

(Date) November 21, 2006

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

CITIZEN PETITION

The undersigned submits this petition under stimulant drugs regulated (relevant statutory sections, if known) of the prescription drug section of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to IS INDICATED AS A TREATMENT OF: to THIS MEDICATION SHOULD ONLY BE USED AS A LAST RESORT IN CHILDREN (OR PEOPLE PRIOR TO HAVING CHILDREN). THERE IS NO LONG TERM EFFECT INFORMATION AVAILABLE TO GIVE ANSWERS TO WHAT LONG TERM EFFECTS ARE ON THESE PEOPLE. THIS IS ONLY A RECOMMENDATION IF ALL OTHER POSSIBILITIES HAVE FAILED. ALSO, IT IS RECOGNIZED THAT PEOPLE THAT WERE BORN ADDICTED TO MEDICATION/DRUGS MAY NEED THIS PRIOR TO OTHER THINGS BEING TRIED ALONG WITH CHILDREN AND ADULTS THAT HAVE BEEN PHYSICALLY/MENTALLY ABUSED THAT SHOULD BE MONITORED CAREFULLY AND REMOVED AS SOON AS POSSIBLE. THERE ARE CASES WHERE THE MENTAL DEFECTS REQUIRE THE USE OF THESE DRUGS AS A MEDICAL NECESSITY AND SHOULD BE FOLLOWED. (issue, amend, or revoke a regulation or order to take or refrain from taking any other form of administrative action).

A. ACTION REQUESTED

2006P-0484

CP 1

1. Currently it is put in stimulant medications (STIMULANT NAME) IS INDICATED FOR THE TREATMENT (MENTAL DISEASE).
2. The proposed change is to make the wording: (STIMULANT NAME) IS INDICATED FOR THE TREATMENT OF (MENTAL DISEASE) ONLY AS A LAST RESORT IN CHILDREN (OR PEOPLE PRIOR TO HAVING CHILDREN). THERE IS NO LONG TERM EFFECT INFORMATION AVAILABLE TO GIVE ANSWERES TO WHAT LONG TERM EFFECTS ARE ON THESE PEOPLE. THIS IS ONLY INDICATED IF ALL OTHER POSSIBILITIES HAVE FAILED. ALSO, IT IS RECOGNIZED THAT PEOPLE WERE BORN ADDICTED TO MEDICATION/DRUGS MAY NEED THIS PRIOR TO THER THINGS BEING TRIED ALONG WITH CHILDREN AND ADULTS THAT HAVE BEEN PHYSICALLY/MENTALLY ABUSED THAT SHOULD BE MONITORED CAREFULLY AND REMOVED AS SOON AS POSSIBLE. THERE ARE CASES WHERE THE MENTAL DEFECTS REQUIRE THE USE OF THESE DRUGS AS A MEDICAL NECESSITY AND SHOULD BE FOLLOWED.
3. The actions that need to be printed on the web site are as follows:
 - a. The physicians that are currently treating patients with medication need to work with patients and attempt to remove children and adults prior to having children from the medication if possible. NOTED: SOME PATIENTS WILL NOT BE READY OR WILLING TO

PART WITH THIS MEDICATION. IT WILL NEED TO BE DONE WHEN THE PATIENT IS READY.

- b. The physicians that are currently treating patients with medication need to have the same patients checked for long term effects of the medication: The effects that need to be checked are the physical growth in size, the stomach, kidneys, lungs, heart, circulatory system, and brain. The treatment of the possible diseases is to be treated with medically necessary treatments.
- c. If possible, the people that are currently taking stimulant medication need to be checked prior to having children of there own for possible effects of sperm and ovulation.
- d. If conception of a child has occurred prior to sperm and ovulation being checked, the pregnancy is labeled as a high risk pregnancy so appropriate tests can be done prior to the 10th week of pregnancy.
- e. Physicians, Insurance Companies, Teachers, and Judges that have followed medical recommendation are protected from law suits related to the abuse of stimulant medication prescribed for children. The exceptions to this rule are: Physicians that have fraudulently and maliciously treated patients with stimulant medication; and Teachers that strongly recommend medication after this change is enacted.

