MEMORANDUM

To: Academy of Doctors of Audiology ("ADA")
Attn.: Stephanie Czuhajewski, CAE, Executive Director
From: Michael H. Cohen, Esq.
Re: **Issues Brief to ADA Members—Dispensing Personal Sound Amplification Products**
Date: June 29, 2016

Introduction

Several ADA members have asked us whether it is legal for audiologists to dispense Personal Sound Amplification Products (PSAPs) to their patients.

While we cannot give our members legal advice, we take the opportunity below to comment generally on various operative legal rules and principles, and to dispel myths and misconceptions.

Specifically, we address the role of:

- Audiologist Licensing
- Consumer Protection Laws; Online Sales of Hearing Devices
- Malpractice Issues:
  - Negligence
  - Informed Consent
- FDA Issues

Note that the legal and regulatory environment is complex. Before you make a business decision that has legal ramifications, consider contacting an attorney for legal advice specific to your situation.

I. Background

Our profession is in flux, with many disruptive technologies (such as PSAPs) challenging and changing traditional clinical practices. Here are some highlights of recent regulatory activity and industry response.

A. FDA Guidance

In 2013, the federal Food and Drug Administration (FDA) issued a Draft Guidance for Hearing Aid Devices and Personal Sound Amplification Products.

FDA explained its view of the difference between hearing aids and PSAPs:

> Hearing aids and PSAPs both affect our ability to hear sound, but the products have different intended uses, and are therefore subject to different regulatory controls. A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. Hearing aids are usually programmed to address an individual's degree of hearing loss across sound frequencies to improve speech intelligibility. Additionally, hearing aids may be coupled

> acoustically or wirelessly to external electronic products such as televisions, MP3 players, and telephones. A hearing health professional (such as an audiologist or a hearing aid dispenser) is usually required to program and optimize the performance of hearing aids with these more complex features. In contrast, a PSAP is 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 certain environments, such as for hunting or other recreational activities.

FDA explained that from a regulatory perspective, FDA looks to the *intended use* of the product to determine whether it is a *medical device* on one hand, or *an electronic product* on the other. Intended use can be shown by labeling or promotional materials.

The 2013 FDA Draft Guidance went on to identify the regulations and accompanying definition of hearing aids; to note that hearing aids must comply with specific labeling requirements; and, to note that conditions for sale set by regulation include that:

- The hearing aid user must provide to the hearing aid dispenser, a written statement from a licensed physician that the prospective user has been medically evaluated within 6 months prior to the date of purchase of the hearing aid, and is a candidate for a hearing aid (this may be waived by a user 18 years or older, upon signing a waiver statement under conditions outlined in the regulation).

- The hearing aid dispenser must maintain records of medical evaluation statements and waivers.

The 2013 FDA Draft Guidance states that PSAPs "are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situation." Specific environments include bird watching, listening to lectures, and listening to distant conversations.

FDA notes that PSAPs are <u>not</u> subject to any FDA regulatory classification or registration/listing requirement.

In sum, the 2013 FDA Draft Guidance makes clear that there are two regulatory buckets: (1) hearing aids, which are intended to compensate for impaired hearing and therefore are regulated as medical devices, and (2) PSAPs, which are not medical devices and as such do not require FDA medical device clearance (unless the intended use—as shown, among other things, by marketing literature—makes medical device claims such as those identified in the 2013 FDA Draft Guidance).

The 2013 FDA Draft Guidance generated considerable controversy among stakeholders. ADA, among others, weighed in with commentary urging FDA to modernize its regulatory approach.

In April 2016, FDA held a Public Workshop - Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids, April 21, 2016. On behalf of ADA, Dr. Alicia Spoor presented.

Among other things, Dr. Spoor encouraged FDA to lift anachronistic regulations that unduly restrict access to audiology services, intrude on clinical practice, and hinder innovation.

Rita Chaiken, Au.D., President of ADA, followed up with a formal comment to FDA on May 6, 2016. In this comment, Dr. Chaiken pointed out that:

- It is no longer possible to use technological features to differentiate hearing aids from PSAPs, since many PSAPs are technologically equivalent to hearing aids.

- The intended use doctrine, for various reasons, does not work. The rule cannot be applied fairly and consistently, does not benefit the consumer, and does not recognize that PSAPs are used as assistive listening devices (ALDs) and not simply to amplify specific environmental sounds.

