Senior Minutes

April 2009

Topics of Discussion:
Off-Label prescriptions
• Necessary and accepted?
• Malpractice
• Moral Issues
• Four controversies
• Steps to take

Off-Label Prescriptions: Liability and Legality Issues

The following information is intended to assistphysicians in eliminating the uncertainty of off-label prescriptions and avoiding the possibilityof being sued for malpractice.

The Necessity and Acceptance of Off-Label Prescriptions

Off-label prescribing is defined as the prescribing of a medication or using a medical device for purposes other than what has been specifically approved on the label by the FDA. Some examples of off-labeling are prescribing a dosage larger than what has been approved for the medication, recommending consumption of the drug in ways other than what has been specified on the label, prescribing to patients who do not meet the age requirements, prescribing for a longer period of time, or at a different dose schedule. The most common reasons for lawsuits from the above include the prescribed amount being higher than the recommended dosage, the drug is prescribed for an illness other then what is recommended on the label, and the patient is outside of the recommended age limits. Off-label prescribing covers a very wide range of medications, from those that have received much support throughout the medical community to those that are just being introduced.

Off-label prescribing is completely legal. The only significance of the **FDA approval** is that it gives the authorization **to sell or market the medication in certain ways.** If a product has been approved by the FDA to be put on the market, **physicians are allowed to prescribe the medication for uses, treatment regimens, or patient populations that are not on the FDA approved label.** The FDA stated, and the American Medical Association agreed, that **as long as a physician is using the medication for a scientifically supported use, they are able to prescribe them freely.** Federal statutes say that FDA approval does not "limit or interfere with the authority of a health care practitioner to prescribe."

The courts encourage off-label prescribing due to the fast pace of medical discovery and the time-consuming approval methods of the FDA. It is important to note that it takes years for the FDA to approve a new drug or a new indication on an existing drug. Meanwhile this takes place; physicians prescribe the off-label medication to their patients.

Off-label Use and Malpractice

Off-label is legal and is usually considered a wise medical practice. If a medication is not approved by the FDA, it does not mean that a medical professional cannot prescribe it, and if they do, it does not make them careless.

Are Humans Being Used as Guinea Pigs?

Many people who have an opinion about off-label prescribing believe that a medication prescribed without FDA approval is a small-scale clinical trial based on a doctor's educated guess about the medicine. They also believe that without FDA approval, there is no

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hard evidence that the product is safe and effective to use. Assuming that this is true, off-label prescribing would require the same precautions as other research trials, such as institution review board approval and consent forms.

Although this may appear to be a reasonable argument, off-label prescribing is not experimentation or research. In research, testing is meant to find general knowledge about the product being tested, while medical therapy is actually for the benefit of individual patients. **Any medical professional that engages in off-label prescribing is doing so based on their patients specific medical needs.** Also, most off-label prescribing is universally followed by physicians, meaning that many physicians may practice off-label prescribing of a certain medication, rather than prescribing something that no other physicians have used before.

If a medication is prescribed as an off-label prescription, it does not necessarily mean that it is dangerous to use. **It is not mandatory that a physician discuss the FDA regulatory status with their patients.** The FDA regulatory status does not have anything to do with disadvantages or advantages of a medication.

Four Controversies of Off-Label Prescribing

1. Limited testing for safety and effectiveness
2. Commercial influence – Pharmaceutical companies, advisory boards, consultant meetings, and continuing medical education events to promote off-label prescriptions
3. Study bias – sponsors of studies can structure the results to appear better than they actually are
4. Legal use of labeling – doctors can be found negligent if their decision to use a medication is careless or amateur

Six Steps to Take as a Physician?

1. **Stay informed with new information** and research on new drug uses, effects, interactions, and adverse effects. Show even more caution when prescribing a drug for something other than what it is intended for.
2. **Keep articles that focus on off-label uses**; however they should be kept separate from your patients' files. If they are located in the medical files, lawyers may be able to use them against you by finding faults.
3. **Be aware how an article applies to your patient.** If you are ever sued, you can use the articles to defend why you made a particular decision. If you are unable to provide a clinical or scientific explanation to your decision, then do more research or re-think the treatment recommendation.
4. **Inform your patient that the proposed treatment is an off-label use**, even though you don't have to. Informing the patient helps them understand why you made a particular decision.
5. **Engage in informed consent.** It is normal to be uncertain in medical practice, which is increased when prescribing off-label. By maintaining an ongoing discussion you can allow the patients to understand, accept, and share the uncertainty.
6. **Documentation of informed consent is something that will only benefit you** and should be used by physicians practicing off-label prescribing. It is important to cover the risks and benefits of the treatment to be provided, other potential treatments, not doing any treatment at all, and their understanding of the discussion. No questions arise when you and the patient discuss and agree upon the treatment.

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