Citizens Commission on Human Rights (United Kingdom)

Dangers and Consequences of the Misdiagnosis and the Prescribing of Mind-altering Drugs to Children

Report presented to the United Nations Committee on the Rights of the Child

September 2015

1.Summary Introduction

This report has been produced for the United Nations Committee on the Rights of the Child (UNCRC) and calls attention to the continuing concern about the massive diagnosis and misdiagnosis of attention deficit hyperactivity disorder (ADHD) and other mental disorders in UK children and adolescents. This has led to skyrocketing psychotropic drug prescriptions in children and adolescents. For example:

- In 2010, it was reported that NHS spent £31m on "child-calming drugs"—up 60 per cent since 2006.[1]

- A recent survey in the UK, carried out by educational psychologists at the University College London Institute of Education and the British Psychological Society, found that "many pre-schoolers are being prescribed drugs for hyperactivity such as Ritalin." More than 20 per cent of educational psychologists are aware of children under six being given the drugs.[2]

- Reported in June 2014, a million prescriptions for Ritalin were being written every year for children as young as three for conditions such as ADHD. An estimated 400,000—650,000 children take the drug, though official figures have not been made public, if they are kept at all. The drug costs the taxpayer almost £50million a year.[3]

- Babies under the age of one and children aged four are being given stimulants for behavioral problems in breach of National Health Service (NHS) guidelines.[4]

- According to the Medicines and Healthcare Products Regulatory Agency, 11 British children on Ritalin have died. The cause of two deaths was heart-related and included heart attack, "sudden death," brain haemorrhage and swelling in the brain.[5]

- David Healy, one of the world's leading psycho-pharmacology experts and Professor of Psychiatry at Cardiff University, said: "The drugs used to treat ADHD are the same as speed and cocaine. We react with horror to the idea that our kids would use such drugs, but don't react about drugs such as Ritalin being given to them….There are high risks that children will go on to use street drugs, too, because they will have grown used to their effects."[6]

- Ritalin has created a culture of drug pushing in school playgrounds, where children craving Ritalin's amphetamine-like hit can buy a stolen pill for as little as £1.[7]

- And all this despite the UK National Institute for Health and Clinical Excellence (Nice) guidance that also says psychotropic drugs should not be prescribed to children under the age of six—at a time when their brains are still developing.[8]

- "We now have a generation of children who are dependent on this drug yet we don't know what the long-term effects will be," Dr Matthew Offord, MP said. "It seems to me the behaviour of children has not changed or deteriorated so much in the last 15 years that it warrants a 1,000 per cent rise in prescriptions. "I can only conclude it is being over-prescribed by doctors who are not looking at alternative treatment options, which may be more long-term but may actually present a better option."[9]

- Some 4% of children and adolescents who are prescribed antidepressants have inadvertent suicidal thoughts (compared with 2% of those using a placebo).[10] This supports an analysis conducted by Manchester University researchers that found children who take antidepressants run a higher risk of

self-harm and attempting suicide. They found five per cent of children taking new-generation antidepressants were involved in self-harm or suicidal events, compared with three per cent of those taking dummy pills. The study's findings published in the *British Journal of Psychiatry* in 2006 studied 1,427 children taking fluoxetine (generic of Prozac), sertraline (Lustral), citalopram (Cipramil), paroxetine (Seroxat), venlafaxine (Efexor) and mirtazapine (Zispin). It was estimated that 40,000 children and adolescents were taking antidepressants, despite drug regulatory warnings against those younger than 18 being prescribed the drugs because of the risk of suicide.[11]

- In 2010 it was reported that the number of UK children prescribed powerful antipsychotics also doubled in the previous ten years and some 15,000 children and adolescents had been prescribed the drugs in 2010. However, Channel 4 news reported at the time: "Astonishingly, no official data is kept on the number of youngsters being given antipsychotics." [12] Their estimates were derived from a drug database company that were only from GP surgeries and primary care trusts and did not include hospital prescribing. The numbers taking the drugs are likely much higher.[13]

- The number of UK children prescribed antipsychotics went from a rate of four per 10,000 in 1992 to seven per 10,000 in 2005. The use of these drugs—*designed for adults* — tripled in children aged 7- to 12-years-old.[14] In 2006, around 8,000 British youngsters were being treated with *two* antipsychotics (Risperdal and Zyprexa), despite the fact that their dangerous side effects range from life-threatening diabetes to brain tumours.[15]

- In 2007, UK's National Health Service spent £3.5million on antipsychotics prescribed to children representing 86,000 prescriptions.[16]

- Furthermore, the prescribing of powerful psychotropics to children for unapproved conditions adds to the risks children are being subjected to. The prescribing of off-label and unauthorized drugs to children is widespread in Europe, accounting for 45-60 per cent of total prescriptions in both inpatient and outpatient care (The European Medicines Agency).[17]

- After almost 11 weeks of treatment, researchers have found that the weight of those being treated with antipsychotics increased by an average of 13.4lbs, compared to just 0.4lbs for those who were not taking antipsychotic medication. The most significant weight gain was seen with olanzapine (Zyprexa), with the 45 children who took the drug gaining an average 18.7lbs.[18]

- Since 2000, government policy has advocated schools promoting "mental health" while "school-based intervention" and mental health screening for those aged 4-11[19] is a likely contributing factor to the epidemic of child drugging the UK is experiencing.

Citizens Commission on Human Rights (CCHR) UK contends that psychotropic drugs are not only far too dangerous to use on children (as can be seen from the following evidence), but that the conditions for which they are prescribed are either poorly or wrongly diagnosed and could be caused by easily explained medical or educational causes. The drugs are a detriment to the children being treated, even to the point of death.

The condition known as Attention Deficit Hyperactivity Disorder (ADHD) has always been contentious. Unlike medical conditions where there is an objective test to determine the presence of hostile bacteria or virus, an x-ray to determine a broken arm or a blood test that will determine the absence or presence of a toxin or nutrient, there has never been an objective test to establish the existence of ADHD.

For many years, ADHD (or hyperactivity and associated symptoms) has been theorised as being caused by a chemical imbalance of the brain and consequently has justified prescribing drugs that were supposed to

adjust the so-called imbalance. However, as there has never been any test to identify the existence of a chemical imbalance of the brain that purportedly causes the condition, psychiatrists moved from the 'chemical imbalance' theory (to some extent) to now calling it a 'complex condition' which can only be diagnosed by observation. This is a completely arbitrary and non-scientific way to diagnose an illness.

James Davies, Senior Lecturer in Social Anthropology and Psychotherapy at the University of Roehampton in London said that "despite nearly 50 years of investigation into the theory that chemical imbalances are the cause of psychiatric problems, studies in respected journals have concluded that there is not one piece of convincing evidence the theory is actually correct."[20]

There is ample evidence to show that the symptoms collectively called 'ADHD' could be caused by any number of external stimuli, *including, but not limited to* poor diet, lead poisoning and other toxic ingestion into the body. Educational problems and lack of discipline have also been sourced to hyperactive behavior. Yet neither the psychiatric profession nor pharmaceutical companies manufacturing the drugs to treat the condition have thoroughly investigated these. Instead, the main treatment pursued and insisted upon is mind-altering drugs that do little for the patient beyond repressing the symptoms and 'dumbing' him or her down.

Far worse, the drugs subject patients to a wide range of unwelcome and debilitating side effects ranging from vomiting to psychosis, heart attacks and suicide. Some of the drugs prescribed to children and adults for so-called ADHD are pharmacologically similar in chemical structure to cocaine. In essence, an "illness" that cannot be objectively tested for is being physically treated with addictive, mind-altering drugs with adverse, even deadly effects.

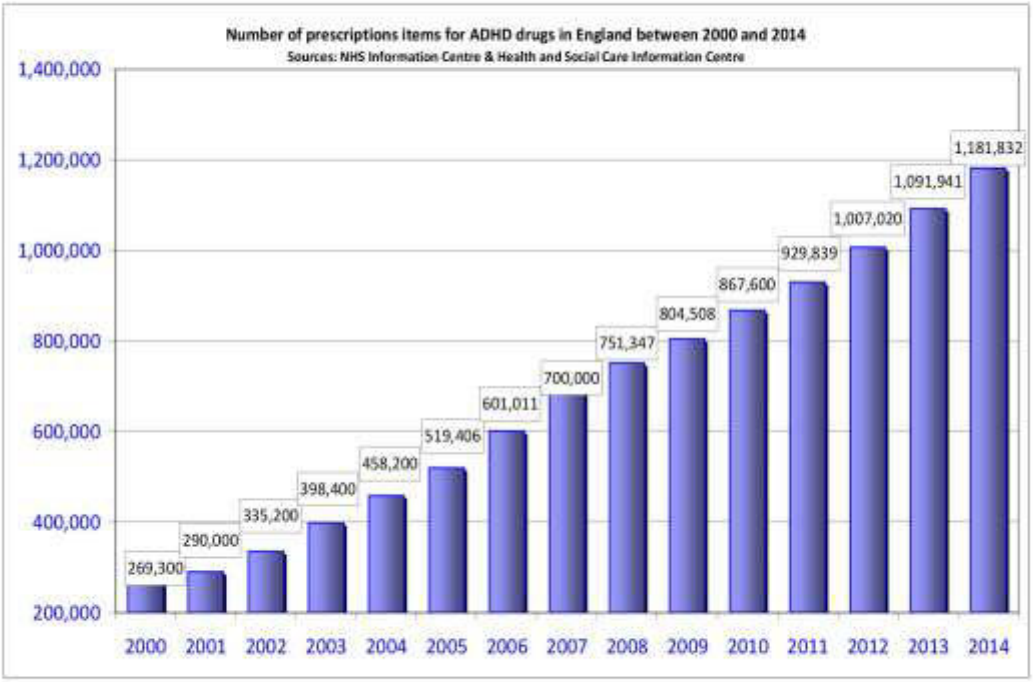
The numbers of children being diagnosed and subsequently drugged in the UK are rising at an alarming rate whilst psychiatrists, drug companies and the government acting on this advice assert (without evidence) that the condition is being under-diagnosed.

Children diagnosed with ADHD or conduct disorder are also often prescribed atypical antipsychotics.[21] As a study published in 2011 reported, "There is a lack of information about the efficacy and safety of antipsychotics in young people."[22]

Additionally, UK children diagnosed with depression are prescribed the antidepressant fluoxetine. This and similar SSRI antidepressants have been linked to many suicides and acts of senseless violence such as mass shootings (in the United States and other countries.) Drug regulatory agencies warn against their use in anyone under the age of 24.

The potential harm to future generations of children grows each year with an almost 500% increase in the amount of drugs prescribed for ADHD over the last fourteen years. The potential for these children to form a pool of legalised future drug addicts needs immediate attention by UK authorities.

2. Increased use of ADHD drugs



UK statistics on the number of children currently taking ADHD (psychostimulant) drugs are not officially recorded. In April 2013, CCHR UK requested the National Health Service Information Centre provide statistics on the number of children who had been prescribed ADHD drugs and was informed that this was not available (and remains so today).

In an answer to a UK Parliamentary Question on this matter in October 2000, the Government reported that the UK National Institute for Health and Clinical Excellence (NICE) estimated the prevalence of ADHD at around 5 per cent of school-aged children, or approximately 345,000 6- to 16-year-olds in England[1]. Yet estimates in the media are that 400,000 children now take the psychostimulant Ritalin. [23]

The fact that there are no figures for the actual number of children receiving ADHD prescriptions shows a lack of transparency. This contravenes recent recommendations by the UNCRC, in particular:

- **Establish a system of expert monitoring of the excessive use of psycho stimulants to children, and take action to understand the root causes and improve the accuracy of diagnoses while improving access to behavioural and psychological interventions.**

The cost and number of prescriptions for all ADHD drugs *are* reported. These show an epidemic 438% increase in the number of prescriptions for psychostimulants over a 15-year period—from almost 270,000 in 2000 to over 1.1 million in 2014.

This alone is alarming, especially when psychiatrists still admit they do not know the cause of “ADHD” which is not a definable disease and is diagnosed without any sound diagnostic criteria (see section Diagnosis or Misdiagnosis below) and is apparently ‘spreading’ at such an alarming rate that it would surely mean that it had reached epidemic proportions were it a viral disease.

With the 2013 publication of the *Diagnostic and Statistical Manual for Mental Disorders* (DSM5) broadening the subjective criteria of ADHD, the number of children in the UK at risk of being further labeled with ADHD and drugged add to the alarm.

Experts say that ADHD symptoms represent common childhood behaviour and that nutritional and environmental factors impacting on young bodies are being ignored and, instead, being lazily diagnosed as ADHD.

The UK government defers to NICE guidelines (see later section on NICE), which, like the DSM, lack thoroughness and are tainted by conflicts of interest.

The following is a list of some of the side-effects of psychostimulants which are used for ADHD.

- abdominal pain
- aggression
- angina (sudden chest pain)
- anorexia (eating disorder)
- blood pressure and pulse changes
- blurred vision
- depression
- dizziness
- drowsiness
- dry mouth
- fever
- hallucinations
- headaches
- heart palpitations
- hypersensitivity
- increased irritability
- insomnia
- involuntary tics and
- twitching called
- Tourette’s syndrome
- liver problems
- loss of appetite
- mental/mood changes
- moodiness
- nausea
- nervousness
- psychosis
- restlessness
- seizures
- stomach pain
- stunted growth
- suicidal thoughts
- tachycardia (heart irregularity)
- toxic psychosis
- unusual weakness or tiredness
- violent behavior
- vomiting
- weight loss and “zombie” appearance.
- suicide

To illustrate this further, as officially stated in the drug manufacturer’s own documentation, there are more than 100 adverse effects of Ritalin, a drug that has been widely used for ADHD, and these are listed in Annexe I. Other methylphenidate drugs used for ADHD like Ritalin have similar side-effects. These are extremely dangerous drugs to be prescribing to a condition – especially to a condition that cannot be medically confirmed.

3. The UK Government's Stance on ADHD

The government stance on ADHD is to officially adopt the guidelines laid out by the National Institute for Clinical Excellence (NICE), the agency established by the government to provide advice on medical matters. There are a number of concerns and inconsistencies regarding NICE's position on ADHD. Furthermore, even NICE's recommendations, which we find lacking, are not even consistently applied.

National Institute for Clinical Excellence

In 2008, NICE issued guidelines on ADHD[24]. NICE had commissioned a Guideline Development Committee (GDC) to write the guidelines and almost two thirds of the CDG[25] had open affiliations with and/or had received funds personally (e.g. consultancies/attending conferences) or professionally (e.g. grants for projects) for activities carried out on behalf of pharmaceutical companies (including those manufacturing methylphenidate and other 'ADHD drugs').

Declarations of interest were correctly declared in the advice[26] - but none-the-less, a strong bias towards a 'drug solution' for treatment of ADHD can be implied from these declarations of interest.

In 2011 NICE reviewed the 2008 guidelines and concluded that there was no need for any change or further review of them. As a consequence no further investigation into the causes of, or other treatments for ADHD symptoms was recommended and the drugging of children with chemicals such as Ritalin was considered to be a suitable treatment[27].

This is quite astonishing, especially in the light of the following facts:

- NICE acknowledged there are no tests to prove the existence of ADHD: *"There is no single definitive psychological or biological test for ADHD. Diagnosis is the outcome of several strands of investigation…."*

- Its description of the diagnostic method necessary to identify ADHD is both complex and vague in direction – hardly inspiring confidence that they have it right. They state: *"The complexity of assessment requires cooperation among a number of professionals employed by different agencies and using a wide variety of techniques – in other words, a multi-modal, multi-professional and multi-agency approach."*[28]

- Conflicts of interest were rife: three of the experts that NICE relied upon by NICE, (a world-renowned Harvard child psychiatrist, Dr. Biederman, Dr. Wilens and Dr. Spencer), had been under U.S. Senate investigation for their failure to disclose financial payments from pharmaceutical companies. *The New York Times* reported that Biederman's work in particular helped fuel an explosion in the use of antipsychotics in children, earned millions of dollars in consulting fees from drug makers[29].

