**FAST READ:** While personal sound amplification products (PSAPs) are not FDA-approved for hearing loss, many consumers with mild, early-stage hearing loss are using them anyway. Some audiologists suggest their peers should incorporate PSAPs into plans of care to provide patients with low-cost options—and to build lasting relationships with those who otherwise can't afford hearing care. But because PSAPs currently lack standards, other audiologists are hesitant.

**TAGS > PSAPs, AUDIOLOGY**

# Add PSAPs to Your Practice?

Like it or not, people with hearing loss are using personal sound amplification products. And while some balk, a cadre of audiologists says the profession needs to embrace the devices as part of patient-centered care. **BY HALEY BLUM**

Etymotic Bean

# It's time to talk about PSAPs.

Half of PSAP owners use the device to listen to television, one-quarter use them in other situations, and one-tenth use them every day in every situation.

Sound World CS50+

If you're an audiologist, you're likely aware of personal sound amplification products (PSAPs)—over-the-counter devices not FDA-approved for hearing loss, though being used for just that by those with mild, early stages of age-related hearing loss. But that doesn't mean you're recommending them.

"I would say the majority of audiologists at this point have not embraced PSAPs as an option," says Barbara E. Weinstein, professor and founding executive officer of the City University of New York Graduate Center's AuD program.

Although audiologists have yet to widely acknowledge or accept the use of PSAPs, one in 25 American adults with hearing loss already owns one, according to a 2014 report (**bit.ly/cea-psap-report**) by the Consumer Electronics Association (CEA). Forty percent say they're interested in over-the-counter products to help them hear better, and two-thirds want the experience of purchasing hearing devices to be more streamlined.

Some audiologists, like Weinstein, are encouraging their peers to embrace the PSAP as a natural extension of patient-centered care, but others caution against using a product that is held to less scrutiny than hearing aids.

So what to do?

## The consumer appeal

Let's consider how PSAPs, sometimes referred to as "hearables," are used.

Richard Einhorn, 63, lives in New York City, where he works as a composer and musician. After developing conductive hearing loss in the 1990s and later being hit with a virus that destroyed much of his remaining hearing, Einhorn became a hearing-aid user, actively seeking out the latest in hearing technology.

"Because I have a background in music and audio production ... I became an advocate for better hearing assistance technology and for better access to it," says Einhorn, who also uses technology like his iPhone as a remote microphone and for listening to music and podcasts. "I don't just use one thing, which makes me kind of unusual in the hearing-loss world, where most people just put their hearing aids in and forget about it. I'm very proactive in the use of technology."

In 2012, he was first introduced to PSAPs by his friend Frank Lin—an associate professor of otolaryngology-head and neck surgery, geriatric medicine, mental health, and epidemiology at Johns Hopkins University—whose research has shown possible links between cognitive decline and hearing loss (**on.asha.org/lin-leader**) and whose team is looking into PSAP use. The devices can look similar to hearing aids, with both behind-the-ear and in-ear options, though some also look like Bluetooth earpieces. PSAPs do not require fitting or testing and are controlled by the user.

Delighted with his results, Einhorn has been using PSAPs alongside his hearing aids ever since. "The price versus sound quality is quite exceptional," he says.

It's this cost value that's appealing to most PSAP users, who generally have mild, early-stage hearing loss (Einhorn says he is near the limit of hearing-loss levels that can be helped by PSAPs) or simply have a difficult time hearing but no official hearing loss. When someone who can't afford to spend thousands of dollars on hearing aids is faced with the alternative of receiving no hearing care at all, a PSAP that costs a few hundred dollars could be an enticing solution, says Neil DiSarno, ASHA's chief staff officer for audiology.

"An unfortunate occurrence that often happens is when a patient comes into an audiologist's office worried about their hearing, undergoes a comprehensive audiologic evaluation, spends the next 30 minutes undergoing extensive counseling, and now feels quite bad because they've been told that they're losing some of the function of one of their senses," DiSarno says.

"Then they're told the treatment [hearing aids] is going to require a substantial cost, and the patient who can't afford it is now

not only a bit depressed about the fact that they're losing one of their senses, they're now doubly depressed because there is very little they can do about it. So it's a tug-of-war between the patient and the audiologist who truly wants to help the patient—how can we address this?"

## Affordability and accessibility

The average PSAP costs $100 to $600, one-tenth of the average price of hearing aids, according to the CEA report. Half of PSAP owners use the device to listen to television, one-quarter use them in other situations, and one-tenth use them every day in every situation. For those interested in using a PSAP, 41 percent foresee using the device in all situations.

