Public opinion regarding U.S. Food and Drug Administration approval of aducanumab and potential policy responses: A nationally representative survey

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Abstract

Background: Despite controversy among experts regarding aducanumab's approval by the U.S. Food and Drug Administration, little is known about public opinion on this matter.

Methods: We conducted a representative survey of U.S. adults ages 35 and older to (1) determine opinions regarding aducanumab's approval, (2) identify any evidence of reputational injury to the Food and Drug Administration, and (3) explore opinions regarding policy responses available to policymakers, such as those relating to a national coverage determination by the Centers for Medicare and Medicaid Services. The survey was administered online and in English and Spanish using a probability-based sample derived from the National Opinion Research Center's AmeriSpeak® panel. Selection probabilities in the panel and survey design account for differences in population distribution and expected response rates by demographic. The survey was analyzed using survey weights to adjust for selection probabilities and non-response.

Results: A total of 1025 respondents completed the survey. While approximately three-quarters of respondents were initially unfamiliar with aducanumab, respondents were less supportive of the drug's approval once given information about the drug's potential clinical and economic impact. Sixty-three percent of respondents support restricting aducanumab access to patients most likely to benefit. Seventy-one percent indicated a willingness to enroll a family member with mild Alzheimer's disease in a "waitlist"-style trial to further study aducanumab; sixty percent indicated a willingness to enroll a family member in a randomized placebo-controlled trial. Eighty-one percent agree aducanumab should be withdrawn from the market if confirmatory trials fail. The median respondent was willing to pay \$1–5 in higher Part B premiums to cover aducanumab.

Conclusion: These findings demonstrate support for a range of proposed policies in response to aducanumab's approval. The opinions of an informed

public ought to be considered when developing policies in response to aducanumab's approval.

INTRODUCTION

On June 7, 2021, the U.S. Food and Drug Administration (FDA) approved aducanumab (Aduhelm) for the treatment of Alzheimer's disease. Even prior to the approval, the case of aducanumab was followed closely because of the long history of failed drug development for Alzheimer's disease,[1,2] specific debate regarding the amyloid cascade hypothesis,[3] and the circuitous path that the product took to market.[4] Since the approval, controversy regarding the product has intensified, concentrated on its unclear safety and effectiveness, the FDA's use of its accelerated approval pathway, and Biogen's initial decision to price the product at $56,000 annually. As a result of these factors, as well as evidence of an irregular relationship between Biogen and the FDA,[5] investigations into the approval were announced by the FDA itself and the U.S. House of Representatives.[6,7] Moreover, several prominent hospitals, health systems, and insurers decided to not provide or cover the product.[8-10]

Despite significant controversy regarding aducanumab, little is known about public opinion on this matter. We performed a nationally representative survey of U.S. adults to understand their views regarding aducanumab's approval, identify any evidence of reputational injury to the FDA, and explore opinions regarding options available to policymakers, including the issuance of a national coverage determination (NCD) by the Centers for Medicaid and Medicare Services (CMS).

Key points

- While approximately three-quarters of respondents were initially unfamiliar with aducanumab, respondents were less supportive of the drug's approval once given information about the drug's potential clinical and economic impact.
- Eighty-one percent of respondents agree aducanumab should be withdrawn from the market if confirmatory trials fail.
- The median respondent was willing to pay $1–5 in higher Part B premiums to cover aducanumab.

Why does this paper matter?

Despite controversy among experts regarding aducanumab's approval by the U.S. Food and Drug Administration, little is known about public opinion on this matter. The public is a key stakeholder served by the Food and Drug Administration and the Centers for Medicaid and Medicare Services; thus, the opinions of an informed public ought to be considered when developing policies in response to aducanumab's approval. We found support for a range of proposed policies in response to aducanumab's approval.

METHODS

Survey fielding

We fielded a custom survey from August 25 to September 8, 2021, through the National Opinion Research Center (NORC) at the University of Chicago using their AmeriSpeak® panel. The AmeriSpeak® panel uses a probability-based design to represent the U.S. household population. Randomly selected US households are sampled using area probability and address-based sampling, with a known, non-zero probability of selection from the NORC National Sample Frame. Sampled households are contacted by mail, telephone, and field interviewers, with the panel providing sample coverage of approximately 97% of U.S. households.