B. STATEMENT OF GROUNDS

Questions need to be answered as to the long term effects of the medication given to children for a long period of time. In a

responsible society where we know that drugs of any nature can and do cause effects on the body that are not necessarily the desired results, we need to know for sure the medication given to children and adults prior to having children these questions are asked:

1. What are the long term effects of medication on the stomach?
2. What are the long term effects of medication on the kidneys?
3. What are the long term effects of medication on lungs?
4. What are the long term effects of medication on the heart?
5. What are the long term effects of medication on the brain?
6. What are the long term effects on the circulatory system?
7. What are the long term effects of medication on sperm/ovulation?

This comes from when I was in elementary school and we had a guest speaker come to our school and speak to us about drugs.

Although I cannot remember his name or where he was from, I can remember the majority of the speech. It goes as:

“Hello. As Mr. Horton said, I am (Unknown) from (Unknown). I am here to speak with you about drugs and the dangers of drug use. It would be easy to stand here and tell you “don’t do drugs” and not give you any reason that the adults know of. It would be easy to just say, “Drugs can hurt you.” I am here to tell you what we

think you can handle and hopefully take with you after you leave the gymnasium.

First of all, prescription drugs can be a good thing. There are some drugs out there that are meant to treat people's problems like diabetes, high blood pressure, or worse. These drugs can prolong people's lives so those people can live to a ripe old age.

Now there are other drugs, street drugs, that as I am sure you have heard about that can kill you on the spot. This is not the kill that "I am going to hurt you." This is the kill "you will be dead."

I am here to talk to you specifically about prescription drugs and the process that goes through the Federal Food and Drug Administration, or FDA, to say it is okay for people to take the medication.

There are many kinds of medication that the FDA deals with. These are referred to as Over the Counter drugs and Prescription drugs.

We all know about Tylenol. We can take Tylenol to relieve pain or break a fever. What did it go through to become approved by the FDA?

Many considerations had to be taken into account. The first question is always going to be, "What are the desired results of the medication to the patient?" The FDA had to do a case study to find out how it affected the majority of patients. Since a verity of

people react in a different way, it had to be a study where people were not taking other medications.

The next question asked is, "Will it interact with other medication?" This case study used other people that took other medications and what the results were.

The next question and most important question asked is, "What are the long term effects?" This is a really important question for the old and the young. The old, what if there was a medication that could save you from cancer but in return it gives you an incurable heart disease? Would that switch off be worth it if the heart disease only let you live a month after the cancer is gone?

The reason this is the most important question is for you guys.

You see your bodies are growing so fast, not only on the outside, but the inside too. So along with your outside, your stomach, your kidneys, your lungs, your heart, and your brain is growing just as fast as you are. Every chemical substance that enters your body can effect that growth. What has to be done is the drugs you take need to be checked to make sure that the drug doesn't affect any of those things in you.

I need to make this clear at this point. Just because you turn 18 years old doesn't mean that you have stopped developing at such a rapid rate. All kids continue to grow for some time after they are

18 and sometimes people are growing physically, on the outside and inside, up to 28 years old.

Here are just some of the questions.....What if you, a child, take a medication that affects the stomach? That part of your stomach is effected start to tell your brain you are full before you get enough nutrition or reverse and your stomach is telling you that you are not full when you have had enough. Either way you listen to your stomach. If you feel full you stop eating and if you don't feel full you keep on eating. Can you imagine, because of a medication or drug you take being able to see your bones? Or what about gaining too much weight? Could you be happy either way?

Your kidneys are an important part of your body that takes the stuff you put in your body, through the stomach, and distributes it to the rest of your body. What if a pill you take makes the kidney's not work right and it starts putting things for your lungs into your heart or what ever? What if it causes your kidney's to stop working all together? What if your kidneys stay the same size they are right now because of a medication/drug you take today? Just to let you know, an adult would have a really hard time living with kidney's that small (laughing).

Your heart. What if a medication/drug effects your heart growth? Heart disease is really nothing to mess around with kids, but,

again, anything you take today could affect it if it is not properly tested.