"Consumers who do not own PSAPs would like to use them with television, in group situations, in large rooms, in noisy rooms—which are the reasons why people go to the audiologist for help," Weinstein says. The CEA report found that 84 percent of consumers would seek out a medical or hearing health care professional for advice on hearing impairments.

Many consumers buy PSAPs from online retailers such as Amazon, or straight from the manufacturers' websites. And although PSAPs don't have all of the customizable features that hearing aids offer, some of the newer models provide users with low-battery alerts, connectivity to smartphones and other devices, and much more control over amplification levels. Most also tout rechargeable batteries.

Though Einhorn says his audiologist doesn't know that he uses PSAPs two or three times a week—and as convenient, inexpensive spares to back up his hearing aids, especially when traveling—Einhorn would "definitely" like audiologists and hearing health professionals to incorporate PSAPs into their care when appropriate for the patient.

But there's some gray area: PSAPs' status with the FDA is a major reason why audiologists have chosen to stay away from the devices. Because FDA regulatory guidance from 2009 (**bit.ly/fda-psaps**), updated by a 2013 draft guidance, deemed a PSAP a "wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing-impaired consumers to amplify sounds in the environment," audiologists cannot legally market PSAPs as devices to treat hearing loss.

However, in addition to the CEA, other large organizations have been investigating and providing recommendations about the devices.

The Institute of Medicine has held open meetings of its Committee on Accessible and Affordable Hearing Health Care for Adults (**bit.ly/iom-committee**) over the past two years, with the regulation and definition of PSAPs a hot topic of discussion. The President's Council of Advisors on Science and Technology (PCAST) has addressed FDA regulations on labeling and marketing of PSAPs, as well as over-the-counter hearing aids.

PCAST's resulting report, "Aging America & Hearing Loss: Imperative of Improved Hearing Technologies," released this fall, recommends that the FDA get rid of its drafted guidance of PSAPs and instead categorize them as "devices for discretionary consumer use," allowing manufacturers to advertise that PSAPs can be and are used by people with age-related mild-to-moderate hearing loss. The report does not mention, however, that audiologists should be consulted before consumer use of these devices (see the sidebar on page 45 for ASHA's response). CEA recommended similar measures in April 2014 (**bit.ly/cea-fda**).

But even with the current FDA regulations, Weinstein says there are ways to incorporate PSAPs into patient care by focusing on their specific situational uses.

"It's important for audiologists to understand that people with milder hearing loss have situational difficulties, and PSAPs are situational devices, in my opinion, akin to hearing-assistive technologies like devices for the television, smoke alarms, doorbell ringers," says Weinstein, who has studied and uses PSAPs with students at her university clinic. "There's little difference between the assistive devices that I recommend for use in


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specific situations and the PSAPs—for those not ready to purchase hearing aids—except the PSAPs look more like hearing aids, so it's kind of a threat, though in my view they lower the barrier to entry to hearing health care."

## Questions and concerns

It's not that audiologists aren't looking for a lower-priced, effective option for clients; what worries some is the current lack of standards and governmental sign-off.

"Their concern is about providing something for their patient that hasn't really undergone close scrutiny as would a medical device—which [a PSAP] isn't," DiSarno says, adding that all PSAPs are not of equal quality. "So they're torn with being able to meet their patients' amplification needs within whatever their financial constraints are, but then also not providing something that may be of lesser quality."

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Tweak Focus

Some PSAPs also do not have controls over how loud they raise sounds. "You want to make sure they don't amplify sound to a dangerously loud level," Weinstein says, though she adds that more and more offer a safe sound limit. Weinstein also warns that consumers should get their hearing checked before purchasing PSAPs to rule out any serious conditions that could be causing the hearing loss.

Audiologists also may shy away from PSAPs because they are unsure of how much maintenance and repair the devices will require, possibly taking up more of their time and inconveniencing patients.

Even Einhorn, who remains positive about PSAPs and their inclusion in audiology, has had some bad experiences.

"There was a very heavily promoted PSAP by a very prominent group of researchers that I was very excited to try—and it was literally worthless," Einhorn says. "It was appallingly bad, both in terms of its usability and sound quality. And it came tremendously hyped."

That's why PSAPs are in need of standards, he says, because "at the moment ... you can get ripped off." In the meantime, to avoid wasting money when purchasing a PSAP, Einhorn offers some advice: Don't trust any device under $200 ("they're junk") and make sure you can get a refund.

