide**. Instead of directing funds to increasing the numbers of or pay of teachers, they'll be given the added workload of screening for behavioural problems that will lead to more paediatric drug prescriptions. The two new ADHD drugs Strattera and Concerta were approved, despite studies showing they can cause **extreme irritability, aggression, mania or hypomania (Strattera) visual hallucinations, suicidal ideation, psychotic behaviour, aggression or violent behaviour (Concerta)**. [See Appendix 2]
- **Violating Informed Consent:** The Guidelines claim that complementary and alternative treatments—that have worked for tens of thousands of children—may be of little or no benefit. They say that there are uncertainties surrounding the efficacy of elimination and restriction diets—a method that has been successfully used for decades to help children with behavioural problems. One alternative method after another is negated as having insufficient scientific studies to substantiate their use in favour of mind-altering drugs.<sup>12</sup> The FDA-acclaimed Center for Science in the Public Interest reviewed 23 controlled studies on the effect of food dyes and diet on the behaviour of children. It found that while "many mental health organizations and medical experts deny that diet can provoke adverse behaviours," this is "misleading." Its report "Diet, ADHD & Behaviour" recommends, "Government, private agencies, and health practitioners...should acknowledge the potential for diet to affect behaviour and should advise parents to consider modifying their child's diet as a first means of treatment."<sup>13</sup> This is not the first option the Guidelines recommend.
- **The Guidelines fail to mention the paucity of scientific evidence to substantiate the existence of ADHD.** While it concedes there are no biological tests—no x-rays, blood or urine tests or MRIs and other brain scans—to diagnose ADHD or any behavioural or childhood psychiatric "disorder," it misleadingly refers to ADHD as a "neurobiological disorder" when there is no scientific evidence to prove this. The report also omits a key 2005 study where researchers at the Evidence-based Practice Center of Oregon Health & Science University reviewed 2,287 studies of 16 ADHD drugs—representing *virtually every* study ever conducted on these drugs—and determined that no trials had shown the effectiveness of these drugs and that there was a lack of evidence that they could affect "academic performance, risky behaviours, social achievements, etc."<sup>14</sup>

- **CONFLICTS OF INTEREST:** The Guidelines rely upon the American Psychiatric Association's (APA) *Diagnostic and Statistical Manual for Mental Disorders (DSM)* —a document criticized for its lack of validity and reliability. Pharmaceutical companies fund the psychiatrists that *vote* to determine which "mental disorders" are included in the DSM, driving up drug sales prescribed to treat them. A 2006 study in the journal *Psychotherapy and Psychosomatics* found that 56% of all the DSM Committee members had undisclosed financial ties to drug makers. For so-called mood disorders (depression and bipolar) and schizophrenia/psychotic disorders, 100% of the DSM panel members had financial involvements with drug companies.<sup>15</sup> The drugs prescribed for these conditions make over \$30 billion a year in worldwide sales. On Saturday, July 12, *The New York Times* exposed how Congress is investigating the APA for its financial ties to the pharmaceutical industry. The U.S. Senate Finance Committee has asked the APA to hand over all its financial records.<sup>16</sup>
- The ADHD Guidelines were developed by a committee with **conflicts of interest**—financial ties to drug companies that manufacture psychiatric drugs the report recommends be used as the first line of treatment. Although each Committee member was required to disclose his or her pharmaceutical company connections, this information was not made public. **Pharmaceutical company funded psychiatrists, psychologists and physicians should have been excluded from the Committee, and "ADHD support groups" should have disclosed all pharmaceutical company connections and funding. [See Appendix 1]**

## **TAKE ACTION: WHAT YOU CAN DO**

Make your objections known. The RACP only gave until Monday, July 28 to respond to its more than 280 page report. Write to your Member of Parliament and Senator to protest the recommendations and financing of them. Schools are not mental health clinics; they are places of learning. The cost of these new guidelines is not just financial, it is potentially at the cost of children's lives.

