BOARD MEETING MINUTES
Teleconference Meeting
January 13, 2022

For the sake of clarity, the meeting minutes are organized in numerical order to reflect their original order on the agenda; however, items may have been taken out of order during the meeting.

1. Call to Order / Roll Call / Establishment of Quorum

Dr. Marcia Raggio, Board Chair, called the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board (Board) meeting to order at 2:03 p.m. Dr. Raggio called roll; seven members of the Board were present and thus a quorum was established.

Board Members Present
Marcia Raggio, Dispensing Audiologist, Board Chair
Holly Kaiser, Speech-Language Pathologist, Vice Chair
Tod Borges, Hearing Aid Dispenser
Karen Chang, Public Member
Gilda Dominguez, Speech-Language Pathologist
Debbie Snow, Public Member
Amy White, Dispensing Audiologist

Staff Present
Paul Sanchez, Executive Officer
Cherise Burns, Assistant Executive Officer
Tenisha Ashford, Enforcement Coordinator
Lisa Snelling, Licensing Coordinator
Heather Olivares, Legislation/Regulation Analyst
Maria Liranzo, Legislation/Regulation/Budget Analyst
Kristy Schieldge, DCA Legal Counsel
Brianna Miller, DCA Executive Office
David Bouilly, DCA Meeting Moderator
Cesar Victoria, DCA Web Cast

2. Public Comment for Items not on the Agenda

There were no comments from the public, outside agencies, or associations.

3. Swearing In New Board Members

Dr. Marcia Raggio swore in Dr. Amy White as a member of the Board, whereupon Dr. White took the oath of office administered by Dr. Raggio.

4. Discussion and Possible Action on Filing of Public Comment Regarding U.S. Food and Drug Administration Proposed Rule on Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dr. Marcia Raggio opened the discussion on the filing of public comment regarding U.S. Food and Drug Administration (FDA) proposed rule on over-the counter (OCT) hearing aids. Paul Sanchez provided a summary on FDA's proposed rule and the materials provided for discussion.

Cherise Burns provided a summary of Board staff concerns regarding the proposed regulations for the Board to consider if the Board wishes to file a public comment. Mr. Sanchez commented on the proposed regulation's use of the term "hearing aid dispensers" instead of "OTC hearing aid sellers". Mr. Sanchez noted that the Board may comment on device designs and other technical requirements.

Dr. Raggio commented on the category for OTC hearing aids not being clear in the proposed regulation.

Tod Borges commented on the concerns with the proposed regulation use of the term "dispensers" for individuals that sell OTC hearing aids. Dr. Raggio and Dr. White expressed their agreement that the use of the term "dispensers" may be confusing to the public. Mr. Sanchez commented on the use of the term being confusing.

Dr. Raggio commented on the proposed regulation labeling requirements and California's new consumer notice requirement for locked hearing aids under AB 435. Dr. Raggio suggested to include in the Board's comment on the proposed regulation's labeling requirements and mention California's new consumer notice requirement.

Dr. White inquired on how "tools, test, or software" is interpreted and read from the proposed rules "Defining tools, tests, or software" from page 58158 of the Federal Register, Vol. 86, No. 200. Dr. Raggio replied that she can't speak for FDA in terms to what they were intending in the paragraph and defer to Board staff for clarification. Ms. Burns commented on tools, test, or software of OTC hearing aids becoming similar to existing prescription hearing aids. Mr. Borges commented on the inclusion of a customization warning as part of the labeling requirement. Dr. Raggio expressed her agreement with the suggested labeling requirement. Holly Kaiser commented on the suggested labeling requirement and asked for clarification on its language. Ms. Burns replied with clarification with what consumer would need to know in regard to customization.

Dr. Raggio commented on the licensees selling OTC hearing aids and inquired if they will have any ability to program OTC hearing aids. Mr. Borges replied that he hasn't heard anything and commented on the issue of locked hearing aids. Dr. Raggio commented that licensees who sell OTC hearing aids would have to abide to the provisions of AB 435, but OTC hearing aid sellers would not. Mr. Borges confirmed and agreed with

Dr. Raggio's remarks. Dr. White replied that she doesn't have direct knowledge and commented on company's role with adjustments of OTC hearing aids. Dr. Raggio expressed her agreement that there isn't enough information to understand what the software customization will look like for OTC hearing aids. Dr. Raggio inquired if anyone is familiar with how programming works for hearing aids from Lively or Eargo. Dr. White replied with comments on how Lively works. Mr. Borges replied with comments on how Eargo works. Dr. Raggio commented on her conversations with representatives from the five major hearing aid manufacturers and their current position on their role in OTC hearing aids. Dr. Raggio further commented on the Board's jurisdiction being on licensees and not OTC hearing aids. Dr. White suggested to include in the Board's comment on the proposed regulation a recommendation of a notice on software and programming to be a part of the external package label.

