American Association of Psychiatric Pharmacists (aapp.org)

What You Need to Know About Off-Label Usage of Medications

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What are FDA-approved medications?

The United States Food & Drug Administration (FDA) is responsible for regulating both prescription and non-prescription medications. One of their roles in regulation is to ensure that medications are safe and effective. This is done through the FDA approval process.

What is off-label medication use?

This means the medication is used in a way that is not stated in the FDA labeling. Medications may be used off-label for several reasons such as:

- For a disease or condition that it is not approved to treat. For example, using some antidepressant medications to treat nerve pain.
- At a different dose than approved. For example, a lower or higher dose of the medication may be used for some patients.
- In a different dosage form than approved. For example, a medication that is approved for use with an oral tablet but prescribed with an oral solution.[1]

Why are medications used off-label?

Off-label use of medications is common. Although common, many patients may not know that a medication is prescribed off-label. So why are medications used off-label?

One reason may be that the FDA approval process is expensive and time-consuming. If the company would like to add an indication to a medication, an additional application is required. For this reason, a medication may still be helpful for off-label use even if it is not approved by the FDA. Off-label use of medications can be particularly useful for patients who have tried all other medications for a disease. Another reason a medication may be prescribed off-label is because there might not be an approved drug to treat a disease. One example is cancer medication. Often a cancer medication may be approved to treat one type of cancer but is used off-label to treat other types of cancers. Although a medication is not approved for a condition, it may have been studied for its benefits in that condition.[1,2]

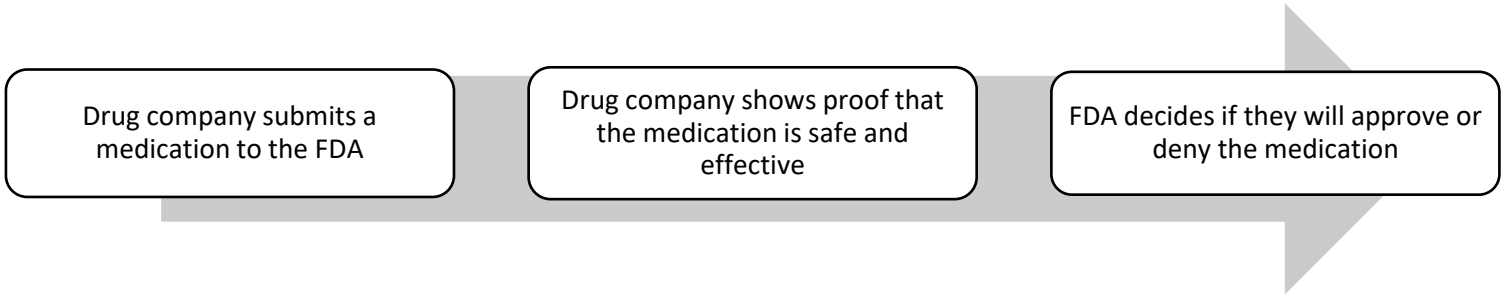
Approximately 20% of prescriptions are for an off-label use.

Examples of Off-Label Medication Use for Mental Health Conditions

Amitriptyline	• Insomnia • Neuropathic Pain • Posttraumatic stress disorder (PTSD)
Clonidine	• Smoking cessation • Excessive saliva caused by clozapine • Opioid withdrawal
Gabapentin	• Alcohol dependence • Social anxiety • Fibromyalgia
Prazosin	• Posttraumatic stress disorder (PTSD) nightmares
Topiramate	• Alcohol dependence • Weight gain caused by antipsychotic medication • Binge eating disorder • Bulimia
Trazodone	• Insomnia

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FDA Approval Process



How does a doctor decide to use a medication off-label?

Once a medication is approved for one use, doctors can decide whether it is right for other uses. Several factors are considered when a health care provider decides to prescribe a medication. This includes deciding whether the medication is safe and effective for a specific patient.[2,3]

Is it safe to use a medication off-label?

In most cases, taking a medication for off-label use is safe. Drug companies are required to prove that a medication is safe for people to use. They just don't need to prove the drug works for treating an off-label condition. Sometimes a medication could help with symptoms of conditions that it was not approved for. There are many off-label uses that most doctors agree are safe and effective.[4]

Remember!

- *Off-label use means that an approved drug is used in a way that is not approved by the FDA.*
- *This may include:*
  - *use of a medication for an unapproved indication or disease*
  - *use of a medication at an unapproved dose*
  - *use of a medication in an unapproved dosage form*
- *Consider asking your doctor about off-label use of medications that you are prescribed.*

Go online to learn more about off-label usage of medications, and to view the references for this toolkit.

https://aapp.org/resource/patients

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