1. **Distribute this information and ask others to help protect our children by doing a submission.**
2. **Write to the Federal Health Minister:** The Hon. Ms Nicola Roxon, 204 Nicholson Street, Footscray, Victoria 3011. **Write to the Shadow Minister for Health:** The Hon. Mr Joe Hockey, PO Box 1107, North Sydney, NSW 2059. **Write to your local federal and state members of Parliament.**
4. **Submissions must have the appropriate submission form or they will not be accepted.** Email your submission to [adhd.guideline@racp.edu.au](mailto:adhd.guideline@racp.edu.au) or mail to ADHD Guideline Review, Royal Australian College of Physicians, PO Box 7210, St Kilda Rd, Vic 8004 by Monday, July 28, 5pm AEST.

To view the Draft Guidelines in full and obtain the submission forms log onto [www.racp.edu.au](http://www.racp.edu.au) The link to the documents is on their home page. **For further information on this summary:** Contact the Citizens Committee on Human Rights National Office on: 02 99649844 or email: [cchranzo@tpg.com.au](mailto:cchranzo@tpg.com.au)

## CONFLICTS OF INTEREST

The ADHD guidelines were developed by a committee with conflicts of interest—financial ties to drug companies that manufacture psychiatric drugs the report recommends be used as the first line of treatment. Although each Committee member was required to disclose his or her pharmaceutical company connections, this information was not made public. Pharmaceutical company funded psychiatrists, psychologists and physicians should have been excluded from the Committee, and “ADHD support groups” should have disclosed all pharmaceutical company connections and funding.

- **ADHD Guidelines Committee Members: Dr. Daryl Efron** was Chair of the Committee until his conflicts were exposed last year in *The Daily Telegraph*. He has been on the advisory boards of Novartis that makes Ritalin and Eli Lilly that manufactures Strattera—both drugs prescribed to treat ADHD. While standing down as Chair, he remained a Committee member. Another Committee member, **Dr. Patrick Concannon**, has served on advisory committees for Novartis and Janssen-Cilag that makes the ADHD drug Concerta.<sup>17</sup>
- **Committee Member Professor David Hay**, is a Professor of Psychology at Curtin University of Technology West Australia; Janssen-Cilag has funded his presentation at educational seminars. Another Committee member, **Ms. Michelle Pearce** helped write a booklet, “Teenagers with ADHD” for Novartis.<sup>18</sup>
- The Committee sought comments from others, including from **Dr Evian Gordon**, who works for the Brain Dynamics Centre and in 2002, he/they received a grant of \$600,000 from Eli Lilly and Pfizer for an integrative approach for the detection of the effects of methylphenidate (Ritalin). Dr Gordon did a study (together with AWF Harris and LM Williams) and they/Brain Dynamics Centre received a Clinical Research grant from Janssen-Cilag for \$62,000 to study the effects of an antipsychotic Risperidal, also prescribed to children.<sup>19</sup>
- **Professor Philip Hazell**, Clinical Director of the Centre for Mental Health Studies in the Hunter was asked for feedback and has received speaker fees from Eli Lilly, and he’s conducted research for Novartis and has been on the advisory boards of Eli Lilly, Janssen, Novartis and Shire.<sup>20</sup> **And Dr Paul Hutchins**, Senior Paediatric Consultant and former Chairman of the NSW Health stimulants sub-committee, has served on advisory panels for Eli Lilly, Janssen-Cilag and Novartis was also asked for feedback.<sup>21</sup>
- There are 75 studies by **Dr. Joseph Biederman**, a psychiatrist currently under U.S. Congressional investigation for violating federal and university research rules. On June 8, *The New York Times* exposed how Biederman earned US\$1.6 million in consulting fees from drug makers between 2000 and 2007 but did not report much of this income to Harvard university officials.<sup>22</sup> Many of his studies are financed by drug companies that make more than US\$38 billion a year in worldwide antipsychotics, antidepressant and stimulant drug sales.
- **Dr. Christopher Gillberg** of the Department of Child and Adolescent Psychiatry, University of Gotheburg, Sweden, is referenced several times, yet in 2005 he was convicted for failing to disclose research he claimed proved the existence of an invented disorder “DAMP” (Deficits in

Attention, Motor control and Perception).<sup>23</sup> Three co-workers destroyed the material rather than make it public.