The sample for this custom survey was drawn from the AmeriSpeak® panel and limited to adults ages 35 years and older so that respondents would be more likely to have had personal or family experience with Alzheimer's disease or dementia. Sampling uses 48 strata including age, gender, race/ethnicity, and education. The size of the selected sample for each stratum is determined by the population distribution for that stratum and expected differences in survey completion rates by demographic groups. NORC also calculates weights to adjust for disproportionate probabilities of selection and non-response in both the panel

and survey sample to ensure balancing to Census benchmarks on age, education, gender, race/ethnicity, and geographic region. The study margin of error was 4.29 percentage points.

Questionnaire

We designed a questionnaire to examine a broad set of issues related to aducanumab's approval (Text S1). Two key premises informed the questionnaire design. First, we expected that many respondents would lack familiarity with aducanumab and the details surrounding its approval. Second, we believe the policymaking process should consider the opinions of a public informed about the potential impact of aducanumab for patients and payers. Thus, we first assessed respondents' baseline opinions about the FDA and its approval of aducanumab. We then provided publicly available information concerning aducanumab's potential clinical and economic impact for Medicare beneficiaries and the Medicare program (Text S1) and asked respondents if each piece of information changed their opinion of the aducanumab approval. Following this, we again assessed opinions about the FDA and its approval of aducanumab. Finally, we queried respondents regarding a variety of policy options available to the FDA and CMS in response to aducanumab's approval. Where appropriate, we used Likert-type response frames. We provided respondents with both the generic and brand name of the drug product but refer to the product with its brand name (Aduhelm) throughout the questionnaire. The questionnaire was offered on the internet and in English and Spanish.

Analysis

We compared respondent and non-respondent characteristics using chi-squared tests. We assessed both the unweighted and weighted proportions of respondents for demographic variables and self-reported measures of experience with Alzheimer's disease or dementia. For Likert-type responses, we combined positive responses (e.g., "strongly agree" and "somewhat agree") or negative responses and calculated proportions and 95% confidence intervals using survey weights in Stata (version 14, StataCorp). Skipped responses were dropped from the analysis of individual questions (<1% of responses to each question).

This study was approved by the Johns Hopkins School of Public Health and NORC Institutional Review Boards.

RESULTS

Respondent characteristics

A total of 1025 respondents completed surveys, reflecting a 31% completion rate. There were statistically significant differences ($p < 0.05$) between respondents and non-respondents with respect to age, gender, race/ethnicity, household income, and education (Text S1). After weighting, all differences in terms of age, gender, race/ethnicity, and education between the study sample and U.S. Census Bureau Current Population Survey (CPS) benchmarks (February 2021) fell within the study margin of error. Differences between the weighted sample and CPS benchmarks exceeded the margin of error for the percentages of respondents from households with incomes less than $30,000 (6.9 percentage points), from $30,000 to $74,999 (6.5 percentage points), and $125,000 or more (−11.2 percentage points).

A total of 52% of respondents in the weighted sample were female, 31% were over 65 years of age, 66% were White, and 23% were from households with less than $30,000 in annual income. Approximately one in four respondents (24%) reported that they were at least a little familiar with aducanumab at the beginning of the survey. Approximately two-fifths (42%) reported that a close family member had been previously diagnosed with Alzheimer's disease or dementia, and one-fifth (21%) reported that they had been a caregiver for someone with Alzheimer's disease or dementia. (Table 1).

Agreement or disagreement with aducanumab approval

At baseline, among respondents with at least some familiarity with aducanumab, 36% (95% CI, 28%–44%) agreed and 26% (95% CI, 19%–33%) disagreed with its approval (Figure 1). After receiving the information about aducanumab, 18% (95% CI, 15%–21%) agreed and 53% (95% CI, 48%–57%) disagreed with the approval. The one information element with the greatest impact on opinions about aducanumab's approval was information about the FDA advisory committee (*An FDA advisory committee met to consider if there was persuasive evidence that Aduhelm slowed cognitive decline in*

