

# Consumer reaction to over-the-counter (OTC) hearing aids

*The market is ready, but retailers must close the information gap before consumers will fully trust OTC hearing aids*

## Introduction and Background

In 2017, the United States Congress passed [legislation](#) aimed at making “over-the-counter” (OTC) hearing aids — hearing aids available without a prescription — a reality. Bureaucratic slowness, and then a global pandemic, delayed regulations. But in 2021, after an [Executive Order](#) from the White House, the FDA finally proposed a [rule](#) to establish a new category of OTC hearing aids. And, though it will still take months to finalize the rule, over-the-counter hearing aids are significantly closer to appearing on the market.

Much has been written about the new law and its potential impact to device makers and audiologists. A [report from Clear Living](#) (2017, updated 2020) was ultimately skeptical that consumers could successfully purchase over-the-counter hearing aids without “critical” guidance from a “licensed professional,” such as an audiologist. Clear Living supported this conclusion with Market Trak data regarding services provided by hearing health professionals:

“The Market Trak study showed that 81% of hearing aid users are satisfied [with their hearing health professional]. And of those individuals that have been wearing hearing aids less than a year, satisfaction increases above 90%.”

However, the Market Trak data focuses solely on existing hearing aid users. There is a much wider



potential market for OTC hearing aid devices among those who, for a variety of reasons, are not current hearing aid users.

Only those with the most severe hearing loss tend to see a hearing health professional and use hearing aids. Studies from the National Institutes of Health (NIH) show that “80% of those who would benefit from a hearing aid, do not use them” (see [“Quick Statistics About Hearing”](#) and [“Why do people fitted with hearing aids not wear them?”](#)). When Clear Living surveyed more than 100,000 people to analyze why those with hearing loss don’t use hearing aids, they found that:

- 57% said their hearing loss is not severe enough
- 36% said they only have trouble hearing in certain situations
- 25% said cost is an issue

Thus, the conclusions that consumers (a) need “guidance” to purchase OTC hearing aids and (b) are happy to work with a “licensed professional” to get that guidance, only applies to the small segment of the market whose hearing loss is “severe enough” that they are already willing to work with an audiologist to become a hearing aid user.

To better understand consumer reaction to OTC hearing aids, Akoio fielded a study focusing on a wider audience, including those who do not currently use hearing aids, to answer questions about the new law and its impact on consumer purchase behavior. The survey included 500 Americans (n=500). Participants were randomly selected from the U.S. population and balanced to represent average demographics for the United States (see “Survey Demographics” below).

## General Awareness of Hearing Loss and Hearing Health

Among survey participants, about 1 in 4 (26%) said they experience some hearing loss. When asked to characterize it, most (74%) of this group described their hearing loss as mild to moderate. In analyzing the data, it’s helpful to segment respondents into distinct groups:

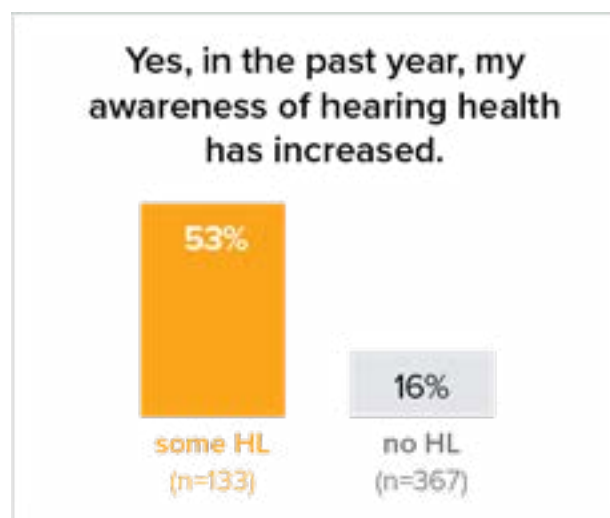
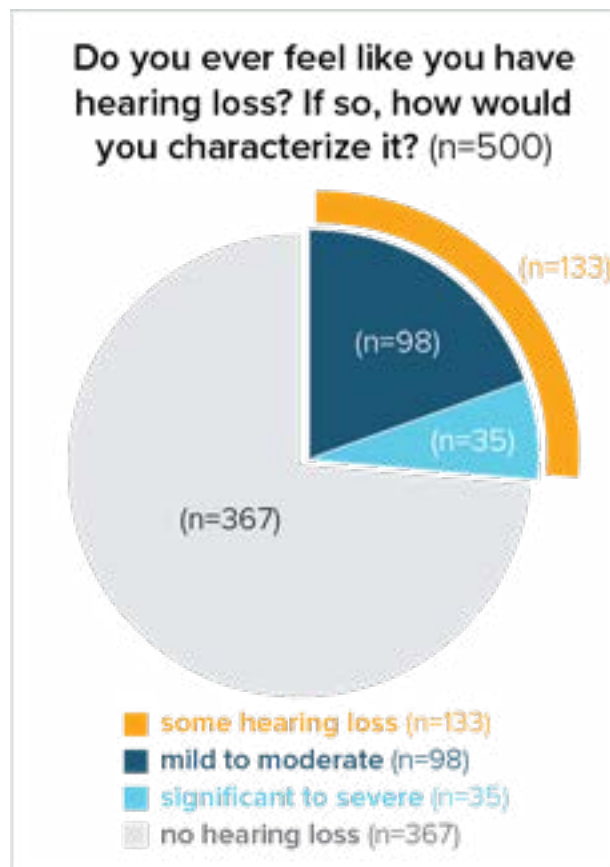
- those reporting no hearing loss (n=367)
- those reporting some hearing loss (n=133)

The “hearing loss group” can be further divided:

- mild to moderate hearing loss (n=98)
- significant to severe hearing loss (n=35)

For example (and perhaps unsurprisingly), more than half (53%) of those reporting some hearing loss (n=133) said their awareness of hearing health increased in the past year. But

even among those participants with no hearing loss (n=367), 16% reported greater awareness of hearing health. For those with hearing loss, awareness was primarily driven by their own hearing loss experience (80%). For those without hearing loss, awareness increased as part of their overall interest in health and wellness (43%) or because of growing news media coverage (42%). A smaller but significant number of both groups (15-20%) reported greater awareness because they help someone with hearing loss.



## Specific Awareness of over-the-counter (OTC) Hearing Aids

Despite growing awareness of hearing health, both groups reported low awareness of OTC hearing aids. Among those not experiencing hearing loss, 90% were unfamiliar (“never heard of them”) or somewhat familiar (“heard of them, but don’t know much about them”) with OTC hearing aids, with just 10% being familiar or very familiar with them. Interestingly, awareness among those who do experience hearing loss was not much greater, with 87% being unfamiliar or somewhat familiar with the new devices, and only 13% being familiar or very familiar with them.

Among both groups, awareness of the 2017 legislation and 2021 FDA rule was even lower, with just 11% of those with, and 7% of those without hearing loss saying they’d ever heard of the law.

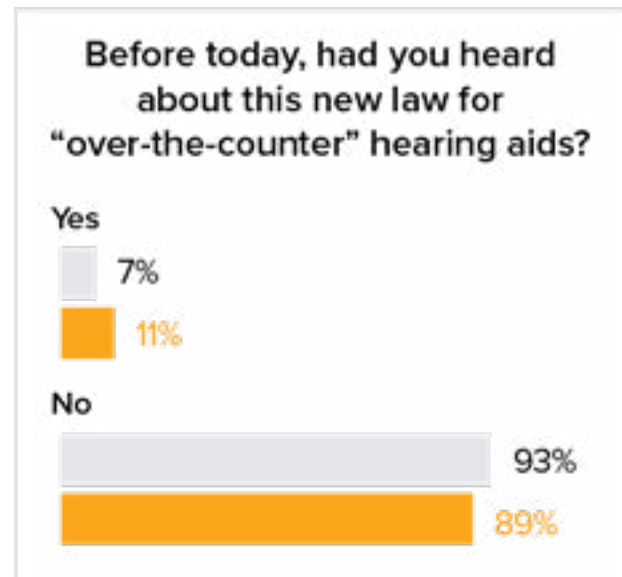
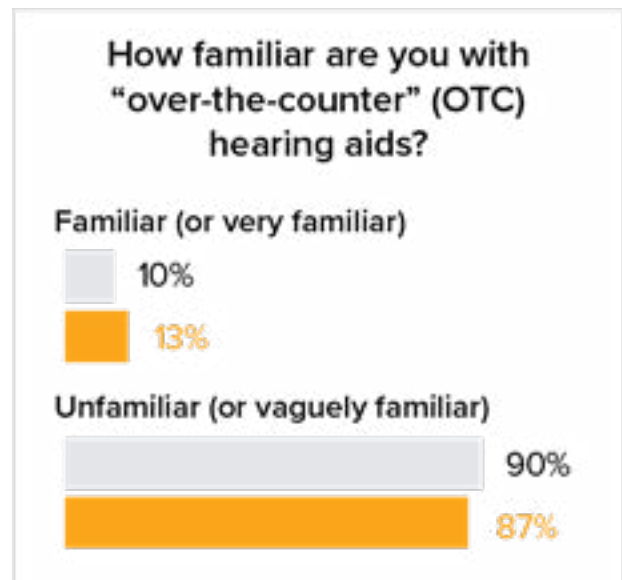
## Consumer Reaction to over-the-counter (OTC) Hearing Aids

To educate participants, Akoio provided the following:

“In 2017, the U.S. Congress passed a new law that would allow hearing aids to be purchased without a prescription. These ‘over-the-counter’ (OTC) hearing aids are expected to be less expensive than hearing aids prescribed by a doctor or professional audiologist.

Such ‘over-the-counter’ (OTC) hearing aids can be made available once the Food and Drug Administration (FDA) establishes guidelines for them. These guidelines were expected in 2018, but have been delayed. The White House recently signed an executive order encouraging the FDA to establish guidelines by the end of 2021.”

Thus informed, the survey then asked if participants would consider purchasing an

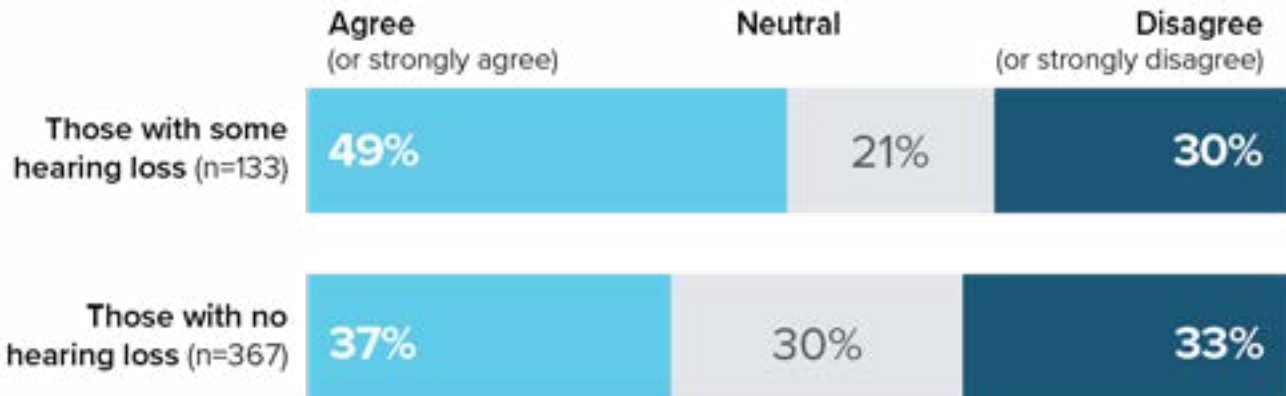


■ no hearing loss (n=367)  
■ some hearing loss (n=133)

OTC hearing aid. More than 70% of those with hearing loss responded positively. Additionally, about 40% of those without hearing loss said they, too, would consider purchasing an OTC hearing aid to help them address any future hearing loss.

Consumers were divided as to whether they would consult a doctor as part of their purchase. Among those not currently experiencing hearing loss, 37% said they would purchase an OTC

## “I would try an OTC hearing aid *before* visiting a doctor.”



hearing aid without consulting a doctor, while 33% indicated they would seek a doctor’s recommendation first. Among those with hearing loss, the inclination to purchase without consulting a doctor was even higher at nearly 49%, with about 30% indicating they’d prefer a doctor recommendation before purchasing.

Among both groups, as much as 30% of respondents remained neutral (neither agree nor disagree with the statement: “I would try an OTC hearing aid before visiting a doctor.”). This indicates a desire for more information, but not necessarily provided by a doctor or “licensed professional.” Similarly, about 50% of both groups remained neutral (neither agreed or disagreed) when asked if they expected OTC hearing aids to give inferior performance when compared to a prescription hearing aid.

Consumers want “more control and personalization in wellness products and services” (see [“The future of wellness: connected and customized”](#) from McKinsey and Company). Thus, this “neutral” group may be more likely to purchase directly if manufacturers and marketers provide clear information about devices, usage, and performance, so that consumers can make informed purchase decisions on their own.

Willingness to try or buy an OTC hearing aid without consulting a doctor may also depend

in part on how “tech savvy” the consumer considers themselves to be. About 40% of participants with hearing loss said they already use earbuds (separate devices from hearing aids) to manage background noise or amplify sound. 48% of that group was likely to forego a doctor recommendation before purchasing an OTC hearing aid, compared with 38.9% of those who do not use earbuds for noise reduction or sound amplification.

## Conclusion

Existing hearing aid users, understandably, appear to be comfortable with the status quo. They’ve already deemed their hearing loss “severe enough” to pay the high costs, both emotionally and financially, of getting a hearing aid via consultation with a “licensed professional,” for example an ENT physician, audiologist or licensed hearing aid dispenser. While this may be comforting to existing manufacturers and practitioners, it largely ignores those consumers who would benefit from using hearing aids, but who are not currently using them. These consumers cite high prices, social stigmas, and the bureaucracy of working through medical offices as barriers to their participation, particularly if they consider their hearing loss mild to moderate.

The promise of over-the-counter hearing aids is less about converting existing hearing aid users and more about providing solutions for a large, underserved population with mild to moderate hearing loss (or with situational hearing loss). Without an OTC option, these people would likely take no action to address their hearing health until their hearing loss becomes “severe enough” to force them to see an audiologist — which may be too late to fully mitigate such harmful effects of hearing loss as loneliness, isolation, decreased cognitive function, or even dementia (see [“The Hidden Risks of Hearing Loss”](#) from Johns-Hopkins).

Low awareness of new legislation or potential devices is not surprising, given that U.S. manufacturers cannot market a device as an OTC hearing aid until the FDA rule is finalized. But the fact that there is some premarket awareness among both groups, those with and those without hearing loss, suggests a market that is eager for alternative options in hearing care. Furthermore, once informed about the law and coming devices, nearly half of respondents indicated a willingness to purchase OTC hearing aids, while an additional 20-30% would likely purchase after reviewing additional information from retailers or device manufacturers, who only need the FDA rule to be finalized so that they can officially bring OTC hearing aids to market.

As consumers take more control of their health, including their hearing health, OTC hearing aids may be a perfect fit for an underserved market, especially those with mild to moderate hearing loss who may be years ahead of the current prescription model.

## About Akoio

*Akoio is a hearing wellness company helping people live their lives to the fullest. Led by life-long hearing aid user and former Apple, Inc. Accessibility Advocate Bill Schiffmiller, Akoio offers and designs products for people who want to better manage sound, noise, and hearing for complete wellness.*

## Survey Demographics

The Akoio survey included 500 Americans (n=500). Participants were randomly selected from the U.S. population and balanced to represent average demographics for the United States.

<b>Age</b>	
18-24	12%
25-34	18%
35-44	16%
45-54	16%
55-64	17%
65+	21%
<b>Ethnicity</b>	
African-American	12%
Asian-American	6%
Hispanic/Latino-American	18%
White/Native American/ Multi-racial/Other	64%
<b>Household Income</b>	
\$0-\$25k	20%
\$25k-\$50k	21%
\$50k-\$75k	17%
\$75k-\$100k	13%
\$100k+	29%
<b>Education</b>	
No college	16%
Some college	27%
2yr degree	11%
4yr degree	30%
Grad school degree	10%
Professional degree	5%
<b>Region</b>	
NorthEast	20%
Midwest	20%
South	41%
West	20%