- It is time for consumers to make informed decisions about PSAPs without undue regulatory interference.

- Devices should be classified by their *actual use*. All amplification devices should be required to adhere to maximum output thresholds according to safety specifications. Labeling should allow consumers to make informed decisions about product use, and include a strong recommendation to seek a medical and/or audiological evaluation in cases of suspected hearing loss, tinnitus, dizziness or other warning signs of ear disease.

ADA encourages members to understand the FDA process as it bears on the overall legal and regulatory environment in which audiologists practice. ADA will continue its dialogue with FDA to advocate for a regulatory system that benefits patients and promotes consumer choice. We include some comments further below about the implications of FDA regulation for audiologists.

B. National Academies of Sciences, Engineering and Medicine/Institute of Medicine Report

In June 2016, the National Academy of Sciences, Engineering, and Medicine (formerly referred to as the Institute of Medicine), released its report, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*.

The report recommended that the U.S. Food and Drug Administration (FDA) remove the regulation requiring adults to have a medical evaluation or sign an evaluation waiver to

purchase a hearing aid, as well as establish a new category of over-the-counter, wearable hearing devices–separate from hearing aids–that could assist adults with mild to moderate hearing loss.

The NAS/IOM press release for the report notes, among other things that:

- The NAS/IOM committee found no evidence that the evaluation or waiver of that evaluation provides any clinically meaningful benefit.

- Over-the-counter, wearable hearing devices could provide an additional easy-to-access and potentially less expensive option to meet the hearing needs of adults with mild or moderate hearing loss, and the committee recommended that FDA establish a new category of over-the-counter hearing devices.

- Hearing health care professionals should improve transparency in their fee structure by clearly itemizing the prices of technologies and related professional services to enable consumers to make more informed decisions.

- The federal Centers for Medicare & Medicaid Services (CMS) should examine pathways for enhancing access to assessment for and delivery of auditory rehabilitation services for Medicare beneficiaries, including reimbursement to audiologists for these services.

NAS/IOM provides a summary of the report and an action guide for hearing healthcare providers.

II. ADA's Brief Response to PSAP Legal Question

With respect to the question that has arisen, as to whether it is legal for audiologists to dispense Personal Sound Amplification Products (PSAPs) to their patients, ADA emphasizes the following at this time:

- We encourage our members to beware of overbroad and generalized statements such as: "It's illegal for an audiologist to dispense PSAPs." The hearing industry has multiple stakeholders, each with various interests and motives.

- Industry representatives should not make unsupported statements, as it is illegal to engage in false and misleading advertising. California law also prohibits unfair and anti-competitive business practices.

Below is a brief discussion of legal issues audiologists should consider, in light of the above regulatory and industry developments, when dispensing PSAPs.

III. Brief Discussion of Legal Issues

A. Audiologist Licensing

State law governs licensing of audiologists.

Licensing laws, in addition to licensing provisions, contain disciplinary provisions for unprofessional conduct. Among other things, these provisions prohibit false and deceptive advertising with respect to clinical and business practices by audiologists. Licensing laws also typically contain legal rules governing the practice of fitting or selling hearing aids.

Audiologists should familiarize themselves with their own state licensing laws as these could potentially apply to audiologists' dispensing of PSAPs as well as of hearing aids.

B. Consumer Protection Laws; Online Sales of Hearing Devices

Consumer protection laws prohibit false, deceptive, and misleading advertising.

On the federal level, these laws are enforced by the Federal Trade Commission (FTC). State laws also prohibit false advertising.

In addition, there are specific state consumer protection laws covering "hearing instruments" or similar devices; and, a whole other set of consumer protection laws governing online sales.

For example—depending on the state—before dispensing a "hearing instrument," the audiologist might be required to give the patient certain warnings or disclosures relating to the advisability of an audiogram, medical evaluation, or other screening or diagnostic procedure. The required disclosure might also have to cover cancellation and refund options.

To complicate the legal landscape, some state laws, restricting sales of online hearing devices, have been legally challenged as violating (and preempted by) FDA rules.

Any audiologist who intends to dispense *either* a hearing aid or a PSAP, should seek to comply with state licensing laws applicable to audiologists and hearing aid dispensers, and also, with relevant consumer protection laws. In addition, audiologists should carefully review relevant legal rules in their states regarding online sales of hearing instruments, as these laws could cover PSAPs as well as hearing aids.