TABLE 1 Respondent characteristics ($n = 1025$)

|	Weighted (%)	Benchmark (%)	Difference (pp)
Gender			
Male	47.9	47.6	0.3
Female	52.1	52.4	−0.3
Age			
35–49	33.9	34.1	−0.2
50–64	34.8	34.8	0.0
65+	31.3	31.0	0.3
Race/ethnicity			
White	66.4	65.9	0.5
Black	11.4	11.3	0.1
Hispanic	14.1	14.7	−0.6
Asian	4.7	6.3	−1.6
Multiple or other	3.4	1.8	1.6
Household income			
Less than $30,000	23.3	16.4	6.9
$30,000 to $74,999	37.6	31.1	6.5
$75,000 to $124,999	22.4	24.5	−2.1
$125,000 +	16.7	27.9	−11.2
Education			
Less than high school	8.6	9.4	−0.8
High school equivalent	28.9	28.6	0.3
Some college/Associate degree	25.2	25.0	0.2
Bachelor's degree	20.1	22.1	−2.0
Graduate degree	17.1	14.8	2.3
How familiar are you with Aduhelm, Biogen's new drug to treat Alzheimer's disease?			
Very/somewhat/a little	24.2	n/a	n/a
Not at all	75.8		
Has a close family member of yours ever been diagnosed with Alzheimer's disease or dementia?			
Yes	42.1	n/a	n/a
No/Not sure	57.9		
Have you ever been a caregiver for someone with Alzheimer's disease or dementia?			
Yes	20.6	n/a	n/a
No/Not sure	79.4		

Note: Skipped responses excluded (<0.5% of responses to each question); Percentages may not equal 100 due to rounding; "Benchmark" values taken from U.S. Census Bureau Current Population Survey Study (February 2021); Margin of error = +/−4.29 pp.
Abbreviation: pp, percentage points.

Alzheimer's patients. Ten of 11 committee members voted "No", and one voted "Uncertain"), with 61% (95% CI, 57%–65%) of respondents saying it changed their opinion from baseline; among those who reported that this information changed their opinion, 88% (95% CI, 83%–92%) said it made them disagree more with the approval (Text S1).

