

**PARENTS,
YOU HAVE A RIGHT TO**

**KNOW
MORE
ABOUT
DRUGS**

TM

KnowMoreAboutDrugs.org

Know Everything You Can About The Drugs Your Child Is Prescribed

As a registered nurse and attorney, I spend a significant amount of my professional time protecting the interests of children as a court appointed guardian ad litem*. Each year, more and more of the children I work with are being prescribed multiple medications designed to alter their behavior, mood or school performance. In conjunction with this increased use of medications, I have seen an alarming increase in anxiety, depression, acts of self-harm, suicides, drug dependence and addiction.

The parents I work with are overwhelmed and confused by their child's behavior and rarely, if ever, have been educated on the side effects of the medication their child has been prescribed. I have referred parents to the Know More About Drugs Alliance website (knowmoreaboutdrugs.org) so they are able to become their child's best advocate. This important and informative website is easy to navigate and provides a link to the FDA Medication Guides.

Until parents, guardians, family members and healthcare providers are fully informed of the known risks of the medications being prescribed to children, they will not be able to act in a child's best interest. The FDA Medication Guides is the tool each one of us must take the time to use.

Camille L. Harlan, RN, JD, CLCP
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* A "guardian ad litem" (GAL) is a person the court appoints to investigate what solutions would be in the "best interests of a child."

EMPOWERING PARENTS WITH FDA APPROVED INFORMATION

The Know More About Drugs (KMAD) Alliance comprises medical experts, consumer drug safety representatives and award-winning documentary filmmakers who have investigated the harmful effects of prescribed psychotropic (mind-altering) drugs and synthetic opioids (pain relievers) on children and teens. The Alliance also includes parents whose children were severely damaged from being prescribed such drugs, and who were not informed of the documented risks before agreeing to administer them to their children.

KMAD does not give parents medical advice; rather its goal is to make them aware of information that the U.S. Food and Drug Administration (FDA) provides on prescription drug risks. In this way, parents can ascertain which drugs can lead to drug dependence, addiction and other serious adverse events (side effects). Armed with FDA-approved information, parents can have an educated conversation with their child's doctor and voice any concerns before making any decision regarding their care.

Many drugs prescribed to children and teens are documented to cause dependence, putting them at risk of addiction.

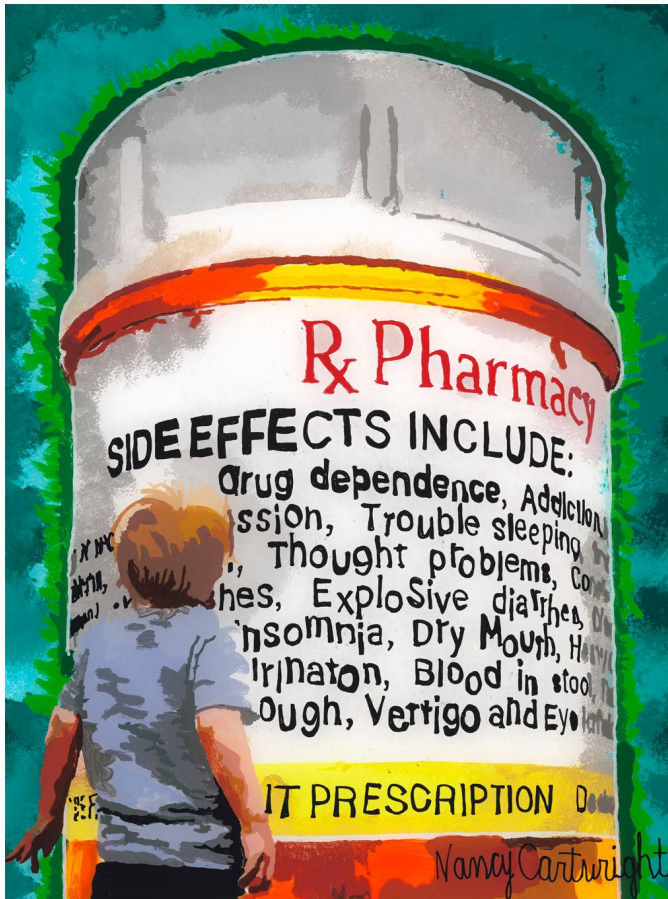


PREScription DRUG DEPENDENCE

Of particular concern to any parent should be the fact that many drugs prescribed to children and teens are documented to cause dependence, putting them at risk of addiction.¹

Given the current opioid crisis, most parents are aware that certain prescription opioids (pain relievers), including, but not limited to, oxycodone (OxyContin) and fentanyl, can be highly addictive and lead to overdose.²

According to the National Institute on Drug Abuse, "Regular use—even as prescribed by a doctor—can lead to dependence and, when misused, opioid



pain relievers can lead to addiction, overdose incidents, and deaths.”³

Aside from drug dependency and addiction risks, there are many other documented prescription drug side effects that parents need to be aware of, including any “pediatric” risks.

