



OPINION EXCHANGE

The hearing aid conversation that needs to happen

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Over-the-counter sales can be a valuable addition to the market, but the focus must be on patients, not profits.

By Brandon Sawalich | JUNE 19, 2022 — 6:00PM



LEXIE HEARING, TNS

Over-the-counter hearing devices are being sold. Last fall, the Food and Drug Administration released proposed rules around these devices that addressed everything from sound limits to labeling.

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"It's the economy, stupid!"

Before it became a pop culture reference, that 1992 line by Democratic strategist James Carville was an important reminder to Bill Clinton's campaign staff: Keep it simple, keep to the facts and stay focused on what matters.

Thirty years later, hearing aids have become a political punching bag. As in 1992, no one is asking the right questions about hearing health care.

In 2017, Congress created a new class of hearing aids to be sold in drugstores for people with perceived mild to moderate hearing loss. Last fall, the Food and Drug Administration released proposed rules around these devices that addressed everything from sound limits to labeling. In the public comment period that followed, the FDA was flooded with concerns from health organizations, countless hearing professionals and nearly every state's attorney general. Nearly all said, as outlined, these devices could potentially do more harm than good. While we wait for the FDA to release final rules that will send over-the-counter devices to market, we must look at how we got here.

The root of the confusion around hearing aids, and the point that must be addressed to open access even more to care, is not cost; it's *expertise* and *care*. For three decades, consumer electronics companies have repeated one line: A hearing aid is a consumer electronics device, and manufacturers are overcharging people. These companies think the device is the "solution," disregarding the hearing professional's role. A hearing aid is *one* piece of the puzzle that must include expert care to ensure patient safety and satisfaction.

Since hearing aids have become part of a political debate, let's look at the hearing health care process as a presidential campaign. The party nomination is like the hearing evaluation, hearing loss like a candidate. No two are the same, and it takes time to sort out the differences. The evaluation determines the kind of loss a person has. Next, the presidential debates begin. While selecting a hearing aid is not as contentious as a debate, it is a process. Just like a debate gives voters clarity, the patient must understand how the device can help. A patient's unique hearing loss and lifestyle factor into device selection. It all comes together on voting day. The patient begins to experience results during the fitting, but it's not the last step. The purchase of this medical device includes professional care for the life of the hearing aid — the adjustments, follow-up appointments, cleanings and device warranties. The purchase is not the finish line but the starting point.

This bundled approach that includes the hearing professional's care is often what Washington overlooks and what consumer electronics companies dismiss. For 30 years, these companies have dipped their toes into the hearing industry, quickly learning that a hearing aid is not a commodity. The thought of offering returns and continued service, under razor-thin margins, has most companies packing up shop. They want to sell a product and move on. They think the same business model for headphones and earbuds can be replicated for selling a medical device. When hearing health is an essential part of living, the process cannot be that simple.

Since 2014, Bose has said it had a solution, telling consumers and lawmakers that manufacturers were overcharging people. After years of lobbying Congress to create an over-the-counter category, [Bose shut down its hearing division](#) just as the FDA is expected to release OTC regulations. Like Zenith, 3M, Sony, Panasonic, Philips, Bausch and Lomb, and Johnson and Johnson, Bose exited this industry as quickly as it entered it. There is one element these companies continue to overlook: care. Patients need more than a do-it-yourself approach to hearing health.

While it's easy to dismiss the Bose news as a business decision, we must ask why that argument is good enough. Bose changed the hearing industry, and it's a change I welcome. If OTC hearing aids help even *one* person with hearing loss, that is a good thing. While I join numerous [professional organizations, state attorneys general](#) and hearing professionals around the country in their concern over upcoming OTC regulations, I believe if OTC hearing aids have the proper guardrails to protect patient safety and satisfaction, they could be a valuable marketplace addition. However, the simplistic view of "experts" outside the hearing industry cannot cause confusion, damage the hearing aid's reputation or discount the importance of hearing professionals.

I hope Bose's sudden departure is a turning point for the conversation around OTC hearing devices — a conversation that should finally focus on the patient, not on profits.

It's not just about cost; it's about care. It's that simple. Hearing is essential, and hearing loss shouldn't be a political punchline. Disregarding the importance of medical device technology and the hearing professional's role is not in the patient's best interests. It's time consumer electronics companies and Washington focus on what matters.

[Brandon Sawalich](#) is president and CEO of Starkey, a hearing aid manufacturer based in Eden Prairie. On Twitter: @BrandonSawalich.