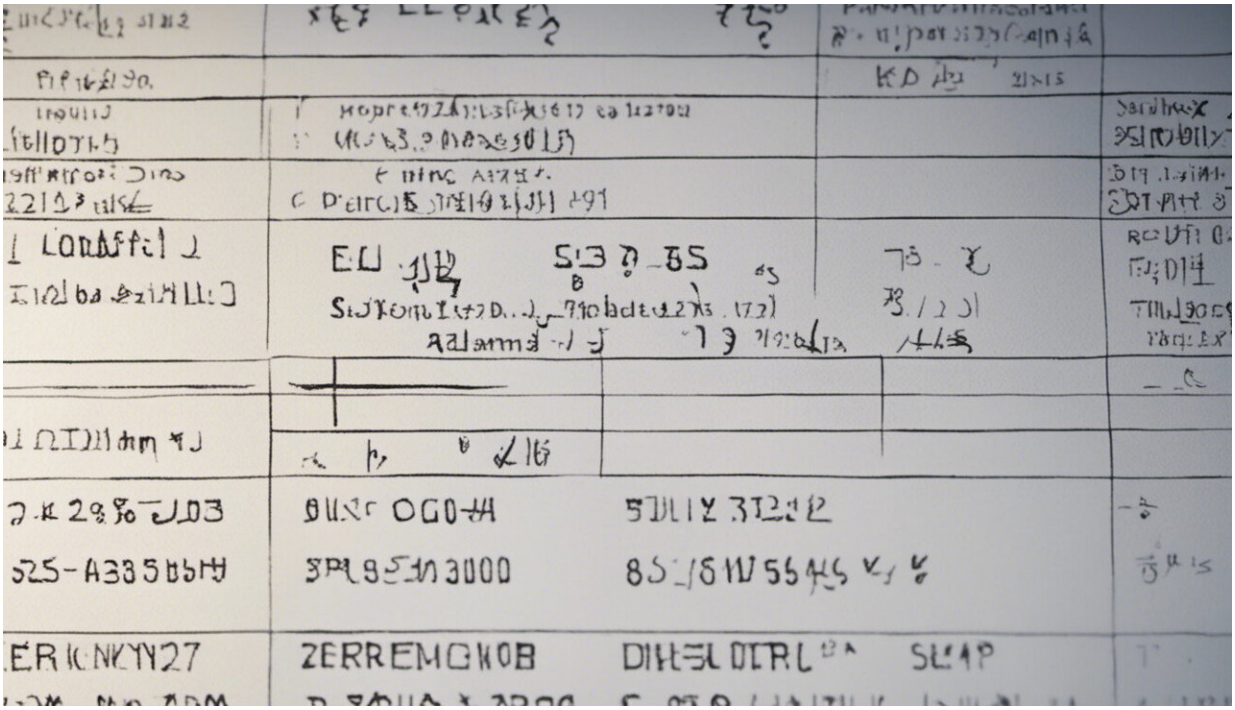
Is prescribing drugs 'off label' bad medicine?

December 8 2017, by Ravina Barrett



Credit: AI-generated image (disclaimer)

A woman, let's call her Sarah, is a young actor looking to make her debut at a major theatre. She is fit and healthy, but gets nervous on opening nights and can't sleep. She's tried zopiclone, but it didn't work, so her GP prescribes a course of quetiapine. Quetiapine is usually used to treat bipolar disorder, but the doctor explains to Sarah that he is prescribing it "off label". In other words, for a condition the drug wasn't licensed to treat.

There are legitimate reason for prescribing off label – although, there are also legitimate criticisms of the practice.

In the UK, doctors, dentists, optometrists and other prescribers are discouraged from prescribing drugs off-label when a licensed alternative is available. But off-label prescribing is done, with caution, for several reasons.

First, each prescription drug has a product licence, that is, the company that makes it had to submit a mountain of evidence to the regulator proving not only that the drug is effective, but it is safe.

Second, the prescriber and the dispensing pharmacist are legally liable when things go wrong, so the patient can sue.

Finally, sometimes there are no alternative drugs for a given health problem. For example, in Sarah's case, quetiapine is not licensed to treat insomnia. However, she has tried all available drugs licensed to treat insomnia, and none of them have worked.

The right to say 'no thanks'

Drugs are prescribed off label based on limited evidence. Sometimes, doctors have to build the evidence as they use each medicine off label and learn from their experience – what works for a given condition and what doesn't. Published case studies can also provide clues about what other uses a drug might be useful for. Case studies, though, are at the bottom of the hierarchy of medical evidence.

GPs and other prescribers have to make decisions based on the available evidence, which may not be very much. Sometimes it's based on little more than an educated guess.

In Sarah's case, the doctor feels that quetiapine might help. If the drug doesn't work for her, she'll have to come back to see him, and perhaps try a different drug – also off label.

This highlights another problem, though. Some patients – especially the elderly – take their doctor's advice as gospel and follow it regardless of how a drug makes them feel. As a result, they can end up taking pills that aren't effective and may even have unpleasant side effects.

In this example, Sarah should go back to her GP if she is concerned and she has the right not to take medicine that she doesn't want to.

Children and pregnant women

Off-label prescribing also covers areas such as using a different formulation of the drug. For example, an antibiotic may have marketing authorisation from the drug regulator in pill form, but not as an eye drop medicine. Off-label prescribing can also describe when a drug is used for a population on which it hasn't been tested. For example, some people, such as children and pregnant women, are excluded from clinical trials because it would be unethical to test drugs on them. So, when it comes to treating children and pregnant women, doctors have to make a best guess about which drug will work.

So off-label prescribing remains in the corner of medicine that isn't based on robust evidence. Although we may know a drug's safety profile, it's not the same as proving it's effective at treating a given condition. Still, it's sometimes the only option we have – which may be better than nothing at all.

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