

## Off-label prescribing: How to limit your liability

Kaustubh G. Joshi, MD, and Richard L. Frierson, MD

Dr. Joshi is Associate Professor of Clinical Psychiatry and Associate Director, Forensic Psychiatry Fellowship, Department of Neuropsychiatry and Behavioral Science, University of South Carolina School of Medicine, Columbia, South Carolina. He is one of CURRENT PSYCHIATRY'S Department Editors for Pearls. Dr. Frierson is Alexander G. Donald Professor of Clinical Psychiatry, Vice Chair for Education, and Director of Forensic Psychiatry Fellowship, Department of Neuropsychiatry and Behavioral Science, University of South Carolina School of Medicine, Columbia, South Carolina.

### Disclosures

The authors report no financial relationships with any companies whose products are mentioned in this article, or with manufacturers of competing products.

doi: 10.12788/cp.0035

The FDA defines “off-label” prescribing as prescribing an FDA-approved medication for an unapproved use, such as for an unapproved clinical indication, for a higher-than-approved dose, or for a patient who is not part of the FDA-approved population (eg, children or geriatric patients).<sup>1</sup> Off-label prescribing is common in psychiatry; approximately 13% of psychiatry patients are prescribed off-label psychotropic medications.<sup>2</sup> The American Psychiatric Association strongly supports “the autonomous clinical decision-making authority of a physician” and “a physician’s lawful use of an FDA-approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence in conjunction with sound medical judgment.”<sup>3</sup> Because many psychiatric diagnoses have no FDA-approved medications, off-label prescribing often may be a psychiatrist’s only pharmacologic option.

Unfortunately, off-label prescribing can increase a psychiatrist’s risk for liability when treatment falls short of patients’ expectations, or when patients allege that they were injured by the use of an off-label medication. Off-label prescribing does not automatically lead to losing a malpractice suit because the FDA states that physicians can prescribe approved medications for any scientifically supported use, including off-label.<sup>1</sup> Medical malpractice lawsuits alleging negligence in prescribing practices, such as off-label prescribing, typically include allegations against the psychiatrist for failure to<sup>4</sup>:

- consult the patient’s medical records
- obtain informed consent from the patient
- appropriately prescribe a medication for the clinical indication, dosage, patient’s age, etc.
- monitor for adverse effects and therapeutic effectiveness.

### Steps to minimize your risk

When prescribing a medication off-label, the following approaches can help reduce your liability risk:

**Conduct a comprehensive clinical assessment.** This should include requesting and reviewing your patient’s medical records.

**Explain your motivation.** Explain to your patient how prescribing an off-label medication can directly benefit him/her. Make it clear that you are not conducting experimental research by prescribing off-label because some patients might perceive this as a covert form of research.

**Know the medications you prescribe.** Although this sounds obvious, psychiatrists should thoroughly understand how each medication they prescribe is likely to clinically affect their patient. This information is available from many sources, including the FDA’s medication information sheets and the manufacturer’s medication package inserts. If possible, make sure that your off-label prescribing is supported by reputable, peer-reviewed literature.

- adequately assess the patient



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**Obtain informed consent.** Tell your patient that the medication you are recommending is being prescribed off-label. Discuss the medication's risks, benefits, adverse effects, associated "black-box" warnings, off-label uses, and alternatives to the off-label medication.<sup>4</sup> Allow time for the patient to ask questions about these treatments.

**Document all steps.** There is an adage in medicine that "If it's not written, it wasn't done." To help reduce your liability risk when prescribing off-label, be sure to document the following<sup>4</sup>:

- your clinical assessment
- information you gleaned from the patient's medical records
- your review of information regarding both therapeutic and adverse effects of the medication you want to prescribe
- your discussion of informed consent, including documentation that the patient is aware that the medication is being prescribed off-label

- your clinical rationale for why the off-label medication is in the patient's best interest.

Also, document the steps you take to monitor for adverse events and therapeutic effectiveness.<sup>4</sup> Overall, the goal of documentation should be to support the adequate continuing care of our patients.

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