LEGAL IMPLICATIONS OF OFF-LABEL USE

Educating the patient and documenting conversations are key factors in preventing legal liability.

BY LISA NIJM, MD, JD

The off-label use of drugs and devices is a common practice in ophthalmology. In fact, for many ophthalmic procedures, off-label uses of antibiotics and pain-control medications have become the standard of care. Physicians can legally prescribe a medication or perform a procedure using a medical device off-label—that is, for an indication not included on the FDA-approved labeling for that product—as long as it is in the best interest of the patient and the use is based on firm scientific rationale. There should be clinical evidence to support that the off-label use of the medication or device is the best option in a particular case.

DISCUSSION WITH PATIENTS

No matter what treatment is prescribed, the patient must understand the risks and benefits of the recommended treatment and possible alternative approaches to manage his or her condition. This takes on added emphasis with regard to off-label use, so ophthalmologists should be certain that their patients are properly informed prior to the initiation of treatment.

To ensure that one is decreasing exposure to legal risk when prescribing or performing an off-label treatment, it is advisable to have both a detailed, signed informed consent document and documentation of relevant discussions in the patient's medical record, providing details about the physician's interaction with the patient.

Ophthalmologists should also be prepared to discuss insurance coverage for off-label procedures or medications with patients. In many instances, off-label uses may not be deemed reimbursable by the

SAMPLE INFORMED CONSENT TEMPLATE FOR A DRUG OR DEVICE

Excerpted from the Ophthalmic Mutual Insurance Company website[1]

When a drug or device is approved for medical use by the FDA, the manufacturer produces a label to explain its use. Once a device/medication is approved by the FDA, physicians may use it off-label for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

[State purpose of the off-label drug/device.]

[State alternatives to the off-label drug or device.]

[State known complications and side effects of the off-label drug/device.]

I understand that [state drug/device] was approved by the FDA for [state approval purpose/conditions]. Nevertheless, I wish to have [state treatment/procedure] performed on my eye/used in my eye and I am willing to accept the potential risks that my physician has discussed with me. I acknowledge that there may be other, unknown risks and that the long-term effects and risks of [state drug/device] are not known.

1. Off-label drugs and devices. OMIC website. 2018. https://www.omic.com/off-label-drugs-and-devices. Accessed August 12, 2018.

insurance company. As such, it is important to include this aspect of treatment in the initial discussion with the patient.

DRAFTING AN INFORMED CONSENT DOCUMENT

Proper informed consent demonstrates an ongoing communication between the physician and the patient to ensure that the patient is fully and accurately informed and has made a voluntary decision to pursue the off-label course of treatment. Using a comprehensive informed consent document is a key component of this process and one of the keys to mitigating risk in off-label use. The ophthalmologist must inform the patient that, although what is being prescribed or recommended is not the FDA-approved purpose of that drug or device, there is substantial clinical evidence to provide a rational basis for prescribing it (see *Sample Informed Consent Template for a Drug or Device*).

The informed consent document should include detailed information regarding the off-label use of the drug or device. This information serves not only to educate the patient, but also to provide supporting documentation in the event of a malpractice claim. The informed consent document should provide information regarding the nature of the treatment; the clinical evidence that supports the treatment; and the benefits, potential side effects, and alternative options.

The ophthalmologist must clearly explain to the patient that this drug or device was approved by the FDA for an on-label indication, but not for the particular indication for which the physician is treating the patient. With this understanding, the patient must explicitly agree to the treatment and state that he or she is willing to accept the potential risks that have been discussed and documented in the informed consent form.

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AVOIDING MALPRACTICE RISK

Ophthalmologists should not hesitate to contact their malpractice insurance carrier if they have any questions or concerns about the off-label use of drugs or devices. Before prescribing anything off-label, one must be certain that the device has an FDA-approved on-label use in the first place. Although this might seem logical, there have been several instances when a physician used a device that was approved outside of the United States but not yet approved by the FDA, opening the door for potential litigation.

Using an FDA-approved product in an off-label manner is much different, both legally and ethically, from using a product that is not approved by the FDA at all.

It cannot be stressed enough that, even if a drug or device is approved by the FDA, the patient must be clearly informed about its off-label status *for this particular use* and the risks and benefits that such use entails. Informed consent is not only a legal obligation but an ethical obligation as well. If the patient is harmed by the off-label treatment, this may expose the physician to malpractice litigation as well as disciplinary action from the state medical licensing board.

UNDERSTAND THE IMPLICATIONS

Pharmaceutical companies and device manufacturers cannot legally recommend products for off-label use. If an off-label use is in any way promoted by the manufacturer, it may be subject to multimillion dollar fines and other severe consequences for violation of state and federal consumer protection laws. Therefore, even though an ophthalmologist may knowingly use a product off-label with the support of clinical data, manufacturers may not promote the use of the product for that indication. This makes it incumbent upon the physician to have a solid understanding of the benefits and risks of using that product off-label.

CONCLUSION

Off-label use is a very common—and legal—practice in ophthalmology. Indeed, off-label uses may be the only type of treatment available for many ocular conditions. As long as there is a scientific rationale, clear communication with the patient, and appropriate documentation in the medical record, ophthalmologists may safely use off-label treatments with minimal legal risk. ■

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