

OMIC DIGEST

Ophthalmic Mutual Insurance Company

Ophthalmic Risk Management Digest

When FDA Leaves Doctors To Their Own Devices

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With the constant development of new devices in the global health care marketplace, ophthalmologists in the U.S. are privy to various treatment alternatives, many of which are tested and employed by their peers around the world long before they are approved for use in the U.S. What are the liability risks and risk management issues that arise if American doctors opt to use devices not yet approved by the Food and Drug Administration (FDA)?

Off-label use—the practice of using an FDA-approved drug or device for a purpose that the FDA has not approved—was explored in “Medicolegal Implications of Using Off-label Drugs and Devices,” (*OMIC Digest*, Winter 1996). The FDA states that doctors, in the exercise of their best judgment, may use approved drugs or devices off-label if they are well informed about the product, base its use on firm scientific rationale and sound medical evidence, and maintain records of its use and effects.

A related, riskier issue—the use of *unapproved* devices—was recently brought to OMIC's attention by an insured who inquired about the soft tissue filler, Restylane, an injectable, gel-like substance containing hyaluronic acid that is currently used throughout Europe and Canada for lip augmentation and facial contouring. The FDA has received the results of US clinical trials of Restylane and is expected to approve it this summer (2003).

Compared to the FDA position on off-label use, the appropriateness of unapproved use is less clear. To understand the liability risks of using a device not approved by the FDA, it is necessary to understand the FDA device approval process. The Food, Drug and Cosmetic Act (FDCA) states that if a device is labeled, promoted or used in the US, it will be regulated by the FDA and is subject to pre-marketing and post-marketing

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Policy Issues

Too often, outpatient surgery is dismissed as low or no risk until a bad outcome reminds physicians and patients alike that there are risks inherent in surgery, regardless of where it is performed. OMIC's underwriting review process is designed to reduce the liability exposure of outpatient surgery by ensuring that surgery centers follow the same standard of care as acute care hospitals.

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Closed Claim Study

Was it negligent to send a 16-year-old trauma patient with an afferent pupillary defect and severe headache to a neurologist instead of to the ER for a neurological exam? When the patient died of a brain hemorrhage the next day, the ophthalmologist was forced to defend his care.

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regulatory controls to assure safety and effectiveness. Devices are broken down into three classes. Like collagen, Restylane, used for purposes similar to dermal collagen implants, is a Class III device (the most stringent regulatory category). Pre-market Approval (PMA) is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Clinical trials using unapproved medical devices on human subjects are performed under an Investigational Device Exemption (IDE). They must be approved by the FDA and by an Institutional Review Board (IRB) before the study can begin. The IDE allows the device to be used in order to collect the safety and effectiveness data required to support the PMA application to the FDA. Ophthalmologists must be aware that gathering new information on multiple patients for publication purposes, or to obtain approval for a new device or new use of an approved device, probably constitutes research and will require an IDE. However, if the use is based on firm scientific rationale and sound medical evidence, it is probably the practice of medicine, which is theoretically unregulated.

While the FDA approves and regulates the production, sale, and clinical research of medical devices, it does not directly regulate the practice of medicine. OMIC's recent inquiries of FDA staff in the ophthalmic devices division reiterated this position. However, some courts will look for exceptions to a completely "hands off" position. For instance, the Pennsylvania Superior Court held that since the FDA had never approved the use of liquid silicone injections, the trial court erred when it gave a jury the instruction that the FDA has no authority to regulate the practice of medicine. The court noted that this instruction gave the jury the incorrect impression that a

physician "can use any drug he wants, irrespective of whether it has been approved or disapproved by the FDA."

Whether the FDA can or will regulate physicians using unapproved devices may be less important than the consequences resulting when a physician uses such a device to treat a patient and the patient files a malpractice lawsuit or disciplinary action with a state licensing board. The crucial question then becomes whether the physician met the standard of care based upon what reasonable physicians in the same specialty would do at the same time under similar circumstances.

Case law has shown that violating the FDCA may be evidence of a breach of the standard of care and consequently result in a determination that malpractice has occurred. A plaintiff attorney could argue that the use of an unapproved device constitutes *negligence per se* (*negligence per se* or *legal negligence* is negligence established as a matter of law, usually arising from a statutory violation). If state laws are stricter than the federal FDCA and specifically prohibit the use of unapproved devices, it would be easier for the plaintiff to prove a violation of the law and argue either negligence per se or breach of the standard of care.

