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Access Points: When “Accessible” Isn’t the Same as “Safe”: What Canada Should Know Before Over-the-Counter Hearing Aids Arrive

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We will have handed people a box and called it care.

I have lived my whole life with profound hearing loss, and I have spent more than three decades as a disability rights lawyer and advocate, arguing that access is not a favour we extend to people—it is something they are owed in law. So when I learned that hearing aids might soon be available over the counter, off a shelf, or shipped to your door without a prescription, my first instinct was cautious optimism. Anything that lowers the wall between a person and the sound of their own life deserves serious consideration.

And the wall is real. Hearing aids are expensive, the wait to see an audiologist can be long, and for someone in a rural community, the nearest clinic may be hours away. For an older adult on a fixed income, the cost can close the door. Over-the-counter (OTC) hearing devices promise to pry that door open, and the Canadian Academy of Audiology, whose members spend their working lives helping people hear, supports better access for everyone. I share that goal completely.

But access and safety are not the same thing. I am not an audiologist, and I will not pretend to the clinical expertise the Academy's members hold; what I bring to this is a consumer's stake and a lawyer's eye. From that vantage point, the closer I look at how OTC hearing devices are arriving in Canada, the more convinced I become that we are about to repeat a familiar mistake: confusing the availability of a product with the solution to a problem.

What We're Actually Talking About

Let me be precise. A hearing aid is a medical device tailored to a person's hearing loss, with controls that balance high and low tones and—critically—limit the output's volume. In most of Canada, fitting one is a regulated act under health professions legislation. That is not bureaucratic fussiness: the law restricts who may fit a hearing aid precisely because a device set too loud can cause permanent harm, and our legislatures decided that risk warranted a trained professional standing between the consumer and the device.

An OTC hearing device is something different. In the United States, where the Food and Drug Administration created the category in regulations that took effect in October 2022, an OTC device is intended for adults aged 18 or older who *believe* they have mild to moderate hearing loss. It can be purchased without ever seeing a hearing professional. No assessment, no prescription, no fitting, no one confirming afterward that it is helping rather than harming. You decide you can't hear well, so you buy a device.

Notice the word "believe." The American rule is built around perceived hearing loss—what a person thinks is happening in their ears. But perception is often wrong. Research shows people tend to underestimate hearing loss, and there is no reliable way to determine its degree or type from your kitchen table.

Why "Mild-To-Moderate" Is Not A Feeling

In casual conversation, "mild to moderate hearing loss" sounds like a soft, forgiving range. In audiology, it is a precise measurement, taken with calibrated equipment in a sound-treated room, that averages your hearing thresholds across specific frequencies. Mild and moderate losses have actual numerical boundaries. A person cannot land themselves in that range by intuition, and the American regulation does not ask them to measure anything. It simply asks how they feel about their hearing.

This matters more than it might appear, because—as any audiologist will tell you—not all hearing loss is the same kind. Some is sensorineural, the gradual, permanent change that comes with age or noise exposure. But some is conductive: earwax, fluid behind the eardrum, or a problem in the middle ear. Conductive loss can frequently be treated medically or surgically, sometimes completely. A device bought off a shelf does nothing to address it—and worse, it can mask a condition a physician should have caught. No consumer can know on their own whether their hearing loss is sensorineural, conductive, or both, and a sound-amplifying device cannot tell the difference. The American studies were conducted on people with carefully measured, diagnosed sensorineural loss; they tell us little about the person who simply suspects they aren't hearing well and reaches for a quick fix.

A Cautionary Tale from the United States

Here is where the American experience should give Canada pause. The United States went first, and the lesson is not that regulators there were careless—it is that even a careful framework left real gaps. If the worst that happened was someone buying a device they didn't need, I would be far less worried. The deeper concern is that the wrong device, or the right device set wrong, can make hearing loss worse. Sound that is too loud damages hearing permanently—the whole reason fitting a hearing aid is a controlled act, and why a legal principle sits underneath this debate that deserves to be named: the duty of care.

> The OTC model does not lower the duty of care. It removes the person who holds it.

When an audiologist fits you, that professional—trained and accountable to a regulatory college—owes you a legal duty to act in your interest—to assess properly, to verify the fitting, to refer you to a physician if something is wrong. That duty is enforceable, and it is why the law placed a professional between you and the device in the first place. The OTC model does not lower that duty of care. It removes the person who holds it. The transaction is quietly restructured so that no one is responsible for whether the device is safe for your particular ears—and the risk the law had deliberately assigned to a trained, answerable professional lands instead on the consumer, the person least equipped to bear it.

Audiologists have a safeguard for exactly this: real-ear measurement. Using a tiny probe microphone in the ear canal, they measure the actual sound level reaching the eardrum while the device runs—because specifications are measured in a metal coupler, not a human ear —and the difference can be as much as 20 decibels, enough to separate safe from harmful. OTC devices, sold without a professional, skip the step entirely; no one measures what is actually happening inside your ear.

And here is the part that should worry us most: despite the regulation's intention to cap these devices at modest amplification, researchers found the output limits high enough that some OTC devices can deliver enough volume for someone with severe-to-profound loss, so for a person with only mild loss, the potential for over-amplification is genuinely dangerous. The framework looked comprehensive on paper, yet it still left that gap. A product designed to help you hear should never create the risk of further hearing loss.