Evidence of reputational injury to the FDA

Figure 2 summarizes general opinions about the FDA before and after receiving more information about aducanumab and its approval. At baseline, 69% (95% CI, 65%–73%) agreed that the FDA is primarily guided by scientific considerations, 69% (95% CI, 64%–73%)
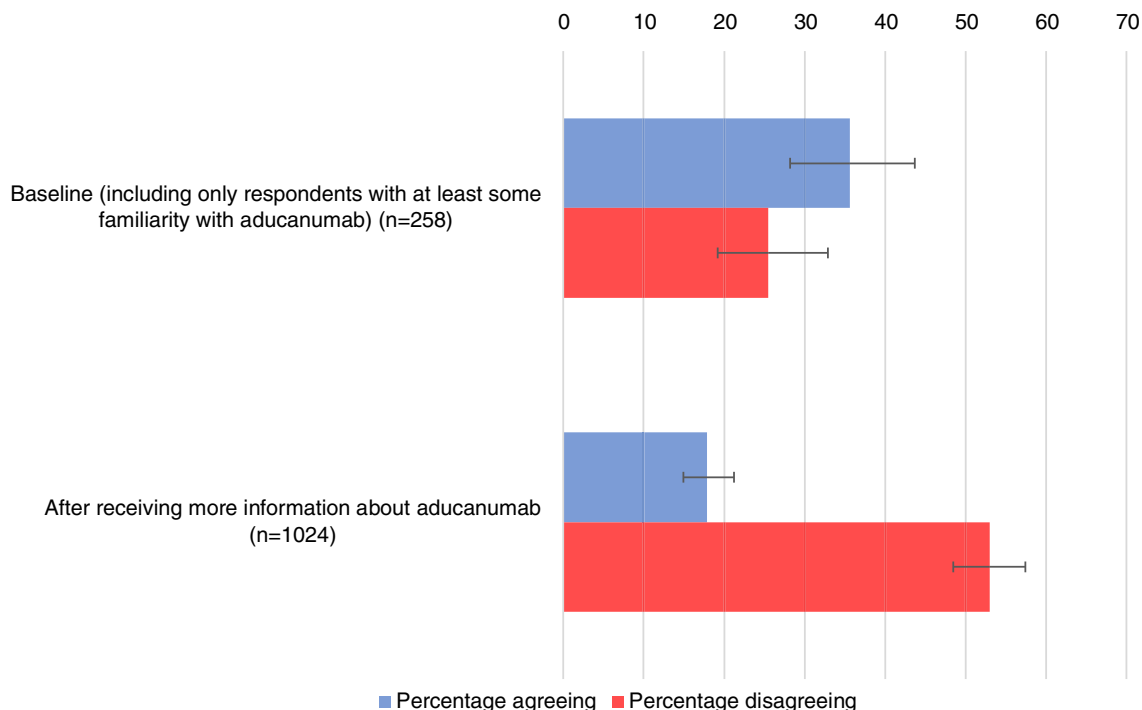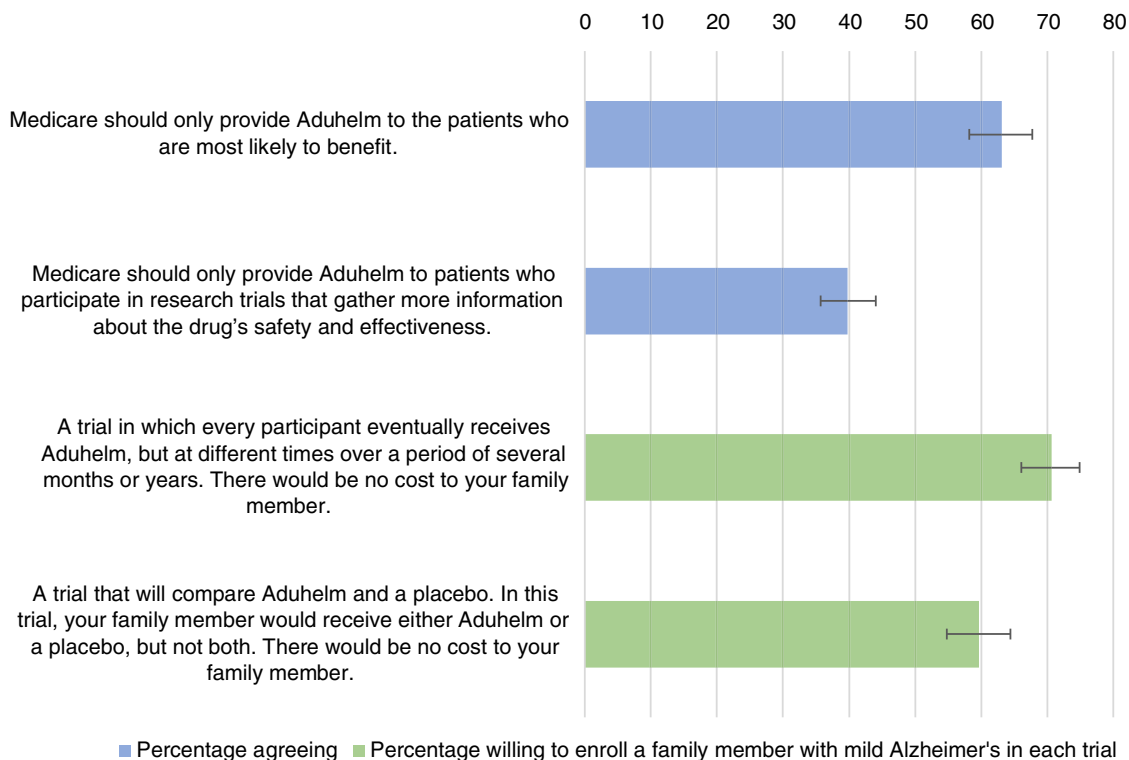
FIGURE 1 Respondent agreement or disagreement with aducanumab (Aduhelm) approval. *Note:* Skipped responses excluded (<0.1% of responses to each question); Error bars depict 95% confidence intervals incorporating survey weights
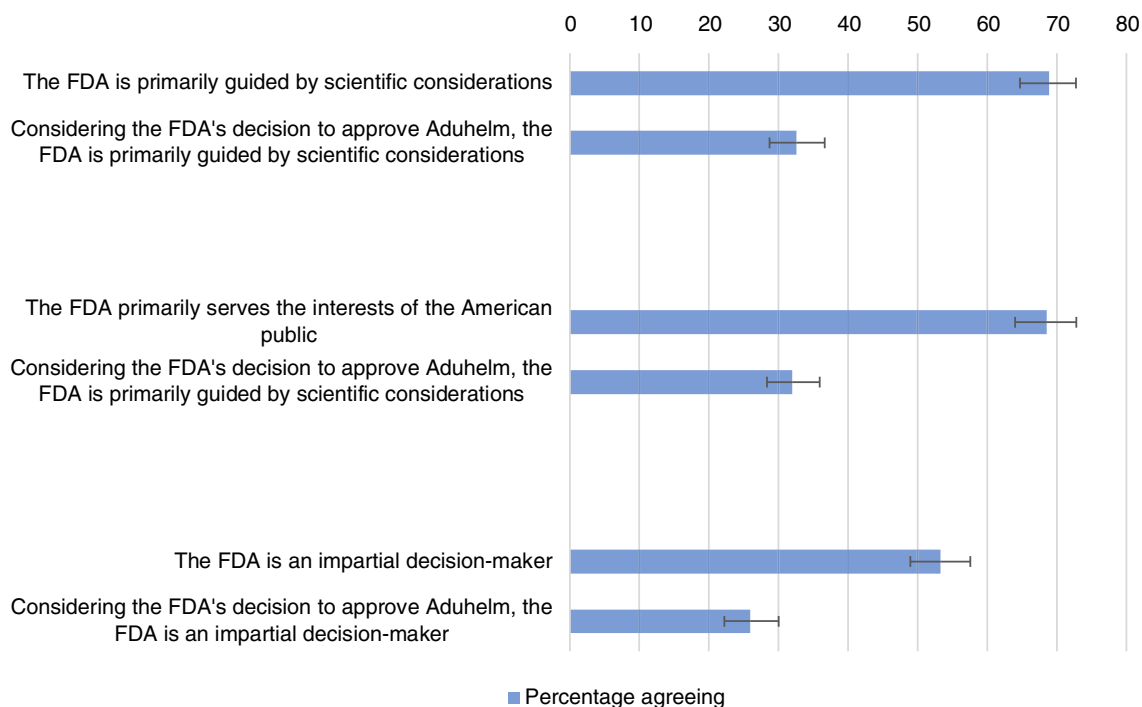
FIGURE 2 Effect of receiving information about aducanumab (Aduhelm) and its approval on FDA reputation ($n = 1025$). *Note:* Skipped responses excluded (<0.7% of responses to each question); Error bars depict 95% confidence intervals incorporating survey weights

