

[California Optometric Association](#)

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**California Optometrists Caution Patients About Unapproved,
Online ‘Vision Tests’ After FDA Warning**

*Opternative and 1-800 Contacts Marketing to California Consumers
Despite FDA ‘Cease’ Demand*

Sacramento, CA – The California Optometric Association today cautioned California consumers that self-administered “vision tests” conducted online come with significant safety concerns and appear to violate federal law. In a letter to the California Attorney General today, the organization representing California’s doctors of optometry said Opternative, and its partner 1-800 Contacts, appear to be violating an October 30, 2017, Food and Drug Administration (FDA) letter demanding Opternative cease marketing its online product in violation of the Federal Food, Drug, and Cosmetic Act.

In a letter to the California Attorney General, COA President Ranjeet S. Bajwa, OD, FAAO, Dipl ABO wrote, “Public health is therefore potentially threatened by a medical device actively marketed to the public despite not having gone through the required review and approval processes demanded by the FDA.” He continued, “Therefore, the California Optometric Association respectfully requests your office take prompt action to protect the health and safety of 39.5 million residents by investigating” the joint venture between Opternative and 1-800 Contacts.

The FDA’s October warning letter to Opternative states, among other things: “The United States Food and Drug Administration (FDA) has learned that your firm is marketing the On-Line Opternative Eye Examination Mobile Medical App device in the United States without marketing clearance or approval.”

Doctors of optometry warned patients that online vision tests cannot replace an in-person examination from an eye doctor. Technology that removes an in-person examination of the eye by an optometrist or physician raises significant health and safety concerns, including:

- As currently marketed, the online tests cannot detect glaucoma, cataracts, or macular degeneration – all sight-threatening conditions.
- The tests cannot distinguish between diabetes-related vision loss and other conditions that would indicate an eyeglass prescription.
- The tests cannot detect problems related to contact lens wear, which can permanently damage sight if not corrected.

- The self-administered exam relies on the patient to measure the distance from their computer, leaving significant room for prescriptive error.
- The technology lacks independent clinical trials; the company-commissioned trial for the Opternative app-based test was not peer-reviewed, lasted only four months, and was limited to 30 people. The Opternative online test is offered to patients outside the scope of the clinical trial, including those ages 40-55 and those with higher refractive errors. The FDA has not reviewed the safety or accuracy of the Opternative technology or claims of accuracy.

Seventeen U.S. states currently limit online vision tests or are considering legislation to limit this technology. **California law requires that only an optometrist or a physician and surgeon can examine human vision.**

“California’s optometrists are warning patients about this unapproved technology because we are committed to protecting Californians’ vision and health. We are deeply concerned that companies may market this technology in a way that exacerbates the already significant health issues faced by California’s underserved communities, who are at greater risk for eye-sight robbing conditions like diabetes and hypertension,” said Dr. Bajwa. “Optometrists embrace the potential of telemedicine to bring patients closer to quality care, unfortunately this product does the opposite – closing crucial windows to detect diabetes and other underlying health conditions that affect vision and can take lives.”

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