However, NICE guidelines do state that:

- *Drug treatment is not indicated as the first-line treatment for all school-age children and young people with ADHD. It should be reserved for those with severe symptoms and impairment or for those with moderate levels of impairment who have refused non-drug interventions, or whose symptoms have not responded sufficiently to parent-training/education programmes or group psychological treatment.*

However, there are no recommendations for doctors to first check a range of potential causes of the symptoms of ADHD and see if these can be addressed in themselves. The NICE guidelines begrudgingly

acknowledge that diet and nutrition can play a part in ADHD, yet there are no recommendations that this be followed up with by doctor.

With vague and unscientific guidelines and the lack of effective recommendations, doctors tend to fall back on an automatic prescription of drugs to address the issues as all they have directing them towards ADHD.

This further reinforces the huge difficulties with diagnosing ADHD which leads to such a mass labeling of children's behavior as a "disorder." For example:

- Orthodox medical and drug establishments have no real explanation for what they call ADHD;

- The *Diagnostic and Statistical Manual of Psychiatric Disorders* states specifically that no laboratory tests have been established as diagnostic in the clinical assessment of ADHD and that there are no specific physical features associated with ADHD.

- The cost of drug treatment is up to at least 50 million pounds a year to the taxpayer (just for drugs alone) and will be at least double this when the costs of 'diagnosis' and 'treatment' are taken into account;

- Children are subjected to mind altering drugs (that also have potentially very harmful physical side effects) based on a subjective and false diagnosis when all they may need is a healthy diet, address nutritional deficiencies, or require additional educational assistance and/or better discipline for their behavior.

- Hypoglycemia, hyperglycemia, anemia, food allergies, increased intake of preservatives and food dyes, vitamin and mineral deficiencies and poor diet in general have similar symptoms to ADHD[30] and have been correlated to ADHD incidence rate in numerous studies. [31] These conditions may not be addressed in a standard physical examination and may require blood work, elimination trials and numerous visits in order to ascertain their existence. [32]

Yet there is no recommendation whatsoever to carry out further trials into this area within the NICE guidelines. There is clearly more than enough evidence available in the scientific community, as can be seen from the selection of studies in Annexe II, to minimally propose that extensive trials be done into the areas of poor nutrition, toxic chemicals in our foods and in the environment. Yet these causes were at best given a mention in the 2008 report from NICE and the 2011 review quoted below:

> *"The influence of dietary factors in ADHD has attracted much public attention: food additives, sugar, colourings and 'E' numbers are often regarded as causes of ADHD, and elimination and supplementation diets are widely used, often without professional advice.*
> *"Nevertheless, epidemiological research indicates a link between additives and preservatives in the diet and levels of hyperactivity (McCann et al., 2007); and at least a small proportion of children with ADHD demonstrate idiosyncratic reactions to some natural foods and/or artificial additives, and may be helped by a carefully applied exclusion diet (see Chapter 9).*
> *"Richardson (2004) reviewed the evidence on associations between ADHD and longchain polyunsaturated fatty acids (PUFA) and commented on the brain's need throughout life for adequate supplies, a relative lack of omega-3 PUFA, and a possibility that males may be more vulnerable because testosterone may impair PUFA synthesis. Scientific uncertainties remain, however, concerning the physiological significance of different measures of PUFA metabolism and they are not used in practice."*[33]

Even the writers of the report were forced to admit this much, so it is hard to understand why a complete lack of follow through exists when we could be radically altering the lives of hundreds of thousands of children by taking them off drugs and treating the actual causes of their problems.

In fact, a later summary in the report dismisses further research with an improper and incomplete analysis of available data. The NICE report even goes so far as to advise against such supplements of fatty acid despite the evidence to the contrary:

> *"Recommendations*
> *… "Dietary fatty acid supplementation is not recommended for the treatment of ADHD in children and young people."*[34]

Dangers of Stimulants

ADHD drugs are linked to serious side effects, including liver toxicity, weight loss, sleep problems, mood swings, and even thoughts of suicide. They can also interfere with growth, according to researchers in a *British Medical Journal* published study in 2013. "Despite extensive research into factors contributing to ADHD etiology, we are no closer to understanding the cause or causes of this disorder," the authors stated. [35]

In 2004, Shire Pharmaceuticals, the psychostimulant Adderall distributor, voluntarily reported 20 deaths by heart attack and 12 strokes: Fourteen of those deaths and two of those 12 strokes were in children. Most of those deaths occurred in individuals who were taking Adderall in a prescribed manner.[36]

In conclusion, NICE did not do a robust examination of the causes of ADHD behavioural symptoms nor, it would appear into the factors, dangers and consequences of the ever-increasing drugging of generations of children. Rather they have slanted any recommendations in the direction of continued drug use.

We find this neglect of help and assistance to millions of young children unacceptable and dangerous.

4. Use of fluoxetine for childhood depression

The number of UK children prescribed antidepressants such as fluoxetine, generic of Prozac, is also of concern. The Medicines and Healthcare Products Regulatory Agency (MHRA) approved the use of fluoxetine for children in December 2003. It still endorses its pediatric use despite the potential risk of suicide in those under 24 years of age taking it.

It is contended that MHRA's decision was marred by a conflict of interest with its manufacturer, Eli Lilly. While MHRA may claim to be independent, it has funding from pharmaceutical companies. In a list of frequently asked questions about MHRA funding, it stated that the costs of medicines regulations are met by fees from the pharmaceutical industry[37].

Richard Brook, Chief Executive of the mental health charity MIND, resigned from an Expert Working Group on SSRI antidepressants because of his concerns about MHRA's conflicts in that it had approached Eli Lilly to make an application for a license for fluoxetine use in children, as reported in *The Guardian* on 14 June 2004. Mr. Brook stated: *"This raises real issues about their impartiality. They are saying they want an SSRI to be given to children. It is not their job to decide such a thing."*

MHRA has maintained its view to allow fluoxetine to be prescribed despite the following:

- 25 April 2005: The European Medicines Agency (EMEA) issued warnings on all antidepressants, including fluoxetine, stating that these should not be given to children and adolescents.

- On 29 April 2005, the MPA (Swedish Medical Products Agency) which supported the UK's view for the approval of fluoxetine in Europe, submitted comments to an evaluation done by France, which opposed that approval. The MPA supported the MHRA's view of fluoxetine being accepted for use in children provided that commitments were made for further studies as well as the appropriate wording of the SPC (Summary of Product Characteristics) [38].

- 31 October 2005: The Dutch Medicines Evaluation Board (CBG) recommended the drug not be approved[39].

- 6 February 2006: France, Ireland and Denmark supported Holland's recommendations to disapprove fluoxetine.

However, the potential conflicts of interest continued when in April 2006, EMEA representatives conducted hearings in London with Eli Lilly. Thereafter, on 6 June 2006, the EMEA granted approval of fluoxetine for pediatric use. There were conditions attached to the approval, which the manufacturer agreed to carry out. They included the following:

1. Investigate the effect of fluoxetine on sexual maturation in children 8-12 years. This was to be an American study ("TADS Jr") under the U.S. National Institute of Mental Health (NIMH). (See Annexe VI. Page 24.)

2. Examine if different registers in Europe could be used to obtain data on how Prozac affects the sexual maturation of children, and

3. In Prozac studies with rats, Eli Lilly investigate the following:

- "neurohormonal [hormone produced by nerve cells and secreted into the circulation] investigation of sexual maturation"
- "characterization of testicular pathogenesis [development]"
- "characterization of effects on specified emotional behavior.

These conditions were not carried out and this fact was accepted by MHRA, arguably putting children at risk.

1.In Sept 2009 (three years after the approval), the MHRA published a summary of what occurred in respect to the TADS Jr study. It stated: *"Now the TADS Jr study will not be conducted because of lack of funding by the NIMH, and consequently the exploration of possible effects of fluoxetine [Prozac] treatment on sexual maturation as part of this study will not be feasible."* (See Annexe VII, page 3, 5th paragraph)

The MHRA further stated that Lilly "*therefore requests* [as this study was not conducted] *that the post-authorisation commitment* [the requirements needed to be fulfilled] *to clinically evaluate the effect of fluoxetine on sexual maturation to be considered fulfilled."* (See Annexe VII, page 3, 5th paragraph)

And that the UK "agrees that any clinical study to investigate the effects of fluoxetine on sexual maturation would be forbiddingly hard to conduct and difficult to interpret" and therefore accepts that the follow up measure required of Lilly to clinically evaluate the effect of fluoxetine on sexual maturation be considered fulfilled." (See attachment 7, page 8)

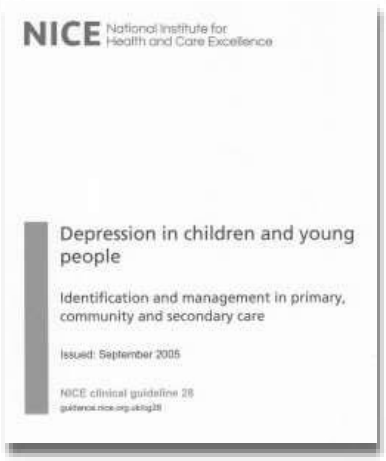
2. Regarding Lilly examining registers in Europe on how Prozac affects sexual maturation, Lilly said there were no suitable records available. Consequently, there was no further examination of the situation.

3.MHRA confirmed that while the manufacturer "has conducted the required pre-clinical studies, confirming a delay in sexual maturation in rodents," it had apparently failed to find "a causal mechanism for this effect." (See Annexe VII, page 3, 3rd paragraph). No further studies were conducted to determine causality.

So, in summary, none of these vital points that were conditional for the approval were carried out.

In August 2015, CCHR wrote to Medicines and Healthcare Products Regulatory Agency to request that an Expert Working Group or the equivalent be convened to re consider the risks and benefits of fluoxetine for the treatment of childhood depression. The fact that there are at least seven deaths connected to the use of fluoxetine in children (see section under anti-depressants below) must surely provide the impetus to bring about a review.

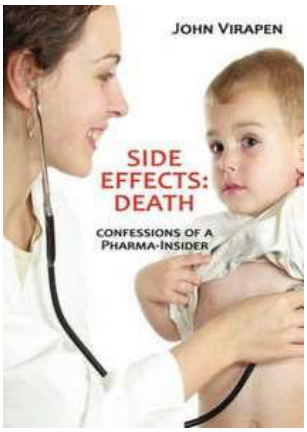
This year marks the 10th anniversary of the publication of NICE's Clinical Guideline 28 (CG28), entitled "**Depression in Children and Young People**."



The Guideline provided an explanation about why NICE considered all brands of TCA and SSRI antidepressants are unsafe for use in children, with the notable exception of fluoxetine. It stated:

"*In December 2003, following a review by an Expert Working Group of the Committee on Safety of Medicines (CSM, 2003), the CSM advised that citalopram, escitalopram, fluvoxamine, paroxetine, sertraline, and venlafaxine should not be used as new therapy for the treatment of depression in under 18-year-olds (Duff, 2003c). Despite the lack of a marketing authorisation for*

fluoxetine in the treatment of major depressive disorder at that time, the CSM advised that the balance of risks and benefits for this drug was favourable."



The assertion that fluoxetine is safer than other SSRI drugs was suspect, later confirmed by reliable sources such as former Eli Lilly executive John Virapen who, in his book *Side Effects: Death: (Confessions of a Pharmainsider*[40]*,* stated: "Fluoxetine was not used on children in the clinical studies that were carried out prior to approval."

NICE ignored tests conducted in the USA in 2004 on behalf of the FDA which showed that there was no noticeable difference between fluoxetine and the other SSRIs available which were banned for children.

Causing Suicide and Violence

Dr. David Healy, M.D., a former secretary of the British Association for Psychopharmacology and author of 20 books, including *The Antidepressant Era* and *The Creation of Psychopharmacology*, estimates that 90 percent of school shooters were users of antidepressants."[41] These include those taking fluoxetine. As far back as 2006, he warned: "We've got good evidence that the drugs can make people violent and you'd have to reason from that that there may be more episodes of violence."[42]

A study published in *Social Psychiatry and Psychiatric Epidemiology in June 2014 that found* psychotropic drugs could make people nearly six times more likely to kill themselves, while having spent time in the previous year in a psychiatric hospital makes them over 44 times more likely to kill themselves. [43]

In a *British Medical Journal* published study, antidepressants were estimated to cause 10 to 44 deaths out of 1000 people over a year, depending on the type of antidepressant. In comparison, the painkiller Vioxx was taken off the market in the face of evidence that it caused 7 cardiac events out of 1000 people over a year. Paul W. Andrews, assistant professor in the Department of Psychology, Neuroscience & Behavior at McMaster University in Canada, says: "Since cardiac events are not necessarily fatal, the number of deaths estimated to be caused by antidepressants is arguably of much greater concern."[44]

Additional Concerns about MHRA Conflicts of Interest

There is also a need for a closer look at the conflicts of interest in MHRA. The present CEO of the MHRA, Ian Hudson, achieved notoriety when, while working for the pharmaceutical company GlaxoSmithKline (GSK), he attempted unsuccessfully to absolve from blame the company's antidepressant Paxil (Seroxat) in a lawsuit brought on behalf of the family of Donald Schell in the U.S. Forty eight hours after having been prescribed Paxil, Donald Schell shot dead his wife, his daughter and his granddaughter before shooting himself through the head.

Antidepressants

During the 10 years since CG28, an unknown number of children in England and Wales have taken their lives after having been prescribed antidepressants and fluoxetine. The following are cases that have been research (though not recorded as having a connection or being caused by drugs under any adverse effects reporting system).

September 2010 - 10-year-old **Harry Hucknell** from Cumbria hanged himself in his bedroom. He had been diagnosed as having ADHD and was subsequently prescribed Ritalin and Prozac.

The following is a summary of a number of inquests in which it was reported that children were prescribed antidepressants before taking their own lives. This is not by any means an exhaustive list.

March 2014 - The youngest of these was 14-year-old **Tom Boomer** from Banbury. Tom was prescribed fluoxetine 11 days before he jumped from a multi-storey car park. The prescribing doctor (who actually increased the dosage after a week or so) claimed bizarrely that the risk of suicide after taking antidepressants was limited to "*the first two or three days of use*."

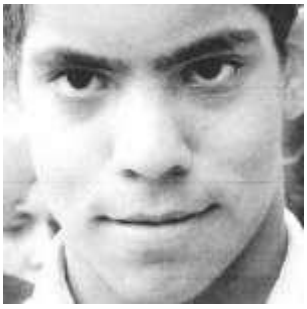
November 2013 - **Jasmine Clarkson** from Gloucestershire was also 14 when she hanged herself from a tree in a local park. On her body she had written: "*The voices made me do it*." Four months earlier, she had taken an overdose of her medication. She was being treated by her GP, but declined an offer of counselling.

June 2013 - 15-year-old **George Werb** was re-prescribed Fluoxetine at a branch of the Priory, even though he had previously had an adverse reaction to the drug. He stepped in front of a train on the line that ran near his home in Devon. The prescribing doctor told the inquest that there was "

October 2012 - **Tallulah Wilson** was struck by a train at St Pancras Station, London. The sensitive 15-year-old schoolgirl and talented ballet dancer had been prescribed antidepressants while she was grieving for her grandmother. Two weeks before her death, she had taken an overdose of her medication. The doctor who treated Tallulah said that he "*did not consider her to be a person at risk of suicide, but rather a person at risk of self-harm*."

December 2013 - **Patrick Roberts** was also 15 when, after texting his friends, he hanged himself in a park near his Hertfordshire home, about a month after being prescribed fluoxetine. He was described by his father as "*a kind, gentle, fun-loving, very intelligent boy who was growing up to be a handsome, lovable young man with a keen sense of fun*."

May 2013 - **Pauline Swatridge** was 15 years old, multilingual, and had been assessed at her school in Bangor as bright, with a particular talent for art and music. Her inquest heard that "*she had taken a variety of drugs prescribed to her by doctors for a mental illness*" before jumping from the Menai Bridge.



