Health Policy Institute

AMERICAN OPTOMETRIC ASSOCIATION

Unproven Claims and Inaccuracies of the Opternative Vision Test

Visibly, formerly known as Opternative, is no longer making its online refractive vision test available on its website, reflecting a Class 2 Device Recall for their refractive vision test by the U.S. Food and Drug Administration (FDA). (See Addendum for Timeline)

Medical device technology can be advantageous when properly tested, evaluated and used. Most importantly, the safety and effectiveness of a device must be rigorously reviewed by independent authorities. Medical devices that are not restricted to use by trained professionals require additional scrutiny.

Through its marketing to the public, Opternative claims its technology enables consumers to self-test their vision and receive accurate results. A doctor can then use the results to remotely write a prescription for eyeglasses and contact lenses—which are regulated medical devices. Opternative claims its scheme is "as accurate as an in-person refractive eye exam" and, as of June 2017, cites a single unpublished study as proof.

In a critical review, the U.S. results have not been sufficiently studied. Unlike testing in a doctor's office, Opternative's conditions and procedures for self-testing are not standardized, and essential controls used routinely in eye care practice are not in place. In one of many examples, ambient light in the patient's environment, the backlighting of the patient's computer screen and smartphone display, and other characteristics of the computer and smartphone are not controlled—all of which, individually or collectively, affect utility of the test results.

Additionally, Opternative device calculations are prone to error because the scheme uses an imprecise method to estimate distance from the screen by asking the patient to enter a shoe size and stand a certain number of foot-lengths away from the screen.

There are also technological reasons to doubt the safety of the Opternative device and the accuracy of the prescriptions generated by this technology. The Opternative device uses untested, adulterated refraction methods in defining spherical and astigmatic corrections, such as power endpoints and axis (direction of power in the final lens prescription), that could cause irreparable harm to individuals who may rely on such determinations for glasses or contact lens prescriptions. For example, Opternative's method for determining the axis of astigmatism appears to have an accuracy of ± 30 degrees. This large amount of variation significantly exceeds the level that would be acceptable for subjective refraction by an optometrist or ophthalmologist, where tolerances range from 2 degrees to 7 degrees.[1]

Although refractive errors are most often asymptomatic and cannot be accurately measured by self-reporting symptoms, the Opternative scheme relies on a series of questions regarding experiences of

eyestrain during near- or distance-viewing activities to aid the determination of refractive error. It's like asking if your teeth hurt when you chew and using the answer to help guess whether you might need a root canal or a filling. The Opternative device also unconventionally relies on the patient report of the level of distortion of vision along a single axis (i.e., blurring around the edges of presented triangles lined up against each other), whereby the size of the space is apparently used to determine the strength of correction needed to address the individual's astigmatism. Furthermore, Opternative uses a Duochrome Chart (Red-Green Chart) in adulterated and misbranded ways to determine whether the patient has myopia or hyperopia in the first instance, beyond its designed use for only a final refinement (whereby the principle of chromatic aberration, in a highly controlled dark environment, assists clinicians from over-prescribing minus power in the final eyeglasses prescription). Thus, the Opternative device uses techniques for different purposes than are taught in school, and in ways not proven effective.

Ultimately, the AOA HPI found there is a high and unacceptable likelihood that doctors relying on data self-generated by consumers using the Opternative device will misdiagnose the user's refractive correction and importantly, the patient misses professional in-person eye care that could identify serious ocular and systemic disease requiring treatment before eyesight is permanently impaired or lost. For example, many underlying conditions or diseases, which would be apparent to a clinician performing an in-person exam with proven ophthalmic devices, are likely to be misdiagnosed by Opternative's device as a refractive error requiring a lens prescription—or missed entirely. These include undiagnosed or uncontrolled diabetes, which can cause an accumulation of fluid in the eye that, in turn, can cause significant but temporary refraction errors that mimic those caused by myopia or hyperopia. The Opternative device relies on technology that does not appear to distinguish between refraction errors caused by complications of diabetes versus refraction errors caused by myopia or hyperopia. The doctor relying on data from the device might generate an improper lens prescription when the patient should instead be treated for an underlying blood sugar imbalance associated with diabetes.