agreed that the FDA primarily serves the interests of the American public, and 53% (95% CI, 49%–58%) agreed that the FDA is an impartial decision-maker.

After receiving the information about aducanumab and its approval, the agreement fell: 33% (95% CI, 29%–37%) agreed that the FDA is primarily guided by

FIGURE 3 Opinions relating to a national coverage determination for aducanumab ($n = 1025$). *Note:* Skipped responses excluded (<0.4% of responses to each question); Error bars depict 95% confidence intervals incorporating survey weights

scientific considerations, 32% (95% CI, 28%–36%) agreed that the FDA primarily serves the interests of the American public, and 26% (95% CI, 22%–30%) agreed that the FDA is an impartial decision-maker.

## Considerations relating to CMS's national coverage determination (NCD)

Two options for an NCD are: (1) limiting access to aducanumab to a subpopulation of Alzheimer's patients in Medicare; or (2) implementing a Coverage with Evidence Development policy where access is provided in the context of further clinical studies.[11] Sixty-three percent of respondents (95% CI, 58%–68%) agreed that Medicare should limit access to the patients most likely to benefit and 40% (95% CI, 36%–44%) agreed that Medicare should limit access to only those participating in further trials of aducanumab (Figure 3). Seventy-one percent (95% CI, 66%–75%) of respondents indicated they would be willing to enroll a family member with mild Alzheimer's disease in a "waitlist"-style trial where participants are randomized to early versus late treatment and serve as their own controls,[12] while 60% (95% CI, 55%–64%) indicated they would be willing to enroll a family member in a randomized placebo-controlled trial.