January 2012 - **Alex Kelly** was serving a 10 month sentence at Cookham Wood YOI for burglary and theft from a vehicle. The 15-year-old hanged himself in his cell after being "*identified as being at risk of self harm*." After his death, a Serious Case Review revealed that he had "*stopped taking his medication in the days prior to his death*."

October 2013 - **Martha Bradbury** was struck by a train at a London suburban station just a week after her 16th birthday. She had started self-harming, and was prescribed antidepressants. The following month, she took an overdose of her medication and was admitted to a residential centre. She had refused the offer of anti-psychotics, and was later discharged. A school-friend told the inquest that, before her death, Martha heard "*bad*" voices in her head and "*really struggled*" with the idea of it continuing for the rest of her life.

May 2014 - **Gail McKinney**, a 16-year-old schoolgirl who lived not far from Cambridge, had been taking fluoxetine for 2 years, as prescribed by her GP. During the month before her death, Gail said that she heard voices in her

head and that she felt "*depressed the whole time*." Shortly before her death, Gail asked her doctor if she could change her Fluoxetine, as she felt it was making her worse. The medication was changed, and Gail took an overdose of the unnamed antidepressants.

March 2011 - **Dana Baker** was 14 when she represented England at karate. However, it emerged later that she was being abused by her instructor. She was taken into care by Worcestershire Social Services and was prescribed antidepressants. At the age of 16, Dana hanged herself. At her inquest, the coroner decided that the authorities had breached her human rights by failing to provide her with proper care.

June 2014 - **Lauren Johnson** was a 17-year-old A-level student, described as "*very intelligent and clearly articulate*," who wanted to be a clinical psychologist. However, she had been diagnosed at various times with "*social anxiety*" and "*a personality disorder*." She was prescribed medication for her "*low mood*." On her way to an interview for work experience, she walked to the top of a multi-storey car park in Accrington, and jumped off.

April 2013 - 17-year-old **Michaela Christoforou** () hanged herself in a specialist treatment centre for eating disorders in North London. Her inquest was told that Michaela had a history of anorexia and severe depression and was known to be at a high risk of suicide. She had previously been treated by community care at home, where she took "*an impulsive overdose*" of her (unidentified) medication, and said that she worried about her suicidal thoughts and wanted help. A Serious Case Review later revealed that she had been prescribed with **fluoxetine** at the centre, and that the dosage was increased shortly before her death.

There were many other inquests which were similar in nature to those that we featured above. In each of the following, however, there is no specific report in the press of antidepressants being prescribed, although it seems probable that psychiatric medication may well have had some involvement. What all these deaths have in common, however, is that in each case the victim was, or had been, receiving treatment from medical professionals at or before the time of their death.

April 2011 - The youngest of these was **Brendon Flynn**, a 13-year-old schoolboy from Liverpool, who hanged himself at home. Brendon's father said that "*the family had concerns about his behaviour from an early age and he thought his son had depression*." Brendon was referred to the local Child and Adolescent Mental Health Service (CAMHS).

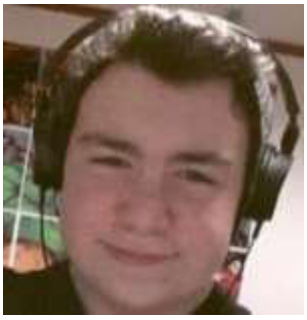
May 2014 - 14-year-old **Severine Hobbs** from Cambridgeshire had also been referred to the local CAMHS after being upset by bullying at school. 3 months before she took an overdose of Amitriptyline prescribed to her mother, the CAMHS had reported that Severine was a "*moderate risk*" to herself, and no further contact was made.

December 2013 - The mother of 14-year-old schoolboy **Derek Brundrett**, who had a "history of self-harming" and who then hanged himself, is taking Pembrokeshire County Council to court over the lack of support he was given. She said that "*Derek had previously attempted suicide, had a history of self-harming which had been overlooked and attempts to get him help failed because he 'did not meet the criteria'*."

November 2012 - 14-year-old schoolboy **Liam Hardy** was taken to a Surrey hospital twice within a short period after attempting suicide. On both occasions, he was discharged within hours, against his mother's wishes. A few days later, he was found hanged in his bedroom. His inquest heard that social services were aware of Liam, who, as well as being epileptic, had displayed complex emotional and behavioural problems throughout his childhood. It was said that he would regularly self-harm and threaten to take his own life. At the time of his death, Liam and his girlfriend were expecting a baby.

July 2013 - **Megan Edmunds** from Birmingham was another 14-year-old to be found hanged in her bedroom. She had previously been sent to a pupil referral unit after being expelled from her school, and was also known to the local family planning services. Relatives told the inquest that "*there was no reason for the bubbly outgoing teenager to have taken her own life*."

September 2014 - At the inquest of 15-year-old schoolgirl **Ashli Blake**, her GP stated that "*she had suffered from low moods and sleeping problems*." She added that Ashli had previously been referred to the Hampshire CAMHS but had been discharged. After a row with her boyfriend, Ashli took her life by jumping from a tower in the Hampshire countryside near to her home.



March 2014 - 15-year-old **Bradley Adams** from Manchester was a talented musician. He had experienced bullying and teasing at school, but had moved to another school where he was "*a lot happier*," and where the head teacher described him as an "*excellent student*" and added: "*He was very popular with other children and staff*." Bradley was found hanged in his bedroom, along with a moving suicide note in which he asked his family to give his possessions to those less fortunate than him. The inquest heard that Bradley had been suffering from depression and was receiving "*specialist mental health treatment and support*." He was described by his mother as "*the light of everyone's life*" who had been "*receiving the correct support and help*."

June 2013 - **Charleigh Disbrey**, a 15-year-old schoolgirl from Hertfordshire went on to nearby railway tracks with her 18-year-old boyfriend, where they were both struck by a train. At the inquest, statements from mental health workers said that Charleigh "*had been suffering from anxiety and depression for a number of months before the incident*," but none of them had deemed her to be in any immediate danger.

January 2013 - 15-year-old **Joshua Maddox** hanged himself at his home in Walsall. He had been diagnosed as being autistic, and also suffered from ADHD. A psychiatrist told the inquest that: "*Joshua had changed the medication he was taking for his ADHD in the weeks leading up to his death*."

March 2013 - Gifted 15-year-old **Stephanie Moreno** became the third pupil in 2 years from her school in Bristol to die by hanging. Her inquest heard that her mood began to deteriorate and that she began to self-harm after her friend Chris hanged himself. The school arranged for her to have an appointment with the CAMHS, but Stephanie was apparently reluctant to have further appointments.

November 2013 - **William Parlby Neale**, described as "*flamboyant and talented*," won a music scholarship to an exclusive boarding school. However, two terms later, he returned to his local Lincolnshire school after being physically and verbally bullied. Months after his return, at the age of 15, William hanged himself at home. His GP said at the inquest that he had been self-harming, had expressed suicidal thoughts, and he may have been suffering from OCD.

July 2009 - The Suffolk coroner was very critical of the standard of care given to 16-year-old **Becky Watkins** at the children's home where she hanged herself. The inquest was told that Becky, who was born with a hole in her heart and had cerebral palsy, suffered with depression, bulimia and suicidal thoughts. A psychiatrist who had treated her told the inquest that Becky could be "*delightful and caring*" and was a "*phenomenal singer with a beautiful smile*."

August 2012 - The inquest of 16-year-old Greater Manchester student **Cameron Brookes** heard that he had Asperger's, which caused him difficulty in communicating and interacting with others. He battled depression and was crippled by a feeling that he didn't belong, but he was "*receiving treatment from family intervention workers and NHS professionals*." Cameron was found hanged in his bedroom.

January 2014 - **Mary Stroman**, 16, went to the same school as Tallulah Wilson (*see above*) and was a close friend. While Tallulah's inquest was taking place, Mary had been admitted to a branch of the Priory in Wiltshire, where she was being treated for PTSD. Mary walked out of the unit to a nearby railway line, where, like Tallulah, she was struck by a train.

October 2013 - An inquest for 16-year-old Cheshire schoolboy **Tom Acton** heard that bullies at Tom's school had forced him to take drugs, and had falsely branded him as a rapist. Days before he was due to testify at the trial of one of the bullies, Tom was found hanged in his bedroom by his father. Tom's GP testified that: "*He was struggling to concentrate and his mood was low; he described it as being dead inside*," while a friend stated that during the last month of his life Tom began to self-harm.

June 2014 - **Pasha Clark** (16) from Cambridgeshire was described as a talented art student. Her inquest heard that she had suffered with mental health issues since she was around 13, and that she had self-harmed, taken overdoses and expressed suicidal thoughts. She "*had received support from Mental Health services*." Pasha took an overdose of Propranolol.

January 2014 - "*Hard-working and talented*" 16-year-old schoolboy **Mohammed Razzak** started to become more withdrawn and anxious as exams approached, and began to self-harm. After he missed a trial exam, child protection services and his school intervened and he spent a weekend in hospital where he was assessed by psychiatrists. After a few weeks, Mohammed told his GP that he had planned suicide six times in the past. Days later, he jumped from a bridge over the motorway near his Oldham home.

November 2013 - 16-year-old **Daisy Holmes** hanged herself in her flat in Hull. She was brought up by adoptive parent, and at the time of her death was an Army cadet, who wanted to be a medic in the armed forces. Her inquest heard that she had a history of self-harming and had tried to kill herself the previous year. A health visitor reported that Daisy also expressed suicidal thoughts from time to time.

February 2013 - **Alex Philbey**, 16, hanged himself in woods near his home in Cornwall. The inquest was told that his GP had referred him a few months earlier for sessions with the local CAMHS.

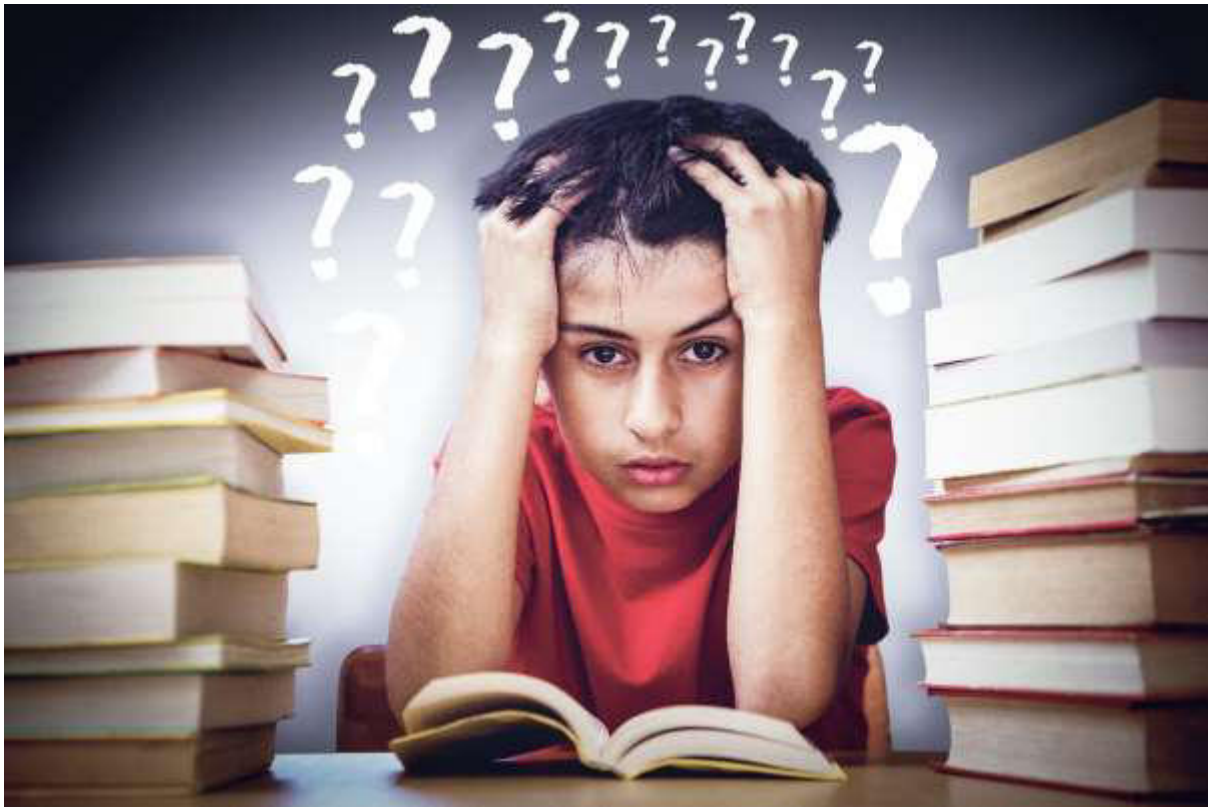
January 2014 - **Sasha Steadman**, a promising 16-year-old South London art student, died of a heroin overdose. At the time of her death, she was being supported by the local CAMHS. She was referred to the service by her GP, whom she visited after experiencing low moods and self-harming. A psychiatrist told her inquest that she used heroin "*to relieve stress and improve her mood*."

December 2013 - 17-year-old care assistant **Leigha Edwards** was found hanged in her bedroom wardrobe at her home in Luton. At her inquest, the coroner said that Leigha had no history of mental illness, but had been encouraged to visit the doctor by her boyfriend where she complained of feeling anxious and depressed.

January 2012 - When **Jake Hardy** arrived at Hindley YOI, it was the first time that the 17-year-old had been in custody. He had previously been diagnosed with ADHD and had recently self-harmed. Jake reported repeatedly that he was being bullied by other inmates. At a hearing 2 weeks before his death, it was recommended that Jake that should be transferred to a specialist unit elsewhere, but he was returned to Hindley. Jake damaged property in his cell and self-harmed; as a result, he began to be monitored. Initially he was put on 5 observations an hour but this was then reduced to 2 per hour. A few days later, Jake again damaged property in his cell and he was not allowed to make a call to his mother. Later that evening, a prison officer found Jake hanged.

All the children mentioned in the last section above had been receiving treatment from their GP and/or from other local medical services. It is important, however, to re-emphasise that whilst these children were not necessarily treated with fluoxetine, or any other form of psychiatric medication, we do not know to what extent as this information is not available publicly. However, this is by no means an exhaustive list and the sheer volume of cases requires further investigation into causes.

5. Diagnosis or Misdiagnosis



Diagnosis

Two of the fundamental questions to ask about ADHD are “what is it?” and “how is it diagnosed?”

ADHD stands for Attention Deficit Hyperactivity Disorder. Its definition has changed from the 1950s to present day. It attempts to collect a number of symptoms together ‘under one roof’ and label it as a specific disease known as ADHD. The main phenomena of the so-called disorder are inward daydreaming, lack of focus, impulsivity, inattention and hyperactivity. The actual classification of ADHD came into effect in 1987 when the American Psychiatric Association (APA) officially voted it into existence as a disease[45]. There were no actual tests that could determine its existence – it was all down to the opinion of the APA Committee who arbitrarily classified various observable phenomena together under the same umbrella and declared this to be ADHD.

To this day, there is no physical test that can identify ADHD, and whilst there is no doubt some or all of the above manifestations can be observed in children and adults, the simple fact of lumping together different phenomena does not make it a disease. There is no objective scientific evidence that proves this to be the case[46] [47] [48].

A division of medical opinion exists, including those working directly in the field of mental health:

"There are no specific treatments for ADHD, with the most widely debated treatment (methylphenidate) being known to have similar effects on otherwise normal children. There is no established prognosis, and association and cause frequently are confused in the literature. ADHD has generated huge profits for the pharmaceutical industry against a background of poor-quality research, publication bias and payments to some of the top academics in this field. Thus, the mainstream dogma on ADHD is contaminated and misleading."
Consultant Child and Adolescent Psychiatrist - Dr. Sami Timimi 2002[49]

Psychiatrists surmised that the cause of these phenomena was a chemical imbalance in the brain. The treatment 'logic' therefore, was that another drug could correct this imbalance and then all would be well. Again it must be emphasised that there has never been a test that has proven or even come close to scientific evidence demonstrating that a chemical imbalance is the cause of any of the symptoms mentioned above – not to mention all of them together. It should also be noted there is no way of testing for a chemical balance in the brain.
Ritalin was first introduced on to the market in the 1950s as one of the first medications to treat the 'disease'. At the time the 'diagnosis' only affected a small proportion of children and psychiatry had not yet labelled it as ADHD but "hyperactivity" or other similar descriptives.