Weinstein agrees that consumers should avoid low-end devices. "The cheaper devices ... are not really good," she says, noting that there are about three or four "really good" PSAPs on the market. "I don't think you can get a good PSAP for $50. You're not going to get a good one that's going to have the technology that you want for people with very specific situational difficulties."

Audiologists may worry that an interaction with a poor-quality device could potentially influence patients' perception of amplification and hearing care in the future, DiSarno says, making them wary of eventually trying a higher-quality product like hearings aids.

"But the models of providing amplification and auditory rehab services to patients are evolving, and I think audiologists are part of that evolution," he says. "What we're seeing is a slow and cautious transition. ... Audiologists have to let the public know that they provide auditory rehab—they don't just provide hearing aids. They develop a plan of care for a patient, and one aspect of the plan of care is amplification. But there are many other treatments the audiologist provides that round out the patient plan of care."

With the price of PSAPs considerably lower than that of hearing aids, some audiologists may worry about maintaining the financial solvency of their business. "It's not that they're concerned necessarily that the PSAPs are going to take over for hearing aids," Weinstein says. "It's that they're concerned that the time [selling them] is going to detract from the time that they can put into selling hearing aids."

## An evolving plan of care

But instead of concern, Weinstein sees opportunity to grow practices and enhance patient care.

"The most important thing for audiologists to think about is that 80 percent of people with hearing loss are not using our technologies," she says. "If we can ensure that more people have the gift of hearing with less expensive technologies earlier, then we're going to entice them to work with us

and to come back. They will be our long-term partners in their care, and it could be a 20- to 30-year relationship.

"By unbundling and charging for the services and the technology separately, that's a win-win for the patient and for the audiologist." Unbundling, however, depends on the insurer. Some private health plans already reimburse separately for devices and services, but others bundle all services together. Medicare and other insurers do not cover devices or device-related services at all.

Unbundling is key to fitting PSAPs into clinical practice, agrees Catherine Palmer, associate professor in the Department of Communication Science and Disorders and the Department of Otolaryngology at the University of Pittsburgh and director of audiology and hearing aids at the University of Pittsburgh Medical Center.

"The audiologist would use their expertise ... to recommend the best plan of action. For some individuals, a PSAP may meet their current needs," Palmer says. "If that is the case, the audiologist would be in the best position to provide a PSAP known to have good sound quality and an appropriate response (not individualized). ... For other patients, they need a customized solution and the service that goes with that."

Weinstein says she uses illustrative "decision aids" that show patients their options, including PSAPs and communication strategies, if they have a certain level of difficulty hearing but are not ready to buy hearing aids. "This is patient-centered care. Give patients a variety of options targeted to their specific problems," she says. "I've had patients who actually have hearing aids and prefer one brand of PSAP over the hearing aids in certain situations."

By charging for evaluation and customized solutions, audiologists would be able to provide patients with many different levels of solutions, Palmer says. "Rejecting PSAPs in a practice will not serve our patients well. They need our advice on this."

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## ASHA Responds to President's Council Report on Aging and Access to Hearing Technologies

A group appointed by President Obama to examine accessibility and technology in hearing health care issued its report in October—and ASHA, while praising the group's interest in the topic, took issue with the report's device-focused recommendations.

The recommendations of the President's Council of Advisors on Science and Technology (PCAST) dismiss the importance of individualized treatment plans for patients with hearing loss and erroneously compare hearing with vision, wrote Judith L. Page, then ASHA president, in response (see **on.asha.org/asha-pcast-response**). One of the recommendations is to rescind the FDA's draft guidance on PSAPs, which notes the devices are not intended to compensate for hearing loss. Page criticized this recommendation, noting that the FDA's guidance helps consumers make informed decisions about PSAP use.

PCAST also suggested a new class of over-the-counter (OTC) hearing aids for those with mild-to-moderate hearing loss, which Page said could pose risk to consumers who are not properly tested and diagnosed by a hearing health care professional.

Page also called for regulations that would distinguish between medical devices (such as OTC hearing aids) and electronics that augment hearing (PSAPs). "The line between PSAPs and hearing aids has become blurred and, at times, differentiated only by its advertised purpose," she wrote. "We would also urge the FDA to include encouragement for consumers to seek a comprehensive audiologic evaluation if they are intending to use the PSAP to treat hearing loss, and that consumer electronic devices are not classified for that use."