SOME PRACTICAL POINTERS FOR OFF-LABEL USE OF AN APPROVED DRUG

Off-label use of medications is a widespread and well-accepted part of medical practice and is not, in and of itself, a professional liability risk. Off-label uses range from those that are clearly controversial to those that are considered the established standard of care. Some typical off-label uses include prescribing a medication for a condition not indicated on its FDA-approved label, prescribing at a different dosage than indicated, or prescribing for a different patient population.

One example of a potentially high-risk off-label use is the prescribing of psychotropic medications for very young children. The prevalence of this prescribing practice is escalating despite the limited knowledge base that underlies it. There have been no large-scale systematic studies, and there is little or no proven efficacy for such treatment. Indeed, the authors of a study in the Journal of the American Medical Association (Vol. 283 No. 8) concluded that "[b]ecause children's responses to medications are not necessarily similar to those of adults, systemic and careful outcome research specifically needs to be done for them." Recent articles and letters in the professional literature have discussed the frequency of and controversy about prescribing psychotropics for this relatively unexamined population. The attention given to this subject has caused an increased awareness among consumers, and psychiatrists should anticipate more questions about off-label prescribing of medications from patients and patients' families.

Malpractice allegations related to the off-label use of medications would most likely claim a deviation from the standard of care in prescribing, administering, and/or monitoring of the medication, and/or a lack of informed consent. Therefore, it is imperative that physicians prescribing medications for off-label uses ensure that their practices in this area meet the applicable standard of care and that their documentation supports the medical treatment that was given.

Set forth below are risk management tips regarding prescribing medication for off-label use:

DO remember that prescribing a drug for *any* use other than that *specifically* approved by the FDA constitutes an *off-label* use. The off-label use of an approved medication is different than the use of non-FDA approved medications.

DO realize that the off-label use of a medication can increase liability risks, if relevant information about using the medication for the proposed off-label use is scarce or non-existent. Educate yourself about off-label uses and stay informed as new information about the medication and its uses becomes available.

DO stay current with professional literature and research regarding the prescribing of medications for off-label use. For example, Practice Guidelines developed by the APA address the off-label use of medications.

DO maintain a file containing any scientific literature, professional information, and contacts with the FDA and others which supports the off-label use of medications. Keep this file separate from patients' files.

DO obtain the patient's informed consent and as always, document the consent. The documentation should reflect that the patient was informed about and understood (1) the nature of the proposed treatment, (2) the risks, benefits, and potential side-effects of the proposed treatment, (3) any alternatives to the proposed treatment, (4) the risks and benefits of the alternatives, and (5) the risks and benefits of doing nothing.

DO clarify to the patient that the proposed treatment is an off-label use of the medication. Do not describe the use as "experimental" or "investigational" as these terms do not accurately reflect the status of medications that have been approved by the FDA and are being prescribed for off-label use. Keep copies in the patient's record of all written instructions or informational materials provided to the patient.

DO remember that informed consent is a continuous process. Document your discussions with the patient about the medication, his/her response to the drug, any subsequent actions taken, and the reasoning behind your clinical decision-making process.

DO realize that the usual issues that are part of the on-going communication between the patient and psychiatrist when medications are prescribed may take on heightened importance with off-label use. Be sure to inquire about the use of other prescription medications, over-the-counter medications, herbal remedies, and any other treatments the patient uses. Clarify dietary and/or activity restrictions. Discuss potential allergic reactions, ways to identify them, and what to do if the patient experiences a reaction. Make sure that the patient knows whom to call if he/she has any questions or concerns.

DO use caution when "stacking" medications/using polypharmacy. Obviously, the greater the number of medications prescribed, the greater the potential for adverse interactions. The potential for problems can increase with off-label uses due to the possibility of unknown interactions. Educate yourself about off-label uses and stay informed as new information becomes available.

DO communicate with other health care providers about the medications that are being prescribed by all physicians involved in the patient's treatment and about signs, symptoms, and responses to the medications.
Communication is an important tool for providing quality care.

DO consider a professional consultation or a referral to another physician with appropriate training and expertise, when appropriate.

DO remain aware of the potential for misuse or abuse of medications by the patient or those who may have access to the medication.

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