- **Russell Barkley, Ph.D.**, a renowned proponent of "ADHD" and stimulant treatment, has some 37 studies referenced. In 2007, almost a quarter (24%) of his income was from drug companies.<sup>24</sup> He is a key advisor to the U.S. Children and Adults with Attention Deficit Hyperactivity Disorder (**CHADD**) that U.S. media in 2006 exposed for its conflicts of interest with the pharmaceutical industry and the fact that it does not publish critical information about ADHD drugs, including an FDA warning in 2005 that the ADHD drug, Strattera, caused suicide. Eli Lilly, the maker of Strattera is one of CHADD's biggest donors.<sup>25</sup>
- **Dr. Laurence Greenhill**: About 7 of the referenced studies are co-authored by **Dr. Greenhill**, who is a paid speaker for the pharmaceutical companies that manufacture ADHD drugs.<sup>26</sup> In the late 1990s, Greenhill, then a high ranking official at the New York State Psychiatric Institute, was exposed for lining his pockets with hefty drug-company speaking fees, consulting deals, board memberships, and subsidized international trips, state records show. Dr. Greenhill picked up extra spending money as a consultant to Alza Corp., Bristol-Myers Squibb, Richwood and GlaxoSmithKline and served on speakers' bureaus for Eli Lilly, Janssen Pharmaceutica and Novartis Pharmaceuticals. He is also a consultant for Eli Lilly, McNeil Pharmaceutical, Novartis Pharmaceuticals, and Solvay.<sup>27</sup>

## DRUG RISKS

**STRATTERA:** A study of Strattera published in the September 2004 *Pediatrics*, the journal of the American Academy of Pediatrics, revealed that 33% of the patients reviewed exhibited **extreme irritability, aggression, mania or hypomania** while taking the drug.<sup>28</sup> In 2006, the British Medicine Regulatory Agency reported Strattera could induce seizures and a potentially dangerous lengthening of time between heartbeats. **They also warned of possible heart problems when Strattera was combined with antidepressants like Prozac and Paxil (Aropax).**<sup>29</sup> In March 2006, the Australian TGA added a black box warning to Strattera to warn of suicidal thoughts and behaviours and the need to monitor for suicidal behaviour in any child/adult on the drug. In 2004, the FDA required revised labelling to warn that severe liver damage may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients.<sup>30</sup>

**STIMULANT DRUGS:** Can cause **stunted growth, hallucinations, psychosis, suicidal ideation, "bipolar disorder," heart attacks, stroke and sudden death.** The TGA reported nearly 400 adverse reactions, including the sudden death of a 7 year old and a 5 year old that suffered a stroke after taking Ritalin.<sup>31</sup> In 2005, the FDA announced labelling changes to **Concerta** and other stimulant packaging to warn of **"visual hallucinations, suicidal ideation [ideas], psychotic behaviour, as well as aggression or violent behaviour."**<sup>32</sup> **Yet the ADHD Guidelines recommend that 3 to 5 year olds be the subjects of stimulant drug experiments, despite even drug companies not recommending use for those under the age of 6.**

**RITALIN AND SUBSTANCE ABUSE:** The Guidelines claim that Ritalin/stimulant usage does not predispose children to later cocaine or illicit drug abuse. It is selective in choosing its studies. A 2002 U.S. Government Reform Committee investigation into "ADHD—Are we Over-Medicating Our Children," saw chairman, Congressman Dan Burton reprimanding the head of the National Institute of Mental Health, Dr. Richard Nakamura for doing the same thing. Dr. Nakamura failed to mention that there had been studies showing an increase likelihood of abuse in children taking stimulants. Congressman Burton cited a *Journal of the American Medical Association* study that said that Ritalin was a more potent transport inhibitor than cocaine: "The big difference 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 normally consumed take about an hour to reach the brain. Like cocaine, chronic use of Ritalin produces psychomotor stimulant toxicity, including aggression, agitation, disruption of food intake, weight loss, stereotypic movements and death."<sup>16</sup> Dr. Nakamura testified that the stimulant properties of Ritalin and cocaine "derive from similar chemical properties." If a person ground up Ritalin into powder form and snorted it, "they would get a high from ground up methylphenidate" and in this form, "that would increase the addiction potential of the methylphenidate [Ritalin]."<sup>16</sup>

A study published in the February 2000 *Journal of the American Academy of Child* determined: "It is well known that psychostimulants have abuse potential." The increased availability of stimulant medications may pose risks for society.<sup>33</sup> In the August 2001 *Journal of the American Medical Association*, Nora Volkow, M.D., psychiatrist, researcher and imaging expert determined that Ritalin acts much like cocaine. Injected as a liquid, it sends a jolt that "addicts like very much," she said. "They say it's like cocaine."

