Abstract

There has been a rapid rise in rates of diagnosis of, and prescription of psycho-pharmaceuticals for, behavioural disorders in children in general, and boys in particular, in North American, North European and Australasian countries. This article concentrates on the evidence base for the prescription of psycho-pharmaceuticals for the two most common of these disorders: ADHD and Autism. The practice of widespread prescribing is based more on successful marketing than scientific evidence. Arab and other non-Western societies can learn from these mistakes and take a more cautious approach before accepting the validity of these diagnoses and the benefits of prescribing medication to ‘treat’ them.

There is a long history in the field of psychiatry of exorbitant claims being made for a variety of practices from inducing insulin comas to performing radical brain surgery such as lobotomies. Each new wave brought enthusiastic claims of ‘miracle’ cures, which over time, when subjected to rigorous objective research showed that these new treatments were not as effective as first claimed with risks having been unduly minimized. In recent decades, waves of optimism about ‘curing’ and ‘treating’ mental illness through modern psychopharmacology has popularised the use of psycho-pharmaceuticals changing the prescribing habits of doctors and the health seeking behaviour of patients. Sadly, closer scrutiny of the scientific evidence reveals that the new age of the mass use of psycho-pharmaceuticals is the result more of good marketing than good science, through a confluence in the interests of neo-liberal policies, the profit motive of pharmaceutical companies, and ‘guild’ interests of psychiatrists. Closer scrutiny of the science shows that, as in previous era’s physical treatments for psychiatric disorders, claims for psycho-pharmaceuticals curative properties have been exaggerated and their dangers minimised.
Childhood psychiatric disorder and the alliance between drug companies and doctors:
The treatment of children with psychiatric drugs is even more contentious as many of the drugs now being used on children are meant for, and have been researched in adults. In a context in which no objective tests exist to verify the ‘diseases’ being diagnosed, pharmaceutical companies realise that a bigger market for their product can be created by ‘disease promotion’. Here the task of the pharmaceutical company becomes that of convincing the medical profession and the public that young people’s emotional and behavioural problems are the result of under-diagnosed and under-treated ‘brain’ disorders, which of course sets the context for their products to then be marketed as ‘treatments’ for these alleged physical disorders. They do this by sponsoring or producing material for doctors’ waiting rooms that alert the medical and lay community to the existence of these conditions, producing ‘educational’ material for parents and teachers, and funding parent support/campaigning groups.
One favoured means of promoting new illnesses is for pharmaceutical companies to invest in consumer support groups. For example, the US based National Alliance for the Mentally Ill received over US $11 million from 18 pharmaceutical companies between 1996 and mid-1999. It is cost-effective for pharmaceutical companies to invest in such groups without any direct promotion of their product, as support groups can increase the number of patients who present to doctors with ready-made diagnoses. This also allows them to present what they are doing as a ‘service’. However, the problem is not just that of the profit motive of pharmaceutical companies, as the problem of professional identity, while making child psychiatry vulnerable to manipulation, must also be owned by the profession. Child psychiatry should sit at the confluence of many different systems of knowledge: medical, psychological, social, paediatric, anthropological, cultural and so on. The move towards favouring biological models and physical treatments has been attractive to sections of the profession that wish to carve out a clearer territory that bolsters a more ‘doctor-like’ image of what they do, rather than the more diffuse, hard to define role a more complex approach that spans several disciplines ‘territories’ provides.
The above dynamics (pharmaceutical company marketing and profiteering combined with some child psychiatrists’ willing collusion with this) has subsequently distorted the evidence and ultimately practice for all psycho-pharmaceuticals currently used with
children. The rest of this article deals with drug treatment for the two disorders that have become the most commonly diagnosed (mainly in the English speaking countries) child psychiatric disorders – ADHD (Attention Deficit Hyperactivity Disorder) and ASD (Autistic Spectrum Disorders). In both cases the diagnosis and prescriptions are given primarily to boys (in the region of about 4:1 boys: girls) and pharmaceutical treatments are aimed at modifying the child’s unruly and non-conformist behaviour. I start with the example of the most widely used psycho-pharmaceutical in children.

