NPA
NATIONAL PARENTS ASSOCIATION
Protecting Parents Rights, Preserving The Family

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SUBMISSION TO QUEBEC'S BILL 125:

An Act To Amend The Youth Protection Act And Other Legislative Provisions

February 22, 2006

Ms. Denise Lamontagne
Secretary to the Commission on Bill 125
By email

Dear Ms. Lamontagne,

The National Parents Association (NPA) was formed in response to the systemic abuse of Quebec parents. Our concern with Bill 125 is that, in its current form, it would increase the abuse and make it virtually impossible for parents to protect their rights. Here are the facts:

ABUSE OF PARENTS:

Every day parents across Quebec are pressured or forced to place their children in psychiatric and psychological programs by schools and agencies such as the Children's Aid Society. These programs typically result in children being labeled "mental ill" and prescribed stimulants (such as Ritalin), antidepressants and other drugs. The results are appalling:

- In just a five-year period the number of prescriptions of stimulant medications doubled and in 2004 were 541,244 or 62 prescriptions per hour.
- During the same period the number of children on these drugs escalated from 12,416 to 19,944 – almost 20,000 kids on stimulants alone. Yet these drugs have been repeatedly linked with adverse reactions such as suicide and liver damage.

THE THREAT OF BILL 125:

According to the Quebec Informed Consent Act *"...the doctor must reveal all the necessary information, including the nature and severity of the medical intervention, possible complications, major risks, and any other particular or uncommon risks."* In the case of parents and schools this is already violated in a routine basis because parents are not given the "necessary information" they need in order to make an educated decision.

It is the responsibility of those administering treatment to inform parents, who are the decision makers when it comes to children, of such information. The problem is that, even with the existing laws, they do not. This is a violation of their fundamental rights.

Just on this point parents are at a significant disadvantage in dealing with schools, etc. simply because of a lack of adequate data upon which to decide. The problem is compounded when the "system" then turns against them and starts applying pressure (and even threats). Bill 125 would essentially eliminate whatever meager protection they currently have.

Many parents who refuse psychiatric treatment for their children, which is their right under law, are forced to deal with enormous pressure to get them to comply. This is illegal and was acknowledged as such by the Quebec Education Department in the media (*Montreal Gazette,* 23 February 2005):

> **No school can force a child to take medication, the Education Department said yesterday as it continued to investigate the case of a child suspended for bad behaviour after failing to take his Ritalin, a drug widely used to treat attention deficit disorder. Schools are mandated to educate children – that's the law, Johanne Methot, an Education Department spokesperson, said yesterday. "But you can't oblige a child to take Ritalin or any other medication. That's up to the parents. Even when a child is bothering others, the school is still obliged to offer him services," she added. "It's up to the school to find the means and the solution, but there have to be educational services."**

Yet despite existing legal protections, parents <u>are</u> coerced, as the following sample cases will illustrate:

1. **Boy kicked out of school:** The *Gazette* story quoted above was published because of a 7-year old boy named Anthony Fournelle, who was sent home for three days because he exhibited "unacceptable behaviour" when he stopped taking his prescription drugs (this typically occurs as a result of withdrawal from the medication).
2. **Mother forced to drug kids:** A Montreal businessman told us of a mother who was forced by the school to place all four of her children on psychiatric drugs or they would be kicked out of school.
3. **Fireman threatened:** In December 2005, we received a call from a fireman from Laval who was desperate for help. He had been sent a letter by his son's school threatening that if the boy didn't go on Ritalin, he would be kicked out of school.
4. **Mother pressured at work:** Just last week we received a call from a lady who works for a telephone company who complained that the school was "calling all over the place," including her work, for her to drug her child.
5. **Quebec City family threatened:** A lady from Quebec City received a call from the police stating that they had received a complaint against her husband, that he had physically abused his daughter. When the father arrived, the Children's Aid Society was waiting for him (there were no actual charges). All they talked about for about two hours was how good Ritalin was in an effort to agree to drug his daughter.

A Montreal human rights group received no less than 13 cases of parents who were forced to drug their kids by schools from a <u>single</u> advertisement.

So, not only are existing legal safeguards abused (through lack of enforcement), with Bill 125 they would essentially be eliminated giving parents no chance whatsoever.

With this bill, parents would be reclassified as "abusers" if they exercise their fundamental rights to refuse treatment (see below).

THE LINK BETWEEN THE CHILDREN'S AID SOCIETY AND PSYCHIATRIC TREATMENT:

It is well known that majority of children who are taken from their parents by the CAS are subjected to psychiatric treatment. A study published in the *Canadian Journal of Psychiatry* in September 1994 and revealed some alarming results regarding youth who enter the system:

- The files of 25 youths with behavioural problems were examined to extract all relevant data. The youths averaged 9 years in treatment.
- Each youth received interventions an average of 19 times from 15 different agencies and each intervention lasted an average of 7 months.
- Before entering the system only 37% of the youths were considered to have behaviour problems; afterwards that number jumped to 100%.
- As for serious behavioural difficulties (problems at home, at school and in the community), only 9% of all youth had them before entering the system compared to 56% afterwards. That's an increase of 620%.

THE DANGER OF BILL 125:

Bill 125 seeks to amend the *Youth Protection Act*, which is the law that was originally designed to protect children from abusive families, by allowing the CAS to remove them from the home. The law already has significant power as evidenced by the more than 13,000 children in the hands of the CAS in Quebec. However, if Bill 125 passes into law it will increase the systemic abuse to levels never before seen in this province. Here's why:

A major reason why the CAS takes children away from their families is neglect (such as not providing sufficient food, a safe environment at home, etc.). No one will argue that this is a worthwhile cause. However, Bill 125 seeks to redefine "neglect" as follows:

> **...failing to give the child the care required for the child's physical or mental health, or not allowing the child to receive such care...**

Under this provision, all the rights parents have at this time under law would be completely eliminated: If a school, psychologist, psychiatrist, etc. wanted to drug a child, the parents would have to agree or be guilty of "neglect" and risk losing their children to the system.

The Bill also allows for virtually unlimited powers for the CAS in these matters. For example, if a "report" was received by the CAS a child can be taken away from his or her family without any judicial process, as can be seen in the following section of Bill 125:

> **If the director accepts the report, he may take immediate protective measures to ensure the security of the child for a maximum period of 48 hours even before making an assessment to determine if the security or development of the child is in danger...If the circumstances warrant it, the director may also take immediate protective measures for a maximum period of 48 hours at any point during the intervention, whether or not a new report has been made.**

Bill 125 goes even further in hampering the rights of families by potentially cutting all communication to and from a child. For example, it says that the Director has the power of:

1. **restricting contact between the child and his parents;**
2. **prohibiting the child from contacting certain persons designated by the director, or prohibiting those persons from contacting the child;**
3. **ordering a person to ensure that the child and his parents comply with the conditions imposed on them and to inform the director if the conditions are not complied with;**
4. **imposing any other measure he considers necessary in the interest of the child.**

Under these provisions a child could not even contact legal council of his or her choosing. It would also potentially prevent any third party from becoming involved without a conflict of interest in the case.

Moreover, the above provisions give the CAS virtually unlimited powers – great than those of any existing law enforcement or other agency. The phrase *"imposing any other measure he considers necessary in the interest of the child"* is particularly troubling. This could potentially include anything.

Additionally, Bill 125 in its current form violates Canadian and international laws and statutes including the Quebec Informed Consent Act, Canadian Charter of Rights and Freedoms and the U.N. Declaration of Human Rights.

ESCALATING WARNINGS ON PSYCHIATRIC DRUGS:

As for the so-called "mental health treatment," there is substantial evidence that shows that the treatment is worse than whatever illness it was meant to cure. Over the past couple of years there have been many official warnings issued internationally. For example:

- **September 22, 1999:** Health Canada issued a warning about Cylert, a prescription drug formerly given to children to treat "mental disorders." After being given to thousands of children across Canada the drug was eventually taken off the market.
- **February 3, 2004:** Health Canada issues a warning about giving antidepressants to those under the age of 18. On June 3, 2004 they followed up with an even stronger warning.
- **October 15, 2004:** The U.S. Food and Drug Administration (FDA) issued their strongest warning (called a "black box") on all antidepressants.
- **December 17, 2004:** The FDA required that a new warning be added to the packaging of the "ADHD" stimulant, Strattera: *"The labeling warns that severe liver damage may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients."*
- **February 9, 2005:** Another psychiatric drug given to kids, Adderal, was suspended from the market by Health Canada *"concerning the association of sudden deaths, heart-related deaths, and strokes in children and adults..."*
- **June 28, 2005:** The FDA announced the identification of possible safety concerns with Concerta, Ritalin and other drugs used to treat children diagnosed ADHD (Attention Deficit Hyperactivity Disorder) such as visual hallucinations, suicidal ideation, psychotic behavior, as well as aggression or violent behavior.

Here are a few highlights from just the past few days:

- **February 17, 2006:** International media coverage revealed that the drug Strattera, often given to children, was connected to 130 reports of suicide in a single month.
- **February 19, 2006:** A report by the Government of the state of New Hampshire exposed that two thirds (66%) of all drug overdose deaths resulted from prescription drugs.
- **February 20, 2006:** U.S. journalist Evelyn Pringle reported that *"According to the latest investigation by the FDA, in the four year period between 1999 and 2003, there were twenty-five deaths in persons using Attention Deficit Hyperactivity Disorder (ADHD) drugs, 19 of which were children. Officials also acknowledged that more than 50 cases of cardiovascular problems had been reported, including stoke, heart attack, hypertension, palpitations and arrhythmia."*

CONCLUDING REMARKS:

We are not targeting the Children's Aid Society. There are many people in the Society that are doing a great job protecting children. The issue is that the CAS will be made an unwitting accomplice in greater abuses of parents' rights in this province (as will the schools). It is primarily for this reason that Bill 125 must be prevented from passing in its current form.

Public surveys, conducted in different cities and towns in Canada and the United States, revealed that better than 80% of the population is opposed to the labeling of children as "mentally ill" and prescriptions drugs as a remedy. Perhaps this is a major reason why the U.S. Government is currently passing a law that will make it illegal for schools or other agencies to force parents to treat their children.

In Quebec we have some of the most humane laws in the world – legislation that has resulted from decades of work by people of good will. We urge you: Let's not throw that all away with a single bill.

Very truly yours,
[Transmitted Electronically]

George A. Mentis
President

thenewstribune.com

Tacoma, WA - Wednesday, February 22, 2006

British report finds new risks of ADHD drug

M. ALEXANDER OTTO; The News Tribune
Last updated: February 20th, 2006 06:44 AM (PST)

There are new safety concerns about the Attention Deficit Hyperactivity Disorder drug Strattera, widely used in Europe and the United States. It's already been linked to rare cases of liver damage and suicidal thoughts and behaviors.

British authorities have associated Strattera with seizures and a potentially dangerous lengthening of the time between heartbeats, called QT interval prolongation, in a handful of the more than 3.7 million people who have used the drug since it hit the market in November 2002.

The warnings are based on an internal report by the British Medicine and Healthcare Products Regulatory Agency, the United Kingdom's equivalent to the U.S. Food and Drug Administration.

The report, which has not been made readily available to the public, was obtained by The News Tribune after a Swedish court ordered it released to a drug-safety activist in that country.

Though the number of seizures and heart-rhythm problems is small, the British agency said problems could be under-reported, and warned doctors and consumers Thursday that the drug should be used with caution in people prone to such problems. In particular, they warned about potential heart problems when Strattera is combined with antidepressants like Paxil and Prozac.

British authorities are updating the drug's label in that country to warn of the possible problems.

Overall, though, the agency concluded Strattera still offers more benefits than risks.

Though the FDA and Strattera's maker, Indianapolis-based pharmaceutical giant Eli Lilly, are aware of the issues raised by the British, they are being handled differently in this country.

No warnings are planned at the moment to U.S. doctors and patients, and the U.S. label for Strattera contains no warning of seizures.

At the FDA's request, Lilly inserted a five-word note about the "very rare" heart problem on page 17 of the drug's 25-page label in January.

The reason there is less concern on this side of the Atlantic ocean is that, unlike the British agency, Lilly "hasn't been convinced" that the problems aren't caused by underlying illnesses, said Dr. Albert Allen, Lilly's medical director for Strattera, which earned the company about $400 million in 2005.

Europeans, Allen noted, are more skeptical of ADHD diagnoses and so are more quick to sound the alarm about potential ADHD drug problems.

ADHD is suspected when people have a harder time than others their ages paying attention, sitting still or controlling impulses. To be diagnosed, those tendencies must interfere with work, school or other activities.

Skeptics say the condition is overdiagnosed and that drugs are used to subdue normal, but often disruptive, rambunctiousness in the classroom and workplace.

The Strattera report comes at a time when the FDA is scrutinizing the safety of all ADHD drugs, including some associated with significant mental and physical side effects.

On Feb. 9, an FDA panel advised that Ritalin, Concerta and other stimulant ADHD drugs include a strong warning of the possibility of heart attacks, strokes and sudden death. Strattera is not a stimulant and wasn't included in the recommendation.

In March, the panel will reconvene to consider the drug's psychiatric side effects.

The British findings "will be another factor in FDA's" review of the drugs, said agency spokeswoman Susan Kruzan.

British investigators found 220 seizure reports among Strattera users through May 2005, which makes seizures "the most commonly reported serious" safety problem.

The red flag the British raised is based mostly on the four seizure reports that could not be convincingly pinned on underlying medical problems. Patients in those cases had no prior seizure history.

The agency noted, though, "there's a number of reports" in which the drug is associated with an aggravation of pre-existing seizure disorders.

There have been 33 cases reported of the heart-ryhthm problem. The possible role of Strattera in at least seven "could not be excluded," the report said.

"No other alternative causes could be identified" in two cases where patients took normal doses; one case was related to an overdose.

Fifteen patients with the heart-rhythm problem recovered after stopping the drug, the report noted. The heart issue seemed most likely when the drug is taken with antidepressants, which restrict the body's ability to break down Strattera.

British authorities also found 130 cases of potentially severe liver problems whose relationship to Strattera "could not be completely ruled out."

The 431 reports of suicidal thinking or behavior could not be clearly linked to the drug because patients had histories of depression and other problems.

But "one cannot exclude the possibility that (Strattera) may have exacerbated the individual's underlying condition," the report noted.

