

years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Matos during his period of debarment is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-14989 Filed 7-23-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS Request for Comment on the Update to the National Plan To Address Alzheimer's Disease

AGENCY: U.S. Department of Health and Human Services (HHS or the Department).

ACTION: Notice of Request for Information (RFI) to inform a comprehensive update to the National Plan to Address Alzheimer's Disease.

SUMMARY: HHS released the first National Plan to Address Alzheimer's Disease in 2012, establishing a comprehensive framework to accelerate scientific progress and improve support for individuals living with Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) and their families. Since then, the National Plan has been updated annually and has guided federal efforts across research, care delivery, public health, and data infrastructure. HHS is now updating the overall National Plan to lead federal efforts through 2035. HHS would like input from the public to inform the future direction of federal efforts. Through this RFI, HHS invites public comment on approaches to advancing AD/ADRD research and development of new interventions to prevent and treat dementia, risk reduction strategies, early detection and diagnostic tools, and/or enhanced care, services, and supports for people living with dementia and their families, caregivers, and care partners. The Department also seeks input on gaps, emerging priorities, and opportunities to strengthen coordination across federal, state, Tribal, local, private sector, and community partners.

The purpose of this RFI is to solicit public input to inform the development of a comprehensive update to the National Plan to Address Alzheimer's Disease, including future goals and priorities.

DATES: Comments on this notice must be received by August 15, 2026.

ADDRESSES: *RFI Docket:* You may examine the RFI docket at [regulations.gov](https://www.regulations.gov) under HHS-ASPE-2026-0298. The docket contains this RFI and all comments received to date. To submit a response, click the "Comment" button inside Docket: HHS-ASPE-2026-0298 and follow all instructions.

FOR FURTHER INFORMATION CONTACT: Maria-Theresa Okafor, Ph.D., MCG, Office of the Assistant Secretary for Planning and Evaluation (ASPE), 771-223-7102 or by email at: maria-theresa.okafor@hhs.gov.

SUPPLEMENTARY INFORMATION: The National Alzheimer's Project Act (NAPA) (Public Law 111-375) was passed by Congress in 2010 and signed into law on January 4, 2011, in recognition of the growing impact of AD/ADRD on the American public. NAPA requires the Secretary of HHS to create and maintain a coordinated national strategy to address AD/ADRD, including advancing research, improving care and services, and enhancing public awareness. The National Plan to Address Alzheimer's Disease serves as the nation's blueprint for achieving the vision of a nation free of AD/ADRD. Congress and federal partners have supported significant advancements in Alzheimer's disease research, care models, and public health infrastructure. These efforts have contributed to meaningful progress in scientific discovery, increased public awareness, and expanded supports for people living with dementia and their caregivers. To sustain and build on this progress, Congress enacted the NAPA Reauthorization Act (Public Law 118-92) on October 1, 2024, extending the federal commitment to addressing AD/ADRD over the next decade. HHS will undertake a comprehensive update of the National Plan in 2026 to identify emerging priorities and future goals with a focus on AD/ADRD research and development of new interventions to prevent and treat dementia, risk reduction strategies, early detection and diagnostic tools and pathways to treatment, and enhanced long-term services and supports for people living with AD/ADRD and their caregivers and care partners.

Request for Information

For this RFI, HHS is seeking input from the public, including individuals living with AD/ADRD, caregivers, researchers, clinicians, service providers, advocates, faith- and community-based organizations, state,

Tribal, and local officials, policymakers and other interested stakeholders. Respondents are encouraged to include supporting facts, research, and evidence in their comments, including citations to the published materials referenced, and active hyperlinks, where available. The questions below are of particular interest.

This RFI should not be construed as a policy, solicitation for applications, or as an obligation on the part of the government to provide support for any ideas in response to it. HHS will use the information submitted in response to this RFI at its discretion and will not provide comments on any respondent's submission. However, responses to this RFI may be reflected in future solicitation(s) or policies. The information provided will be analyzed and may appear in reports.

Instructions

Responses submitted at [regulations.gov/deregulation](https://www.regulations.gov/deregulation) should follow the format provided there. You may respond to one or more of the questions listed below and please include question numbers provided in the response. Each responding entity (person or organization) is requested to submit only one response. Unless submitted anonymously, responses should include the name(s) of the person(s) or organization(s) submitting the comment. If a comment is submitted on behalf of an organization, the individual respondent's role in the organization may also be provided.

This RFI is voluntary, and responses may be submitted anonymously. Comments submitted in response to this RFI may be posted on HHS websites or otherwise released publicly. Please do not submit proprietary, classified, confidential, or sensitive information, to include personally identifiable (PII) or personal health information (PHI), in response to this RFI.

This RFI is for information and planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the government to provide support for any ideas in response to it. HHS will use the information submitted at its discretion and will not comment on any respondent's submission. However, responses to this RFI may be reflected in future solicitation(s) or policies. The information provided will be analyzed and may appear in reports. Respondents are advised that the government is not obligated to acknowledge receipt of submissions. Those submitting responses are solely responsible for all expenses associated with response preparation.