As suggested, legal definitions of hearing devices vary by state and are not necessarily consistent with definitions under federal law. If in doubt, the audiologist should consult an attorney.

C. Malpractice Issues

Negligence

The general legal definition of malpractice is conduct below the standard of care, which injures the patient.

Standards of care for audiologists are continually evolving. ADA is not aware of any civil litigation or disciplinary cases involving audiologists and PSAPs.

In fact, ADA is aware of recent studies, testing hearing aids versus PSAPs in clinical settings to study clinical outputs, and assess which device is better for the patient. Such studies could inform malpractice claims in the future, as the body of evidence accumulates.

ADA's understanding is that merely recommending or dispensing a PSAP does not in itself constitute professional negligence, assuming the standard of care is met, and clinical practice otherwise complies with relevant law.

Informed Consent

In general, clinical providers must tell patients about reasonable and feasible therapies of potential benefit, and disclose and discuss risks, benefits and alternatives.

Failure to satisfy the obligation of informed consent, can be considered malpractice.

One could argue that the general legal and ethical obligation of informed consent, in fact obliges audiologists to disclose and discuss the risks and benefits of PSAPs vs. hearing aids where this will be material to a patient choice between PSAPs and hearing aids.

D. FDA Issues

As suggested above, ADA does not necessarily see unusual liability or discipline involved in dispensing PSAPs, versus other consumer electronics. The caveat is that, as mentioned, members should familiarize themselves with licensing, consumer protection, and other legal rules that could potentially apply to PSAP dispensing and sales.

Nor does FDA see particular dangers for clinical practice involving PSAPs from an FDA perspective. FDA does not regulate the practice of medicine, audiology, or any other clinical practice. Clinical practices are within the purview of state regulation under the 10th Amendment to the U.S. Constitution. Thus, for example, medical doctors can prescribe drugs off-label to patients, and FDA does not intervene. Clinicians also recommend and sell dietary supplements, which while regulated under the Dietary Supplement Health Education Act, do not require pre-market proof of safety and efficacy.

However, ADA provides a caveat that, to the extent an audiologist is marketing or selling PSAPs, the audiologist—like any distributor—must take care to avoid making the kinds of medical or "hearing aid" claims for PSAPs, such as those that the 2013 FDA Draft Guidance identifies as prohibited by federal law. Although, as noted above, ADA has urged FDA to change its regulatory position, FDA is not bound to follow ADA's recommendations. Rather,

FDA may continue to enforce its understanding of current law and regulatory—and in particular, to initiate enforcement action where FDA believes it has jurisdiction and that claims run afoul of current prohibitions.

IV. Conclusions

As noted, ADA encourages members to beware of overbroad and generalized statements such as: "It's illegal for an audiologist to dispense PSAPs."

We recommend the following to our members:

- Any audiologist who intends to dispense *either* a hearing aid or a PSAP, should seek to comply with both state licensing laws applicable to audiologists and hearing aid dispensing, and consumer protection laws. Legal definitions of hearing devices vary by state and are not necessarily consistent with definitions under federal law, and consequently, some state law definitions *may* include PSAPs as well as hearing aids for purposes of various laws and regulations. If in doubt, the audiologist should consult an attorney.

- Merely recommending or dispensing a PSAP does not in itself constitute professional negligence, assuming the standard of care is met, and the practice otherwise complies with relevant law.

- In fact, one could argue that the general legal and ethical obligation of informed consent obliges audiologists to disclose and discuss the risks and benefits of PSAPs vs. hearing aids, where this will be material to a patient choice.

- FDA does not regulate the practice of audiology or any other clinical practice. In general, dispensing a PSAP is like selling any other consumer electronic product. However, the audiologist should take care not to make prohibited medical or "hearing aid" types of claims for PSAPs. The audiologist can reference the 2013 FDA Draft Guidance and subsequent updates for examples of kinds of prohibited claims. ADA will continue to attempt to persuade FDA to remove unnecessary and antiquated barriers to hearing healthcare.

- Audiologists should review the NAS/IOM Report and consider its implications, such as the call for itemizing and unbundling products from services, ensuring portability in records and technology and other recommendations designed to increase transparency in service delivery. While ADA has not, in this issues brief, analyzed the legal implications of bundling, the IOM Report is clearly calling for a change in professional practice.

Once again, note that the legal and regulatory environment is complex. Before you make a business decision that has legal ramifications, consider contacting an attorney for legal advice specific to your situation.