Strattera's label was updated last fall in Europe and the United States to warn of rare suicidal behavior risks.

Strattera, the only ADHD drug that is not a stimulant, typically is used as an alternative to drugs like Ritalin, which have been on the market much longer and whose safety records are more clearly known, said Dr. Brian King, director of Child and Adolescent Psychiatry at Children's Hospital and Medical Center in Seattle.

Strattera offers two advantages: as a nonstimulant, it has no abuse potential, plus it stays in the body for a few hours longer, so ADHD control is extended into the evening if necessary, Allen said.

More online

Strattera's label is at www.strattera.com/hcp/1-0_strattera_homepage.jsp under "full-prescribing information."

The British Strattera report is at www.thenewstribune.com/documents/news/strattera_report.pdf .

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Originally published: February 20th, 2006 02:30 AM (PST)

OpEdNews.com

Original Article at
http://www.opednews.com/articles/opedne_evelyn_p_060219_ssris___nightmares_b.htm

February 19, 2006

SSRIs - Nightmares by the Dozen

By Evelyn Pringle

Gail and Rhonda Schmidkunz describes their 20-year-old son Zach as an "All American Boy," with no criminal record and no history of angry outbursts or losing his temper. However, this non-violent, law-abiding "All American Boy" is now serving a 35-year prison sentence for killing a friend after he abruptly stopped taking the SSRI, Zoloft.

In an all too familiar story by now, a family doctor sent Zach home with samples packs of Zoloft because he was depressed, without advising Zach about any of the adverse events he might experience. He took the pills for 21 days and then stopped because he felt the drug was not helping.

"Zach stopped taking the Zoloft on a Friday," Gail notes. "By Saturday, there were symptoms of discontinuation syndrome," he recalls. "They continued to intensify through Monday when the murder happened," he said.

Without knowing about the problems with the drug, Gail explains, Zach missed the signs that might have warned him that he was having a withdrawal reaction from Zoloft.

During a chat session on the internet with a friend, Zach said that he was depressed and saw no reason to live and was considering suicide. The friend was a girl and offered to come over and talk. During the visit, she said that depressed people usually kill themselves which apparently set Zach off.

He drove off in a rage, and three hours later when his head began to clear, he thought he remembered shooting someone.

Zach went and turned himself in to police, Gail said, but he did not know that he had murdered the girl until he was charged.

The rage that he felt was like nothing he ever felt before, Zach told his father and mother. "The intensity was indescribable," he told Gail.

Like so many other people who have committed violent acts while on SSRIs, Zach said, "it was like watching himself in a movie going to get the shotgun."

"He had this over-powering urge to shoot something and tried to stop himself but was powerless to do so," he told his parents.

At the criminal trial, Dr Maureen Hackett, a forensic psychiatrist from Minneapolis, who had evaluated Zach, testified that abruptly stopping the drug had lead to "a discontinuation syndrome rage and insanity that caused the homicide."

However, with the help of a Zoloft manual provided by Pfizer, Gail says, the "prosecutor convinced the jury my son was a monster and that Dr. Hackett was a hired gun bought for a price and would tell the court whatever we wanted her to say."

"What is important in this case," he points out, "is that we had an expert that proved that discontinuation syndrome is real and established in the medical community."

Gail urges everyone who has had an adverse reaction to an SSRI to contact their lawmakers and tell their story.

"Somehow," he says, "we need to pressure the FDA and the drug companies to come clean about the dangers of these drugs and make them responsible for the lives their drugs have destroyed."

Joyce Storey's son, Brian, was also called an "All American Boy" in the media, and according to Joyce, he was.

This mother's "All American Boy" is now serving life in prison without the possibility of parole for a murder he committed while on Zoloft

Brian was 17-years-old when the family doctor diagnosed him with depression and put him on Zoloft. Once again, the family was not warned about any side effects of the drug and in fact, the doctor told Joyce, "even if a person is drinking or doing drugs, that Zoloft works well with them."

Brian killed a woman five days after he began taking the drug. Authorities found no illegal drugs in his system, only Zoloft.

The psychiatrist that examined him after the crime, a faculty member at Yale University, Dr James Merkangis, testified that Brian had suffered a manic reaction to Zoloft.

Like so children who commit violent crimes while on SSRIs, Brian told Dr Merkangis that his recollection of the crime "was like being in a dream."

Six months after Brian's arrest, another boy at his high school, Jeff Franklin, attacked his parents and three of his brothers and sisters with an ax while on Prozac.

"Both of his parents died and Jeff is now serving two life sentences," Joyce said. "This is not a coincidence," she warns, "there is a common denominator, teenager, severely depressed, on an SSRI antidepressant."

According to Joyce, "there are 6 to 8 million children on these drugs."

"The question is why are we handing these drugs out like candy," she wants to know.

"The answer is a $17 billion a year business," she says.

In Washington state, on April 15, 2001, 16-year-old Cory Baadsgaard took a hunting rifle to school and held a teacher and 23 classmates hostage for 45 minutes.

A few months earlier, Corey had been diagnosed as having a social anxiety disorder, and was prescribed Paxil by the family doctor. When Paxil did not seem to work, the doctor upped the dose.

A few months later when Paxil still did not seem to work, the doctor took Corey off the drug and placed him on another SSRI, Effexor, with instructions to gradually increase the dose to 300 milligrams over 3 weeks.

The day that Corey took the first full 300 milligram dose, he did not feel well so he stayed home from school and went back to bed. That evening he woke up in a juvenile detention center.

Corey had no idea what he had done. "I asked one of the members of the juvenile detention center and I found out that I had taken my high-powered rifle that I use for hunting to my third period class, took 23 of my classmates hostage and teacher hostage," he said.

Cory has no recollection of his actions that day although he had plenty of time to try and remember as he sat in jail for 14 months before being released based on testimony by psychiatrists explaining the adverse effects of Paxil and Effexor.

Before this incident, Corey had never been violent and he has never been violent since.

One of his friends who watched Corey at school that day described his actions to his father, Jay. "Cory was yelling" he said, "and then he just stopped, looked down and saw the gun in his hand and woke up."

Delnora Duprey is a grandmother who mourns the loss of the years since she has seen her grandson Christopher play ball, ride a bike, talk on the phone, or run in to ask, "hey, grandma,

what's for dinner?"

According to Delnora, Chris is a tall, thin quiet boy, well-liked and respectful to everyone, "who loved his family dearly, and had hopes and dreams for a future."

The family's nightmare began when at 12-years-old, Chris was diagnosed with depression, and "placed on medication that was never tested on children and never meant for their use," according to Delnora.

After Christopher became depressed and threatened to commit suicide, he was hospitalized and put on Paxil. A short time later his father sent him to South Carolina to live with his paternal grandparents. By all accounts, Christopher liked living there and truly loved his grandparents.

When it came time to refill the Paxil prescription, his grandparents took him to their family doctor who had no Paxil and sent Christopher home with a bag of sample packets of Zoloft instead, and wrote the instructions for use on the outside of the bag.

For the record, in Pfizer's 2004 Annual Report, under product description, it says that Zoloft is not approved for treating pediatric patients. Christopher was a 12-year-old child at the time he was sent home with a bag of Zoloft.

He was never weaned off Paxil before the drugs were switched and Paxil has a well-documented history of side effects itself. When Christopher complained about how the medication made him feel, the doctor upped the dose to 200 milligrams

About 48 hours later the 6th grader shot and killed his paternal grandparents as they slept and burned the house down around them.

Christopher was tried as an adult, and despite testimony by two psychiatrists that he was "involuntarily intoxicated" on Zoloft at the time of the crimes, the jury found him guilty.

Prior to being placed on SSRIs, Christopher "was a sweet boy who never hurt himself or anyone else before," she added.

A child like Christopher could not have possibly known what he was up against in the courtroom, when it came to convincing members of the jury of his guilt or innocence depending on their understanding of the adverse effects of Zoloft.

Realizing how costly it would become if a jury were to blame Zoloft for the crimes, Pfizer got involved behind the scenes and provided the prosecutor with guidance on how to cross-examine expert witnesses like Dr Anne Blake Tracy and Dr Peter Breggin, who were scheduled to appear and testify on Christopher's behalf.

State Prosecutor, John Justice, admitted during a court hearing that Pfizer had provided him with information to help him prepare for the trial. As it turns out, the company had provided FDA reports along with instructions for their interpretation and presentation in court, in addition to records of previous testimony given in other cases by Christopher's expert witnesses.

South Carolina has a minimum 30 year prison sentence for adults who commit murder. Christopher's aunt, Melinda Pittman Rector, the daughter of his murdered grandparents, appeared at the sentencing hearing and begged the judge for leniency, saying that her parents would want the court to show mercy toward their grandson.

Even after listening to his aunt's plea for mercy, the judge sentenced Christopher to the full 30 years in an adult penitentiary.

In a letter written in jail, Christopher describes the same recollection about the night he killed his grandparents that so many other children on SSRIs have described when committing violent crimes.

"Through the whole thing, it was like watching your favorite TV show," Christopher wrote, "you know what is going to happen but you can't do anything to stop it."

Last summer the South Carolina Supreme Court agreed to hear Christopher's appeal and needless to say, his family members, as well as advocates from all over the country are hoping for a reversal of the guilty verdict.

But the headlines with stories about children committing violent acts due to the adverse effects of SSRIs seem like they will never end.

On January 26, 2006, a psychologist on Court TV reported that Cody Posey, the 14-year-old child who killed his parents and his sister in the summer of 2004, was on Zoloft at the time that of the murders.

Cody started taking Zoloft on April 20, 2004 and killed his family members on July 5, 2004. His father was the range manager for the well-known TV reporter Sam Donaldson.

Evelyn Pringle

For information on justice for injured go to

Lawyers and Settlements

http://www.lawyersandsettlements.com/articles/adhd_fda.html

"Scoop," INDEPENDENT NEWS http://www.scoop.co.nz/stories/HL0602/S00149.htm

Evelyn Pringle: ADHD Drugs - Cash Cow For Pharma

Wednesday, 15 February 2006, 11:21 am
Opinion: Evelyn Pringle

ADHD Drugs - Cash Cow For Pharma

By Evelyn Pringle
February 13, 2006
lawyersandsettlements.com

"Our society viewed with loathing those who 'pushed' stimulant drugs on children," says child psychiatrist Dr Peter Breggin. "Yet today, there are more children taking Ritalin and amphetamines from doctors than ever received them from illegal pushers," he says.

"Parents and teachers and even doctors have been badly misled by drug company marketing practices," he warns. "Drug companies have targeted children as a big market likely to boost profits and children are suffering as a result."

The marketing campaign referred to by Dr Breggin has proven to be extremely successful At a February 10, 2006, FDA advisory committee hearing, it was reported by Dr Andrew Mosholder, a medical officer in the FDA's Office of Drug Safety, that about 2.5 million children in this country between the age 4 and 17, currently take ADHD drugs. A government survey found 9.3% of 12-year-old boys, and 3.7% of 11-year-old girls are on the drugs, he said.

In 1980, the so-called Attention Deficit Disorder (ADD), which amounts to little more than a list of behaviors, was voted into existence as a mental illness by the American Psychiatric Association, so it could be included in the psychiatric billing Bible known as the Diagnostic & Statistical Manual for Mental Disorders, DSM.

In 1987, an H was added to the label and the illness became, "Attention Deficit Hyperactivity Disorder." Within one year, 500,000 children in the US were diagnosed with this cash-cow disorder.

A few years later, it was classified as a disability and a cash incentive program was initiated for low-income families with children diagnosed with ADHD. A family could get $450 a month for each child diagnosed with the disorder, and the cost of treatment and medication for low-income children would be covered by Medicaid.

Then in 1991, schools began receiving educational grants of $400 annually for each ADHD child. The same year, the US Department of Education classified the disorder as a handicap, which required special services to be provided to each disabled child.

By 1996, close to $15 billion was spent annually on the diagnosis, treatment, and study of the so-called attention deficit disorder.

Over roughly the past 2 years, public health officials in the US, Canada and the UK have issued warnings about previously known, but undisclosed, risks associated with the stimulant drugs used to treat ADHD.

In September 2005, Canadian public health officials asked drug makers to turn over data from all clinical trials and post-marketing reports for the medications by the end of 2005 to be reviewed in 2006.

The February 2006 hearings, represent the third time in 2 years that the FDA has addressed the heart related side effects of ADHD drugs. This whole charade is beginning to look more and more like a repeat of the Vioxx debacle.

Foot-dragging earned the FDA a rebuke this month from Senator, Chuck Grassley (R-Iowa), chairman of the Senate Committee on Finance, which has exclusive jurisdiction over the Medicare and Medicaid programs which, according to Sen Grassley, pay hundreds of millions of dollars for prescription drugs each year, including drugs used to treat ADHD.

In a February 6, 2006, letter to acting FDA commissioner, Dr Andrew von Eschenbach, Sen Grassley said in part, "I remain concerned that while both psychiatric and cardiovascular risk signals have cropped up across this class of drugs this past year, it appears that FDA is just now beginning to 'discuss approaches' for studying these risks."

"More specifically," Sen Grassley wrote, "I question why it has taken nearly an entire year for FDA to begin to address these concerns given the serious nature of the adverse events associated with these drugs."

In the letter, Sen Grassley noted that the FDA had recently announced upcoming meetings of two different advisory committees to examine different ways of studying adverse events related to ADHD drugs when studies showing the risks had already been done. He accused the FDA of taking a slow approach to regulating the drugs.

As examples of risk already established, Sen Grassley pointed out that in February 2005, cardiovascular concerns raised in adverse event reports led Canadian health officials to suspend market authorization of Adderall XR for six months due to a review of safety information from Shire that showed 20 international reports of sudden death and that in 2004, the FDA required Shire to include the risk of sudden death on the label.

He noted that last summer, the safety of the drugs was called into question when the FDA publicly stated that it had concerns about psychiatric side effects from the use of Concerta and specifically stated on its website that it had "identified two possible safety concerns with the methylphenidate drug products: psychiatric adverse events and cardiovascular adverse events."

Sen Grassley also pointed out that in September of 2005, the FDA had issued an alert to healthcare professionals regarding the use of Strattera, after reviewing data showing an increase in suicidal thoughts in 12 separate studies, and directed Eli Lilly, to "revise the labeling...to include a boxed warning and additional warning statements regarding an increased risk of suicidal thinking in children and adolescents."