Ritalin is classed as a stimulant medication and is a methylphenidate. The chemical construction of Ritalin is very close to that of cocaine – earning it the title of 'kiddie-coke'[50]. There are other methylphenidates on the market today, the other main drug used for ADHD in the UK is called Concerta.

A great failure in scientific reasoning occurred at the point when Ritalin was selected as the cure for hyperactivity and has been perpetuated ever since. To state the case simply: –

1) Physical manifestations are observed in a child.
2) It is assumed this is a chemical imbalance of the brain.
3) A drug is sold to 'rebalance the imbalance' even though no scientific evidence is available to determine the existence of an imbalance.
4) The drug becomes the 'treatment' for the observed phenomena at the time and then continues to be the treatment for additional phenomena that are voted upon to make it an official psychiatric disease even though there is still no scientific evidence to support or determine the cause of the manifestations observed.
5) More and more children and adults are diagnosed as having this disease.
6) 'Diagnosis' of the condition called ADHD increases in leaps and bounds.
7) Ever increasing amounts of drugs are given to children and adults at massive cost to the taxpayer.

This may seem an over-simplification but the truth does not vary significantly from the above.
The further illogic of the drug treatment is that even though the symptoms have changed throughout time along with the supposed causes – the 'treatment' has remained largely the same – drugs that are supposed to change chemical imbalance. This in itself makes no sound scientific sense.

There have been many vocal critics about the diagnosis of ADHD:

- Dr Bruce Perry, a neuroscientist and a senior fellow of the ChildTrauma Academy in Houston, Texas, said ADHD is not "a real disease."[51]

- Neurologist Dr Richard Saul concurred, when he wrote in TIME magazine stating that ADHD — as currently defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) and as understood in the public imagination — does not exist.[52]

- In 1998, a founding member of the Royal College of General Practitioners, Dr. Edward C. Hamlyn stated, "ADHD is fraud intended to justify starting children on a life of drug addiction."[53]

Unfortunately, both vocal academic and scientific critics have been ignored, blacklisted or ridiculed by what might be called the mainstream medical establishment, whilst research into the actual causes of the

different phenomena labelled ADHD have been difficult to fund. Nevertheless, there is a robust body of evidence pointing to a range of factors that can cause these phenomena as will be covered in the following section.

Probable Causes of the Symptoms labelled as ADHD

We do not go into any great detail in this submission with regards to the probable causes of ADHD and there is clearly a great deal more research that needs to be done into this area. However, it is clear that diet, nutrition, chemical additives, environmental pollution, pesticides, endocrine function and other external stimuli are amongst some of the factors that cause the different phenomena diagnosed as ADHD.

Faulty misdiagnosis by many psychiatrists and finances directed mostly into research focusing on the 'drug solution' have prevented proper scientific analysis and deduction from occurring.

An annexe to this report lists studies supporting many of the likely causes of ADHD symptoms. See Annexe II.

Misdiagnosis

Whilst the existence of ADHD as an actual verifiable disease is unfounded, the confusion and consequent misdiagnosis around the condition is compounded even further as shown in a recent study published in the Journal of Consulting and Clinical Psychology[54]. The study found that 16.7 per cent of diagnoses were wrong – and this alarming figure was even higher if the child was a boy. The report states that cases of ADHD have risen dramatically over the last 10 years along with prescriptions for pharmaceuticals - yet diagnosis is alarmingly unscientific, random and even biased. Psychotherapists and psychiatrists are routinely diagnosing ADHD wrongly. The study found that boys were diagnosed up to 3 times more than girls as having ADHD even though both had exactly the same symptoms.

Clearly, diagnosis is highly subjective which only substantiates further the lack of any real scientific evidence to support the existence of the condition.

6. To Protect the Rights of the Child, Governments Must Fund Research into Real Causes and Alternatives to Mind-Altering Drugs

Misdiagnosis by many psychiatrists and funding directed mostly into research focusing on the 'drug solution' have prevented proper scientific analysis and deduction from occurring.

The following are a number of studies that clearly point to the need for in a completely different direction than a 'drug solution' and why governments must demand or fund research into alternatives to mind-altering drugs to treat childhood behavior and adolescent problems.

Psychostimulants

McGuire Woods, a legal company in the United States representing drug manufacturers reported[55] that:

"A summary of clinical trials of ADHD medications showing adverse psychiatric events put together by the product manufacturers for the FDA at its request showed that in studies lasting under one year:

- In double blind studies of 383 children taking Ritalin LA (the extended release formulation), there are reports of two psychosis/ mania events, two aggression events, and no suicidal events. In open studies involving 125 children on Ritalin LA, one suicidal event was recorded, and no psychosis/mania events or aggression events were reported.

- Of 2,824 children taking Concerta, eight experienced psychosis/mania events; six suicidal events, and fifty-two aggression events (five of which were deemed serious).

- In a double blind study of children taking Metadate CD, three aggression events were reported out of 493 participants. In the open label trials, six aggression events were reported out of 322 participants. All aggression events occurred in boys. One of them was deemed serious.

- MTS (methylphenidate transdermal system – designed to release methylphenidate continuous on application of the patch to skin) use by children suggested that of 471 participants in a double blind trial, four experienced psychosis/mania events, six experienced aggression events, and none experienced *suicidal events.* Of 617 participants in an open trial, there were six psychosis/mania events, one suicidal event, and seven aggression events (two of which were deemed serious).

- In a double blind study of 1,236 children and adults taking Adderall XR, there was one suicidal event, and twenty aggression events. In an open study involving 5,177 adults and children, fourteen had psychosis/mania events (nine children), eight had suicidal events (all children), and 166 had aggression events (150 children). (See Annexe III for further information)

As mentioned earlier we have also attached in Annexe II a significant selection of scientific studies that clearly show that symptoms diagnosed as ADHD can be caused by a range of external factors from nutritional deficiencies to food additives to toxins in the environment. There is clearly a great deal more research needed

to be done in this area, however, existing evidence shows that each child is likely have his or her own allergies, intolerances or reactions to external factors in the environment. There is no evidence to show that a psychostimulant drug has cured anything.

The Rights of the Child

It is the right of every child to be properly diagnosed and treated. This means a thorough examination by qualified medical staff who are aware of the range of environmental factors that could affect a child. Each child is different and should be treated as such, not given drugs at the first instance or for long and extended periods, especially without ever thoroughly investigating the real cause of the symptoms being exhibited.

Drug companies have no interest at all in doing research into this area. It will not lead to profits. However, it will lead to actual cures for many children. It is for this reason government must fund research in this area.

7. Summation and Recommendations

There has been a systemic failure, even neglect, by the psychiatric and drug industries to properly research and find correct causes to the phenomenon labelled as ADHD. Whilst there is no scientific evidence to support the validity of giving addictive mind-altering drugs (that are very similar to cocaine) to a child, these drugs are commonly prescribed to children as "safe and effective".

Alarmingly, ever-increasing numbers of children are subjected to potentially harmful and debilitating drug treatments that can result in the child becoming addicted, violent, aggressive and suicidal, leading to an increased burden to the state through addiction, crime and illiteracy in their teenage years. This adds to the already overwhelming costs to the Government and tax-payer.

Since 2005, the UNCRC has expressed deep concern about children "being misdiagnosed and therefore psycho-stimulant drugs are being over-prescribed, despite growing evidence of the harmful effects of these drugs." The Committee recommended that each country conduct further research into the negative effects of psycho-stimulants and "that other forms of management and treatment be used as much as possible to address these behavioural disorders."[56]

In October 2011, the UNCRC also issued a recommendation that "greater attention" be given to "other kinds of treatment," including "educational and social measures, and strengthen the support to parents and teachers."[57]

The UK has ignored this, still largely relying upon the drug model.

Instead, we see an ever-increasing number of future generations at risk. A responsible society would never sanction giving cocaine-like drugs to children for any reason, yet ADHD drugs (methylphenidates, amphetamines and dexamphetamines) are legally prescribed. They are made 'acceptable' by pharmaceutical marketing campaigns, pretending to treat a fictitious disease.

While the prime responsibility for this scandal lies with the profit driven psychiatric and pharmaceutical industry, the government and government bodies such as the Department of Health and NICE have a responsibility for ensuring parents, teachers and social workers engaged in the care and well being of children have all available information so that informed decisions regarding the well being of children can be assured.

Parents have the right to know there are other non-drug workable solutions that can address underlying causes of ADHD symptoms.

As for antidepressants, there are serious concerns that pediatric and adolescent use of fluoxetine has resulted in a significant number of suicides in children and adolescents in the UK.

The approval process for the drug fluoxetine is flawed or at least is not being enforced by the agencies responsible.

Ultimately, children should be able to experience childhood without it being labeled a mental disorder or dysfunction. As Dr. Jerome Groopman, a professor of medicine at Harvard Medical School and the author of *How Doctors Think* puts it: "There's a tremendous push where if the kid's behavior is thought to be quote-unquote abnormal — if they're not sitting quietly at their desk — that's pathological, instead of just childhood."[58]

Recommendations

1. That the UNCRC advise the NICE to review and revise its ADHD Guidelines to more effectively monitor the use of psychostimulants for children and adolescents and the use of alternative modalities.

2. That the UNCRC advise the UK government to collect and publicly release statistics on the number of children and adolescents prescribed psychostimulants, antidepressants, antipsychotics, anti-anxiety and other psychotropic drugs.

3. Thorough government investigations (by individuals without conflicts of interest with the psychiatric-pharmaceutical industries) must be instigated into the following:
   a) The vested interests and financial motivations behind the neglect of proper research and correct diagnosis of symptoms that are labelled as ADHD as well as other childhood disorders.
   b) The role of NICE in perpetuating the continued drug regime for ADHD, any vested interests in pharmaceutical companies and the exclusion of other alternatives to the 'drug regime.'
   c) The prescription of ADHD drugs as opposed to other methods of treatment.

4. Legislation must be adopted to make it illegal to prescribe drugs to children without incontrovertible proof that the drug addresses a sound scientific diagnosis and treats a medically substantiated physical illness.

5. A thorough medical examination and tests must be conducted on any child manifesting symptoms classed as ADHD (or other childhood 'disorders'). This must be the first line of diagnosis, thereby eliminating any underlying physical and biological causes or any undetected physical or medical illnesses. Medical tests for a range of deficiencies or toxins, allergy tests and analysis for dietary deficiencies should all be carried out on a broad scale by professionals who are responsible for children's health.

6. Parents must be fully informed of all the possible side effects of any psychotropic drug being recommended for their child and that there is no medical or scientific test for ADHD and no known cure, according to psychiatrists.

7. Criminal proceedings should be brought against anyone found responsible for prescribing psychiatric drugs to a children in violation of the parents' informed consent rights, including failure to provide information covered in (6) above and where this has resulted in harm or loss to the child.

8. A full review of the dangers of authorizing the use of the drug fluoxetine for children and adolescents must be carried out and a fluoxetine prohibited for use in children and adolescents.

The Citizens Commission on Human Rights (United Kingdom)

PO Box 188
East Grinstead
West Sussex
RH19 4RB
Email info@cchr.org.uk
Phone 44 (0) 1342 313 926

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The Citizens Commission on Human Rights

The Citizens Commission on Human Rights (CCHR) in the United Kingdom is a branch of the non-profit, non-political, non-religious international mental health watchdog.

It functions solely as a mental health watchdog, working alongside many medical professionals including doctors, scientists, nurses and those few psychiatrists who have taken a stance against the biological/drug model of "disease" that is continually promoted by the psychiatric/ pharmaceutical industry as a way to sell drugs.

It was co-founded in 1969 by members of the Church of Scientology and Professor of Psychiatry Emeritus Dr. Thomas Szasz, at a time when patients were being warehoused in institutions, abused, stripped of their constitutional, civil and human rights, and left without recourse.

CCHR has long fought to restore basic unalienable human rights to the field of mental health, including, but not limited to, full informed consent regarding the medical legitimacy of psychiatric diagnosis, the risks of psychiatric treatments, the right to all available medical alternatives, and the right to refuse any treatment considered harmful. CCHR does not advocate any particular medical, educational or particular treatment, but does advocate giving people alternatives and resources to assist them in finding non-harmful solutions.

CCHR has worked for more than 40 years for full informed consent in the field of mental health, and the right to all the information regarding psychiatric diagnoses and treatment, not just the information coming from those with a vested interest in keeping them in the dark.

Mission Statement

"To eradicate psychiatric abuse and brutality in the field of mental health, bringing about safety and security for those suffering any degree of mental problems."

On 10 December 1948, the General Assembly of the United Nations adopted and proclaimed the Universal Declaration of Human Rights, which has been the foundation of all human rights legislation since that time and is at the heart of CCHR's work.

When CCHR was formed in 1969, public accountability and external review of psychiatry's abusive practices were non-existent. Damaging treatment could be given to patients without their consent and often without their knowledge. Through 'easy seizure' involuntary commitment laws, people could literally be grabbed off the street and locked away, enabling psychiatrists to operate as a law unto themselves.

If the concept of full informed consent were a reality in the field of mental healing, the psychiatric profession would likely be a humane or forgotten ideology. The pharmaceutical industry is already being brought to account for its marketing practices and its lies about the risks of psychotropic drugs. As more and more information is revealed through media channels that exist in this contemporary society, full informed consent can and is becoming a reality, with the ultimate reform of an industry built on falsehoods.

CCHR's work to expose the falsehoods has seen it become a powerful voice in the vanguard of mental health reform

Endnotes:

