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Contact: Lawrence Hoffheimer, Chairman
lhoffheimer@maculardegenerationassociation.org
(941) 960-8112

EYE ASSOCIATION ISSUES URGENT SUPPLEMENT WARNING

Genetic Swab Test Can Help Doctors Determine if Helpful or Harmful

SARASOTA, Fla., March 7, 2016—The Macular Degeneration Association, a nonprofit dedicated to preventing blindness, today issued an urgent warning to patients suffering from a form of the disease known as “intermediate dry age-related macular degeneration.” MDA leaders and ophthalmologists are advising patients to talk with their doctors about a proven and commonly prescribed vitamin supplement containing zinc, an ingredient that might actually be harmful in some cases. They are recommending a simple, personalized genetic test that could potentially indicate the difference between slowing or accelerating the progression of vision loss.

Age-related macular degeneration (AMD) is the leading cause of legal blindness in people over 55 in the US.

The MDA cites mixed reviews on the supplement, which is known medically as the AREDS formulation and goes by many brand names. In studies published in the journal *Ophthalmology*, genetic test results suggested that AREDS could help about 35 percent of patients, while accelerating vision loss for 13 percent. A non-zinc formula is available for the latter group.

“AREDS supplements have been shown to benefit the average patient with moderate macular degeneration, but our research suggests that this average benefit is the result of significantly different individual responses,” says Carl Awh, MD, a retina

specialist from Nashville, Tenn. “The AREDS supplement was beneficial for most patients, but almost 15% did worse with treatment than with placebo. This adverse outcome appears to be due to the high-dose zinc component of the AREDS formulation. More research is indicated but, in the meantime, I perform genetic testing to select the optimal nutritional supplement for each patient.”

“What we’re recommending is an abundance of caution and an informed dialogue between patients and their doctors,” says MDA founder and chairman Lawrence Hoffheimer, a retired healthcare attorney and federal prosecutor whose mother suffered from the disease. “This supplement can be very helpful to some patients, but if there’s a likely possibility that zinc can accelerate vision loss, and a simple genetic test can determine if a patient may be at risk, it makes sense to consider the test.”

As reported recently in *Ophthalmology Times*, the American Academy of Ophthalmology is not recommending routine genetic testing and still considers the test to be “under evaluation.”

However, a review of the National Eye Institute’s data by Dr. Rafal Kustra of the University of Toronto, which was independently reviewed by Dr. Bernard Rosner, Professor of Medicine in the Department of Biostatistics at Harvard Medical School’s T.H. Chan School of Public Health, suggested that zinc can be harmful in patients with the suspect genetic profile. “I agree with the report by Dr. Rafal Kustra,” Dr. Rosner says. “There definitely is an interaction.” His review suggests that all of the AREDS genetic data as published demonstrates a detrimental effect in at least 13 percent of patients with macular degeneration.

“Nobody wants to accelerate blindness,” says Hoffheimer. “But I encourage everyone to examine the financial incentives. “The makers of these supplements have made millions and could be exposed to legal risks in cases where zinc is proven harmful. Doctors at the National Eye Institute have earned nearly \$2 million by legally

transferring this technology to the private sector. Conflict of interest are everywhere and we just don't want patients to get hurt."

Hoffheimer acknowledges that there is only one provider of the personalized genetic test, which costs about \$500.00, is accepted by many insurers, and requires a prescription from an ophthalmologist or optometrist for the cheek swab and processing. The test was developed by a Canadian company, ArcticDx, which processes samples in its lab in Grand Rapids, MI.

"We are not supporting ArcticDx specifically. However, they are currently the only provider for this particular test," says Hoffheimer.

Age-related macular degeneration is expected to affect almost 20 million people by 2020. Because overall life expectancy continues to increase, age-related macular degeneration has become a major public health problem. AMD affects a person's ability to see details and images straight ahead. More than 85 percent of patients with AMD have the dry form, for which there is no cure and no treatment other than the AREDS supplement.

The Macular Degeneration Association is a 501(c)(3) organization providing the latest research information and advocacy for patients with all visual diseases, including AMD, diabetic macular edema, glaucoma and cataracts. MDA does not provide medical advice and encourages patients to talk with their doctors about their individual needs. To learn more about MDA, visit www.macularhope.org or call (941) 960-8112.

Physicians, patients and insurers can learn more about the personalized genetic test to determine if AREDS supplements with zinc may be helpful or if a non-zinc formula should be considered by visiting the ArcticDx website, www.macularisk.com.

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