OMIC OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

Unapproved Devices: Checklist for Risk Analysis

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The FDA approves and regulates the production, sale, and clinical research of medical devices. It does not directly regulate the practice of medicine. Prior to using an unapproved device, use this checklist to perform a risk analysis to determine the patient safety and professional liability risks associated with its use.

- What is the device?
- What is its FDA status?
    - Unapproved but undergoing clinical trials under an IDE (Investigational Device Exemption)
    - Unapproved but not yet undergoing trials
    - Unapproved and unlikely to undergo trials
- Who is manufacturing the device
    - A manufacturer or compounding pharmacy
        - Is the manufacturer or compounding pharmacy reputable and known to you?
        - Does the manufacturer or compounding pharmacy follow industry guidelines for sterility and quality assurance?
            - Keep material documenting the sterility and quality in your file on the device
- Are you distributing or reselling it?

    - If the device is labeled, promoted, or distributed in US, it is regulated by the FDA and subject to pre-marketing and post-marketing regulatory controls to assure safety and effectiveness
    - Distributing or selling greatly increases risk of FDA action
- How are you using it?
    - Research:
        - Gathering new information on multiple patients for publication purposes, or to obtain approval for a new device or a new use of an approved device, is probably research and requires an IDE
        - Part of an IDE (Investigational Device Exemption) to collect safety and effectiveness data required to support the PMA (pre-market approval) application to the FDA
            - Follow federal and state requirements for
                - obtaining approval of an IRB (Institutional Review Board) for the trials and
                - obtaining informed consent of the patient for research on human subject
                - disclosing any financial interests/incentives
    - "Practice of medicine"
        - Not for research AND
        - Use based on firm scientific rationale and sound medical evidence
        - The "practice of medicine" is theoretically unregulated by FDA but some case law exists limiting the use of unapproved devices as part of the practice of medicine
- What role does the device play in the treatment?
    - Does the treatment consist primarily of using this device? If so, the risk of using it prior to FDA approval is greater
        - Example: Restylane, used for lip augmentation and facial contouring
    - Does the device play an ancillary or supportive role in the performance of a procedure or treatment? If so, there is less risk.
        - Example: use of the dye, trypan blue, to stain the anterior capsule to facilitate visualization during cataract surgery
- What are the patient safety risks and how do you know about them?
    - Has a federal agency 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?
        - Keep a file containing these articles and presentations
    - 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 your specialty use the device?
    - Is the use of the device in the best interest of this particular patient?
- Is the procedure "therapeutic" or cosmetic?
    - Therapeutic use of an unapproved device is less risky than cosmetic

- If cosmetic
    - 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 fully 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?
- Informed consent discussion
    - Content of the discussion
        - Nature of the device or technique
        - Scientific basis for its use
        - FDA-unapproved status
            - It is always prudent to respect patient's right to obtain the information needed to make reasoned decisions about his or her own health care
            - If physician reasonably believes that the approval status of the device will be a factor in the patient's decision, disclose the information
        - Benefits
        - Risks
        - Alternatives
        - Possible drawbacks or criticisms from other practitioners
        - Especially with cosmetic procedures, other options and possibility of obtaining 2nd opinion
    - If part of research or IDE
        - Must follow federal and state guidelines for informed consent
    - If not part of IDE
        - Consult legal counsel about whether state law requires physician to disclose the device's unapproved status to the patient as part of informed consent discussion
    - Document the informed consent discussion of the risks, benefits, and alternatives, and include the fact that the patient was informed of the device's unapproved status
        - If the treatment consists primarily of using the device, consider developing a specific consent **form** for the device that outlines the risks, benefits, and alternatives, and the FDA status, and give the patient a copy
- Verify coverage with your professional liability insurance carrier
- Consequences of violating the FDCA (Food, Drug and Cosmetic Act)
    - May be evidence of breach of the standard of care and result in determination that medical malpractice has occurred
    - May constitute *negligence per se*, due to statutory violation

        - Easier to prove if state law is stricter than FDCA and specifically prohibits the use of unapproved devices
    - Prosecution by FDA
        - Unlikely if only practice of medicine, and no distribution or sales

OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC's confidential Risk Management Hotline at (800) 562-6642, extension 641.