As an added pressure, Sen Grassley asked for a complete list of names of participating panel members and a complete list of conflict disclosures for both the February 9-10 2006, advisory committee and the March 22, 2006, Pediatric Advisory Committee.

The latest report made public by the FDA at the February 2006 hearings, said that between 1999 and 2003, there were twenty-five deaths in persons using ADHD drugs, including the deaths of 19 children. Officials also admitted to receiving reports of more than 50 cases of cardiovascular problems, including stoke, heart attack, hypertension, palpitations and arrhythmia.

The report only covers a 4 year period and because only between 1 and 10% of adverse events are ever reported, the numbers above represent a gross understatement of actual cases of harm from these drugs.

The report could not have considered the increase in emergency room visits associated to Ritalin abuse alone over the past decade. According to the Drug Abuse Warning Network, while there were 271 Ritalin-related emergency room visits in 1990, there were 1,478 Ritalin-related visits in 2001.

According to the National Institute of Drug Abuse, in 1999, some 165 Ritalin-related poison calls were made in Detroit; 419 cases were reported in Texas, and only 114 of those cases involved intentional misuse or abuse.

While the FDA foot-dragging has continued for years, the drug companies have been making a fortune by pushing the exact same pills that have been pedaled on the street for 50 years under names like black beauties, yellow jackets, uppers, white crosses, and bennies.

These are the exact same drugs that were handed out like candy in the 1960s and 1970s, when prescribed under the guise of diet pills, and used by truckers to stay awake, by entertainers and athletes to perform, and by people who wanted to party for days in the general population, until they were banned.

The drugs contain the exact same amphetamine that was THE main ingredient in the once popular "B-12" injections given weekly to wealthy patients in doctor's offices all over the country until they were banned.

So here we are in 2006, with pharma making a killing by selling dangerous drugs that have been outlawed time and time again. What kind of profits are we looking at? As of September 2005, Walgreen's prices for a 30 day supply for the lowest dosage of the top selling drugs were:

- Methylphenidate (generic Ritalin) $15.69
- Ritalin (brand name): $27.79
- Amphetamine/dextroamphetamine (generic Adderall): $47.09
- Adderall (brand name): $94.49
- Concerta: $103.99
- Strattera: $123.99

According to Dr Mosholder, since March 2002, prescriptions written for adults rose by 90%, to about 1 million a month as of June 2005, and to about 2 million a month for children.

If the three million people are on the lowest priced Ritalin, a round number of $30 per month times 3 million would create over $1 billion a year for the drug company alone. Then add in the medical and psychological professional fees and the grand total easily exceeds $2 billion per year. And if the patients

are on Adderall, the cost of the drug triples to over $3 billion a year.

The money earned by prescribing shrinks is nothing to sneeze at either. A 2003 American Psychological Association study on "financial disincentives" for psychotherapy found that doctors could earn about $263 an hour for doing three 15-minute "medication management" sessions, verses about $156 for a single 45 to 50-minute therapy session. That represents a pay cut of 41% an hour for doing therapy only, the study determined.

However, hopefully we are about to see a dwindling of the above profit margins.

On February 10, 2006, the Drug Safety and Risk Management advisory committee said that ADHD drugs should carry the strongest warning label that they may be linked to an increased risk of death and injury.

One of the committee members who pushed for the label, Cardiologist, Steven Nissen, said something must be done to curtail the prescription rates. "I feel strongly we need to slow the growth of utilization," he said. "When you have that kind of exposure for drugs that are suspicious, that does create a major public health concern," he added.

This legally prescribed speed is being passed around between students in schools and colleges all over the nation. A 2002 study by the University of Wisconsin estimated that one of five college students takes Adderall, many for recreational reasons.

On July 25, 2005, CBS News reported that "Adderall and Ritalin have in fact become "street drugs" at America's colleges and universities, where prescription stimulants often replace coffee and CliffsNotes as the study aids for today's college students."

According to Dr Sean Esteban McCabe, interim director of the University of Michigan Substance Abuse Research Center, a recent survey found that 6.9% of American college students have taken prescription stimulants illicitly, and up to 25% at certain elite universities with high academic pressures and admission standards.

The study canvassed students at 119 four-year colleges and universities nationwide and was published in the January 2005 issue of the journal Addiction. The specific focus of the study was the non-medical use of Ritalin, Dexedrine and Adderall.

Based on his survey, Dr McCabe found that, prescription stimulant abuse tends to lead to higher rates of other drug abuse and driving while drinking.

The survey found that students who had used a prescription stimulant non-medically in the past year were 10 times more likely to report the use of marijuana, twenty times more likely to use cocaine, and 5 times more likely to report driving after binge drinking.

On December 5, 2005, the Nashville, Tennessee based newspaper, The Tennessean reported that Athletes aren't the only ones popping pills to gain a competitive edge these days.

"College students are turning to prescription stimulants such as Adderall and Ritalin to get them through late-night cram sessions, risking potential side effects and unknown long-term effects for a chance at a better grade," it wrote.

"I would say it's pretty common," says Matthew Fleischer, a senior philosophy major at Vanderbilt University. "I know people who use it; I know people who call me and ask me if I can find some for them," he told the Tennessean.

More than 50 college newspapers have already published articles describing Adderall abuse on campus according to CBS News.

For school age children, these drugs are providing a spring-board into early addiction. Over the past few years, high school students have been busted for using the legal speed all across the country.

For instance, on March 16, 2001, in Norwich Connecticut, 3 eighth-graders were hospitalized when they overdosed on Adderall at school.

On September 12, 2002, NBC TV News reported that 11 students were transported to Antelope Valley and Lancaster Community Hospital in Los Angeles California, for treatment of possible overdose from Ritalin. The school confiscated a large amount of Ritalin pills. "I would say in excess of 150," said school principal Mark Bryant.

In three separate cases in 2004, Tucson, Arizona area students were caught with Adderall. Six Catalina Foothills High School students were suspended for taking or possessing Adderall while on campus, according to reports from the Pima County Sheriff's Department reports.

Two Ironwood Ridge High School students, ages 15 and 17, were cited for exchanging Adderall in January, 2004, according to an Oro Valley, Arizona police report.

And 6 football players at Millennium High School in Goodyear, Arizona were disciplined by the Agua Fria Union High School District for taking Adderall before a game.

In both of the Tucson cases, students who had legal prescriptions for Adderall and brought the pills to school and gave them to classmates.

On October 13, 2005, a 17-year-old Waukesha, Wisconsin boy was arrested on felony charges for possession of Adderall, after the car he was riding in was stopped for a broken taillight.

On January 20, 2006, Florida Okaloosa County Sheriff Department received word that a student at Richbourg Middle School had illegally shared the prescription drug Adderall.

"Unfortunately and sadly," Sheriff Rick Hord told reporters, "the news value may not be how unusual this is but rather how common it is."

"We've had 22 cases so far that have been investigated primarily by the resource officers but in a couple of incidents by other deputies, of drugs on campus at just about every school you can name," he said.

On February 7, 2006, two Harrington, Delaware middle school students were arrested for distributing Adderall at WT Chimpan Middle School over a period of 3 months. Both students were expelled.

If children are having problems, they need therapy not speed.

William Pelham, a well-known researcher involved with clinical trials of both Concerta and Adderall, says a major study, sponsored by the National Institute of Mental Health, showed that behavioral

therapy often eliminates the need for drugs altogether.

During a one-year trial, he told The Street.com, 75% of the children who relied on behavioral treatments functioned well without the drugs. Moreover, he added, most of those children remained off the drugs a full year later.

"What this means to me is that two-thirds of ADHD kids could be taken off the medications," Pelham told Street.com. "I do think they are grossly overused as a first line of intervention," he added.

According to Dr Peter Breggin: "We are encouraging a generation of youngsters to grow up relying on psychiatric drugs rather than on themselves and other human resources."

"In the long run," he warns, "we are giving our children a very bad lesson, that drugs are the answer to emotional problems."

ENDS

Prescription pills cause half of N.H. drug deaths

AP Associated Press

February 19, 2006

PORTSMOUTH -- Prescription pills caused nearly two-thirds of the drug overdose deaths in the state last year, according to authorities.

That comes as no surprise to a 22-year-old Brentwood man who says he was addicted for three years to OxyContin, a powerful prescription narcotic and painkiller.

"I've been to hell and back," said the young man, who spoke to the Portsmouth Herald on condition his name not be used.

The man, who went to a small public high school in the area, can list several friends whose lives were ruined by OxyContin.

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"Dave, Rachel, Eli," he said. "OxyContin became a problem for my entire extended friend network. It took over us like the plague."

Methadone, OxyContin, diazepam (Valium), hydrocodone, fentanyl, morphine and other prescription medications were responsible for killing 96 of the 147 people who died of drug overdoses last year, according to Dr. Thomas Andrew, the state's chief medical examiner.

After Winnacunnet High School student Lloyd Chapin Jr. died of an overdose two weeks ago, his cousin, Seabrook Fire Chief Jeff Brown, spoke publicly about the problem.

He said most of his overdose calls involve teenagers and young adults ages 14 to 25, who often combine alcohol with prescription narcotics.

"They're not just taking one or two, either," he said. "They're taking handfuls."

State statistics show a big increase in overdose deaths among 40- to 50-year olds, however.

"There has been an increase in prescription drug abuse in all levels at all ages," said Brian Cressy, director of Quitting Time, an outpatient drug-treatment facility in Hampstead.

Among middle-aged adults, addiction usually starts with a legitimate

need for pain medication, Cressy said.

Often, these adults suffer increasing pain, leading them to take more pills and develop multiple addictions. Also, they may not be monitored by anyone else and might not have any idea how addicted they are until it's too late, he said.

Teenagers often get started by going "medicine cabinet shopping" and taking pills prescribed for their parents, Cressy said.

Richard Cram, program director for Family Mediation and Juvenile Services of Southern Rockingham County, said many younger addicts also take drugs prescribed for other kids, like Ritalin and Adderall, which contain powerful stimulants intended to treat Attention Deficit Hyperactivity Disorder.

Those drugs have been nicknamed "kiddy coke" for the quick high people get from snorting them, he said. Typically, teenagers take the pills for fun and then find themselves addicted.

"A lot of parents look at their kids who might get good grades and play sports and think, 'Not my kid,'" said Portsmouth police Detective Corey MacDonald, the school resource officer at Portsmouth High. "The troubled kids aren't the only ones involved in this. It spans all socioeconomic backgrounds, sports teams and intelligence."

The 22-year-old man told the Herald he isn't sure when he became addicted to Oxycontin, but eventually figured out he had problem.

"It freaked me out that I was doing a pill every day," he said. "But it freaked me out even more when I didn't have one."

Emergency room doctors who treat drug overdoses say they also see plenty of healthy patients who lie to get prescriptions for narcotics.

"There are people who make a living going into the ER with fake injuries to get drugs," said Dr. David Heller, an emergency room physician at Portsmouth Regional Hospital. "It's a constant balancing act, trying to do what's best for the patient and trying to keep them from having a side business."

Cressy said after OxyContin became a major problem, doctors began prescribing methadone instead. Methadone is now the leading cause of drug deaths in the state.

Yet few prescription drug addicts show up in treatment centers -- and there isn't enough drug treatment available.

"The rehabilitation services just aren't there," said Portsmouth Police Chief Michael Magnant. "They have all dried up," especially since the closing of the Portsmouth Hospital Pavilion, he said.

Information from: Portsmouth Herald, http://www.seacoastonline.com

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HealthSentinel.com

Eli Lilly's Strattera - 130 reports of suicidality in one month

Janne Larsson, "Eli Lilly's Strattera - 130 reports of suicidality in one month", 24-7 Press Release, February 16, 2006,
Link: http://www.24-7pressrelease.com/view_press_release.php?rID=11216

Strattera is a failed antidepressant, which Eli Lilly didn't succeed to get approved. It was recycled and used as an "ADHD medication", and marketed as the first "non stimulant medication for ADHD". As many parents, despite all published lies about the "benefits" of stimulants like Ritalin, Concerta and Adderall, don't want to give dangerous narcotic drugs to their kids, Lilly saw the chance to get a good market share for Strattera.

But miracle drugs can fast turn into disasters - as proven through the whole psychiatric history.

In April 2005 the European Agency for the Evaluation of Medicinal Products (EMEA) issued warnings that Strattera could give " hostility and emotional lability" in children and in September 2005 a Black Box Warning for suicide risk was issued for Strattera.

When the truth about the actual risks was revealed, spontaneous reports also started to come in: In one month (23 September 2005 - 25 October 2005) 130 cases of suicidal and self-injurious behaviour were reported! This should be compared to the 301 cases reported in the period November 2002 - September 2005 - in 3 years. This means that 30 percent of all reports of suicidality were received in one month!

This information is revealed in a not released discussion paper from 9 December 2005, written by the British MHRA and sent to the Swedish MPA. The information is gotten as a result of FOIA-requests, and released by court order.

The main part of the information is classified - as suicide risk and other serious harmful effects of psychiatric drugs still are seen as "trade secrets" by the medical authorities. But the 130 new cases are now publicly known and can never be hidden again!

In addition to the suicides and suicide attempts reported, the paper from the MHRA also tells about 766 spontaneous reports of cardiac disorders and 172 reports of liver injury.

All information about the harmful effects of this psychiatric drug should now be made public by the medical authorities and an impartial evaluation of the data should be done. Psychiatrist should no longer be allowed to prescribe poisonous drugs to normal children; children who do not have any objective abnormality but whose behaviour are deemed inappropriate.

Janne Larsson
writer from Sweden - investigating psychiatry

Comments:

Comment on Article **(Your Comment will be reviewed before posting)**

Left by: Anonymous on Feb. 17, 2006
Subject:
Documents speak for themselves and it is heartening to see that requests are being made to get the truth out about psych drugs. This is a great case for the consumer, who has fell victim of the bogus disorders dished out by psychs and MD's. Get these documents posted on the Internet so they can see the light of day!
Left by: Anonymous on Feb. 17, 2006
Subject: ADHD drugs
ADHD has absoutley no scientific basis in fact. There is no single thing a child (or adult for that matter) can do that has not been labeled as a disorder for which drugs can be perscribed. Beware of the psychiatric-pharmeceutical racket and keep your friends and family away from it.
Left by: Anonymous on Feb. 17, 2006
Subject: Psychiatry
I've always thought that this whole idea of popping a pill to get rid of your emotional and behavioral problems was a joke. But then when so many people fell for it, I thought, there must be something behind it. Now I've come to realize that the only thing behind it is money-hungry drug companies and their stooge-like "doctors", the psychiatrists.