Your lungs are what you breathe with. What if your lungs refuse to take in enough air because it believes it is full? You don't get enough air; you will have a lot of problems there.

What if a medication or drug affects your brain in a negative way? To be honest with you, we don't have the brain mapped in a way to be able to repair it much less treat it. Right now there are a lot of street drugs out there that has negatively affected the brain. There are people that have dead brain cells out there that are able to move with only a lot of thought. They are not safe to be in public because so many brain cells have been damaged.

Now what I haven't mentioned yet but yet may be the most important is sperm and ovulation. Girls, this is major important to you because you are born with the eggs that you will produce your children with. If a chemical substance enters your body and affects the ovulation process, you are out of luck. You may have possibly hurt all of the eggs in your body that you will one day have children with. Boys, this may be just as important to you because what if a drug you take today effects the way your sperm sack grows? You may not be able to produce enough sperm to create a child. Both boys and girls, what if you do have a baby with the damaged eggs or sperm? That baby you have could have problems

I would not wish upon a worst enemy. Very import the sperm and ovulation. See, "What you do to your bodies today can effect your children tomorrow." This can be done by over the counter drugs, illegal drugs, or prescription drugs.

The over the counter drugs and prescription drugs is controlled by the FDA that should have medical fact that backs up the use and long term effects of this medication. The illegal drugs, do you honestly believe somebody that is willing to sell drugs illegally is honestly considering your health or your body? The illegal drug dealer just wants your money. They don't care if it causes you to have a heart attack or if it affects your brain cells.

The last thing you need to keep in mind is that all of these side effects can happen with just one pill or drug use. ONE PILL!!! You don't have to be considered an addict for a medication/drug to have these effects.

Well, that is all I have to say. Please, take with you what I have said today and remember. Thank you (Bricker Elementary, between the years 1980-1985, guest speaker unknown).

The prescribing of medication typically occurs with children said to have Attention Deficit Hyper Disorder (ADHD) and Attention Deficit Disorder (ADD).

According to the Web MD website, trusted by a lot of people that have questions regarding disease and medications, the following is said regarding ADHD and medication.

Attention Deficit Hyper Disorder (ADHD) the symptoms are as follows:

“The symptoms of ADHD include inattention, impulsiveness and hyperactivity that are inappropriate for a persons age level.

Children who have ADHD often: Are easily distracted by sights and sounds in the environment; Are unable to concentrate for long periods of time on low stimulations tasks (homework vs. video games); Are restless and impulsive; Have a tendency to daydream; and Are slow to complete tasks. Adults who have ADHD often: Miss work deadlines; Miss Appointments; Appear hectic and disorganized; and have significant problems prioritizing.

Symptoms in adults and children vary by individual and range from mild to severe (

<http://www.webmd.com/content/article/89/100391.htm>).”

“The most effective form of treatment for children and adolescents with ADHD is multidisciplinary treatment. That means the treatment includes multiple elements which work best together and support each other. They are various interventions that reinforce each other and produce the best outcomes for children and adolescents with ADHD. The elements of this approach include:

Parent and child education about diagnosis and treatment; specific behavior management techniques; and Medication.

Working closely with health care providers and school personnel, treatment should be tailored to the unique needs of each child and family (<http://www.webmd.com/content/article/89/100390.htm>).”

“Adults with ADHD also benefit from multidisciplinary approach to treatment that includes: Counseling to learn skills and coping strategies to help in everyday life; medication; and support and education (<http://www.webmd.com/content/article/89/100390.htm>).”

“Stimulants are a class of drugs call psychostimulants or stimulants have been used to effectively treat ADHD for years. These medicines help users to focus their thoughts and ignore distraction. Stimulant medications are effective in 70% to 80% of patients. They are used to treat both moderate and severe ADHD. The drugs are approved for use in adolescents or children over age 6 who are having difficulty with ADHD symptoms both at school or at work, as well as at home.

Stimulant drugs to treat ADHD include: Adderall and Adderall XR; Concerta; Dexedrine; Focalin; Metadate CD and Metadate ER; Methylin; and Ritalin, RitalinLA.