[1] Laura Clark, "NHS spending on chemical cosh child-calming drugs soars 60% to £3m," *Daily Mail*, 11 May 2010.
[2] "Children under six being prescribed behavioural drugs against medical guidelines: More than a fifth of educational psychologists are aware of children under six being given medication," The Independent, 24 Dec. 2014, http://www.independent.co.uk/life-style/health-and-families/health-news/children-under-six-being-prescribed-behavioural-drugs-against-medical-guidelines-9939190.html
[3]Caroline Wheeler, "Zombie generation: Fears rise for children as prescriptions for ADHD drug soar," *The Express* (UK), 29 June 2014, http://www.express.co.uk/life-style/health/485533/ADHD-drug-prescriptions-for-children-soar; Graeme Paton, "Children given 'chemical cosh' drugs for shyness," *Daily Telegraph,* 4 May 2011; Barbara Davies, "Ritalin: The scandal of kiddy coke," *Daily Mail*, 27 Nov. 2007.
[4] Paul Sims, "GPs 'giving Ritalin to babies under a year old,'" *Daily Mail*, 30 July 2007, http://www.dailymail.co.uk/news/article-471676/GPs-giving-Ritalin-babies-year-old.html#ixzz3lkd8YjJO
[5] *Ibid.*
[6] *Ibid.*
[7] *Op. cit., Daily Mail*, 4 May 2011.
[8] Lauren Higgs, Lauren Higgs, "Psychologists warn of growing use of psychotropic drugs on children," *Children & Young People Now*,25 Sept. 2011.
[9]Caroline Wheeler, "Zombie generation: Fears rise for children as prescriptions for ADHD drug soar," *The Express* (UK), 29 June 2014, http://www.express.co.uk/life-style/health/485533/ADHD-drug-prescriptions-for-children-soar
[10] *Olfson M, Marcus SC, Shaffer D (2006). Antidepressant Drug Therapy and Suicide in Severely Depressed Children and Adults: A Case-Control Study. Arch Gen Psychiatry; 63 (8):865-872; http://www.luusci.co.uk/mental-health-and-big-pharma-a-cause-for-concern/*
[11] "Anti-depressants may increase risk of child suicide, say researchers," *The Evening Standard*, 1 Nov. 2006, http://www.standard.co.uk/news/anti-depressants-may-increase-risk-of-child-suicide-say-researchers-7193300.html
[12] "Number of children on antipsychotic drugs doubles," Channel 4 News, 9 Nov. 2011, http://www.channel4.com/news/numbers-of-children-on-antipsychotic-drugs-doubles
[13] http://anh-europe.org/2011/11/11/british-tv-survey-exposes-drugging-of-children/
[14] "'Zombie drug' kids on the rise," Metro.co.uk, 5 May 2008.
[15] Op. cit., Barbara Davies, 27 Nov. 2007.
[16] *Op. cit.,* Jenny Hope, *Daily Mail*, 30 Oct. 2009.
[17] "Off-label, unauthorised Rxing in children "widespread" in Europe," Pharma Times, 27 Jan., 2011, http://www.pharmatimes.com/Article/11-01-27/Off-label_unauthorised_Rxing_in_children_%E2%80%9Cwidespread%E2%80%9D_in_Europe.aspx
[18] Christoph U. Correll, MD, *et al,* "Cardiometabolic Risk of Second-Generation Antipsychotic Medications During First-Time Use in Children and Adolescents," *Journal of the American Medical Association*, Vol. 302, No. 16, 28 Oct. 2009, pp. 1768, 1770.
[19] Christopher McCabe, PhD., *A Systematic Review of Cost Effectiveness Analyses of Whole School Interventions to Promote Children's Mental Health*, Academic Unit of Health Economics (AUHE), Leeds Institute of Health Sciences, University of Leeds, 10 July 2007.
[20] "Does your child really have a behaviour disorder? A shocking book by a leading therapist reveals how millions of us – including children – are wrongly labeled with psychiatric problems," *The Daily Mail (UK)*, 6 May 2013.
[21] http://www.pharmaceutical-journal.com/opinion/comment/atypical-antipsychotics-overrated-and-overprescribed/20067929.article
[22] http://ep.bmj.com/content/96/5/192.abstract
[23]Hansard HC Deb, 7 July2005 c573W
[24] "Diagnosis and management of ADHD in children, young people and adults" *National Clinical Practice Guideline Number 72*
National Collaborating Centre for Mental Health commissioned by the National Institute for Health & Clinical Excellence published by
The British Psychological Society and The Royal College of Psychiatrists
[25] http://www.nice.org.uk/nicemedia/live/12061/42060/42060.pdf - appendix 2 of the above NICE ADHD guideline
[26] Ibid.
[27] http://www.nice.org.uk/nicemedia/live/12061/57052/57052.pdf
[28] http://www.nice.org.uk/nicemedia/live/12061/57052/57052.pdf
[29] http://www.nytimes.com/2008/06/08/us/08conflict.html?scp=1&sq=Researchers+fail+to+reveal+full+drug+pay&st=nyt&_r=1&
[30] (Hospital for Sick Children Canada resource website) symptoms of anemia, hypo and hyperglycemia; http://www.aboutkidshealth.ca
[31] *Nutrition Research and Practice, Nutr* Res Pract, 2011; 5(3):236-245 : McCann Donna et al, 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, Sept. 2007; Kanarek, Robin B, Artificial Food Dyes and Attention Deficit Hyperactivity Disorder, Nutrition Reviews Vol. 69(7); 385–391;Howard Amber L., "ADHD Is Associated With a 'Western'Dietary Pattern in Adolescents," *Journal of Attention Disorders* 15(5) 403–411, 2011;Newmark Sanford C., MD, "Nutritional Intervention in ADHD," EXPLORE May/June 2009, Vol. 5, No. 3.
[32] Dr. Kathleen Kerr (General Practitioner), Personal Communication.
[33] http://www.nice.org.uk/nicemedia/live/12061/57052/57052.pdf
[34] Ibid.
[35] "ADHD is overdiagnosed, leading to needless and harmful treatment, researchers say," *Minnesota Post*, 7 Nov. 2013, .minnpost.com/second-opinion/2013/11/adhd-overdiagnosed-leading-needless-and-harmful-treatment-researchers-say
[36] http://www.lawyersandsettlements.com/lawsuit/adderall.html#.UzJJqs7Xlqw
[37] https://detenganlavacuna.files.wordpress.com/2010/04/john-virapen-side-effects-death-confessions-of-a-pharmainsider.pdf
[38] Lalkemedelsverket Medical Products Agency. Mutual Recognition Variation Response Report. Comments from the Medical Products Agency on the Final Variation Assessment Reports (FVARS). Prozac (Fonex, Fontex Basal) UK/H/636,3/II/02. April 29, 2005. See Annexe IV
[39] Referral under article 6(12) of Commission Regulation (EC) No 1084/2003 EMEA/H/A-6(12)/671. Prozac (fluoxetine) – Paediatric indication. Rapporteurs' Assessment Report. Assessment of MAH Response to CPMP List of Questions. See Annexe V
[40] https://detenganlavacuna.files.wordpress.com/2010/04/john-virapen-side-effects-death-confessions-of-a-pharmainsider.pdf

[41] "Radical increase in kids prescribed Ritalin," WND, 1 Apr. 2013, http://www.wnd.com/2013/04/radical-increase-in-kids-prescribed-ritalin/#hQjxdxIizztQyRWY.99
[42] Steve Mitchell, "Analysis: Anti-depressants tied to violence," UPI, 11 Sept. 2006.
[43] Matthew M. Large, Christopher J. Ryan, "Disturbing findings about the risk of suicide and psychiatric hospitals," *Soc. Psychiatry Psychiatr Epidemiology* (2014), 49: 1353-1355.
[44] Paul Andrews, "Things Your Doctor Should Tell You About Antidepressants," Mad in America: Science, Psychiatry and Community, 12 Sept. 2012, http://www.madinamerica.com/2012/09/things-your-doctor-should-tell-you-about-antidepressants/
[45] The condition of ADHD was voted into existence in the DSM-III-R (DSM is the Diagnostic and Statistical Manual – an official listing of psychiatric diseases) by a show of hands of APA (American Psychiatric Association) committee members.
[46] The condition of ADHD was voted into existence in the DSM-III-R (DSM is the Diagnostic and Statistical Manual – an official listing of psychiatric diseases) by a show of hands of APA (American Psychiatric Association) committee members.
[47] Dr. Mary Ann Block, author of No More ADHD – "ADHD is not like diabetes and Ritalin is not like insulin. Diabetes is a real medical condition that can be objectively diagnosed. ADHD is an invented label with no objective valid means of identification."
[48] Elliot S. Valenstein, Ph D, Biopsychologist – "[T]here are no tests available for assessing the chemical status of a living person's brain. Also, no biological, anatomical or functional signs have been found that reliably distinguish the brains of mental patients."
[49] http://bjp.rcpsych.org/content/184/1/8
[50] http://healthimpactnews.com/2013/adhd-drugs-new-study-reveals-the-fraud-of-kiddie-cocaine/
[51] http://www.theguardian.com/society/2014/mar/30/children-hyperactivity-not-real-disease-neuroscientist-adhd
[52] http://time.com/25370/doctor-adhd-does-not-exist/
[53] http://www.cchrint.org/2013/10/30/adhd-is-a-fictitious-disease/
[54] Source: Journal of Consulting and Clinical Psychology, 2012; 80: 128-38
[55] McGuire Woods ADHD Litigation White Paper, http://www.mcguirewoods.com/news-resources/publications/products_liability/adhd.pdf
[56] "Consideration Of Reports Submitted By States Parties Under Article 44 Of The Convention," Committee On The Rights Of The Child, Fortieth session, October 20, 2005, p 10.
[57] "Consideration Of Reports Submitted By States Parties Under Article 44 Of The Convention," Committee On The Rights Of The Child, Fifty-eighth session, October 6, 2011, p 8.
[58] "A.D.H.D. Seen in 11% of U.S. Children as Diagnoses Rise," *The New York Times*, 21 Mar. 2013, http://www.nytimes.com/2013/04/01/health/more-diagnoses-of-hyperactivity-causing-concern.html?pagewanted=all

Annexe I

Side effects of ADHD drugs

The following is taken from the official list of side-effects warning patients about the risks of taking Ritalin (a drug that has frequently been used for ADHD). Other similar drugs (methylphenidate hydrochloride) used for ADHD with different names will have similar side-effects. Prescribing doctors or psychiatrists rarely "inform" parents and children on all these side-effects.

It can be argued that the side-effects listed below amount to a potential criminal offence of bodily harm and violate the patients' (or parents') right to be fully informed of the consequences of taking the drug if they are not fully informed of these consequences, particularly as these affect children.

Under 'Very Common' (1 in 10) the side effects are **Psychiatric disorders** - insomnia, nervousness and **Nervous system disorders**: Headache.

Under 'Common' (a 1/10 to a 1/100 chance) your child risks **Infections and infestations** Nasopharyngitis (common cold); **Metabolism and nutritional disorders -** anorexia, decreased appetite, moderately reduced weight and height gain during prolonged use in children; **Psychiatric disorders :** anorexia, affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour; **Nervous system disorders**: Dizziness, dyskinesia, psychomotor hyperactivity, somnolence; **Cardiac disorders** Arrhythmia, tachycardia palpitations; **Vascular disorders:** Hypertension; **Respiratory, thoracic and mediastinal disorders:** Cough, pharyngolaryngeal pain **Gastro-intestinal disorders**: Abdominal pain, diarrhoea, nausea, stomach discomfort and vomiting. (You'll be glad to know that these last ones usually occur at the beginning of treatment and may be alleviated by concomitant food intake). Dry mouth. ; **Skin and subcutaneous tissue disorders***:* Alopecia, pruritis, rash, urticaria; **Musculoskeletal, connective tissue and bone disorders:** Arthralgia; **General disorders and administration site conditions***:* Pyrexia, growth retardation during prolonged use in children; **Investigations***:* Changes in blood pressure and heart rate (usually an increase), weight decreased.

'Uncommon' risks (1/100 and 1/1000) include **Immune system disorders :** hypersensitivity reactions such as angioneurotic oedema, anaphylactic reactions, auricular swelling, bullous conditions, exfoliative conditions, urticaria, pruritis, rashes and eruptions; **Psychiatric disorders** auditory, visual, and tactile hallucinations, anger, suicidal ideation, mood altered, mood swings, restlessness, tearfulness, tics, worsening of pre-existing tics or Tourette's syndrome, hypervigilance, sleep disorder ; **Eye disorders :** Diplopia, blurred vision; **Nervous system disorders**: Sedation, tremor ; **Cardiac disorders***:* Chest pain; **Respiratory, thoracic and mediastinal disorders**: dyspnoea; **Gastro-intestinal disorders**: Constipation; **Hepatobiliary disorders**: Hepatic enzyme elevations; **Skin and subcutaneous tissue disorders***:* Angioneurotic oedema, bullous conditions, exfoliate conditions; **Musculoskeletal, connective tissue and bone disorders***:* Myalgia, muscle twitching ; **Renal and urinary disorders***:* Haematuria; **General disorders and administration site conditions***:* Chest pain, fatigue; **Investigations***:* Cardiac murmur, hepatic enzyme increased.

The 'rare' category (1/1000 to 1/10000). Your child will risk **psychiatric disorders,** mania, disorientation, libido disorder ; **eye disorders** *:* difficulties in visual accommodation, mydriasis, visual disturbance ; **cardiac disorders***:* angina pectoris ; **Skin and subcutaneous tissue disorders***:* hyperhidrosis, macular rash, erythema ; **reproductive system and breast disorders***:* gynaecomastia

<u>At the top end - 'very rare'</u> (more than 1 in 10,000– though better hope your child is not one of these) **psychiatric disorders suicidal attempt (including completed suicide)**, transient depressed mood, abnormal thinking, apathy, repetitive behaviours, over-focusing; **Nervous system disorders**: convulsions, choreo-athetoid movements, reversible ischaemic neurological deficit, neuroleptic malignant syndrome (NMS: reports were poorly documented and in most cases, patients were also receiving other drugs, so the role of methylphenidate is unclear); **cardiac disorders** Cardiac arrest, myocardial infarction ; **Vascular disorders** Cerebral arteritis and/or occlusion, peripheral coldness, Raynaud's phenomenon; **hepatobiliary disorders**: Abnormal liver functions, including hepatic coma; **Skin and subcutaneous tissue disorders**: erythema multiforme, exfoliate dermatitis, fixed drug eruption; **musculoskeletal, connective tissue and bone disorders***:* muscle cramps ; **general disorders and administration site conditions***:* **sudden cardiac death** ; **investigations***:* blood alkaline phosphatase increased, blood bilirubin increased, platelet count decreased, white blood count abnormal.

Annexe II

The following summarises and references a significant number of scientific studies which demonstrate direct links between physical conditions causing symptoms that are classified as ADHD.

Poor diet is a significant cause of symptoms wrongly classified as ADHD

Poor diet, high sugar intake, fast foods, processed meats, high fat dairy products and confectionary are causal factors of symptoms associated with ADHD.

i. A randomised controlled trial that consisted of an open-label phase with masked measurements followed by a double-blind was carried out by Dr Lidy M Pelsser and others[1]. The trail aimed to investigate whether there was a connection between diet and behaviour in an unselected group of children.

After completion of the trial Dr. Pessler did not mince words, “Food is the main cause of ADHD,” she said adding, “After the diet, they were just normal children with normal behaviour. They were no longer more easily distracted, they were no more forgetful, there were no more temper-tantrums.”

The study found that in 64 percent of children with ADHD, the symptoms were caused by food. “It’s a hypersensitivity reaction to food,” Pessler said.

Dr Plessler also reported that that “The teachers thought it was so strange that the diet would change the behaviour of the child as thoroughly as they saw it. It was a miracle, the teachers said.”

They concluded that 'dietary intervention should be considered in all children with ADHD, provided parents are willing to follow a diagnostic restricted elimination diet for a five-week period, and provided expert supervision is available.‘

ii. A trial of the RPAH Elimination Diet with 140 behaviourally disturbed children found that nearly two thirds (61%) improved significantly and that a suitable diet could usually be devised for each child within three months. It was recommended that the RPAH Elimination Diet supervised by an experienced and supportive dietician to members of the Food Intolerance Network because it is equally effective and much easier to use than the Few Foods diet.[2]

iii. In 2003 at the Dingle School in Cheshire, UK, a class of 6-year-olds was asked to avoid additive-free food (39 additives) at home and at school for two weeks while a twin in that class and his brother eating normally in another class were monitored by Professor Jim Stevenson from Southampton University. At the end of two weeks, 57 per cent of parents reported an improvement in their child's behaviour and 56 per cent recorded better sleep patterns and cooperation in the additive-free class. As well, the IQ of the twin on the additive free diet had improved by 25% while the additive-eating twin’s IQ had only improved by 10%.[3]

iv. Nine children with persistent anti-social, disruptive and/or criminal behaviours were assessed and treated for food intolerance and allergy. All were found to have a number of food allergies or intolerances and mineral imbalances, particularly in zinc. Three showed marginally raised cadmium

[1] The Lancet, Volume 377, Issue 9764, Pages 494 - 503, 5 February 2011
[2] Swain A, Soutter V, Loblay R, Truswell AS. Salicylates, oligoantigenic diets, and behaviour. Lancet 1985;2(8445):41-2.
[3] Nicole Martin. Food additives affect concentration: twin study. The Daily Telegraph, 1/5/2003, page A14.
http://www.telegraph.co.uk/news/uknews/1428657/Twin-outshines-brother-on-additive-free-diet.html

while one had considerably raised cadmium. The children remained at home in the care of their parents while undergoing a restrictive dietary regime with the avoidance of identified problem foods. The health and behaviour of all nine subjects improved both physically and psychologically. However, three children abandoned the dietary regime, two of whom re-offended and were placed in care while the third moved home and accepted enzyme-potentiated desensitization (EPD) treatment. He and the other six continued to improve in health, behaviour and school performance over 6 months. In the following 18 months, two more re-offended but with much reduced frequency and violence than before the project. After 2 years, five of the nine had not re-offended. The feasibility of applying nutritional and biochemical assessment and treatment in the community to divert young offenders and disruptive schoolchildren from criminal behaviour was demonstrated. Criminal justice, education and health agencies could incorporate and develop this approach in furtherance of their statutory objectives.[4]

v. A questionnaire-based research addressed the young offender population in order to estimate the proportion likely to have food allergic and other nutritionally related disorders such as hyperactivity. A controlled health and dietary survey was conducted with 100 young offenders and 100 matched non-offenders. The offender group reported significantly higher rates of ill health than the non-offender group. It is suggested that the nutritional health of young offenders could be investigated as part of present statutory requirements to consider the physical and mental health of young criminals. There was no real difference between the diets of the two groups. Further research is justified into the association between nutrition, health and behaviour problems. From this study, the proportion of the persistent **young offender population with maladaptive behaviours linked to food allergy, food intolerance and nutritional problems is cautiously estimated to be 75%** whereas 18% of the young non-offender population is similarly affected.[5]

vi. The introduction of a diet policy which lowered sucrose, synthetic food colour/flavours, and two preservatives (BHA and BHT) over 4 years in 803 public schools was followed by a 15.7% increase in mean academic percentile ranking above the rest of the nation's schools who used the same standardized tests. Prior to the 15.7% gain, the standard deviation of the annual change in nation percentile rating had been less than 1%. Each school's academic performance ranking was negatively correlated with the percent of children who ate school food prior to the diet policy changes. However, after the policy transitions, the percent of students who ate school lunches and breakfasts within each school became positively correlated with that school's rate of gain.[6]

vii. Numerous studies conducted in juvenile correctional institutions have reported that violence and serious antisocial behaviour have been cut almost in half after implementing nutrient-dense diets that are consistent with the World Health Organization's guidelines for fats, sugar, starches, and protein ratios. Two controlled trials tested whether the cause of the behavioural improvements was psychological or biological in nature by comparing the behaviour of offenders who either received placebos or vitamin-mineral supplements designed to provide the micronutrient equivalent of a well-balanced diet. These randomized trials reported that institutionalized offenders, aged 13 to 17 years or 18 to 26 years, when given active tablets produced about 40% less violent and other antisocial behaviour than the placebo controls. However, generalization could not be made to typical schoolchildren without a controlled trial examining violence and antisocial behaviour in public schools.