Parents may not be aware that according to the U.S. Drug Enforcement Administration (DEA), many psychotropic stimulants

(Attention Deficit Hyperactivity [ADHD] drugs) are in the same “high potential for abuse” category as prescribed opioids, such as OxyContin and fentanyl, and can lead to “severe psychological or physical dependence.”⁴

There are also certain antianxiety drugs, which are also prescribed to children, documented to cause “Abuse, misuse and addiction.”⁵

Aside from drug dependency and addiction risks, there are many other documented prescription drug side effects that parents need to be aware of, including any “pediatric” risks.

This information can be found in the FDA’s Medication Guides.

FDA MEDICATION GUIDES (MEDGUIDES)

According to the FDA, “Medication guides are FDA-approved documents that address issues that are specific to particular drugs and can help patients avoid serious adverse events (side effects).”⁶

The FDA’s MedGuide program, which began in 1998 under the U.S. Code of Federal Regulations, was created to make consumer-oriented, FDA-approved information sheets (which can be found online), for any prescription drug that has a “serious and significant public health concern.”⁷

MedGuides are very different from the small package inserts that usually accompany a prescription drug. Those small package inserts can be extremely lengthy, use medical terminology that is incomprehensible to the average consumer and are often printed in a very small font that is difficult to read.

Conversely, MedGuides were specifically designed to be easier for the average consumer to read and understand. Therefore, MedGuides must include the following:

- Use a larger font (no smaller than 10 point).
- They must be written using “nontechnical, understandable language.”
- They must describe “the particular serious and significant public health concern that has created the need for the Medication Guide.”
- The MedGuides must also note any “pediatric risks.”
- They must include “a statement of the risk, if there is one, of the patients developing dependence on the drug product.”

This last point is vital, as parents may not know which prescription drugs are documented to cause dependence by both the FDA and the DEA.

MedGuides were specifically designed to be easier for the average consumer to read and understand.



THE U.S. DRUG ENFORCEMENT ADMINISTRATION (DEA)

The DEA is responsible for regulating the manufacture and distribution of controlled substances, which are either illegal, or are prescription drugs regulated by the Controlled Substances Act (CSA) in the United States. Controlled substances include prescription drugs that can cause physical and mental dependence. The DEA categorizes these drugs into five different “schedules” depending on the drug’s accepted medical use and potential for abuse and dependence.

The drugs with the highest abuse potential are placed in *Schedule I*, and those with the lowest abuse potential are in *Schedule V*.⁸

It is important to note that the DEA does not categorize all prescription drug side effects from highest to lowest, only their potential for abuse.



methamphetamine (Desoxyn) or lisdexamphetamine (Vyvanse).⁹

The MedGuides specifically note when a drug can cause dependence, addiction or abuse.

Below are examples of such warnings taken from Medication Guides:

- Can be abused or lead to dependence¹⁰
- Risk of abuse, misuse, and addiction¹¹
- Can cause physical dependence and withdrawal reactions¹²

The MedGuides specifically note when a drug can cause dependence, addiction or abuse.

In addition to the risk of drug dependence, the MedGuides also cite psychological or mental side effects associated with many of the psychotropic drugs usually prescribed to children and teens for behavioral issues.

Such side effects can include:

- New or worse behavior and thought problems¹³
- New or worse aggressive behavior or hostility¹⁴
- Agitation, hallucinations, coma, or other changes in mental status¹⁵
- Delirium, paranoia, suicidal thoughts or actions¹⁶

For example, *Schedule I* drugs are those with no current accepted medical use and a **high potential for abuse**. This schedule of drugs includes illegal drugs such as LSD and heroin.

Schedule II drugs are those that also have a **high potential for abuse** but can be prescribed. This category includes the synthetic opioids such as oxycodone (OxyContin) and fentanyl.

Schedule II drugs also include stimulant drugs made from methylphenidate, (such as Concerta, Metadate, Methylin and Ritalin, often prescribed to treat ADHD), amphetamine (Adderall and Dexedrine),

The MedGuides also include specific “pediatric” side effects or warnings for children and teens, such as these:

- New psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms¹⁷
- Increased suicidal thoughts or actions in some children, teenagers, or young adults¹⁸
- Aggressive reaction¹⁹
- Abnormal increase in muscle movement or agitation²⁰
- Weight gain, especially in children and adolescents aged 10 to 17²¹
- Possible slowed growth rate²²
- Increases in blood pressure²³

The MedGuides are simple, non-technical and easy-to-read online fact sheets about prescription drug side effects. Although the FDA website states, “The Food and Drug Administration wants you to know the importance of reading Medication Guides,” the vast majority of parents and consumers may not even know they exist.

When it comes to the well-being of a child, knowledge can be lifesaving. It is for this reason, the Know More About Drugs Alliance seeks to empower parents with enough information to make educated, informed choices.

We believe parents have a right to Know More About Drugs.



**AS FAR AS WE KNOW,
NO PARENT EVER
OVERDOSED ON
TOO MUCH
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KNOWLEDGE IS POWER

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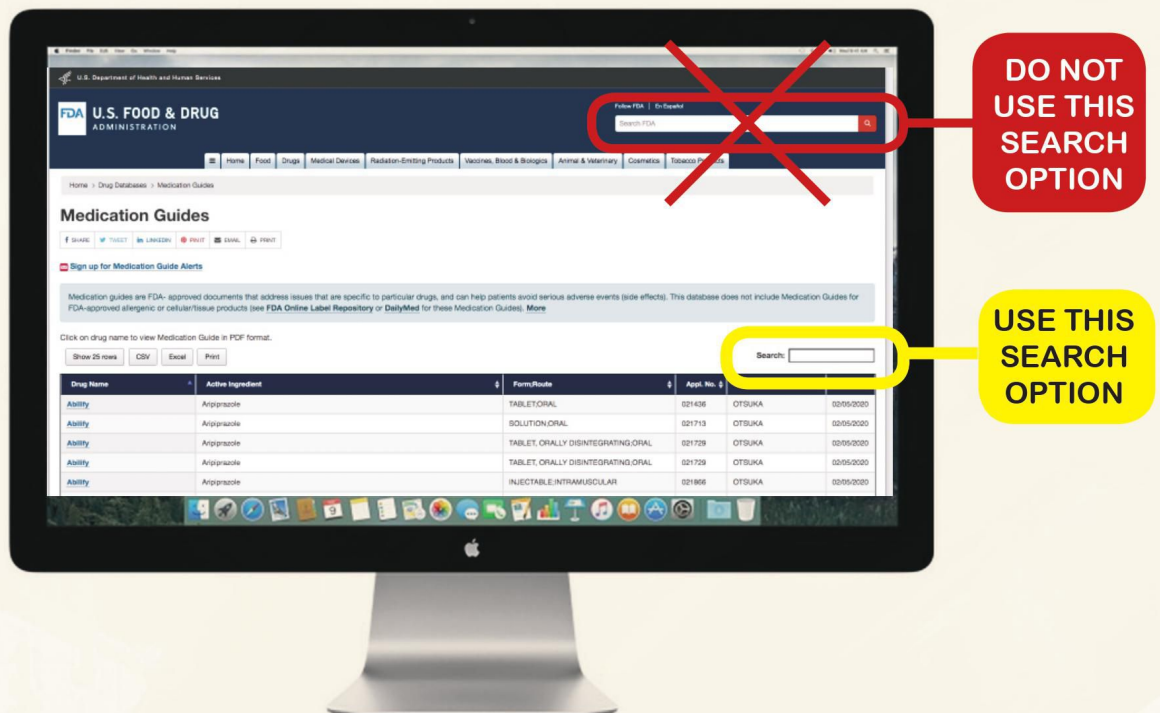
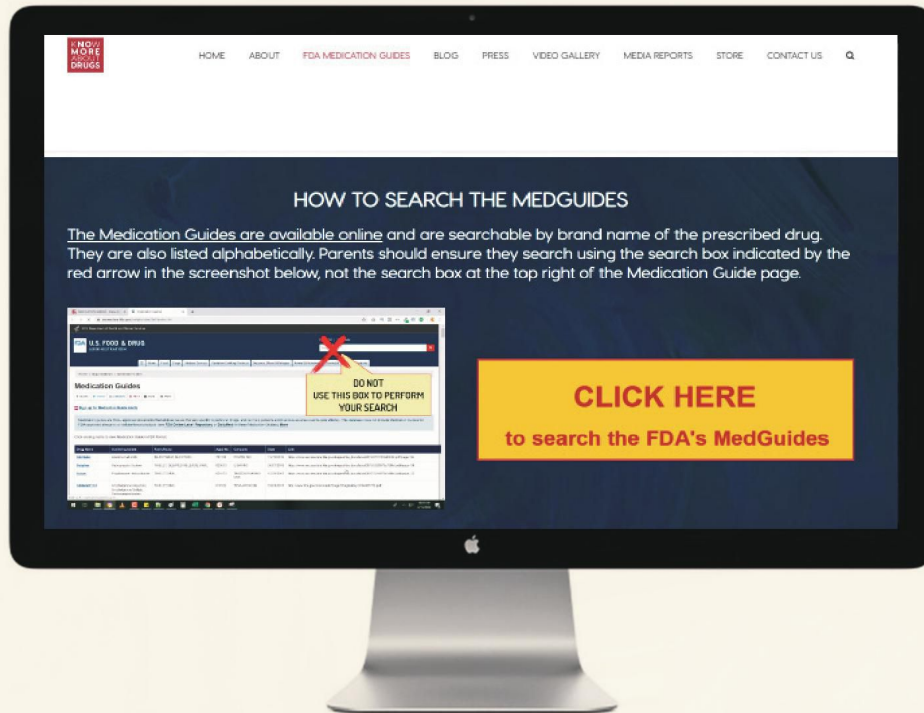
We believe parents have a right to Know More About Drugs.

Find out more at
KnowMoreAboutDrugs.org/medication-guides/



Addendum

When searching the FDA's Medication Guides (available online), be certain to use the correct search box as depicted below.



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Iconic voice-over actress, NANCY CARTWRIGHT, is the Emmy Award-winning voice of Bart Simpson. She is also an accomplished painter. These paintings were inspired by the pediatric side effects listed in the FDA's Medication Guides, along with headline press on the prescription drug epidemic and how it is affecting minors.



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