Optometry Making the Most of FDA's MedWatch

The Food and Drug Administration (FDA) MedWatch system was introduced in 1993 for "voluntarily reporting a serious adverse event, product quality problem, product use error, or therapeutic inequivalence/failure that may be associated with the use of an FDA-regulated drug, biologic, medical device, dietary supplement or cosmetic."[i] In order to keep effective medical products available on the market, the FDA relies on the voluntary reporting of these events. FDA uses these data to maintain safety surveillance of these products. While this form of passive surveillance is often incomplete because of the limited reporting incentives, doctors of optometry might view reporting as a professional opportunity. This includes a unique opportunity to 1) share information for the benefit of patients and the advancement of human knowledge and welfare;[ii] 2) protect the health and welfare of society;[iii] and 3) participate actively, as primary health care providers, in efforts that enhance the eye, vision and general health of patients and the public.[iv]

OPTOMETRY'S OPPORTUNISTIC REPORTING TO THE FDA MAY BE THE CRITICAL ACTION THAT PROMPTS A MODIFICATION IN USE OR DESIGN OF A PRODUCT, IMPROVES ITS SAFETY PROFILE AND LEADS TO INCREASED PATIENT SAFETY AND IMPROVED PUBLIC HEALTH.

Voluntary reporting can be done through the FDA online reporting portal or by downloading, completing and then submitting FDA Form 3500 (Health Professional) or 3500B (Consumer/Patient) to MedWatch: The FDA Safety Information and Adverse Event Reporting Program. It is often useful for both the doctor and patient to file an FDA MedWatch report about the adverse event, even if they are reporting the same adverse event.

What type of information should doctors and their patients report to MedWatch?

- **Unexpected side effects or adverse events** can include everything from skin rashes to more serious complications. For example, this should include serious problems associated with contact lens use (e.g., corneal ulcer, corneal neovascularization, corneal keratitis).
- **Product quality problems** such as information that a product isn't working properly or that it has a defect. This would include medical devices used by patients and found to be dangerous to their health.[v]

- **Product use/medication errors that can be prevented.** These can be caused by various issues, including choosing the wrong product because of labels or packaging that look alike or have similar brand or generic names. Mistakes also can be caused by difficulty with a device due to hard-to-read controls or displays, which may cause an individual to record a test result that is not correct.

- **Therapeutic failures.** These problems can include when a medical product does not seem to work as well when you switch from one generic to another.

What types of FDA regulated products might doctors of optometry and their patients report through MedWatch?

- Medical devices such as diabetes glucose-test kits, contact lenses and many more products including but not limited to on-line apps for vision testing.
- Prescription and over-the-counter medicines.
- Biologics such as stem cell contact lenses for eye disease, gene therapies and human cells and tissue transplants.
- Combination products such as prefilled drug syringes, auto-injectors, metered-dose inhalers, contact lenses coated or embedded with a drug and nasal sprays.
- Special nutritional products such as dietary supplements.
- Cosmetics such as moisturizers, makeup, shampoos, conditioners, hair dyes and tattoos.

It is important to know that other products that intersect the profession of optometry and that are regulated by the FDA, such as tobacco products, and vaccines, utilize different reporting pathways. It is recommended that reports concerning these products be submitted directly to the appropriate portals linked above.

FDA MedWatch offers several ways to help doctors stay informed about the medical products they prescribe, administer or dispense every day: e-mail (MedWatch E-list), Twitter and RSS. Learn more about the MedWatch E-list.

Remember, optometry's opportunistic reporting to the FDA may be the critical action that prompts a modification in use or design of a product, improves its safety profile and leads to increased patient safety and improved public health.[vi]

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[i] https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

[ii] https://www.aoa.org/about-the-aoa/ethics-and-values

[iii] https://www.aoa.org/about-the-aoa/ethics-and-values

[iv] https://www.aoa.org/AOA/Documents/About%20the%20AOA/Ethics%20%26%20Values/Standards-of-Professional-Conduct_Adopted-June-2011.pdf

[v] https://www.aoa.org/AOA/Documents/Advocacy/HPI/Unproven%20Claims%20and%20Inaccuracies%20of%20the%20Visibly.pdf

[vi] https://www.aoa.org/AOA/Documents/Advocacy/HPI/Unproven%20Claims%20and%20Inaccuracies%20of%20the%20Visibly.pdf