**Stimulants for ADHD**

In November 2004, an article, containing several interviews, was published which highlighted the fact that questions about the scientific credibility of psychiatric drug research of stimulants were widespread. Gene Haislip, the now retired director of the US Drug Enforcement Agency (DEA), set production quotas for controlled substances such as the federally restricted stimulant ‘Methylphenidate’. During that time, he fought hard to raise public awareness about the drug’s high rate of non-prescription use/misuse and about its long-term health impact on young patients. He notes that, “When I was at the DEA, we created Awareness about this issue. But the bottom line is we didn’t succeed in changing the situation because this – prescribing methylphenidate, for example – is spiralling”, adding, “A few individuals in government expressing concern can’t equal the marketing power of large companies”.

Haislip suspects that the dubious marketing tactics of big pharmaceutical companies supported by a small group of prolific researchers in ADHD, whose work is funded by corporate producers of ADHD drugs, fuelled the spiralling use of stimulants. He also suspects that one or more ADHD patient advocacy groups that receive pharmaceutical company donations have essentially become fronts to push the prescribing of stimulants to children.

William Pelham, a prominent ADHD researcher and former member of the scientific advisory board for McNeil Pharmaceuticals, was also interviewed for the article. Between 1997 and 1999, he was paid by McNeil to conduct one of three studies used to get US Food and Drug Administration (FDA) approval for a long-acting slow-release version of methylphenidate and, according to Hearn, the company now uses these three studies to claim that 96% of children taking this drug experience no problems with appetite, growth, or sleep. But Pelham says the studies were flawed and this claim is misleading because his study started with children who had already been taking the
drug and who had experienced no significant side-effects—children who exhibited side-effects were not included in the study to begin with. Pelham mentions that the company pressured him to change the final article, saying, “It was intimidating to be one researcher and have all these people pushing me to change the text”.

In the world of ADHD advocacy, Children and Adults with Attention Deficit Hyperactivity Disorder (CHADD), a large US-based ‘parent support group’, engages in lobbying and claims to provide science-based, evidence-based information about ADHD to parents and the public. Pharmaceutical companies donated to CHADD nearly $700,000 in the fiscal year 2002–2003. Pelham, listed by CHADD as a member of its professional advisory board, came face to face with what he says are the group’s glaring conflicts of interest. In 2002, after he received the CHADD Hall of Fame Award, he was subsequently interviewed for ‘Attention!’ the organisation’s magazine. In the interview, Pelham said, among other things, that stimulant drugs have serious limitations. Eight months later, ‘Attention!’ published Pelham’s interview but with a large part cut out, particularly his comments about the limitations of the stimulants. Commenting on this Pelham says, “In recent years, I have come to believe that the individuals who advocate most strongly in favour of medication – both those from the professional community, including the National Institutes of Mental Health, and those from advocacy groups, including CHADD – have major and undisclosed conflicts of interest with the pharmaceutical companies that deal with ADHD products.”

In a world run by those with the power to buy media attention, it is not uncommon for single studies to become the basis on which practice develops. One such study was the Multimodal Treatment Study of ADHD (MTA), a large multicentre trial in the USA testing the efficacy of the stimulant methylphenidate. This publication led to widespread publicity claiming that the results show that we should be treating children who have ADHD with stimulant medication as the first line and possibly only treatment. In the years since the publication and popularisation of this study there has been a sharp rise in the rates of stimulant prescription in all over North America, Northern Europe, Australasia, and beyond. In the UK this had resulted in a prescription rate for stimulants of over 550,000 per annum by 2006, a staggering rise of over 7000% in a decade.

The MTA study compared four groups of children who were given: medication only; intensive behavioural therapy only;
combined behavioural therapy and medication; and standard community care. The study lasted 14 months and concluded that the medication-only and combined behavioural therapy and medication groups had the best outcome, with the ‘combined’ group having only a marginally better outcome than the medication-only group. A closer look inevitably brings up important questions of methodology and the hidden question of conflict of interest as many of the researchers were found to have extensive links with the pharmaceutical industry.

Methodologically this was not a placebo-controlled double-blind clinical trial, and the parents and teachers who participated were exposed to pro-drug literature at the start of the study, thus potentially putting them in a mindset of positive expectation for change in the children receiving medication. There are also many question marks with regard to the selection and recruiting process, the behavioural interventions used, the placebo effect of the active medication arm continuing until the end of the 14 months but the behaviour therapy component finishing many months prior to 14 months, the lack of attention to the number of children experiencing side-effects, and the dismissal of some reported side-effects as probably being due to non-medication factors. In addition, two-thirds of the community-care group were also receiving stimulant medication during the study, yet the community-care group was the poorest outcome category.