Back

Published Saturday, February 18, 2006

FDA Debates ADHD Drug Warning

Some new evidence suggests stimulants may trigger heart problems in kids.

By CURTIS KRUEGER, LISA GREENE & ELENA LESLEY
St. Petersburg Times

Cheri Flores' middle son set fires, smashed furniture and brandished knives before he started taking medicine for attention deficit hyperactivity disorder.

"He was getting kicked out of school every other day," said Flores, 35, of Inverness. "Medication saved him."

Now the Food and Drug Administration may put strong warning labels on medications like the one Flores' son and millions of others take because of concerns that these stimulants may be linked to heart problems experienced by some patients.

For many parents, the news has created fresh worries. They have been calling their doctors and schools, asking if the medicines intended to help their children could end up hurting them.

For Flores, the medicine has proved so effective in helping her 12-year-old son's behavior that she already knows she wants to continue it. In fact, one of her other sons takes the same medicine.

"Taking my kids off these medications would be setting them up for failure," Flores said.

The risk of heart problems is small compared to the benefits of medication for children with ADHD, said three Florida child psychiatrists.

Dr. Mark Cavitt, medical director of pediatric psychiatry services at All Children's Hospital in St. Petersburg, has 500 to 600 patients who take Ritalin or a similar drug. Several have contacted him since the news came out, he said, but nobody has decided to take a child off the drug after talking it over.

"It's a point of concern," Cavitt said. "Parents need to be aware and physicians need to talk to parents . . . but it shouldn't necessarily rule out using psycho-stimulant medication. Because if ADHD goes untreated, it has risk factors too."

Children with untreated ADHD are more likely to have accidental injuries, experiment with drugs and have other behavioral problems, said Cavitt and other psychiatrists.

"People need to get the whole picture," said Dr. Elias Sarkis, associate clinical professor of child psychiatry at the University of Florida. "ADHD can be a devastating disorder with really bad consequences, or it can be treated with medications . . . and people can be very productive."

ADHD is the most frequently diagnosed mental health condition in American children, according to the American Psychiatric Association. Children with the disorder may be impulsive, unable to focus and hyperactive.

Stimulants such as Ritalin are designed to affect behavior by increasing the level of certain chemicals in the brain, such as dopamine, to make it easier for people to regulate their behavior.

About 2.5 million children between age 4 and 17 take ADHD drugs, according to federal survey data cited by the FDA.

Doctors say the medication needs to be prescribed on a case-by-case basis. Although some children with ADHD display disruptive behavior, others do not, and some children with ADHD may have other disorders as well, such as anxiety or depression, which also need treatment.

An advisory committee to the Food and Drug Administration recently voted to place a "black box" warning on the medicines, which include Ritalin, Concerta, Methylin and Metadate. The recommendation came after the committee heard about the deaths of 25 people, including 19 children, who had been taking the medications.

But even then, it was a close decision. The committee vote to recommend the warning label was 8-7, with one abstention, and all sides agree more study is needed. The FDA has not yet decided whether to adopt the recommendation, but it typically follows the advice of its advisory committees.

The medicines Adderall and Adderall XR, which are both amphetamines, already carry strong warnings. The heart risk warning would not be placed on Strattera, which is not a stimulant.

Dr. Esther Gonzalez, a pediatrician who runs the Comprehensive Behavioral Institute in Crystal River, knows parents are keenly aware of the warning label debate.

"Lots of people called here and were worried their kids would die," Gonzalez said.

Gonzalez and other doctors said they look at whether children have any history of heart problems before putting them on medication.

Compared to the large number of children taking the medicine, the risk of death is low, said Dr. Saundra Stock, assistant professor of psychiatry at the University of South Florida College of Medicine.

"I think a black-box warning for such rare events serves mostly to scare people," Stock said. "And delay treatment rather than benefiting the public."

Sarkis said more study is needed, but at this point, a warning label isn't.

Still, the drugs are known to increase pulse and blood pressure. In most people, the change is slight. But in a child with a real heart problem, perhaps some undiagnosed congenital defect, that increase could trigger heart problems, Cavitt said.

Even so, some studies suggest that the rate of sudden cardiac arrest may even be lower in people taking Ritalin than in the general population, Cavitt and Sarkis said.

GO

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ADD Drug Strattera, Already Under FDA Scrutiny, Raising New Safety Concerns in UK as Well

Date Published: Tuesday, February 21st, 2006

Although pharmaceutical giant Eli Lilly (Lilly) continues to maintain that its attention deficit drug, Strattera, is safe, the company's actions as well as those of the FDA would seem to indicate quite the opposite.

On September 28, 2005 for example, Lilly declared it was adding a black-box warning to Strattera. That warning advises that the drug may increase suicidal thoughts among youths.

FDA officials said Eli Lilly must also create a medication guide for patients and healthcare providers pertaining to the new black box warning. Black box warnings are the most prominent and serious of medication warnings.

The FDA said Lilly submitted results from a Strattera clinical trial of 1,357 youths taking the medication that found five of them had increased suicidal thoughts, while none of 851 youths taking a placebo showed such changes. Lilly said one youth attempted suicide during its Strattera trials, but that researchers saw no signs of increased suicidal thoughts among adults.

Strattera has also been linked to liver problems. In 2004, Lilly warned doctors to stop prescribing Strattera in patients with jaundice or who show signs of liver damage.

Lilly warned that Strattera can cause severe drug related liver injury that can progress to acute liver failure resulting in death or the need for a liver transplant. In December 2004 the FDA updated Strattera's label to include the serious liver side effects.

In December of last year, Dr. Thomas Laughren, director of the FDA's division of psychiatry products, said the federal government requested Lilly to assess 13 clinical trials conducted on children to measure a suicide risk.

"The risk for any individual patient taking this drug is quite low, but from a public health standpoint, four (case) per thousand is a fairly big signal, given there are tens of thousands of patients taking this drug," Laughren said.

In June 2005, the FDA announced it will be investigating all attention deficit hyperactivity disorder drugs including Strattera, Ritalin, Concerta, and Adderall in response to reports of serious psychiatric side effects in patients taking Concerta and Ritalin. Some ADHD drugs are also associated with cardiovascular side effects.

In what many experts are viewing as an unusual turn of events, an FDA advisory panel, in January of this year, voted (8-7-1) to recommend that the agency order the inclusion of the most serious "black box" warning on all stimulant ADHD medications due to evidence of a potential risk of heart attacks, strokes, and sudden death. The drugs include amphetamines, such as Adderall, and methylphenidates, sold as Ritalin, Concerta, Methylin, and Metadate.

The panel also voted 15-0-1 to recommend that the FDA require that the drugs include a medication guide for patients and parents.

This new controversy was prompted by data that showed that widely prescribed ADHD drugs like Ritalin may be lined to as many as 25 deaths that occurred between 1999 and 2003. Of these deaths, 19 involved children.

In addition, the FDA was advised of 54 cases involving serious cardiovascular problems like heart attacks, strokes, hypertension, heart palpitations and arrhythmias in both adults and children taking these medications.

There is also the open issue of another 26 deaths between 1969 and 2003 in medicated ADHD patients involving suicide, intentional overdose, drowning, heat stroke, and underlying diseases.

The panel's vote also caught the FDA off guard because the committee was convened to advise the agency on how to design studies to assess possible risks associated with stimulant ADHD medications. (Adderall is the only non-stimulant ADD drug).

During the meeting, however, talk soon turned to the over-prescribing of these drugs and the public as well as many doctors were unaware of these serious potential risks. The panel then agreed to consider the enhanced-warning issue that was outside of its planned agenda.

The FDA has attempted to back off from the unexpected action by the panel by issuing a statement that it would be reluctant to require a black box warning based on a "theoretical risk."

Such warnings could unreasonably deter patients and doctors from using a drug that could benefit them, said Robert Temple, MD, director of medical policy at the FDA's Center for Drug Evaluation and Research. He stated: "The absence of bona fide problems in your hand pushes against the box. We will also, frankly, worry about the possibility that overstatement can do active harm."

Thus, Temple indicated the full FDA would wait for the recommendation of a pediatric advisory committee scheduled for March before reaching any decision with respect to new warnings. That panel, which is made up of pediatricians and psychiatrists, is considered more likely to look favorably on the benefits of ADHD drug treatment as outweighing the potential risks.

Now comes word that Strattera is faring no better in the UK in light of these safety concerns well as the possibility that the drug is also associated with seizures and a potentially dangerous lengthening of the

interval between heartbeats.

According to ***IndyStar.com***, the ***Tacoma (Washington) News Tribune***, and ***Reuters***, the "warnings are based on an internal report by the British Medicine and Healthcare Products Regulatory Agency...The report, which has not been made readily available to the public, was obtained by The News Tribune after a Swedish court ordered it released in that country.

"Though the number of seizures and heart-rhythm problems is small, the British agency said problems could be under-reported, and it warned doctors and consumers that the drug should be used with caution in people prone to such problems.

"In particular, they warned about potential heart problems when Strattera is combined with antidepressants like Paxil and Prozac."

Although British authorities still believe the drug's benefits outweigh its risks, they are updating the drug's label in that country to warn of the possible problems. Presently, no warnings regarding the seizure risk are contained in the U.S. labeling. The heart problem risk, however, was inserted in the 25-page U.S. label in January at the request of the FDA.

This entry was posted on Tuesday, February 21st 2006 at 5:43 am and is filed under Legal News, Drug Side Effects, Health Concerns.

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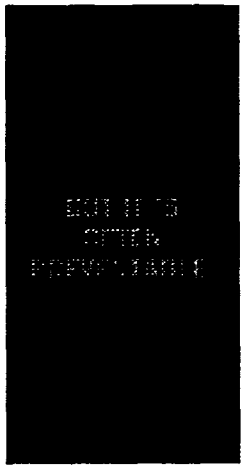

THE NATION

Warning Urged for ADHD Drugs

An FDA panel cites heart risks in its advisory on Ritalin and similar medications.

By Ricardo Alonso-Zaldivar
Times Staff Writer

February 10, 2006

WASHINGTON — A Food and Drug Administration advisory panel Thursday urged that the strongest possible safety warning be issued for drugs used by millions of children and adults to treat attention deficit hyperactivity disorder, because of emerging concern that they may increase the risks of heart attacks, strokes and sudden death.

The FDA had called the drug safety experts together to help design further research into such risks. But in an unexpected twist, the committee concluded that the evidence of serious risks was so great that a strong new warning — not just more research — was needed.

"This is out-of-control use of drugs that have profound cardiovascular consequences," said Dr. Steven Nissen, a cardiologist at the Cleveland Clinic and member of the panel. "We have got a potential public health crisis. I think patients and families need to be made aware of these concerns."

Although ADHD is commonly associated with children, members of the safety panel emphasized that the drugs could pose a greater danger to adults. The FDA has received reports of about 25 deaths linked to the drugs and of a larger number of cases involving serious health consequences, such as heart attacks.

The panel voted, 8 to 7, to call for a "black box" warning on literature distributed with the drugs — which include well-known brands such as Ritalin, Adderall and Concerta. As many as 4 million Americans take the medications, and government figures show that about 10% of all 10-year-old boys in the United States get the drugs; about 4% of girls that age use them.

"No one is saying that there aren't children who are desperately dysfunctional and need these drugs," Nissen said. "But it isn't 10% of 10-year-olds."

The safety experts also voted unanimously to recommend that a brochure be provided to patients and families to inform them in greater detail about the risks and benefits of using the drugs. And it urged the FDA to expedite studies to better understand the drugs' effects.

Senior FDA officials said that they would study the panel's recommendations and that they planned to refer the issue to another advisory committee dealing with psychological problems in children. The

agency has been criticized in the past as being slow to respond to evidence of health risks associated with medications, including painkillers and antidepressants.

"You don't want to over-scare people and make them not use an important drug," said Dr. Robert Temple, a top policy official at the FDA. "But you don't want people using drugs if they don't have to."

Drug makers said Thursday that the attention deficit medications were safe when taken as directed. They noted that some had been in use for more than 50 years.

Shire Pharmaceuticals Group, the maker of Adderall, said that it would work with the FDA to make sure patients had the necessary information, but that stronger warnings were not needed. Novartis, which makes Ritalin, said it had reviewed its own data and had not seen any increase in heart risks for patients.

The companies suggested there probably were other explanations for the deaths and serious health issues reported to the FDA, such as heart problems that had gone undetected before the patient began taking the medication.

Most of the attention deficit drugs are derived from powerful stimulants, including amphetamines. They are believed to help patients concentrate, though exactly how they work is not clear. But they also raise blood pressure, a major risk factor for heart disease and stroke.

Attention deficit hyperactivity disorder can make it difficult for children to apply themselves in school; adult patients may have trouble with multi-tasking. In the United States, about 2.5 million children and 1.5 million adults are taking medication for the condition.

The drugs have been widely prescribed for children since the 1990s, but their use to treat adults is relatively new. Prescriptions written for adults increased by 90% from 2002 to 2005. And the risks for adults may be greater, since high blood pressure and heart conditions are more prevalent among adults.

Currently, 10% of those taking ADHD drugs are 50 or older.

FDA officials convened Thursday's meeting amid concerns about the drugs' potential health problems.

"We wouldn't be going through this exercise if we didn't think there was a real possibility of an increase in risk," said Dr. David Graham, the FDA drug safety investigator who was one of the first to call attention to the heart risks of Vioxx, a leading painkiller withdrawn from the market in 2004. "There's smoke. Does that represent fire, or not? We want to answer that question."

The risks appeared to be different for children and adults. Graham and his colleagues undertook a preliminary study using information in the databases of large health insurers and government programs.

Their early findings indicated a higher-than-expected number of heart attacks and strokes among adults taking the medications. Among children through age 18, the number of strokes was higher than expected, but the number of heart attacks was lower.

Not all ADHD drugs are the same. Strattera, made by Eli Lilly & Co., is not classified as a stimulant. But several panel members said the warnings should apply to the entire class of drugs, without exception. That might help put a brake on over-prescribing, they said.

Panel member Thomas Fleming, a biostatistician at the University of Washington, suggested that the heart risks of attention deficit drugs might be comparable to those of the painkiller Vioxx and other so-

called Cox-2 inhibitors.