In order to provide the best alternative to the patient and stay one step ahead of the market competition, ophthalmologists may be tempted to offer the very latest in products or services. Before deciding whether to use the newest device available, several factors should be considered (see **Questions to Ask Before Using a Non-FDA Approved Device**). The analysis for non-FDA approved devices is based upon the same exercise of professional judgment that should be used in determining whether to use approved or off-label treatment alternatives. Physicians

should take special care before using a device for an elective cosmetic procedure. Defense attorneys postulate that juries more closely scrutinize the care of the physician when problems arise in an elective procedure, rather than in an emergency or life-saving procedure. A 2001 OMIC survey found that 73% of ophthalmologists polled believed that elective surgery patients are more likely than other patients to sue their surgeon. Given the higher risk that elective procedures pose, ophthalmologists should consider additional factors in order to make sound decisions to use non-FDA approved devices (see **Additional Questions to Ask Before an Elective Cosmetic Procedure**).

Applying this risk analysis to three different devices shows how fact-dependent the outcome of the analysis can be. First, in the case of Restylane, it appears that its use prior to FDA approval would be difficult to defend in a lawsuit. Even though physicians throughout Europe and Canada have been using Restylane with positive results since the mid-1990s, surgeons in the U.S. will need to gather data based on larger numbers of patients over extended periods of time in order to determine its long-term safety and efficacy. Patient expectations also will have a profound influence on the risk of using Restylane. Web sites already tout Restylane as a method that is "fast and safe and leaves no scars or other traces on the face." Because the efficacy of Restylane is dependant on many variables, such as age, skin type, lifestyle, and muscle activity, patients with unrealistic expectations may be disappointed if they do not achieve the volume, smoothness, or long-lasting effects they anticipated. These factors create an especially risky environment in which to use a non-FDA approved device; prudent physicians would

Questions to Ask Before Using a Non-FDA Approved Device

Has a federal or state regulatory agency specifically banned the use of the device because it was determined to be unsafe?

Is there sound medical evidence supporting the use of this device?

Have peer reviewed articles been published supporting the use of this device?

Can its use be expected to bring good results without a higher complication rate?

If there is an increased risk, do a reasonable number of physicians in this specialty use the device?

Is the use of this device in the best interest of this particular patient?

Additional Questions to Ask Before an Elective Cosmetic Procedure

Does the patient have reasonable expectations?

Has the patient had problems with other treating physicians in the past?

Is he or she set on a certain procedure because of advertisements and recent popularity?

What are the patient's motivations for having this procedure?

Does the patient truly understand what this procedure entails and the possible outcomes?

Does the patient understand that he or she will have to pay out-of-pocket not only for the procedure but also for any enhancement or follow-up?

be well advised not to use Restylane (outside of an approved clinical trial) until it is approved by the FDA. A disappointed patient and plaintiff attorney will not have to look hard for theories of liability or experts to support a lawsuit against an ophthalmologist who injects this "unproven" material.

The second device group assessed for use prior to FDA approval is capsular tension rings, Class III devices marketed by Morcher and Ophtec and currently undergoing pre-market approval review with the FDA. These devices are being used in cataract surgery with some regularity and ophthalmologists are sharing their results with their peers. Because these devices are being used therapeutically for medical treatment, some of the patient expectation variables that arise in cosmetic procedures are avoided. Nevertheless, because they are relatively new to the market, ophthalmologists should use them with caution.

The final example is cyanoacrylate adhesive, used by ophthalmologists for the medical treatment of corneal perforations. One variant of this product, Dermabond Topical Skin Adhesive (2-octyl cyanoacrylate), was approved by the FDA in 2002 to seal out infection-causing bacteria. Yet cyanoacrylate adhesives have been used in the US for wound repair as an alternative to sutures since the Vietnam War in the mid-1960s. Even before Dermabond's FDA approval, variations of this adhesive had a long and proven track record and near universal acceptance in the ophthalmic community. Because of its widespread peer use and longevity, ophthalmic use of cyanoacrylate adhesive for the treatment of small perforations or leaks would most likely be considered standard medical practice in the community even when applying the most conservative analysis criteria.

After review, if the ophthalmologist decides that there is sound medical evidence and it is in the patient's best interest to use a non-FDA approved device, he or she should conduct and document a thorough and careful informed consent discussion. The patient should be informed of the nature of the technique or device being used, its scientific basis, its benefits, and any possible drawbacks or criticisms from other practitioners. Especially with cosmetic procedures, other options should be discussed, and the patient should be encouraged to seek a second opinion before proceeding.

If the unapproved device in question is used under an IDE, the federal government requires that the physician have a special, detailed informed consent discussion with the patient which addresses its unapproved status. If the device is not being used under an IDE, physicians should consult with legal counsel about whether state law requires them to disclose the device's unapproved status to the patient as part of the informed consent discussion. Regardless of state or federal law, from a risk management perspective, it is always advisable to respect the patient's right to obtain the information needed to make reasoned decisions about his or her own health care. If the physician reasonably believes that the approval status of the device to be used in the patient's treatment will be a factor in the patient's decision to undergo the procedure, this information should be disclosed.

Finally, ophthalmologists should always check with the Underwriting Department of their professional liability carrier to ensure that they will be covered for any off-label or non-FDA approved procedure they are contemplating.