The 3-year outcome for the MTA study was finally published in 2007 – 8 years after the results of the study at 14 months were published. All the advantages with regard to symptoms of ADHD for the medication-only and ‘combined’ groups had been lost, whereas the improvements in the behavioural therapy-only group had remained stable. At the end of the original 14 month long study, participants had been free to pursue whatever treatment they wanted. Some children had started taking medication and others on medication had stopped. The therapy-only group remained the group with the lowest use of medication. When the researchers analysed outcomes for those who had used medication in the previous year they found that they had a worse outcome than those who had not. Furthermore, those who had taken medication continuously had higher rates of delinquency at 3 years, and were significantly shorter (by an average of over 4 cm) and lighter (by an average of over 3 kg) than those who had not taken medication. The likelihood of ending up being prescribed medication was not related to initial severity of symptoms. The 3-year outcome data, therefore shows that the study that is repeatedly quoted as providing the scientific basis...
for prescribing stimulants to children\(^6\), actually demonstrates that there is little advantage (compared to behaviour therapy) associated with its use, but considerable risks. According to Pelham, who is on the steering committee for the MTA studies:

“No drug company in its literature mentions the fact that 40 years of research says there is no long-term benefit of medications [for ADHD]. That is something parents need to know” (Pelham, quoted in Hearn, 2004)\(^6\).

The children in the MTA study have been followed up for 8 years. Although details for these outcomes have not been published, it seems that outcomes for the ‘medication management’ group continued to deteriorate. Reporting on a recent conference presentation by James Swanson (another member of the steering committee for the MTA studies), Mytas (2009) notes that Swanson reports that:

“The medication management group functioned better at 14-24 months, but was associated with worse functioning and greater need of additional school services at 36, 48, 72, and 96 months”\(^13\)

Thus we come back full circle. The study that was most widely quoted as the study that ‘proved’ that ADHD should be treated with medication as a first line treatment has found that such a treatment (when compared to non-medication based first line treatments) is associated with the worst outcomes and highest level of needing extra support. This adds to the accumulating evidence on stimulants for ADHD, which, despite being the most researched drug treatment for a child psychiatric disorder, has failed to find long term benefits accruing from their use. Systematic reviews of ADHD medication treatment\(^14,15,16,17,18\), have noted the inadequate reporting of study methodology, possible publication bias, limited reliability of results, inadequate data regarding adverse events, and the lack of Randomised Control Trial evidence of any long term benefit from taking stimulants. In the face of such findings it is impossible to continue to claim that using stimulants for treatment of ADHD is evidence based with the benefits outweighing the risks. Unfortunately practice is already so strongly established in some countries that reversing this trend is proving very difficult to achieve. Hopefully, preventing the uptake of such non-evidence based approaches will be easier to achieve in parts of the world where such practice has yet to take root, although the might of the drug companies still means this is an uphill battle.

The above example shows the extent to which the so-called scientific literature on the use of psycho-pharmaceuticals for childhood behavioural and emotional problems has demonstrated that it is...
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unreliable and compromised in particular by conflict of interest issues. Psychiatry appears to be the top ‘offender’ amongst medical specialities with regards use of and sponsorship from drug companies. Perhaps this is not surprising given the enormous potential markets that can be (and have been) developed if psychiatry is successful in medicalising peoples’ emotional responses and behaviour, in a field so reliant on subjective interpretations of normalcy and deviance. Child psychiatry seems particularly vulnerable\(^\text{19}\), with, most recently, an influential group of child psychiatrists at Harvard, extensively involved in research promoting the use of psycho-pharmaceuticals (particularly for ADHD and paediatric bipolar disorder), found to have received millions of dollars of income from pharmaceutical companies most of which they had not disclosed\(^\text{20}\). These types of problems have resulted in a growing distrust of the claims made for the use of psycho-pharmaceuticals with children, not only in the general public, but within the medical profession more generally. For example, an editorial in 2008 in one of the world’s oldest and most respected medical journals concluded:

“We know little about the long-term effects of psychiatric drugs in children. Side-effects of anti psychotics include shaking, damaged bones, reduced fertility, obesity, and increased risk of heart attack, diabetes, and stroke. Stimulants can damage the heart and stunt growth. Antidepressants can increase the risk of suicide in children. Do these drugs work? Evidence is often scant – and, where it exists, is largely discouraging… Many patients have argued for years that psychiatric drugs are often more harmful, and less effective, than doctors believe. Increasingly, these patients are seen to be right. If psychiatry is to retain its claim to rationality, it must allow patients, including children, to be heard, and not merely drugged.”\(^\text{21}\)

Anti-psychotics for autism
As far back as 1973, Ornitz commented that:

“Almost every conceivable psychotropic medication has been used with autistic children. The classes of medication have included sedatives, anti-histamines, stimulants, major and minor tranquillizers, anti-depressants, psychomimetics and anti-Parkinsonism drugs… As with psychotherapy, behaviour modification, special modification and speech therapy, no single medication or class of modification has made an autistic child any less autistic. Nor has any medication or class of medication proven successful in removing any particular symptom of the autistic syndrome.”\(^\text{22}\).
These decades’ old observations are as true today as they were then, despite his comments referring to a much narrower group of children, as this was prior to the broader concept of ‘Autistic Spectrum Disorder’ (ASD) taking root. However, this is not the impression you get if you observe current practice in child and adolescent psychiatry. A good example of this comes from an editorial entitled ‘Antipsychotic drugs in children with autism’ that appeared in 2007 in the world’s most read medical journal; the British Medical Journal. Use of antipsychotics, particularly Risperidone, for ‘treating’ children with autism who have concurrent behavioural problems has become popular in recent years and well before any evidence for the safety and efficacy of such practice was available. Studies in this area appear to have the purpose of trying to justify an already established practice. In this article, ‘opinion leaders’\textsuperscript{23} take an apparently moderate stance suggesting that antipsychotic drugs should not be used indiscriminately in children with autism but reserved for those with more ‘serious’ behaviour problems. This apparent moderate position is possibly more dangerous than a more overtly stated position, as it effectively sanctions the use of anti-psychotics for ‘aggressive’ behaviours in those diagnosed with autism and without presenting sufficient evidence that such practice is either safe or effective, yet it is written in a style that suggests they are being evidence based and cautious. They state “We consider off label use [of anti-psychotics] is justified when other approaches fail or are unfeasible”\textsuperscript{23}. This effectively leaves the door open for the continued increase in the use of (off-label) anti-psychotics as the reading doctor is left to wonder what other approaches to use and for how long before deciding they have failed (an important point, particularly bearing in mind what Ornitz, above, had to say about the lack of efficacy for any treatment in autism). Furthermore, unfeasibility of other approaches is near universal as the increasing popularity of the diagnosis of autism, together with this diagnosis becoming more often than not the responsibility of busy community paediatricians, means ‘other approaches’ are thin on the ground. They further recommend “Diagnosis should distinguish between aggression and other seriously challenging behaviours (which may justify an antipsychotic agent) and lesser levels of irritability (which may not)”\textsuperscript{23}. However, they don’t explain how a clinician is supposed to differentiate between what one should consider ‘seriously’ challenging behaviour and ‘irritability’. Not only is the conceptual basis of the article shaky, in addition the
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authors fail to approach the evidence with anything like sufficient rigour. In support of their recommendation to use anti-psychotics for challenging behaviour they refer to 2 studies only. A more critical review of these 2 studies reveals anything but encouraging news for this practice. Firstly, both studies were of only 8 weeks in duration, far off the many years that drugs’ prescribed to pacify behaviour are usually used for. Secondly, one of the studies reviewed their subjects at 6 months and found a familiar pattern seen with drug treatment for behavioural problems – that of diminishing returns, with less than half of the group that had received Risperidone (the antipsychotic) now rated as ‘improved’ (interestingly they do not provide the data for how the placebo group were doing after 6 months). Thirdly, a decrease in challenging behaviour in those receiving an antipsychotic at a sufficient dose is really a foregone conclusion, after all anti-psychotics are not classified as ‘major tranquillisers’ for nothing. Whether this is viewed as a therapeutic effect or side effect depends on your perspective. Reflecting this fact, both studies rated high levels of somnolence (sleepiness or drowsiness), for example, Shea et al (2004) recorded a 72% rate of somnolence in the group receiving Risperidone, leading to the rather peculiar scenario where arguably the same pharmacological effect is simultaneously rated as therapeutic (decrease in aggressive behaviours) and an adverse effect (somnolence) - after all you can’t get up to much mischief if you’re drowsy. What is most shocking however, is Morgan and Taylor’s minimising of the serious adverse effects of the antipsychotics, which were prevalent in both studies. To give just one example, both studies found the group receiving Risperidone put on more weight than the group with the placebo; in McCracken et al (2002) this was an average of 2.7 v 0.8 Kg, and in the Shea et al (2004) study this was an average of 2.7 v 1.0 Kg. Remember this was after only 8 weeks of ‘treatment’. Thus these children were being put at a greatly increased risk of serious illnesses such as cardiovascular disease and diabetes. The article revealed that Morgan and Taylor are most certainly not the moderates they wished to present themselves as. Indeed they note that Janssen-Cilag withdrew their application for Risperidone to be licensed in the UK for use in behavioural problems associated with autism. As a result they actually outdo a drug company in their keenness for the use of psycho-pharmaceuticals in controlling autistic children’s behaviour and go on to suggest doctors should carry on using anti-psychotics for this (off licence) indication. As influential clinicians and
researchers writing in an influential journal, their position effectively encourages the use of powerful, risky and largely ineffective medicines to control the behaviour of a group of citizens (children) who have never really had a say in what is being imposed upon them and with scant evidence to back up the validity or utility of such practice, but sufficient evidence to demonstrate that such practice exposes children to significant risks.

