Hearing Aids: Over-the-counter (OTC), Direct-to-consumer (DTC) and Connectivity Q&A

1. How do you expect existing companies like Eargo, Innerscope, etc. to have to adjust when the FDA finalizes its guidance? In your opinion, do you think they will continue with medical waivers? or will they have to go through the 510K process? Any additional insight around how that may cause friction for them?
   While we don't have the guidance as of now, I do expect there will be at least a requirement to register as device manufacturers and possibly an initial 510K submission for their first device in the new OTC category. They may need to adjust their technical specifications if they exceed the gain/output in the guidance regulations. The FDA has indicated that while they suspended the medical clearance during the NASEM meetings, they fully intend to eliminate the medical clearance when the final regulations are announced.

2. The cost of hearing aids through conventional (audiologist) routes has been astronomical and getting worse. Do you think the OTC and DTC options entering the market will finally put downward pressure on exorbitant prices? We simply cannot bear the escalating costs. Yes, I do think these will be significantly less. Remember part of the reduction is the elimination of the professional services component.

3. Do hearing aids help those with hidden hearing loss? If so, how do you know, as an audiologist, know how to program them? Those individuals with "hidden hearing loss" have normal threshold but are having trouble in difficult listening situations like background noise. Mild gain hearing aid with effective noise reduction, directional microphone technology and counseling can provide some assistance.

4. Given the poor uptake of hearing aids, do you anticipate a large percentage of people with mild/moderate hearing loss will choose to wear an OTC instead of getting by without one? I do expect that many will try the OTC devices. Not all will have success as they may not be receiving the appropriate amplification for their hearing loss. Having an accurate hearing test can provide some basis for selection of a device.

5. What role do you expect major tech firms like Apple, Google, Samsung, etc. to play in the OTC device market? They have indicated that they have interest in this area through the patent applications they have filed. Samsung has introduced an "earbud" that has some hearing aid characteristics. We will know more after the FDA releases the regulations which will tell them the rule they need to follow.

6. Follow up on preemption: OTC will have express preemption over state dispensing laws but what about "classic" hearing aids? Would AuDs prescribing HAs still be subject to limitations that OTCs will be relieved of? This is a difficult situation. It is unclear what part of current state license requirements might be pre-empted by the OTC regulations. Many feel this is the most difficult part and what may be holding up the documents from the FDA. Since many consumer protections line return policy, warranty, bill of sale requirements, etc. "flow" through the license requirements this become complicated.

7. Any news on when the regulations might come out or what stage they are in now? The OTC regulations was listed on the June report from Health and Human Services (and FDA). This does not mean it is ready for immediate release. So, we are still waiting.

8. The hearing aids that are supposedly available with Medicare plans - are they any good? Would they work for someone with moderate loss? Currently Medicare does not cover hearing aids, but many Medicare Advantage programs do. Under these programs the full range of hearing aids are available including moderate losses.

9. Some insurance plans cover hearing aids. Do you expect that they will reimburse people who self-diagnose hearing loss and buy an OTC device? At the present time this is not expected.

10. Confusion - Regulation labeling for OTC devices are "hearing aids" or "personal amplifiers" The OTC regulations will define a new class of hearing devices that are for mild-moderate losses. In addition, the OTC legislation required the FDA to revise the PSAP guidance document to further define the intended use of PSAP devices for those with normal hearing and that they are not intended to be used to compensate for hearing loss.

11. Why do you think Bose is only being sold in those 5 states? Partially related to available number of devices and they are testing the acceptance of the devices in limited markets.

12. Do you know what the typical current hearing aid benefit is in these plans (my sources say ca $500/year). They vary by program. It is hard to make a blanket statement. Best to contact you provider.

13. Could those plans offer those $$ to be applied to OTC, DTC and/or hearables?" It is not likely that current insurance plans will cover OTC devices.

14. What are the implications for traditional brick and mortar audiology practices? What will be the impact on hearing aid pricing? Not clear at this point, but there does appear to be a trend toward unbundling the product and service portion of the cost. Also, some audiology practices have indicated they intend to carry OTC devices in their practice. These would be at reduced prices and of course with a very limited service/testing component.

15. Are the DTC devices approved by the FDA to be able to call themselves hearing aids or are they considered PSAPS or hearables? DTC are not clearly device. DTC is more a designation of the sales channel than a class of devices. If they are registered with the FDA (and some are) then they can be marketed as hearing aids. PSAP do not have their intended us to compensate for hearing impairment. This primarily relates to their marketing claims in advertising. They cannot say the PSAP devise are hearing aid and that they can help those with hearing loss.

16. Can the OTC devices be programmed for low frequency (conductive) hearing losses? We do not have any OTC devise as this category has not yet been defined by the FDA. I am not sure of companies coming into the OTC market will provide products for this type of loss, but we still do

not know for sure.

17. How can we, as advocates who need communication access via technology in public places, find ways to educate the people who buy these OTC and DTC hearing devices about their rights via the American's with Disabilities Act? We work very hard to educate on the value of telecoil connectivity to these communication access technologies. This appears to me to be another barrier to getting information to the right people, and to letting hard of hearing people know they have rights within the ADA. I agree, getting the correct information on OTC/DTC and PSAP devices will be critical. I expect a flood of advertising on these new devices when they hit the market. I hope the FDA provides guidance on the parameters of the device and the advertising. However, the advertising resides more with the Federal Trade Commission (FTC)

18. Will packing show whether the device includes a telecoil? Unclear currently.

19. Will audiologists embrace OTC, or dismiss them and refuse to service them? I believe this will be a split decision. Some have indicated they will have them in their clinics. Since many of these will not have programmable controls/software, they ability to serviced or adjust will be limited and therefore what hearing care professionals can do with these devices is still unknown.

20. When will persons who have been long term hearing aid users be allowed to program their own hearing aids for severe to profound losses? This may have to wait until we see how successful self-programming for mild-moderate losses is under the current OTC guidelines. The FDA may then expand this self-programming to more severe losses.

21. What is the price range for these OTC devices? The OTC category does not exist yet, however the products being sold through the DTC channel range from $300 - $1700.

22. It has always bothered me when someone feels they need hearing aids, but the audiologist tells them they don't have enough loss to get hearing aids. Do you think audiologists will shift their attitudes and work with the hearables so that the consumer will go away with some sort of solution and come back when they need more than a hearable? Yes, I think both hearable and the new OTC devices will give audiologists and hearing professionals new tools to help those with minimal hearing loss

23. Do these devices have t-coils? Some of the DTC devices have T-coils but sine the OTC regulation are not out yet we do not know the technical specifications.

24. Is there any data yet on OTC attempts giving up on hearing aids because they couldn't get them to work well for their needs? No data on this.

25. Bluetooth cannot do what hearing loops can do - what consumers need is hearing devices that have it all Agree however the combining of the technologies at present is difficult. I do think the new Bluetooth low energy protocol will have new applications. Loops will still be around for

a while.

26. Do over the counter hearing aids have a tele-coil within? If not is this not a disadvantage for the user? Since the OTC guidelines are not released, we don't have this category yet. I expect some of these devices will have a T-coil.

27. The FDA has stated they may release the OTC hearing aid regulations this month. Do you have further knowledge Not beyond what has been published, that the documents are in the pipeline.

28. What kind of time delay will be experienced by existing manufacturers if a 510K is req? This depends on whether the company anticipates a 510K and prepares some of the documentation ahead of time. Some delay may be expected if a large number of applications occur at the same time.

29. Will the OTC devices be locked? Meaning that they could not be taken to an audiologist to be programmed or reprogrammed? We do not know yet. Many will not have programming software. Some will have a user operated app.

30. If there is still a fuller review process through the FDA how will this decrease the cost from current processing? Plus, so much of the cost is related to the care/assessments will not audiologists who integrate these charge more? Not sure if I understand the question, but the cost to submit to the FDA are fixed and have little impact on the cost of the device. Related to the cost of care/assessments by hearing professionals – some are moving to unbundling these costs to provide more transparency on each component.

31. Will the labeling of OTC have a public comment period by consumers? Yes, it is anticipated there will be a 30 or 60 day public comment period.