Ask the Expert

The Patient Medication Guide Mandate



This month, we present excerpts from a discussion with Diane Buckingham, M.D., about the recent FDA action requiring **Patient Medication** Guides. Dr. Buckingham is a child and adolescent psychiatrist, chair of the psychiatry and behavioral sciences section of the National Medical Association (NMA), and a member of CHADD's professional advisory board. For the full version of the chat. see www.chadd.org/ asktheexpert.

What the recent FDA action means for you

On February 21, 2007, the U.S. Food and Drug Administration (FDA) directed manufacturers of attentiondeficit/hyperactivity disorder (AD/HD) medications to develop Patient Medication Guides to alert consumers of possible health risks. What are these guides and what do they mean?

Diane Buckingham: The FDA has directed that all medications approved for the treatment of AD/HD have Patient Medication Guides. This will help parents and patients to understand the benefits and potential risks of these very effective medications. At this time, only a few pharmaceutical companies provide handouts describing the risk factors and benefits. The FDA's action mandates that these companies provide patients with better education about their medication.

All medications have risks, and it is important to get a good evaluation, including a physical examination, and to review these risk factors with your health-care providers. The risk of cardiac issues will require ongoing monitoring, so be sure doctors get good baseline data about heart rate, blood pressure, and weight, as well as a detailed patient and family health history. Generally, patients who have been newly prescribed medications for AD/HD should be seen within two to four weeks to check response to the medications. Weight, heart rate, blood pressure, and emotional status should be reviewed at that time and at regular follow-up visits.

Are any populations or age groups at greater risk than others?

Patients with a history of cardiac problems or surgery have a higher risk. Risks for those without a history of heart problems are still being investigated. It is important to watch for heart-rate changes in children and adolescents, such as slow heart rates that have become faster. Patients with a personal or family history of Wolff-Parkinson-White Syndrome,

an electrical abnormality of the heart, have a greater risk, as do those with a history of Q-T wave syndrome, which affects how the heart beats. Other medications that the patient is taking can also increase risk for heart problems.

Many people take over-the-counter medications or herbal supplements and don't inform the doctor. Some OTC medications, including cold medications, may increase the risk of heart problems. Combined with medications for AD/HD, the patient may be more at risk for an adverse reaction. Report any problems or side effects to the doctor.

Anyone can have an adverse reaction to medication, but the benefits may outweigh the associated risks for each individual. The improvement of life functions must be compared to the risks of the medications.

Are there any age-specific risk factors for people older than 60 taking AD/HD medications?

That information is still being researched, but it is important to check for drug interactions and talk with your doctor. Check for drug interactions with medications that impact dopamine receptors.

Are the new guidelines only about heart risks or do they include other risks?

There are other slight risks associated with AD/HD medications. These risks include hearing voices and experiencing paranoia or manic symptoms. These risks will also be addressed in patient educational tools.

Is the possible heart-risk factor new information?

Heart-risk information for psychotropic medications and stimulants is not new and has been in the news and a part of patient education for some time. What is new is that these warnings are being placed on the nonstimulant AD/HD medication. Now, with the new FDA guideline, all doctors and pharmaceutical companies will have to educate the people they treat. I have given handouts on medications to all my patients since starting my



practice and have included information about heart risks for more than five years. Anyone taking these medications should be educated about them. The most important thing is to have knowledge of the risks. Most people prescribed medication for AD/HD have been safely and effectively treated under these guidelines.

How does the everyday parent know what to look for, and how to ask a provider the right questions?

1. Keep a record of vital information, starting at birth.

- 2. Keep a journal of prescribed medications.
- 3. Ask family members about their health history.
- 4. Keep a folder of the handouts about each medication.
- 5. Keep a standard list of questions about medications handy, such as:
 - What are the risks vs. the benefits?
- What is the specific risk of heart problems and other side effects?
- What heart rate and blood pressure is normal for my child?
- What was my child's blood pressure and heart rate?

Anyone can have an adverse reaction to medication, but the benefits may outweigh the associated risks for each individual. The improvement of life functions must be compared to the risks of the medications.

■ How often should I follow up on these

With any changes that occur in your child's health status, schedule an appointment or call the physician to be seen right away.

We hear a lot about the possibility of side effects when consumers take these medications. Please talk about the side effects of not taking the medications. Since the science shows treatment involves a multimodal approach that includes medication among other things, describe some of the problems that can happen if someone is not treated appropriately for this

The risk of poor attention can lead to problems in learning and function. The risk of impulsive behavior can lead to injury and, when not redirected, can lead to agitation and aggressive behavior in some people, resulting in car accidents, physical altercations, impulsive climbing, falling accidents, and even death. There is also a risk of failure in school. Fifty percent of students with mental disorders, ages 14 and older, drop out of high school. Suicide remains a serious public health concern and is the third leading cause of death in youth from ages 10 to 24. Adjustments in home and school environments impact the person's ability to function. The treatment of serious emotional and mental disorders is effective with therapy, behavioral management and medications.

Overall, medication can be a useful therapy. Management of AD/HD is an individual decision, but it should not be based on negative campaigns against medications. The new Patient Medication Guides required by the FDA will give patients greater ability to be educated about their medications and make informed decisions about their mental health care.