"While there is a lot of focus on children ... the numbers tell me that the magnitude of the excess risk is quite profound in adults," Fleming said.

For adults to continue taking ADHD drugs, the benefits of therapy would have to be shown to be substantial, he said. But some panel members said the benefits and risks of the medications for adults had not been extensively studied.

Temple, the FDA policy official, said agency officials would discuss internally how to address the problem of the emerging risk for adults.

The committee members suggested several types of studies to look at safety issues for all patients. One option would be to pore through the databases of insurers, as Graham's preliminary study had done. Another would be to compare heart function in patients taking ADHD medications with that of people who have similar characteristics but don't take the medicines.

Such studies might take two years or more to complete.

The FDA's database of reports of adverse drug reactions is not thought to be complete enough to base a study on it. Experts estimate that 1% to 10% of serious drug reactions are reported to the agency.

Canada halted sales of Adderall last year after health authorities there received 20 reports of sudden deaths in patients. But the drug was allowed back on the market after statistical studies indicated it was no riskier than other medications. It is not recommended for patients with underlying heart problems, however.

CONTRA COSTA TIMES

Posted on Fri, Feb. 10, 2006

Panel calls for ADHD drug effect warning

By Ricardo Alonso-Zaldivar
LOS ANGELES TIMES

WASHINGTON - A Food and Drug Administration advisory panel Thursday urged that the strongest possible safety warning be issued for drugs used by millions of children and adults to treat attention deficit hyperactivity disorder because of emerging concern that they may increase the risks of heart attacks, strokes and sudden death.

The FDA had called the drug safety experts together to help design further research into such risks.

But in an unexpected twist, a majority of the panel members concluded the evidence of serious risks was so great that a strong new warning -- not just more research -- was needed.

"This is out-of-control use of drugs that have profound cardiovascular consequences," said Dr. Steven Nissen, a Cleveland Clinic cardiologist and member of the panel.

Although ADHD is commonly associated with children, members of the safety panel emphasized that the drugs could pose a greater danger to adults.

The FDA has received reports of several dozen deaths linked to the drugs, and a larger number of cases involving serious health consequences, such as heart attacks.

The safety panel voted 8-7 to call for a "black box" warning on literature distributed with the drugs -- which include well-known brands such as Ritalin, Adderall and Concerta.

The safety experts also voted unanimously to recommend that a brochure be provided to patients and families to inform them in greater detail about the risks and benefits of using the drugs.

And it urged the FDA to expedite studies to better understand the drugs' effects.

Senior FDA officials said they would study the panel's recommendations and that they planned to refer the issue to another advisory panel dealing with psychological problems in children.

The agency has been criticized in the past for being slow to respond to evidence of health risks associated with drugs, including painkillers and antidepressants.

"You don't want to over-scare people and make them not use an important drug," said Dr. Robert Temple, a top policy official at the FDA.

"But you don't want people using drugs if they don't have to."

Drugmakers said Thursday that the attention-deficit medications are safe when taken as directed. They noted that some have been in use for more than 50 years.

Shire, the maker of Adderall, said it would work with the FDA to make sure patients have all the information they need, but that stronger warnings are not needed.

Novartis, which makes Ritalin, said it has reviewed its own data and has not seen any increase in heart risks for patients.

The companies suggested there probably were other explanations for the deaths and serious health issues reported to the FDA, like heart problems that had gone undetected prior to the patient taking the medication.

Most of the attention deficit drugs are derived from powerful stimulants, including amphetamines.

They are believed to help patients concentrate, though exactly how they work is not clear.

But they also raise blood pressure, a major risk factor for heart disease and stroke.

Attention deficit hyperactivity disorder can make it difficult for children to apply themselves in school; adult patients may have trouble with multi-tasking.

In the United States, an estimated 2.5 million children and 1.5 million adults are taking medication for the condition.

While the drugs have been widely used by children since the 1990s, their use to treat adults is a relatively new.

And the risks for adults may be greater, since high blood pressure and heart conditions are more prevalent among adults.

Currently, 10 percent of those taking ADHD drugs are age 50 or older.

FDA officials convened Thursday's meeting after they began to worry that the drugs could be present problems.

"We wouldn't be going through this exercise if we didn't think there was a real possibility of an increase in risk," said Dr. David Graham, the FDA drug safety investigator who was one of the first to call attention to the heart risks of Vioxx, a leading painkiller withdrawn from the market in 2004.

The risks appear to be different for children and adults. Graham and his colleagues undertook a preliminary study using information in the databases of large health insurers and government programs.

Their early findings indicated a higher-than-expected number of heart attacks and strokes among adults taking the medications.

Among children and teens through age 18, the number of strokes was higher than expected but the number of heart attacks was lower.

Not all ADHD drugs are the same. One medication, Strattera, is not classified as a stimulant.

But several panel members said the warnings should apply to the entire class of drugs, without exception.

That may put a brake on over-prescribing, they said.

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BIG BOOM

About 2.5 million children between ages 4 and 17 take ADHD drugs, according to federal survey data cited by Dr. Andrew Mosholder, a medical officer in the Office of Drug Safety. The survey found 9.3 percent of 12-year-old boys and 3.7 percent of 11-year-old girls take the drugs, Mosholder said.

Adult use of the drugs grew 90 percent between March 2002 and June 2005, he said. About 1.5 million adults take the medication

Sales of ADHD drugs rose from $759 million in 2000 to $3.1 billion in 2004, according to IMS Health, a pharmaceutical information and consulting firm.

-- Associated Press

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FDA Panel Calls for Strongest Warning on ADHD Drugs

THURSDAY, Feb. 9 (HealthDay News) -- A U.S. advisory panel recommended on Thursday the strongest possible label warning for Ritalin and other stimulants used to treat attention-deficit hyperactivity disorder because of potential cardiac risks.

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The Food and Drug Administration advisory committee voted 8-7, with one abstention, to add a "black box" warning to the drugs, which include methylphenidates such as Ritalin, Concerta, Methylin and Metadate. Amphetamines, including Adderall, are also commonly used for the disorder. In August 2004, the FDA added a warning to Adderall, telling patients with heart conditions not to use the drug.

The recommendation came after reports of the deaths of 25 people, 19 of them children, among people using both types of medications.

The FDA usually, but not always, follows the recommendations of its advisory committees. This instance was unusual, however, because the committee was originally charged only with discussing whether further studies were feasible and necessary.

"It doesn't astonish me that the committee wanted to weigh in on the virtues of revising the labeling, but that is not the primary matter we went to them for," said Dr. Robert Temple, director of the FDA's Office of Medical Policy. "We're going to consider what this committee said."

"You don't want to overscare people with data that isn't very solid," he continued. "We're going to be weighing all those things, and I can't give you an answer yet."

About 2 million children and 1 million adults are prescribed medications for attention-deficit hyperactivity disorder (ADHD) each month. Adult use of the drugs grew 90 percent between March 2002 and June 2005, according to the FDA.

Committee member Dr. Steve Nissen, medical director of the Cardiovascular Coordinating Center at The Cleveland Clinic, characterized this explosion in adult use as "out of control growth," the *Associated Press* reported. Nissen was

in favor of a black-box warning.

The spiraling growth in use of the medicines has spurred both scrutiny and controversy. One drug, Strattera, is now required to carry a black-box warning that it may prompt suicidal thoughts in children. Last year, Health Canada briefly pulled Adderall from the market. And, in July 2005, an FDA advisory committee considered, but rejected, labeling changes for Ritalin, Metadate and other methylphenidates. The panel also suggested that changes to Adderall and Strattera be delayed until more safety data was collected.

Thursday's meeting was prompted by reports of 25 deaths and 54 cases of serious cardiovascular problems in adults and children between 1999 and 2003.

An earlier FDA review found less than one death or serious injury per 1 million ADHD drug prescriptions filled. In the case of nonfatal cardiovascular or cerebrovascular problem, the number was 1.79 cases per 1 million in adults treated with amphetamines.

The agency said it found an additional 26 deaths between 1969 and 2003.

At a news conference held late Thursday, FDA officials seemed reluctant to embrace the committee's recommendations.

"I think it's important not to minimize the benefits of these drugs," said Dr. Thomas Laughren, director of the division of psychiatry products at the FDA's Center for Drug Evaluation and Research. "We put a black box on antidepressants for adolescents, but it did have an impact on prescribing and there's been a lot of negative feedback from the clinical community. It's important to recognize that something as dramatic as a black box can have a dramatic effect on prescribing."

"It's clear that we are going to tell people about things at a lower degree of uncertainty than we have in the past, but there's still a threshold," Temple added. "We still believe what we tell people should reflect data... We didn't find the sudden death data very persuasive. Having said that, other things are reasonably persuasive."

One reasonably persuasive finding was the affect of the drugs on people with heart failure, Temple noted.

Clinicians seemed to agree with the FDA official's assessment.

"You have to look at the cost-benefit ratio," said Dr. Jon A. Shaw, director of child and adolescent psychiatry at the University of Miami School of Medicine. "ADHD is probably the most common psychiatric diagnosis in school-aged children. It's a real medical condition, and it's associated with neurobiological chemical aberrations. Hundreds of studies have shown that psychosocial stimulants improve academic performance, social behavior, relationships."

"Nothing is chicken soup except chicken soup," added Dr. Karen Ballaban-Gil, a professor of clinical neurology and clinical pediatrics at Albert Einstein College of Medicine and Montefiore Medical Center in New York City. "We use medication because, at times, we have no choice. There is a low, but not zero, risk to these drugs and it's felt that, in the majority of the cases, the benefit outweighs the risk. If we had an alternative to medication that did not have side effects and had an equally good outcome that would be wonderful, but it doesn't exist."

Many of the issues will be revisited when another advisory committee meets in March.

More information

Visit the U.S. Food and Drug Administration for more on this advisory committee meeting.

FDA considers new warning on labels of antidepressants

The Boston Globe

Use during pregnancy may endanger infants

By Diedtra Henderson, Globe Staff | February 9, 2006

WASHINGTON – The Food and Drug Administration is again considering revising labels of popular antidepressants, this time in response to an article in today's New England Journal of Medicine that linked use of drugs like Paxil, Prozac, and Zoloft late in pregnancy with a condition that can endanger infants' lives.

During a hastily called press conference yesterday, the FDA called the results of a study cited in the article "very concerning."

The agency will issue a public health advisory within days, said Dr. Sandra Kweder, deputy director of the FDA's Office of New Drugs. Its regulatory options include updating drug labels, searching public and private databases to corroborate the drug link to the lung condition, and requiring additional trials from drug manufacturers.

But because the condition – persistent pulmonary hypertension of the newborn – is rare and failure to treat maternal depression can cause its own problems, the study's lead author does not expect the FDA to follow the lead of Canadian regulators, who warned against using new-generation antidepressants during pregnancy.

In October 2004, the FDA told manufacturers to add warnings on boxes alerting patients that the antidepressants increase suicidal thoughts and behaviors in children taking them. Last December it warned of an association between Paxil and heart defects when the drug is taken early in pregnancies.

The study described in the Journal article was observational and included interviews with 1,200 women within six months of giving birth. It is unethical to give pregnant women experimental drugs to gauge birth defect risks.

"This is an approach to looking at all medications that pregnant women might take and doing it in a systematic, consistent fashion so that we don't wait years to find out if a drug might cause a problem," said Christina Chambers, the study's lead author and director of a California program that fields 8,000 calls annually about the safety of medicines for developing fetuses.

Up to 15 percent of women of reproductive age suffer major depressive disorders.

The study focused on new-generation antidepressants called selective serotonin reuptake inhibitors. They were the nation's fifth-highest selling class of prescription drugs in the first nine months of 2005, accounting for 122.6 million prescriptions, according to IMS Health a pharmaceutical market research firm. About 3 percent of women take that type of antidepressant at some point during pregnancy.

Normally, one to two newborns per 1,000 suffer from persistent pulmonary hypertension, which means their pulmonary arterial pressure is too high at birth. As a result, their lungs can't provide enough oxygen, causing their bodies to produce oxygen-poor blood, sometimes resulting in death. In one study, nearly half the survivors were cognitively delayed, had major neurological problems, and could not hear.

When pregnant women took selective serotonin reuptake inhibitors after 20 weeks gestation, the risk of their infants developing persistent pulmonary hypertension rose sixfold, to about one in 100 newborns. The study size was too small to determine whether one antidepressant was riskier than another.

"This is the latest in a series of troubling reports of possible adverse events" of selective serotonin reuptake

inhibitors on fetuses, Dr. James Mills of the National Institutes of Health wrote in an accompanying editorial in the Journal.

Previous studies linked the antidepressants with infants' rapid breathing, jitteriness, bluish skin color from lack of oxygen, difficulty nursing, and low blood sugar.

The FDA said it does not want pregnant women to stop medication without consulting both their obstetricians and doctors providing their mental healthcare.

"This isn't a cause for panic," the FDA's Kweder said. "The risk is small enough that 99 percent of women's babies who are taking these medicines would not be at risk."

Diedtra Henderson can be reached at dhenderson@globe.com. ■

Health Supreme by Sepp Hasslberger
Networking For A Better Future - News and perspectives you may not find in the media

February 14, 2005

Adderall Deaths - Canada Suspends ADHD Drug, FDA Disagrees

Categories
Pharma

Linked to 20 deaths, Shire Pharmaceuticals' Attention Deficit and Hyperactivity Disorder drug Adderall was suspendec by Health Canada, resulting in a ten per cent drop in the UK company's shares, according to a Bloomberg report.

The US FDA instead, citing their evaluation of Adderall before approval of the drug, says it has no plans to change the status of the drug in the United States.

This uncovers a fault in the regulation of pharmaceutical drugs: the absence of ongoing monitoring of the "performance" and especially the safety of drugs. Once approved, it appears that the FDA relies on voluntary reportin by the drug companies to tell it about side effects - a bit like having the fox guard the hen house.

According to Senator Grassley of Iowa, the US agency has even asked its Canadian counterpart not to suspend the drug. Grassley is quoted in the article, published in the New York Times, as saying that the Food and Drug Administration had made the request of Canadian health officials because the F.D.A. could not handle another "drug safety crisis."

Why is there such a difference in the treatment of the drug's safety problems by Canadian and US authorities? One reason may be a difference in the laws of the two countries, where Canadian legislation allows suspension of a drug while security concerns are investigated, while US law apparently does not support such a course of action.