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[4] **The Shipley Project: Treating Food Allergy to Prevent Criminal Behaviour in Community Settings**, Bennett CPW, McEwen LM, McEwen HC, Rose, EL, *Journal of Nutritional & Environmental Medicine* , Vol.8, No.1,Mar.1998, pp.77-83

[5] **The Health of Criminals Related to Behaviour, Food, Allergy and Nutrition: A Controlled Study of 100 Persistent Young Offenders**, Bennett CPW, Brostoff J., *Journal of Nutritional & Environmental Medicine*, Vol.7, No.4 Dec 1997 pp.359-366

[6] The Impact of a Low Food Additive and Sucrose Diet on Academic Performance in 803 New York City Public Schools, Schoenthaler SJ, Doraz WE, Wakefield JA, *Int J Biosocial Res.,* 1986, 8(2); 185-195.

It was concluded that poor nutritional habits in children that lead to low concentrations of water-soluble vitamins in blood, impair brain function and subsequently cause violence and other serious antisocial behaviour. Correction of nutrient intake, either through a well-balanced diet or low-dose vitamin-mineral supplementation, corrects the low concentrations of vitamins in blood, improves brain function and subsequently lowers institutional violence and antisocial behaviour by almost half. This paper adds to the literature by enabling previous research to be generalized from older incarcerated subjects with a history of antisocial behaviour to a normal population of younger children in an educational setting.[7]

viii. High sugar intake is also associated with hyperactive behaviour and ADHD. Sugar intake makes a marked contribution to hyperactive, aggressive, and destructive behaviour[8] [9] [10]. A large study by Langseth and Dowd found 74 percent of 261 hyperactive children manifested abnormal glucose tolerance in response to a sucrose meal[11]. Other studies have been conducted, but industry interests may have influenced their outcomes in a manner inconsistent with good scientific research. For example, Wolraich and collaborators conducted a trial on sugar and hyperactivity that was published in the *New England Journal of Medicine* in 1994[12]. The findings were portrayed by the study investigators and the media as proving that sugar did not significantly contribute to hyperactivity. Yet the control, "low-sugar" diet averaged 5.3 teaspoons of refined sugar per day, fed to children aged 6-10 years. This "baseline" level of sugar intake is arguably so high that the investigators should not have been surprised the "test" group on a higher sugar diet did not show significantly more symptoms than the "controls." No attempt was made to eliminate dietary allergens such as milk, wheat, and egg, which trigger behavioural problems in some hyperactive children, and all the children were allowed to consume soda drinks during the study. At the end of their report, the authors acknowledged their gratitude to General Mills, Coca-Cola, PepsiCo, and Royal Crown.[13]

ix. Inadequate micronutrient intake. Supplementation to correct micronutrient deficiencies has been shown to improve ADHD symptoms.[14]

x. A **low-nutrient diet** high in processed foods and soft drinks at age 4½ has been associated with hyperactivity in children at age 7.[15]

xi. Similarly, a "western" dietary pattern has also been associated with ADHD in 14-year-olds.[16]

xii. Furthermore, a 2004 meta-analysis of 16 studies in children who were already hyperactive showed that their hyperactive behaviour increased after ingesting food colourings.[17]

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[7] The effect of vitamin-mineral supplementation on juvenile delinquency among American schoolchildren: a randomized, double-blind placebo-controlled trial. Schoenthaler SJ, Bier ID. http://www.ncbi.nlm.nih.gov/pubmed/10706231

[8] Murray MT, Pizzorno JT. *Encyclopedia of Natural Medicine*. Rocklin, CA: Prima Publishing; 1998.

[9] Crook WG. Sugar, yeast and ADHD: fact or fiction? In: Bellanti JA, Crook WG, Layton RE, eds. *Attention Deficit Hyperactivity Disorder: Causes and Possible Solutions (Proceedings of a Conference).* Jackson, TN: International Health Foundation; 1999.

[10] Prinz RJ, Roberts WA, Hantman E, et al. Dietary correlates of hyperactive behavior in children. *J Consult Clin Psychol* 1980;48:760-769.

[11] Langseth L, Dowd J. Glucose tolerance and hyperkinesis. *Fd Cosmet Toxicol* 1978;16:129- 133.

[12] Wolraich M, Wilson D, White J. The effects of sugar on behavior and cognition in children: a meta-analysis. *J Am Med Assoc*1995;274:1617-1621.

[13] Parris M. Kidd, PhD Alternative Medicine Review, Volume 5 Number 5, 2000

[14] Kidd PM: Attention deficit/hyperactivity disorder (ADHD) in children: rationale for its integrative management. Altern Med Rev 2000;5:402-428

Curtis LT, Patel K: Nutritional and environmental approaches to preventing and treating autism and attention

[15] Wiles NJ, Northstone K, Emmett P, et al: 'Junk food' diet and childhood behavioural problems: results from the ALSPAC cohort. Eur J Clin Nutr 2009;63:491-498.

[16] Howard AL, Robinson M, Smith GJ, et al: ADHD is associated with a "Western" dietary pattern in adolescents. J Atten Disord 2011;15:403-411.

[17] McCann D, Barrett A, Cooper A, et al: 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. Lancet 2007;370:1560-1567.

xiii. Probably the most significant study was done in Australia in 2011, a project known as the *Raine Study* collected a large amount of health, developmental, and environmental information on 2,868 children in Australia from birth. The information on the children's diets was analysed and whether they had a diagnosis of ADHD. Dr. Wendy Oddy, Leader of Nutrition Studies at the Perth Telethon Institute for Child Health Research was clear when she reported that "When we looked at specific foods, having an ADHD diagnosis was associated with a diet high in takeaway foods, processed meats, red meat, high fat dairy products and confectionary," She went on to say, "We suggest that a Western dietary pattern may indicate the adolescent has a less optimal fatty acid profile, whereas a diet higher in omega-3 fatty acids is thought to hold benefits for mental health and optimal brain function". The researchers also concluded that, those children raised on stimulants for the treatment of ADHD, did not progress academically.

xiv. The Centre for Autism and Integrative Health, LLC have done extensive research into this field. Dr Nancy O'Hara, MD, MPH, FAAP and Gail Szakacs, MD reported that subtle dietary changes can promote significant behavioural and cognitive changes. The impact of early poor nutrition depends on timing in relation to critical brain development, but if poor nutrition continues or develops later, it can have profound negative effects. Liu, *et al*, showed a 15.3 point IQ deficit in a prospective, longitudinal study of malnourished children at age 3. As far back as 1922, there were published reports of improvement in hyperactivity and learning issues with an elimination diet (Shannon WR), a diet that eliminates certain foods like wheat, soy or dairy. Dr. Ben Feingold's work in the 1970's highlighted the relationship between hyperactivity and artificial food colorings, flavorings, preservatives, and salicylates. Many other researchers have found similar results.[18]

xv. The relationship between dietary peptides (like gluten from wheat and casein from dairy) and neurologic function and behaviour is well documented as well. Horvath, *et al*, and others, have shown that increased intestinal permeability can allow poorly digested peptides (as well as toxins, allergens, etc) into the bloodstream where they can trigger inflammation, immune dysregulation, and affect neurologic and psychologic function. In 2006, Niederhofer showed that ADHD-like symptomatology is often present among untreated celiac disease (lifelong gluten intolerance) patients and a gluten-free diet can improve those symptoms.[19]

Vitamin, Mineral and other Nutrient Deficiencies

Medical Research Indicates that vitamin, mineral and other nutrient deficiencies correlate with symptoms of ADHD and show that supplementation can improve symptoms.

The information below on supplements (or simply correct nutrition) and how they can affect behaviour and cognition, illustrates the importance of finding and treating nutritional imbalances in those with ADHD.

In terms of general nutrition, it is clear that vitamins and minerals are essential to cognitive function. Various researchers have found low levels of vitamins and minerals in children with a range of neurodevelopmental disorders, as well as cognitive, behavioural, and academic improvement in those receiving specific supplementation. For instance, in one study by Schoenthaler, *et al*, 50% of US daily RDA (daily vitamin-mineral supplement) for 4 months (versus placebo) lowered institutional violence and antisocial behaviour by nearly 50%.[20]

[18] Centre for Autism and Integrative Health Care, Dr. Gail Szakacs, http://www.epidemicanswers.org/wp-content/uploads/2010/05/ADHD-Without-Drugs.pdf
[19] Ibid.
[20] Ibid.

Nutrient deficiencies are common in ADHD; supplementation with minerals, the B vitamins (added in singly), omega-3 and omega-6 essential fatty acids, flavonoids, and the essential phospholipid phosphatidylserine (PS) can ameliorate ADHD symptoms. When individually managed with supplementation, dietary modification, detoxification, correction of intestinal dysbiosis, and other features of a holistic/integrative program of management, the ADHD subject can lead a normal and productive life.[21]

The role of other nutrients is widely covered in the literature available. The following are some examples that relate to symptoms incorrectly diagnosed as ADHD.

Iron

- Children with moderately severe iron-deficiency anaemia as infants had lower scores on tests of mental and motor functioning at school entry[22].
- Low iron was associated with changes in serotonin, noradrenaline, and dopamine levels; iron supplementation has short and long-term benefits in behaviour and psychomotor development[23].
- 23 children with ADHD, ages 5 to 8, with serum ferritin (iron stores) < 30. For 12 weeks, 18 were given iron-sulfate and 5 given placebo. The result showed decreased ADHD rating scales[24].
- In an 8 week study 73 girls with low serum ferritin were randomly assigned ferrous sulfate or placebo. Those in the iron group performed better on verbal learning and memory tests[25]

Essential fatty acids

Essential fatty acids are the "good fats" such as Omega 3s found in cod liver oil and flaxseed oil.

- Drawing on a number of studies[26] Dr. Randi Fredricks, Ph.D. reports that fish oil improves the symptoms of attention deficit hyperactivity disorder (ADHD) without any of the side effects of drugs like Ritalin and Concerta, and were more effective, according to a study by the University of Adelaide in Australia. Other studies have found evidence supporting the use of the omega-3 fats found in fish oils to effectively address the underlying deficiency that is present in most of these children and appears to be contributing to the ADHD. According to one of the studies, when 130 children between the ages of 7 and 12 with ADHD were given fish oil capsules daily, behaviour dramatically improved within three months. In addition, the study revealed the following:
    - After seven months, the children were less restless and showed improvements at school
    - Improvements in concentration and attention improved by one-third

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[21] Attention Deficit/Hyperactivity Disorder (ADHD) in Children: Rationale for Its Integrative Management Parris M. Kidd, PhD. Altern Med Rev 2000;5(5):402-428

[22] Lozoff, et al. 1991 NEJM;325(10):687-694

[23] Parks, et al. 1989 Acta Paediatr Scand Suppl;361:71-7

[24] Konofal E, et al. Jan 2008 Pediatr Neurol;38(1):20-6

[25] Bruner AB, et al. Oct 1996 Lancet;348(9033):992-6

[26] Burgess, J. R., Stevens, L., Zhang, W., & Peck, L. (2000). Long-chain polyunsaturated fatty acids in children with attention-deficit hyperactivity disorder. *Am J Clin Nutr, 71*(1 Suppl), 327S-330S.

Fredricks, R. (2008). *Healing & wholeness: Complementary and alternative therapies for mental health.* Bloomington, IN: Author House.

Hamazaki, T., Sawazaki, S., Itomura, M., Asaoka, E., Nagao, Y., Nishimura, N., Yazawa, K., Kuwamori, T., & Kobayashi, M. (1996). The effect of docosahexaenoic acid on aggression in young adults. A placebo-controlled double-blind study. *J Clin Invest, 97*(4), 1129-1133.

Richardson, A. J., & Montgomery, P. (2005). The Oxford-Durham study: A randomized, controlled trial of dietary supplementation with fatty acids in children with developmental coordination disorder. *Pediatrics, 115*, 1360-1306.

Sinn, N. (2008). Nutritional and dietary influences on attention deficit hyperactivity disorder. *Nutr Rev, 66*(10), 558-568.

Stevens, L. J., Zentall, S. S., Abate, M. L., et al (1996). Omega 3 fatty acids in boys with behaviour, learning and health problems. *Physiology and Behaviour, 59*, 915-920.

    - After 15 weeks, 30 to 40 percent of the children taking fish oil had improvements
    - After 30 weeks, 40 to 50 percent improved
    - Children who had been taking the placebo capsules were later switched to fish oil and subsequently also experienced improved behaviour
    - Improvements were still being seen after the study ended, which indicates the fish oils may have long-term effects. When the researchers compared their results to studies of Ritalin and Concerta for ADHD, they found that fish oils were more effective.
- A study with 44 hyperactive children and 45 matched controls demonstrated that various essential fatty acid levels were significantly lower in the hyperactive group[27].
- A randomized, double-blind, placebo-controlled 6-week pilot trial was carried out on 13 children with autistic disorders and severe tantrums, aggression or self-injurious behaviour to examine the effects of omega-3-fatty acids. The Aberrant Behaviour Checklist was done at 6-week where there was an advantage of omega-3 fatty acids compared with placebo for hyperactivity and stereotypy[28].
- Pure EPA is effective for depression and schizophrenia; a combination of EPA and DHA better for ADHD.[29]
- Omega-3 fatty acids (especially DHA) are the building blocks a child needs to build a healthy brain. **Insufficient omega-3 levels** are common in children with ADHD, and there is evidence that omega-3 supplementation, especially in combination with the omega-6 fatty acid gamma-linolenic acid (GLA; found in borage oil and evening primrose oil) improves behavior and ADHD symptoms.[30]

Pycnogenol: Pycnogenol is a natural plant extract that has powerful antioxidant and anti-inflammatory effects.

- Helps to regenerate vitamins C and E, improved anti-inflammatory properties, immune support, treats allergies, reports of improvements in EEG, handwriting, improvement in attention and academic success[31]

Vitamin B6 improved behaviour of some children with ADHD, compared to methylphenidate[32]

Carnosine can be neuroprotective[33].

Zinc is often low in ADHD patients[34].

Phosphatidylserine is important for synaptic membrane and neurotransmitter function.