Dr. Raggio commented on consumer protection, return policy, and OTC hearing aids. Dr. Raggio noted the proposed regulation includes warning to contact FDA for injuries, malfunction, and other adverse events but has no language on return policy and suggested the Board should comment on this. Ms. Kaiser expressed her agreement with return policy for the vulnerable population who will be consumers of OTC hearing aids. Mr. Borges commented on return policy for OTC hearing aids. Dr. Raggio commented on enforcement jurisdictions for licensees and OTC sellers. Mr. Sanchez commented on jurisdictional issues with OTC hearing aid sellers. Ms. Burns commented on general sales and warranty as described on page 58160 of the Federal Register and its implementation through private remedies with no state actor like the Board or Attorney General. Mr. Borges inquired if Board staff would want to enforce the Song-Beverly Consumer Warranty Act. Ms. Burns replied that she doesn't think the Board would be able to. Mr. Sanchez suggested to include in the Board's comment on the proposed regulation that there will be consumers who will be vulnerable without some type of return policy specified. Dr. Raggio inquired if the California's Attorney General has a portal where consumers can go to complain about consumer products. Dr. Raggio commented that most OTC hearing aid manufacturers will offer a return policy as do most consumer products. Kristy Schieldge commented on how enforcement under the proposed regulation will look. Dr. Raggio inquired if FDA has representation in every state. Mr. Sanchez replied that the FDA has a list of contacts called Consumer Complaint Coordinators. Ms. Burns replied that the California Attorney General has an online form where consumers can go to complain and commented that the Board can add this on the Board's website to direct consumers of OTC hearing aids provided by OTC sellers. Gilda Dominguez commented on the accessibility to consumer protection assistance. Dr. Raggio expressed her agreement to include comments on consumer protection return policy in the Board's letter to the FDA's proposed regulation.

Dr. Raggio commented on the output and other technical requirements in the OTC hearing aid devices and the lack of gain limits. Dr. White commented on proposed electroacoustic requirements and what is already on the market for non-hearing aid devices. Dr. Raggio expressed her agreements with Dr. White's remarks and commented on proposed electroacoustic requirements and non-hearing aid devices. Mr. Borges

commented on the output levels and the long-term affect for having it set too loud. Dr. Raggio commented on the duration for safe use under the proposed output levels.

Mr. Borges commented on the use of OTC hearing aids and consumer's ability to determine the level of their hearing loss. Dr. Raggio suggested the inclusion of gain range in OTC hearing aid devices and commented on consumer's inability to determine the level of their hearing loss. Dr. Raggio further commented on the value of the Board to comment on the proposed regulation concerns about the lack of technical stipulations or range values. Dr. Raggio suggested the Board should comment on labeling requirement that informs consumers to seek a hearing test by a professional. Mr. Borges noted that this is one of the labeling requirements. Ms. Burns confirmed that it is a labeling requirement and shared her experiences with family members who have hearing loss. Dr. White commented on the challenges in creating electroacoustic requirements for mild to moderate hearing loss. Dr. Raggio commented on a range instead of an absolute gain limit to serve both moderate and mild hearing loss without the potential to cause damage. Dr. White suggested to include in the Board's comment on the proposed regulation a recommendation for a labeling requirement on the potential harm due to prolonged use of OTC hearing aids at high output limit.

Mr. Borges commented on age verification at the time of purchase. Dr. White commented on FDA's reasoning for not requiring age verification at the time of purchase. Dr. Raggio, Dr. White, and Debbie Snow expressed agreement to include in the Board's comment on the proposed regulation a recommendation to require age verification at the time of purchase. Kristy Schieldge noted that OTC hearing aids are prohibited for those under the age of 18 under the proposed regulations and inquired if the Board's comment will be a recommendation to verify age at the time of purchase. Mr. Borges confirmed that the Board's comment will be for an age verification recommendation.

Dr. Raggio opened the discussion for public comment. There were no comments from the public, outside agencies, or associations.

Debbie Snow made a motion to delegate to the Board Chair and Executive Officer the responsibility of combining and submitting the Board's comments regarding the FDA's proposed regulations for OTC Hearing Aids prior to the end of the public comment period.

Holly Kaiser seconded the motion.

The motion carried 7-0. (Ayes: Raggio, Kaiser, Borges, Chang, Dominguez, Snow, White)

5. Future Agenda Items

Dr. Marcia Raggio solicited future agenda items from there Board. There were no comments from the Board.

Dr. Raggio solicited future agenda items from the public. There were no comments from the public, outside agencies, or associations.

6. The Board will Meet in Closed Session Pursuant to Government Code Section 11126(c)(3), the Board will Meet in Closed Session to Discuss Disciplinary Matters Including Proposed Decisions, Stipulated Decisions, Defaults, Petitions for Reductions in Penalty, Petitions for Reconsideration, and Remands

The Board did not meet in a closed session.

7. Adjournment

The meeting adjourned at 3:27 p.m.