Other policy considerations

More than four-fifths (81%; 95% CI, 77%–85%) of respondents agreed that the FDA should stop sales of aducanumab if confirmatory trials do not show evidence of effectiveness (Figure 4). Additionally, 62% (95% CI, 57%–66%) agreed that the FDA should be more strongly bound by advisory committee recommendations. Half of the respondents (50%; 95% CI, 46%–54%) agreed that aducanumab should be priced according to the benefits it provides. Greater than 60% agreed that the money Medicare will spend on aducanumab would be better spent elsewhere, such as on long-term care for Medicare beneficiaries who need it, whether or not they have Alzheimer's, or on other effective care for Medicare beneficiaries. We found no evidence that respondents who have personal experience with Alzheimer's disease or dementia are more likely to disagree with policies that would limit access to aducanumab (Text S1).

Respondents were also asked to imagine that their monthly health insurance premium is $150, which is roughly equivalent to the Medicare Part B premium for beneficiaries with incomes below $88,000. They were then asked how much of an increase to this premium would be acceptable to cover aducanumab. Respondents were randomized to receive either a range-based or open-ended response type. Combining the results from
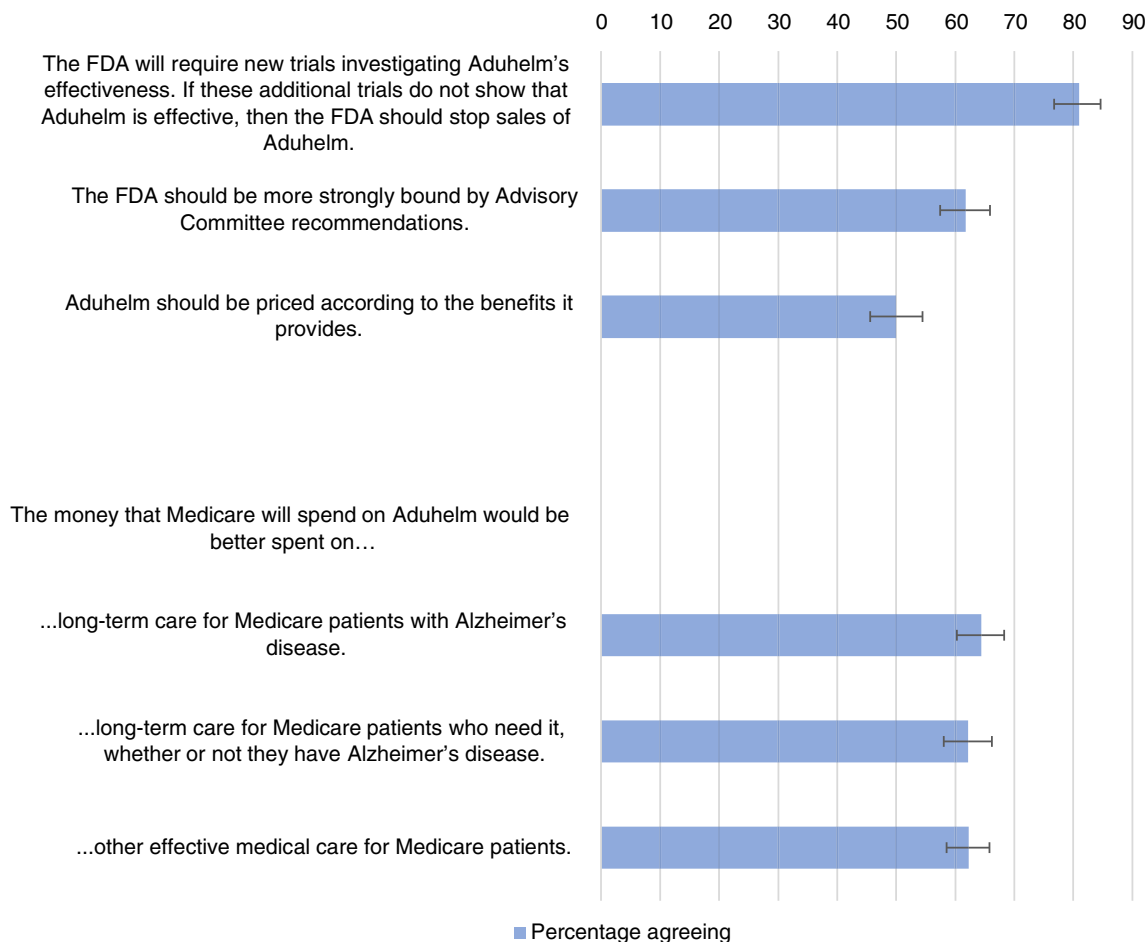
FIGURE 4 Opinions relating to other policy options ($n = 1025$). *Note:* Skipped responses excluded (<0.4% of responses to each question); Error bars depict 95% confidence intervals incorporating survey weights