Another reason is that there seems to be a much closer relation of the pharmaceutical industry and the FDA than thei is to corresponding agencies in other countries. After all, the FDA is looked upon as a "lead agency" in drug approvals and drug safety. Expanding sale of drugs to other countries is much easier after FDA approval has been obtained.

That would presume that the FDA is upholding the highest standards on drug safety, which however does not seem tc be the case. Perhaps the agency should take a cue from National Institutes of Health chairman Dr. Elias Zerhouni, wh according to the LA Times, says that consulting payments from drug companies are "a systemic problem" and asks fo an ethics summit, a forum for wider discussion on conflicts of interest in medical research.

Shire Shares Fall After Canada Pulls Adderall XR Drug

(original here)

Feb. 10 (Bloomberg) -- Shares of Shire Pharmaceuticals Group Plc, the U.K.'s third-biggest drugmaker, fell the most i two years after Canada ordered the withdrawal of its best-selling product, Adderall XR, after it was linked to at least 2 deaths.

Adderall XR, used to treat attention deficit hyperactivity disorder, had third-quarter sales of $140 million, more than 4 percent of Shire's revenue for the period. Shire, whose shares fell 10 percent, maintains the drug is safe and "strongl disagrees with the conclusions drawn by Health Canada," the Basingstoke, England-based company said today in a statement on Regulatory News Service.

Health Canada told Shire yesterday to take Adderall XR off the Canadian market, where it had sales of $10 million las year, based on information the company supplied about the deaths of 14 children and six adults. The drug remains available in the U.S., its biggest market, where regulators advised parents to consult their doctors before changing th children's medication.

"We do expect this to have a negative influence on U.S. sales," said Javier Latorre, a fund manager at Deutscher Investment Trust in Frankfurt, which has about 56 billion euros under management. "What we do find astonishing is that two regulators have come to different conclusions on the basis of the same data."

Shares of Shire fell 64.5 pence to 577.5 pence at the close of trading in London. The 10 percent drop was the steepes percentage decline for the shares since January 2003.

Drug Safety Concerns

The U.S. Food and Drug Administration has allowed the drug, sold as Adderall in the U.S., to remain on the market w a revised label warning against its use in patients with heart conditions.

"I think for kids who are stable on these medications and who don't have cardiac problems, there's no reason to mak an immediate change," said David Fassler, 48, a professor at the University of Vermont College of Medicine in Burlington and a child and adolescent psychiatrist. "However I expect there will be parents who have questions and concerns."

Some doctors may "alter their prescribing patterns until they have more information," he said.

Drug safety is getting increased attention since Merck & Co.'s Vioxx painkiller was withdrawn last September because a link to heart attacks, prompting U.S. and European regulators to assess the risks of all painkillers in the same class

'Climate Is changing'

"I do think the climate is changing," Fassler said. "I think we are becoming more aware that the FDA has had less resources to devote to post-marketing surveillance. Most of the emphasis in recent years has been on the approval of new medications. My sense is that there may be a re-evaluation of that balance under way."

Adderall, has about 24 percent of the market share for attention deficit hyperactivity disorder treatments, which are most commonly prescribed for children. Adderall is an amphetamine, which stimulates the central nervous system an can increase the heart rate. The drug isn't sold in Europe.

"Health Canada's decision comes as a result of a thorough review of safety information provided by the manufacturer which indicated there were 20 international reports of sudden death" in patients taking either Adderall or Adderall XR the agency said.

"Although we are complying with this request we strongly disagree with this decision," Shire spokeswoman Jessica Mann said in an interview. "We have confidence in the safety and efficacy of Adderall XR."

None of the reported deaths occurred in Canada, Health Canada said. Adderall XR has been sold in Canada for a year

'Real Question'

"The real question is whether this suspension could spill over into the U.S.," Nomura International Plc analyst Frances Cloud wrote in a note to clients. "In our view, the risk of this is low since the FDA has already seen this data and only requested a labeling revision."

Nomura raised its rating on Shire shares to "buy" from "neutral" today. Of 21 analysts who cover Shire, 16 have a "buy" rating, two have "hold" ratings and three rate the shares a "sell."

The FDA is consulting with Canadian authorities on their action and plans no immediate changes to the drug's labeling or approved use, the agency said in a statement on its web site.

"At this time, FDA cannot conclude that recommended doses of Adderall can cause sudden unexplained death, but is continuing to carefully evaluate these data," the agency said on its web site.

The FDA said in a public health advisory that it had evaluated the risk of sudden death with Adderall before approving the drug for use in adults last year. The agency said it decided not to take action at this time because, "it does not appear the number of deaths reported is greater than the number of sudden deaths that would be expected to occur this population without treatment."

The FDA drew that conclusion from the rate of sudden death based on 30 million prescriptions written between 1999 and 2003.

To contact the reporter on this story: Angela Zimm

To contact the editor responsible for this story. Mark Rohner

Last Updated: February 10, 2005 11:51 EST

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New York Times:
Senator Says F.D.A. Asked Canada Not to Suspend Drug
By GARDINER HARRIS and BENEDICT CAREY

Published: February 11, 2005

(go to original)

WASHINGTON, Feb. 10 - A day after Canadian officials suspended the use of a hyperactivity drug amid reports of deaths associated with its use, Senator Charles E. Grassley of Iowa contended that United States health officials had asked the Canadian regulators not to do so.

Senator Grassley, a Republican, said on Thursday that the Food and Drug Administration had made the request of Canadian health officials because the F.D.A. could not handle another "drug safety crisis." Mr. Grassley said he was basing his contentions on reports from whistle-blowers within the agency.

Dr. Robert Peterson, director general of the therapeutic products directorate at Health Canada, said through a spokeswoman that reports that F.D.A. had asked Health Canada to refrain from suspending the drug "are untrue."

Brad Stone, a spokesman for the F.D.A., declined to respond directly to Mr. Grassley's contention but said of Dr. Peterson's rejection that, "We believe the Canadian response is the correct one."Canadian health officials, citing 20 deaths among patients taking the British-made drug Adderall XR, said on Wednesday night that they were suspendin sales of the hyperactivity drug indefinitely. The F.D.A. is allowing the drug to continue to be sold in the United States, saying there is little evidence that Adderall XR caused the deaths.

Mr. Grassley, who has been investigating the Food and Drug Administration for about a year, demanded in a letter written on Thursday that the agency answer questions about any discussions its officials may have had with the Canadians about the drug.

Dr. Robert Temple, director of the F.D.A.'s office of medical affairs, said the agency's decision to permit the continuec sale of Adderall was not influenced by the controversies swirling around the F.D.A.

"It's still our job to get as close as we can to the right answer and not panic and do things for the wrong reasons," Dr Temple said.

Matthew Cabrey, a spokesman for the maker of Adderall, Shire Pharmaceuticals Group of Britain, said Adderall was s and effective. "We are very surprised at the actions of Health Canada, and we disagree with their interpretations of th data around these extremely rare cases of sudden death," Mr. Cabrey said.

The controversy - and the sudden appearance of Mr. Grassley, the chairman of the Senate Finance Committee, in it - promises to engulf the F.D.A. in more questions about its oversight of the pharmaceutical industry.

Critics have accused agency officials of being too cozy with drug makers and of being slower than their counterparts i other nations to acknowledge drug-safety problems.

The controversy is also bound to fuel a long-running battle over whether drugs like Adderall and Ritalin are overprescribed to children, and whether the drugs' longterm risks have been adequately explored.

More than 700,000 Americans use Adderall and its extended release counterpart, Adderall XR. Shire sold $759 millior Adderall products in the United States last year and $10 million in Canada.

In the letter Thursday to the F.D.A., Mr. Grassley wrote that reports given to his staff suggested that the agency was not acting with scientific integrity.

"Unfortunately, such allegations raise additional concerns about the culture at the F.D.A.," he wrote.

Dr. Peterson of Health Canada described discussions between the two regulatory bodies as "collegial."

Differing health regulations govern the differing responses of the two agencies to the Adderall reports, Dr. Peterson

said. Canadian law lets regulators suspend a drug's sales while safety questions are investigated; United States law does not. Health Canada approved Shire's application to sell Adderall XR in January 2004. In September, the compan reported to Canadian authorities that 20 people, 12 of them children, had died suddenly in the United States while taking the drug.

Shire asked the Canadian regulators for permission to change the drug's label to reflect the possible dangers, as had been done in the United States that month.

Some of the deaths, which had not been previously reported to Canadian authorities, occurred well before Health Canada approved Adderall XR for sale, Dr. Peterson said.

Canada and the United States both require pharmaceutical companies to report all adverse outcomes from drugs promptly.

"We were surprised to find these cases," Dr. Peterson said in an interview on Thursday.

Dr. Peterson said that an early analysis of the data suggested that Adderall XR might be linked to two to three times many sudden deaths as Ritalin and its cousin, Concerta, which are prescribed for similar disorders.

Further, Dr. Peterson said that Canadian authorities were uncertain about how to warn patients about the risks of sudden death.

"It's very difficult to generate a benefit-to-risk balance when the risk is sudden and unexpected death," Dr. Peterson said.

Mr. Cabrey of Shire Pharmaceuticals said that the company had forwarded reports of the deaths to Canadian authorit promptly.

Dr. Temple of the F.D.A. said that 7 children taking Ritalin and Concerta died during the same period that 12 children taking Adderall died, suggesting equivalent risks. Many had structural problems with their hearts and several were engaged in vigorous exercise, he said.

There is little evidence that the drugs caused any of the deaths, he said."There is a tendency to believe that sudden death doesn't occur in children. That is wrong," Dr. Temple said. He added: "Psychiatrists say that these drugs are needed. To get rid of them for something that may well be a background rate of death is not responsible."Doctors ha known since the 1930's that stimulant medications like these can calm hyperactive, or aggressive, children. But no or knows precisely how the drugs induce this effect, and there have always been concerns about the drugs' long-term effect on development.

Prescriptions for these drugs to be used by children with attention-deficit disorder more than doubled in the 1990's, experts say, heightening the concerns of some doctors.

The drugs are far more popular in the United States than in Europe. Last year, doctors in the United States wrote mo than 23 million prescriptions for the four most popular drugs used to treat attention deficit disorder.

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LA Times:
NIH Chief Calls for Ethics Summit
Dr. Elias Zerhouni, who banned drug company payments to agency scientists, wants a wider discussion o conflicts in medical research.
BETHESDA, Md. — *The director of the National Institutes of Health — describing consulting payments from drug companies as a "systemic problem" that threatened the integrity of his agency — has called for a summit of government and academic leaders to address conflicts of interest throughout American medical research.*

Update 19 February: Here is the FDA's statement on Adderall. A nagging question in my mind: "What are children doing taking amphetamines, anyway?

Adderall and Adderall XR (amphetamines) Information

FDA ALERT [2/9/2005]

Sudden Deaths in Children

Health Canada has suspended marketing of Adderall XR products from the Canadian market due to concern about reports of sudden unexplained death (SUD) in children taking Adderall and Adderall XR. SUD has been associated with amphetamine abuse and reported in children with underlying cardiac abnormalities taking recommended doses of amphetamines, including Adderall and Adderall XR. In addition, a very small number of cases of SUD have been reported in children without structural cardiac abnormalities taking Adderall. At this time, FDA cannot conclude that recommended doses of Adderall can cause SUD, but is continuing to carefully evaluate these data.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

See also:

Adderall's Rollercoaster Year
For the past year, Shire has been a continuous rollercoaster ride. The company took a major tumble in February 200[illegible] when Canadian health authorities pulled Adderall off the market due to reports of 20 sudden heart-related deaths and strokes in children and adults using the extended-release pill. Fourteen of the deaths were children and two of the 12 strokes were in children. The adverse events were reportedly not associated with drug overdose or misuse of the dru[illegible]

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posted by **Sepp Hasslberger** on **Monday February 14** 2005
updated on **Friday February 3** 2006

URL of this article:
http://www.newmediaexplorer.org/sepp/2005/02/14/adderall_deaths_canada_suspends_adhd_drug_fda_disagrees.h

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Vioxx Shows: FDA Unable To Protect Public From Deadly Medical Drugs
According to recent congressional testimony, "the FDA as currently configured is incapable of protecting America against another Vioxx. We are virtually defenceless," said David Graham, associate director of the agency's Office of Drug Safety. The quote is from an article published in South Africa, titled Doctor: FDA is too cosy with drug firms. The FDA is the national food and medicines regulatory agency of the US but it has been... [read more]
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Prozac, called fluoxetine by generic name, is a psychiatric drug prescribed to over 50 million people including millions children. The drug was linked to increased suicides and violence as early as 1988, in a recently emerged document. Apparently the evaluation was known to Prozac's maker Eli Lilly as early as the 'eighties, but was never even given to the FDA. This is the preoccupying picture that emerged just days... [read more]
January 01, 2005 - Sepp Hasslberger

Attention Deficit Hyperactivity Disorder Ruse
After Pharmagiant Pfizer recently launched a $ 40 M ad campaign to sell "Zoloft for everything", now comes Eli Lilly a

Co. to tell us if we're not patiently standing in line we might have ADD and should see our doctor for their new prescription drug. According to an article on CNN today, the questions on Eli Lilly's site include "How often are you distracted by activity or noise around... [read more]
July 19, 2003 - Sepp Hasslberger

Antidepressants - Drugging kids in school
Image credit: Emma Holister Attention deficit hyperactivity disorder or ADHD, is a custom-made "disease" to start selling drugs quite legally to school kids. Have the doctor prescribe them. Your kid will be that much better off - or no It appears that the real dough about the adverse effects of antidepressant drugs has been kept secret so as not to ru sales. Violence and suicide are common side effects... [read more]
February 11, 2004 - Sepp Hasslberger

Crime and Nutrition
Tjarko Holtjer, a friend in the Netherlands who runs a well fed multilingual website about health freedom, nutrition issues and more, has sent an article which I would like to pass on. Criminal behaviour and violence depend very mucl on nutrition. Some vitamins or essential minerals - if out of balance - can make the difference between a sane fellow and a violent criminal. Same thing at school - nutrition... [read more]
October 15, 2003 - Sepp Hasslberger

The Individual Is Supreme And Finds Its Way Through Intuition

Cylert® (pemoline) Linked to Liver Failure

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In the News :: Medical Drug Injuries :: Cylert®, Taken Off the Market

ADHD Medication, Cylert®, Taken Off the Market

ABBOTT PARK, IL — June 24, 2005 — Abbott Laboratories is taking Cylert® (pemoline) off the market "based on declining sales," according to a letter the company sent to doctors last month. One can only wonder whether the real reason for the decision is bad publicity about Cylert®'s link to liver problems. Prescribing information, enclosed with the letter, reveals that Cylert® can cause "life threatening hepatic [liver] failure" and "should not ordinarily be considered as first line drug therapy."