The Opternative exclusion criteria does not adequately protect at-risk patients from irreparable harm. For example, though the Opternative device use is excluded for patients with known diabetes, one-third of all individuals with diabetes are in fact unaware of having diabetes and thus unaware they should be excluded from using the Opternative device. This currently represents approximately 10 million Americans. For this reason alone, the FDA's review should also assure that the device is contraindicated in patients at risk for any eye condition that could be misdiagnosed by the device and that requires treatment other than a lens prescription.

The Centers for Disease Control and Prevention and the National Eye Institute agree that the only way to know if your vision is healthy is to have a comprehensive eye examination. The National Academies of Science, Engineering and Medicine, in its landmark 2016 report on vision and public health, explained that an eye examination is an in-person service.

Finally, the Opternative device does not meet the standards for telehealth approved by the AOA House of Delegates. The AOA HPI recommends the Opternative device should not be marketed to the public in any manner, nor relied upon by the public or eye care professionals, for eye health and vision care.

[1] https://www.thevisioncouncil.org/sites/default/files/ANSI%20Z80%201-2015_Quick%20Reference%20v2.pdf

ADDENDUM

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TIMELINE

- **Sept. 18, 2014 –** Opternative files patent for an online eye exam app.
- **July 27, 2015 –** Opternative becomes available to consumers.
- **Aug. 17, 2015 –** Steven A. Loomis, O.D., AOA president, issues an appeal to the FDA to investigate misleading claims connected to the unproven use of a medical device by one such online "eye exam" service, calling itself Opternative. The letter questions the company's news release for asserting that its smartphone-derived technology is "Food and Drug Administration registered," a claim appearing to convey that the FDA has performed an assessment of this technology and viewed it favorably.
- **Oct. 23, 2015 –** The AOA submits a new letter to the Food and Drug Administration (FDA), reaffirming the AOA's initial request for a full investigation of Opternative's claims connected to the unproven use of a medical device, and reported a further questionable practice—namely, the use of a doctor locator function on the business's website and its ambiguous wording.
- **April 4, 2016 –** The AOA submits an official complaint to the FDA "MARKETING OF UNAPPROVED AND UNCLEARED OPHTHALMIC DEVICE BY OPTERNATIVE, INC." pointing out that Opternative's continued marketing to consumers without federal approval is in violation of the Food, Drug and Cosmetic Act (FDCA).
- **Nov. 4, 2016 –** Meeting between FDA and AOA held at FDA. Representing the AOA is Christopher J. Quinn, O.D., AOA president-elect, together with AOA staff.
- **Jan. 18, 2017 –** AOA supplement to complaint, "MARKETING OF UNAPPROVED AND UNCLEARED OPHTHALMIC DEVICE BY OPTERNATIVE, INC." is filed with Robin Newman, MSN, EdD, director, Office of Compliance, Center for Devices and Radiological Health, at FDA.
- **Oct. 30, 2017** (but not made public until **March 9, 2018) –** The FDA issues a warning letter to Opternative indicating the company was in violation of the FDCA and requests the company "immediately cease activities that result in the misbranding or adulteration of the On-Line Opternative Eye Examination Mobile Medical App device, such as the commercial distribution of the device through your online website."
- **Dec. 11, 2018 –** Opternative rebrands itself and changes its name to "Visibly."
- **May 20, 2019 –** The FDA issues Visibly a Class 2 Device Recall for their refractive vision test. The FDA will be monitoring the company's actions in light of the device recall.
- **Aug. 8, 2019 –** The FDA releases public notice of the Class 2 Device Recall to Visibly for its refractive vision test being offered in violation of federal law. The recall reflects longstanding AOA concerns made through formal complaints to the FDA.
    - The recall document cites Visibly's "lack of 510(k) clearance."
    - The recall notice reads, "The Visibly Online Refraction Vision Test is being recalled since the firm has not received authorization from FDA to market the product."