In 2003, the first nonstimulants medication, Strattera, was approved by the U.S. Food and Drug Administration. It’s used in

adults, children and adolescents and is the first treatment approved to control ADHD symptoms in adults. When stimulants or Strattera are ineffective or not well-tolerated, several other medications are available to treat ADHD. These medications include: Pamelor or other tricyclic antidepressants; Catapres or Tenex; Welbutrin; and Effexor.

ADHD drugs sometimes have side effects, but these tend to happen early in treatment and are usually mild and short-lived. The most common side effects include: Decreased appetite/weight loss; Sleep problems; Headaches; Jitteriness; Social withdrawal; and Stomachaches.

In most cases, side effects can be relieved using one of the following strategies: Changing the medication dosage; Adjusting the schedule of medication; and Using a different medication.

Always consult your health care provider before making any changes in your ADHD treatment regimen (

<http://webmd.com/content/article/89/100397.htm>).”

According to the Eli Lilly and Company website the following is said regarding ADHD and medication.

“The focus of ADHD treatment is the management of symptoms. Medication is typically the backbone of therapy. Among the most common types of medication to treat ADHD:

Non-stimulant Strattera (atomoxetineHCl) is a non-stimulant treatment option for ADHD and is part of a class of drugs called “selective norepinephrine reuptake inhibitors” or SNRIs. Strattera is the first non-stimulant medication approved by the FDA to treat ADHD in children, adolescents, and adults.

Strattera works differently from other available ADHD medications by blocking the reuptake of norepinephrine, a chemical neurotransmitter. The precise role that norepinephrine plays in the treatment of ADHD is not known. However, scientists believe it may be important in regulating attention, impulsivity, and activity levels.

Used since the 1930s, stimulants are a very common treatments option for ADHD. The primary effect of stimulants is through regulation of dopamine and nonrepinephrine.

Stimulants used in the treatment of ADHD include:\

Short-acting (4-5 hour): Adderall; Dexedrine; DextroStat; Focalin; Methylin; and Ritalin.

Intermediate-acting (6-8 hour): Dexedrine Spansule; Metadate ER; Methylin ER; Ritalin SR; Metadate CD; and Ritalin LA.

Long-acting (10-12 hour): Adderall XR; Concerta; and Focalin XR.

Although they are not officially FDA approved for ADHD, antidepressants and antihypertensive (high blood pressure)

medications are also sometimes used to treat the symptoms of
ADHD

(http://www.adhd.com/parents/parents_treatment_medications.jsp)

C. ENVIRONMENTAL IMPACT

1. In making this change children will be free to live in a drug free environment in the home and school setting.
2. The adverse effect would be:
 - a. Children needing to learn how to behave without drugs and dealing with life instead of covering it up with drugs.

Teachers would be required to teach and parents would be required to parent.
 - b. The children that are currently taking drugs would have to face they are addicts. The process of becoming un-addicted will be hard on all individuals (doctors, parents, teachers, friends, and children). Hopefully no doctor will be so cruel as to just remove a child/adult from this addiction.
 - c. The children or young adults that are having difficulties stopping doing drugs will need to go through a drug rehabilitation process. Some of these same children and young adults will have to go through the process of detoxification.

- d. The drug company will see the \$5 billion dollar profit seen for the end of 2005 dropped to less than \$250,000 by the year of 2011. The \$250,000 is so high due to the people that are now suffering from diagnosed brain diseases and the people that cannot stop due to addiction.
3. An alternative to the action is leaving it as it is set. Not to consider the long term physical effects of these children. Not consider the next generation in which our children will have children of there own, and have the next generation born with deformities of the body, mind, heart, lungs, stomach, and possibly still birth.
4. In the Fathers name, any child given a chance to do life without drugs can take there life a step further than what any doctor suppressing that life with drugs. This is true for any adult as well. Yes at first people may feel depressed or withdrawn or maybe even have work that suffers, but in the end they will end up being better people.
5. The irreversible and irretrievable comments the Federal Food and Drug administration will begin watching all drugs that are approved for children. Long term effects will be noted by case studies done in adults.

D. ECONOMIC IMPACT STATEMENT

Not required for this petition.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Mary G Poff McDole
(Signature)

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