Dr. Weisman will not be attending the meeting; thus, this waiver is null and void.



## Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: David Weisman, M.D.

## Committee: Peripheral and Central Nervous System Drugs Advisory Committee

## Meeting Date: June 9, 2023

I acknowledge that contingent upon public disclosure of the following financial interests related to the agenda item described below, I may be considered for participation in the advisory committee meeting.

On June 9th, the committee will discuss supplemental biologics license application 761269/s-001, for Leqembi (lecanemab) solution for intravenous infusion, submitted by Eisai, Inc., for the treatment of early Alzheimer's disease. This product was approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) for the treatment of Alzheimer's disease. Confirmatory studies are studies to verify and describe the clinical benefit of a product after it receives accelerated approval. The committee will discuss the confirmatory study, BAN2401-G000-301, conducted to fulfill post-marketing requirement 4384-1 detailed in the January 6, 2023, approval letter, available at <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2023/761269Orig1s000ltr.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2023/761269Orig1s000ltr.pdf</a>.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family		
None		
II. Other Imputed Interests		
contract/grant	Biogen, party to the matter	<ul> <li>\$ (b) (4) total to</li> <li>Abington Neurological</li> <li>Associates</li> <li>\$5,000 - \$15,000 per year in</li> <li>salary support to Dr. Weisman</li> </ul>
	Eisai, party to the matter	<ul> <li>\$ (b) (4) per year to</li> <li>Abington Neurological</li> <li>Associates</li> <li>\$0 - \$5,000 per year in salary</li> <li>support to Dr. Weisman</li> </ul>

I hereby request that FDA make this information publicly available on my behalf if the agency grants a waiver allowing me to participate in the meeting described above. I understand that without public disclosure of these interests, I will not participate in the advisory committee meeting described above.

/S/

5/17/2023

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov

Signature

Date