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US Food and Drug Administration Commitment to OTC Hearing Aids: Reflections for Canadian Practice

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In a press release dated December 7, 2016, The Food and Drug Administration (FDA) in the United States announced important steps to “better support consumer access to hearing aids”. The agency

issued a guidance document explaining that “it does not intend to enforce the requirement that individuals 18 and up receive a medical evaluation or sign a waiver prior to purchasing most hearing aids.” Furthermore, the FDA also announced “its commitment to consider creating a category of over-the-counter (OTC) hearing aids that could deliver new, innovative and lower-cost products to millions of consumers.”

Some of the reasons cited for this decision included the following:

1. The President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering and Medicine (NAS) both concluded that the medical clearance regulation was “providing little to no meaningful benefit to patients.”
2. Despite the high prevalence of hearing loss, only about one fifth of Americans who have a hearing loss seek intervention.
3. Hearing aid cost over \$2000 each in the US and this high cost presents a barrier for many people with hearing loss.
4. Consumers can currently purchase OTC reading glasses and the same model should apply to hearing aids.
5. The American Association of Retired Persons (AARP) and the Hearing Loss Association of America have both endorsed the movement toward lower cost OTC hearing aids.
6. Drive toward more competition and innovation in the hearing aid industry will eventually lower prices for consumers.

While the FDA has no jurisdiction in Canada, it would be naïve to think that these changes will not have an effect on audiologists in our country. Depending on the province in which you reside, prices for hearing aids are relatively similar in many parts of Canada. As such, there is no doubt in my mind that lower costs OTC hearing aids will make their way into the Canadian market, driven by an equally robust Canadian consumer movement.

As both a consumer of hearing devices and an audiologist, what I find most interesting is how little the professional services of an audiologist is valued by either consumers or the government. There seems to be some recognition that children with hearing loss, and adults with more severe losses require more and consequently will not have access to over-the-counter technology. But still, it is disheartening to see the lack of value placed on our services by this FDA decision.

How did this happen? The following may have contributed.

1. The business model of bundling of audiological services into the price of the hearing aid. We have not been transparent about the cost of our services. Consumers were led to believe that the price they were paying was for the hearing device only. The consumer has no idea how the audiological assessment itself was paid for. For example, in the province of Ontario, most patients would likely conclude that OHIP pays for the hearing test provided by any audiologist, even those in private practice since the patients are asked to present the Ontario Health Card at the time of the appointment. In fact, they are asked to present their OHIP card in order to access the Assistive Devices Program funding which only partially covers some of the hearing instrument cost and does not cover the cost of the assessment.
2. The Business to Consumer (B2C) marketing employed by some audiologists focuses on the hearing

aid itself, rather than their professional services. So as such, the message to the consumer is that buying a hearing aid is a one-time transaction rather than an ongoing service based relationship.

3. Many audiologists do not offer any additional service other than a standard hearing test followed by the fitting of a hearing aid. Only a few seem to do a speech in noise test, the results of which are critical to appropriate equipment selection. A thorough needs assessment also needs to be conducted to truly understand the patient's hearing challenges. Provision of these services would differentiate the experience of seeing an audiologist for hearing equipment from the OTC transaction.
4. A lack of understanding of the role of the consumer and the role of the audiologist. Henry Ford once said "If I had asked people what they wanted, they would have said faster horses". What he meant of course is the people would like to get from point A to B faster. The need is for speed, not faster horses. Similarly, the consumer knows where he or she would like to communicate better. That is the real need, and the sole solution is not necessarily cheaper hearing aids.

In short, we have not adequately demonstrated to the consumer the value of our services. We have descended to the level of a hearing aid fitter, rather than working to our full scope of practice as a profession that specializes in meeting the communication needs for people with hearing loss.

Reframing the role of audiology is based on the assumption that the value of a good or service is defined by the customer. In other words, when a good or service meets a customer need, the customer sees value in that good or service. Those that produce the good or service are more successful when they have a clear understanding of these customer specifications and tailor the features of their product or service to meet those specifications. If a gap exists between what customers identify as valuable and what is readily available, it presents an opportunity for those that produce the good or service to close that gap by modernizing what they produce. This is an ongoing challenge, since what customers want and value often changes regularly over time.

Our audiological services must be viewed with this patient/customer-centred definition of value. Audiologists need to step up their game. Just fitting hearing aids is not going to ensure the audiology profession continues in the future, as signalled by the US decision regarding over the counter hearing aids. To remain viable, we must do a better job of identifying patient needs. And when those needs are met, our services will be recognized by patients as valuable. The patient is not an expert on hearing aids and does not know the frequency and gain requirements they require. Nor will the patient know when more than a hearing aid will be required to meet their auditory needs and lifestyle. But the patient does know where he or she experiences communication challenges and how it feels to struggle to communicate. Even alerting needs should be examined. It is shocking how many adults with hearing loss find simple tasks such as waking up in the morning to be a big challenge. This may not be as complex as performing an ABR test, but from the patient's perspective, the inability to reliably wake up in the morning could be the most pressing need.

We need to perform more speech in noise assessments on each and every potential hearing aid user. The number one patient complaint with hearing aids continues to be inability to communicate in the presence of noise. Completing speech in noise assessments, and prescribing additional technology to improve function in noisy environments, would add further value by addressing this common customer complaint and would further differentiate our services from the over the counter purchase model.

We need to be more transparent. Let the patient know that hearing testing is not covered by provincial

health care plans. Take the time to explain the need for every service you provide, so that the patient can perceive its value.

We need to provide additional services such as communication training and tinnitus management to name a few. Always tailored to patient needs. If it is valued, people will pay for the service. People pay for fitness trainers, why not communication trainers?

Market yourself as a professional willing to listen to the patient's needs and partner with the patient to find solutions. Focus on your relationship with your patient, and identifying solutions to their functional needs, and less on the devices you are selling. Selection of hearing devices should be framed as a means to an end rather than the end in itself.

Links:

1. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532005.htm>
2. <https://www.whitehouse.gov/blog/2016/12/07/fda-takes-action-deliver-lower-cost-innovative-hearing-aids-millions-more-americans>
3. <http://nationalacademies.org/hmd/~media/Files/Report%20Files/2016/Hearing/Hearing-Recs.pdf>