Canada Hasn't Built the Guardrails Yet

The United States, for all its limitations, at least built a framework: labelling requirements, consumer disclosures, hard limits on maximum output, and technical performance standards. Canada has nothing equivalent at the federal level. Health Canada has historically licensed hearing aids as Class II medical devices and has recently begun approving newer consumer devices under the same category, without a distinct framework for non-prescription hearing aids at all. Prescription and non-prescription devices are largely approved under one undifferentiated heading.

And a Class II licence does not mean what people might assume—a distinction that matters enormously in law. It does not require the manufacturer to prove the device is safe or that it sounds good; it chiefly requires quality control in manufacturing, with safety information available only on request. It is a manufacturing standard, not a guarantee of hearing safety. As a lawyer, I find that

gap troubling because it creates a false sense of security: most consumers, seeing a Health Canada licence on a box, would reasonably believe that someone had verified the product was safe for their ears. No one has. When a regulatory label implies a protection it does not deliver, the law has not closed a gap—it has papered over one, and the consumer who trusted it pays the price.

Cheap Is Not the Same as Accessible

There is a tempting story in which OTC devices are affordable hearing aids. The American market is messier. Prices range widely, and better-performing devices often cost as much as hearing aids obtained through Canadian clinics. Several high-profile partnerships between consumer electronics brands and established hearing aid makers have already dissolved, and some inexpensive devices have suffered from serious durability problems.

That last detail leads somewhere a consumer-protection lawyer cannot ignore. Ontario's Right to Repair Act (Bill 91, 2025), a proposed amendment to the *Consumer Protection Act*, 2023 that has so far passed only first reading, would give consumers the right to repair information, parts, and tools, with remedies when suppliers fail to comply. But its scope—electronics, appliances, vehicles, farm equipment, mobility aids—does not clearly extend to medical hearing devices. Quebec has gone considerably further on repair rights. The result is an inconsistency worth examining: an identical device bought in Gatineau may carry repair protections that the same device bought in Ottawa does not. If Health Canada keeps approving OTC hearing devices as Class II medical devices, that classification is exactly what strips Ontario buyers of recourse. The fix is squarely within the province's power: bring medical hearing devices within the scope of the Act, so an Ontarian whose device deteriorates in six months is not left holding a broken device and an empty wallet.

What Access Actually Requires

This is where my own ground is firmest. In human rights law, the duty to accommodate is not satisfied by a token gesture—it requires meaningful access, not mere appearance. The same principle applies to this debate. Real accessibility in hearing health care is not a cheaper amplifier; the audiologists are right that technology is only the tip of the iceberg. It means clinicians who recognize the consequences of untreated hearing loss—depression, isolation, and strain on work and relationships. It means counselling and rehabilitation, and rooms designed so people can use visual cues, not just a device dropped in your ear. A device alone does not undo the impact of hearing loss; professional support is what delivers access, and it is precisely what the over-the-counter model leaves out.

I want to hold two truths at once. The first is that the status quo fails too many people, and the cost and inconvenience of hearing care keep too many in silence. The second is that a poorly built, unverified, unregulated device is not the answer—and may deepen the problem.

> Adding low-quality devices to the market is not the same as adding access. It can be the opposite.

A reasonable path forward

None of this is an argument for slamming the door. It is an argument for opening it carefully, and the audiologists have already sketched the middle road I would endorse. Ontario should hold off on its own OTC policy until Health Canada establishes a real national framework—ideally splitting the Class II category in two, one for prescription hearing aids and one for non-prescription devices, each with its own requirements. Devices should meet a genuine technical standard and carry evidence of their safety and sound quality. Packaging should plainly warn that any amplifying product can expose you to sound loud enough to worsen your hearing. And because these devices are not medically necessary, funding intended for hearing aids should not be diverted to them.

I will also give credit where it is due. Some devices—Apple's AirPods Pro 2 among them—now include a built-in hearing test that sets amplification to a measured, factory-specified level rather than leaving it wide open. When professional care genuinely isn't available, that is a reasonable floor, and I hope other manufacturers treat it as the minimum rather than the exception. Some have already voluntarily added safety warnings. That is the right instinct.

I want OTC hearing devices to succeed. Too many Canadians remain isolated by cost, geography, and uneven access to hearing care. Technology should expand access. The question is whether we are willing to insist that innovation and safety go hand in hand.

I have spent my life insisting that people with disabilities deserve to participate fully in the world, and hearing is central to that participation. I want every Ontarian struggling to hear to have a real, affordable, dignified path to better hearing. That is precisely why I am cautious about a shortcut that appears to offer access but may not deliver it—and could cause harm along the way.

Let's give people the real thing: devices we can trust, professionals within reach, protections when something goes wrong, and the recognition that being able to buy something is not the same as being helped by it. Get that right, and over-the-counter hearing devices could become a meaningful part of a much larger answer. Get it wrong, and we will have handed people a box and called it care. **Accessibility done badly is not kindness. It is liability dressed up as progress.**

For the Canadian Academy of Audiology's full position statement to the Ontario Ministry of Health, including the technical standards and research behind these concerns, please consult the CAA submission on over-the-counter hearing devices.

Legislation referenced: Bill 91, Right to Repair Act, 2025 (Ontario), amending the Consumer Protection Act, 2023, S.O. 2023, c. 23, Sch. 1 (first reading); Bill 29, An Act to protect consumers from planned obsolescence and to promote the durability, repairability and maintenance of goods (Quebec, 2023).