each, more than one-third (37%; 95% CI, 33%–41%) answered they would not accept any increase to their monthly premium (Text S1). The median respondent was willing to pay $1–5 more per month.

DISCUSSION

Despite enormous controversy and scrutiny of the FDA's approval of aducanumab for the treatment of Alzheimer's disease, little is known regarding public opinion about this matter and about potential policy responses. We conducted a nationally representative survey of U.S. adults ages 35 and older to examine views regarding the product's approval, as well as beliefs regarding the reputation of the FDA and policy responses available to the FDA and CMS. The public reported greater concern with both aducanumab's approval and the FDA itself after receiving information about the drug's potential clinical and economic impact for Medicare beneficiaries and the Medicare program. In addition, a majority of the general public supported restricting coverage of aducanumab to

patients most likely to benefit, and indicated a willingness to enroll family members with Alzheimer's disease in further randomized trials to study aducanumab.

As we expected, despite outcry among experts over aducanumab's approval, most of the public was not familiar with the product, and thus baseline opinions regarding aducanumab may reflect the public's general degree of trust or distrust in FDA decision-making more than informed views on the specific case of aducanumab. However, receiving more information resulted in significantly greater concern with aducanumab's approval, and information about discordance between FDA leadership and the advisory committee had the greatest impact on this shift, suggesting the important and trusted role that outside advisory committees may have in guiding the FDA during especially complex or fraught scientific matters.

Interestingly, we found evidence for reputational injury to the FDA because of its management of aducanumab, although it is unclear whether any such injury will endure. Among other matters, aducanumab has raised awareness and concern around the FDA's use

of its accelerated approval pathway, since products approved based on surrogate endpoints may remain on the market for years without confirmatory trials being performed.[13–15] Moreover, even once performed, confirmatory trials are often designed to examine a surrogate outcome[16] rather than a clinical endpoint that ultimately captures what matters to patients (i.e., how a treatment makes them feel, function, or survive). Reforms of the accelerated approval pathway and reimbursement policies for products approved through the accelerated pathway are therefore needed.[14,17]

Although Biogen was initially given until 2030 to complete confirmatory trials for aducanumab, CMS recently proposed a Coverage with Evidence Development policy to further study the safety and effectiveness of aducanumab (as well as other monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease) in randomized controlled trials.[18] We found strong public support for withdrawing aducanumab from the market if such trials do not show evidence of effectiveness. To incentivize speedier completion of confirmatory trials for other drugs in the future, the Center for Medicare and Medicaid Innovation or Congress could consider policies that link coverage or reimbursement with meeting key trial benchmarks, such as completing participant enrollment.

CMS has also proposed limiting participation in these randomized controlled trials to patients without comorbidities that may accelerate cognitive decline or increase the likelihood of adverse events.[18] Our findings support this proposal, as a majority of survey respondents agree with limiting access to aducanumab to patients most likely to benefit. We also found that 60% of respondents would be willing to enroll a family member in randomized placebo-controlled trials of aducanumab. This finding provides evidence against a common objection to Coverage with Evidence Development, namely, that too many people would be unwilling to enroll in randomized placebo-controlled trials when the drug under study is already FDA-approved.[14,17] An even greater number of respondents (71%) indicated a willingness to enroll a family member in a "waitlist"-style trial where participants are randomized to early versus later treatment. CMS could consider permitting this type of trial in addition to placebo-controlled trials when it issues a final Coverage with Evidence Development decision. Importantly, these findings regarding willingness to enroll depend on there being no cost to trial participants. CMS did not indicate in its proposal how these additional trials of aducanumab would be paid for. Our findings suggest that CMS should aim to minimize the cost to Medicare beneficiaries who participate in these trials.