Cylert® was approved in 1975 for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children. Used to increase attention and decrease overactive behavior, Cylert® is in the class of medications called central nervous system stimulants. Other related drugs in this category, also used to treat ADHD, include Dexedrine® (dextroamphetamine) and Ritalin® (methylphenidate).

Cylert® users have reported 15 cases of liver failure to the Food and Drug Administration (FDA) since 1998, according to Abbott. Twelve of these cases resulted in liver transplants or death. Although the total number of cases of liver failure is small, most medical experts believe that adverse drug reactions are vastly under-reported. An FDA analyst, Dr. David Graham, estimates a 16.8-fold increased risk of acute liver failure in patients taking Cylert® compared to the general population (Press Release, Public Citizen, March 24, 2005; CDER, Cylert® Approval Package, Fulminant Hepatic Failure with Pemoline, FDA Memorandum from Medical Officer, April 17, 1996).

The consumer group, Public Citizen, noted 21 cases of liver failure from Cylert® since the drug was marketed in 1975. The group also points out that reports of liver problems appeared in clinical trials even before Cylert® was approved. Between the 1975 approval and 1996, there were 193 adverse drug reactions involving the liver, according to Public Citizen, which unsuccessfully petitioned the FDA in March of this year to ban the drug.

Our Belie
Our basic simple—t clients wi represent service....
Related Interest
Injuries Drugs
Cylert® may be a second- in ADHD not as th first cho are requ monitor enzyme Cylert®

Cylert® Label Warnings Were Not Always Heeded

Before approving Cylert®, the FDA expressed concern about the rate of liver failures caused by the drug. As a condition for approval and continued sales, Abbott was required to establish a national registry for reporting adverse reactions from Cylert® (CDER, Cylert® Approval Package). To date, Abbott has not created such a registry.

In 1996, the FDA required Abbott to modify the Cylert® label to indicate that patients should try other types of ADHD drugs before they were given Cylert®. Because of the risk of liver toxicity, the new label instructions said, Cylert® should be used only as a second-line therapy. In June, 1999, the label was again revised to require that the patient's liver enzymes be checked every two weeks. Both changes were included in a prominent, bolded black box, the highest caution level for a drug that is still on the market.

An FDA study showed, however, that compliance with the Cylert® warnings was low (J Am Acad Child Adolesc Psychiatry. 2002 Jul; 41(7): 785-90). The report looked at 688 patient claims in a health care database between January 1998 and March 2000. It found that only 237 patients (34%) had received another drug for ADHD before taking Cylert®. The researchers also divided the data into two six-month periods before and after the June 1999 labeling change that required doctors to monitor the patient's liver enzymes. Prior to the label change, only 12% of Cylert® users were given baseline liver enzyme tests; after that date, only 11% were given these tests. Doctors performed follow-up liver enzyme tests in only 9% of patients during the pre-label change period. Only 12% of patients in the post-label change group had these tests.

Cylert® Withdrawn in UK and Canada

The United Kingdom banned Cylert® in 1997, and Canada removed it from the market two years later. In the United States, Abbott will allow Cylert® to remain on pharmacy shelves until supplies are exhausted. Although Cylert® will no longer be available in the country at that time, the generic form of the drug, pemoline, may still be legally marketed by other companies.

Injuries from Unsafe Medications

Brayton Purcell is committed to helping people who have been injured by unsafe medicines. We will keep you up-to-date on any further efforts to ban pemoline. Meanwhile, please feel free to contact us if you would like more

information about medical drug injuries and your legal choices. We have been handling medically-related consumer cases for over 20 years, and work hard to defend the legal rights of our clients.

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- Meridia

CYLERT / PEMOLINE

Pemoline (Cylert) Warnings
Public Citizen Petitions FDA to Take Pemoline Off the Market

CYLERT (pemoline) is a central nervous system stimulant, used as a prescription therapy for Attention Deficit Hyperactivity Disorder (ADHD). ADHD is the most common behavioral disorder in children, and is typically characterized by a short attention span, hyperactivity, impulsivity, and moderate to severe distractibility. Some researchers estimate that up to 10% of school-aged children are affected.

Cylert was approved by the FDA in 1975. In the 30 years Cylert (Generic: Pemoline) has been on the market the FDA has twice had to strengthen the warning labels of the medication. While both Britain and Canada have banned the pharmaceutical drug, the FDA has instead encouraged Abbott Laboratories to perform additional studies.

Reports given to the Food and Drug Administration show that at least 193 patients have suffered serious consequences from the drug, said Dr. Peter Lurie, deputy director of Public Citizen. "This is an outmoded drug," he said, "and there is no reason for it to be still on the market.

In 1996 Abbott Laboratories sent an 'Important Drug Warning' to doctors regarding the dangerous side effects of Pemoline (Cylert). In this letter Abbott Laboratories disclosed ten deaths of acute liver failure in children (U.S.), with additional reports worldwide.

A new 'boxed warning' label for the prescription drug was announced. This warning included Abbott Laboratories' recommendation that "Because of its association with life threatening hepatic failure, CYLERT should not ordinarily be considered as first line drug therapy for ADHD..."

Despite the dangerous side effects, and the serious concerns from both the FDA and Abbott Laboratories, Pemoline (Cylert) continues to be on the market and was prescribed to 117,000 patients last year.

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PPA
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Disclaimer

We believe that drug companies who place profit above people must be held accountable for their negligence and the damage they cause to innocent victim's lives.

At Brown & Crouppen our experienced team of pharmaceutical lawyers provide tough, aggressive representation for victims and their families. When you choose us to handle your pharmaceutical negligence lawsuit, our entire team becomes fully committed to your cause. We'll find answers, hold negligent companies responsible and get you the compensation you deserve.

Brown & Crouppen can help you make informed decisions about your legal rights, so please call Brown & Crouppen at **Toll Free: 866-991-4700** for your free legal consultation or save time with our online Contact Form.

If you have taken Cylert / Pemoline and have suffered any side effects, please **contact our experienced Cylert lawyers** now for a free evaluation.

Your Name:

City:

State:

Contact Phone:

Contact Email:

How long was Cylert used?:

Did effects from Cylert include:

Liver Dysfunction (Organ Failure, Hepatitis, Jaundice): ○ YES ○ NO

Seizures: ○ YES ○ NO

Skin Rash: ○ YES ○ NO

Aplastic Anemia: ○ YES ○ NO

Other Medications:

Comments:

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Related Pemoline News Links

Public Citizen Petitions FDA to Take Pemoline Off the Market (03/24/2005)
WASHINGTON, D.C. - Public Citizen today petitioned the U.S. Food and Drug Administration (FDA) to immediately remove pemoline (Cylert), a central nervous system stimulant used in the treatment of attention deficit hyperactivity disorder (ADHD), from the market because it is known to have caused at least 21 cases of liver failure, including 13 resulting in liver transplantation or death.

Pemoline Alert > Full Public Citizen Petition

Abbott Laboratories Urged to Remove Drug
Abbott Laboratories and other drugmakers should withdraw a medicine used to treat attention-deficit-hyperactivity disorder from U.S. markets because of links to liver failure and death, a consumer group said Thursday.

The generic drug pemoline, sold by North Chicago-based Abbott as Cylert, has caused 21 cases of liver failure that led to transplants and death since its debut in 1975, according to a statement by Washington-based Public Citizen. About 117,000 prescriptions were filled in the U.S. last year, the group said. The drug was withdrawn in the United Kingdom and Canada.

Letter from Abbott Laboratories sent to doctors in 1996 regarding Pemoline (Cylert) drug dangers, possible liver damage, and announcing a new 'boxed warning' for the medication labeling.

FDA Pemoline (Cylert) Prescription Drug Information - including full 'box warning'

Call Brown & Crouppen at **Toll Free: 866-991-4700** for your free legal consultation or save time with our online Contact Form.

Toll Free: 866-991-4700

CBC.CA News - Full Story:

Health Canada strengthens antidepressant warning

Last Updated Thu, 03 Jun 2004 18:52:43 EDT
CBC News

OTTAWA - People of all ages who take newer antidepressant drugs may experience behavioural and emotional changes that may increase the risk of harming themselves or others, Health Canada warned Thursday.

The department strengthened its warning about Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Noradrenalin Re-uptake Inhibitors (SNRIs).

The advisory applies to:

- Bupropion (Wellbutrin and Zyban)
- Citalopram (Celexa)
- Fluoxetine (Prozac)
- Fluvoxamine (Luvox)
- Mirtazapine (Remeron)
- Paroxetine (Paxil)
- Sertraline (Zoloft)
- Venlaflaxine (Effexor)

A small number of patients taking the drugs may feel worse instead of better, the advisory said.

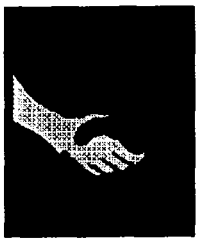
Doctors, patients, families and other caregivers should be on the lookout for signs of suicidal thoughts or worsening depression, such as hostility, anxiety or insomnia, especially when a patient begins the drug therapy or whenever the dose is changed.

If someone feels worse, they should consult a doctor immediately. It is very important that patients do not stop taking their medication without first consulting a doctor, the advisory stressed.

- FROM : U.S. expands antidepressant warning

In February, Health Canada advised patients under the age of 18 who were being treated with the SSRIs to consult a doctor.

Thursday's stronger advisory is similar to a U.S. warning issued earlier this spring. Drug regulators in the U.K. have banned the use of most SSRIs in children.



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AHRP is a national network of lay people and professionals dedicated to advancing responsible and ethical medical research practices, to ensure that human rights, dignity and welfare of human subjects are protected, and to minimize the risks associated with such endeavors.

Pfizer Zoloft Warnings to Canadian Doctors Contrast to US - FDA Caves In Pharma lobbying

Thu, 10 Feb 2005

The FDA has, once again, quietly colluded with industry, compromising the safety of children's lives to maintain drug manufacturers' cash flow.

After two FDA advisory committee hearings (Feb 2-3 and Sept 13-14, 2004) and independent analyses of the data from 24 clinical trials in which childrer were exposed to an SSRI antidepressant, the FDA was convinced that a ca relationship had been scientifically established between SSRIs and suicidali (suicide attempts) in children and adolescents.

On October 15, 2004 the FDA issued label warnings to reflect the scientific evidence, stating:

"A causal role for antidepressants in inducing suicidality has been establishe pediatric patients."
http://www.fda.gov/cder/drug/antidepressants/SSRIlabelChange.htm

However, under pressure from the manufacturers of SSRI antidepressants whose $17 billion dollars in sales began to suffer, the FDA caved in, and changed the wording. Once again, the FDA is instrumental in hiding from physicians, parents, the scientifically established fact that the drugs - not the underlying condition--pose a suicide risk for children. The omission of this vi information from SSRI drug labels deliberately misleads the courts as well. [CNN report below]

Below, is Pfizer's letter to Canadian physicians acknowledging that the use SSRI antidepressants has generated reports - in clinical trials and post-marketing reports - "in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment."

Why has the FDA failed to ensure that US physicians and parents are as we informed about the hazards of widely advertised drugs as their Canadian neighbors are?

Contact: Vera Hassner Sharav
212-595-8974

Accomplishments

Endorsements / Acknowledgements

Conflicts of Interest

Law Suits / Court Decisions

Risks: Drugs / Vaccines

Links

veracare@ahrp.org

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/zoloft_hpc_e.html

Health Canada Endorsed Important Safety Information on ZOLOFT (sertrali hydrochloride)

May 26, 2004

Subject: Stronger WARNING for SSRIs and other newer antidepressants regarding the potential for behavioural and emotional changes, including risl self- harm

Dear Health Care Professional,

Pfizer Canada Inc., following discussions with Health Canada, would like to inform you of important safety information regarding the possibility that SSR (selective serotonin reuptake inhibitors) and other newer antidepressants m be associated with behavioural and emotional changes, including risk of sel harm.

The new Class warning incorporated in the Product Monograph of ZOLOFT (sertraline hydrochloride) capsules is provided below.

POTENTIAL ASSOCIATION WITH THE OCCURRENCE OF BEHAVIOUR/ AND EMOTIONAL CHANGES, INCLUDING SELF-HARM

Pediatrics: Placebo-Controlled Clinical Trial Data

Recent analyses of placebo-controlled clinical trial safety databases from S and other newer antidepressants suggest that use of these drugs in patients under the age of 18 may be associated with behavioural and emotional changes, including an increased risk of suicidal ideation and behaviour over of placebo. The small denominators in the clinical trial database, as well as variability in placebo rates, preclude reliable conclusions on the relative safe profiles among these drugs.

Adult and Pediatrics: Additional data

There are clinical trial and post-marketing reports with SSRIs and other new antidepressants, in both pediatrics and adults, of severe agitation-type adve events coupled with self-harm or harm to others. The agitation-type events include: akathisia, agitation, disinhibition, emotional lability, hostility, aggres depersonalization. In some cases, the events occurred within several weeks starting treatment.

Rigorous clinical monitoring for suicidal ideation or other indicators of potent for suicidal behavior is advised in patients of all ages. This includes monitori for agitation-type emotional and behavioural changes.

Discontinuation Symptoms

Patients currently taking sertraline hydrochloride should NOT be discontinued abruptly, due to risk of discontinuation symptoms. At the time that a medical decision is made to discontinue an SSRI or other newer antidepressant drug, a gradual reduction in the dose rather than an abrupt cessation is recommended.

It should be noted that a causal role for SSRIs and other newer antidepressants in inducing self-harm or harm to others has not been established. The possibility of a suicide attempt is inherent in depression and other psychiatric disorders, and may persist until remission occurs. Therefore, high-risk patients should be closely supervised throughout therapy with appropriate consideration to the possible need for hospitalization. The updated warning informs practitioners that all patients being treated with SSRIs and other newer antidepressants should be rigorously monitored for clinical worsening, or onset/ worsening of agitation-type adverse events, or other indicators of potential for suicidal behaviour.

