

As a, Nationally Board Certified Hearing Instrument Specialist, practicing for over 9 years, I am strongly opposed to the PCAST recommendation to create a purported subclass of hearing aids to be fit without the requirement of a hearing test and fitting by a credentialed dispenser for the following reasons:

Untrained consumers do not have the skills required to self-diagnose the etiology of their hearing loss.

Countless numbers of consumers have come in to see me for hearing aids over the years, only to find that hearing aids are not the correct treatment for their hearing troubles. Many times I have found wax impaction, ear infections and drainage to be the problem. I see cases of Meniere's Disease, punctured eardrums, brain tumors and many other varying maladies.

These clients were referred to a physician for medical treatment and many did not require hearing aids, but did require immediate medical attention. I have uncovered several life or death situations by simply following the current FDA red flag protocol.

One part of the FDA red flag protocol requires the hearing professional to determine if there is an air-bone gap by using sophisticated masking techniques in many cases. An air-bone gap is one symptom of brain tumor. An untrained consumer will not be able to perform this test accurately nor identify it on an audiogram.

Many consumers are sure to misdiagnose themselves and purchase hearing aids that will only cover up another undetermined affliction. Untrained consumers do not have the training to self-diagnose the etiology of their hearing loss and the results will range from frustrating to life threatening.

Untrained consumers do not have the training and expertise to properly test and fit themselves optimally to safe and comfortable hearing levels with a hearing aid that fits their ear properly.

I have many instances of self fittings gone wrong. For example, in April, I had a younger pre-med client, named Michael, come in to see us. He purchased pair of hearing devices at an Expo for \$2500. He was unable to tell me if they were hearing aids or PSAP's.

The manufacturer claimed that they provided amplification for better hearing and also protected the ears from loud sounds. He like the idea because he was a target shooter. He decided to purchase the hearing devices.

He was required to make his own ear impression from home and send them into the manufacturer. When he received them back in the mail, he said they were painful to wear. He demonstrated in my office how difficult they were to insert. It took him about 15 seconds of wincing pain to insert them. When inserted, he had trouble opening and closing his jaw. They were also so loud that he could not wear them long. He also experienced occlusion and it sounded like he was in a tunnel when he talked. By looking at them, it was questionable if they actually provided hearing protection when shooting.

It was obvious by his hearing loss that he had the wrong device. A hearing professional would have been able to fit him with the correct style and technology to save him time, money and hassle. Keep in mind, this was a younger client who was pre-med, yet he could not self fit his own hearing aids.

Training and expertise is required to test and fit hearing aids safely and optimally.

Consumers do not have the training or expertise to monitor or care for their hearing aids. They also cannot do a professional otoscopic evaluation. Consumers cannot see inside their own ears. Even if they could, they do not have the training to understand what they are seeing.

Hearing aids need adjusted and maintained by a trained professional and ear canals must be examined periodically for optimal hearing.

We see clients every day for adjustments and maintenance. Hearing aids will not work properly without this service.

I recently had a gentleman named Ken come in who bought hearing aids in 2007 from another provider. He stopped going in for services over a year earlier and was having problems. He called us because we were close to his home. I examined his ears and found one impacted with wax and a hearing aid tip embedded in the wax.

It is only a matter of time before a wearer will experience this type of issue without receiving proper aftercare.

Clients who purchase hearing aids will inevitably experience changes in hearing. This may be due to Presbycusis or other reasons such as a medication change that causes their hearing to fluctuate. In these types of cases we need to find the cause and make adjustments or maybe come up with new strategies and educate as to what is causing their new found troubles.

Consumers do not have the ability to monitor or care for their hearing or hearing aids and they cannot perform a professional otoscopic evaluation. This eventually leads to frustration and the consumer will not be able to wear their aids.

Creating a “new” class of hearing aids would lead to “no” class of hearing aids. Manufactures may not see a reason to make a regulated hearing aid. The senior population would also be opened up to unregulated and untrained wrongdoers who could sell hearing aids on the run.

Bypassing trained and credentialed hearing aid professionals and replacing regulated hearing aids with a so-called “lower class” of hearing aids would open the door to many problems. Untrained retailers would have an advantage over trained hearing professionals who currently follow long established best practices. Swindlers would see a great opportunity to take advantage of the older population with no oversight.

Former fitters who have lost their licenses for breaking the law would have new life. These changes will hurt the hearing impaired, more than help.

Hearing aids are complicated little computers that require an understanding of different types of hearing loss and also how the physical structure of the ear and hearing aid can affect the sound clarity. This requires a professional to determine the proper fitting, as well as safe gain levels.

Unlike most vision issues, that simply require refocusing light to see better, sensorineural hearing loss is nerve damage. Each consumer needs counseling to understand their limitation and sometimes other cognitive listening issues require even more counseling and education.

Most of the time, we are dealing with an older population who have medical issues that make wearing hearing aids difficult. For instance, many have arthritis and cannot change the battery easily. Some cannot see well enough to clean the aids. Many have cognitive issues that require much more care than would be expected. It takes time, it takes experience and it takes patience. This is what hearing professionals do everyday and is misunderstood.

Moreover, the electronics are constantly exposed to moisture and earwax. They are used all day long, everyday. Hearing loss does not stay the same, it changes. Part of most hearing aid aftercare programs include periodic follow up hearing tests. These tests are used to determine changes in hearing so the proper adjustments can be made for the client to hear optimally. We can also determine if any FDA red flags have shown up.

We cannot forget that there was a time when hearing aids had little to no regulations. The reason the regulations came about were to fix all of the problems. Now we are talking about turning back the clock and bringing back all of these old issues...and they will come back. Why would we do that?

The forces who are pushing for these changes either don't know what they don't know or are pushing this for financial advantage and don't care. They are talking about making hearing professionals, who have an extremely high customer satisfaction rating, obsolete and replacing them with untrained self care or worse.

A separate class of hearing aids will not help with the above issues. Proper training is required to perform a proper hearing test and marry the loss to the best hearing technology and style for the job. Professional programming is required to fit the aid for optimal performance, especially in noise, at a safe listening level for the individual.

The FDA should not approve a stated subclass of hearing aids to be fit without the requirement for a hearing test and fitting by a credentialed dispenser.

Professional testing, fitting and ongoing aftercare is a requirement for optimal hearing and public safety.