- Study of 21 patients with ADHD, ages 4 to 19 during a 4-month trial helped approximately 90% with attention and learning.[35]

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[27] Mitchell EA, et al. 1987;26:406- 411

[28] Amminger GP. Feb 2007 Biol Psychiatry;61(4):551-3

[29] Richardson AJ. 2006 Int Rev Psychiatry;18(2):155-172

[30] Antalis CJ, Stevens LJ, Campbell M, et al: Omega-3 fatty acid status in attention-deficit/hyperactivity disorder. Prostaglandins Leukot Essent Fatty Acids 2006;75:299-308.
Transler C, Eilander A, Mitchell S, et al: The impact of polyunsaturated fatty acids in reducing child attention deficit and hyperactivity disorders. J Atten Disord 2010;14:232-246.

[31] Greenblatt, et al. 199 J Am Acad Child Adolesc Psychiatry;38(10):1209-1210,
Liu, et al. 1998 Cell Mol Life Sci;54(10))):1168-1172, Liu, et al. 2000 Biol Pharm Bull;23(6):735-737, Rohdewald P. Int J Clin Pharmacol Ther;40(4):158-168

[32] (Coleman, et al. 1979 Biol Psychiatry;14:741-751)

[33] (De Marchis S, et al. 2000 Biochemistry (Moscow);65(7):874-93 and Trombley PQ, et al. 2000 Biochemistry (Moscow);65(7):807-16)

[34] Bekaroglu, et al. 1996 J Child Psychol Psychiatry;37:225-227

[35] (Ryer, et al. Lancet (letter), Benefits of PS against attention deficit in a preliminary study)

Toxins in the environment

Toxic metals and allergens can cause oxidative stress, increased burden on the immune system, and behavioural and cognitive changes. Infections, trauma/injury, stress, and poor diet can all further increase oxidative stress.

Many chemicals and metals are recognized causes of neurodevelopmental disorders and subclinical brain dysfunction. Exposure during early foetal development can trigger brain injury at doses much lower than those affecting adult brain function. The information below from various studies highlights the importance of exploring causes of oxidative stress as contributing factors in symptoms assigned to ADHD.

i. Children exposed to higher chlorpyrifos (insecticide) levels were more likely to experience Psychomotor Development Index and Mental Development Index Delays, attention problems, ADHD, and pervasive developmental disorder problems at 3 years of age[36]

ii. Prenatal environmental tobacco smoke is a risk factor for ADHD.[37]

iii. Dose-response relationship between childhood lead exposure and ADHD.[38]

iv. In a Texas report – on average, for each 1000 lbs of environmentally released mercury, there was a 43% increase in the rate of special education services and a 61% increase in the rate of Autism.[39]
In one case report a 4 year-old boy diagnosed with ADHD and Autism who had increased blood lead level was treated with succimer (a medicine used to remove lead and other metals) and repetitive behaviour and hyperactivity stopped; there was regression when succimer was stopped (and presumably levels of lead increased).[40]

v. Environmental lead exposure in children who have maximal blood lead < 7.5 g/dl is associated with intellectual deficits.[41]

vi. Pollen exposure is a cause of regression in neurobehavioral function in children with Autism and ADHD.[42]

vii. Three large German studies suggest a strong and independent association between atopic dermatitis and ADHD – one of the studies (by Schmitt, et al) reported a 2.67-fold increased likelihood of ADHD in those with atopic dermatitis and parent-reported sleep problems.[43]

viii. More than 80 percent of schools in America use toxic pesticides as a preventative measure, whether it's needed or not. Mark Lame, an entomologist and professor at Indiana University's School of Public and Environmental Affairs, believes this is an entirely unnecessary practice that carries more risks than benefits to students and faculty. The most widely used pesticides are, in fact, nerve poisons. They cause uncontrolled nerve firing, and disrupt the delicate hormone systems. The link between pesticide exposure and health problems in children is already well established. Research has connected these endocrine-disrupting pesticides to health problems such as ADHD, autism, and infertility -- all of which are on the rise.

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[36] (Rauh, et al. 2006 Pediatrics'118;e1845-1859)
[37] (Braun JM, et al. Dec 2006 Environ Health Project;114(12):1904-1909)
[38] (Braun JM, et al. Dec 2006 Environ Health Project;114(12):1904-1909)
[39] (Palmer, et al. Helath & Place 12; 2006:203-209)
[40] Eppright, et al. 1996 Mo Med;93(3):136-8
[41] Lanphear BP, et al. 2005 Environ Health Perspect;113(7)
[42] Boris MJ, et al. 2004 J of Nutritional and Environmental Medicine;14(1):47-54
[43] Article by Bruce Jancin in Internal Medicine News; studies from JAMA and Pediatric Allergy Immunology journals cited in this article.

Professor Lame says pest problems are better managed through an integrated approach -- by preventing the conditions that attract pests into school facilities in the first place. Lame serves as a consultant for schools around the country, helping them reduce the toxic load by implementing his Integrated Pest Management (IPM) process.[44]

ix. There is preliminary evidence that certain **pesticides** (called organophosphates) commonly found on some fruits are associated with ADHD.[45]

Artificial colouring in food and drinks cause hyperactivity

A randomised, double-blinded, placebo-controlled trial study into food additives and hyperactive behaviour was carried out on 3-year-old and 8/9-year-old children in the community.[46] The researchers undertook to test whether intake of artificial food colour and additives (AFCA) affected childhood behaviour. 153 3-year-old and 144 8/9-year-old children were included in the study. The challenge drink contained sodium benzoate and one of two AFCA mixes (A or B) or a placebo mix. The main outcome measure was a global hyperactivity aggregate (GHA), based on aggregated z-scores of observed behaviours and ratings by teachers and parents, plus, for 8/9-year-old children, a computerised test of attention. The conclusion was that artificial colour or a sodium benzoate preservative (or both) in the diet result in increased hyperactivity in 3-year-old and 8/9-year-old children in the general population.

A meta-analysis of double-blind placebo-controlled trials conducted by Pediatrist J Dev Behav with regards to f**ood additives and dyes** found that many coloured foods are marketed to children, and hyperactivity in children following ingestion of food dyes is well documented in placebo-controlled studies.[47]

Television and video games

Guidelines from the American Academy of Pediatrics recommend no "screen time" for children less than 2 years old, no more than 1 to 2 hours a day of quality television and video for older children, and no electronic media in young children's rooms. Yet a recent survey found that 43% of children less than 2 years old watch television every day, and 26% have a television in their bedrooms. The study also showed that 68% of children less than 2 years old spend slightly less than 2 hours a day using screen media.[48] Somehow, the considered message of the American Academy of Pediatrics is not hitting the target.

Endocrine imbalance

The thyroid gland regulates all the processes to do with releasing energy from cells and the body as a whole. Symptoms such as anxiety and irritability, fatigue, memory loss, poor concentration, slow thinking and depression[49] are attributed to poor thyroid gland function.[50] (This being only a partial list of selected symptoms to demonstrate that those classed as ADHD can have cause in a malfunctioning thyroid gland). The condition of hypothyroidism has traditionally been among the most widespread

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[44] Science Daily July 21, 2007

[45] Bouchard MF, Bellinger DC, Wright RO, et al: Attention-deficit/hyperactivity disorder and urinary metabolites of organophosphate pesticides. Pediatrics 2010;125:e1270-1277.

[46] The study, was carried out by *Donna McCann, Angelina Barrett, Alison Cooper, Debbie Crumpler, Lindy Dalen, Kate Grimshaw, Elizabeth Kitchin, Kris Lok, Lucy Porteous, Emily Prince, Edmund Sonuga-Barke, John O Warner, Jim Stevenson.* This clinical trial is registered with Current Controlled Trials (registration number ISRCTN74481308).

[47] Artificial food colouring and hyperactivity symptoms in children. Prescrire Int 2009;18:215.
Schab DW, Trinh NH: Do artificial food colors promote hyperactivity in children with hyperactive syndromes? A meta-analysis of double-blind placebo-controlled trials. J Dev Behav Pediatr 2004;25:423-434.

[48] Rideout VJ, Vandewater EA, Wartella EA. *Zero to Six: Electronic Media in*

[49] Joffe, R.T. (1990) A Perspective of the thyroid and depression. Canadian Journal of Psychiatry 35: 375-378

[50] Durrant-Peatfield B.J.(1996) Aspects of a missed diagnosis: Thyroid dysfunction and management. Journal of Nutritional and Environmental Medicine 6(4) 371-378

and underdiagnosed. As early as 1933, a Dr Kimball stated that there is "no more important underdiagnosed condition than hypothyroidism." In his 1976 book Dr Barnes stated that "Hypothyroidism was the most frequent and often overlooked chronic condition affecting people residing all over the US."[51] He also stated that an "unfortunate regression" has occurred in modern medicine, whereby "sound global clinical evaluation has been replaced, almost exclusively by snap diagnostic decisions based on laboratory tests" and deplored the modern trend of patients' complaints not being taken seriously.

The adrenal glands are known as "the stress glands" and their job is to help the body deal with stress from every possible source – ranging from bereavement, relationship problems, emotional upsets, trauma, pain, injury and disease. Hormones secreted by the adrenal glands influence all major physiological processes in the body and malfunction includes anxiety, memory loss, confusion, low blood sugar and salt/sugar cravings – again symptoms that can be classed as, or lead to the classification of ADHD. [52] [53]

Whatever the source of stress on the individual, the stress response from the adrenal glands will not vary[54] but follow the same pattern, high output of cortisol, followed by a period of adaptation, then if the stressor persists, a gradual descent into adrenal fatigue followed by eventual exhaustion.[55]

"The tendency of the medical profession to ignore this syndrome results in many unnecessary health problems for millions. Even if you are aware that you have adrenal fatigue, you may not find any sympathy or understanding from your doctor. Medicine only officially recognizes Addison's disease as hypoadrenia."[56]

[51] Hypothyroidism, The Unsuspected Illness, Dr Broda Barnes
[52] Durrant-Peatfield,(2006) Your Thyroid and How To Keep It Healthy London:Hammersmith Press Ltd.
[53] Tintera, J.W.(1967) Endocrine aspects of schizophrenia: hypoglycaemia of hypoadrenocorticism. Journal of Schizophrenia (5): 150-181
[54] Selye H. (1984) The stress of life. New York:The McGraw-Hill Companies Inc.
[55] Adrenal Fatigue: The 21st Century Stress Syndrome by Dr James Wilson (2007)
[56] Ibid.

Annexe III

ADHD Litigation White Paper by McGuire Woods

McGuire Woods (ADHD Litigation White Paper)[1] – a legal company in the United States representing drug manufacturers – reports that litigation arising from ADHD drug prescription is becoming an ever increasing threat for the drug companies. Simple black-box warnings are not adequate to divert responsibility for damage caused by the drug itself and especially in light of recent massive awards against drug companies.

Billions of U.S. dollars have been paid by manufacturers of psychotropic drugs in the U.S. in recent years because of illegal marketing and failing to fully disclose adverse effects.

Two recent cases are Johnson & Johnson (and its subsidiary Janssen) were fined for downplaying the risks to its antipsychotic drug amounting to $1.5bn[2] and GlaxoSmithKline agreed to plead guilty to criminal charges and pay $3 billion to settle what government officials described as the largest case of healthcare fraud in U.S. history[3].

There is a growing documented body of evidence demonstrating that profits have overruled reason and ethics. Drug companies have raked in many billions of pounds and dollars of profit in the UK and USA alone and are being punished for their illegal activities.

As reported, McGuire Woods listed a number of trials and studies covering serious side effects including suicide. As a result of these findings, the FDA Pediatric Advisory Committee met in March 2006 and urged the use of new warnings about the possible risks of psychosis or mania associated with ADHD drugs.[4] The Committee noted that the most important finding of the review of psychiatric adverse events was that the signs and symptoms of psychosis or mania, particularly hallucinations, can occur in some patients with no identifiable risk factors, at usual doses of any of the drugs currently used to treat ADHD.[5]

According to the FDA's Division of Drug Risk Evaluation (DDRE), a substantial portion of psychosis-related cases were reported in children age 10 or younger, a population in which such hallucinations are highly uncommon.[6] The DDRE went on to note that the predominance of patients reporting hallucinations, both visual and tactile, that involved insects, snakes, or worms is striking and deserves further evaluation. In many patients, reportedly, the events ceased after they stopped taking the drug.

Dr. Kate Gelperin, one of the FDA reviewers noted, "[i]t was striking how often young children described various insects, bugs and worms, both visual and tactile—which we haven't seen elsewhere."[7]

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[1] McGuire Woods ADHD Litigation White Paper, http://www.mcguirewoods.com/news-resources/publications/products_liability/adhd.pdf
[2] BBC, 11 April, 2012
[3] Reuters Mon Jul 2, 2012
[4] 46 "FDA Rx Safety Officials Urge New Psychosis Warnings on ADHD Drugs," Drug Industry Daily 5, no. 53 (March 16, 2006)
[5] Gelperin, Kate, MD, MPH, et. al., "Psychiatric Adverse Events Associated with Drug Treatment of ADHD: Review of Postmarketing Safety Data" [FDA Center for Drug Evaluation and Research Memorandum], PID D050243, March 3, 2006.
[6] FDA Rx Safety Officials Urge New Psychosis Warnings on ADHD Drugs."
[7] Alonso-Zaldivar, Ricardo, A-12

According to some physicians, it is no surprise that ADHD medications have these effects since they are "exactly the same chemicals" as popular street drugs known to trigger psychosis.[8]

McGuire Woods further states that *"For those manufacturers of ADHD drugs, now is the time to really prepare for the possible onslaught of litigation. Lawsuits over the use of such prescriptions and the side effects looks to be the proverbial "perfect storm."*

McGuire Woods conclude that *"industry executives and in-house counsel are wise to watch the development of novel legal theories being used by the Plaintiffs' lawyers in bringing new product liability and toxic tort actions. These novel arguments, which appear to be gaining traction around the country, are being used to thwart statutory limitations limiting the old tried and true causes of action.*

"As the science continues to evolve towards establishing a link between various ADHD drugs and medical problems it is certain to attract even more attention from trial lawyers around the country. No doubt this is an area where strategic planning and preparation are required right now in order to prepare for the possible and likely onslaught of litigation."

Of course, the legislative system in the USA is well known for its potential for bringing high profile legislation for large sums of damages which may not be possible in the UK system. However, this does not lessen the liability of drug manufactures or those misdiagnosing and civil claims are currently under discussion in the UK where the likelihood of bringing successful cases is being examined.

[8] Rubin, Rita, "Re: Labeling ADHD drugs as psychosis/mania risk; advisory panel takes up question," USA Today, March 21, 2006, p. 6D).

Annexe IV

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

MUTUAL RECOGNITION VARIATION RESPONSE REPORT

1 COMMENTS FROM THE MEDICAL PRODUCTS AGENCY ON THE FINAL VARIATION ASSESSMENT REPORTS (FVARS)

Name:	**Prozac (Fontex, Fontex Basal)**
Procedure No.:	UK/H/636/1,3/II/02 :
Dosage form and strength:	**20 mg capsules; 20 mg/5ml oral liquid**
Date of the Response Report:	April 29, 2005

Name:	**Prozac (Fontex, Fontex Basal)**
Procedure No.:	FR/H/242/01/II/002
Dosage form and strength:	**20 mg dispersible tablet**
Date of the Response Report:	April 29, 2005

On 11 March 05, the MPA raised 'potentially serious public health concerns' within the FR procedure (FR/H/242/01/II/002) for a pediatric indication for fluoxetine, by supporting issues raised by FR as well as pointing to additional questions to be solved before recommendation of approval (Appendix 1). Although concerns remain regarding these points (see further below), the MPA currently supports the overall view of the UK, i.e. that approval may be recommended provided commitments of further studies and appropriate wording of the SPC. It is a fact that SSRIs, including fluoxetine, are used 'off label' in children and adolescents, and approving use of fluoxetine allows for providing treatment recommendations, better post marketing surveillance in these populations and possibilities to request further studies. In addition, in 2002, the CPMP issued a positive opinion within a referral (EMEA/H/A/-11/376) for another SSRI, **fluvoxamine,** which resulted in dose recommendations for the treatment of OCD in patients aged 8-17 years. Similar safety concerns were discussed at that time. Nevertheless, we also find it important that the timing of approval is considered, and would be in favour of awaiting the finalisation (i.e. Commission Decision) of the ongoing referral for SSRIs.