We also found evidence that the public would be willing to pay very little in higher premiums to cover the cost of aducanumab. The median respondent would be willing to pay just $1–5 more, which is less than the increase to 2022 Part B premiums already set by CMS in response to aducanumab's estimated budget impact. The Secretary of the Department of Health and Human Services has instructed CMS to reconsider this premium increase.

Finally, our finding that the public is willing to make tradeoffs between spending on aducanumab and other clinical or social services is notable given that Medicare does not currently cover social services like homemaker services, such as shopping and cleaning, that may benefit those with mild Alzheimer's disease or dementia and their caregivers.[19] Therefore, as part of its NCD decision, CMS could consider permitting trials that compare aducanumab and a set of relevant social services; our findings suggest that there would be a willingness to enroll in such trials.

Our study has limitations. We used weights to adjust for the sampling strategy and non-response bias, yet there remains a potential for sampling and non-response bias. Compared to Census benchmarks, our study disproportionately included individuals from households with lower incomes. Some findings reflect opinions after respondents received information about the potential impact of aducanumab for patients and payers, and while this information is publicly available, it could have biased the respondents. Our survey was conducted online only and thus the findings may not be generalizable to individuals who lack any internet or smartphone access. Finally, our findings are generalizable only to adults ages 35 and older.

CONCLUSION

The decision by the FDA to approve aducanumab has been highly controversial from the start. We conducted a nationally-representative survey of U.S. adults ages 35 and older to understand opinions regarding aducanumab's approval, the FDA, and options available to policymakers. The public is a key stakeholder served by the FDA and CMS. Thus, the opinions of an informed public ought to be considered by policymakers when responding to aducanumab's approval. While most members of the public were unfamiliar with aducanumab, they were less supportive of its approval once given additional information about its potential clinical and economic impact for Medicare beneficiaries and the Medicare program. Most respondents support restricting coverage of aducanumab to the patients most likely to benefit and there is little willingness to pay the increased premiums likely associated with covering

even a small fraction of Medicare beneficiaries with Alzheimer's disease. Most respondents are willing to enroll family members with mild Alzheimer's disease or dementia in further randomized controlled trials to study aducanumab, especially "waitlist"-style trials.

CONFLICT OF INTEREST

Dr. Alexander is past Chair and a current member of FDA's Peripheral and Central Nervous System Advisory Committee; is a co-founding Principal and equity holder in Monument Analytics, a health care consultancy whose clients include the life sciences industry as well as plaintiffs in opioid litigation; and is a member of OptumRx's National P&T Committee. These arrangements have been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. Dr. Polsky has provided consulting services for Extend Health. Drs. DiStefano and Anderson have no conflicts of interest to report.

AUTHOR CONTRIBUTIONS

All authors meet the criteria for authorship stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. We additionally acknowledge the role of NORC in the acquisition of subjects and data, as well as input regarding study design. *Study concept and design*: Michael J. DiStefano, G. Caleb Alexander, Daniel Polsky, Gerard F. Anderson. *Acquisition of subjects and/or data*: see above. *Analysis and interpretation of data*: Michael J. DiStefano, G. Caleb Alexander, Daniel Polsky, Gerard F. Anderson. *Preparation of manuscript*: Michael J. DiStefano, G. Caleb Alexander, Daniel Polsky, Gerard F. Anderson.

SPONSORS' ROLE

The sponsors had no role in the design, methods, subject recruitment, data collections, analysis, or preparation of the paper.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

Text S1. The following information is included in the downloadable supplementary file:

1. Information provided to respondents
2. Survey questionnaire
3. Comparison of respondents (n = 1025) and non-respondents (n = 2299)
4. Whether and how different information changed opinions on the approval of aducanumab (Aduhelm)
5. Odds of agreeing with policies that would limit access to aducanumab, comparing those with and without a close family member who had been diagnosed with Alzheimer's disease or dementia
6. Odds of agreeing with policies that would limit access to aducanumab, comparing those who have and have not been a caregiver for someone with Alzheimer's disease or dementia
7. Percentage of respondents willing to accept a premium increase of different amounts on $150/month (n = 1025)