- <sup>1</sup> Figures based on PBS spending an additional \$48.4 million, Mental Health Clinics costing an estimated \$25 million and Schools being paid between \$220 and \$440 for every ADHD labelled child (See # 9).
- <sup>2</sup> Australia third in use of 'kiddy speed,'" *The Daily Telegraph*, 16 Nov. 2002; "NZ third-equal in drug consumption stakes," AAP, November 2002, citing study in the *Medical Journal of Australia*; 'Kiddy speed' use worries agency," *Dominion Post*, NZ, 18 Nov. 2002.
- <sup>3</sup> Alan Cassels, "Spreading disease by word of mouth," *Star.com*, 4 Mar. 2008.
- <sup>4</sup> Based on PBS records and Medicare; the Royal Australasian College of Physicians estimated in 2006 that ADHD affected 3-5% of children but only 1-2% take medication, which is 80% successful. The statistics in this Executive Summary are based on numbers of children reported to be taking ADHD drugs and the 2008 RACP report stating that 6.8% of Australian children are likely to have ADHD. Ref. "Good News in ADHD: Important changes to the management of Attention Deficit Disorder," RACP, 20 Dec. 2006.
- <sup>5</sup> The ABS estimates that the population of Australian children under the age 18 in 2015 will be 4,933,800.
- <sup>6</sup> 2007: the Federal Government spent \$12,232,375 on the PBS for ADHD drugs; 79% of these were children (46,586 kids out of 59,243 people total on the ADHD drugs) representing \$9,633,437 or an average of \$206.78 per child. Take the figure to 6.8% or 278,800 and it could cost \$57,652,562. [Extrapolated this to 2015 and a conservative estimate is it will cost \$69.3 million, not taking in inflation].
- <sup>7</sup> Michael Bradley, "Common Anti-depressant may increase child suicide", *Sydney Morning Herald*, 11 June 2003.
- <sup>8</sup> "Final Public Summary report, Methylphenidate Hydrochloride, extended release tablets, 18 mgs, 36 mg and 54 mg Concerta®, PBAC Meeting, Nov. 2006.
- <sup>9</sup> Based on \$1.1 million for a clinic in WA (that will provide alternatives to drugs, unlike the planned Guideline clinics) and based on the per capita estimates of 2 clinics in SA, 5 in Vic, 1 in ACT, 1 in NT, 1 in Tas, 4 in Qld, 6 in NSW; 22 clinics at a cost of \$1.12 million per equals \$24.64 million per year.
- <sup>10</sup> Currently in the Northern Territory schools can receive depending on the severity of child, between \$220 and \$440 a week to pay for wages for staff to help a child with "ADHD." An average \$220 could add \$8.8 million per week (\$17.6 million for \$440) just to existing number of kids or \$61.3 million for 6.8% and \$122.6 million at \$440 per child. Multiply these by 37 weeks of school to get total for the year.)
- <sup>11</sup> "Damage Control," Australian Education Union, <http://www.aeufederal.org.au/Publications/AE?Spr03pp16-19.html>, 10 Sept. 2003.
- <sup>12</sup> Pages xxii, xxiii, 15, 154, 155, 156, 159, 161 in Guidelines.
- <sup>13</sup> Michael F. Jacobson, Ph.D., David Schardt, M.S., "Diet, ADHD & Behaviour," Center for Science in Public Interest, Sept. 1999.
- <sup>14</sup> "Drug Class Review on Pharmacologic Treatments for ADHD," Final Report, Evidence-based Practice Center of Oregon Health & Science University, Sept. 2005; M. Alexander Otto, "Are ADHD Drugs Safe? Report Finds Little Proof," *The News Tribune*, 26 Sept. 2005.
- <sup>15</sup> Lisa Cosgrove, Sheldon Krinsky, et al, "Financial Ties between DSM-IV Panel Members and the Pharmaceutical Industry," *Psychotherapy and Psychosomatics*, May 2006, 75:154-160.
- <sup>16</sup> Gardiner Harris, Benedict Carey, "Psychiatric Group Faces Scrutiny Over Drug Industry Ties," *New York Times*, 12 July 2008.
- <sup>17</sup> [http://www.cec.health.nsw.gov.au/pdf/specialreports/adhd\\_080211.pdf](http://www.cec.health.nsw.gov.au/pdf/specialreports/adhd_080211.pdf) See page 64
- <sup>18</sup> <http://www.adhdsupport.com.au/pdf/adolescent.pdf> See page 2.
- <sup>19</sup> <http://www.brain-dynamics.net/people/details.jsp?lastname=Gordon&memberID=100> See 10<sup>th</sup> entry in link
- <sup>20</sup> *Australian Prescriber*, Vol. 28, No. 5, Oct. 2005 <http://www.australianprescriber.com/upload/pdf/articles/727.pdf> See page 3. <http://www.cheri.com.au/documents/TheAdolescentwithADHDPhilHazellprint.pdf> See page 1. [http://clinicalevidence.bmj.com/ceweb/conditions/chd/1008/1008\\_contribdetails.jsp](http://clinicalevidence.bmj.com/ceweb/conditions/chd/1008/1008_contribdetails.jsp) See page 3. <http://www.newcastle.edu.au/centre/cmhs/cmhs-report-002-062004.pdf> See Page 20.
- <sup>21</sup> [http://www.cec.health.nsw.gov.au/pdf/specialreports/adhd\\_080211.pdf](http://www.cec.health.nsw.gov.au/pdf/specialreports/adhd_080211.pdf) See page 64.
- <sup>22</sup> Gardiner Harris, Benedict Carey, "Researchers Fail to Reveal Full Drug Pay," *New York Times*, 8 June 2008.
- <sup>23</sup> "The Gillberg Affair," [www.informath.org/apprise/16400.html](http://www.informath.org/apprise/16400.html)
- <sup>24</sup> Russell A. Barkley, Ph.D., Official Site, <http://www.russellbarkley.org/about-dr-barkley.html>
- <sup>25</sup> Thomas Ginsberg, "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.
- <sup>26</sup> "Study warns of Side Effects for PreSchoolers," American Associated Press, 20 Oct. 2006.
- <sup>27</sup> Greg, Birnbaum, Doug Montaro, "Analyze This," "Shrinks for Sale?" *New York Post*, 28 Feb 1999.
- <sup>28</sup> Kelly O'Meara, *Psyched Out, How Psychiatry Sells Mental Illness and Pushes Pills that Kill*, AuthorHouse, 2006, citing Theodore A. Henderson, M.D., Ph.D., Matrix ADHD Clinic, Neurobehavioural Research, Keith Hotman, M.D., "Aggression, Mania, and Hypomania Induction Associated with Atomoxetine," *Pediatrics* Vol. 114, No. 3, Sept. 2004.
- <sup>29</sup> M. Alexnader Otto, "British report find new risks of ADHD drug," *The News Tribune*, 21 Feb. 2006.
- <sup>30</sup> "Attention Drug to Get New Warning," *Los Angeles Times*, 18 Dec. 2004.
- <sup>31</sup> Clara Pirani, "Children on ADHD drugs hit by heart attacks and stroke," *Weekend Australian*, 27 Mar. 2006.
- <sup>32</sup> FDA "Statement on Concerta and Methylphenidate for the June 30 Pediatric Advisory Committee," 28 June 2005.
- <sup>33</sup> National Institutes of Health Consensus Development Conference Statement: Diagnosis and Treatment of Attention-Deficit/Hyperactivity Disorder ADHD" *Journal of the American Academy of Child and Adolescent Psychiatry*, February 1, 2000 p. 5.