

# Letters

## Response From Johnson & Johnson Vision

In response to Dr. J.T. Kavanagh's letter (Letters, June), Abbott Medical Optics Inc. (AMO) can confirm that the complaint raised in his letter was investigated, the root cause of the issue was identified, and corrective actions were implemented in the manufacturing processes to prevent this issue from occurring in the future. We reached out and spoke directly to the surgeon when the matter was brought to our attention. No patient injury has occurred in connection with this complaint.

At AMO, we are fully dedicated to delivering quality products and take patient safety and customer complaints very seriously. I, and my colleagues around the world, strive every day to help transform lives by providing high quality, innovative surgical technologies that help improve the way people see. If you have product complaints or adverse events to report regarding any AMO product, please call our customer service line at 877-266-4543.

We thank the ophthalmic community for their continued partnership.

*Tom Frinzi*

*President, Johnson & Johnson Vision, Surgical Platform*

(Please note that Abbott Medical Optics Inc. is now a member of the Johnson & Johnson Family of Medical Device Companies.)

## Genetic Testing for Patients With AMD: A Response

I write in response to Dr. Parke's column, "An Issue Settled ... for Now" (Current Perspective, July). For the CEO of the American Academy of Ophthalmology to state that a scientific issue is "settled" is troublesome, particularly when the issue is as complex as the role of genetic testing for patients with AMD.

Dr. Parke insinuates that being "paid" is the same as being "bought." Many Academy members collaborate ethically and effectively with industry. Rather than critiquing the substance of our publication, he cautions that 2 authors have equity in a genetic testing company. Having invested and having received equity as a consultant to the company (but no compensation for publications or presentations), I am one. The other is an academic geneticist who co-founded the company. Our conflicts were disclosed and considered as our manuscript was peer-reviewed and accepted for publication in *Ophthalmology*. The same was true of our second publication on this topic in *Ophthalmology*.

Dr. Parke implies bias on our part, yet provides justification for royalties paid to the National Eye Institute (NEI) for

the sale of AREDS supplements. How can conflict of interest be so corrupting on one hand yet so appropriate on the other? Dr. Parke dismisses 2 independent statistical analyses critical of AREDS Report 38 for no reason other than that the academic statisticians who provided consulting services were "paid." How many high-quality statisticians work for free, and how else is a company to obtain a valid statistical review?

Dr. Parke misrepresents the meaning of 3 statistical reviews recently obtained by the National Institutes of Health (NIH). The NIH reviews were the result of a complaint made by the genetic testing company to an NIH internal ethics office about the methodology of AREDS Report 38 and its unsupported conclusion that the AREDS formulation "reduced the rate of AMD progression across all genotype groups." The ethics investigation was not intended to conclusively determine the appropriate role of genetic testing in AMD. In fact, the statisticians, none of whom are AMD researchers or ophthalmologists, were explicitly instructed to confine their analyses to raw data provided by the genetics company and the NEI, and not to consider other more recent analyses and publications which support the use of genetic testing.

Dr. Parke's statement that the reviews "upheld the methodologic integrity and conclusions of the NEI scientists" is incorrect. The NIH analyses, which were not peer-reviewed, do not address or discuss the methodology of AREDS Report 38. In fact, the data presented in the reviews demonstrate a statistically significant interaction between genetic risk, nutritional supplements, and AMD progression. They show that nutritional supplements do not benefit patients in all genotype groups. The conclusions of the statisticians, that genetic testing is not indicated, are inconsistent with the data and have been questioned. However, before these questions were addressed, unnamed person(s) released the NIH reviews to the Academy and to the Centers for Medicare and Medicaid Services (CMS).

CMS recently announced its decision to provide coverage for a physician-ordered (not direct-to-consumer) genetic test to be used prior to recommending an AREDS or AREDS2 supplement for patients with AMD. This decision was the result of a thorough CMS review of relevant publications, professional society statements, and communications with experts. However, after receiving the NIH statistical reviews from an undisclosed source and Dr. Parke's editorial regarding the reports, CMS has now withheld coverage.

The NIH has taken in \$1.2 billion in royalties over the past decade, and revenue related to the sale of AREDS supplements is a top source of this NIH income. Dr. Parke does not address the fact that the NIH-solicited statistical reviews were performed at no charge to the NIH, by NIH-funded



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**Program:**  
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researchers. It is inconsistent to imply that bias on one side is disqualifying, yet to diminish or ignore the potential for bias on the other. It is ironic (and consistent with the current political climate) that an NIH internal ethics review is now used against the company who made the complaint. CMS coverage of a one-time genetic test that would cost little more than 1 year's worth of eye vitamins has been derailed. Who benefits from eliminating coverage for this optional test? Perhaps, those who sell AREDS supplements and those who receive royalties from those sales—certainly not the subgroup of patients who loyally purchase these over-the-counter supplements yet who derive no benefit, and may even be harmed by them.

In my opinion, genetic testing can identify individuals who maximally benefit from the AREDS formulation, as well as the smaller percentage who may be harmed. I've never stated that my opinion is conclusive. Instead, I think there is enough evidence for a reasonable physician to perform genetic testing before recommending a nutritional supplement. Six peer-reviewed publications have demonstrated a statistically significant interaction between genetics, nutritional supplements, and progression of AMD. Many well-informed Academy members agree that this interaction is clinically relevant and would like to apply this knowledge to the care of their patients.

Dr. Parke has a right to his opinion, but to declare this issue "settled" is a pronouncement that discourages further discussion and debate and is antithetical to the scientific method. To add the disclaimer, "... for now," rings hollow. The NIH statistical reports deserve scrutiny and discussion. They add to the growing body of science regarding the issue of genetics and AMD, but to represent them as conclusive is both inappropriate and misleading. New ideas should be challenged, but not suppressed. New tests, if supported by compelling evidence, should be made available to patients and their physicians. Give us accurate information, and let us decide for ourselves.

*Carl C. Awh, MD  
Nashville, Tenn.*

## STAY IN TOUCH

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