Sertraline hydrochloride is not indicated for use in the pediatric population.

New Information Added to the Consumer Information Section

The Consumer Information Section of the Product Monograph has been updated to reflect this new Class warning, and to advise patients that treatment with SSRIs and other newer antidepressants is most safe and effective when there is good communication with the treating physician about how the patient is feeling.

Background

In February 2004, a scientific advisory panel set up by Health Canada was asked to provide the clinical practice perspective on the pediatric clinical trial safety data, and the spontaneous post-marketing reports for SSRIs and other newer antidepressants. The panel agreed that a contraindication was not warranted for these medications, and supported Health Canada's recommendation for stronger warnings, while providing suggestions and comments. The record of proceedings, and other information about the panel, can be found on Health Canada's website at : http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/sap_ssri_2004-02-20_rop_e.html .

Pfizer Canada Inc. continues to work closely with Health Canada to monitor adverse event reporting and to ensure that up-to-date information regarding the use of ZOLOFT (sertraline hydrochloride) is available.

The identification, characterization and management of drug-related adverse events are dependent on the active participation of healthcare professionals in adverse drug reaction reporting programs. Healthcare professionals are asked to report any suspected adverse reactions in patients receiving ZOLOFT (sertraline hydrochloride) directly to Pfizer Canada Inc. or Health Canada at the following addresses:

Pfizer Canada Inc.
Medical Information
P.O. Box 800
Pointe-Claire, Quebec
H9R 4V2
1 800 463-6001

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866 234-2345
Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

For other inquiries: please refer to contact information.

The http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.html AR Reporting Form and the http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.html AR Guidelines can be found on the Health Canada web site or in The Canadian Compendium of Pharmaceuticals and Specialties.

Your professional commitment in this regard has an important role in protecting the well-being of your patients by contributing to early signal detection and informed drug use.

Any questions from healthcare professionals may be directed to the Pfizer Medical Information Group at Tel: 1 800 463-6001.

Sincerely,

original signed by

Bernard Prigent, M.D.
Vice President & Medical Director
Pfizer Canada Inc.

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Pfizer Canada Inc. Licensee

FDA backs away from antidepressant warning
Change comes to light during murder trial of teen blaming Zoloft
By Jim Polk
CNN
Wednesday, February 9, 2005 Posted: 4:14 PM EST (2114 GMT)

CHARLESTON, South Carolina (CNN) -- The Food and Drug Administration has backed off its warning that antidepressants such as Zoloft, Paxil and Prozac can cause suicidal actions among children and teens taking those prescription drugs.

Instead, the FDA, in a revised warning posted last week on its Web site, changed the wording to say only that the drugs "increased the risk of suicidal thinking and behavior in short-term studies of adolescents and children" with depression and other psychiatric disorders.

News of the FDA's warning change surfaced Wednesday in testimony here in the murder trial of 15-year-old Christopher Pittman. The defense contends Zoloft drove him to kill his grandparents when he was 12.

Dr. Steve Romano, a psychiatrist and a vice president of Pfizer, which makes Zoloft, mentioned the FDA change at Pittman's trial while being questioned about the company's own clinical trials for Zoloft.

Limiting the warning language to a risk seen in studies, rather than saying the drugs actually could cause suicidal behavior in younger patients, is a significant retreat for the FDA and came after several months of lobbying by the pharmaceutical industry.

The agency has never approved Zoloft, Paxil or most similar drugs for use by younger patients with depression. Even so, many doctors prescribe them for children and teens. Prozac is the only such antidepressant approved to treat depression in children.

The version of the warning that the agency posted on its Web site in October included this sentence: "A causal role for antidepressants in inducing suicidality has been established in pediatric patients."

The latest version omits that sentence.

The sentence was not part of the boldface black-box warning placed at the start of the insert that accompanies any prescription, but instead appeared in the first paragraph of a separate section on "Suicide Risk" which appeared just below that black box.

The replacement sentence, however, appears as the first sentence inside the black box. That first sentence was broader in the original version, saying: "Antidepressants increase the risk of suicidal thinking and behavior in children." The new version qualifies that by inserting the phrase "in short-term studies."

Romano acknowledged that the wording change was preceded by an extended "dialogue" between his drug company and others, and the FDA.

Romano was called by the defense in the Pittman case to testify about suicide-related warnings issued both in Canada and the United States.

The FDA never has suggested there is any link between these drugs and violence against others -- the issue in the Pittman murder trial.

The trial is in its eighth day and appears likely to spill over into a third week, rather than go to the jury by this weekend, as originally predicted.

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This document is also available in PDF format [zoloft_hpc_e.pdf]
Pages: 4, Size: 62 K, Date: 2004-06-02

The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **Pfizer Canada Inc.**.
Contact the company for a copy of any references, attachments or enclosures.

Health Canada Endorsed Important Safety Information on ZOLOFT (sertraline hydrochloride)

Pfizer Canada Inc.
P.O. Box 800/C.P. 800
Pointe-Claire/Dorval (Québec)
H9R 4V2

May 26, 2004

Subject: Stronger WARNING for SSRIs and other newer antidepressants regarding the potential for behavioural and emotional changes, including risk of self- harm

Dear Health Care Professional,

Pfizer Canada Inc., following discussions with Health Canada, would like to inform you of important safety information regarding the possibility that SSRIs (selective serotonin reuptake inhibitors) and other newer antidepressants may be associated with behavioural and emotional changes, including risk of self-harm.

The new Class warning incorporated in the Product Monograph of ZOLOFT* (sertraline hydrochloride) capsules is provided below.

POTENTIAL ASSOCIATION WITH THE OCCURRENCE OF BEHAVIOURAL AND EMOTIONAL CHANGES, INCLUDING SELF-HARM

Pediatrics: Placebo-Controlled Clinical Trial Data

- **Recent analyses of placebo-controlled clinical trial safety databases from SSRIs and other newer antidepressants suggest that use of these drugs in patients under the age of 18 may be associated with behavioural and emotional changes, including an increased risk of suicidal ideation and behaviour over that of placebo.**

- **The small denominators in the clinical trial database, as well as the variability in placebo rates, preclude reliable conclusions on the relative safety profiles among these drugs.**

Adult and Pediatrics: Additional data

- **There are clinical trial and post-marketing reports with SSRIs and other newer antidepressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment.**

Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behavior is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes.

Discontinuation Symptoms

Patients currently taking sertraline hydrochloride should NOT be discontinued abruptly, due to risk of discontinuation symptoms. At the time that a medical decision is made to discontinue an SSRI or other newer antidepressant drug, a gradual reduction in the dose rather than an abrupt cessation is recommended.

It should be noted that a causal role for SSRIs and other newer antidepressants in inducing self-harm or harm to others has not been established. The possibility of a suicide attempt is inherent in depression and other psychiatric disorders, and may persist until remission occurs. Therefore, high-risk patients should be closely supervised throughout therapy with appropriate consideration to the possible need for hospitalization. The updated warning informs practitioners that all patients being treated with SSRIs and other newer antidepressants should be rigorously monitored for clinical worsening, or onset/ worsening of agitation-type adverse events, or other indicators of potential for suicidal behaviour.

Sertraline hydrochloride is not indicated for use in the pediatric population.

New Information Added to the Consumer Information Section

The Consumer Information Section of the Product Monograph has been updated to reflect this new Class warning, and to advise patients that treatment with SSRIs and other newer antidepressants is most safe and effective when there is good communication with the treating physician about how the patient is feeling.

Background

In February 2004, a scientific advisory panel set up by Health Canada was asked to provide the clinical practice perspective on the pediatric clinical trial safety data, and the spontaneous post-marketing reports for SSRIs and other newer antidepressants. The panel agreed that a contraindication was not warranted for these medications, and supported Health Canada's recommendation for stronger warnings, while providing suggestions and comments. The record of proceedings, and other information about the panel, can be found on Health Canada's website at : http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/sap_ssri_2004-02-20_rop_e.html.

Pfizer Canada Inc. continues to work closely with Health Canada to monitor adverse event reporting and to ensure that up-to-date information regarding the use of ZOLOFT (sertraline hydrochloride) is available.

The identification, characterization and management of drug-related adverse events are dependent on the active participation of healthcare professionals in adverse drug reaction reporting programs. Healthcare professionals are asked to report any suspected adverse reactions in patients receiving ZOLOFT (sertraline hydrochloride) directly to Pfizer Canada Inc. or Health Canada at the following addresses:

Pfizer Canada Inc.
Medical Information
P.O. Box 800
Pointe-Claire, Quebec
H9R 4V2
1 800 463-6001

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866 234-2345
Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

For other inquiries: please refer to contact information.

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

Your professional commitment in this regard has an important role in protecting the well-being of your patients by contributing to early signal detection and informed drug use.

Any questions from healthcare professionals may be directed to the Pfizer Medical Information Group at Tel: 1 800 463-6001.

Sincerely,

original signed by

Bernard Prigent, M.D.
Vice President & Medical Director
Pfizer Canada Inc.

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FDA warns against Paxil for teens and kids

Last Updated Fri, 20 Jun 2003 18:21:34

WASHINGTON - U.S. regulators warned consumers Friday that no one under the age of 18 should be using the drug Paxil for depression because the antidepressant designed for adults may increase their risk of suicide.

The Food and Drug Administration's warning came a week after the British government banned prescribing the drugs to anyone under the age of 18.

The FDA had asked all makers of adult antidepressants to submit research on how their drugs affect children.

Paxil's manufacturer, GlaxoSmithKline's studies found that their drug did not seem to help pediatric depression.

However, the FDA noticed some safety concerns and ordered GlaxoSmithKline to analyse the data again.

The latest analysis found the risk of suicidal thoughts and suicide attempts to be three times greater among Paxil users, mostly teens, than among children given dummy pills, according to the FDA.

The FDA said youth using Paxil should not suddenly stop using it. Rather they need to ease off the drug under medical supervision.

- FROM Jan. 25, 2002: Going off Paxil? Do it slowly

Paxil is approved in Canada and the United States for adult treatment of a number of psychiatric illnesses including depression.

Both Health Canada and the FDA have never approved of the drug for people 18-years-old and younger. But some doctors prescribe the drug anyway.

In Canada, Paxil or Paroxetene is the eighth most

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commonly prescribed drug, according to IMS Health statistics. In 2000, more than three million prescriptions were filled for Paxil.

- FROM May 6, 2002: Paxil caused withdrawal illness: Ontario lawsuit

Paxil has been the subject of several class-action suits in both countries. Plaintiffs argued that they suffered from dependency and withdrawal reactions.

Paxil is listed as an SSRI drug - selective seratonin re-uptake inhibitor - which means it is not supposed to be addictive. Other SSRI drugs are Prozac and Zoloft.

GlaxoSmithKline changed its labelling early last year, making it clear some patients will suffer serious effects if they're taken off the drug too quickly.

Written by CBC News Online staff

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Health

U.S. says Paxil may pose suicide risk to children

Updated Mon. Jun. 23 2003 8:40 AM ET

Associated Press

WASHINGTON — No one under age 18 should be prescribed the drug Paxil for major depression because the adult antidepressant may increase a child's risk of suicide, the U.S. government said.

The Food and Drug Administration's recommendation came a week after Britain issued an even stronger warning against pediatric use of Paxil, sold there under the name Seroxat. Paxil is also sold in Canada. Children and teenagers already taking Paxil should not suddenly stop the pills, the FDA stressed. Some doctors may feel the drug is helping enough to keep a particular patient on the medication, which the FDA warning doesn't forbid. Those who do stop taking Paxil need medical supervision to taper off and avoid rebound side-effects, such as abnormal dreams and shock-like sensations.

Paxil is approved for adult treatment of a number of psychiatric illnesses, including depression. While there have been lawsuits alleging Paxil caused violent or suicidal reactions, the FDA said Thursday there is no scientific evidence linking the drug to increased suicide risk among adults.

The FDA has never approved use of Paxil in children or teens. But some doctors prescribe the adult drug for children anyway.

The FDA had asked all makers of adult antidepressants to submit research showing how their drugs affect children. Three studies of Paxil found it didn't seem to help pediatric depression - but FDA scientists spotted some safety concerns and ordered manufacturer GlaxoSmithKline to re-analyse the data.

That new analysis - submitted last month, first to the British government and then to the FDA - found the risk of suicidal thoughts

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and suicide attempts was three times greater among Paxil users, mostly teens, than among children given dummy pills, the FDA said.

There were no deaths during the studies, but FDA officials wouldn't release the actual number of suicide attempts, citing manufacturer confidentiality.

GlaxoSmithKline would detail only the rate of all "emotional side-effects," ranging from mood swings to suicide attempts: 3.2 per cent of pediatric Paxil patients compared with 1.5 per cent of those given dummy pills in studies that included about 1,000 children and teens.

The FDA cautioned that it still is investigating and hasn't definitively concluded there is a suicide risk to children.

"There is no definitive action or even decision about what ought to be done," said the FDA's Dr. Russell Katz. But "we wanted to let people know" about the possible risk.

Why would Paxil cause such a side-effect in depressed children but not adults?

The FDA said it's not clear, but noted that childhood depression itself is different from adult depression, probably because of changes the child's brain undergoes as it grows. A number of adult antidepressants have failed to work in children. Plus, children often suffer different side-effects from a variety of medications than adults do.

GlaxoSmithKline couldn't provide prescription data Thursday, but spokeswoman Mary Anne Rhyne said an extremely small percentage of Paxil users are children with depression. The company is seeking FDA approval to sell Paxil to treat another illness, obsessive-compulsive disorder, in children. Rhyne said studies found no sign that giving the drug to those patients triggered suicidal thoughts.

There is one FDA-approved treatment for depression in children, the competing drug Prozac.

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Comeau, Christian A

De: Denis Paul Bouffard [dpb@caaq.org]
Envoyé: 24 février 2006 08:44
À: Comeau, Christian A
Cc: Claire Bolduc; Bolduc, Claire (travail); 'Samson Jean-K'
Objet: Confirmation de présence devant la CAPA

Monsieur Comeau,

Ceci est pour confirmer notre présence à 16H15 pour être entendus à la CAPA le 28 février prochain.

Les personnes présentes seront Mme Claire Bolduc, présidente, monsieur Denis P. Bouffard, Directeur général ainsi que Me Jean-K Samson.

Merci

Denis-Paul Bouffard
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