**Conclusion**

There has been a rapid increase in diagnosis of psychiatric disorders in children and adolescents in most Western societies, particularly for behavioural problems and, amongst these, particularly for boys. Childhood problems are increasingly medicalized resulting in an apparent ‘epidemic’ of several psychiatric disorders in children in the West and a rapid rise in the prescription of psychotropics to the young. I have summarized the problematic nature (in terms of lack of evidence for a biological substrate, high co-morbidity, lack of cross-cultural validity, boundary issues, marginalization of certain types of evidence, and lack of evidence for effectiveness of medications used) of current popular child psychiatric diagnoses elsewhere. In this paper I have concentrated on the way evidence (or rather lack of it) for the safety and efficacy of using psychotropics for children diagnosed with ADHD or ASD, has been distorted to increase the potential market and bolster a more ‘doctor-like’ image for child psychiatrists.

Figures for prescriptions of psychotropic medication to children and adolescents both illustrate the depth of this problem and the peculiar cultural style of responding to it. For example, researchers analyzing prescribing trends in nine countries between 2000 and 2002, found significant rises in the number of prescriptions for psychotropic drugs in children were evident in all countries – the lowest being in Germany where the increase was 13%, and the highest being in the UK where an increase of 68% was recorded. Of particular concern is the increase in rates of stimulant prescription to children. By 1996 over 6% of school-aged boys in America were taking stimulant medication with children as young as two being prescribed stimulants in increasing numbers. Surveys in the late 90s showed that in some schools in the United States over 17% of boys were taking stimulant medication and recent estimates suggest that about 10% of school boys in the United States have been or are being prescribed a stimulant. In the UK prescriptions for stimulants have increased from about 6,000 prescriptions a year in 1994 to
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over 450,000 by 2004; a staggering 7,000% rise in one decade. Rates of diagnosis of ASDs have gone from about 4 per 10,000 children a few decades back – with Kanner’s criteria being used and identifying almost exclusively children with moderate to severe learning difficulties – whereas now it is thought to affect about 1% of children. Both ADHD and ASD are diagnoses that target boys and their behaviour. The increasing popularity of certain diagnoses, in this case ADHD and ASD, owes more to social, political, and economic processes than to scientific breakthroughs. The popularity of these diagnoses can act as a barometer for the cultural attitudes toward boys and how to deal with them. Those countries with high rates of diagnoses of these conditions and high rates of using medication for essentially social control purposes, demonstrate their lack of tolerance for ‘boyishness’. Countries that have yet to take up this practice could do well by not following this example of bad behaviour by the elite toward their society’s children.

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