COMMITMENTS OF FUTURE STUDIES:
We agree with the UK proposal. In addition, we support the comment by FR (AR dated 5 April 2005), that further work should be undertaken to explore the mechanisms of the testicular toxicity observed in the juvenile toxicity study.

RESTRICTION OF PATIENT POPULATION:
Until additional data become available, we suggest that only patient having reached/passed puberty are to be treated with fluoxetine, since main safety concerns are related to potential effects on growth and sexual development. Appropriate wording of the SPC should be included.

DOSE RECOMMENDATION
During the break-out session, the UK stated that the maximum recommended dose has been changed to 20 mg/d, which should be confirmed. Moreover, one issue raised by SE in Mar 04 has not been adequately addressed by the MAH, and should be responded to, namely:

Annexe V

Referral under article 6(12) of Commission Regulation (EC) No1084/2003
EMEA/H/A-6(12)/671

PROZAC® (fluoxetine) – Paediatric indication

RAPPORTEURS' ASSESSMENT REPORT
Assessment of MAH Response to CPMP List of Questions

Rapporteur:	Dr. Barbara van Zwieten - Boot
Co-Rapporteur:	Dr. Tomas Salmonson
Arbitration Procedure restart date:	15 September 2005
Date of Preliminary report:	31 October 2005
Deadline for CHMP members' comments:	8 November 2005

I. Recommendations

It is not recommended to grant an indication to fluoxetine for the treatment of depression in children and adolescents because the benefit/risk balance in the claimed indication is deemed negative.

Concerns about safety issues were not resolved, specifically concerns about suicide related behaviours, including suicide attempt and suicidal ideation, and, from non-clinical data, about the effect on growth, sexual maturation, cognitive and emotional development. The limited evidence concerning long-term safety is a concern as well, especially given these safety signals.

Moderate effects, though somewhat inconsistent across trials, were seen, but there are doubts about the external validity of these results due to the stringent selection procedure. In addition, the lack of evidence to support dose recommendations in this young patient population, add to the negative balance regarding this new indication.

II. Executive Summary

II.1 Problem Statement

Fluoxetine, an SSRI, is an antidepressant that is registered for the treatment of major depression, obsessive compulsive disorders (OCD), and bulimia nervosa in adults in most EU member states. The Reference Member States (RMS) for Prozac are the UK (for the 20 and 60 mg oral capsules and 20 mg oral solution formulations) and France (for the 20 mg dispersible tablets).

The CHMP advised in April 2005 to include a warning for the class of all serotonin selective re-uptake inhibitors (SSRIs), including fluoxetine, indicating that these products should not be used in children and adolescents except in their approved indications.

A request to extend the indication of Prozac to include treatment of major depression in children and adolescents aged 8 to 17 (only for the 20 mg capsules, the oral solution and the dispersible tablets) was submitted by the company and evaluated in a mutual recognition type II variation procedure with the UK and France as RMS.

In addition to objections that were raised in response to the request, during the course of this procedure new information concerning safety have become available from preclinical as well as clinical studies. Animal studies have raised concerns with respect to effects of early exposure on growth and sexual maturation. A non-company sponsored clinical study (the Treatment of Adolescents with Depression Study (TADS)) demonstrated that fluoxetine, in common with other SSRIs, is associated with increased risk of suicidal behaviours in young persons.

Overall there were unresolved objections and concerns with respect to the following issues:

Annexe VI

Fluoxetine Regulatory Response: Revised Reponse Assessment Report Following CMS Comments on Post-licensing Commitment to Assess Sexual Maturation in Children

Prozac®
(Fluoxetine hydrochloride)

UK/H/0636/001,003, FUM no. 2:
Approved: 31 January 2007

The information contained in this document will undergo revisions, during the lifecycle of this plan, as new information about risks, exposures, and other important safety information about fluoxetine becomes available to the Global Product Safety division within Eli Lilly and Company.

5.1. 31 May 2006 Letter of Undertaking

Eli Lilly European Regulatory Team
Tel: 044 1276 483381

Date: 31 May 2006

Dr. D. Brasseur

European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Dear Dr Brasseur,

Re: EMEA/H/A-6(12)/671 (Fluoxetine capsules and oral solution, Eli Lilly and Company)

Eli Lilly and Company agree to undertake the following Post-Authorisation Commitments requested by the CHMP and commit to submit the data listed below within the specified timeframes.

We also agree to submit any variation application resulting from the assessment of the below mentioned data.

PIL User Testing

Additionally, as requested, we commit to review the need for and timing of user testing for the PL and labelling with the UK as Reference Member State.

Yours sincerely,

John C Saunders

(Acting on behalf of Dr. D Mackleston, for Eli Lilly and Company Fluoxetine MA Holders)

Specific Obligations:

Description:	Due Date
Module 4 – Pharmaco –Toxicological[1]	
Juvenile rat study – neurohormonal investigation of sexual maturation (see also Attachment 1)	Draft Protocol: 30/06/06 Protocol: 31/08/06 Study Report: 31/10/07
Juvenile rat study – characterization of testicular pathogenesis (see also Attachment 2)	Draft Protocol: 30/06/06 Protocol: 31/08/06 Study Report: 31/10/07
Juvenile rat study – characterization of effects on specified emotional behaviours. In this study, fluoxetine would be administered to CD rats from postnatal day 33 to postnatal day 62 with evaluations in the elevated zero maze, forced swimming test and prepulse inhibition test, once during treatment and 2 months post-treatment.	Draft Protocol: 30/06/06 Protocol: 31/08/06 Study Report: 31/10/07
Module 5 – Clinical	
We undertake to work with clinical investigators who are developing a protocol under the auspices of National Institute of Mental Health in United States to include the evaluation of the effect of fluoxetine on sexual maturation in children aged 8 – 12 years old. The protocol for this study is still being developed, but outline information is provided in Attachment 3. No more detail is available currently, but we agree to	Lilly / NIMH meeting minutes: 30 June 2006 Draft Protocol: 01/10/06 NIMH Approval & funding: 01/07/07

[1] The timeline for the final reports for these three preclinical studies varies by study. The characterization of testicular pathogenesis has a six-month live-phase. Hence, with the protocol being finalise 31 August and a study start in October 2006, the live phase will be complete by April 2007. Taking into account the time needed for pathological examinations and report writing, we estimate that the final report will be available by 31 October 2007. We propose that we provide the three preclinical reports together to CHMP at this one time.

provide the protocol from this study to EMEA and CHMP as soon as it is provided to Eli Lilly and Company by the investigators. This study is colloquially termed "TADS Jr" With regard to extending the duration of follow-up, increasing the upper age range of patients in this study and accelerating the enrolment rate, we undertake to pursue these matters with the study investigators at our scheduled meeting with them in June. We agree to provide the minutes of this meeting between Lilly and the investigators.	Final Protocol: 01/08/07 FPV: 4Q/07 LPV: 4Q/12[2] Final Study Report: 2013

Follow-up Measures:

Description:	Due Date
Module 4 – Pharmaco –Toxicological	
If the RMS considers that the results of the preclinical studies warrant label changes or further study, we agree to discussions with RMS to assess what further measures would be valid, useful and achievable.	24/12/07
Module 5 – Clinical	
We undertake to investigate further whether or not existing registries in Member States can be used to provide evaluable data on the effects of fluoxetine on sexual maturation.	30/11/06 & 30/11/07
We undertake to evaluate mania and hypomania in the paediatric population as specific topics in future PSURs.	Ongoing

[2] We apologise for this long duration, but we only heard 25 May that the timeline for conducting this study is much longer than we previously anticipated, but this does illustrate the problems associated with such studies. We undertake to investigate the possibility of interim data analysis being made available for a subset of patients.

Attachment 1. Proposed Rat Neurohormonal Study

Purpose: evaluate neurohormonal status of hypothalamic-pituitary-gonadal (HPG) axis during sexual maturation of juvenile CD male and female rats administered fluoxetine

Doses: 0, 10, and 30 mg/kg

Dosing Schedule: daily from Postnatal Day (PND) 21 to 61

Neuroendocrine Assessment

- Females: LH, FSH, prolactin, inhibin, estradiol, progesterone on PNDs 28, 30, 33, 35, 44 and 50
- Males: LH, FSH, prolactin, inhibin, testosterone on PNDs 28, 40, 50, and 61

Results from this study would demonstrate whether fluoxetine is associated with an effect on the HPG axis in juvenile rats.

Attachment 2. Proposed Rat Testicular Study

Purpose: to characterize the development and potential reversibility of testicular toxicity (ie, neurohormonal and histopathologic evaluations) in male juvenile CD rats administered fluoxetine

Dose Levels: 0, 10, and 30 mg/kg

Dosing Schedule: daily

- 2 groups/dose level dosed from PND 21 to PND 55
- 2 groups/dose level dosed from PND 21 to PND 70
- 2 groups/dose level dosed from PND 21 to PND 91

Neuroendocrine assessment on PND 55, 70, 91 and 181

- LH, FSH, testosterone, inhibin b

Pathology at each scheduled necropsy (PND 55, 70, 91 and 181)

- Organ weights (absolute): testes, prostate
- Histopathologic evaluation of testes, prostate, seminal vesicles, and epididymis

Results from this study will characterize the development of testicular lesions, and the reversibility of these findings at multiple time points; and potentially identify specific cellular targets and/or neurohormonal mechanisms involved in the development of these lesions.

Attachment 3. Clinical Evaluation of the Effects of Fluoxetine on Sexual Maturation in Children

Lilly has the opportunity for participation in a prospective placebo-controlled study that is planned by an external investigative group and is being funded by the National Institute of Mental Health (NIMH) in the U.S. This study is the best option to explore possible effects of paediatric fluoxetine treatment on sexual maturation. It is Lilly's understanding at this time that it contains the following design criteria:

- Initiate study with approximately 500 children, ages 8 to 12 years of age, with diagnoses of major depression
- 6 weeks of cognitive behavioural therapy (CBT) is first phase of study
- Patients with inadequate response after the 6 weeks of CBT (estimated to be N=360) will be randomized to 12 weeks of one of the following treatment groups:
    - Continued CBT alone (N=120)
    - CBT plus placebo treatment (N=120)
    - CBT plus fluoxetine treatment (N=120)
- Possibility for a longer-term follow-up (up to 24 weeks*)
- Includes Tanner Staging evaluation at 0, 12, 24 weeks*

Lilly's proposal to this external investigative group will be to evaluate the percentage of patients that progress at least one Tanner Stage in 12 weeks and after 24 weeks*, recognising that this will probably be a secondary endpoint in the study. One-sided 97.5% confidence intervals will be created for each treatment group to allow a clinical evaluation of the potential association of fluoxetine and delayed puberty.

* Lilly is further investigating the possibility to have longer term evaluations at 52 and / or 104 weeks.

Annexe VII

RMS

Assessment Report

Post-licensing commitment to assess sexual maturation in children

CLINICAL

Prozac

(fluoxetine)

UK/H/0636/001,003

Applicant: Eli Lilly

Start of the procedure:	14 September 2009
Date of this report:	9 September 2009
Deadline for comments:	

1 EXECUTIVE SUMMARY AND RECOMMENDATIONS

In 2006 the indication of Prozac™ was extended to include the treatment of children and adolescents aged 8 years and above suffering from moderate to severe major depressive episodes unresponsive to psychological therapy after 4-6 sessions.

As non-clinical data in rats had identified concerns regarding effects on sexual development, growth, and testicular toxicity the MAH undertook as a Postlicensing Commitment/Follow-up Measure (FUM) to conduct further preclinical studies and to clinically evaluate possible effects of fluoxetine treatment on sexual maturation in humans.

The MAH has conducted the required preclinical studies, confirming a delay in sexual maturation in rodents but apparently failing to elucidate a causal mechanism for this effect.

With respect to clinical evaluation, the MAH undertook to use registries in some EU Member States - if such registries could be identified - and to participate in a prospective placebo-controlled study of children with MDD which was to be performed by the NIMH (the TADS Jr study) and to explore possible effects of fluoxetine treatment on sexual maturation by protocol amendment.

The MAH could not identify any registries that might be used and brought forward various reasons for not setting up a prospective registry. Now the TADS Jr study will not be conducted because of lack of funding by the NIMH, and consequently the exploration of possible effects of fluoxetine treatment on sexual maturation as part of this study will not be feasible. The MAH therefore requests that the post-authorization commitment to clinically evaluate the effect of fluoxetine on sexual maturation to be considered fulfilled.

The RMS agrees that any clinical study to investigate the effects of fluoxetine on sexual maturation would be forbiddingly hard to conduct and difficult to interpret. The RMS therefore recommended accepting the company's request that the FUM to clinically evaluate the effect of fluoxetine on sexual maturation be considered fulfilled.

2 BACKGROUND

On 1 June 2006, following a European referral procedure article 6(12) of Commission Regulation (EC) No1084/2003, a positive opinion was adopted by the Committee for Medicinal Products for Human Use (CHMP) to extend the use of Prozac in combination with a concurrent psychological therapy to the treatment of children suffering from moderate to severe major depressive episodes unresponsive to psychological therapy after 4-6 sessions.

Non-clinical data in rats and mice submitted as part of the procedure had identified concern regarding effects on sexual development, growth, testicular toxicity and potential long-term neurobehavioural effects. Consequently, the MAH undertook as a follow-up Measure (FUM) to further investigate in juvenile rats the effects of fluoxetine on emotional behaviours, to explore the mechanism for and the reversibility of the testicular effects and to assess effects on the hypothalamic-pituitary-gonadal (HPG) axis during sexual maturation.

4.2 Data from literature

The MAH performed a literature search which did not reveal any published human studies relating to antidepressants and effect on puberty or sexual maturation. One publication was identified discussing four children with decreased growth during therapy with SSRIs (Weintrob et al, Arch Pediatric and Adolesc Medicine 2002, 156(7),696-701)

Assessor's comment

The assessor's literature search did not identify any additional studies or case reports relating to any impact that antidepressants may have on puberty or sexual maturation, nor any publications relating to any impact depression itself may have on puberty/sexual development.

5 OPTIONS FOR OBTAINING FURTHER CLINICAL DATA

The MAH has explored and judged as unfeasible various ways of obtaining additional clinical data with respect to sexual development. Table 5 summarises the options explored and the reasons for rejecting them.

Table 5: Options explored for obtaining additional data for sexual development

Option	Reason for rejection
Clinical trial specifically designed to investigate sexual development	Recruitment challenges arising out of public discussion regarding the use of SSRIs in the child and adolescent population
Data collection as part of NIMH-sponsored TADS Jr trial	TADS Jr trial will not be conducted as now not sponsored by NIMH
Use of existing registries to obtain retrospective data	Existing registries do not include relevant data; problems with privacy restrictions in some countries
Set up a UK registry to obtain prospective data	Most prescriptions for fluoxetine are for generic products which do not necessarily contain paediatric indication and relevant warnings.
GPRD study	Tanner stages not recorded in GPRD can not be followed for children ?
European College of Neuropsychopharmacology (ECNP) study	Study has been amended to investigate risperidone only

A discussion of the reasons is contained in the MAH's FUM response document. The reasons for rejecting the conduct of a clinical trial were extensively discussed as part of the referral procedure and are not repeated here.

The MAH now requests that the post-authorization commitment to clinically evaluate the effect of fluoxetine on sexual maturation to be considered fulfilled - without conducting any clinical evaluation at all.

6 RECOMMENDATIONS

The RMS agrees that any clinical study to investigate the effects of fluoxetine on sexual maturation would be forbiddingly hard to conduct and difficult to interpret. The RMS therefore recommendeds accepting the company's request that the FUM to clinically evaluate the effect of fluoxetine on sexual maturation be considered fulfilled.