

Improving Awareness On The Lived Experience Of ApoE4 Homozygotes Through FDA Patient Listening Session

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BACKGROUND

- ApoE4 homozygotes represent the largest population of at-risk people for developing Alzheimer's disease (AD) but perhaps have the greatest unmet medical needs.
- Approximately 2-5% of the general population are ApoE4 homozygotes, nearly all of whom exhibit AD pathology.
- AD symptoms arise earlier in ApoE4 homozygotes and the disease progresses more rapidly.
- Amyloid-targeting therapies in the form of monoclonal antibodies are not viable treatment options for ApoE4 homozygotes due to increased risk of ARIA.

RESULTS

- Approximately 52 FDA staff members attended the listening session to learn about ApoE4 homozygosity and the lived experiences of people at increased genetic risk for AD. FDA attendees engaged directly with the speakers through a Q&A discussion.
- UsAgainstAlzheimer's later hosted an ApoE4-focused advocacy webinar to summarize key discussion themes, amplify patient voices, and advocate for policies and research advancements that address their unique needs.

“The clock is ticking for me- and APOE4 carriers want and need more treatment options.” - ApoE4 Homozygote living with amnestic mild cognitive impairment due to AD

METHODS

- UsAgainstAlzheimer's organized a Patient Listening Session with the Food and Drug Administration (FDA) to educate the agency about the clinical reality, lived experience, and perspectives of ApoE4 homozygotes. A behavioral neurologist provided remarks on the scientific background of ApoE4 homozygosity and four ApoE4 homozygotes shared the human toll of genetic status, cyclical nature of AD in their families, and their hopes for the future of AD treatment for their population.



CONCLUSION

- A formal Patient Listening Session was an effective way to bring a population with unmet need to the table, and to improve awareness and understanding among scientists, regulators, and public health officials.
- The Alzheimer's research and ApoE4 community have made significant strides in studying and uplifting the unique risks, familial nature, and needs for additional support and treatment for ApoE4homozygotes due to their genetic status.
- This matter requires continued attention, advocacy, research, and exploration to further care for this population, which will also help advance research for all populations with AD or those bearing increased risk for the disease.

REFERENCES

1. Addressing Alzheimer's Disease and the Needs of Apoe E4 Homozygotes. UsAgainstAlzheimer's. https://www.usagainstalzhaimers.org/sites/default/files/2025-11/07222025-FDA_Patient_Listening_Session-APOE4_Homozygosity_Summary_Final.pdf.
2. Grant WB. A Brief History of the Progress in Our Understanding of Genetics and Lifestyle, Especially Diet, in the Risk of Alzheimer's Disease. *J Alzheimers Dis.* 2024;100(s1):S165-S178. doi:10.3233/JAD-240658
3. Di Battista AM, Heinsinger NM, Rebeck GW. Alzheimer's Disease Genetic Risk Factor APOE-ε4 Also Affects Normal Brain Function. *Curr Alzheimer Res.* 2016;13(11):1200-1207. doi:10.2174/1567205013666160401115127
4. Fortea, J., Pegueroles, J., Alcolea, D. et al. APOE4 homozygosity represents a distinct genetic form of Alzheimer's disease. *Nat Med* 30, 1284–1291 (2024). <https://doi.org/10.1038/s41591-024-02931-w>

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