Questions

1. What opportunities or challenges exist in advancing research and development of interventions to prevent or treat AD/ABRD, including translating scientific progress into effective and scalable treatments and care?
2. What opportunities or challenges exist in improving risk reduction and promoting brain health across the lifespan?
3. What barriers or challenges affect early detection and timely diagnosis of AD/ABRD?
4. What are the most significant gaps in dementia care, services, and supports for people living with AD/ABRD and their families, caregivers and care partners, including caregiver well-being?
5. What models, programs, or practices are currently working well in supporting people living with AD/ABRD and their families, caregivers, and care partners, and what factors contribute to their success (e.g., effectiveness, scalability, or applicability across settings)?
6. What health outcomes and care goals are most meaningful to people living with AD/ABRD and their families, caregivers, and care partners, and how should these be measured and incorporated into care over time?
7. What barriers exist to accessing timely, high-quality, person-centered care across different community settings and stages of disease progression?
8. What workforce or infrastructure challenges most affect:
 - a. AD/ABRD research and intervention development
 - b. risk reduction activities
 - c. public health AD/ABRD initiatives
 - d. delivery of healthcare and long-term care
 - e. support for families, caregivers, and care partners?

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Pigment Epithelium-Derived Factor Peptides and Their Use for Treating Retinal Degeneration

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Eye Institute (NEI) seeks research co-development partners and/or licensees for the development of an AAV2-based delivery system or an eyedrop formulation to deliver a Pigment Epithelium-Derived Factor (PEDF) peptide as a gene-agnostic approach to treating inherited retinal diseases.

FOR FURTHER INFORMATION CONTACT:

Inquiries related to this license opportunity should be directed to: Ricquita Pollard, Ph.D., Unit Supervisor, NCI, Technology Transfer Center, Email: ricquita.pollard@nih.gov or Phone: 240-276-5490.

SUPPLEMENTARY INFORMATION: Retinitis pigmentosa (RP) is one of the most common inherited retinal diseases (IRDs)—estimated to affect 1 in 4,000 people worldwide. Over 100,000 people in the US and 1.5 million people worldwide suffer from RP. This disease leads to progressive photoreceptor cell degeneration and, ultimately, vision loss. More than 90 genes are implicated in molecular pathways towards photoreceptor cell death. Due to this high heterogeneity, therapeutic approaches targeting specific genes generally benefit few patients. For most forms of RP, few or no medical options are available. Thus, there remains a need to identify new and more effective treatments for RP and other inherited retinal degenerations. Mutation-independent strategies to protect photoreceptors against continued damage and degradation are appealing approaches.

To delay photoreceptor degeneration, NEI proposes using neurotrophic molecules as a mutation-independent approach using PEDF. PEDF is a multifunctional member of the serine proteinase inhibitor (serpin) family with neurotrophic and antiangiogenic properties in the retina. Researchers at the NEI developed a peptide of 17 amino acid residues (17-mer) from the receptor-binding domain of PEDF. It contains amino acid substitution at position 105 from a histidine to an alanine (PEDF 17-mer[H105A]). H105A exhibits a highly potent protective effect on photoreceptors using *in vivo* mouse models of RP.

The technology encompasses two delivery approaches for this proprietary peptide: (1) an eyedrop formulation and/or (2) an Adeno-Associated Vector 2 (AAV2). A sustained delivery system delivers the 17-mer [H105A] to treat or prevent photoreceptor degradation and vision loss in patients with IRDs (e.g., retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy, Stargardt-like macular degeneration or

maculopathy) or age-related macular degenerations (AMD). The technology is available for licensing and co-development.

“This Notice is in accordance with 37 CFR 404.4 Authority to grant licenses.”

NIH Reference Number: E-028-2023.

Related Technologies: E-156-2023.

Product Type: Therapeutic.

Therapeutic Area(s): Eye/Ear/Nose/Throat | Ophthalmology.

Development Stage: Pre-clinical (*in vivo* validation).

Publications:

- Bernardo-Colón A, et al. H105A peptide eye drops promote photoreceptor survival in murine and human models of retinal degeneration. (PMID: 40118996)

- Valiente-Soriano FJ, et al. Pigment Epithelium-Derived Factor (PEDF) Fragments Prevent Mouse Cone Photoreceptor Cell Loss Induced by Focal Phototoxicity *In Vivo*. (PMID: 33008127)

- Hernández-Pinto A, et al. PEDF peptides promote photoreceptor survival in rd10 retina models. (PMID: 30980815)

- Kenealey J, et al. Small Retinoprotective Peptides Reveal a Receptor-binding Region on Pigment Epithelium-derived Factor. (PMID: 26304116).

Patents: National Phase.

Potential Commercial Applications:

- Minimally invasive therapy to prevent photoreceptor degeneration in retinal disorders IRDs and AMD.

- RP, macular degeneration, and other related diseases.

- AAV2 vectors for delivery of genes to retinal cells both preventative and therapeutic.

- Prevent disease progression to late-stage RP.

Competitive Advantages:

- Favorable safety profile.
- Large addressable market given applications to IRDs and AMD (USD 13.7 billion in 2023 and an estimated compound annual growth rate (CAGR) of 9.6% from 2024 to 2032).

- Partially established regulatory path, as their AAV2 vector is identical to Luxturna, an FDA-approved therapy for retinal dystrophy.

- Superior diffusion and penetrability than biologics.

- Demonstrably less immunogenicity and lower production costs than biologics.

- Eye drop formulation has larger addressable market.

- Eye drop formulation provides easy administration route.

- Broad-spectrum therapeutic approach: