UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

IN RE: 3M COMBAT ARMS EARPLUG PRODUCTS LIABILITY LITIGATION	Case No. 3:19md2885
This Document Relates to: *Baker*, 7:20cv039 *Estes*, 7:20cv137 *Hacker*, 7:20cv131 *Keefer*, 7:20cv104 *McCombs*, 7:20cv094	Judge M. Casey Rodgers Magistrate Judge Gary R. Jones

ORDER[1]

The first of three bellwether trials in this multidistrict products liability litigation is set for March 29, 2021; the two others will follow in May and June 2021,

[1] The Court assumes the parties' familiarity with the nature of this multidistrict litigation, the claims and defenses, and the current evidentiary record. Thus, this Order sets out only what is necessary to explain the Court's rulings. The Court previously indicated that a single, omnibus order would be entered resolving all of the parties' Rule 702 and *Daubert* challenges, rather than piecemeal rulings on discrete issues. After reviewing the parties' briefing and the record, it became apparent that certain issues would be better addressed sooner rather than later; namely, the parties' respective challenges to expert testimony on the Army Safety Program and, more specifically, the Army Hearing Program, as well as expert opinions on the success or failure of the Army's hearing conservation efforts and on a purported "culture" of compliance or non-compliance with the Army's programs and regulations governing safety and hearing protection. This led to the Court's Order dated February 11, 2021, ECF No. 1651, which resolved all of the parties' respective challenges to Dr. James Crawford, Dr. Eric Fallon, Lt. Col. Vickie Tuten, Gen. Timothy Edens, and Sgt. Maj. Blaine Huston. As trial is now imminent, the Court has decided to enter the instant order resolving most, but not all, of the remaining expert challenges. The following expert challenges will be resolved by separate order: Dr. Marc A. Fagelson (PTSD and sleep disorder testimony only), Robert W. Johnson, Dr. Packer (PTSD testimony only), Drs. Gregory A. Flamme and Mark R. Stephenson, Dr. John Casali, Dr. Harri Kytomaa, Dr. Richard Neitzel, Jennifer Sahmel, and Dennis Driscoll.

respectively.[2] Omnibus motions to exclude expert testimony and opinions, in whole or in part, under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), have been filed by both sides.[3] Having considered the law, the voluminous record, and the parties' arguments, the Court rules as follows.

I. Legal Standard

Rule 702, as explained by *Daubert* and its progeny, governs the admissibility of expert testimony. *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005). Under Rule 702 and *Daubert*, district courts are compelled to act as "gatekeepers" to ensure the reliability and relevancy of expert testimony. *Id.* (quoting *Daubert*, 509 U.S. at 589). Expert testimony is reliable and relevant—and, therefore, admissible—when the following criteria are met: (1) the expert is sufficiently qualified to testify about the matters he intends to address; (2) the methodology used is "sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific,

[2] The consolidated trial for Plaintiffs Luke and Jennifer Estes (No. 7:20cv104), Lewis Keefer (No. 7:20cv104), and Stephen Hacker (No. 7:20cv131) will proceed on March 29, 2021. The individual trial for Plaintiff Dustin McCombs is set for May 17, 2021, followed by the individual trial for Lloyd Baker on June 7, 2021. *See* Order, ECF No. 1583.

[3] On February 19, 2021, a *Daubert* hearing was held with respect to issues involving certain of Plaintiffs' experts, Dr. David A. Eddins and Roger Juneau, and Defendants' experts, Drs. Gregory A. Flamme and Mark R. Stephenson. *Daubert* hearings for Dr. Richard Neitzel and Jennifer Sahmel are set for mid-March 2021. The Court found a *Daubert* hearing unnecessary with respect to the remaining issues raised in the parties' briefing. *See Cook ex rel. Est. of Tessier v. Sheriff of Monroe Cty., Fla.*, 402 F.3d 1092, 1113-14 (11th Cir. 2005) (determining whether a *Daubert* hearing is necessary is a decision within the district court's discretion).

technical, or specialized expertise, to understand the evidence or to determine a fact in issue." *Id.* The Eleventh Circuit refers to these criteria separately as "qualification, reliability, and helpfulness," *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004), and has emphasized that they are "distinct concepts that courts and litigants must take care not to conflate," *Quiet Tech. DC-8, Inc. v. Hurel–Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003). The party offering the expert has the burden of showing, by a preponderance of the evidence, that each of these requirements is met. *Rink*, 400 F.3d at 1292.

To meet the qualification requirement, a party must show that its expert has sufficient "knowledge, skill, experience, training, or education to form a reliable opinion about an issue that is before the court." *Hendrix ex. Rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183, 1193 (11th Cir. 2010) (citing Fed. R. Evid. 702) ("*Hendrix II*"), *aff'g* 255 F.R.D. 568 (N.D. Fla. 2009) ("*Hendrix I*"). Importantly, if a "witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Frazier*, 387 F.3d at 1261 (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendments). The qualifications standard for expert testimony is "not stringent" and "[s]o long as the witness is minimally qualified, objections to the level of [his]

expertise [go] to credibility and weight, not admissibility." *Hendrix I*, 255 F.R.D. at 585.

To meet the reliability requirement, an expert's opinion must be based on scientifically valid principles, reasoning, and methodology that are properly applied to the facts at issue. *Frazier*, 387 F.3d at 1261-62. The reliability analysis is guided by several factors, including: (1) whether the scientific technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review or publication; (3) whether the technique has a known or knowable rate of error; and (4) whether the technique is generally accepted in the relevant community. *Daubert*, 509 U.S. at 593-94, 113 S.Ct. 2786. "[T]hese factors do not exhaust the universe of considerations that may bear on the reliability of a given expert opinion, and a federal court should consider any additional factors that may advance its Rule 702 analysis." *Quiet Tech.*, 326 F.3d at 1341. The court's focus must be on the expert's principles and methodology, not the conclusions they generate. *Daubert*, 509 U.S. at 595, 113 S.Ct. 2786. The test for reliability is "flexible" and courts have "broad latitude" in determining both how and whether this requirement is met. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141-42 (1999).

Finally, to satisfy the helpfulness requirement, expert testimony must be relevant to an issue in the case and offer insights "beyond the understanding and experience of the average citizen." *United States v. Rouco*, 765 F.2d 983, 995 (11th

Cir. 1985). Relevant expert testimony "logically advances a material aspect of the proposing party's case" and "fits" the disputed facts. *McDowell v. Brown*, 392 F.3d 1283, 1298-99 (11th Cir. 2004). Expert testimony does not "fit" when there is "too great an analytical gap" between the facts and the proffered opinion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997).

"Because of the powerful and potentially misleading effect of expert evidence, sometimes expert opinions that otherwise meet the admissibility requirements may still be excluded [under Federal Rule of Evidence] 403." *Frazier*, 387 F.3d at 1263 (internal citations excluded). "Exclusion under Rule 403 is appropriate if the probative value of otherwise admissible evidence is substantially outweighed by its potential to confuse or mislead the jury, or if the expert testimony is cumulative or needlessly time consuming," or if it is otherwise unfairly prejudicial. *Id.* "Indeed, the judge in weighing possible prejudice against probative force under Rule 403 . . . exercises more control over experts than over lay witnesses." *Id.* "Simply put, expert testimony may be assigned talismanic significance in the eyes of lay jurors, and, therefore, the districts must take care to weigh the value of such evidence against its potential to mislead or confuse." *Id.*

When scrutinizing the reliability, relevance, and potential prejudice of expert testimony, a court must remain mindful of the delicate balance between its role as a gatekeeper and the jury's role as the ultimate factfinder. *Frazier*, 387 F.3d at 1272.

The court's gatekeeping role "is not intended to supplant the adversary system or the role of the jury." *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1312 (11th Cir. 1999). Only the jury may determine "where the truth in any case lies" and the court "may not usurp this function." *Frazier*, 387 F.3d at 1272. Thus, a court may not "evaluate the credibility of opposing experts" or the persuasiveness of their conclusions, *Quiet Tech.*, 326 F.3d at 1341; instead, its duty is limited to "ensur[ing] that the fact-finder weighs only sound and reliable evidence," *Frazier*, 387 F.3d at 1272.

II. Defendants' Experts

Plaintiffs move to exclude the testimony and opinions, in whole or in part, of 13 experts proffered by Defendants. This Order addresses Plaintiffs' challenges to Elliott Berger and Drs. John House, Derek Jones, Jennifer LaBorde, and Margaret Richards.[4] The Court addresses each expert in turn.

A. Elliott Berger

Elliott Berger is an acoustical engineer with decades of experience developing hearing protection devices. *See* Berger Discl., ECF No. 1595-55 at 2. He is a former 3M employee, and he has been identified by the Defendants as a "hybrid-witness"

[4] Again, the Court's Order dated February 11, 2021 resolved all of Plaintiffs' objections to Dr. James Crawford, Dr. Eric Fallon, and Lt. Col. Vickie Tuten. Plaintiffs' *Daubert* challenges to Dr. John Casali, Dr. Harri Kytomaa, Dr. Richard Neitzel, Jennifer Sahmel, and Dennis Driscoll will be addressed by separate order.

who will provide both fact and opinion testimony, "based on his personal knowledge of Aearo's design, development, and testing of the CAEv2." *See id.*, ECF No. 1595-55 at 2-3.

Plaintiffs have moved to exclude Berger's testimony on the grounds that it does not satisfy *Daubert*'s reliability standard. They also argue that certain aspects of his testimony should be excluded as outside the scope of permissible hybrid testimony. *See* Pl. Mot., ECF No. 1595 at 54-59.

Under Fed. R. of Civ. P. 26(a)(2)(A), parties are required to disclose the identity of any witness who is expected to provide expert testimony under Fed. R. of Evid. 702, 703, or 705. Rule 26(a)(2)(B) also requires that parties disclose the expert's opinion testimony, and the bases for those opinions, in a written report. *See* Fed. R. Civ. P. 26(a)(2)(B); *Pediatric Nephrology Assocs. v. Variety Children's Hosp.*, 2017 U.S. Dist. LEXIS 200023, at *9 (S.D. Fla. Nov. 6, 2017). For hybrid witnesses, however, parties are only required to disclose "a summary of the facts and opinions to which the witness is expected to testify." *See* Fed. R. Civ. P. 26(a)(2)(C); *Pediatric Nephrology Assocs.*, 2017 U.S. Dist. LEXIS 200023, at *12 (citing *Moshe Ashkenazi v. South Broward Hosp. Dist.*, 2012 U.S. Dist. LEXIS 30692, at *1 (S.D. Fla. Mar. 8, 2012)) (internal quotes omitted). Hybrid witnesses are non-retained expert witnesses who can provide both fact and opinion testimony that is grounded in their scientific, technical, or specialized knowledge. *See Pediatric Nephrology*

Assoc., 2017 U.S. Dist. LEXIS 200023, at *4. Hybrid witnesses may testify on "their observations based on personal knowledge as well as their lay opinions, consistent with Rule 701, when such opinion testimony is based upon the witness' experience as a professional and is helpful in understanding the witness' decision making process." *See Kaplan v. Kaplan*, 2012 U.S. Dist. LEXIS 66114, at *5 (M.D. Fla. May 11, 2012) (citing *Williams v. Mast Biosurgery USA, Inc.*, 644 F.3d 1312, 1317 (11th Cir. 2011). The distinction between lay and expert testimony is a critical one, requiring that "trial courts be vigilant in ensuring that the reliability requirements set forth in Rule 702 not 'be evaded through the simple expedient of proffering an expert in lay witness clothing.'" *See Williams*, 644 F.3d at 1317 (quoting Fed. R. Evid. 701 advisory committee's note to the 2000 amendment). Thus, to the extent that a hybrid witness' testimony goes beyond an account of "their own observations and technical experience" the trial court must determine whether the testimony meets the evidentiary standards of Rule 702 and *Daubert*. *See Williams*, 644 F.3d at 1317. In addition to providing both fact and expert testimony, Berger has also been identified by Defendants as a witness who will provide testimony on behalf of 3M under Fed. R. Civ. P. 30(b)(6).[5] Plaintiffs move to exclude Berger's testimony regarding (1)

[5] Defendants do not separately identify the portions of Berger's testimony that constitute fact-based testimony, expert-opinion testimony, and Rule 30(b)(6) testimony. *See* Berger Discl., ECF No. 1595-55 at 2-12. Please note, at trial, the Court will require Defendants to differentiate between each category of testimony. Berger can offer testimony under one category described

federal regulatory testing requirements and Aearo's EARCAL lab's conformity with those requirements; (2) Aearo's REAT testing of the CAEv2; and (3) his opinion that there was no feasible alternative design for the CAEv2.[6]

1. Federal regulatory testing requirements and Aearo's EARCAL lab's conformity with those requirements.

According to Defendants, Berger will provide testimony on federal regulatory testing requirements as they relate to the CAEv2.[7] Plaintiffs do not dispute Berger's qualifications to opine on regulatory topics; however, they do argue that Berger's testimony concerning regulatory opinions should be excluded as unreliable under

---

above followed by cross-examination before providing testimony under a different category. This requirement will also apply to the testimony of Dr. Eric Fallon.

[6] Plaintiffs do not argue to exclude Berger's testimony regarding the military's hearing protection problem and the Army's interest in the ISL filter, or Aearo's disclosure to the military regarding the best practices for fitting the CAEv2.

[7] Per Berger's Rule 26(a)(2)(C) Disclosure, he is expected to provide the following testimony regarding regulatory matters: (a) EPA regulations require manufacturers of HPDs to conduct experimenter-fit REAT tests on their products under the ANSI S3.19-1974 standard, and to include the resulting Noise Reduction Rating on the labels they provide to the *civilian* market; (b) It is well known that experimenter-fit REAT tests, in which the experimenter attempts to obtain "optimum protector performance" of the product, overestimate the degree of attenuation that a typical user will obtain; (c) The EPA has not approved any other REAT protocol, including the Method B protocol set forth in ANSI S12.6, for labeling tests; (d) Aearo's EARCAL lab has been conducting tests on HPDs since 1979, and was the first lab (1992) accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) to conduct such tests; (e) Through the accreditation process, EARCAL's testing policies and procedures are reviewed annually by NVLAP, and independent NVLAP auditors conduct on-site inspections every other year, to ensure compliance with the HPD testing standards to which the lab is accredited; (f) NVLAP has observed and approved of Aearo's experimenter-fit testing policies and procedures, including Aearo's selection of test subjects, discretion to stop labeling tests to modify the product or its instructions, and its statistical basis for identifying and excluding outlier data. *See* Berger Discl., ECF No. 1595-55 at 6-7 (emphasis added).

Rule 702 and *Daubert*. *See* Pl. Mot., ECF No. 1595 at 57. Plaintiffs specifically object to two aspects of Mr. Berger's testimony.

First, Plaintiffs argue that Berger should not be permitted to testify that, "the EPA requires HPD manufacturers to include 'Noise Reduction Rating[s] on the labels they provide on the *civilian* market,' appearing implicitly to opine that labeling is *not* required in other markets." *See id.* Plaintiffs point to an email from 2016, in which Berger, while an employee of 3M, stated that after he "researched this topic extensively," he determined that the "NRR must be on all products, including those sold to the military." *See* ECF No. 1595-59. Plaintiffs argue that Berger's anticipated testimony would conflict with his prior held belief; as a result, it should be deemed unreliable and excludable. Defendants respond that "Berger does not intend to offer that opinion in his testimony," and that Berger's reference to the "civilian market" was "made in passing, in the course of explaining the background to Aearo's REAT testing of the CAEv2." *See* Def. Resp., ECF No. 1627 at 45. Because Berger does not plan to testify that that the EPA's labeling regulations apply only to products supplied to the civilian market, the Court need not rule on Plaintiffs' objection to that testimony.

Plaintiffs also argue that Berger should not be permitted to testify that Aearo's premature stopping of REAT test #213015 was done in accordance with EARCAL's NVLAP-approved testing policies. *See* Pl. Mot., ECF 1595 at 57. In response,

Defendants state that as "the director of Aearo's EARCAL lab for decades," Berger can reliably testify to NVLAP's review of EARCAL lab's policies. *See* Def. Resp., ECF 1627 at 46. Defendants further argue that Berger does not need to have previously been an NVLAP auditor in order to testify that NVLAP approved Aearo's lab policies. *See id.* The Court agrees.

Berger worked for Defendants[8] his entire career, which has spanned several decades. *See* Berger Discl., ECF No. 1595-55 at 3. During his career, Berger has worked in, and managed, Defendants' acoustical laboratory (EARCAL). *See id.*; Berger Dep., ECF No. 1558-6 at 27. Defendants' laboratory has been accredited for hearing protector attenuation testing by NVLAP since 1991, and per Berger, "we have undergone 14 separate, independent audits from the NVLAP assessors, approximately every other year . . . ." *See* Berger Dep., ECF No. 1558-6 at 27 and 120. Given Berger's role as the director of the EARCAL lab during two plus decades of accreditation reviews, he necessarily would have had a thorough understanding of the lab's policies and procedures. Additionally, given his leadership position within a scientific organization focused on developing standards on hearing

[8] Berger previously worked for Aearo before Aearo was acquired by 3M, and prior to working for Aearo, Berger worked for E-A-R, which was acquired by Aearo during the time Berger was an employee. *See* Berger Discl., ECF 1595-55 at 2-3.

protection,[9] it would appear that he has an understanding of the scope and meaning of the NVLAP accreditation process. Thus, due to the experience described above, the Court finds that Berger can reliably opine on EARCAL's laboratory policies and what policies were and were not approved by NVLAP.

Plaintiffs also argue that there is nothing to support Berger's testimony that the NVLAP approved EARCAL's policy related to test-stopping. *See* Pl. Mot., ECF 1595 at 58. Plaintiffs cite to deposition testimony from an EARCAL lab technician, Ron Kieper, in which Kieper testifies that there was no written lab policy instructing a technician that "before he finishes a test to convey the NRR to the lab director so that he can advise the technician whether or not it's good to finalize the test. . . ." *See* Kieper Dep., ECF No. 1595-60 at 6. If Berger intends to testify that EARCAL's lab policies, including the policy and procedures for halting tests, were approved by NVLAP, there appears to be a question of fact regarding whether certain components of those procedures were written down and reviewed by NVLAP. In evaluating the reliability of expert testimony, "a court must remain mindful of the delicate balance between its role as a gatekeeper and the jury's role as the ultimate factfinder. *See Navelski v. Int'l Paper Co.*, 244 F. Supp. 3d 1275, 1287 (N.D. Fla. 2017) (citing *Frazier*, 387 F.3d at 1272). Thus, a court may not "evaluate the credibility of

[9] Berger has served as the chair of a working group within the Acoustical Society of America focused on the development of standards for hearing protection since 1985. *See* Berger Dep., ECF No. 1558-6 at 15-16.

opposing experts" or the persuasiveness of their conclusions, *Quiet Tech*, 326 F.3d at 1341; instead, its duty is limited to "ensur[ing] that the fact-finder weighs only sound and reliable evidence." *Frazier*, 387 F.3d at 1272. The question of whether EARCAL's test-stopping policy was approved by the NVLAP is a question of fact that should be left to the jury. Berger will be permitted to testify as to his understanding of EARCAL lab policies and the extent of NVLAP's accreditation related to those policies.

2. Aearo's REAT testing of the CAEv2

According to Defendants, Berger will also testify that during Aearo's REAT testing of the CAEv2, "the experimenter did *not* need to fold back the opposing flanges to obtain 'optimum protector performance' for most subjects." *See* Berger Discl., ECF No. 1595-55 at 9. Berger will testify further that it would have been unnecessary and misleading to instruct all users to fold back the opposing flanges in order to obtain an adequate fit. *See id.*

Plaintiffs argue that this testimony is beyond Berger's personal knowledge, and as a result, the testimony does not constitute proper hybrid testimony and should be excluded. *See* Pl. Mot., ECF 1595 at 58. As a hybrid witness, Berger is permitted to testify regarding facts and opinions that arise from his "direct and personal knowledge 'in the ordinary course' of his" job function. *See Hartford Steam Boiler Inspection and Insurance Company v. Menada, Inc.*, 2018 WL 3911212 at *6 (S.D.

Fla. Apr. 4, 2018) (citing *Rossi v. Darden,* 2017 WL 2129429, at *3 (S.D. Fla. May 17, 2017). The court in *Rossi* found that while a company's vice-president appeared to have personal knowledge of some facts of the case, he did not qualify as a hybrid-witness because his opinions were based on data analysis and testing he performed at the direction of counsel in preparation for the litigation. *See Rossi*, at *3-4. Thus, to the extent Berger's testimony is derived from his recollection and experience in testing and developing the CAEv2 while an employee of Aearo and 3M, that testimony falls within the confines of hybrid witnesses testimony; however, Berger's testimony must still comply with applicable rules of evidence, such as the prohibition on hearsay. To the extent Berger's opinion testimony is based on his review of materials in preparation for this litigation, such as in preparation for his Rule 30(b)(6) deposition,[10] the testimony would fall outside the scope of permissible hybrid witness testimony.

Plaintiffs argue that Berger cannot testify about the experimenter not needing to fold back the opposing flanges on most subjects in order to obtain an optimal fit because he has no personal knowledge about the number of subjects who were tested with the flanges folded back in test #213017. *See* Berger Dep., ECF No. 1595-61 at

[10] Berger stated that to prepare for his Rule 30(b)(6) deposition he reviewed documents on his 3M computer, including personal notes, reports, and files, and he reviewed documents provided by the attorneys to help him refresh his memory; and he also interviewed current and former employees on various topics. *See* Berger Dep., ECF No. 1560-7 at 40-41.

5. Defendants respond that Berger's testimony is actually based on the results of test #213015, where no flanges were folded back and that "[a] majority of the subjects…received attenuation in the range Mr. Kieper and Mr. Berger expected." *See* Def. Resp., ECF 1627 at 46 (internal quotes omitted).

Berger's disclosure makes clear that he intends to testify that "Aearo's REAT testing of the CAEv2 established that the experimenter did *not* need to fold back the opposing flanges to obtain 'optimum protector performance' *for most subjects*." *See* Berger Discl., ECF No. 1595-55 at 9 (emphasis added). Accordingly, Berger's testimony is not limited to only the subjects of test #213015. At least three REAT tests were conducted on the CAEv2: #213015, #213016, and #213017. *See* Berger Dep., ECF No. 1558-3 at 59-60. Defendants argue that Berger's opinion is based on the results of just one of those tests, #213015; however, this test only included eight subjects rather than ten because Berger and his colleagues halted the test before it could be completed. See Def. Resp., ECF No. 1627 at 46-47. Additionally, Berger did not serve as the experimenter, i.e. the individual who personally fit the subjects, for any of the three REAT tests, including test #213015.[11]

As the director of the EARCAL lab, Berger can reliably provide expert opinions related to the testing policies and procedures of the lab.[12] Based on this

[11] Ron Kieper served as the lead technician/experimenter who fitted the test subjects. *See* Berger Dep., ECF No. 1558-3 at 60-61 and 241-242.

[12] *See* discussions *supra* pg. 10-14.

experience, Berger can also provide opinions regarding the established testing policies and procedures that were applied to REAT tests #213015, #213016, and #213017. Berger can also provide expert opinion testimony regarding the results of the REAT tests listed above. What he cannot do, however, is testify to all testing conditions (for all three tests), because he admittedly does not have this personal knowledge. *See* Berger Dep., ECF No. 1595-61 at 5-6; Berger Dep., ECF No. 1595-62 at 6. The results of one incomplete REAT test are not a sufficient basis for Berger's opinion that most of the test subjects in all three tests did not need to have the opposing flange folded back to achieve an optimum fit. The Court also finds under Rule 403 that relying solely on test #213015 would be misleading to the jury because this ignores test #213017, which was completed and appears to have included at least one subject who had the flanges folded back.

Defendants have not provided any additional support for Berger's opinion that it would have been unnecessary and misleading to instruct all users that it was necessary to fold back the opposing flanges in order to achieve an adequate fit. Simply stating that nothing from the Flange Report, "is to the contrary," is not a sufficient basis for providing such a broad expert opinion. *See* Pl. Mot., ECF 1595-55 at 9. Berger's opinion on this topic is mere *ipse dixit*, which the Court must exclude. *See Frazier*, 387 F.3d at 1261.

3. No feasible alternative design for the CAEv2

In Berger's disclosure, his opinions were organized by subheadings. One subheading read: "There Was No Feasible Alternative Design for the CAEv2." There were three subsections under this opinion: (1) The CAEv2's adapter stem did not dimmish its effectiveness; (2) the nonlinear filter used in the CAEv2 was effective; and (3) both militaries opted against a single-ended, dual-mode design. *See id.* at 10-11.

Plaintiffs argue that Berger's opinion concerning the feasibility of alternative designs should be excluded because it is not based on a reliable methodology. *See* Pl. Mot., ECF 1595 at 54. Defendants respond that Berger is not offering the opinion that there was no feasible alternative design to the CAEv2. According to Defendants, Berger's opinion "is more targeted." *See* Def. Resp., ECF 1627 at 44. Specifically, Defendants argue that Berger should be permitted to testify that the rigidity of the adapter stem of the CAEv2 was necessary, and that a more flexible stem was not feasible. *See id.* Defendants also argue that Berger should be permitted to testify that the width of the CAEv2's stem, and the corresponding width of the nonlinear filter, had no effect on the CAEv2's performance. *See id.* Despite including these opinions in a subsection under the heading, "There Was No Feasible Alternative Design for the CAEv2," Defendants state that Berger does not intend to offer the opinion "that it was not feasible to make a thinner filter." *See id.*

Defendants also argue that Berger's testimony regarding the design choices of the French and United States militaries is not opinion testimony concerning the feasibility of alternative designs to the CAEv2; rather, it is fact-based testimony, offered to show that both militaries opted against an alternative design that has been suggested by the Plaintiffs in the course of this litigation. *See id.* at 45. The Court agrees and disagrees with the Plaintiffs.

Berger will not be permitted to offer testimony regarding the feasibility of alternative designs for any component of the CAEv2. Despite being a hybrid witness, Berger must still have a reliable basis for that testimony. *See Frazier*, 387 F.3d at 1261. Defendants have not included any information regarding the methodology applied by Berger as the basis for his opinion on the feasibility of alternative designs, such as the testing of alternative designs. *See McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1256 (11th Cir. 2002) (affirming the district court's decision to exclude expert testimony on alternative designs for a medical device because the expert failed to test alternative designs, talk to medical personnel, or cite scientific literature supporting his theories).

However, Berger can testify regarding the performance of the adapter stem and the nonlinear filter. Based on his role in the design and development of the CAEv2, as well as his position as the director of the EARCAL lab, which conducted attenuation testing on the CAEv2, Berger can offer opinion testimony regarding the

performance of the adapter stem and the nonlinear filter because this testimony is based on his "direct and personal knowledge 'in the ordinary course' of his" job function. *See Menada*, 2018 WL 3911212 at *6 (citing *Rossi v. Darden,* 2017 WL 2129429, at *3 (S.D. Fla. May 17, 2017). Berger, however, will not be permitted to relate this testimony to a conclusion or opinion on the feasibility of alternative designs for the reasons discussed in the paragraph above.

Berger is also permitted to offer fact testimony regarding the design and development of the CAEv2, including testimony regarding the design choices of certain customers, such as the French and United States militaries, provided that this testimony conforms with all applicable rules of evidence, such as the prohibition against hearsay.

B. Dr. John House

Dr. John House is a board-certified otologist/neurotologist in private practice at House Clinic in Los Angeles, California. He is also a clinical professor in the Departments of Otolaryngology at both the University of Southern California and University of California, Los Angeles. He has over 45 years of clinical experience, has published over 130 papers and book chapters, and has performed more than 300 independent medical examinations on patients with hearing loss and other hearing-related injuries. For two years, he served in the United States Army Medical Corps as a captain and chief of the Ear, Nose, and Throat service at Beach Army Hospital

in Fort Wolters, Texas. Dr. House intends to offer opinions in Estes' and Hacker's cases regarding the extent, cause(s), and effects of their alleged hearing injuries. Plaintiffs do not challenge Dr. House's qualifications. Instead, they challenge his opinions as unreliable and also as inadmissible lay speculation.

Dr. House opines that there is "insufficient evidence" to link Estes' hearing injuries to his use of the CAEv2. More specifically, according to Dr. House, there is "insufficient evidence" to link Estes' tinnitus and mild hearing loss in his left ear to the two events where Estes says he felt the CAEv2 loosen in his ear in 2010 and 2014. *See* House Rep. (Estes), ECF No. 1595-65 at 14-15. Dr. House also concludes that Estes' repeated exposure to hazardous noise while wearing other hearing protection devices cannot be ruled out as a cause of Estes' hearing injuries. *See id.* at 15. Additionally, Dr. House offers an opinion that there is "no evidence" linking Hacker's tinnitus to his use of the CAEv2. This is based on his conclusion that Hacker's tinnitus was "more likely than not" caused by head trauma instead of noise exposure.

Plaintiffs argue that Dr. House's opinions as to Estes are unreliable and unhelpful to the jury because they "question[] the accuracy" of Estes' testimony on underlying factual issues, and are based on "unsupported lay speculation" rather than any expertise. According to Estes, Dr. House "opines that he essentially does not believe [Estes] can prove [his] hearing damage is due to using the CAEv2." Pl. Mot.,

ECF No. 1595 at 66. Hacker argues that Dr. House's causation opinion about his head trauma is unreliable because he did not conduct a differential analysis and rule out noise as a cause of his tinnitus. Defendants argue in response that Dr. House applied a proper methodology in reaching this opinion. The Court disagrees with Plaintiffs on their argument as to Estes and but agrees with them as to Hacker.

First, to the extent Dr. House's conclusions contradict or challenge Estes' own testimony regarding how often he used the CAEv2 or when he recalls developing symptoms of his hearing injuries, that alone does not render his opinions inadmissible because "[a]n expert may testify as to his opinion on an ultimate issue of fact."[13] *Montgomery v. Aetna Cas. & Sur. Co*., 898 F.2d 1537, 1541 (11th Cir. 1990); Fed. R. Evid. 704; *Williams v. Tristar Prod*., *Inc*., 418 F. Supp. 3d 1212, 1223 (M.D. Ga. 2019) (finding that expert's extensive knowledge and experience, and examination of the record and product at issue supported his opinions, "despite conflicting with portions of [p]laintiff's testimony"); *see also In re Cryolife, Inc. Sec. Litig.*, No. 1:02-CV-1868-BBM, 2005 WL 8155579, at *7 (N.D. Ga. June 17, 2005) ("[E]xperts may offer opinions about the objective truth or falsity of

[13] Dr. House testified at his deposition that he does not challenge the truthfulness of Estes' testimony that he first experienced his alleged tinnitus in 2014 or that he used the CAEv2 as his primary form of hearing protection until 2015. *See* House Dep., ECF No. 1595-64 at 11, 16. In his report, however, he does seem to question whether Estes has tinnitus at all. *See* House Rep. (Estes), ECF No. 1595-65 at 10. In any event, Dr. House does not ultimately reject Estes' tinnitus claim, but instead opines that Estes' tinnitus is "likely associated with his mild hearing loss . . . that resulted from repeated noise exposure over time," as well as his depression, anxiety, and excessive caffeine use. *See id.* at 15.

statements based on their specialized or scientific knowledge."). Second, Dr. House's opinions are not based on "unsupported lay speculation." He evaluated independent medical examinations of Estes conducted by audiologists from his clinic. He also evaluated Estes' medical records, including audiograms, and deposition testimony. From there, Dr. House applied his specialized knowledge in otology, otolaryngology, and neurotology, and over four decades of experience as a treating physician.[14] This is sufficient under Rule 702 and *Daubert*. *See, e.g., In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig*., 127 F. Supp. 3d 1306, 1337 (N.D. Ga. 2015) (finding sufficiently reliable specific causations opinion of "an experienced orthopedic surgeon who reviewed [p]laintiff's medical records, digital x-rays of her original right hip replacement . . . and photographs of the explant in reaching his opinion that [p]laintiff's hip implant failed because of the consequences of metallosis"). Any remaining challenge Plaintiffs have to the bases and sources of Dr. House's opinions impact the weight, and not admissibility, of his opinions, and thus are more appropriately addressed during cross-examination. *See Garcia v. Scottsdale Ins. Co.*, No. CV 18-20509-CIV, 2019 WL 1318090, at *2 (S.D.

[14] Plaintiffs argue that Dr. House "admits he is applying no . . . expertise" in reaching his opinions. This is wrong. In his report, Dr. House states that in rendering his opinions, he relied on his "education and experience as a treating physician for over four decades and a clinical professor." *See* House Rep. (Estes), ECF No. 1595-65 at 4; House Rep. (Hacker), ECF No. 1595-66 at 4. Dr. House used that expertise to supervise the independent medical examinations by audiologists at his clinic and to review Estes' medical records in order to reach his opinions.

Fla. Mar. 22, 2019); *In re Disposable Contact Lens Antitrust*, 329 F.R.D. 336, 372 (M.D. Fla. 2018) ("If [d]efendants believe that the basis for [the expert's] opinions is insufficient, they can explore that with [the expert] on cross examination and argument for the benefit of the trier of fact.").

Plaintiffs also challenge Dr. House's opinion that Hacker's tinnitus was "more likely than not" caused by head trauma and not noise exposure as mere *ipse dixit*, unsupported by an accepted and reliable methodology because Dr. House failed to perform a differential analysis. *See* House Rep. (Hacker), ECF No. 1595-66 at 12-13.[15] As noted, the Court agrees.

Although Defendants do not have the burden to prove causation, Dr. House's tinnitus opinion is a causation opinion, which must be supported by a reliable methodology. Dr. House testified that his causation opinion is based on the several concussions listed in Hacker's medical records between 2002 and 2017, *see id.*, ECF No. 1595-66 at 12, his extensive clinical experience with patients who have had traumatic head and neck injuries and develop tinnitus, but have no hearing loss, *see* House Dep., ECF No. 1595-64 at 44-59, and a single publication (ECF No. 1627-50). He did not perform a differential etiology. As the Eleventh Circuit has

[15] Dr. House also offers several other causation opinions regarding the cause of Hacker's tinnitus, including that (1) his right-ear tinnitus is "most likely explained" by hearing loss in that ear from a facial nerve abnormality; and (2) it is possible that Hacker does not have left-ear tinnitus. *See* House Rep. (Hacker), ECF No. 1595-66 at 12-13. Plaintiffs do not challenge these opinions.

explained, differential etiology is a "scientifically accepted methodology" that requires an expert to consider potential causes of the claimed injury and then eliminate all causes but one. *Chapman v. Procter & Gamble Distrib*., LLC, 766 F.3d 1296, 1308 (11th Cir. 2014); *see also infra* at Section III(A). Although Dr. House reviewed some of Hacker's medical records, he admitted he did not take a full medical history from Hacker and did not know the extent of Hacker's noise exposure. *See* House Dep., ECF No. 1595-64 at 12, 48-50. Significantly, and more specifically, he did not rule out *any* other potential cause of Hacker's tinnitus, including noise exposure, before identifying Hacker's multiple head injuries as "more likely than not" the cause. [16] *See id.* Noise exposure is obviously a *potential* cause of tinnitus, which Dr. House himself admits. *See id.* at 12, 48-50 (acknowledging that one of the most common causes of tinnitus is hearing loss, including noise-induced hearing loss). Thus, Dr. House needed to consider it and rule it out in giving his causation opinion. Because he did not, his causation opinion regarding Hacker's head trauma is not supported by a reliable methodology and thus is inadmissible.

[16] Notably, the publication on which Dr. House relies in reaching his opinion concludes that tinnitus resulting from a head injury "seems to be reversible most of the time." *See* ECF No. 1627-50. Dr. House does not explain how this supports his opinion regarding Hacker, who claims that his tinnitus has persisted for years.

Dr. House also offers opinions that both Plaintiffs are capable of hearing and discerning speech in noisy environments. Plaintiffs argue that this opinion is not supported by a reliable methodology. The Court agrees. Dr. House and his audiologists administered speech discrimination (SDS) tests in quiet rooms for each Plaintiff, which, according to Plaintiffs, do not assess a person's ability to discriminate speech in a noisy environment. Plaintiffs argue that Dr. House should have performed a speech-in-noise (SIN) test to support his opinion. In the absence of SIN testing, Plaintiffs argue that Dr. House's opinion is based "on experience alone" and thus fails under Rules 702 and 703. *See* Pl. Mot., ECF No. 1595 at 68 ("Because [Dr.] House bases his opinion on experience alone, it fails under Rules 702 and 703.").

Dr. House admitted in his deposition that he did not conduct an SIN test, or any other test to assess Plaintiffs' alleged problems discerning speech in noisy environments. *See* House Dep., ECF No. 1595-64 at 34-35 (Q: [I]n terms of conducting a test to try to assess [Estes'] testimony ["that in fact he does have problems with discriminating speech in noisy environments"], you did not do one? A: "We did not do one."); *id.* at 59-61 (Q: "What about testing [Hacker's] left ear in a noisy environment. You didn't do it, right? A: Correct."). From this admission, the Court concludes that the SDS test Dr. House conducted in a quiet environment

does not, by itself, support any conclusion regarding Plaintiffs' ability to discern speech in noisy environments.

The Court also disagrees with Defendants' argument that the SDS testing, coupled with Dr. House's experience, make his opinion about Plaintiffs' ability to discern speech in noisy environments reliable. Although an expert may rely solely on his experience in reaching his opinions, "the witness must explain *how* that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Frazier*, 387 F.3d at 1261 (quoting Fed. R. Evid. 702). Dr. House has not provided any such explanation here.[17] He testified that Estes "can hear in noise" and "should be able to do well in noise" because he has only "very mild hearing loss" at 3 kHz and 4kHz. *See* House Dep., ECF No. 1595-4 at 25-29. According to Dr. House, a SIN test was therefore not needed.[18] *See id.* But he does not explain how Estes' degree of hearing loss, or hearing loss coupled with his SDS test results, provides reliable information about his ability to hear in noisy environments. Similarly, for Hacker, Dr. House

[17] Defendants argue that Dr. House "went above and beyond the standards that are typically demanded in his professional field" by averaging Plaintiffs' hearing threshold levels at higher frequencies over 4 kHz to measure his hearing impairment at higher frequencies. *See* Def. Resp., ECF No. 1627 at 57-58. But neither Defendants nor Dr. House have cited a single study or otherwise explained how this translates to a reliable measurement of a person's ability to hear speech in noisy environments.

[18] Oddly, Dr. House reaches this conclusion despite recognizing that the 4 kHz frequency "is most sensitive to loud noise." *See* House Rep. (Estes), ECF No. 1595-65 at 14.

testified that he is "doing extremely well" in noisy environments based on the fact that Hacker was recently employed as a blackjack dealer at a casino, an environment where "there's a lot of noise," and he had no reported hearing issues. *See id.* at 60-61. Dr. House does not rely on any expertise or methodology (he doesn't even reference the SDS test he performed) or otherwise explain how his experience informs that conclusion. Accordingly, his opinion that Plaintiffs can discern or hear speech in noisy environments is speculative and unreliable.[19] *See also McGee v. Evenflo Co.*, No. 5:02cv259-4(CAR), 2003 WL 23350439, at *9 (M.D. Ga. Dec. 11, 2003), *aff'd*, 143 F. App'x 299 (11th Cir. 2005) ("[T]he absence of testing is a consistent factor in court decisions excluding expert testimony.") (citation omitted).

C. Drs. Derek Jones, Jennifer LaBorde, and Margaret Richards

Plaintiffs move to exclude the opinions of Drs. Jones, Richards, and LaBorde relating to Keefer's and McCombs' permanent impairment ratings.[20] Plaintiffs argue that these experts' opinions are based solely on the 1996 Florida Uniform Permanent

---

[19] This opinion was given by Dr. House at his deposition, not in his reports. In his reports, Dr. House stated that the SDS test results in Estes' left ear was 100% and right ear was 96%, and he has "full word discrimination," *see id*, ECF No. 1595-65 at 11, 17, and for Hacker, that his speech discrimination test was 100% in both ears, "showing that he is capable of hearing ordinary conversation without any difficulty," *see* House Rep. (Hacker), ECF No. 1595-66 at 13. Although Dr. House cannot give the "noisy environment" opinions at trial, he may testify that Estes is capable of "full word discrimination" *in quiet environments*, *see* House Rep. (Estes), ECF No. 1595-65 at 16-17, and that Hacker's "speech discrimination test is 100% in both ears, showing that he is capable of hearing ordinary conversation without difficulty" *in quiet environments*, *see* House Rep. (Hacker), ECF No. 1595-66 at 13.

[20] Drs. Jones and LaBorde filed a report addressing Keefer. Dr. Richards joined Drs. Jones and LaBorde in a separate report addressing McCombs.

Impairment Rating Schedule ("FUPIRS") and should therefore be excluded because (1) FUPIRS is an inappropriate basis for determining the effect of tinnitus and hearing loss for any Plaintiff in this case, (2) evidence of a permanent impairment rating under FUPIRS will not be helpful under Rule 702 because it is not designed nor capable of measuring actual injury or harm caused by a product, (3) Defendants have not met their burden to show that FUPIRS is based on scientifically valid principles, (4) Dr. Richards nor Dr. LaBorde are audiologists, not medical doctors, and are therefore not qualified to offer a permanent impairment rating under FUPIRS, and (5) FUPIRS does not apply to Keefer's and McCombs' hearing impairments because they are progressive and not stable. The Court finds that these experts' opinions relating to Keefer's and McCombs' permanent impairment ratings are due to be excluded under Rule 702 and Rule 403 because they are unhelpful, and any probative value is substantially outweighed by a danger of confusing the jury.

First, the experts' opinions are unhelpful because they do not "fit" the facts of either Plaintiff's case. This is not a Florida workers' compensation case, and FUPIRS is a tool designed for setting workers' compensation benefits for Florida workers. *See* Fla. Stat. § 440.15(3)(b)–(c). Indeed, Drs. Jones and LaBorde conceded in their deposition testimony that they do not typically assess/evaluate hearing ability based on the FUPIRS in any context other than workers' compensation cases. *See* Jones Dep., ECF No. 1595-70 at 7 ("It's not something we

do clinically . . . when we see a patient and do an evaluation, we're not gonna document their Florida impairment rating."); LaBorde Dep., ECF No. 1595-71 at 6 (testifying that she has used FUPIRS in workers' compensation cases or "when I have patients who insist on me describing their hearing ability in a percent format, when that's not typically how we describe it"). Dr. Richards testified that because "the concept of an audiogram can feel abstract to people," she "might use [FUPIRS] like . . . a tool to help supplement someone that's having a little trouble connecting with this abstract concept of hearing loss and maybe just needs to say like what percent hearing loss do I have . . . ." Richards Dep., ECF No. 1595-74 at 5. Thus, the experts' opinions about Keefer's and McCombs' FUPIRS permanent impairment ratings "do not have a 'valid scientific connection to the pertinent inquiry' " and must be excluded. *See Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1232 (11th Cir. 2009) (quoting *Daubert*, 509 U.S. at 591–92).

Second, even to the extent a FUPIRS permanent disability rating could have probative value as a way to "contextualize hearing loss information," *see* Def. Resp. at 66, the Court finds that any probative value is substantially outweighed by a danger that the testimony will confuse the jury. *See* Fed. R. Evid. 403. Expert testimony regarding an impairment rating schedule grafted from Florida workers' compensation law—combined with the objections Plaintiffs raise regarding Drs. LaBorde's and Richard's qualifications to give an impairment rating under FUPIRS,

FUPIRS's scientific validity, and FUPIRS's requirement that the impairment be "stable or non-progressive at the time evaluation is made"—will "lead an already complex, hyper-technical trial far astray, down a long and winding road that will lead to nothing but jury confusion." *See Nunez v. Coloplast Corp.*, No. 19-cv-24, 2020 WL 2315077, at *12 (S.D. Fla. May 11, 2020).

III. Plaintiffs' Experts

Defendants move to exclude the testimony and opinions, in whole or in part, of 15 experts proffered by Plaintiffs—Dr. Moises Arriaga, Dr. Eric Bielefeld, Rear Adm. Althea Coetzee, Elizabeth Davis, Dr. David Eddins, Dr. Marc Fagelson, Dr. John Franks, Roger Juneau, Kristin Kucsma, Dr. Lawrence Lustig, Dr. David Madigan, Richard McKinley, Dr. Mark Packer, Eric Rose, and Dr. Christopher Spankovich.[21] Several of Defendants' objections are common, or at least consistent, among multiple experts, including their challenges to the reliability and/or helpfulness of various experts' differential etiologies, hidden hearing loss opinions, and so-called "attorney mouthpiece" testimony. The Court first addresses the differential etiology and hidden hearing loss challenges, then considers the

[21] The Court's previous Order, ECF No. 1651, resolved all objections to Gen. Timothy Edens and Sgt. Maj. Blaine Huston, two additional Plaintiffs' experts. Dr. Marc A. Fagelson's PTSD and sleep disorder testimony, Dr. Packer's PTSD testimony, and the testimony of Robert Johnson, will be addressed by separate order.

remaining expert-specific *Daubert* challenges, and concludes with the attorney mouthpiece arguments.

A. Reliability of Plaintiffs' Experts' Differential Etiologies

Defendants move to exclude the specific causation opinions of Drs. Christopher Spankovich, Mark Packer, Lawrence Lustig, Moises Arriaga, and Marc Fagelson on reliability grounds. More specifically, Defendants argue that these experts each failed to conduct a proper differential etiology by "reliably rul[ing] out significant alternative causes [for plaintiffs' hearing conditions], including those related to other hearing protection devices and prior medical history." *See* Def. Mot., ECF No. 1605 at 89.

Each expert relied primarily on the differential etiology method to link Plaintiffs' injuries to an alleged defect in the CAEv2. "Differential etiology is a medical process of elimination whereby the possible causes of a condition are considered and ruled out one-by-one, leaving only one cause remaining." *Hendrix II*, 609 F.3d at 1195. "A reliable differential etiology analysis is performed in two steps." *Id*. "First, the expert must compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration." *Id*. (internal quotes omitted). "Second, the expert must eliminate all causes but one." *Id*. The expert must "appl[y] the facts of the patient's case to the list created in the first step in order to form an opinion about the actual cause of the patient's symptoms." *Id*.

at 1197. While the expert's "differential analysis need not rule out all possible alternative causes, [] it must at least consider other factors that could have been the sole cause of the plaintiff's injury." *Chapman*, 766 F.3d at 1309 (internal quotes omitted). The expert must provide "more than subjective beliefs or unsupported speculation" for rejecting alternative causes. *Hendrix II*, 609 F.3d at 1197 (citation omitted).

Applying these principles in this litigation, the Court finds that Plaintiffs' experts conducted reliable differential etiologies for Estes, Keefer, Hacker, McCombs, and Baker. Defendants' criticisms of their specific causation opinions are more appropriately addressed on cross-examination.

1. *Estes*—Drs. Spankovich and Packer

Drs. Spankovich and Packer conducted differential etiologies for Estes. Defendants argue that neither doctor adequately ruled out Estes' use of other hearing protection devices as a possible cause of his injuries.[22] The Court disagrees. Both

[22] Defendants also assert that Dr. Spankovich's specific causation opinions are unreliable because he "entirely fail[ed] to consider the issue of user error" in his differential analyses for Estes, Hacker, and Keefer. *See* Def. Mot., ECF No. 1605 at 90. The Court finds no merit to this argument. Dr. Spankovich and Plaintiffs' other experts are entitled to rely on their evaluations of the Plaintiffs and their review of Plaintiffs' testimony and medical and audiological histories in forming their opinions. Defendants' objection that the Plaintiffs may have misused the CAEv2 goes to the weight of Dr. Spankovich's opinion testimony, not its admissibility. *See Grantham v. CSX Transp., Inc*., No. 2:17cv151, 2019 WL 2161727, at *6 (S.D. Ga. May 17, 2019) (explaining that an expert "has no obligation to accept Defendant's version and reject the testimony of his client); *In re Delta/Airtran Baggage Fee Antitrust Litig*., 245 F. Supp. 3d 1343, 1361 (N.D. Ga. 2017) (explaining that expert testimony is reliable "so long as the expert relies upon record evidence and identifies the facts on which he relies," and that "mere weaknesses in the factual basis of an expert witness' opinion bear on the weight of the evidence rather than on its

doctors expressly considered the fact that Estes used multiple hearing protectors during his military service and/or recreationally.[23] However, both doctors also determined that Estes' primary earplug was the CAEv2 from 2009 to 2015, that Estes reported having first perceived the onset of hearing loss and tinnitus in 2014, and that Estes' audiometric and military records support his report that the symptoms arose in 2014.[24] Given the temporal relationship between the onset of Estes' hearing loss and tinnitus and his use of the CAEv2, each doctor concluded that a lack of noise attenuation from the CAEv2 was the cause of Estes' alleged hearing injuries.[25]

---

admissibility); *cf. Roper v. Kawasaki Heavy Indus., Ltd.*, 646 F. App'x 706, 707-08 (11th Cir. 2016) (affirming district court's exclusion of expert testimony where the expert's differential analysis failed to exclude operator error as a possible cause where "[t]here was evidence of such other causes in th[e] case" and there was a "complete absence of any plausible way that the [allegedly defective product] could have caused the accident.").

[23] *See* Spankovich Rep. (Estes), ECF No. 1631-35 at 14 (stating that Estes' "hearing protection use included the Moldex Battleplug, the CAEv2, foam earplug, triple flange earplugs, and the Crew Vehicle Helmet"); Packer Rep. (Estes), ECF No. 1630-62 at 22 (stating that Estes has used foam earplugs, triple flange earplugs, the CAEv2, and "the CVC Helmet," and noting that Estes also used the Moldex BattlePlug after he was diagnosed with noise-induced hearing loss). As already noted, Plaintiffs' experts are entitled to rely on the Plaintiffs' representations regarding their use of the CAEv2. To the extent Defendants question these experts' reliance on Plaintiffs' statement, they are free to question them about it on cross-examination.

[24] *See* Spankovich Rep. (Estes), ECF No. 1631-35 at 14 ("Estes reported perceiving the onset of the hearing loss and tinnitus in 2014 while he was participating in shooting exercises and wearing the [CAEv2]. He denied any hearing loss or tinnitus prior to this incident, which his audiometric records support; all military records show normal hearing sensitivity prior to this event."); Packer Rep. (Estes), ECF No. 1630-32 at 21-22 ("Estes' loss manifest[ed] subjectively in 2014 and was later confirmed by audiogram after wearing the CAEv2 on the range in non-linear mode.")

[25] *See* Spankovich Rep. (Estes), ECF No. 1631-35 at 15 (opining "to a reasonable degree of scientific and medical certainty that more likely than not, the CAEv2's failure to provide proper hearing protection was the primary cause and the most likely significant contributing factor to Mr. Estes' hearing loss and tinnitus" because "[t]he most common military noise exposures consistent

Although "[t]emporal proximity is generally not a reliable indicator of a causal relationship," it "may constitute probative evidence in certain circumstances." *Guinn v. AstraZeneca Pharm., LP*, 602 F.3d 1245, 1254 (11th Cir. 2010). "For example, 'depending on the circumstances, a temporal relationship between exposure to a substance and the onset of a disease or a worsening of symptoms can provide compelling evidence of causation.'" *Floyd ex rel. Ray v. United States*, No. 3:08cv122, 2010 WL 4905010, at *15 (M.D. Ga. Nov. 26, 2010) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265 (4th Cir. 1999)) (concluding that the temporal relationship between the plaintiff's ingestion of Prozac and her suicide attempt provided support for her expert's causation opinion where the expert explained why the timing of the suicide attempt "was especially probative"). Here, the Court finds that the doctors have adequately explained why Estes' circumstances make the temporal relationship between his use of the CAEv2 and the onset of his injuries reliable evidence of causation. In doing so, they adequately and reliably ruled out other hearing protectors as part of their differential etiologies for Estes.

2. *Keefer*—Drs. Spankovich and Lustig

Drs. Spankovich and Lustig conducted differential etiologies for Keefer. Defendants argue that neither doctor adequately considered Keefer's use of other

---

with his [noise-induced hearing loss] occurred while he was using the CAEv2"); Packer Rep. (Estes), ECF No. 1630-62 at 22-23 (same).

hearing protection while in the military or his progressive hearing loss that started before he entered the military. Again, the Court disagrees. As to the former, both doctors explained that Keefer's reported use of the CAEv2 as his primary hearing protection device during his military noise exposures enabled them to rule out other hearing protectors as the cause of his injuries.[26] The doctors also analyzed Keefer's pre-military tests, which showed "slight" to "mild" hearing loss, together with his military and post-service medical records. *See* Spankovich Dep., ECF No. 1631-38 at 23; *see also* Lustig Dep., ECF No. 1631-27 at 17-18.[27] They concluded from those records that Keefer experienced "significant" worsening in his pre-military hearing and the onset of tinnitus that was caused by his undisputed use of the CAEv2. *See* Spankovich Dep., ECF No. 1631-38 at 32-33; Lustig Dep., ECF No. 1631-27 at 18. As both doctors provided more than "subjective beliefs or unsupported speculation" for rejecting these potential alternative causes of Keefer's noise-induced hearing problems, *see Hendrix II*, 609 F.3d at 1197, their differential analyses are reliable and admissible.

---

[26] *See* Spankovich Dep., ECF No. 1631-38 at 24 ("[W]hat I observed in [Keefer's] information is that [the CAEv2] was his go-to earplug, and there was limited use of anything else."); Lustig Dep., ECF No. 1631-27 at 16 ("[B]ased on my understanding of the medical records and my review of everything that's available to me, suggests that, in fact, [Keefer] was using the CAE[v]2 for the majority of the time while serving in the military.").

[27] Defendants separately object that Dr. Lustig relied too heavily on Keefer's March 2007 audiogram instead of his pre-military audiograms because, in his view, it was "the best we've got," *see* Lustig Dep., ECF No. 1631-27 at 18. This objection goes to the weight of Dr. Lustig's testimony, not its admissibility.

3. *Hacker*—Drs. Spankovich and Arriaga

Drs. Spankovich and Arriaga conducted differential etiologies for Hacker. Defendants argue that: (a) neither doctor adequately considered Hacker's use of other hearing protection while in the military or recreationally; and (b) Dr. Spankovich failed to consider Hacker's prior head trauma and pre-existing conductive hearing loss in his right ear. These arguments fail.

First, in connection with their review of Hacker's patient history—including his military and recreational noise exposure—each doctor adequately considered and discounted Hacker's use of other hearing protectors, based on Hacker having reportedly used the CAEv2 as his primary hearing protector between 2003 and 2010, and evidence that Hacker's first complaints of tinnitus in 2006 and his subsequent hearing loss in his left ear aligned temporally with his use of the CAEv2 during military noise exposure. Having identified and explained a relevant temporal relationship between alleged the cause and effect of Hacker's alleged injuries, they adequately and reliably ruled out other hearing protectors as part of their differential etiologies.

Second, Dr. Spankovich offered a reasoned explanation for his opinion that Hacker's history of head trauma was not the cause his left-ear hearing loss and tinnitus. First, Dr. Spankovich explained that he ruled out the conductive right-ear hearing loss as a potential cause of Hacker's left-ear tinnitus because Hacker "does

not have a conductive hearing loss of his left ear" and "[i]t would be unlikely for him to have tinnitus in his left ear, due to a unilateral hearing loss of a conductive nature." *See* Spankovich Dep., ECF No. 1631-38 at 52-53. Second, he determined that none of Hacker's pre-2016 head traumas "appear[ed] to be of the nature or severity to have caused his tinnitus." *See* Spankovich Rep. (Hacker), ECF No. 1631-39 at 12. Moreover, Dr. Spankovich observed that two of the "more serious" incidents of head trauma in Hacker's medical history—a 2016 car accident and a 2017 incident where an ammunition can fell on Hacker's head—took place nearly ten years after Hacker first reported his tinnitus, and therefore do not appear to be temporally related to any damage to his auditory system. In short, Dr. Spankovich's differential etiology included adequate consideration of Hacker's prior right-ear hearing loss and head trauma.

4. *McCombs*—Drs. Arriaga and Fagelson

Drs. Arriaga and Fagelson conducted differential etiologies for McCombs. Much like with the other Plaintiffs, Defendants argue that neither doctor adequately considered McCombs' use of other types of hearing protection during other military, recreational and/or vocational/educational noise exposures as a possible cause of his tinnitus and related symptoms. Again, Defendants are incorrect. Dr. Arriaga ruled out other noise exposures based on McCombs records documenting that his tinnitus first arose after a 2009 IED noise exposure and that it predates any recreational or

vocational/educational noise exposures. Similarly, Dr. Fagelson's report notes that while McCombs used disposable foam earplugs during the first months of his military service, he used the CAEv2 "almost exclusively" after June 2008 and his tinnitus symptoms began following the IED incident in 2009 while McCombs was wearing the CAEv2. *See* Fagelson Rep. (McCombs), ECF No. 1631-48 at 6. As both doctors demonstrated a relevant temporal relationship between the alleged cause and effect in McCombs' case, they adequately and reliably ruled out McCombs' use of other hearing protectors as part of their differential etiologies.

5. *Baker*—Dr. Packer

Dr. Packer conducted a differential etiology for Baker. Defendants argue that Dr. Packer's differential analysis is unreliable because, "[o]ther than ruling out an incident in which Baker fired two rounds without wearing hearing protection, [Dr.] Packer did nothing in his report to evaluate and rule out Baker's other noise exposures in the military while wearing other protection devices." *See* Def. Mot., ECF No. 1605 at 91. Defendants are incorrect. In his report, Dr. Packer expressly noted that Baker's injuries "manifested subjectively – later confirmed by audiogram . . . when he was wearing the CAEv2 in non-linear mode," and that Baker was exposed to "thousands of rounds of weapons fire while wearing the CAEv2." *See* Packer Rep. (Baker), ECF No. 1630-61 at 27, 29. Dr. Packer ruled out other hearing protectors as the cause of Baker's injuries because, in his opinion, the evidence

showed it was Baker's use of the CAEv2 during "episodes of dangerous noise that is the etiology of his hearing loss." *See id*. at 29. Because Dr. Packer provides more than "subjective beliefs or unsupported speculation" for rejecting the alternative causes, *see Hendrix II*, 609 F.3d at 1197, his differential diagnosis of Baker is reliable.

Based on the foregoing, the Court finds that Plaintiffs' experts conducted reliable differential etiologies for Estes, Keefer, Hacker, McCombs, and Baker. Accordingly, Defendants' motion to exclude the specific causation opinions of Drs. Spankovich, Packer, Lustig, Arriaga, and Fagelson is denied.

B. "Hidden Hearing Loss" Expert Testimony

Defendants move to exclude the expert opinions of Drs. Arriaga, Bielefeld, Fagelson, Packer, and Spankovich regarding cochlear synaptopathy or hidden hearing loss ("HHL").[28] Defendants argue that these experts' HHL-related opinions are not relevant and thus are unhelpful under Rule 702 because no Plaintiff has been diagnosed with cochlear synaptopathy or HHL. Defendants further argue that Dr. Fagelson's HHL-related opinions are due to be excluded because they are (1)

[28] According to Plaintiffs' experts, cochlear synaptopathy and HLL are distinct concepts. Cochlear synaptopathy refers to the loss of synaptic connections between auditory nerve fibers and the inner hair cells of the cochlea. *See*, *e.g.*, Arriaga Rep. (General), ECF No. 1605-14 at 19–22. HHL describes the inability to observe this loss of synaptic connections on an audiogram. *See id.* at 21; *but see* Fagelson Dep., ECF No. 1631-49 at 13 (testifying that HHL "is another word for synaptopathy"). For purposes of this Order, the Court will use the phrase "HHL-related opinions" to encompass the experts' testimony regarding both cochlear synaptopathy and HHL.

unreliably based on animal studies and (2) unhelpful because Dr. Fagelson only opines that McCombs' symptoms are "consistent with" HHL. The Court agrees that these experts' HHL-related opinions are due to be excluded because they do not fit the facts of these Plaintiffs' cases.[29]

According to Dr. Arriaga, "[t]he exact mechanisms for tinnitus are different in each individual." Arriaga Rep. (McCombs), ECF No. 1630-36 at 12. But no expert offers an opinion to any degree of medical certainty that cochlear synaptopathy is the mechanism for any Plaintiff's tinnitus or that any Plaintiff has HHL. In his deposition testimony, Dr. Arriaga explained that while cochlear synaptopathy "may be part of" the mechanism of McCombs' tinnitus symptoms, he does not have an

[29] Defendants challenge the reliability of Dr. Fagelson's HHL-related opinions on the grounds that his report omitted citations to scientific literature supporting these opinions and that the uncited studies involve animal, not human, studies. When confronted with this omission at his deposition, Dr. Fagelson listed four scientific publications that he "would like to add if [he] could have the opportunity." *See* Fagelson Dep., ECF No. 1631-49 at 34. Defendants do not raise challenges to the reliability of any other experts' HHL-related opinions. The Court does not reach Defendants' objection to the reliability of Dr. Fagelson's HHL-related opinions because they are due to be excluded as unhelpful. The Court notes, however, that it has serious concerns about the reliability of Plaintiffs' experts' HHL-related opinions. As Dr. Bielefeld explained in his report, while animal studies "suggest noise exposure without threshold shifts can be classified as a risk factor [for] speech-in-noise difficulties . . . *human data have not yet confirmed this relationship*." Bielefeld Rep. ECF No. 1605-4 at 57 (emphasis added); *see also* Fagelson Dep., ECF No. at 20-21 (explaining that "extrapolating from the animal studies to the expected behaviors and findings in humans . . . is opening . . . a door for us"); Arriaga Dep., ECF No. 1606-44 at 13-14 ("[W]hether [McCombs] actually has synaptopathy or he has got some other form of central damage to the auditory system from his voluminous noise exposure . . . is almost an academic question."). Although medical science may in time reliably establish the specific physiological mechanism(s) behind cochlear synaptopathy and HHL, until such time as medical science understands these mechanisms, the "insights and innovations" discussed by Plaintiffs' experts do not provide a scientifically valid basis for these experts' HHL-related opinions. *See Hendrix I*, 255 F.R.D. at 602.

opinion "as to what the specific mechanism is." *See* Arriaga Dep., ECF No. 1606-61 at 15-16. Similarly, Dr. Arriaga testified that whether Hacker "actually has synaptopathy or he has got some other form of central damage to the auditory system from his voluminous noise exposure . . . is almost an academic question." Arriaga Dep., ECF No. 1606-44 at 13-14. In his deposition testimony, Dr. Fagelson conceded that he cannot testify to a reasonable degree of medical certainty that McCombs has cochlear synaptopathy or HHL. *See* Fagelson Dep., ECF No. 1631-49 at 26-27. Moreover, while Dr. Packer opines that cochlear synaptopathy "explains the continued hearing loss in both" of Baker's ears and that HHL "is a term to describe this observation," *see* Packer Rep. (Baker), ECF No. 1630-61 at 29, he clarified in his deposition that Baker's "clinical symptoms and his audiometric evaluation" are only "consistent . . . with synaptopathy." *See* Packer Dep., ECF No. 1606-9 at 21-24. Finally, in his deposition testimony, Dr. Spankovich explained that while "synaptopathy is usually an early event in noise exposure" that "has incurred in every individual that has noise-induced pathology," *see* Spankovich Dep., ECF No. 1631-36 at 10, he did "not rule out or rule in that there's evidence of synaptopathy" for Estes, *see id.* at 9, or conduct any tests to look for signs of synaptopathy in Hacker or Keefer, *see id.* at 11-12.[30]

[30] Dr. Bielefeld filed only a general report and does not offer opinions related to any specific Plaintiff. *See* Bielefeld Rep., ECF No. 1605-4 at 73-75; Bielefeld Dep., ECF No. 1605-3 at 4-5.

Thus, no expert opines to any degree of medical certainty that any Plaintiff has cochlear synaptopathy or HHL. *See Alsadi v. Intel Corp.*, No. CV-16-3738, 2019 WL 4849482, at *10 (D. Ariz. Sept. 30, 2019) ("[M]erely stating that [a syndrome] is . . . consistent with [the plaintiff's] symptoms is not sufficient to support a medical diagnosis of [the syndrome] under Rule 702.").[31] They may not speculate as to the specific mechanism(s) of Plaintiffs' tinnitus symptoms, and their HHL-related opinions are due to be excluded as unhelpful. *See Allison*, 184 F.3d at 1316–17 ("[A] district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist." (citation omitted)); *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:23-MD-2327, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014) (excluding expert's testimony about a product's propensity to cause secondary infections where the plaintiff "did not suffer from a secondary . . . infection" and the opinions "therefore do not fit the facts of this case").

[31] Plaintiffs assert that courts in this Circuit permit causation testimony using "consistent with" language. But the cases Plaintiffs cite in support of this assertion involve experts opining on the biomechanical cause of certain injuries, not the diagnoses of medical conditions. *See Hendrix I*, 255 F.R.D. at 592 (finding expert was qualified to opine as to whether, "from a biomechanics standpoint," the plaintiff's injuries were "consistent with those expected from an exploding airbag" but finding the expert was "not qualified to offer medical causation testimony"); *Kinney v. Mack Trucks, Inc.*, No. 3:10cv431, 2012 WL 12871204, at *3 (N.D. Fla. May 14, 2012) (concluding that a biomechanical engineer "should be permitted to testify that the plaintiff's injuries were consistent with [impact with a particular truck component] . . . but not that they were caused by it"); *Stern v. NCL Bahamas Ltd.*, No. 19-20280, 2020 WL 6820877, at *4–5 (S.D. Fla. Sept. 28, 2020) (permitting a biomechanics expert to testify that the plaintiff's injuries were "consistent with falling forward").

C. Dr. Eric Bielefeld

Eric Bielefeld, Ph.D., CCC-A is a licensed audiologist and associate professor in the Department of Speech and Hearing Science at The Ohio State University with nearly two decades of professional experience researching, publishing, teaching, diagnosing and treating, and/or consulting for private industry and the government in the field of audiology. Dr. Bielefeld offers opinions describing the anatomy and physiology of the human auditory system, and the nature, etiology, diagnosis, treatment/management, effects and prevention of hearing loss, particularly noise-induced hearing loss. Additionally, based on his review of select documentary evidence produced in this litigation, Dr. Bielefeld identifies "numerous problems" with the "development, efficacy, and warnings/instructions" for the CAEv2, from which he concludes that "many" service members who used the device "were not adequately protected from [noise-induced hearing loss] and tinnitus, despite believing that they were." *See* Bielefeld Rep., ECF No. 1605-4 at 75. Defendants challenge certain portions of Dr. Bielefeld's opinions under *Daubert*, which is addressed below, and they characterize various of his other opinions as "attorney mouthpiece" testimony, which is addressed at the end of this Order.

Defendants challenge Dr. Bielefeld's opinion that there is a correlation between hearing loss and rate of employment, earnings, psychological distress, loneliness, social isolation, and dementia. They argue: (1) he is unqualified to offer

this opinion; (2) the opinion is unsupported *ipse dixit*; (3) general correlation testimony without Plaintiff-specific facts will be unhelpful; and (4) causation is not supported by scientific evidence. The Court disagrees, with two exceptions.

First, Dr. Bielefeld's extensive background and experience researching, diagnosing, and treating in the field of audiology provide him with sufficient expertise to review the scientific literature and offer an opinion on correlative consequences of noise-induced hearing loss, such as declines in rate of employment and earnings, psychological distress, loneliness, and social isolation. *See Smith v. United States*, No. 3:95cv445, 2012 WL 1453570, at *40 (S.D. Ohio Apr. 26, 2012) (aerospace medicine physician "eminently qualified" to opine on correlative physiological effects of levels of carbon monoxide on pilots based on his 40 years' clinical experience and review of relevant literature and studies). Second, Dr. Bielefeld's correlative consequences opinion is not *ipse dixit*, as it is grounded in scientific literature that was accurately cited in his expert submissions.[32] General correlation testimony of this nature will supply helpful "piece[s] of the puzzle" that a jury may consider in evaluating Plaintiffs' damages claims. *See Tuscaloosa v. Harcros Chems., Inc*., 158 F.3d 548, 564 (11th Cir. 1998) ("[An expert's] data and testimony need not prove the plaintiffs' case by themselves; they must merely

[32] *Compare* Bielefeld Rep., ECF No. 1605-4 at 58, 60, *and* ECF Nos. 1606-54 to 59 (various articles accurately cited by Dr. Bielefeld in support of his correlative consequences opinion).

constitute one piece of the puzzle that the plaintiffs endeavor to assemble before the jury.").

However, to the extent Dr. Bielefeld extrapolated from the literature to reach a conclusion about causation that the authors themselves did not make—i.e., an opinion that noise-induced hearing loss *causes* certain consequences—that conclusion must be excluded as unreliable.[33] *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233 (11th Cir. 2005) (affirming exclusion of expert opinion that drew "unauthorized conclusions from limited data—conclusions the authors of the study [did] not make"); *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 825-26 (7th Cir. 2010) (affirming exclusion of expert opinion based on medical literature that "stops short of" supporting the expert's conclusion). Moreover, his opinion correlating noise-induced hearing problems with dementia must be excluded as: (1) unreliable, because dementia is a medical diagnosis requiring reliable evidentiary support establishing general causation in order to be admissible under Eleventh Circuit precedent;[34] (2) unhelpful, because none of the Trial Group A Plaintiffs is alleged to

[33] Dr. Bielefeld's expert report does not describe his correlative consequences opinion in terms of causation. At his deposition, he acknowledged the "important" distinction between causation and correlation, and agreed that none of his source materials established the existence of a causal relationship between noise-induced hearing loss and various consequences. However, he then testified that he believed the scientific literature "can be interpreted that there's a causative relationship." *See* Bielefeld Dep., ECF No. 1605-3 at 19. As no scientifically reliable basis has been offered for this interpretation, it must be excluded under Rule 702 and *Daubert*.

[34] General causation is established by demonstrating, often through a review of scientific or medical literature, that a mechanism is "generally capable of causing" the type of harm alleged

suffer from dementia; and (3) unduly prejudicial under Rule 403, because its potential to mislead the jury substantially outweighs any marginal probative value of the opinion. Beyond these limitations, factual disagreements with the bases and/or persuasiveness of Dr. Bielefeld's opinion bear on its weight, not its admissibility. *See Viterbo v. Dow Chem. Co*., 826 F.2d 420, 422 (5th Cir. 1987) ("As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration."); *Wright Med. Tech.*, 127 F. Supp. 3d at 1325.

D. Dr. Elizabeth Davis

Elizabeth Davis, Ph.D., is a Registered Nurse and Vocational Rehabilitation Counselor with a master's degree in rehabilitation counseling and a doctoral degree in human services, and she is certified as an International Psychometric Evaluator by the American Board of Vocational Experts. Davis used the Rehabilitation Plan, Access to the Labor Market, Placeability, Earning Capacity, and Labor Force Participation ("RAPEL") model to evaluate Plaintiffs Estes, Keefer, McCombs and Baker's earning capacity and worklife expectancy but for their noise-induced hearing loss and/or tinnitus. Davis also opines on the vocational activity limitations

---

by the plaintiff. *See Hendrix II*, 609 F.3d at 1195; *see also Navelski v. Int'l Paper Co*., 244 F. Supp. 3d 1275, 1293 (N.D. Fla. 2017).

that she says result from each Plaintiffs' impairments, as well as the impact on each Plaintiffs' performance of household services.

Defendants do not dispute Davis' qualifications as a vocational expert; however, they do object to her testimony on reliability and helpfulness grounds. *See* Def. Mot., ECF No. 1605 at 98-107. Specifically, Defendants argue that Davis' opinions do not tie to the facts of each Plaintiff and that her methodology is unreliable. *See id.* Defendants' objections largely stem from Davis' reliance on the worklife expectancy tables found in a 2015 paper written by David S. Gibson, titled *Use of ACS to Estimate Lifetime Loss of Earning Capacity as a Result of Disability* (hereinafter the "Gibson Paper"). In this paper, Gibson relied on data collected by the United States Census Bureau-administered American Consumer Survey ("ACS") in order to project the potential future earnings and potential future employment for disabled individuals.

Defendants argue that the Gibson Paper is unreliable because it is not published in a peer-reviewed journal. *See* Def. Mot., ECF No. 1605 at 101-104. Davis stated in her deposition that she obtained the Gibson Paper from a free, publicly accessible, file sharing website named "ResearchGate." *See id.* at 101; *and* Davis Dep., EFC No. 1606-27 at 9. Davis further testified that while the paper was presented at an ACS Data Users Group Conference, she was not aware of the Gibson Paper having been published in any peer-reviewed journal. *See id.* at 8-10.

Plaintiffs' point out that the ACS Data Users Group also published the Gibson Paper on their website. *See* Pl. Resp., ECF No. 1630 at 75. Additionally, Plaintiffs state that the methodology implemented in the Gibson Paper has been included in two other articles authored by Gibson, both of which were published in the official journal of the International Association of Rehabilitation Professionals, *The Rehab Professional*. *See id.* Plaintiffs argue that this constitutes peer review for purposes of *Daubert*. *See id.* at 75-76. The Court agrees.

Peer review of a methodology supports the reliability of that methodology because it increases the likelihood that any substantive flaws will be detected. *See Daubert*, 509 U.S. at 593. However, while peer review is a relevant consideration in assessing the scientific validity of an expert's methodology, it is not a requirement for admissibility. *See id.* at 594.

Based on Davis' testimony, there does not appear to be a substantive review process regarding the content of a given submission for papers posted on ResearchGate. *See* Davis Dep., EFC No. 1606-27 at 13-14. Additionally, Plaintiffs have not shown whether the Gibson Paper underwent any sort of formal review process prior to, or during, the ACS Data Users Conference. The fact that the Gibson Paper was presented at the ACS Data Users Conference, published on ResearchGate, and published on the ACS Data Users Group website does not mean that the Gibson Paper has undergone a review process sufficient to identify substantive flaws in its

methodology. With that said, the fact that the Gibson Paper's methodology has been included in two papers published by a peer-reviewed journal[35] indicates that the methodology has been subject to several instances of peer review. The Gibson Paper relies on the use of ACS data, and courts have found that statistics established by the United States Census Bureau do "provide a solid basis for expert opinions of loss of future earnings." *See Hutchens v. Abbott Laboratories, Inc.*, 2016 WL 10566144, at *4 (N.D. Ohio Dec. 22, 2016); *see also Haines v. Get Air LLC*, 2019 WL 3501054, at *2 (D. Ariz. Aug. 1, 2019) (finding the vocational expert adequately showed that experts in his field would reasonably rely on ACS data). The Court finds, based on the factors discussed above, that the Gibson Paper's methodology has been sufficiently exposed to peer review.

Defendants also argue that the Gibson Paper is unreliable because it fails to categorize work-life expectancy by occupation and fails to categorize earnings capacity by specific age, occupation, or veteran status. Defendants cite a 2009 paper written by Thomas R. Ireland titled *Why the Gamboa-Gibson Disability Work-Life Expectancy Tables Are Without Merit*, which criticizes the use of ACS data for

[35] *See* David S. Gibson, *Use of ACS to Improve Occupation Earnings Estimates*, 26(1) THE REHAB. PROF'L 41-56 (2018) (describing the approach of this paper as consistent with the approach taken in the Gibson Paper), ECF No. 1630-66 at 5; David S. Gibson & Erin P. Gibson, *Age-Earning Profiles: Refinement and Applications*, 25(1) THE REHAB. PROF'L 13-34 (2017) (describing the approach of this paper as consistent with the approach taken in the Gibson Paper), ECF No. 1631 at 3.

measuring disability prevalence and the use of certain worklife expectancy tables derived from that data. Ireland's paper was published six years prior to the Gibson Paper, and it is unclear from Defendant's motion what specific critique from Ireland's paper they believe renders the Gibson Paper less reliable.

Defendants also identify two cases in which courts rejected the "Gamboa-Gibson" worklife expectancy tables. Defendants contend that the Gamboa-Gibson tables are "more detailed, published worklife expectancy charts" than the tables in the Gibson Paper. Defendants argue that if courts have excluded tables that are "more detailed" due to unreliability, such as the Gamboa-Gibson tables, than the tables in the Gibson Report should also be considered unreliable. In both of the cases cited by Defendants the courts excluded expert testimony that relied on the Gamboa-Gibson tables because that testimony did not sufficiently tie the data from the tables to the specifics of the individual plaintiffs, an argument the Defendants make here. *See Lackey v. Bosch*, 2017 WL 129891, *9-10 (E.D. Ky. Jan. 12, 2017) (finding expert did not sufficiently connect the data from Gamboa-Gibson tables to the plaintiff who had two amputated fingers and nerve damage in one hand); *and Noel v. Inland Dredging Co.*, 2018 WL 1911821, at *2 (E.D. La. Apr. 23, 2018) ("[p]laintiff fails to show that these tables can reliably predict the future work-life expectancy of a specific person.").

Plaintiffs argue in response that Ireland's criticisms are not relevant because Ireland's paper addressed 2002 ACS data and not the 2010 ACS data used by Gibson. According to Plaintiffs, the 2010 survey collected different information regarding disability types, which responds directly to Ireland's criticism. Plaintiffs also cite to a case in which the court found that Ireland's criticisms on the use of ACS data did not warrant exclusion. *See Haines*, 2019 WL 3501054, at *2 (rejecting Ireland's criticisms of Dr. Gamboa's methodology by finding "experts in Dr. Gamboa's field would reasonably rely on the data and methodology used by Dr. Gamboa"). Plaintiffs also point to cases where courts have allowed opinions based on the Gamboa-Gibson tables, finding the opinions reliable. *See e.g.*, Bennett v. U.S., 2018 WL 6265092, at *6 (C.D. Cal. Mar. 22, 2018) (finding that the tables were reliable, and their weight and credibility were best challenged on cross-examination); *Haines*, 2019 WL 3501054, at *2.

Davis can rely on the worklife expectancy tables from the Gibson Paper. Defendants' arguments regarding the underlying inadequacies of the ACS data, such as the criticisms found in Ireland's 2009 paper, go to weight. *See Bazemore v. Friday*, 478 U.S. 385, 400, 106 S. Ct. 3000, 92 L. Ed. 2d 315 (1986) ("Normally, failure to include variables will affect the analysis' probativeness, not its admissibility."); *Quiet Tech.*, 326 F.3d, at 1345 ("'in most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the

weight of the evidence rather than its admissibility.'") (citing *Hemmings v. Tidyman's Inc.*, 285 F.3d 1174, 1188 (9th Cir. 2002); *and In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1317 (N.D. Fla. 2018) (finding alleged inadequacies in a database that is the basis of a study go towards the weight afforded to the study and not the study's admissibility).

The Court also notes that in the two cases cited by Defendants, in which the courts excluded the Gamboa-Gibson tables as unreliable (*Lackey*, *Noel*), the plaintiffs suffered from physical injuries rather than hearing loss. The ACS specifically collects information from respondents on hearing disabilities. *See* ACS, ECF No. 1606-28 at 10. The ACS does not, however, include questions related to finger amputation or lower back pain. *See id.* This adds to the reliability of the ACS data for these Plaintiffs who allege hearing related injuries.

Defendants further argue that Davis' opinions are unreliable and unhelpful because they, "are not tied to the facts of each Plaintiff's case." *See* Def. Mot., ECF No. 1605 at 98. First, the Defendants point out that "[d]espite differences in education, occupation, and other factors," Davis has opined that each of the Plaintiffs will incur a six percent annual decrease in loss of earning capacity. According to Defendants, the use of an average for all four Plaintiffs necessarily means that Davis' opinions are not tied to the specific facts of each case.

Defendants also argue that Davis reached her conclusion by misapplying the ACS data represented in the Gibson Paper, specifically Figure 21 – *Male Median FTYR*[36] *Earnings by Level of Education*. *See id.* at 104-105. Figure 21 presents data for FTYR workers between the ages of 25 and 64 based on their education level and disability-type, and includes the percentage difference between earnings of those with a disability compared to those with no disability. *See* The Gibson Paper, ECF No. 1630-63 at 34. For example, Figure 21 shows that the median earnings for FTYR workers with a professional degree is $125,000 annually. *See id.* Figure 21 also shows that FTYR workers with a professional degree *and* a hearing disability only earn $111,500 annually, which is a reduction of eleven percent. *See id.* This example shows the percentage of lost earnings for one education level, i.e. those with a professional degree. Defendants are critical of Davis' approach because rather than relying on the percentage of lost earnings for the education level specific to each Plaintiff, Davis relied on the average loss of earnings across all education levels for those suffering from a hearing disability; i.e., an average annual loss of six percent. *See* Davis Dep., ECF No. 1606-29 at 15-18. Defendants insist that by not utilizing the loss of earnings that corresponded to each Plaintiffs' specific education level, Davis failed to apply her own methodology to the facts, which "renders her

[36] Gibson uses "FTYR" as shorthand for "those employed full-time (at least 35 hours/week) and year-round (at least 50 weeks/year)." *See* The Gibson Paper, ECF No. 1630-63 at 7.

methodology inherently unreliable." *See* Def. Mot., ECF No. 1605 at 104-105. In response, Plaintiffs state that Davis used the six percent annual decrease in earnings loss as a "touchstone." *See* Pl. Resp., ECF No. 1630 at 61. Plaintiffs referred to Davis' expert reports, in which she stated that she considered each Plaintiffs' specific education level, earning capacity, employment history, and age in forming her opinions. *See id.* Plaintiffs state that Davis also consulted with each Plaintiffs' medical experts. *See id.* at 60-61. After considering all of these sources, Davis then determined whether the six percent annual loss in earnings from the Gibson Paper fit each Plaintiffs' specific circumstances. *See, e.g.*, Davis Dep., ECF No. 1630-50 at 13-14 (answering questions regarding her analysis of Keefer and McCombs). Plaintiffs state that this is sufficient for reliability. *See* ECF No. 1630 at 63-64. The Court agrees.

As discussed above, to satisfy *Daubert*'s reliability requirement, an expert's opinion must be based on scientifically valid principles, reasoning, and methodology that are property applied to the facts at issue. *See Frazier*, 387 F.3d at 1261-62. A court must focus on the expert's principles and methodology, not the conclusions that they generate. *See Daubert*, 509 U.S. at 595. The fact that Davis determined that each of the Plaintiffs would suffer from the same percentage of future lost earnings does not in itself render Davis' opinion unreliable or unhelpful. While it is true that the Plaintiffs have reached various levels of education and work in different

professions, it is also true that the Plaintiffs share similarities that could impact their future earnings in similar ways, such as gender, prior military experience, and race. For sure, Davis will need to explain this in her testimony, but the fact that she came to the same conclusion on earnings loss for each Plaintiff does not make her methodology unreliable or unhelpful. Defendants objection to Davis' use of the Gibson Paper, specifically her use of the average loss in earnings, as opposed to the education-level specific loss in earnings, goes to the weight of Davis' conclusions rather than their admissibility. *See Fox v. Safeco Ins. Co. of Ill.*, 2018 WL 792093, at 4 (M.D. Fla. Jan. 23, 2018) (a party's argument that a vocational rehabilitation expert should have considered additional information is a question of weight and not admissibility).

Defendants also argue that Davis' opinion from the ACS data is not reliable because none of the Plaintiffs qualify as deaf or suffer from serious difficulty hearing. Defendants cite to portions of Davis' deposition testimony describing the Plaintiffs' medical reports and employment records to "show [Plaintiffs] can function normally without hindrance from any hearing-related disability," and further that any alleged disability is not serious because treatment will improve their hearing. *See* Def. Mot., ECF No. 1605 at 99. Defendants further argue that the ACS data is not applicable here because tinnitus is not specifically included in the ACS' definition of a hearing disability. *See id.* at 100. Plaintiffs respond that Defendants

are distorting facts by claiming that the Plaintiffs do not suffer from serious hearing loss, and they cite to their own deposition testimony[37] and the opinions from their medical experts[38] in support. Plaintiffs also disagree with Defendants' assertion that treatment will prevent future wage loss, citing to the Plaintiffs' medical experts' reports, which conclude that Plaintiffs hearing impairment will worsen with age. Davis acknowledges in her deposition that there are records identifying Plaintiffs' hearing impairments as minor and not something that limits their abilities to function in their jobs.[39] However, given the conflating evidence, the degree of severity of the

[37] *See* Baker Dep., ECF No. 1630-55 at 14 (discussing how his impairment has affected him, Baker states in restaurants, "I can't hear anything but noise. It's not even intelligible noise. It's just noise."); Keefer Dep., ECF No. 1630-56 at 19 ("I know that if I can't focus solely on the person that is talking to me … I really can't hear them all that clearly. So ambient noise, for example, in a restaurant where there's other conversations going on or … something of that nature where there's background noise, it is hard to hear."); Estes Dep., ECF No. 1630-57 at 9-10 ("The symptoms of hearing loss that I experience, include, but are not limited to, my ability to hear background noises while on the phone. I have to be on speaker. I have to constantly ask people to repeat themselves … I hear the wrong word on many occasions."); and McCombs Dep., ECF 1630-58 at 13 ("I went to the VA … it was 2015 and was trying to explain to my doctor I can't deal with this ringing in my ears all day long. It sounds like, you know, crickets.").

[38] *See* Lustig Rep. (Keefer), ECF No. 1630-59 at 8 (discussing Mr. Keefer's ongoing hearing issues); Packer Rep. (Baker), ECF No. 1630-61 at 60 (discussing Mr. Baker's ongoing hearing issues); Packer Rep. (Estes), ECF No. 1630-62 at 54 (discussing Mr. Estes's ongoing hearing issues); Arriaga Rep. (McCombs), ECF No. 63 at 10 (discussing Mr. McCombs's ongoing hearing issues).

[39] *See* Davis Dep., ECF No. 1605-64 at 45 (discussing Mr. Baker's email to his employer stating "my hearing loss is minor and only in my left ear. It will in no way effect my abilities to perform my duties."); at 59 (discussing Mr. Keefer's medical report by Dr. Lustig stating "Mr. Keefer is capable of working with accommodations as his hearing loss is mild and he can deal with the impairment."); Davis Dep., ECF No. 1605-65 at 41 (discussing a physician's report from Mr. McCombs employer, which "doesn't note any limitation for Mr. McCombs working based on hearing issues."). Defendants' also state that "Davis acknowledges that Estes's medical experts and VA disability ratings do not indicate hearing loss or tinnitus affect his employability;" however, it is not clear from the portions of Dr. Davis' deposition transcript cited by the

Plaintiffs' injuries are questions of fact, and, "[a]ny weaknesses in the factual underpinnings of [the expert's] opinions go to the weight and credibility of [the expert's] testimony, not to its admissibility." *Sorrels v. NCL (Bahamas) Ltd.*, 796 F.3d 1275, 1285 (11th Cir. 2015) (quoting *Hurst v. United States*, 882 F.2d 306, 311 (8th Cir. 1989). Additionally, the ACS includes six questions related to categorizing the disability status of the respondents completing the survey, and one of these questions specifically collects data on those suffering from hearing loss by asking the respondents, "Is this person *deaf* or does he/she have *serious difficulty hearing*?" *See* ACS, ECF No. 1606-28 at 10 (emphasis added). In sum, to the extent Defendants believe that Davis misapplied the Gibson Paper data because the Plaintiffs do not qualify as deaf or have serious difficult hearing, Defendants can test her opinions on cross-examination and through competing expert testimony. *See Quiet Tech*, 326 F.3d at 1345.

E. Dr. David A. Eddins

David A. Eddins, CCC-A, Ph.D. is an audiologist, professor of biomedical engineering, and Director of the Auditory & Speech Sciences Laboratory at the University of South Florida. He has more than three decades of clinical research experience in the fields of auditory perception, hearing loss, voice quality, and

---

Defendants that Dr. Davis acknowledges this point. *See* Def. Mot., ECF No. 1605 at 100 (citing Davis Dep., ECF No. 1605-65 at 34-35.

hearing technologies. Dr. Eddins offers an opinion that the CAEv2's "fit, function, and usability" were "compromised" by design defects in the length, width, and rigidity of its stem; the position of its filter and opposing flanges; and the inability of wearers to assess whether the plug's open-end was fitted properly. *See* Eddins Rep., ECF No. 1605-11 at 3. His opinions are based on his examination of the CAEv2, his review of Defendants' REAT testing and internal documents, and a series of tests he conducted under controlled laboratory conditions: (1) REAT testing of the CAEv2; (2) *h*MIRE (human-microphone in real ear) testing on a replica of the CAEv2; and (3) *m*MIRE (molded-microphone in real ear) testing of the CAEv2 on silicone human ear replicas.[40] Defendants argue that Dr. Eddins' opinions should be excluded in their entirety because they include impermissible factual narratives (which is discussed in the attorney mouthpiece section of this Order), unreliable comparisons to other hearing protection devices, and/or are based on novel methodologies developed for the purpose of this litigation or methodologies that do not apply to these Plaintiffs.

[40] Real-ear attenuation at threshold (REAT) testing is a subjective method of evaluating hearing threshold levels on an individual with (occluded) and without (unoccluded) hearing protectors. *h*MIRE testing measures the difference in hearing thresholds with and without an earplug using a probe tube positioned inside each test subject's ear. Dr. Eddins' *m*MIRE testing measured that difference using a standard microphone positioned inside a standard ear simulator coupled to silicone molds individualized to the ears of each test subject.

1. Dr. Eddins' REAT Testing

Dr. Eddins conducted REAT Method B (inexperienced-subject fit) testing for both ends of the CAEv2 using 30 test subjects with little or no prior earplug training or experience. *See* Eddins Rep., ECF No. 1605-11 at 27. The results of Dr. Eddins' Method B testing reflected "large" inter-subject variability in attenuation obtained and "low" overall NRR values for each end of the CAEv2. *See id*. at 32. Defendants concede that Method B testing is one of several generally accepted methodologies for evaluating the performance of a hearing protection device, and they do not challenge the reliability of Dr. Eddins' Method B testing procedures or his conclusions with respect to untrained, inexperienced users. Instead, Defendants argue that Dr. Eddins' REAT testing is unhelpful and cannot provide a reliable basis for his opinion regarding the CAEv2's performance when used by military service members, who have training and experience with hearing protection devices.

Putting aside the irony of Defendants' argument, for *Daubert* purposes, that service members are properly trained users of hearing protectors, when the theory of their defense is exactly the opposite, Dr. Eddins explained that Method B testing better approximates service members' real-world experience with hearing protection—limited training often occurring many months before use—than does the alternative, Method A, which involves experienced test subjects receiving "word for word, action for action" fitting instructions from a test administrator in a

controlled environment within minutes before the REAT test. *See* Eddins Dep., ECF No. 1630-4 at 15-16. Moreover, Defendants themselves have used Method B to test the CAEv2, *see id*. at 19, and their lead scientist, Dr. Elliott Berger, has previously opined that Method B testing data—and not Method A testing data—more closely corresponds to the real-world hearing protection achievable "by *groups* of informed users in workplace[] hearing conservation programs," *see* ECF No. 1630-8 at 4.[41] Because Dr. Eddins explained how and why his Method B testing can reliably approximate the attenuation that service members could expect to attain with the CAEv2, and Defendants have endorsed and employed the Method B technique, Dr. Eddins' REAT testing may reliably support his opinions in this litigation and will help the jury evaluate the attenuation provided by the CAEv2. This includes his opinion comparing the results of his REAT testing to the results Aearo obtained in prior tests of the CAE and UltraFit earplugs. *See* Eddins Rep., ECF No. 1630-2 at 34.

[41] Elliott H. Berger, *So, How Do You Want Your NRRs: Realistic or Sunny-Side Up?*, 6(9) THE HEARING REV. 68-70 (September 1999), ECF No. 1630-8; *see also* Elliott H. Berger et al., *Experience with a New ANSI Standard for Measuring the REAT of Hearing Protectors* (S12.6-1999), 1052 J. ACOUST. SOC. AM. 1129 (1999) ("[S]ubject-fit values provide a closer correspondence to real-world performance for groups of users than do the experimenter-supervised fit data."), ECF No. 1630-5.

2. Dr. Eddins' *h*MIRE Testing

Dr. Eddins conducted *h*MIRE testing ostensibly designed to measure whether and to what extent the CAEv2 loosens in wearers' ears after (i) three minutes of jogging; and (ii) four hours of regular use. *h*MIRE testing involves measuring the difference in sound pressure levels in a test subject's ear canal with and without an earplug inserted—or, as here, before and after certain activities—through the use of a probe measurement device, consisting of a thin tube threaded through the earplug and connected to microphones. Testing of this nature can be tricky because placing and removing a probe, microphone cables, and microphone can impact the positioning of an earplug, thereby introducing leaks in the earplug's acoustic seal and resulting in erroneous measurements. For this reason, and because the *h*MIRE technique is now widely used to evaluate hearing protector performance, manufacturers—including 3M—routinely build "probed" versions of their products, specially modified with a stationary probe tube embedded within the earplug that allows for *h*MIRE testing while eliminating, or greatly reducing, the potential for leaks caused by positioning the probe instruments. Significantly, there is no *h*MIRE-modified version of the CAEv2. *h*MIRE testing "was not common practice" when the CAEv2 was developed, so Defendants did not produce an *h*MIRE-modified version of the device at the time, nor have they done so in the years since. *See* Eddins Rep., ECF No. 1630-2 at 43. Dr. Eddins thus built and tested his own *h*MIRE-

suitable surrogate for the CAEv2, and Plaintiffs offer the results of those tests as evidence of how the actual CAEv2 would have performed on Dr. Eddins' *h*MIRE testing and, as relates to this litigation, when worn by some service members.

On consideration, the Court does not doubt the reliability of *h*MIRE testing generally, or of Dr. Eddins' specific findings as to the surrogate earplug. The reliability problem here (and the consequent helpfulness problem) is one of extrapolation. More specifically, the surrogate earplug differs from the CAEv2 in critical ways that, in the Court's view, impact the reliability of Dr. Eddins' conclusions about the CAEv2's alleged propensity to loosen during normal wear from evidence that the surrogate earplug loosens. To begin with, the surrogate earplug has a different weight, a different stem, and is hollow from end to end, with no filter through one-half of the stem.[42] Further, *h*MIRE testing of the surrogate requires insertion and removal of the probe instruments *after* the earplug is seated in a test subject's ear. All of these physical characteristics of the surrogate have the potential to impact its positioning in an ear and contribute to "loosening" as measured by insertion loss.[43] None of these characteristics are present in the CAEv2.

---

[42] Plaintiffs insist the CAEv2 and the surrogate earplug are the same weight. However, Dr. Eddins acknowledged that the surrogate's weight *is* different—by "no more than 5 percent . . . when it has . . . the probe tube through the middle of it," *see* Eddins Dep., ECF No. 1605-10 at 115, and by even more when the probe tube was removed for the physical activity portion of Dr. Eddins' loosening tests, which, as Defendants' aptly observe, is "when it mattered" most, *see* Def. Mot., ECF No. 1605 at 62.

[43] Relatedly, at the *Daubert* hearing, Dr. Eddins testified that he did not consider or determine the center of gravity for either the CAEv2 or the surrogate earplug, or validate that the

It is true that Dr. Eddins "validated" that the surrogate earplug attenuates noise comparably to the CAEv2, at least up to certain decibels. However, the instant evidentiary record well establishes that earplugs of all designs—for example, Aearo's UltraFit earplug, earlier and later versions of the CAE, the Surefire Sonic Defender, and the Moldex BattlePlug—can have similar noise attenuation capabilities, and not share "the uniquely problematic characteristics of the CAEv2" that allegedly result in imperceptible loosening. *See, e.g.*, McKinley Rep., ECF No. 1630-18 at 108-110; Eddins Rep., ECF No. 1631-23 at 52-57, 105-07. Dr. Eddins did not, and could not, methodologically validate that the surrogate plug and the CAEv2 loosen in wearer's ears at a similar rate. *See* Eddins Dep., ECF No. 1605-10 at 118-22. And there is the rub, because when we are talking about alleged earplug movement on the order of fractions of a millimeter, imperceptible to wearers and trained fitting professionals alike, loosening tests performed on a "fairly close" approximation of the CAEv2 are not sufficiently reliable to advance the ultimate question of whether and to what extent the actual CAEv2 imperceptibly loosens. *See id*. at 116.

---

center of gravity was the same for each device. This strikes the Court as significant because, according to Richard McKinley, another of Plaintiffs' experts, a hearing protector's ability "to stay in the ear" and any "tendency . . . to work itself loose while in real-world use such as walking, running, climbing, and jumping" is "influenced by the location of [its] center of gravity." *See* McKinley Rep., ECF No. 1630-33 at 39.

The Court recognizes that *h*MIRE testing of "probed" versions of earplugs is now common practice in the hearing protection industry. But Dr. Eddins has acknowledged that the probe tubes in those industry tests are *stationary* and built into the otherwise identical design of the subject earplug by its manufacturer. Plaintiffs have not identified a single study or other example from the scientific literature in which a manufacturer or a researcher "engineered" a new earplug, *see* Eddins Rep., ECF No. 1630-2 at 44, and *h*MIRE-tested it using a "probe insertion and removal" methodology, then offered the results of those tests as evidence of how another earplug performs. In other words, Dr. Eddins' variation of the *h*MIRE technique has not yet been considered and generally accepted in the hearing protection community, tested by anyone other than him, or subjected to peer review or publication.[44] Moreover, the rate of error for Dr. Eddins' technique is unknowable because, again, there is no way to evaluate comparative loosening of the actual CAEv2. All of these factors present reliability problems under Rule 702 and *Daubert* that Plaintiffs have not overcome. They are matters of admissibility, not weight or credibility. *See Frazier*, 387 F.3d at 1261 ("[U]nder Rule 702, the *reliability* criterion remains a discrete, independent, and important requirement for

[44] The Court understands that time constraints precluded Dr. Eddins from obtaining peer review before offering his methodology and opinions in this litigation. But this is precisely the sort of scientific research that *should* be the subject of peer review and validated, as appropriate, for the benefit of the entire scientific community.

admissibility."). Accordingly, Dr. Eddins' opinions and related testimony based on *h*MIRE testing must be excluded.

3. Dr. Eddins' *m*MIRE Testing

Dr. Eddins also conducted what he refers to as *m*MIRE testing on the CAEv2, to measure the continuous and impulse noise attenuation the earplug provided, as well as how much it loosened after simulated mandibular motion. The measurements were taken using a microphone positioned inside an industry standard ear simulator (called an "acoustic test fixture," or "ATF") that was coupled to silicone replicas of the human ear.[45] Mandibular motion was simulated by a computer-driven testing apparatus designed and built by Dr. Eddins and Roger Juneau, another of Plaintiffs' proposed experts, consisting of a motorized plunger and support structure that was mounted to the ATF and positioned to produce "a back and forth movement against" the "mandibular bump" on the model ear canal of the silicone replica ears.[46] *See* Juneau Rep., ECF No. 1630-3 at 34, 89.

[45] The model ears were manufactured by Roger Juneau of Soft Touch Labs, based on ear impressions that Dr. Eddins made of the external ears and portions of the ear canals for the 30 human test subjects used in his REAT testing. The ear simulator was a G.R.A.S. RA0045-S9.

[46] The mandibular bump is where the mandible meets the wall of the ear canal, creating "a protrusion" in the canal "that is visible from an ear impression made with an open jaw." *See* Eddins Rep., ECF No. 1630-2 at 64.

Defendants challenge two aspects of Dr. Eddins' *m*MIRE testing as novel and unreliable—his use of a mandibular motion simulator and silicone ear replicas.[47]

a. Mandibular Motion Simulator

The basic anatomical principles that inspired Dr. Eddins and Juneau's mandibular motion simulator are fairly straightforward and well-supported in the relevant literature.[48] Earplugs are worn in the soft, cartilaginous portion of the ear canal. The cartilaginous portion of the ear canal is adjacent to the mandible. When the mandible moves (during chewing or speech, for example), it pushes and pulls the tissue surrounding the ear canal, which can cause the ear canal to change shape in ways that can impact the fit of an earplug. This all sounds simple enough, but that turns out not to be so.

"Movement in the ear canal has not been well-studied," *see* Oliveira 1995 at 85, but despite advancements in knowledge about the physical properties of the ear, the field of ear canal dynamics remains "a very complicated subject" on which "few

---

[47] Dr. Eddins separately evaluated the non-linear function of the CAEv2 using only the industry standard ear simulator. *See* Eddins Rep., ECF No. 1630-2 at 68-70. Defendants did not challenge this evaluation.

[48] *See, e.g.*, Sune Darkner, *Shape and Deformation Analysis of the Human Ear Canal* (2009) (Ph.D. thesis, Technical University of Denmark) ("Darkner 2009"); Robert Oliveira *et al.*, *The Dynamic Ear Canal and Its Implications*, 12(2) Hearing Review 18 (Feb. 1, 2005) ("Oliveira 2005"), available at https://www.hearingreview.com/practice-building/practice-management/the-dynamic-ear-canal-and-its-implications; Robert Oliveira, *The Dynamic Human Ear*, *in* THE HUMAN EAR CANAL: THEORETICAL CONSIDERATIONS AND CLINICAL APPLICATIONS INCLUDING CERUMEN MANAGEMENT 83 (Bopanna Ballachanda ed. 1995) ("Oliveira 1995"); Robert Oliveira *et al.*, *A Look at Ear Canal Changes with Jaw Motion*, 13(6) Ear & Hearing 464 (1992) ("Oliveira 1992").

people have published" and only a "few of the published papers are peer reviewed," *see* Darkner 2009 at 5, 32. The limited body of research attempting to quantify shape changes in the ear canal due specifically to mandibular motion has analyzed ear impressions together with magnetic resonance imaging (MRI) scans, computed tomography (CT) scans, and/or statistical shape modeling. *See id*. at 31-32. The sum and substance of the research findings to date is that shape changes of this nature are "rather complex and not just deformation of the [ear] canal in a particular direction." *See id*. at 82.

Dr. Eddins took the existing research further, and simplified it quite a bit, by applying simulated jaw motion to the ear canal of silicone ear replicas to investigate whether, and how much, the CAEv2 loosened as a result. This was a remarkably innovative technique and, in this Court's humble view, may have the potential to advance the scientific community's approach to analyzing ear canal dynamics in the years to come. Right now, however, the technique is novel and, based on the current record, nothing as rudimentary as Dr. Eddins' testing apparatus has ever before been employed to investigate or draw conclusions about mandibular motion-induced ear canal changes. *See, e.g*., Darkner 2009 at 31-32; *see also* Eddins Dep., ECF No. 1605-10 at 149-50.[49] Dr. Eddins did not, and could not, methodologically validate

[49] *See also* Juneau Dep., ECF No. 1630-15 at 18 (stating that the mandibular motion simulator was seen as "a very incredible product because *for the first time* we could simulate

that the mandibular motion simulator actually replicated human jaw movement or its impact on the human ear canal, given the limits of current scientific research and technology.[50] The simulator has not yet been considered and generally accepted in the relevant scientific community, tested by anyone other than Dr. Eddins, or subjected to peer review and publication, and its rate of error is unknowable. Moreover, Dr. Eddins' technique is not backed by studies or other scientific literature substantiating that the "very complicated" relationship between mandibular motion and the human ear canal, *see* Darkner 2009 at 4, can be reliably encapsulated in the "back and forth movement" of a motorized plunger against a single point on a model ear replica, *see* Juneau Rep., ECF No. 1630-3 at 34.

Ingenuity and innovation play critical roles in scientific and medical research. Courts, however, cannot be pioneers, forging new trails in scientific thinking, even where, as here, an expert's approach would seem to naturally advance the existing body of knowledge in a field and may one day prove to be so. *See Rider v. Sandoz Pharm. Corp*., 295 F.3d 1194, 1202 (11th Cir. 2002) ("[C]ourts may only admit the state of science as it is. Courts are cautioned not to admit speculation, conjecture or

---

mandibular motion and demonstrate that . . . motion affected things that were in the human ear") (emphasis added).

[50] *See* Eddins Dep., ECF No. 1605-10 at 150-52 (explaining that "human jaw movement creates such a complex series of changes in the ear canal that it's extremely difficult to actually measure specifically what's happening [there]" and "because . . . there aren't known accurate methods to measure that, we decided just to manipulate the movement over a series of steps . . . that seemed biologically plausible").

inference that cannot be supported by sound scientific principles. The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it."). On this record, "there is simply too great an analytical gap between" current scientific knowledge about the dynamics of ear canal movement and Dr. Eddins' opinions based on the mandibular motion simulator. *See Joiner*, 522 U.S. at 146. Dr. Eddins may testify generally about how jaw movement can impact the shape of an ear canal and, consequently, the fit of a hearing device positioned in the ear canal, based on the scientific literature as it presently stands. But his opinions and related testimony based on the mandibular motion simulator must be excluded.[51]

b. Static Testing on Silicone Ear Replicas

Dr. Eddins also performed static *m*MIRE testing (i.e., no mandibular motion) with the silicone ear replicas coupled to the ATF. Defendants argue, in essence, that all testing on the ear replicas was unreliable because the replicas and ATF do not precisely reproduce the anatomy and function of the human ear. This argument is easily rejected.

ATFs have been used for decades to obtain objective measurements of the insertion loss of hearing protectors, particularly with high noise levels to which

[51] Likewise, Juneau's opinions related to the mandibular motion simulator are excluded.

human test subjects cannot be safely or ethically exposed.[52] Most ATFs are simplified models of the human head and auditory system, equipped with universal rubber or silicone external ears, including the pinna, acoustic ear couplers, and cylindrical metal ear canal extensions. No artificial ear and ATF apparatus precisely reproduces the anatomy and function of the human ear. Nevertheless, the American National Standards Institute (ANSI) encourages and provides standards for their use. *See* ANSI/ASA S12.42-2010, ECF No. 1630-14. Critically, ANSI acknowledges that no existing ATF or head and torso simulator "includes all of the features described in th[e] standard," and therefore, "a laboratory may construct its own." *See id.*, Annex B, ECF No. 1630-14 at 47. In this litigation, Dr. Eddins and Juneau did just that.

Defendants criticize Dr. Eddins and Juneau's silicone ear replicas for not capturing the entire ear canal, being made from silicone (as opposed to "flesh, cartilage and bone, each of which has unique acoustical properties"), and using a mixture of artificial wax and sebum to approximate ear wax. *See* Def. Mot., ECF No. 1605 at 69-71. All of these statements are equally true of ATF testing using a standard universal ear, coupler and ear canal, which Defendants do not appear to claim is unreliable. *See id*. at 68-69 (stating that an ATF is "a common industry term

[52] *See, e.g.*, M.D. Burkhard & R.M. Sachs, *Anthropometric Manikin for Acoustic Research*, 58 J. ACOUST. SOC. AM. 214-222, at 218 (1975), ECF No. 1630-12.

for non-human test systems used to test protectors"); *see also* Eddins Dep., ECF No. 1630-4 at 41 (observing that all of Defendants and others previous ATF testing on the CAEv2 was performed on ATFs that did not comply with ANSI); Eddins Dep., ECF No. 1605-10 at 132-33. The only *meaningful* distinction between Dr. Eddins' silicone ear replicas and the standard universal ear model is the former's ability to accurately capture the anatomies of human external ears of varying shapes and sizes up to the cartilaginous bony juncture, whereas the latter cannot.[53] From a reliability standpoint, this is not a bug, but a feature. Indeed, Defendants have not shown how or why this—or any of their other criticisms to the silicone ear replicas—impacts the reliability of Eddins' calculations or results. Defendants challenges may present fodder for cross-examination, but they are not grounds for exclusion of Dr. Eddins' opinions based on his static *m*MIRE testing (i.e., with no mandibular motion) with the silicone ear replicas.[54]

F. Dr. John Franks

John Franks, Ph.D. is as an audiologist. He worked as a physical scientist at the National Institute for Occupational Safety and Health (NIOSH) from 1987 through 2005. He now provides advisory services in the private sector concerning,

[53] It is impossible to safely create an ear mold of the entire length of the human ear canal from living human subjects because the area beyond the cartilaginous bony juncture is highly pain-sensitive and susceptible to damage. *See* Juneau Rep., ECF No. 1630-3 at 21-22.

[54] Juneau's opinions related to the silicone ear replicas are admissible for the same reasons.

among other things, prevention of occupational hearing loss, noise control products and strategies, and new product development. Dr. Franks is proffered as an expert on the testing and labeling of hearing protection devices, and offers opinions relating to Defendants' testing and labeling of the CAEv2. Defendants do not dispute Dr. Franks' qualifications to opine on those topics. Rather, they argue that certain of his opinions constitute inadmissible legal conclusions, which is addressed in the "attorney mouthpiece" section of this Order, or are otherwise unreliable.

1. Reliability of Dr. Franks' Opinion that the NRR of 22 for the Green End of the CAEv2 was Inaccurate

Dr. Franks offers an opinion that the 22 NRR label for the green end of the CAEv2 was inaccurate for several reasons, only two of which are challenged by Defendants. First, Dr. Franks opines that Defendants "violated generally accepted methods for testing [hearing protection devices]" to obtain the 22 NRR, by using a different panel of test subjects for Test 213017 (green end) than was used for Tests 213015 (green end) and 213016 (yellow end). According to Defendants, Dr. Franks provided no support for his opinion that generally accepted industry practice called for all three tests of the CAEv2 to have been conducted with the same panel of test subjects. The Court disagrees. Dr. Franks' decades of specialized experience with the testing and labeling of hearing protection devices, together with his explanation of how that experience informed his opinion in this litigation, establishes an adequate factual basis for his opinion, particularly given that Defendants' rebuttal

expert, Dr. John Casali, acknowledged that using a "common set" of test subjects for all three tests "may have been a preferable practice."[55] *See Frazier*, 387 F.3d at 1261 (experts may rely on professional experience to offer opinion testimony so long as they "explain how that experience leads to the conclusion reached, why that experience is sufficient basis for the opinion, and how that experience is reliably applied to the facts"); *United States Sec. & Exch. Comm'n v. Spartan Sec. Grp*., 2020 WL 7024885, at *4-5 (M.D. Fla. Nov. 30, 2020) (expert's professional experience in the transfer agency industry, review of relevant documents, and explanation of how his experience informed his analysis provided adequate factual basis for opinion testimony regarding transfer agency industry standards and how a party's conduct measured up against those standards). Any alleged inadequacies in Dr. Frank's analysis may be tested on cross-examination and through competing expert testimony. *See Quiet Tech*, 326 F.3d at 1345.

Second, Dr. Franks opines that the 22 NRR label was inaccurate because Defendants did not instruct users to fold back the opposing flanges of the CAEv2 to achieve the labeled level of noise reduction. *See* Franks Supp., D36 at 2169-70. Defendants argue that this opinion is "untenable" in light of Dr. Franks' subsequent deposition testimony "admitting he does not know whether folding back the flanges makes any difference to anyone." *See* Def. Mot., ECF No. 1605 at 79. The Court

[55] Casali Rep., ECF No. 1630-24 at 62-63.

disagrees. Defendants overstate Dr. Franks' deposition testimony. At most, he acknowledged other factors—e.g., test subject variation; instruction variation—that might have contributed to the difference in results between Tests 213015 and 213017. To the extent Dr. Franks' actual deposition testimony can be viewed as conflicting with his previously given opinions on the necessity of a fold-back instruction, that is a matter affecting the weight and credibility of his opinion, not its admissibility. *See Gonzalez v. Inman Trucking, Inc.*, 2017 WL 7905499, at *5 (W.D. Tex. June 20, 2017) ("The fact that [an expert] arguably contradicted himself during his deposition testimony does not bear upon the admissibility of his testimony, but upon his credibility, which is a jury determination."); *Exim Brickell LLC v. Bariven*, 2011 WL 13131317, at *5 (S.D. Fla. Mar. 11, 2011) (same with respect to arguable "contradictions and concessions" in deposition transcript and written reports).

2. Reliability of Opinion that REAT Testing Reveals Certain Design Defects in the CAEv2

Based on his review of Defendants' REAT testing and internal documents, Dr. Franks concluded that the CAEv2 has three defects: (a) it is too short for proper insertion for many wearers; (b) once inserted, it loosens imperceptibly in some wearers' ears as its opposing flanges press against the wearers' ear canal; and (c) its "overly wide and stiff stem" make it "especially difficult" to insert the earplug into the natural curve of the "typical adult ear," which prevented wearers from receiving

adequate hearing protection. *See* ECF No. Franks Rep., ECF No. 1606 at 13, 54. Defendants challenge the latter two opinions as unreliable.

Regarding Dr. Franks' opinion on flange positioning, Defendants essentially argue, again, that this opinion is untenable in light of his deposition testimony, which they characterize as an admission that "he has no way of knowing whether folding back the flanges has any effect on attenuation." *See* Def. Mot., ECF No. 1605 at 82. As already discussed, Defendants have mischaracterized the scope of Dr. Franks' testimony, which was limited to acknowledging various factors that may have contributed to the different results obtained from Tests 213015 and 213017. *See* Franks Dep., ECF No. 1605-34 at 13-14. In any event, an opinion about the effectiveness of a potential remedy for the alleged flange positioning defect—i.e., folding back the external flanges—would not undermine the reliability of Dr. Franks' opinion that the alleged defect exists in the first place. To the extent Defendants disagree, that may be a proper subject of cross-examination, but it is not a basis for exclusion under Rule 702.

Defendants' challenge to the factual basis for Dr. Franks' opinion about the width and rigidity of the CAEv2's stem fares no better. Based on his knowledge of outer ear anatomy and the readily observable characteristics of the CAEv2's stem, Dr. Franks opines that the curvature of a "typical" ear canal would not easily accommodate the CAEv2's "overly wide and stiff" stem, making proper insertion

(and, thus, adequate hearing protection) difficult to achieve. *See* Franks Rep., ECF No. 1606 at 54. Additionally, he compared the results of Test 213015 (green end of the CAEv2, opposing flanges not folded back) with an earlier Aearo REAT test (Test 213014) of the UltraFit Plus, a single-ended, linear earplug fitted with the same tip as the green end of the CAEv2, but which unlike the CAEv2, had a flexible stem. Aearo used five of the same subjects for both tests. Dr. Franks compared these subjects' data across tests and determined that four of them obtained "substantially less attenuation" in Test 213015 than in Test 213014. *See id*. at 53-54. He offers an opinion that the discrepancy is due, in part, to the "stiffer wide stem" of the CAEv2. *See id*. at 54. Defendants argue that Dr. Franks "ignore[d] another significant difference between" the two earplugs—the CAEv2 is dual-ended, and on [Test 213015] none of the flanges of the opposing earplug were folded back." *See* Def. Mot., ECF No. 1605 at 82. In their view, he thus has no basis to conclude that the CAEv2's stem, rather than interference from the opposing flanges, caused the different attenuation results. Defendants misstate Dr. Franks' opinion. He did not attribute the discrepancy *solely* to the "overly wide and stiff" stem of the CAEv2; rather, he opined that this was an "additional" defect that prevented wearers from receiving adequate hearing protection. *See* ECF No. Franks Rep., ECF No. 1606 at 54. Because that opinion is supported by elementary anatomical facts and Defendants' REAT testing data, it meets the "good grounds" standard for reliability.

See Quiet Tech., 326 F.3d at 1345. Any alleged weaknesses in the opinion bear on its weight, not its admissibility. S*ee Jones v. Otis Elevator*, 861 F.2d 655, 663 (11th Cir. 1988).

3. Reliability of Opinion that CAEv2 Performed Poorly on Method B Testing

Defendants also challenge Dr. Franks' opinion that the 4.4 dB Subject-Fit NRR obtained from Defendants' Method B testing of the CAEv2 in June 2006 (Test 213030) was "very low" and driven by "abnormally large standard deviations of at least 10 dB at each test frequency." *See* Franks Rep., ECF No. 1606 at 56-57. They argue that Dr. Franks provided no basis for his assertion that the 4.4 dB Subject-Fit NRR demonstrates the CAEv2 provided inadequate hearing protection because he did not compare the CAEv2's Method B results to Method B tests for any other earplug. This is incorrect.

Dr. Franks' conclusions about Test 213030 are based on his review of the laboratory report for that test and other REAT testing laboratory reports in evidence in this litigation, *see id.*, and are informed by his extensive and specialized knowledge, education, and practical experience evaluating REAT tests and analyzing the variability in attenuation provided by hearing protection devices, *see id*. at 4-10. There is also an apparent wealth of peer-reviewed literature on the subject, some of which Dr. Franks cited as "[d]ocuments [r]elied on" in preparing his expert report. *See id*. at 111-114. Moreover, Dr. Franks' reasoning and

conclusions about Test 213030 are consistent with those of Defendants' own expert, Elliott Berger, who agrees that the 4.4 dB Subject Fit NRR showed the CAEv2 was not providing much protection "for some of the users," *see* Berger Dep., ECF No. 1630-31 at 6, and who testified that "highly variable" attenuation results across subjects in another test, Test 213015, demonstrated the test subjects were not getting "proper protection," *see* Berger Dep., ECF No. 1630-32 at 4. On this record, there is a reliable factual basis and scientifically valid reasoning supporting Dr. Franks' opinion about the results of Test 213030. To the extent Defendants believe Dr. Franks should have gone further and evaluated how the CAEv2's Method B results stacked up against Method B results for other earplugs, that criticism goes to the weight of Dr. Franks' opinion, not its admissibility. *See Quiet Tech.*, 326 F.3d at 1345 ("So long as [an] expert's testimony rests upon 'good grounds,' it should be tested by the adversary process . . . rather than excluded from" a jury).

4. Reliability of Opinion that Certain REAT Subjects Received "Inadequate" or "Poor" Fits with the CAEv2

Dr. Franks' report reflects that he conducted a subject-by-subject review of the attenuation results from Defendants' REAT testing of the CAEv2 and identified subjects who, in his opinion, received "inadequate" or "poor" fits, based on "large variances" in their individual attenuation results across tests, *see* Franks Rep., ECF No. 1606 at 64, and also a comparison of their individual attenuations and NRRs to the means across all test subjects, *see* Franks Dep., ECF No. 1630-25 at 53-60.

Defendants argue that this opinion is inadmissible because Dr. Franks "has disavowed the methodology he applied, and in any case the methodology lacks any scientific basis." *See* Def. Mot., ECF No. 1605 at 80.

As to the former, Dr. Franks has not disavowed his methodology or otherwise "admitted" that it does not reliably identify individuals who had poor or inadequate fits. *See id*. Defendants are mischaracterizing an insignificant semantic distinction between the terms Dr. Franks used to describe his *conclusions* about the REAT tests in which two "dramatically different" sets of attenuation outcomes were obtained for individual test subjects across three separate trials conducted over the course of 15 minutes.[56] *See* Franks Dep., ECF No. 1605-34 at 17. In his report, Dr. Franks stated that such "large variances" in an individual's attenuation results signal that the earplug was not "adequately fitted" for at least one of the tests. *See* Franks Rep., ECF No. 1606 at 64-66. He later testified that a more precise descriptor would be to say that the earplug's fit in at least one of the tests was "inconsistent" with its fit

---

[56] Dr. Franks identified a number of specific instances where this occurred, including the results for TRS, a test subject in Test 213015. According to Dr. Franks,

> TRS's trial one attenuation levels were far lower than his second and third trial attenuation levels at all tested frequencies. For instance, At 500 Hz, TRS's trial one attenuation was *-4 dB*, compared to 25 and 24 dB in trials two and three, respectively. At 1000 Hz, TRS's trial one attenuation was *0 dB*, compared to 26 and 22 dB in trials two and three, respectively. At 6300 Hz, TRS's trial one attenuation was *5 dB*, compared to 34 and 41 dB in trials two and three respectively.

See Franks Rep., ECF No. 1606 at 65-66. Dr. Franks explained that the "huge variances are indicative of TRS not being adequately fit with the closed-end of the CAEv2 during trial one." *See id*. at 66.

in the other tests, *see* Franks Dep., ECF No. 1605-34 at 17, meaning the fitter's "success of getting the earplug in [was] inadequate," *see id*. at 18, and the subjects did not receive a "good fit" consistent with ANSI standards, *see* Franks Dep., ECF No. 1630-25 at 92. In other words, Dr. Franks' semantic choice between the terms "inadequate" and "inconsistent" does not undermine his substantive conclusion or amount to a repudiation of his methodology.

There is also a scientific basis for Dr. Franks' methodology. Notably, Defendants do not challenge the reliability of Dr. Franks' overall analytical technique; that is, his comparative analysis of variances in individual and group test results to evaluate fit. Instead, Defendants argue that his threshold for identifying wide variances—6 dB to 10 dB—is purely subjective and not "set forth in writing anywhere." *See* Def. Motion, ECF No. 1605 at 81. This is incorrect. As Dr. Franks explained, ANSI S3.19 requires consistent open-ear (without hearing protection) thresholds within a 6 dB range in order for a test subject to qualify for participation in a study. *See* Franks Dep., ECF No. 1630-25 at 109-10. He further testified, based on his decades of professional experience analyzing REAT tests, that it was "pretty widely accepted" in his field to use a range of 6 to 10 dB to identify large variances in a subject's REAT test data. *See id.* at 115. This testimony is corroborated by Defendants' own description of variances between 6.9 dB and 11.8 as "very large." *See* Def. Mot., ECF No. 1605 at 61-62. Because Dr. Franks predicated his variance

thresholds on ANSI and generally accepted industry standards, and explained how those standards reliably identify poorly fit REAT test subjects, his methodology is supported by "good grounds." *See Frazier*, 387 F.3d at 1261. Therefore, Dr. Franks' opinion that certain REAT subjects obtained poor fits with the CAEv2 is reliable and admissible.

G. Roger Juneau

Roger Juneau is a mechanical engineer with more than 40 years' experience designing, developing, and testing—including REAT and MIRE testing—custom ear molds, hearing aids, hearing protection devices, and a "range" of other "products to benefit the clinical audiological health industry." *See* Juneau Rep., ECF No. 1605-32 at 3. Juneau offers opinions explaining how the anatomy and physiology of the ear and jaw impact "the fitting and effectiveness of a one-size-fits-most" earplug, like the CAEv2, and identifying specific design characteristics of the CAEv2 that resulted in fit and acoustic seal problems. *See id*. at 48. He also manufactured the silicone ear replicas and mandibular motion simulator that Dr. David Eddins used to perform *m*MIRE testing. The Court has already found that Juneau's opinions on the silicone ear replicas are admissible but his opinions regarding the mandibular motion simulator are not. Defendants also move to exclude Juneau's opinions that the CAEv2's stem is too wide on grounds that it is

based on inaccurate data and unhelpful, as well as Juneau's opinions relying on conversations with companies that he did not disclose in his expert report.

As to Juneau's opinions about the width of the CAEv2's stem, there are no reliability or helpfulness problems. Juneau examined the CAEv2 and its underlying design schematics, together with a number of authorities in the scientific literature describing the width of the ear canal. *See* Juneau Rep., ECF No. 1630-3 at 36-38. His proffered opinion that the CAEv2's stem is too wide is consistent with those authorities.[57] The opinion is supported by "good grounds" and would assist the jury in evaluating whether the CAEv2's stem is defective. That is all that Rule 702 and *Daubert* require.

Regarding Juneau's opinions relying on conversations with companies that he did not disclose in his expert, those opinions will be excluded. Pursuant to Federal Rule of Civil Procedure 26(a)(2)(B)(i), an expert's written report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." If a party fails to provide information as required by Rule 26(a), that party "is not allowed to use that information to supply evidence at a trial, unless the failure was substantially justified or is harmless." *Hughes v. GEICO Gen. Ins. Co*.,

[57] *See, e.g.*, Staab, The Human Ear Canal I-V, Hearing Health & Tech. Matters (June – July 2014), available at https://hearinghealthmatters.org/waynesworld/2014/human-ear-canal/ (last visited Feb. 26, 2021); Ahmad *et al*., *External Auditory Canal Measurements: Localization of the Isthmus*, 10 Oto. Rhino. Laryngol. Nova 183-86 (2000), ECF No. 1630-17.

2017 WL 7000273, at *2 (M.D. Fla. Aug. 31, 2017), *decision clarified on reconsideration*, 2018 WL 490506 (M.D. Fla. Jan. 19, 2018); *see also Mitchell v. Ford Motor Co*., 318 F. App'x 821, 824 (11th Cir. 2009). Here, Juneau gave deposition testimony about his conversations with the manufacturers of the artificial ear wax formula he used, and about certain hardness data he obtained for the silicone used in his ear replicas, none of which was disclosed in his expert report. The Court agrees with Plaintiffs that their experts' ear replica testing in this litigation does not rise and fall on the ear wax formula, or on the relative hardness of the silicone. But the fact remains that Juneau failed to properly disclose this information, and Plaintiffs have not shown that the failure was substantially justified or is entirely harmless. Therefore, Juneau will not be permitted to testify at trial based on these conversations or reference materials. He will, however, be allowed to testify about the ear wax formula and/or the silicone hardness data based on his personal knowledge and experience, as well as any reference materials that were properly disclosed under Rule 26(a)(2)(B).

H. Kristin Kucsma

Kristin Kucsma is a forensic economist who offers opinions on economic loss for Estes, Keefer, McCombs, and Baker, including loss of earnings and fringe benefits, based on their future earning capacity, associated vocational impairments, and their respective inabilities to provide support to spouses and/or children.

Defendants challenge the reliability of Kucsma's lost earnings and fringe benefits opinions. *See* Def. Mot., ECF No. 1605 at 107-108. Specifically, Defendants argue that Kucsma's lost earnings opinions are unreliable because they are based on Dr. Davis' opinions regarding Plaintiffs' loss of earning capacity and worklife expectancy, which Defendants have separately argued are unreliable. In addition, Defendants argue that Kucsma's reliance on nationwide data to estimate the value of Plaintiffs' projected loss of fringe benefits is unreliable because nationwide data is not specific to the facts. Defendants do not dispute Kucsma's qualifications nor the helpfulness of her testimony.

Defendants first contend that Kucsma relied entirely on Davis' reports for her lost earnings opinions, and therefore, given the unreliability of Davis' opinions, Kucsma's are unreliable as well. Plaintiffs respond that Kucsma relies on multiple sources, not just Davis. Plaintiffs also point out that experts are permitted to rely on other experts. Having previously found Davis' opinions reliable (*see supra* at 46-57), the Court will not exclude the portions of Kucsma's reports that rely on them. *See Hendrix I*, 255 F.R.D. at 607 n.75 (N.D. Fla. 2009) ("An expert may properly rely on the opinion of another expert.").

Defendants also argue that Kucsma's fringe benefits opinions for Keefer and Baker[58] are unreliable because her calculations are based on estimated national averages of employer contributions to retirement and savings plans. Defendants argue that in making these calculations, Kucsma should have used more tailored figures based on Plaintiffs' individual occupations, geographic location, and the specific benefit contributions made by Plaintiffs' employers. In support, Defendants cite *Joffe v. King & Spalding, LLP*, in which Kucsma's fringe benefits opinion was excluded for this reason. *See Joffe v. King & Spalding LLP*, 2019 WL 4673554, at *8 (S.D.N.Y. Sept. 24, 2019) (finding that Kucsma did not "explain why this nationwide figure is an appropriate estimate for fringe benefits earned," by those in the plaintiff's particular profession and geographic region). Plaintiffs respond that *Joffe* is an outlier case, and they cite to several cases where courts accepted the use of estimates and averages in calculating fringe benefits. *See Kohl v. Young*, 2018 WL 3104447 (N.D.N.Y. June 22, 2018) (admitting Kucsma's fringe benefits calculation); *Chavez-Acosta v. Sw. Cheese Co., L.L.C.*, 2013 WL 12040013, at *3 (D.N.M. Aug. 5, 2013) (overruling objection to expert's use of an estimate for fringe benefits rather than basing calculation on fringe benefits actually received by plaintiff while employed); *Ashford v. Wal-Mart Stores, LP*, 2013 WL 152853, at *4

[58] Kucsma does not calculate a loss of fringe benefits for Estes or McCombs. *See* Kucsma Rep. (McCombs), ECF No. 1631-10 at 12; *and* Kucsma Rep. (Estes) ECF No. 1631-4 at 6.

(S.D. Miss. Jan. 15, 2013) (overruling objection to expert's use of plaintiff's employer contribution data and labor statistics from United States Census Bureau in calculating fringe benefits opinion); *and Easly v. Waterfront Shipping Co.*, 2012 WL 812354, at *9 (W.D. Wash. Mar. 9, 2012) (admitting fringe benefit calculation that utilizes statistics from United States Department of Labor).

While Defendants only cite to *Joffe*, the Court notes that other courts have excluded fringe benefit opinions based on national averages as not sufficiently precise to be reliable. *See e.g.*, *Phelps v. CBS Corp.*, 2020 WL 7028954 (S.D.N.Y. Nov. 30, 2020) (excluding fringe benefits opinion based on average estimates, citing *Joffe*); *and Teenier v. Charter Commc'ns, LLC*, 2017 WL 3141051, at *3-4 (E.D. Mich. July 25, 2017) ("Failing to account for precise and contrary factual data and instead using a national average does not appear to rise to the intellectual rigor expected from a forensic economist."). Nonetheless, the Court disagrees with these cases and finds that Kucsma's fringe benefits opinion is admissible. Defendants have not argued that Kucsma's methodology was not subject to peer review or that her methodology was not generally accepted in the scientific community. Defendants have also not argued that Kucsma's testimony cannot be tested; in fact, Kucsma's fringe benefits opinion appears to the Court to be readably testable by an opposing expert. To the extent that Defendants believe Kucsma's fringe benefits calculation is inaccurate they can provide an alternative calculation that includes

Plaintiffs occupations, geographic locations, and benefits contributed by their current employers. Because Defendants can offer an alternative calculation and question Kucsma's calculation on cross-examination, Kucsma's testimony does not run the risk of misleading the jury. The jury is capable of evaluating two alternate fringe benefits calculations and the reasoning supporting each. Thus, the Court finds that Defendants' objections go towards the weight of Kucsma's fringe benefits opinion rather than its admissibility.

I. Dr. David Madigan

David Madigan, Ph.D. is a biostatistician with over thirty years of experience researching, publishing, teaching, and consulting in the fields of statistics, biostatistics, epidemiology, and pharmacovigilance. He comparatively analyzed the results from Aearo's REAT testing of the green end of the CAEv2, both with and without the opposing flanges folded back, as well as Aearo's REAT testing results for the CAEv3, CAEv4 and three versions of the company's UltraFit earplug. Dr. Madigan concluded there were statistically significant differences between the individual NRRs and mean attenuations reported from the tests of the unfolded and folded green end of the CAEv2, and also between the results reported for the tests of the unfolded green end of the CAEv2 and the other earplugs.[59]

[59] Dr. Madigan found only one exception. Although the difference in NRRs reported for the unfolded green end of the CAEv2 and the corded UltraFit earplug was statistically significant,

Defendants' only argument with respect to Dr. Madigan is that he should be precluded from offering a causation opinion. He will be so precluded, although it is largely beside the point because neither Dr. Madigan's expert report nor his deposition testimony even hint at an opinion about causation. His statements about the reported procedural differences between the 213015 and 213017 tests are admissible descriptions of the record evidence on which he relied in conducting his statistical analysis. Those statements are appropriate for cross-examination at trial, but are not subject to exclusion under *Daubert*. *See Viterbo*, 826 F.2d at 422; *Wright Med. Tech.*, 127 F. Supp. 3d at 1325.

J. Richard McKinley

Richard McKinley is a bioacoustics engineer with 40 years' experience developing and assessing the quality and performance of hearing protection and communication products for the United States military, and more recently, as a consultant for Booz Allen Hamilton. McKinley offers opinions that the CAEv2 was defectively designed and that Defendants' quality control and assurance processes for the CAEv2 were deficient, in part, because Aearo did not comply with International Standards Organization (ISO) 9001 standards and failed to conduct accurate acoustic impedance testing, as required by the MPID, to verify the quality

---

the comparative variability of attenuation between the two products was not. *See* Madigan Rep., ECF No. 1606-62 at 8.

of the final product. Defendants object to certain of McKinley's opinions on qualifications, reliability, and helpfulness grounds.

1. Qualifications to Opine on ISO 9001

Defendants argue that McKinley is not qualified to provide expert testimony regarding their alleged noncompliance with ISO 9001 quality assurance standards because he has very limited and dated experience with ISO 9001. This is incorrect. A witness need not be the best or most qualified authority on a subject to be admitted as an expert under Rule 702, *see Navelski*, 244 F. Supp. 3d at 1293, and his experience "does not always need to be narrowly tailored to match the exact point of dispute in a case," *see Trilink Saw Chain, LLC v. Blount, Inc*., 583 F. Supp. 2d 1293, 1304 (N.D. Ga. 2008). While a witness may not qualify as an expert in "an entirely different field or discipline," which includes areas "outside of—but related to—his expertise," the "liberal" standard for qualification under Rule 702 is met so long as he is "minimally qualified" and his proposed opinions "stay within the reasonable confines of his subject area." *Id*. at 1304-05.

Here, McKinley's knowledge and decades of experience in the field of quality management and assurance, of which ISO 9001 is a part, *see Vizio Inc. v. Gemtek Tech. Co. Ltd.*, No. 8:13cv160, 2014 WL 10538995, at *9 (C.D. Cal. Aug. 27, 2014), qualify him to offer expert opinions about the adequacy of Defendants' quality assurance procedures. Early in his career, McKinley gained "some exposure" to ISO

9001 while applying it in connection with the development of an active noise reduction headset for the military with Bose. *See* McKinley Dep., ECF No. 1605-24 at 12. Since that time, he has evaluated other government contractors' ISO-compliant "quality assurance programs" as part of his review of their "design documents for other pieces of hardware, such as aircraft intercom systems for just about every aircraft in the Air Force inventory." *See id*. at 13. McKinley proposes to do much the same here—that is, evaluate Aearo's quality assurance program, including its ISO compliance, as part of his review of its design process for the CAEv2. Given McKinley's extensive background in product development and quality assurance, his knowledge of ISO 9001, and the liberal standard for admission of expert testimony under Rule 702, *see Frazier*, 387 F.3d at 1294, the Court concludes that he is qualified to offer his opinion as to ISO 9001 in this litigation. Objections to the level of his expertise go to the weight and persuasiveness of his opinion, not its admissibility. *See Hendrix I*, 255 F.R.D. at 585.

2. Reliability of Quality Assurance Testing Opinion

McKinley offers opinions about alleged deficiencies with Defendants' acoustic impedance testing of the CAEv2, which was a quality assurance measure required by the MPID and performed using a proprietary box called an Acoustical Resistance Checker ("ARC"). Defendants maintain that McKinley's opinions about their ARC testing are speculative and would be unhelpful to the jury because

McKinley has no personal experience with ARC testing and, to the extent the ARC testing revealed "significant problems" with the CAEv2, *see* McKinley Rep., ECF No. 1630-18 at 87, McKinley cannot show what effect, if any, those problems had on product performance.

McKinley's opinion that deficiencies existed with (and were revealed by) the ARC testing is based, in part, on Defendants' own assessments that deficiencies existed and were revealed during the testing. *See id*. at 79-87. He identified critical information about the ARC testing program—from Defendants' internal documents—that may not be obvious to an untrained eye, explained its significance, and connected it to his broader opinion that Defendants' overall quality assurance process for the CAEv2 was substandard. This is not speculative. Indeed, analyses of this nature are well within the scope of McKinley's expertise in evaluating government contractors' quality management systems, and will aid the jury in considering the quality assurance aspects of Defendants' overall development process for the CAEv2. His testimony is not excludable simply because he has not personally conducted ARC testing. *See In re Zofran (Ondansetron) Prod. Liab. Litig*., No. 1:15md2657, 2019 WL 5685269, at *4 n.2 (D. Mass. Nov. 1, 2019) ("An expert's testimony is not excludable simply because she has not personally engaged in the specific task on which she is testifying."). For these reasons, McKinley's

quality assurance testing opinion is relevant, reliable, and helpful. Thus, it is admissible under Rule 702 and *Daubert*.

3. Reliability of McKinley's Comparisons of the CAEv2 to Other Hearing Protectors

McKinley also offers opinions that the CAEv2 was comparatively less safe than several other hearing protectors, including the CAEv4, CAEv4.1, Surefire Sonic Defender EP4 ("Surefire EP4"), and Moldex BattlePlug. *See* McKinley Rep., ECF No. 1630-18 at 108-111. Defendants argue McKinley's comparisons are unreliable because he did not compare the CAEv2's performance on REAT and other testing to field tests of the comparator earplugs. This argument fails. To begin with, McKinley testified that he was involved in comparative testing of the Surefire EP4 and the CAEv2, *see* McKinley Dep., ECF No. 1605-24 at 20, and his report reflects he is familiar with the results of Defendants' own internal comparative tests of the CAEv4 and Surefire EP4, *see* McKinley Rep., ECF No. 1630-18 at 109. Moreover, McKinley examined the comparator earplugs and explained how each one's design avoids the safety problems allegedly inherent in the design of the CAEv2. This was an acceptable, discernible, and repeatable methodology for comparing the various hearing protectors. Criticisms of the particular data points that McKinley used in his comparison are directed at the probative value of his opinion, not its admissibility. *See Rosenfeld v. Oceania Cruises, Inc.*, 654 F.3d 1190, 1193 ("[I]n most cases, objections to the adequacies of a study are more

appropriately considered an objection going to the weight of the evidence rather than its admissibility."); *Quiet Tech.*, 326 F.3d at 1345 ("[N]ormally, failure to include variables will affect [an] analysis' probativeness, not its admissibility) (quoting *Bazemore*, 478 U.S. at 400).

Based on the foregoing, the Court finds that McKinley's challenged opinions are within the scope of his expertise, the product of reliable principles and methods, and the result of a reliable application of those methods to the facts of this litigation. Accordingly, Defendants' motion to exclude certain of McKinley's opinion is due to be denied in its entirety.

K. Dr. Mark Packer

Dr. Mark Packer is board-certified in otolaryngology, neurotology, and otology, and now serves as Medical Director of Neurotology at Mercy Hospital in St. Louis, Missouri. He previously served in the United States Air Force as, among other things, a flight surgeon, Chief Otolaryngology Element at Elmendorf Air Force Base, and Chief of Neurotology and Cranial Base Surgery at Lackland Air Force Base. His work in those roles involved the "full scope of otolaryngology medical and surgical practice," including the diagnosis and treatment of noise-induced hearing loss and tinnitus sustained by service members, as well as noise hazard identification and analysis, occupational audiometric analysis, performing medical board profiles regarding occupational hearing loss and vestibular injury, and

evaluating the fit, safety, and efficacy of hearing protection devices. From 2009 to 2016, when Dr. Packer retired from the Air Force, he served as Executive Director of the Department of Defense Hearing Center of Excellence, advising the Assistant Secretary of Defense for Health Affairs and the Surgeon General of the Uniformed Services on hearing health-related matters and developing and executing the Center's "mandate to oversee the prevention, diagnosis, mitigation, treatment, and rehabilitation of hearing loss and auditory system injury" in the military. *See* Packer Rep., ECF No. 1605-7 at 5.

Dr. Packer offers general expert opinions that, among other things, the CAEv2 is unreasonably dangerous and can cause noise-induced hearing loss and tinnitus; Defendants were negligent in testing, marketing, and selling the CAEv2; Defendants failed to adequately warn about the CAEv2's dangers; and there were safer alternative designs to the CAEv2. Defendants challenge certain aspects of Dr. Packer's opinions on reliability and helpfulness grounds, and characterize other aspects of his opinions as impermissible factual narratives, legal conclusions, and state-of-mind opinions.[60] The former challenges are addressed below, whereas the latter arguments are addressed in the attorney mouthpiece section of this Order.

[60] Defendants also challenge the adequacy of Dr. Packer's differential diagnoses for Plaintiffs Estes and Baker; however, the Court has already found those differential diagnoses are reliable. *See supra* Sec. II(A). Defendants' objections to Dr. Packer's opinion regarding Baker's PTSD will be addressed in a separate order.

1. Reliability of Comparison of CAEv2 to Other Hearing Protectors

Dr. Packer offers a general expert opinion that "numerous" safer alternative designs existed when the CAEv2 was on the market, all of which were cost-effective and feasible, and none of which had the design flaws of the CAEv2. *See* Packer Rep. (General), ECF No. 1605-7 at 105. According to Dr. Packer, these safer alternatives included the various foam and premolded flanged earplugs listed in the 2006 United States Army Center for Health Promotion and Preventive Medicine Technical Guide 41; the CAEv1, CAEv3, CAEv4, and CAEv4.1; the Surefire Sonic Defender; the Moldex BattlePlug; and custom molded earplugs. Defendants argue Dr. Packer's comparisons are unreliable because he did not review internal corporate documents from the manufacturers of the comparator plugs—such as the companies' corporate reporting structure or the design and development data for their respective products—to ensure that testing and labeling protocols were followed, even though he reviewed this same data from Defendants as part of his evaluation of the CAEv2. This argument fails. Several of Dr. Packer's proposed safer alternatives are 3M products, and his general report cites a multitude of testing and other internal documents that he analyzed with respect to those products. *See, e.g.*, Packer Rep. (General), ECF No. 1631-23 at 132-177. Dr. Packer's general report also demonstrates his knowledge and review of a slew of design materials, testing data,

and scientific literature related to the Surefire and Moldex products.[61] At his deposition, Dr. Packer confirmed that he reviewed attenuation ratings for the Moldex BattlePlug, as well as testing and comparisons of that product to different earplugs. *See* Packer Dep., ECF No. 1606-9 at 9. Taken together, Dr. Packer's general report and deposition testimony establish good and reliable grounds for his safer alternative designs opinion. To the extent Defendants believe there are relevant additional materials that Dr. Packer should have considered, that criticism may be appropriately addressed through cross-examination and the "presentation of contrary evidence." *See Daubert*, 509 U.S. at 596.

2. Future Prognosis Opinions

Dr. Packer offers opinions that both Plaintiffs Estes and Baker's noise-induced hearing loss and tinnitus "will almost certainly worsen" if the plaintiffs develop certain comorbidities in the future.[62] *See* Packer Rep. (Baker), ECF No.

---

[61] *See, e.g.*, Packer Rep. (General), ECF No. 1631-23 at 157 (emails discussing problems with the Surefire plug dated Nov. 10, 2009); *id*. at 159 (Michael & Associates Letter re Impulse Testing of CAEv2 and Moldex BattlePlug dated Aug. 16, 2010); *id*. at 160 (thread re New CAE Competitor from Moldex dated March 7, 2011); *id*. (email attaching Moldex Filter Technical Drawing and Patent No. 6,068,079 dated March 15, 2011); *id*. (IL Tests of Combat Arms Earplug and Moldex Combat Earplug Using KEMAR dated March 21, 2011); *id*. at 163 (Evaluation of the Surefire Sonic Defenders Plug dated April 13, 2012); *id*. at 165 (email attaching memos re Similarity of Moldex Battleplugs and CAE dated June 12, 2013); *id*. at 168 (Williams, *et al*., USAARL *Assessment of Four Passive Hearing Protection Devices for Continuous Noise Attenuation, Impulsive Noise Insertion Loss, and Auditory Localization Performance*, dated Nov. 17, 2014); *id*. at 183-84 (Abel and Nakashima, *An Investigation of the Attenuation Provided by the Surefire EP3 Sonic Defender Earplug*).

[62] Dr. Packer offered several examples of possible comorbid conditions that could arise and "affect things," including sleep apnea, arthritis requiring the use of nonsteroid anti-inflammatory drugs, weight gain, and elevated cholesterol. *See* Packer Dep., ECF No. 1606-9 at

1630-61 at 61; Packer Rep. (Estes), ECF No. 1630-62 at 54. He also opines that Baker and Estes are "more likely than not at increased risk for dementia," given their respective early ages when their noise-induced hearing problems began. *See id*., ECF No. 1630-61 at 30; ECF No. 1630-62 at 23. Defendants challenge these opinions as speculative, unreliable, and unhelpful because neither Estes nor Baker currently suffers from dementia or any other comorbidity found to be associated with hearing loss in the scientific literature.

The Court agrees that Dr. Packer's opinion about the myriad of possible medical conditions (including dementia) that *could* one day "crop up" and "lead to worsening of" these plaintiffs' hearing problems is speculative, given Dr. Packer's acknowledgement that this opinion was essentially a "walk[] down a path of possibilities," *see* Packer Dep., ECF No. 1606-9 at 4, and the fact that current scientific literature has not established that a causal relationship exists between the possible medical comorbidities described by Dr. Packer and noise-induced hearing loss or tinnitus, *see* Packer Rep. (General), ECF No. 1605-7 at 40-42.[63] Accordingly,

---

5. He also opined that Estes and Baker's noise-induced hearing loss and tinnitus "will almost certainly worsen with age." *See* Packer Dep., ECF No. 1606-9 at 3. Defendants do not challenge Dr. Packer's opinion regarding age-related decline with Plaintiffs' noise-induced hearing problems. *See* Def. Mot., ECF No. 1605 at 133-34.

[63] Again, in the Eleventh Circuit, the requisite causal relationship is established by demonstrating, through primary and secondary methodologies, that a mechanism is "generally capable of causing" the type of harm alleged by the plaintiff. *See Hendrix II*, 609 F.3d at 1195; *Navelski*, 244 F. Supp. 3d at 1293.

Dr. Packer will not be permitted to testify that Estes or Baker may, or will, develop certain medical conditions (including dementia) in the future that may, or will, worsen their noise-induced hearing problems. *See Williams v. Int'l Paper Co*., No. 1:08cv045, 2009 WL 10678735, at *5 (S.D. Ga. June 30, 2009) (expert allowed to testify "to a reasonable degree of medical certainty" that Cushing syndrome is a known consequence of taking corticosteroids, but could not testify that the plaintiff may, or would, develop Cushing syndrome as a result of his exposure to corticosteroids). However, as with Dr. Bielefeld, Dr. Packer may offer opinions on the non-medical correlative consequences of noise-induced hearing problems that are discussed in his report, such as garden variety psychological distress, fatigue, irritability, and decreased workplace safety and productivity.

L. Eric Rose

Eric Rose is an industrial engineer with 40 years of experience in the design, developing, prototyping, testing, and manufacturing of consumer, medical, and industrial products, including hearing protection devices and other personal protective equipment. As part of that work, he has written, taught, and audited International Standards Organization (ISO) 9001 procedures, certification, and compliance for more than 25 years. Rose offers an opinion that Aearo's design and development process for the CAEv2 departed from both industry and its own design quality standards, which "increas[ed] the risk of product defects in the CAEv2 and

[c]ontributed to the [s]ale of a [p]roduct that [w]as [u]nreasonably [d]angerous [w]hen [u]sed as [i]ntended." *See* Rose Rep., ECF No. 1630-33 at 25.

Defendants do not challenge Rose's qualifications or his opinions that Aearo violated industry and internal corporate standards. Rather, they seek to exclude "his unsupported leap" to the conclusion that their alleged violations increased the risk of product defects and was a substantial factor in their sale of an "unreasonably dangerous product." *See* Def. Motion, ECF No. 1605 at 84. In Defendants' view, Rose's "defect-related" opinions are inadmissible because they are not supported by any methodology, he lacks evidence that a Plaintiff used a CAEv2 with the supposed defects he alleges, his increase-the-risk opinion is vague and unhelpful, and the opinions are impermissible legal conclusions.

1. Methodology for Rose's "Defect-Related" Opinions

Defendants first argue that Rose's opinions that the CAEv2 was defective and that Aearo's design process was flawed are not based on any methodology. In their view, Rose "simply assume[d] these conclusions based on his interpretations of [internal corporate] documents . . ., without conducting any testing or analysis," *see* Def. Mot., ECF No. 1605 at 85; therefore, his defect-related opinions should be excluded. This is incorrect.

Rose's methodology for identifying alleged product defects and design process flaws was straightforward and readily apparent from his expert report. He

reviewed Defendants' internal documents relating to the design and development of the CAEv2 (including drawings of the device) and commissioned a CAD drawing of the CAEv2 and UltraFit earplugs to examine whether and how much the center of gravity moved in the CAEv2. From those materials, he identified alleged deficiencies in the CAEv2 itself and in Aearo's design process, relying on his undisputed product development and engineering expertise, applicable industry standards, Aearo's internal quality and design control standards, relevant industry literature, and the testing and opinions of other engineering and testing experts in this litigation. As to each alleged deficiency, Rose clearly explains both his conclusions and on what bases those conclusions were made, and connects the conclusions to his broader opinion that Defendants' quality assurance process for the CAEv2 was flawed, which contributed to product defects that could have been avoided with adequate quality controls. A methodology of this nature satisfies Rule 702 and *Daubert*.[64]

[64] *See McGee v. Evenflo Co., Inc*., No. 5:02cv259-4, 2003 WL 23350439, at *5 (M.D. Ga. Dec. 11, 2003) (citing *Milanowicz v. Raymond Corp*., 148 F. Supp. 2d 525 (D.N.J. 2001) ("[W]hen an engineer offers an opinion with respect to a product defect . . . it is relevant to weigh: (1) whether the expert relied on applicable standards, industry practice, or professional publications; or (2) whether the expert engaged in any substantive testing, measurements, or calculations to support his theories, or otherwise created illustrative models, charts or diagrams of any proposed design changes."); *see also Reid v. BMW of North America*, 430 F. Supp. 2d 1365, 1370 (N.D. Ga. 2006) ("In a products liability case, a technical field like engineering often relies on more idiosyncratic methods of design and testing. Therefore, it is more common that engineering experts state that their opinions are not based upon any scientific method but on general experience and knowledge after a review of evidence.") (internal cites omitted).

2. "Fit" of Rose's "Defect-Related" Opinions

Rose offers an opinion that Aearo's "substandard and out of control" design review and verification processes yielded a product with design inadequacies that, among other things, could—and sometimes *did*, in his opinion, based on his review of Aearo's internal documents—cause the stem to crack under stress or, during manufacturing, cause the earplug to be assembled backwards and/or its filter to be inserted backwards. *See* Rose Rep., ECF No. 1606-1 at 27; Rose Dep., ECF No. 1630-34 at 7-10. Defendants argue that this opinion does not fit the facts of this litigation because Rose has no evidence that any of the Plaintiffs used a CAEv2 with those alleged defects. This is incorrect. All of the Plaintiffs allegedly used a CAEv2 with other defects that Rose attributes to design process failures, most notably, an overly rigid and short stem connecting poorly positioned opposing flanges. Rose's opinion about additional design inadequacies and their consequences provides further relevant support for his general opinion about design process failures in violation of industry and internal corporate standards, which will assist the jury in evaluating Defendants' design and development phase for the CAEv2 in connection with the plaintiffs' negligence claims. Rose's "defect-related" opinions thus "fit" the facts of this litigation. Any potential for prejudice may be cured with a limiting instruction, if requested.

3. Specificity of Rose's "Increase-the-Risk" Opinion

Defendants also challenge Rose's opinion that their alleged departure from industry and their own design quality standards increased the risk of product defects.[65] In their view, that opinion is "vague and unspecific" because it "does not attempt to quantify or specify by how much this risk is increased." *See* Def. Mot., ECF No. 1605 at 87-88. This argument fails. Rose's expert report precisely identifies and describes *existing* product defects and specifically explains how those defects would have been prevented had Defendants' design review process complied with applicable quality assurance standards. In other words, Rose is not opining on "[m]ere possibilities," *see Mahli, LLC v. Admiral Ins. Co*., No. 1:14cv175, 2015 WL 4915701, at *11 (S.D. Miss. Aug. 18, 2015), or unspecific probabilities, *see Wu v. Miss. State Univ*., No. 1:13cv002, 2014 WL 5799972, at *12 (N.D. Miss. Nov. 7, 2014). And he is not offering a quantitative statistical analysis of relative risk, nor is one required to support his substantive conclusions on this issue. In short, there is no "analytical gap" in Rose's opinion. *See Cook ex. rel. Estate of Tessier v. Sheriff of Monroe Cnty*, 402 F.3d 1092, 1111 (11th Cir. 2005). His analytical steps are

[65] It is worth noting that Rose's actual opinions are not framed in terms of Aearo's alleged design and development failings "increasing the risk of product defects." While that phrase is clearly used in a header in Rose's report, *see* Rose Rep., ECF No. 1606-1 at 25, it does not appear anywhere else in the report, either explicitly or implicitly. Rather (and, again), Rose's substantive opinion is that the existing defects in the CAEv2 would have been avoided if Defendants had implemented adequate quality controls, which is no different than Defendants' witnesses opining that the military's alleged failure to properly fit and train Plaintiffs on the use of the CAEv2 increased the risk of hearing-related injuries for Plaintiffs, in light of their noise exposures.

clearly articulated and substantiated by a verifiable factual basis, which meets the precision and specificity requirements of Rule 702 and *Daubert*.

M. "Attorney Mouthpiece" Testimony

Defendants move to exclude portions of the opinions of Drs. Arriaga, Bielefeld, Eddins, Franks, Lustig, Packer and Spankovich, and Adm. Leslie and Eric Rose relating to the CAEv2's design, testing, and labeling on the basis that their opinions impermissibly narrate the factual record, offer legal conclusions, or speculate as to Defendants' state of mind. Defendants additionally embed within these objections challenges to the experts' qualifications to offer opinions on these topics. The Court first addresses Defendants' challenges to certain experts' qualifications before turning to Defendants' specific objections to the substance of the experts' testimony.

1. Qualifications

To fulfill its role as gatekeeper, the Court must determine whether an expert is "qualified to testify competently regarding the matters he intends to address." *Seamon v. Remington Arms Co., LLC*, 813 F.3d 983, 988 (11th Cir. 2016) (citation omitted). While "[a]n expert is not necessarily unqualified simply because [his] experience does not precisely match the matter at hand," *see City of S. Miami v. DeSantis*, No. 19-cv-22927, 2020 WL 7074644, at *4 (S.D. Fla. Dec. 3, 2020), an expert must "have at least some minimum training, education, experience,

knowledge, or skill" pertaining to the particular subject matter of his proposed testimony. *See Bouton v. Ocean Beach Props., Ltd.*, No. 16-cv-80502, 2017 WL 4792488, at *15 (S.D. Fla. Oct. 23, 2017); *see also Bowers v Norfolk S. Corp.*, 537 F. Supp. 2d 1343, 1376 (M.D. Ga. 2007) ("Rule 702 and *Daubert* still require that the area of the witness's competence match the subject matter of the witness's testimony."). Thus, "[a]n expert may be generally qualified but may lack qualifications to testify outside his area of expertise." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003).

a. Dr. Moises Arriaga

Moises Arriaga, M.D. is an otolaryngologist and professor at Louisiana State University Health Sciences Center. He has maintained an active clinical and surgical practice in the fields of otology and neurotology for nearly 30 years—first as an active duty physician in the United States Air Force from 1991 to 1996, and in civilian private practice thereafter. Defendants argue that Dr. Arriaga is not qualified to offer opinions regarding product design, testing, and labeling. The Court disagrees, with one exception.

i. Product Design

Defendants argue that Dr. Arriaga is not qualified to opine on the CAEv2's design because he is not an engineer and has not designed a preformed earplug. The Court disagrees. Dr. Arriaga has experience designing custom hearing protection

devices, including designing custom earplugs for military service members "for their individual anatomy." *See* Arriaga Dep., ECF No. 1631-22 at 73. Thus, while Dr. Arriaga is not qualified to opine on the CAEv2's design from an engineering perspective, he is qualified to opine on how various aspects of the CAEv2's design prevented proper fit and seal due to the variability in the anatomy of the human ear and ear canal. *See* Arriaga Rep. (General), ECF No. 1605-14 at 35, 43; *see In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013) (finding urogynecologist's "experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions" related to the product's design and materials "notwithstanding his lack of expertise in the particular areas of product design or biomaterials"). To be clear, however, Dr. Arriaga's opinions regarding the CAEv2's design may not exceed the scope of his experience-based expertise in ensuring earplugs fit an individual user's ear anatomy. *See Bouton*, 2017 WL 4792488, at *15.

ii. Product Testing

Defendants argue that Dr. Arriaga is not qualified to opine on the CAEv2's testing because he has never performed REAT testing in accordance with ANSI standards on a preformed earplug. Again, the Court disagrees. Dr. Arriaga has decades of experience evaluating hearing protection devices from a clinical perspective, based partially on NRR labelling. In particular, Dr. Arriaga testified at his deposition that he reviews REAT testing data in "selecting hearing protection

devices for [his] patients" and therefore has to "rely on that information all the time." *See* Arriaga Dep., ECF No. 1631-22 at 8. Moreover, while Dr. Arriaga has not conducted "a large commercial test like ANSI," he regularly performs "microphone-in-ear testing on [his] individual patients" for hearing protection devices. *See id*. Based on his familiarity with REAT testing data, Dr. Arriaga is qualified to opine on the data from REAT testing of the CAEv2. *See In re C.R. Bard., Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2018 WL 514753, at *3 (S.D. W. Va. Jan. 23, 2018) (finding urogynecologist qualified to opine on the sufficiency of a manufacturer's testing based, in part, on his experience "reviewing information from clinical trials regularly"); *cf. Trevino v. Bos. Sci. Corp.*, No. 2:13-cv-1617, 2016 WL 2939521, at *12 (S.D. W. Va. May 19, 206) (excluding urogynecologist's opinions on a product's testing because his "experience as a surgeon alone . . . does not translate into experience with or knowledge about the appropriate testing a medical device manufacturer should undertake when preparing a product for the market"). To be clear, however, Dr. Arriaga's opinions regarding the CAEv2's testing may not exceed the scope of his experience-based expertise in interpreting REAT testing data. *See Bouton*, 2017 WL 4792488, at *15.

iii. Product Labeling

Defendants also challenge Dr. Arriaga's qualifications to testify concerning the adequacy of the CAEv2's labeling. The Court agrees that Dr. Arriaga's

experience as a physician does not qualify him to opine on the EPA's regulatory requirements or whether the CAEv2's labels and warnings satisfy those requirements. *See* Arriaga Rep. (General), ECF No. 1605-14 at 37-38 (opining on EPA labeling requirements); *cf. Cason v. C.R. Bard, Inc.*, No. 1:12-CV-1288, 2015 WL 9913809, at *12 (N.D. Ga. Feb. 9, 2015) (permitting expert to opine on regulatory requirements where there was no dispute that the expert was qualified "in the field of FDA regulation of medical devices"). However, as an otolaryngologist, Dr. Arriaga is qualified to opine on the completeness and accuracy of the CAEv2's labels and warnings from a clinical perspective. *See* Arriaga Rep. (General) at 5 ("As part of my medical practice . . . I advise patients to, among other things, compare products by reviewing the NRRs. The manufacturers reported NRR is an important indicator for protection and relied upon by my patients and by me in giving advice."); *Trevino*, 2016 WL 2939521, at *13 (permitting urogynecologist to opine on the completeness and accuracy of a product's warnings "from a clinical perspective"); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 (S.D. W. Va. 2014) (finding that, "as a urogynecologist," an expert was "qualified to opine generally about the [product's] warnings and marketing materials").

b. Dr. Eric Bielefeld

Dr. Eric Bielefeld, as already discussed, is a licensed audiologist and associate professor with nearly two decades of professional experience researching,

publishing, teaching, diagnosing and treating, and/or consulting for private industry and the government in the field of audiology. Defendants argue that the portion of Dr. Bielefeld's opinions in which he identifies "numerous problems" with the "development, efficacy, and warnings/instructions" for the CAEv2 must be excluded because those opinions fall outside his expertise. Again, with one exception, the Court disagrees.

i. Product Design

The Court finds Dr. Bielefeld is qualified to opine on the CAEv2's design. Defendants argue that Dr. Bielefeld has no earplug design experience. But, like Dr. Arriaga, Dr. Bielefeld has created "custom-molded earplugs" for his patients. *See* Bielefeld Dep., ECF No. 1605-3 at 8. Thus, while Dr. Bielefeld is not qualified to opine on the CAEv2's design from an engineering perspective, he is qualified to opine on how various aspects of the CAEv2's design prevented proper fit and seal due to the variability in the anatomy of the human ear and ear canal. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 612. As with Dr. Arriaga, Dr. Bielefeld's opinions regarding the CAEv2's design may not exceed the scope of his experience-based expertise in ensuring earplugs fit an individual user's ear anatomy. *See Bouton*, 2017 WL 4792488, at *15.

ii. Product Testing

Defendants argue that Dr. Bielefeld is unqualified to opine on the CAEv2's testing because he has never tested an earplug to determine whether it is defective. The Court disagrees. Dr. Bielefeld teaches a class on hearing conservation to upper division audiology graduate students in which he teaches them about fit testing and REAT testing and evaluates whether the students correctly perform the tests. *See* Bielefeld Dep., ECF No. 1605-3 at 11-12. Based on his familiarity with REAT testing, Dr. Bielefeld is at least "minimally qualified" to opine on the REAT testing of the CAEv2. *See In re C.R. Bard., Inc.*, 2018 WL 514753, at *3; *cf. Trevino*, 2016 WL 2939521, at *12. The Court reiterates that Dr. Bielefeld's opinions may not exceed the scope of his experience-based expertise with REAT testing. *See Bouton*, 2017 WL 4792488, at *15.

iii. Product Labeling

Defendants also challenge Dr. Bielefeld's qualifications to opine on adequacy of the CAEv2's labeling. The Court agrees that Dr. Bielefeld's experience as a physician does not qualify him to opine on the EPA's regulatory requirements and whether the CAEv2's labels and warnings satisfy those requirements. *See* Bielefeld Dep., ECF No. 1605-3 at 34-35 (conceding that the EPA's labeling requirements "goes outside my area of expertise"); *cf. Cason*, 2015 WL 9913809, at *12. However, based on his clinical experience as an audiologist, Dr. Bielefeld is

qualified to opine on the completeness and accuracy of the CAEv2's labels and warnings from a clinical perspective. *See* Bielefeld Dep., ECF No. 1605-3 at 34 ("I can look at an instruction and think whether this would work or not for the patient. And that's the focus that I have . . . ."); *Trevino*, 2016 WL 2939521, at *13; *Huskey*, 29 F. Supp. 3d at 704.

c. Dr. Lawrence Lustig

Dr. Lawrence Lustig is a physician (board-certified in otolaryngology and neurotology), professor, and Chair of the Department of Otolaryngology (Head & Neck Surgery) at Columbia University Irving Medical Center and New York Presbyterian Hospital in New York. He has maintained an active medical and surgical practice in the fields of otolaryngology and neurotology for more than 25 years, while also researching, publishing, consulting, and teaching on a wide range of hearing-related issues, including noise-induced hearing loss, tinnitus, and hearing protection devices. Defendants move to exclude portions of Dr. Lustig's opinions regarding the CAEv2's design, testing, and labeling on the basis that these topics are "outside his treating-physician expertise." *See* Def. Mot., ECF No. 1605 at 34. The Court agrees, in part.

i. Product Design

The Court finds Dr. Lustig qualified to opine on the CAEv2's design to the extent his opinions fall within the scope of his experience in designing devices that

go into the ear "on a daily basis." *See* Lustig Dep., ECF No. 1631-27 at 7. In particular, Dr. Lustig's experience in sizing and fitting hearing protection devices for his patients qualifies him to opine on how various aspects of the CAEv2's design prevented proper fit and seal due to the variability in the anatomy of the human ear and ear canal. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 612. As with Drs. Arriaga and Bielefeld, Dr. Lustig may not offer opinions regarding the CAEv2's design that exceed the scope of his experience-based expertise in ensuring earplugs fit an individual user's ear anatomy. *See Bouton*, 2017 WL 4792488, at *15.

ii. Product Testing

Defendants challenge Dr. Lustig's opinions regarding the testing of the CAEv2 because he has never performed laboratory research on the safety of a hearing protection device. The Court disagrees. In his experience as a clinician, Dr. Lustig has "an understanding of how [an earplug's] NRR is calculated" because he "oversee[s] a team of audiologists that routinely do" REAT tests and has reviewed REAT testing data for hearing protection devices. *See* Lustig Dep., ECF No. 1605-2 at 9, 21. Based on his familiarity with REAT testing, Dr. Bielefeld is qualified to opine on the REAT testing of the CAEv2, but his testimony may not exceed the scope of his experience-based expertise. *See In re C.R. Bard., Inc.*, 2018 WL 514753, at *3; *Bouton*, 2017 WL 4792488, at *15; *cf. Trevino*, 2016 WL 2939521, at *12.

iii. Product Labeling

The Court agrees that portions of Dr. Lustig's opinions must be excluded to the extent he attempts to render an opinion on the adequacy CAEv2's labels or warnings based on the Noise Control Act or EPA regulations. Dr. Lustig's experience does not qualify him to opine on these topics. While Dr. Lustig's experience qualifies him to opine generally on "the types of information that goes into a label" of "ear-related products" from the perspective of an otolaryngologist, *see* Lustig Dep., ECF No. 1605-2 at 3-4 (explaining that he is "very familiar" with the data that goes into labels of "ear-related products"), he is not qualified to opine on the EPA's regulatory requirements relating to the labelling of hearing protective devices, *see id.* at 6, 8 ("I can say that I . . . was aware that there were EPA regulations surrounding the use of hearing protective devices and how they're labeled. I can't tell you specifically or whether or not I've read the specific EPA regulations prior to this case . . . . So if you're asking was I looking at the actual regulations themselves on a regular basis, I would say the answer is no."). *See Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 440 (E.D.N.Y. 2011) (excluding physicians' opinions regarding compliance with FDA labeling regulations, but explaining that "this does not mean that [the physicians] cannot opine as to the adequacy of the labels from the perspective of oncologists and prescribing physicians"); *cf. Cason*, 2015 WL 9913809, at *12. Thus, Dr. Lustig may testify, based on his experience and expertise,

that Defendants "violat[ed] general industry norms" regarding the labeling of hearing protection devices. *See, e.g.*, Dr. Lustig Report at 48. He may not, however, opine that the CAEv2's labelling did not comply with EPA regulations. *See id.*

d. Dr. Christopher Spankovich

Dr. Christopher Spankovich is an associate professor, Vice Chair of Research, and Director of Audiology Education in the Department of Otolaryngology and Communicative Sciences at The University of Mississippi Medical Center. He is also a licensed audiologist with a clinical practice that is "heavily weighted toward differential diagnos[e]s" and management of acquired forms of hearing loss, tinnitus, and sound sensitivity. *See* Spankovich Rep. (General), ECF No. 1605-8 at 4. Defendants seek to exclude Dr. Spankovich's opinion regarding the design of the CAEv2 on the basis that it falls outside the realm of his expertise. The Court agrees that Dr. Spankovich is not qualified to opine on the CAEv2's design from an engineering perspective. *See* Spankovich Dep., ECF No. 1631-36 at 13 ("I am not an engineer of hearing protection devices."). However, as a clinical audiologist, Dr. Spankovich has extensive experience fitting patients with hearing protection devices. *See id*. at 14-15; *see also id.* at 19 (explaining that "we want the foam earplug sitting deeply as possible in the ear canal, flush, if possible, with the external opening of the ear canal to achieve the greatest attenuation"). The Court finds that Dr. Spankovich's clinical experience qualifies him to opine on how various aspects

of the CAEv2's design prevented proper fit and seal due to the variability in the anatomy of the human ear and ear canal. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 612. Of course, Dr. Spankovich may not offer opinions regarding the CAEv2's design that exceed the scope of his experience-based expertise in ensuring earplugs fit an individual user's ear anatomy. *See Bouton*, 2017 WL 4792488, at *15.

2. "Attorney Mouthpiece" Objections

Defendants object to portions of various experts' opinions on the grounds that they impermissibly narrate the factual record,[66] offer legal conclusions, or speculate as to Defendants' state of mind. Because the substance of Defendants' objections to each expert's opinions largely overlap, the Court finds it is appropriate to generally address the proper scope of these experts' testimony before addressing expert-specific issues.

"Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing

[66] In addition to their objection that portions of numerous experts' opinions improperly narrate evidence, Defendants further object that these portions "are fatally defective because . . . they also do not narrate a fair sample of that evidence." The Court disagrees. Defendants "criticisms regarding the universe of documents the experts considered go to the weight to be accorded these experts' opinions, rather than its admissibility." *See In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769, 2009 WL 3806436, at *4 (M.D. Fla. July 20, 2009); *United States ex rel. Howard v. Lockheed Martin Corp.*, No. 1:99-cv-285, 2014 WL 1233081, at *7 (S.D. Ohio Mar. 25, 2014) (finding defendant's objection that the plaintiff's experts "rel[ied] on only a set of documents hand-picked by [the plaintiff's] attorneys . . . bear[s] more on the weight of the evidence than its admissibility"). Defendants may subject the factual bases for the experts' opinions to vigorous cross-examination at trial.

arguments." *Cook*, 402 F.3d at 1111. Accordingly, an expert may not speculate as to a person's state of mind or "simply recount[] the facts and then offer[] an opinion as to the conclusion which the jury should reach." *See Omar v. Babcock*, 177 F. App'x 59, 63 n.5 (11th Cir. 2006); *see also United States v. Hawkins*, 934 F.3d 1251, 1263 (11th Cir. 2019) (finding allowance of expert witness's testimony constituted plain error where his testimony "strayed into speculation and unfettered, wholesale interpretation of the evidence"). An expert may, however, "explain[] the basis of admissible opinions through commentary on documents and exhibits in evidence." *Arevalo v. Coloplast Corp.*, No. 3:19cv3577, 2020 WL 3958505, at *21 (N.D. Fla. July 7, 2020); *see Ohio State Troopers Ass'n , Inc. v. Point Blank Enters., Inc.*, No. 18-CV-63130, 2020 WL 1666763, at *15–16 (S.D. Fla. Apr. 3, 2020) (an expert may narrate facts "which many be necessary to provide the facts supporting his opinions); *FNB Bank v. Park Nat'l Corp.*, 996 F. Supp. 2d 1187, 1190 (S.D. Ala. 2014) (declining to exclude portion of expert's report that "provide[d] the necessary factual underpinning for his opinions").

Moreover, "questions of law are not subject to expert testimony." *Commodores Enter. Corp. v. McClary*, 879 F.3d 1114, 1128–29 (11th Cir. 2018); *see Montgomery*, 898 F.2d at 1541 ("A witness . . . may not testify to the legal implications of conduct; the court must be the jury's only source of law."). While "[a]n opinion is not objectionable just because it embraces an ultimate issue" *see*

Fed. R. Evid. 704, "courts must remain vigilant against the admission of legal conclusions," and have therefore "excluded expert testimony that employs terminology with legal import . . . ." *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1325 (M.D. Fla. 2015) (citation omitted). A non-lawyer expert therefore "cannot testify about the meaning of a statute or regulation or about whether someone violated a law." *Claussen v. PowerSecure, Inc.*, No. 3:18-CV-607, 2019 WL 4941109, at *8 (M.D. Ala. Oct. 7, 2019). An expert may not "testify that . . . statutes [or] laws were violated as a matter of law, about the meaning of legal terms . . . or the legal effect of" the statutes or laws. *Id.* Nor may an expert use terms that "have a separate, distinct and specialized meaning in the law different from that present in the vernacular." *Tillman*, 96 F. Supp. 3d at 1325 (quoting *Torres v. Cty. of Oakland*, 758 F.2d 147, 151 (6th Cir. 1985)). Relatedly, "[a]bsent any need to clarify or define terms of art, science, or trade, expert opinion testimony to interpret contract language is inadmissible." *Howard*, 2014 WL 1233081, at *8 (citation omitted); *see Sparton Corp. v. United States*, 77 Fed. Cl. 1, 8 (Fed. Cl. 2007) ("In the absence of specialized trade usage, expert testimony regarding proper contract interpretation is inadmissible, as is expert testimony regarding the legal significance of the contract language.").

"But where 'the substance of the expert's testimony concerns ordinary practices and trade customs which are helpful to the fact-finder's evaluation of the

parties' conduct against the standard of ordinary practice in the [] industry, his passing reference to a legal principle or assumption in an effort to place his opinions in some sort of context will not justify the outright exclusion of the expert's [testimony] in its entirety." *Claussen*, 2019 WL 4941109, at *8. Accordingly, a qualified expert may "testify about industry standards of care, which may be reflected in regulations and statutes, and he can testify about how a reasonable operator in the industry would comply with these statutes and regulations." *See id.*; *Haines v. Webb*, No. 1:13-CV-1783, 2014 WL 12828962, at *9 (N.D. Ga. Sept. 26, 2014) (an expert may "offer opinions as to the applicable standard of care and what conduct he believes fell short of that standard"); *Arevalo*, 2020 WL 3958505, at *21 ("[T]estimony regarding the 'standard of care' in the context of explaining the standard of care in the industry, as opposed to the legal standard of care, is permissible.").

Applying these standards, the Court finds that, while perhaps occasionally crossing the line into improper factual narration, the experts' opinions are not unhelpful narrative accounts but are instead commentary on evidence that explains the factual bases of their opinions related to the CAEv2's development, efficacy, and warnings/instructions. *Arevalo*, 2020 WL 3958505, at *21; *Ohio State Troopers Ass'n , Inc.*, 2020 WL 1666763, at *15; *FNB Bank*, 996 F. Supp. 2d at 1190. The Court will not issue a "blanket ban" on discussions of internal documents and

declines to parse the experts' reports and depositions for statements that may cross the line into improper factual narration. However, the parties are cautioned that the experts may testify as to their review of internal corporate documents only to the extent necessary to explain the factual underpinnings of their admissible opinions. They will not be permitted to stray into "unfettered, wholesale interpretation of the evidence" or to testify to "simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs' theory of the case." *See Hawkins*, 934 F.3d at 1263; *Cason*, 2015 WL 9913809, at *13; *Huskey*, 29 F. Supp. 3d at 702–03.

With respect to Defendants' objection that Plaintiffs' experts' improperly offer legal conclusions, the Court will permit the experts to opine—within their spheres of expertise—on the problems they identified with the design, fitting, testing, and labeling of the CAEv2 because it will assist the jury in determining the ultimate issue of fact of whether the CAEv2 was defectively designed and/or whether Defendants' warnings were sufficient. *See Tillman*, 96 F. Supp. 3d at 1322–23, 26 (permitting experts to opine on "the adequacy of Bard's testing" and to testify "that the testing performed was incompetent as a matter of engineering and design principles"); *Arevalo*, 2020 WL 3958505, at *21 (permitting experts to use phrases such as "safer alternative design," "risks . . . outweigh the benefits," "adequate," and "inadequate"). The experts may also opine as to whether Defendants adhered to industry standards of care to the extent they are qualified to offer such an opinion.

See Arevalo, 2020 WL 3958505, at *21; *Anderson v. Techtronic Indus. N. Am., Inc.*, No. 6:13-cv-1571, 2015 WL 12843836, at *5 (M.D. Fla. Apr. 14, 2015); *Haines*, 2014 WL 12828962, at *9. The experts may not, however, couch their opinions in terms that "carry special meaning under the law and are contingent upon application of the appropriate standard of care" such as "defective," "duty," "unreasonably dangerous," or "failed to warn."[67] *See Tillman*, 96 F. Supp. 3d at 1325–26; *Arevalo*, 2020 WL 3958505, at *20; *Montgomery*, 898 F.2d at 1547; *In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2018 WL 4212409, at *3 (S.D. W. Va. Sept. 4, 2018) (precluding an expert witness from testifying that "omission of instructions or warnings . . . rendered the [product] not reasonably safe" and that the product's design was "unreasonably dangerous and defective").

