

Vantage point - Over the counter hearing aids could shake up an industry



[Elizabeth Cairns](#)

Around 25 years ago low-power reading glasses became available over the counter. Steps are now being taken in the US to allow some hearing aids to be sold in a similar way – patients will no longer require a prescription or even to undergo a hearing test before obtaining a device.

The hearing aid segment is dominated by six companies. Competition is fierce and margins are tight. But the market is surprisingly underpenetrated, partly owing to lack of reimbursement: less than a quarter of people in the US who need hearing aids have them. Allowing simpler devices to be sold without prescription could see manufacturers' margins eroded further as prices become a sticking point, but importantly it could also increase uptake.

Either way the FDA seems committed to loosening the red tape on hearing aids. Last week, the agency said that as well as mulling the creation of a category of over-the-counter hearing aids it would, with immediate effect, cease enforcing the current rules requiring patients either to undergo a medical evaluation or to sign a waiver before buying a hearing aid.

Patient journey

The big deal, though, will be legislative change. The Over-the-Counter Hearing Aid Act of 2016 will, if passed, “remove unnecessary and burdensome requirements that currently create barriers for consumers who could benefit from hearing aids”. The bill has bipartisan sponsorship, and there is no obvious reason why the coming change of administration should make it any less likely to become law.

On the face of it this could hit companies' profit margins. “The instrument itself is probably about a quarter of what you find you are paying,” Lukas Braunschweiler, chief executive of the largest hearing aid company, Sonova, tells *EP Vantage*. The other three quarters pays for support: finding the right hearing aid for the patient, adjusting the settings and follow-up.

“Administering, supporting and servicing the right hearing aid is of utmost importance – it's not just that you can buy a hearing aid and stuff it into your ear, you need help from a professional who understands how to do a hearing test, to find the right solutions for you and to support you,” he says.

Sonova is one of the most involved of the big six in the retail side of the business, and as such could lose out if OTC hearing aids do become available. Chris Cooper, an analyst at Jefferies, believes that companies with a retail aspect to their business will bear the largest burden, since testing patients and fitting hearing aids – something retailer businesses are reliant on – would no longer be necessary for OTC devices.

Even so, Sonova is not entirely opposed to the idea. “For very mild hearing loss patients could go for solutions which are a bit simpler,” Mr Braunschweiler says. “We have simpler hearing aids which would be candidates [for sale] over the counter.”

He adds that this would probably be the start of a “patient journey”, as reading glasses often are – if the patient's hearing worsens they would move to a more powerful, prescription-only device.

Another group with a retail business, William Demant, is more opposed to the proposals.

“Over-the-counter hearing aids are unregulated and have been available in many markets for many years but they do not deliver the same satisfaction because they are an insufficient solution,” says Søren Nielsen, chief executive of Oticon, which is owned by William Demant. He believes that even if the regulations are relaxed there will not be a huge change to the market. “For a hearing aid to work well and really meet the need requires a professional interaction with a skilled person.”

Mr Nielsen could have a point. There are already devices available via mail order in the US called PSAPs – personal sound amplification products – that are very similar to basic hearing aids, though according to [draft guidance issued by the FDA in 2013](#) PSAPs are intended for use by non-hearing impaired consumers. They may not be marketed as hearing aid replacements and unlike true hearing aids they are not regulated by the

agency.

The intriguing thing is that PSAPs, like hearing aids themselves, do not sell. “They never really took off,” says Mr Braunschweiler. “The issue is they look like a hearing aid, but for what you pay, a couple of hundred dollars, they are probably not serving you too well.”

Affordability

The question, then, is whether allowing hearing aids to be sold over the counter and marketed to hearing-impaired patients will actually have any effect – particularly as they will be more expensive than PSAPs.

Even a basic hearing aid costs around \$1,000, and reimbursement is limited – they are not generally covered by Medicare or Medicaid, and [most private insurance plans exclude them](#).

If OTC devices do come about, the same criteria would apply, according to Matthew Clyburn, a spokesperson for the insurance company Aetna. “If there is a device available over the counter without a prescription that has been cleared by the FDA as a hearing aid and is substantially equivalent to hearing aids available by prescription, we would be able to cover it,” Mr Clyburn says – but only if that patient has a prescription for the hearing aid, thus defeating the purpose of the initiative.

The only group of people in the US who can rely on having hearing aids paid for are military veterans: about 800,000 devices a year – around a quarter of the US market – are provided by the Department of Veterans Affairs.

With Medicare and private insurance covering just 5% of the devices sold in the US, roughly 70% of the market is private-pay. Theoretically OTC hearing aids would be cheaper than prescription ones, since the cost of evaluation by an audiologist or doctor would not have to be factored in.

“One of the reasons behind [making hearing aids OTC] is to secure broader access to more affordable hearing aids – I certainly want to challenge whether that will happen,” Anders Hedegaard, chief executive of GN Resound, another of the big six, tells *EP Vantage*. He points out that even in markets where hearing aids are widely reimbursed penetration of the market is not much better than in the US.

It is salutary that Mr Hedegaard is cautious given that GN has no retail business – instead it sells its devices to audiologists and dispensing chains such as Amplifon or Costco, which oversee testing and fitting. It therefore ought to be relatively insulated against the coming changes.

Making some hearing aids available without prescription is intended to expand the market, but Mr Hedegaard believes it is more likely that these devices will cannibalise sales of prescription products.

Penetration vs profits

As well as cutting into sales of prescription hearing aids, the new regulations might also hurt prices. Jefferies' Mr Cooper wrote that as an increasingly online-savvy generation approach the target market age – 60-plus – he expects a greater proportion to opt for a device that helps at a lower cost rather than one offering a slightly greater benefit at significantly higher cost.

The basic end of the industry makes up around 25% of volumes, and if the move towards OTC does improve access this is likely to “initiate a pull-down effect” on pricing of the more profitable premium products, Jefferies suggests.

So the upshot of this for the big six – Sonova, William Demant, GN Resound, Siemens, Starkey and Widex – could be a trade-off between market penetration and profit margins. With the players in the space so few and so similar, M&A to mitigate the pressure on profits is likely to run into antitrust problems.

Perhaps in time manufacturers will be able to switch their OTC customers to more profitable prescription devices. But the first few years after the changes come in could be lean.

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow [@LizEPVantage](https://twitter.com/LizEPVantage) on Twitter