



Questions to Ask Your Doctor or Pharmacist

Patients must understand that accepting drugs into their body is an invasion *into* their body, no less so than serious surgery. Even though that bodily invasion leaves no external scars, drugs often have powerful and lasting effects on patients' basic physiology and may not be safe or effective, even when approved by the Food and Drug Administration (FDA). Patients must ask questions about any new drug they are prescribed.

The first question to ask is whether lifestyle changes might be effective rather than drugs. Many people

report a "cure" from diabetes simply by major and sustained changes in diet and exercise. Likewise exercise and dietary changes can stave off the progression toward hypertension as we age. Now let's suppose that there are no alternative to taking a therapeutic drug.

The most important question is to ask whether the drug is being prescribed to you off label – that is for purposes or populations of people other than the ones for which the FDA has approved it. The very young and very old are often prescribed drugs that have never been evaluated in these extreme age groups where drug metabolism and effects at the target organ are unknown. Many drugs are *not* approved for use in the very young and the elderly. Off-label prescribing by physicians is basically human experimentation with no formal oversight. Unless you enjoy being a guinea pig, you will know whether your drug is being prescribed to you off label.

If you determine that your drug is prescribed to you off label, then you must know why this has been done. Does your doctor have data showing that it is safe and effective for people like you? Does his personal experience with patients like you warrant a prescription for you? Does your doctor have a "close" relationship with the manufacturer of the drug? Does your doctor even know if he is prescribing it to you off label? Many won't.

The second question to ask is how soon you will know the positive effects of the drug and how that will be known. Many drugs take weeks to exert the favorable effects they are alleged to provide. Likewise, you must know the potential side effects of the drug and how to report these if they occur in your case. You should also ask how the drugs you are already taking might interact with the new drug you have been prescribed. In general this is not going to be known by your doctor or pharmacist, but you should ask anyway.

The patient must know how long a new drug prescribed to them has been approved by the FDA. The FDA approves drugs based on quite time-limited data, so the full adverse effects of a newly approved drug may not be known for many years. Drug companies are slow to perform post-marketing, follow-up

studies once they have gotten FDA approval for a drug. I would recommend not taking any drug that has been on the market for less than three years unless there is no other choice.

The patient needs to ask if there is a “black box” warning for the drug they have been prescribed. This means that the FDA has determined that the drug may be especially risky for certain types of patients. Ask if there is an alternative without such a warning. If you are taking a “black box” drug you must be especially vigilant for side effects and adhere strictly to the prescribed dosage.

If you are taking more than four drugs you should ask about medication reconciliation. This is a systematic process of reducing the number of drugs you are taking. Studies have shown that in elderly people a reduction of an average of eight drugs to an average of four drugs per patient provided remarkable improvement in patient wellbeing with no adverse effects.

Overuse of antibiotic prescriptions is widespread and facilitates the appearance of multi-drug resistant organisms. If you are prescribed an antibiotic, ask about the rationale for this. Perhaps your condition is due to a virus and not to a bacterium. Is the antibiotic specifically targeted to the type of bacterium you are presumed to be suffering from? Ask for a culture-and-sensitivity test if your physician is not confident that the antibiotic is going to be effective against the organism causing your illness.

The victims of overuse and misuse of therapeutic drugs appear by the hundreds of thousands at emergency rooms each year. Medication errors in hospitals are among the leading causes of lethal adverse events in hospitals. There are critical times in hospitals when patient advocates must be vigilant for drug mistakes. Were medications changed after admission and if so, then why? Have medications been mistakenly deleted? What is the purpose and risk associated with any new medication? At discharge, does the patient fully understand how to take any new drug she has been prescribed? Can the patient afford the new drug?

Each patient or their advocate must take responsibility for being fully aware of the rationale for the drugs they are prescribed. Unfortunately, the patient or patient’s advocate cannot depend on anyone else to do that.

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