Finally, the Court agrees with Defendants that portions of the experts' opinions constitute impermissible state-of-mind testimony. While the experts may testify as to whether information contained in Defendants' internal documents indicated certain risks to users of the CAEv2, they may not opine as to what Defendants "knew," what they intended, or what their motives were. *See Deutsch*, 768 F. Supp. 2d at 443; *Tillman*, 96 F. Supp. 3d at 133 (permitting expert to opine "on what information and knowledge was available to [the defendant]," but

[67] Likewise, Defendants' experts may not use terms such as "non-defective," "reasonably safe," or "properly warned."

excluding opinions on defendant's "intent, motive, or what it should have done with that information"); *Ma v. Equifax Info. Servs., LLC*, 288 F. Supp. 3d 1360, 1367 (N.D. Ga. 2017) ("[A]lthough [the expert] may not know Defendant's subjective intent, he may be able to testify as to what information would mean to a reasonable credit reporting agency in a more objective sense."); *Szott v. Baxter Healthcare Corp.*, No. 03-80693, 2007 WL 9702568, at *4 (S.D. Fla. Aug. 14, 2007) (precluding expert testimony regarding the defendant's "financial motivations" in modifying its processes); *Cason*, 2015 WL 9913809, at *13 (excluding expert testimony that the defendant "knew about the hazards associated with the [product]," "knew that its testing was inadequate to address these hazards," and that it was the defendants' "intent to make it easier to pass tests by using less demanding standards instead of improving design"). Such determinations are properly made by the factfinder.

a. Dr. Moises Arriaga

i. Factual Narratives

Defendants move to exclude portions of Dr. Arriaga's Report on the basis that they constitute impermissible factual narrative. In support, Defendants cite to a single paragraph in Dr. Arriaga's report that states, in part, "3M had no idea whether the CAEv2 was safe and effective when it started selling it because it had never tested it. It did not 'occur' to 3M that it did not have any data on the earplug until four months after it started selling the earplugs to the military." Arriaga Rep., ECF

No. 1605-14 at 47 (citing 3M_MDL000257805). The Court addresses this testimony in connection with Defendants' objection that this statement constitutes impermissible "state-of-mind" testimony.

ii. Legal Conclusions

Defendants object to Dr. Arriaga's opinions that the CAEv2 "is Defective," that 3M "Had a Duty to Stop Selling the Product And To Tell The Military," "Had a Duty to Test," and "Failed to Warn" on the basis that these opinions are improper legal conclusions. The Court agrees that Dr. Arriaga may not couch his opinions in legal terms. *See Tillman*, 96 F. Supp. 3d at 1325–26; *Arevalo*, 2020 WL 3958505, at *20; *Montgomery*, 898 F.2d at 1547; *In re C.R. Bard, Inc.* , 2018 WL 4212409, at *3.

iii. State-of-Mind

Defendants object that Dr. Arriaga improperly opines on 3M's state of mind, including his opinion as to what 3M "hop[ed]," had "no idea" about, and what 3M knew or did not know. The Court agrees that these opinions are improper. *See Deutsch*, 768 F. Supp. 2d at 443; *Tillman*, 96 F. Supp. 3d at 133; *Ma*, 288 F. Supp. 3d at 1367; *Szott*, 2007 WL 9702568, at *4; *Cason*, 2015 WL 9913809, at *13.

b. Dr. Eric Bielefeld

i. Factual Narratives

Defendants object to Dr. Bielefeld's opinions that the CAEv2 was defective, that 3M failed to give a warning about the defect, and "other opinions" on the grounds that they are based solely on impermissible characterization of documentary evidence. In support, Defendants cite to two examples from Dr. Bielefeld's deposition testimony and Report. First, at his deposition, Dr. Bielefeld testified that "the flange memo speaks for itself." Bielefeld Dep., ECF No. 1605-3 at 37-38. Second, in his Report, Dr. Bielefeld states that "3M did not share their full test reports or internal documentation about the plug's weaknesses with either the military or other end users," and that "3M did not share their full test reports." *See* Bielefeld Rep., ECF No. 1605-4 at 69. The Court disagrees. The statements cited by Defendants are not an unhelpful narrative account of events but are instead commentary on evidence that explains the factual bases of his opinions related to the CAEv2's development, efficacy, and warnings/instructions. *Arevalo*, 2020 WL 3958505, at *21; *Ohio State Troopers Ass'n , Inc.*, 2020 WL 1666763, at *15; *FNB Bank*, 996 F. Supp. 2d at 1190.

ii. Legal Conclusions

Defendants object to Dr. Bielefeld's opinions that the CAEv2 was "defective," that Defendants put CAEv2 users "at an unreasonable risk of harm,"

that Defendants "failed to . . .warn" on the ground that these opinions constitute improper legal conclusions. Defendants also object that Dr. Bielefeld's testimony as to what "reasonable" audiologists would do is also an improper legal conclusion. The Court agrees, in part. Dr. Bielefeld may opine as to the standard of care in audiology. *See Arevalo*, 2020 WL 3958505, at *21; *Anderson*, 2015 WL 12843836, at *5; *Haines*, 2014 WL 12828962, at *9. He may not, however, opine that Defendants "failed to warn," put CAEv2 users "at an unreasonable risk of harm," or that the CAEv2 was "defective," because those terms "carry special meaning under the law and are contingent upon application of the appropriate standard of care." *See Tillman*, 96 F. Supp. 3d at 1325–26; *Arevalo*, 2020 WL 3958505, at *20; *In re C.R. Bard, Inc.*, 2018 WL 4212409, at *3.

c. Dr. David Eddins

i. Factual Narratives

Defendants object to the "Background" section of Dr. Eddins' Report on the basis that it contains a "narrative description" of military noise exposures, the DoD hearing program, rates of hearing loss among service members, and Aearo's design and development activities relating to the CAEv2. The Court disagrees. A review of this section of Dr. Eddins' Report reveals that his commentary on these topics is necessary to explain his opinions regarding the fit, function, and usability of the

CAEv2. *See Arevalo*, 2020 WL 3958505, at *21; *Ohio State Troopers Ass'n , Inc.*, 2020 WL 1666763, at *15; *FNB Bank*, 996 F. Supp. 2d at 1190.

d. Dr. John Franks

i. Legal Conclusions

Defendants object to certain opinions offered by Dr. Franks on the basis that they are improper legal conclusions. Specifically, Defendants move to exclude Dr. Franks' opinion that the EPA's labelling regulations apply to military sales, that Aearo violated those regulations, and that the CAEv2 did not meet the "Salient Characteristics" requirements set forth in the military's purchasing contracts. The Court agrees, in part. Dr. Franks' experience advising the EPA "on all matters regarding the testing and labeling of hearing protectors," *see* Franks Rep., ECF No. 1606 at 4, qualifies him to testify as to whether Defendants complied with the applicable standard of care in the hearing protection device manufacturing industry, which may be reflected in EPA regulations. *See Claussen*, 2019 WL 4941109, at *8; *cf. Tillman*, 96 F. Supp. 3d at 1329 (permitting expert to "testify regarding the regulatory process by which medical devices like the G2 Filter are brought to market" and to opine "as to whether [the defendant] complied with all FDA regulatory requirements applicable to the G2 Filter"); *Loewen v. Wyeth, Inc.*, No. CV 03-J-2166, 2011 WL 6140908, at *2 (N.D. Ala. Nov. 14, 2011) (finding expert qualified to testify "with respect to the FDA's rules, regulations and requirements,"

as to "whether defendants complied" with the FDA's regulations, and "the reasonableness of defendants' conduct in light of" the FDA's regulations); *Forman v. Novartis Pharms. Corp.*, 794 F. Supp. 2d 382, 384 (E.D.N.Y. 2011) (permitting expert "to render opinions on 'the reasonableness of Novartis' conduct in its . . . compliance with FDA regulations . . . including Novartis' interactions with FDA with respect to labels and warnings"). He may also explain the military purchasing contract's "Salient Characteristics" requirements to the extent the requirements have specialized meaning or are based on trade practice or usage and may testify as to whether the CAEv2 conformed to the requirements. For example, Dr. Franks may explain the meaning of the various ANSI standards referenced in the contracts and the meaning of the term "NVLAP-accredited laboratory." *See* Franks Rep., ECF No. 1606 at at 44; *Sparton*, 77 Fed. Cl. at 8; *Howard*, 2014 WL 1233081, at *8. He may not, however, opine as to his interpretation of the EPA's labelling regulations, as to whether Defendants violated the regulations, or as to whether Defendants breached or "satisfied" the terms of the military purchasing contracts. *See Sparton Corp.*, 77 Fed. Cl. at 8; *Claussen*, 2019 WL 4941109, at *8.

e. Rear Adm. Althea Coetzee Leslie (ret.)

i. Factual Narratives

Defendants move to exclude portions of Rear Adm. Leslie's opinions on the basis that they improperly narrate the content of documents she reviewed.[68] In particular Defendants argue that an entire section of Rear Adm. Leslie's expert report—"Aearo Did Not Provide What Was Promised"—should be excluded because the opinions it contains are based on her review of "documents and the facts that [she] pulled from them." The Court disagrees. While "[s]imply rehashing evidence about which an expert has no personal knowledge is impermissible under Rule 702," the factual narrative in this section of Rear Adm. Leslie's report "is necessary to provide the facts supporting [her] opinions." *See Ohio State Troopers Ass'n , Inc.*, 2020 WL 1666763, at *15–16 (citation omitted). For example, Rear Adm. Leslie's review of Aearo's testing procedures and results for the CAEv2 is

[68] Defendants also object on the grounds that (1) Rear Adm. Leslie's opinion is not based on a review of "scientific or peer-reviewed literature, . . . tests or experiments," and (2) that Leslie "is unqualified to offer these opinions in any event." These arguments are misplaced because they are based on a mischaracterization of Rear Adm. Leslie's testimony. Rear Adm. Leslie is not proffered as a scientific expert but rather as an expert in the field of government procurement. *See, e.g.*, Leslie Dep., ECF No. 1631-56 at 74 ("All I can look at is what was required [by the contract] and what was delivered and the fact that what was required and what was delivered were not the same thing results in a defect."); *id.* at 80 ("Based on the testing documentation that I reviewed, I would say that the items were not free from all defects that detract from their serviceability."); *id.* at 85 ("I was looking at it strictly from the contracting perspective of requirements and what was actually delivered."). Based on her qualifications and experience, Rear Adm. Leslie is qualified to testify as an expert regarding government procurement. *See* Leslie Rep., ECF No. 1631-55 at 2; *cf. Howard*, 2014 WL 1233081, at *7 (permitting government procurement expert to opine on Lockheed's quality assurance program for the F-22 aircraft based on his reviewed of "a variety of Lockheed internal inspection reports, internal audits, quality alerts, and emails").

necessary to explain the factual underpinnings of her opinion that Aearo did not disclose important information regarding the CAEv2's performance issues to the DoD. *See* Leslie Rep., ECF No. 1631-55 at 9-10; *Arevalo*, 2020 WL 3958505, at *21. The Court therefore declines to strike or limit any portions of Rear Adm. Leslie's report on this basis.

Importantly, while Rear Am. Leslie may explain the factual underpinnings of her admissible opinions, her "commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge." *See Cason*, 2015 WL 9913809, at *12–13.

ii. Legal Conclusions

Defendants move to exclude Rear Adm. Leslie's opinions in their entirety on the grounds that she improperly offers legal conclusions. Specifically, Defendants argue that Rear Adm. Leslie offers legal conclusions when she opines (1) that the CAEv2 "failed to meet the represented performance specifications" of the Medical Procurement Item Description ("MPID") contract with the Defense Logistics Agency ("DLA") within the DoD, and (2) that Aearo was "obligated to disclose" certain information to the DoD. The Court agrees, in part.

The Court finds that Defendants' argument to exclude Rear Adm. Leslie's opinions in their entirety "fails because the majority of [her] proffered testimony relates to the complex subject of federal government procurement law and its application" to the CAEv2. *See Advanced Training Grp. Worldwide, Inc. v. Proactive Techs. Inc.*, No. 19-cv-505, 2020 WL 4574493, at *10 (E.D. Va. Aug. 7, 2020). For example, the sections of Rear Adm. Leslie's expert report on the "Background of Procurement of CAEv2," the "Significance of an NSN," "How the DoD Acquires Materiel," and the "Procurement of the CAEv2" provide an explanation of the web of contracts, procurements, and regulations governing the CAEv2 that will be helpful to the jury. These portions of Rear Adm. Leslie's opinions are not inadmissible legal conclusions and will therefore not be excluded on this basis.

The Court agrees, however, that portions of Rear Adm. Leslie's opinions in the "Aearo Did Not Provide What Was Promised" section of her report constitute improper legal conclusions. In this section, Rear Adm. Leslie opines that "the CAEv2 did not meet the stated performance characteristics" in the MPID and, citing to 18 U.S.C. § 1001, states that "Aearo/3M was obligated to provide an item that satisfied the performance characteristics and specifications it had provided to the DoD when the first purchases [of the CAEv2] were made and at all times thereafter" and that "[i]f Aearo subsequently learned that these salient performance

characteristics of the CAEv2 were not accurate or truthful, it was obligated to disclose this information to the DoD prior to filling any additional orders." *See* Leslie Rep. ECF No. 1631-55 at 8-9. The Court finds that Rear Adm. Leslie's experience in government acquisition and contracting qualifies her to testify as to the standard of care for government contractors/vendors, which may be reflected in statutes and regulations, and opine as to whether Defendants' conduct conformed to that standard. *See Claussen*, 2019 WL 4941109, at *8; *cf. Tillman*, 96 F. Supp. 3d at 1329; *Loewen*, 2011 WL 6140908, at *2. She may also explain the MPID's performance characteristics and specifications to the extent they have specialized meaning or are based on trade practice or usage. For example, Rear Adm. Leslie may explain the meaning of the term "ANSI standards." *See* Leslie Rep., ECF No. 1631-55 at 10; *Sparton Corp.*, 77 Fed. Cl. at 8–9 ("Government contract experts have been allowed to testify in federal courts regarding the meaning of contract terms when the meaning depends on trade practice."); *Howard*, 2014 WL 1233081, at *8. She may not, however, testify that Defendants had a legal obligation or duty to disclose certain information, failed to satisfy the MPID's performance characteristics as a matter of law, or violated statutes or regulations. *See Montgomery*, 898 F.2d at 1547; *Sparton Corp.*, 77 Fed. Cl. at 8; *Claussen*, 2019 WL 4941109, at *8.

iii. State-of-Mind

Defendants object that "much" of Rear Adm. Leslie's report "is devoted to describing the state of mind" of various entities. In support, Defendants point to her (1) description of why the DLA procured the CAEv2 and the reasons the DLA utilized certain contracting procedures, (2) description of how the DoD "Reli[ed] on Aearo's Stated Performance of the CAEv2," and (3) conclusions that Aearo/3M was "aware" of alleged issues with the CAEv2 and "believed" various propositions. The Court agrees that this is not proper expert testimony.

First, while Rear Adm. Leslie may testify regarding the process by which the military procured the CAEv2 and the standard procedures utilized by military contracting officers based on her experience and review of documents in evidence, she may not speculate as to why, for example, "the contracting officer used streamlined commercial procedures." Leslie Rep., ECF No. 1631-55 at 6; *see In re Abilify*, 299 F. Supp. 3d at 1370 & n.178 (precluding expert from "simply read[ing] FDA materials to the jury and then testify[ing] to what the FDA meant or intended by including or excluding certain language"). Similarly, while Rear Adm. Leslie may opine that "[i]t is standard practice for DoD officials in the contracting and procurement departments to rely on contractors/vendors to provide honest and accurate representations about supplies or services they offer to the DoD" and to "disclose all known defects, risks, and warnings for the proper use of their items,"

she may not opine on whether the DoD actually relied on certain statements and data provided by Aearo. *See In re Abilify*, 299 F. Supp. 3d at 1370 n.178; *Dugas v. 3M Co.*, No. 3:14-cv-1096, 2016 WL 7327666, at *5 (M.D. Fla. Mar. 30, 2016) (excluding expert testimony "regarding what the Navy knew regarding the dangers of asbestos"). Moreover, while Rear Adm. Leslie may testify as to whether certain information or test results would have been useful to military procurement officials, she may not opine on what Defendants "believed" or were "aware" of. *See Deutsch*, 768 F. Supp. 2d at 443; *Tillman*, 96 F. Supp. 3d at 133; *Ma*, 288 F. Supp. 3d at 1367; *Cason*, 2015 WL 9913809, at * 13.

f. Dr. Lawrence Lustig

i. Factual Narratives

Defendants move to exclude Dr. Lustig's opinions regarding the development, marketing, and design of the CAEv2 and his opinions regarding "CAEV2's design defects and 3M's negligence, misrepresentation, and failure to warn of the CAEv2's inadequate hearing protection." Defendants object that "[f]or all of these opinions, [Dr.] Lustig relies only on company documents or other experts' testimony . . . not his own analysis." Defendants' objection is without merit. Dr. Lustig does not "simply parrot" Defendants' corporate documents or other experts' testimony. Rather, he properly explains the factual underpinnings of his opinions through commentary on documents and exhibits in evidence. *See Arevalo*, 2020 WL

3958505, at *21; *Ohio State Troopers Ass'n , Inc.*, 2020 WL 1666763, at *15; *FNB Bank*, 996 F. Supp. 2d at 1190. For example, Dr. Lustig's review of the data and information from Defendants' testing of the CAEv2 is necessary to explain his conclusion that the CAEv2 was "capable of causing or contributing to cause NIHL and tinnitus" because of its "problems with being consistently fit and with maintaining its seal including imperceptible loosening." *See* Lustig Rep. (General), ECF No. 1631-25 at 47. Similarly, Dr. Lustig's review of data and information from Defendants' testing of the CAEv2 and of Defendants' labeling, instructions, and warnings relating to the CAEv2 are necessary to explain his conclusion that Defendants did not provide adequate warnings to the military. *See id*. at 49–54.

ii. Legal Conclusions

Defendants also move to exclude portions of Dr. Lustig's opinions on the basis that they constitute impermissible legal conclusions. First, Defendants object to Dr. Lustig's opinions regarding "CAEv2's design defects and 3M's negligence, misrepresentations, and failure to warn of the CAEv2's inadequate hearing protection," his opinion that the CAEv2 is a "defective product," and that 3M has acted "unreasonably." Second, Defendants object to Dr. Lustig's interpretations and conclusions regarding various statutes and regulations governing the CAEv2's labeling. The Court agrees. Dr. Lustig may opine on whether Defendants adhered to the standard of care from a clinical perspective. *See Arevalo*, 2020 WL 3958505, at

*21; *Anderson*, 2015 WL 12843836, at *5; *Haines*, 2014 WL 12828962, at *9. He may not, however, opine that Defendants' conduct was "unreasonable" or constituted "negligence," that Defendants "failed to warn" the military and purchasers, or that the CAEv2 was "defective." *See Tillman*, 96 F. Supp. 3d at 1325–26; *Arevalo*, 2020 WL 3958505, at *20; *In re C.R. Bard, Inc.*, 2018 WL 4212409, at *3.

As to Defendants' second objection, the Court agrees that Dr. Lustig may not testify as to his interpretation of the Noise Control Act ("NCA") and related EPA regulations, as to whether Defendants violated the NCA or EPA regulations, or as to whether Defendants had a legal "duty" to provide an NRR on the CAEv2's label. *See Montgomery*, 898 F.2d at 1547; *Claussen*, 2019 WL 4941109, at *8.

iii. State-of-Mind

Defendants object that "substantial portions" of Dr. Lustig's opinions constitute inadmissible speculation as to "3M's state of mind and motivations." Defendants point to Dr. Lustig's testimony that 3M "knew" about certain problems and misrepresentations relating to the CAEv2, his suggestion that there was "pressure" on the 3M employees who were testing the CAEv2 because 3M "desire[d] the highest possible NRRs for HPDs" in order to sell more CAEv2, and his opinion that "3M only stopped selling the CAEv2 when it was caught." The Court agrees that these opinions are improper. While Dr. Lustig may testify as to whether

information contained in Defendants' internal documents indicated certain risks to users of the CAEv2,he may not opine as to Defendants' knowledge or motives. *See Deutsch*, 768 F. Supp. 2d at 443; *Tillman*, 96 F. Supp. 3d at 133; *Ma*, 288 F. Supp. 3d at 1367; *Cason*, 2015 WL 9913809, at * 13; *Szott*, 2007 WL 9702568, at *4.

g. Dr. Mark Packer

i. Factual Narratives

Citing eleven pages of Dr. Packer's Report, Defendants object to his "rehashing [of] the Flange Memo and other documents." Defendants' objection is without merit. A review of the cited portions of Dr. Packer's Report reveals that his commentary on the Flange Memo and other documents is necessary to explain the factual basis of his opinion regarding the problems with CAEv2 and Defendants' conduct relating to the CAEv2. *See Arevalo*, 2020 WL 3958505, at *21; *Ohio State Troopers Ass'n , Inc.*, 2020 WL 1666763, at *15; *FNB Bank*, 996 F. Supp. 2d at 1190. For example, Dr. Packer's review and commentary on the Flange Memo forms part of the factual basis for his opinion that Defendants did not "properly evaluate and act after uncovering problems with fit and seal and performance of the CAEv2." *See* Packer Rep. (General), ECF No. 1605-7 at 81.

ii. Legal Conclusions

Defendants object to Dr. Packer's opinions that the CAEV2 "Has Design Defects," "was Defective," is "Unreasonably Dangerous," and that 3M "failed to

warn" on the basis that these opinions are improper legal conclusions. Defendants further argue that Dr. Packer's opinion as to what a "reasonable" manufacturer of a hearing protective device would do also constitutes an improper legal conclusion. The Court agrees in part. Dr. Packer may opine on whether Defendants adhered to the standard of care from a clinical perspective. *See Arevalo*, 2020 WL 3958505, at *21; *Anderson*, 2015 WL 12843836, at *5; *Haines*, 2014 WL 12828962, at *9. He may not, however, opine that Defendants' conduct was "unreasonable," that Defendants "failed to warn," or that the CAEv2 was "defective" or "unreasonably dangerous." *See Tillman*, 96 F. Supp. 3d at 1325–26; *Arevalo*, 2020 WL 3958505, at *20; *In re C.R. Bard, Inc.*, 2018 WL 4212409, at *3.

iii. State-of-Mind

Defendants object to portions of Dr. Packer's opinion on the basis that they constitute impermissible speculation as to what Defendants "knew" about certain problems relating to the CAEv2. The Court agrees that this is not proper expert testimony. While Dr. Packer may testify as to whether information contained in Defendants' internal documents indicated "certain risks," he may not opine as to what Defendants "knew." *See Deutsch*, 768 F. Supp. 2d at 443; *Tillman*, 96 F. Supp. 3d at 133; *Ma*, 288 F. Supp. 3d at 1367; *Cason*, 2015 WL 9913809, at * 13; *Szott*, 2007 WL 9702568, at *4.

h. Eric Rose

i. Legal Conclusions

Defendants object to Rose's opinions that the CAEv2 was "defective" and "Unreasonably Dangerous" as improper legal conclusions. The Court agrees. *See Tillman*, 96 F. Supp. 3d at 1325–26; *Arevalo*, 2020 WL 3958505, at *20; *In re C.R. Bard, Inc.*, 2018 WL 4212409, at *3.

i. Dr. Christopher Spankovich

i. Factual Narratives

Defendants object to portions of Dr. Spankovich's Report on the basis that he improperly narrates 3M documents. In particular, Defendants cite to a portion of Dr. Spankovich's Report in which he states that the CAEv2 is "too short for proper insertion" and prone to "imperceptibl[e] loosen[ing]" based on his review of the Flange Memo and other internal 3M documents. The Court disagrees. A review of the cited portion of Dr. Spankovich's Report reveals that his commentary on the Flange Memo and other documents is necessary to explain the factual underpinning of his opinion regarding the problems with CAEv2 and Defendants' conduct relating to the CAEv2. *See Arevalo*, 2020 WL 3958505, at *21; *Ohio State Troopers Ass'n , Inc.*, 2020 WL 1666763, at *15; *FNB Bank*, 996 F. Supp. 2d at 1190. For example, Dr. Spankovich's review and commentary on the Flange Memo is necessary to explain the factual basis of his opinion that the CAEv2 "would be reasonably likely

to cause damage to the auditory system of users who were exposed to hazardous noise." *See* Spankovich Rep. (General), ECF No. 1605-8 at 73-74.

IV. Conclusion

In sum, the parties' omnibus motions to exclude expert opinions under Rule 702 and *Daubert* , ECF Nos. 1595 and 1605, are granted in part and denied in part, consistent with this Order, as to the following experts: Elliott Berger, Drs. John House, Derek Jones, Jennifer LaBorde, Margaret Richards, Moises Arriaga, Eric Bielefeld, Elizabeth Davis, David Eddins, Marc Fagelson, and John Franks, Roger Juneau, Kristin Kucsma, Rear Adm. Althea Coetzee Leslie, Drs. Lawrence Lustig and David Madigan, Richard McKinley, Dr. Mark Packer, Eric Rose, and Dr. Christopher Spankovich. The remaining expert challenges will be resolved by separate order.

DONE AND ORDERED, on this 28th day of February, 2021.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE