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 All Cases

Judge M. Casey Rodgers Magistrate Judge Gary R. Jones

ORDER

This is a multidistrict products liability action against 3M Company and its predecessor, Aearo Technologies, LLC, for damages related to Plaintiffs' use of the Combat Arms Earplug ("CAEv2").¹ Defendants have invoked the government contractor defense and both sides have moved for summary judgment on the applicability of the defense to some or all of the claims in this litigation. After thorough consideration and for the following reasons, the Court finds the record evidence insufficient, as a matter of law, to establish the elements of the government contractor defense as to any of Plaintiffs' claims. Accordingly, Plaintiffs' motion for summary judgment is granted and Defendants' motion is denied.

¹ The 3M Defendants acquired the Aearo Defendants in November 2007. *See* Master Long Form Complaint ¶ 18; Am. Answer ¶ 18. Defendant 3M Co. is the sole member of Defendant 3M Occupational Safety LLC, who is the sole member of Defendant Aearo Holding LLC, who is the sole member of Defendant Aearo Intermediate LLC, who is the sole member of Defendant Aearo LLC, who is the sole member of Aearo Technologies LLC. *See* Master Long Form Complaint ¶ 19; Am. Answer ¶ 19. Defendant Aearo Technologies LLC is the successor of Aearo Company I. Am. Answer ¶ 21.

I. Background

The CAEv2 was a dual-ended, triple-flanged earplug designed to provide two different options for hearing protection, depending on which end was worn. Each end of the CAEv2 was constructed from a single-ended, triple-flanged earplug called the Ultrafit, which was independently designed and patented by Defendants in 1989.² The two ends were joined by a stem. The olive-colored (or "closed") end was a traditional, linear earplug designed to protect a wearer from steady-state noise. The yellow (or "open") end housed a non-linear filter designed to provide protection from loud impulse noises, such as weapons fire, while still allowing the wearer to hear lower-level sounds, such as normal speech. The non-linear technology was invented and patented by the French-German Research Institute of Saint-Louis ("ISL") in 2000. Defendants sold the CAEv2 and/or its feature-identical commercial equivalent from July 1999 until the product was discontinued in 2015.

The Department of Defense ("DoD") has long prioritized protecting its personnel from hearing loss resulting from occupational noise exposure. To that end, the DoD established a comprehensive Hearing Conservation Program administered, in part, by the United States Army Center for Health Promotion and

² The patent for the single-ended, "multiple flange" earplug that came to be known as the E-A-R UltraFit was issued to Robert N. Falco on September 19, 1989 and assigned to Cabot Corporation. *See* United States Patent No. 4,867,149, dated September 19, 1989 (multiple flange earplug), PX3, ECF No. 1072-5. Cabot Corporation later became known as Aearo Corporation.

Preventive Medicine ("CHPPM"). During the time period relevant to this litigation, the Hearing Conservation Program was managed by Dr. Doug Ohlin, who was then a civilian employee of CHPPM.³ Various Army research facilities—including the United States Army Laboratory and the United States Army Aeromedical Research Laboratory—assisted with the hearing conservation efforts.

The record reflects that the Army was interested in non-linear hearing protection since at least the mid-1990s. During that period, Army audiologists learned that ISL had developed a non-linear technology designed to "dramatic[ally] improve[]" the sound attenuation performance of the currently available non-linear hearing protection devices. *See* Garinther Trip Report, D1, ECF No. 1071-2 at 3. In 1995, the Army tested ISL's non-linear filter against several other non-linear hearing protectors using twenty-seven active duty military subjects exposed to simulated battlefield noise conditions.⁴ For these tests, ISL's non-linear filter was housed in a single-sided, triple-flanged Ultrafit earplug with a shortened stem. The study showed that the modified-Ultrafit earplug "performed better" than the other devices

³ Dr. Ohlin was Program Manager for the Hearing Conservation Program for approximately 25 years. In that role, he was "in charge of the approve/disapprove list for earplugs." *See* D13, ECF No. 1071-14 at 2. Dr. Ohlin left government service on June 1, 2007 and began working for Defendants. He passed away on June 27, 2013.

⁴ See Blast Overpressure Studies Report dated May 1998, D10, ECF No. 1071-11 at 4, 19, 28, 29, 51, 144. The nonlinear earplug study was part of a larger study designed to determine the safe limits of occupational exposure to soldiers while wearing hearing protection. The principal investigator of this study was Dr. Daniel Johnson of the United States Army Aeromedical Research Laboratory.

tested and concluded that the modified-Ultrafit earplug "may be a satisfactory solution" to the Army's non-linear hearing protection needs, although "not enough subjects were exposed to provide a definitive answer." *See* Blast Overpressure Studies Report dated May 1998, D10, ECF No. 1071-11 at 145. Aearo, itself, had no involvement in this study.

In 1996, Georges Garinther, an Army researcher, "participated" in a series of non-linear earplug tests conducted by ISL and the French Army.⁵ For these tests, three different stand-alone earplugs were fitted with ISL's non-linear filter, one of which was the single-ended, triple-flanged Ultrafit earplug designed by Aearo.⁶ Preliminary testing results showed that all three earplugs incorporating ISL's non-linear technology worked as intended; that is, they protected hearing "as effectively as" the standard foam earplugs typically worn by French soldiers, while also enabling the test subjects to hear commands "much better" than the standard earplug. *See* Garinther Trip Report on Visit to ISL (5 to 23 December 1996) dated March 19, 1997, D1, ECF No. 1071-2 at 5. Garinther shared the preliminary results with Dr.

⁵ Garinther was a Guest Researcher for the United States Army Research Laboratory's Human Research and Engineering Directorate. *See* Garinther Trip Report on Visit to ISL (5 to 23 December 1996) dated March 19, 1997, D1, ECF No. 1071-2 at 9. The testing occurred at a large French Army training area near Nimes, France. The test subjects were French soldiers. In his Trip Report, Garinther wrote that he "*participated* in a series of experiments conducted by ISL." *See id.* at 4 (emphasis added). However, his report reflects that his role was limited to observing ISL conduct tests on French soldiers, listening to the soldiers' feedback during testing, and reporting the test results to the United States Army. *See id.* at 3-7.

⁶ The other two earplugs were the "Bilsom" and the "PERFIT." *See id.* at 4.

Ohlin and another Army official, Felix Sachs, and sent them samples of three nonlinear earplugs used in the testing. Aearo was not present for, or involved in, this study.

In the late 1990s, Aearo makes its first appearance in this story. On June 9, 1997, ISL wrote a letter to Dr. Elliott Berger, a Division Scientist with Aearo at the time, advising him of the "very good" results of recent "field experiments"—again, with the French Army—using the single-ended and triple-flanged Ultrafit, modified to incorporate ISL's non-linear filter.⁷ See D1, ECF No. 1088-2 at 2. At that time, ISL requested "unofficial" pricing information for Ultrafit earplugs containing ISL filters and invited Aearo to attend "final testing" of the device later that same year.⁸ See id. at 2-3. Shortly thereafter, Aearo sent 200 single-ended Ultrafit prototypes to ISL for testing. From the testing, ISL concluded that the prototype's stem was too long, which reduced its noise attenuation capabilities. See id. at 2-3. As a solution, ISL proposed a final prototype with a shorter stem and suggested ways in which Aearo could shorten the stem. See id. at 2-3. There is no evidence that the U.S. Army was a part of these discussions between ISL and Aearo.

⁷ Dr. Ohlin was copied on the letter, but there was no subsequent correspondence directed to or from Dr. Ohlin to Aearo. *See* June 9, 1997 Letter from ISL to Aearo, DX1, ECF 1088-2 at 2.

⁸ These earplugs containing the ISL filter were also considered "perforated," since they contained a hole at the tip to support the filter. *See* March 19, 1997 Trip Report on Visit to ISL, 5 to 23 December 1996, D1, ECF No. 1071-2 at 3-4 (describing the earplugs as containing "two orifices in series (like a drum)."

In November 1997, Garinther again "participated" in earplug tests conducted by ISL and the French Army.⁹ See Garinther Report on Visit to ISL (21 to 29 November 1997) dated March 2, 1998, D1, ECF No. 1071-2 at 9-12. Although it is unclear from Garinther's report which earplug housing the ISL filter was tested, given ISL's recent collaboration with Aearo on prototypes, it is reasonable to infer that it was the single-ended UltraFit. See also id. at 11 (noting that the French Army was going to issue a request for proposal for 300,000 non-linear earplugs and that it was "probable" that Aearo would manufacture it as the manufacturer of the Ultrafit). Once again, French soldiers were used as test subjects. See id. at 9-11. Preliminary analysis of the testing data showed that no soldiers had unacceptable hearing loss within 24 hours of using the nonlinear earplug in firing exercises. See id. at 10-11. Based on the test results, Garinther concluded that the non-linear, single-ended Ultrafit earplug provided "acceptable hearing protection." See id. at 11. He further recommended that the United States Army "consider[]" using the non-linear Ultrafit earplug "since its use by weapon crews would reduce hearing loss among soldiers while permitting them to hear voice commands and combat related sounds." See id. at 12. Aearo was not present for, or involved in, this testing.

⁹ Garinther again characterized the purpose of his visit as "[t]o participate in testing" of the earplug, but there is no evidence that Garinther did anything more than observe the testing and draw conclusions from the test results. *See generally id.* at 9-12.

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 7 of 56 Page 7 of 56

In light of the recent test results, the French Army issued a request for proposal for 300,000 non-linear, single-ended UltraFit earplugs. *See id.* at 11. The French Army also needed traditional earplugs, which, again, would provide protection against steady-state noise. ISL appears to have proposed three configurations to fulfill the French Army's dual hearing protection needs: (1) two separate earplugs, one non-linear and one traditional earplug; (2) a non-linear earplug with two tiny holes that could be closed for attenuation of constant noise; and (3) a dual-ended or "reversible" earplug with a non-linear end and a traditional end. *See id.*

On December 16, 1997, Aearo and officials from the United States Army met and discussed a non-linear earplug for the first time. That day, the Army—more specifically, Garinther, Dr. Ohlin, and two other Army officials—hosted representatives from ISL and Aearo, including Dr. Elliot Berger, at Aberdeen Proving Ground, a U.S. Army facility located in Aberdeen, Maryland (hereinafter "Aberdeen Meeting"). *See* Aearo Aberdeen Meeting Notes, D2, ECF No. 1071-3 at 3.¹⁰ At the Aberdeen Meeting, the attendees discussed ISL's recent field tests of the non-linear, single-ended Ultrafit earplug with the ISL filter, and ISL noted that the French Army preferred the UltraFit as the "best vehicle" for ISL's non-linear filter. *See id.* at 3-4. The attendees also discussed ISL's three proposed configuration

¹⁰ The Aberdeen Meeting notes were authored by one of Aearo's representatives at the meeting, Dr. Elliott Berger. *See* Berger Deposition dated December 12, 2019, D56, ECF 1071-57 at 13.

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 8 of 56 Page 8 of 56

options: (1) a single openable/closeable non-linear earplug; (2) two separate earplugs, one non-linear and one traditional; and (3) a dual-ended or "reversible" earplug with a non-linear end and a traditional end. *See id.* at 4. According to Dr. Berger's meeting notes, Dr. Ohlin said the United States Army would only be "interested in [the] 2-ended plug" because it was "easier to dispense" and "less-labor intensive" to use. *See id.* The notes reflect that ISL had already applied for a patent on a two-ended earplug with ISL's non-linear filter on one end.¹¹ *See id.* at 4.

The record contains no evidence of further communication between Aearo and the Army following the Aberdeen Meeting until March 1998. Aearo independently created design drawings for the first version of the CAEv2 and assembled the parts—the Ultrafit ends, the ISL filter, and the stem—"in a way [it] thought could work for the military." *See* Berger Deposition dated December 12, 2019, D56, ECF No. 1072-57 at 21. The company then manufactured 25 production samples, which it sent to Dr. Ohlin.¹² There is no evidence that Dr. Ohlin, or any other Army official, requested the production samples. Significantly, none of the

¹¹ ISL had not yet applied for the patent at that time. Instead, two days after the Aberdeen Meeting, the company filed a U.S. patent application for the dual-ended earplug. *See* United States Patent No. 5,936,208, dated August 10, 1999 (dual-ended earplug), PX6, 1072-8.

¹² See Aearo Letter to Dr. Ohlin dated March 24, 1998, D12, ECF No. 1071-13; Drawing of dual-ended earplug, D11, ECF No. 1071-12; Berger Deposition dated December 12, 2019, D56, ECF No. 1071-57 at 20-21; see also PX13, ECF No. 1072-15 at 3 (crediting 3M/Aearo as the "creator" of the Combat Arms Earplug); PX14, ECF No. 1072-16 at 5 (describing Aearo's Elliott Berger as the "inventor" of the Combat Arms Earplug)

detailed design descriptions or drawings for the CAE were discussed with or sent to the Army.

During the next year, there were no communications between Aearo and the U.S. Army regarding the 25 production samples or anything else. Then, on April 6, 1999, Dr. Ohlin sent a memorandum to the Army's Joint Readiness Clinical Advisory Board requesting an increase in the height and width of the Army's current earplug carrying case to accommodate the "proposed" earplugs from Aearo, which did not fit in the current case. *See* Request for Modification of Earplug Carrying Case, PX72, ECF 1089-6 at 2. Dr. Ohlin attached to the memorandum design drawings from the supplier showing how the carrying case could be modified to fit the dual-ended earplugs. *See id.* at 4-5.

By April 8, 1999, Aearo was aware that the first production samples did not fit the Army's current earplug carrying case. *See* Email from Brian Myers to Dr. Ohlin, D3, ECF No. 1071-4. That day, Brian Myers, a Senior Marketing Director for Aearo, informed Dr. Ohlin that Aearo could "probably shorten the plug by the [one-quarter inch] required to fit [the Army's] current container." *See id.* Myers said that Aearo's "designer" would take a look at the issue when he returned from vacation and that if Dr. Ohlin could provide the company with a carrying case, it would help "expedite the redesign." *See id.* On April 9, 1999, Dr. Ohlin responded to Myers stating that, "[in addition to the plug being too long for the [carrying] case

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 10 of 56 Page 10 of 56

and [having] an incre[a]sed potential for wind noise," it also "sticks out too far for the [K]evlar combat helmet," which was "a show stopper." *See* Email from Doug Ohlin to Brian Myers dated April 9, 1999, D4, ECF No. 1071-5 at 2. That same day, Aearo held an internal design review meeting with Myers and several of his Aearo colleagues where they discussed the length of the earplug, and that "[i]t has been requested by the military that the earplug fit into a case, which is in current use by the military, [and] this would require reducing the length by ¼ of an inch." *See* Aearo Design Review Memorandum, D17, ECF No. 1071-18 at 3.

Three days later, Dr. Ohlin reiterated his three concerns about the first production samples of the dual-ended earplugs in an email to an Army colleague, Belva Hoffman, copying Mr. Myers.¹³ *See* Doug Ohlin email to Belva Hoffman dated April 12, 1999, D5, ECF No. 1071-6. In his email, Dr. Ohlin said that there were "at least three reasons why [Aearo was] going to have to shorte[n] the production sample[]" earplugs: (1) to fit the Army's standard carrying case; (2) "[t]o minimize wind noise;" and (3) "[t]o be compatible with the [K]evlar helmet when the chinstrap is fasten." *See id.* at 2. Once again, Dr. Ohlin emphasized that the "last one is a show stopper if [the Army] can't get the modification." *See id.*

On April 13, 1999, Dr. Ohlin shared those same three concerns about the first production samples with four other Army officials, by email. *See* Email from Doug

¹³ There is no evidence that Myers responded to Dr. Ohlin's email.

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 11 of 56 Page 11 of 56

Ohlin to Wayne Loyborg et al. dated April 13, 1999, D3, ECF No. 1071-4 at 3. Because the samples "were at least a quarter of an inch too long," Dr. Ohlin told the four officials that he, on his own, cut down the samples he was sending them by separate cover. *See id.* Dr. Ohlin did not indicate how he "cut[] down" the samples, or by how much he shortened them. Nor did he share this information with Aearo or otherwise instruct Aearo how to shorten the earplugs. In fact, for an entire month, there was no documented discussion between Dr. Ohlin and Aearo at all, let alone any discussion on how Aearo could or would modify the earplug length. Nor were there any exchanges of any design drawings for the earplugs.

Aearo independently redesigned the CAEv2 as reflected in a drawing dated April 27, 1999. *See* Drawings of dual-ended earplug and its components, D14, ECF No. 1071-15 at 10-11. The company then manufactured a new set of production samples and sent those samples to Dr. Ohlin. Once again, no design descriptions or drawings for the earplug were discussed with or sent to Dr. Ohlin. It is unclear exactly when Dr. Ohlin received the second set of production samples; however, it is clear that he had received the samples and found them "acceptable" by May 12, 1999. *See* Email from Doug Ohlin to Belva Hoffman dated May 12, 1999, D3, ECF No. 1071-4 at 4.

Dr. Ohlin requested a National Stock Number (NSN) for the CAEv2, which is an official label used by the government to identify items that are routinely

purchased and stocked in large quantities. In a memorandum justifying the request, Dr. Ohlin stated that the DoD Hearing Conservation Working Group recommended that the military adopt for its own use a non-linear earplug "configured to the specifications of the enclosed production samples." See Request for National Stock Number (NSN) and Bulk Purchase of Combat Arms Earplug, PX57, ECF No. 1072-60 at 2. Dr. Ohlin did not submit any design drawings with the request, presumably because he never had any drawings. He also did not submit any formal military specifications for the CAEv2; indeed, neither he nor the Army ever issued any specifications for the earplug. See id.; see also Email from Douglas Ohlin to Marion Burgess, dated March 14, 2006, PX53, ECF No. 1072-56 ("There is no DOD specification for the [C]ombat [A]rms [E]arplug.").¹⁴ Interestingly, Dr. Ohlin's memorandum noted that "[t]he American military's contribution in this development effort has been to *recommend* an American-made earplug, the UltraFit, to house the French filter, the color scheme and blast overpressure testing." See id. at 4 (emphasis added). An NSN was not issued for some time.¹⁵

Prior to the NSN, Dr. Ohlin advised colleagues at the Navy of his pending NSN request for the CAEv2 and sent them instructions, which he prepared, on how

¹⁴ See also infra note 31.

¹⁵ The CAEv2 NSN was 6515-01-466-2710. *See* January 22, 2003 Draft Specification Sheet, D35, ECF No. 1071-36 at 4. There is no evidence in the record showing when the NSN was issued.

to use the earplug. See Letter from Doug Ohlin to John Page dated May 18, 1999, D15, ECF No. 1071-16. Dr. Ohlin also requested a price quote from Aearo for 1,000 pairs of the CAEv2 to be purchased by the Army's Southern European Command. See Email from Doug Ohlin to Brian Myers dated May 18, 1999, D3, ECF No. 1071-4 at 6. The first official purchase order for the CAEv2 was dated July 22, 1999 and was later shipped to CHPPM at Aberdeen Proving Ground. See CAEv2 SKU data, PX47, ECF No. 1072-50 at 4. Additional purchase orders followed from all branches of the military. See CAEv2 SKU data, DX3, ECF No. 1088-4. The government did not formally enter into a procurement contract with Aearo until 2006, when it awarded Aearo the first in a series of Indefinite-Delivery, Indefinite-Quantity Contracts ("IQCs") to supply the CAEv2 or its "equal," or a "double-ended, swept-back triple-flange style earplug" the military.¹⁶ See to Solicitation/Contract/Order for Commercial Items, PX37, ECF No. 1072-40. Aearo continued selling the CAEv2 to the military for over a decade. See Sales of the Combat Arms Version 2, 1999-2010, PX46, ECF No. 1072-49.

¹⁶ The applicable Solicitation/Contract/Order for Commercial Items stated that the product "shall be in accor[d]ance with the Medical Procurement Item Description No. 2 dated 16 July 2006" and that "preservation, packaging, packing, labeling and marking . . . shall be as specified in the Medical Procurement Item Description No. 2." *See* PX37, ECF No. 1072-40 at 38. In other words, the government contract incorporated by reference the MPID. *See id.* The MPID includes the CAEv2's NSN at the top. Defendants disclaim that the MPID provides the Army's design and performance specifications for the CAEv2. *See generally* Def. Mot., ECF No. 1071-68; *see also* Oral Argument Transcript dated June 15, 2020, ECF No. 1199, at 102.

In November 1999, after having supplied the CAEv2 to the Army for four months, it "occurred" to Aearo that it had never before performed sound attenuation testing on the CAEv2 and, therefore, had "no [testing] data on the actual version" of the earplug being sold in the United States. See Email from Elliott Berger to Brian Myers dated November 19, 1999, PX20, ECF No. 1072-23 at 2. Thereafter, Aearo's Ronald Kieper and Dr. Elliott Berger began performing Real Ear Attenuation at Threshold testing on each of the CAEv2 to determine the earplugs' Noise Reduction Rating ("NRR"). The parties hotly dispute the facts surrounding Aearo's testing procedures, the results of the tests, and what information about the tests results was shared with the government, if any. A full recount of those facts is unnecessary to resolve the instant motions for summary judgment. Suffice it to say, it is undisputed that the tests led Dr. Berger to report to his colleague, Brian Myers, that "the [CAEv2] ha[d] problems unless the user instructions [were] revised." See Email from Elliott Berger to Brian Myers dated May 12, 2000, PX32, ECF No. 1072-35 at 2. Thereafter, on July 10, 2000, Kieper and Berger authored an internal report (known as the "Flange Report") "document[ing] that the current length of the [green] end of the [CAEv2]" was "too short for proper insertion, [especially in subjects with medium and large ear canals], and how changing the fitting technique affected the results of [REAT] tests of" the earplug." See PX32, ECF No. 1071-25 at 3. The Flange Report also documented that "the geometry of the ear canal opening

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 15 of 56 Page 15 of 56

sometimes prevented [the required] deep . . . insertion" of the CAEv2 in test subjects and that, at times, when the green end was inserted, the flanges on the yellow end "tended to return to their original shape and this sometimes loosened the plug, often imperceptibly to the subject." *See id.* Finally, the Flange Report described an alternative procedure for fitting the plug–i.e., folding back the opposing flanges before inserting the earplug into a test subject's ear— that Kieper and Dr. Berger used to achieve acceptable REAT test results. This alternative procedure was not how the CAEv2 was originally designed to be worn.

The record reflects that the Flange Report was never shared with the Army and, in fact, it was not made available to *anyone* outside of Aearo until it was produced by 3M in a lawsuit brought against 3M by a competitor, Moldex-Metric, Inc. ("Moldex") in 2014. Immediately following the release of the Flange Report in that litigation, the CAEv2 was discontinued. *See* Email from Brian Myers to Kay Chaussee dated October 8, 2015, PX38, ECF No. 1072-41. In light of the Flange Report, Moldex also filed a *qui tam* complaint against 3M, alleging that the company violated the False Claims Act by knowingly supplying the "dangerously defective" CAEv2 to the military "for more than a decade" while deliberately concealing the defects by falsely certifying its testing methods and results in connection with its IQCs. *See United States ex rel. Moldex-Metric, Inc. v. 3M Co.*, 3:16cv1533, ECF No. 1 at 2, 5-6 (D.S.C. May 12, 2016). More specifically, Moldex claimed that the

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 16 of 56 Page 16 of 56

CAEv2 was defective in that its stem was too short for proper insertion and the positioning of its flanges could cause the earplug to loosen "imperceptibly" in some wearers' ears, thereby allowing harmful levels of sound to enter the ears and pose serious risks of hearing damage. *See id.* at 5-6. The United States Army Criminal Investigation Command, in coordination with the Department of Justice, investigated the matter. Thereafter, the United States intervened in the *qui tam* action and settled it in July 2018. *See id.* at ECF Nos. 22-23. This litigation followed.

In this litigation, Plaintiffs assert state law claims for negligence and strict product liability based on design defect and failure-to-warn theories, as well as warranty, misrepresentation, fraud, gross negligence, negligence *per se*, and consumer-protection claims. Plaintiffs' design defect claims target two features of the CAEv2, alleging that: (1) its stem was too short for certain users—primarily those with medium to large ear canals—to insert the device deeply enough into their ears to obtain the airtight seal necessary to provide hearing protection; and (2) when the earplug was inserted according to standard fitting instructions, the positioning of the opposing flanges relative to the outer ear caused the basal edge of the third flange of the non-inserted side of the earplug to press against some users' ear canal openings and fold up, causing imperceptible loosening of the seal, which, they claim, results in little to no hearing protection for the user. Plaintiffs' failure-to-warn

claims are based on allegations that Defendants failed to provide warnings regarding the alleged dangers inherent in the use of the CAEv2. Defendants dispute these allegations.

II. Legal Standard

Cross-motions for summary judgment are examined under the same legal standard applied when only one party files a motion. *See Torres v. Rock & River Food Inc.*, 244 F. Supp. 3d 1320, 1327 (S.D. Fla. 2016) (citing *Am. Bankers Ins. Grp. v. United States*, 408 F.3d 1328, 1331 (11th Cir. 2005).¹⁷ Summary judgment is appropriate where the record reflects there are no genuine disputes of material fact and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56; *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). A fact is "material" if, under the applicable substantive law, it might affect the outcome of the case. *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1259-60 (11th Cir. 2004). A dispute of fact is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

¹⁷ "Cross-motions may, however, be probative of the absence of a factual dispute where they reflect general agreement by the parties as to the controlling legal theories and material facts." *Certain Underwriters at Lloyds, London Subscribing to Policy No. SA 10092-11581 v. Waveblast Watersports, Inc.*, 80 F. Supp. 3d 1311, 1316 (S.D. Fla. 2015) (citing *United States v. Oakley*, 744 F.2d 1553, 1555-56 (11th Cir. 1984)).

The moving party bears the initial burden of "informing the court of the basis for its motion and of identifying those materials that demonstrate the absence of a genuine issue of material fact." Rice-Lamar v. City of Fort Lauderdale, 232 f.3d 836, 840 (11th Cir. 2000) (citing Celotex, 477 U.S. at 323). Once that burden is met, the nonmoving party must "go beyond the pleadings" and present competent record evidence showing the existence of a genuine, material factual dispute for trial. Celotex, 477 U.S. at 324. In doing so, and to avoid summary judgment, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). The "mere existence of a scintilla of evidence" supporting the nonmovant's case is insufficient to defeat a motion for summary judgment. Liberty Lobby, 477 U.S. at 252. In assessing whether a movant is entitled to summary judgment, a court must view the evidence and factual inferences drawn therefrom in the light most favorable to the non-moving party. See id. at 255; Allen v. Tyson Foods, 121 F.3d 642, 646 (11th Cir. 1997). Ultimately, summary judgment must be entered where "the nonmoving party has failed to make a sufficient showing on an essential element of [its] case with respect to which [it] has the burden of proof." Celotex, 477 U.S. at 323.

III. Discussion

Defendants argue they are entitled to summary judgment on Plaintiffs' design defect and failure-to-warn claims based on the federal government contractor defense. More specifically, Defendants maintain they are immune from tort liability under state law because the CAEv2 was designed according to the military's specifications. Plaintiffs move for summary judgment in their own favor on the defense, arguing that Defendants cannot satisfy any of the requirements for the defense with respect to their design defect and failure-to-warn claims, and that the defense does not apply to the remaining claims.

A. The Federal Government Contractor Defense

The government contractor defense is an affirmative defense that shields federal contractors from third-party state tort liability for certain defects in products designed and developed for the federal government. It is a common law doctrine of federal preemption aimed at protecting governmental policy decision-making against collateral attack in the courts. Its origins trace to the federal government's sovereign immunity and the principle that a contractor "act[ing] under the authority and direction of the United States" should receive the benefit of that immunity. *Harduvel v. Gen. Dynamic Corp.*, 878 F.2d 1311, 1316 (11th Cir. 1989); *see also Burgess v. Colo. Serum Co., Inc.*, 772 F.2d 844, 846 (11th Cir. 1985); *Carley v. Wheeled Coach*, 991 F.2d 1117, 1120 (3d Cir. 1993).

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 20 of 56 Page 20 of 56

The modern formulation of the defense was first recognized and adopted by the Supreme Court in Boyle v. United Techs. Corp., 487 U.S. 500 (1988), in which the father of a Marine pilot who died in the crash of a military helicopter sued the manufacturer of the helicopter, alleging that the helicopter's escape hatch was defectively designed.¹⁸ Following a jury verdict in Boyle's favor, the district court denied the manufacturer's motion for judgment notwithstanding the verdict and the manufacturer appealed. On appeal, the Fourth Circuit reversed on grounds that the contractor was immune from suit by virtue of the "military contractor defense" because the Navy had selected and approved the design for the helicopter and, in particular, the design and operation of the escape hatch. See id. at 503. Certiorari was granted. See id. at 504. In relevant part, Boyle argued before the Supreme Court that the manufacturer could not escape liability because, absent legislation immunizing government contractors from civil liability for design defects, which did not exist, nothing in the common law afforded them protection from civil liability to third-parties under state law. See id. The Supreme Court disagreed.

¹⁸ Before *Boyle*, the government contractor defense had developed largely in the lower federal courts without a cohesive analytical underpinning. Some courts grounded the defense in the *Feres-Stencel* doctrine, *see McKay v. Rockwell Int'l Corp.*, 704 F.2d 444 (9th Cir. 1983), others in the separation of powers doctrine, *see Shaw v. Grumman Aerospace Corp.*, 778 F.2d 736 (11th Cir. 1985), and still others through an extension of sovereign immunity, *see Boruski v. United States*, 803 F.2d 1421 (7th Cir. 1986).

While acknowledging that federal law generally preempts state law only when the United States Constitution or a federal statute specifically provides for preemption, or when a direct conflict exists between applicable federal and state law, the Court observed that there are also

a few areas, involving "uniquely federal interests," ... [that] are so committed by the Constitution and laws of the United States to federal control that state law is preempted and replaced, where necessary, by federal law of a content prescribed (absent explicit statutory directive) by the courts—so-called "federal common law."

Id. at 503-04.19

The Court found that disputes involving the civil liability of government contractors performing work under federal procurement contracts, as in *Boyle*, border on two areas that it had previously found to involve "uniquely federal interests" sufficient to justify the application of federal common law: the obligations to and rights of the United States under its contracts and the civil liability of federal

¹⁹ Although "[t]here is, of course, no federal general common law," the Supreme Court "has recognized the need and authority in some limited areas to formulate what has come to be known as federal common law." *Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 640 (1981) (quoting *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938) (internal marks omitted). However, the Court has emphasized that "[t]hese instances are 'few and restricted' . . . and fall into essentially two categories: those in which a federal rule of decision is 'necessary to protect uniquely federal interests,' . . . and those in which Congress has given the courts the power to develop substantive law." *Id.* The Court further underscored that the instances in which it would be necessary to apply a federal rule of decision to protect uniquely federal interests are "narrow" and concern only the rights and obligations of the United States or our relations with foreign nations, and admiralty cases" *Id.* at 641. According to the Court, "[i]n these instances, our federal system does not permit the controversy to be resolved under state law, either because the authority and duties of the United States as sovereign are intimately involved or because the interstate or international nature of the controversy makes it inappropriate for state law to control." *Id.*

officials for actions taken in the course of their duties. *See id.* at 504-05. Federal, rather than state, law controls these two areas because both "obviously implicate[] the same [federal] interest in getting the [g]overnment's work done," either through its contracts or its employees. *See id.* at 507.

The Court found the same to be true in the context of private disputes like Boyle's, which do not *directly* involve contractual rights and obligations of the United States or the immunity of federal officials, but nonetheless arise from a contractor's performance of work for, or on behalf of, the government under a procurement contract. *See id.* at 504-06. By their nature, the Court reasoned, such disputes are sufficiently related to the contract to justify federal preemption.²⁰ *See id.* at 505. Moreover, they can "directly affect" the terms of government contracts

²⁰ The Boyle Court found support for this holding in Yearsley v. W.A. Ross Constr. Co., 309 U.S. 18 (1940), a case involving a public works project for the Army Corps of Engineers in which the contractor sought immunity from the claims of landowners whose property had been damaged during the construction project. Yearsley extended immunity to the contractor, reasoning that "if the authority to carry out the project was validly conferred, that is, if what was done was done within the constitutional power of Congress, there is no liability on the part of the contractor for executing its will." Boyle, 487 U.S. at 505 (quoting Yearsley, 309 U.S. at 20-21); see also In re KBR, Inc., Burn Pit Litig., 744 F.3d 326, 352 n.5 (5th Cir. 2014) ("Yearsley allows government contractors to enjoy immunity from suit only if they adhere to the terms of their contracts with the government[.]"). Although the contractor in *Yearsley* was an agent of the United States whereas the defendant in Boyle was an independent contractor, and although the contract in Yearsley was one of performance and in Boyle the contract was one of procurement, these distinctions were of no significance to the Boyle Court insofar as the interests of the United States were concerned. Indeed, *Boyle* made clear that a "uniquely federal interest" is present whenever a third-party seeks to impose liability on a government contractor for work performed on behalf of the United States. Id. (rejecting any distinction between performance contracts and procurement contracts as far as the federal government's interest "in getting its work done" is concerned.); see also Carley, 991 F.2d at 1120.

and interfere with federal officials' ability to "get[] the [g]overnment's work done." *See id.* at 505, 507. Without some form of protection from financial liability arising from the performance of their obligations to the federal government, contractors will either "decline to manufacture the design specified by the [g]overnment" or increase their prices to cover against potential liability. *See id.* at 507. Thus, the Court held, disputes involving the procurement of equipment by the federal government implicate interests that are "uniquely federal" and may, where necessary, require displacement of state tort law. *See id.*

Under *Boyle*, displacement is necessary where "a significant conflict exists between an identifiable federal policy or interest and the operation of state law" or where "the application of state law would frustrate specific objectives of federal legislation." *See* 487 U.S. at 507. The Supreme Court found the "potential for" a significant conflict between the federal policies embodied in the discretionary function exception to the Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 2680(a), and state laws holding contractors liable for design defects in military equipment where the federal government specified the equipment's design. *See Boyle*, 487 U.S. at 511. More specifically, and in relevant part, the FTCA's discretionary function exception preserves the government's sovereign immunity from suit for its own discretionary acts—that is, its acts based on judgment or choice involving matters of federal policy—lest the courts would be free to impermissibly "second-guess" the

policy judgments of federal agencies and the threat of suit would "handicap efficient government operations."²¹ See United States v. Varig Airlines, 467 U.S. 797, 814 (1984). The Boyle Court explained that the federal government's selection of the appropriate design for military equipment is—without question—a discretionary act within the meaning of the discretionary function exception because "[i]t often involves not merely engineering analysis but judgment as to the balancing of many technical, military, and even social considerations, including specifically the tradeoff between greater safety and greater combat effectiveness." See 457 U.S. at 511. Allowing state tort suits against contractors who merely execute the government's design decisions would permit unwarranted judicial interference with those decisions and force the government to bear liability costs resulting from its own discretionary acts (because, again, contractors will inevitably pass those costs on to the government), producing the very effects sought to be avoided by the discretionary function exception. See id. Accordingly, the Court concluded that state laws holding government contractors liable for design defects in military equipment may present "significant conflicts" with federal policies, requiring displacement of the state law by the federal common law. See id.

²¹ "The discretionary function exception . . . marks the boundary between Congress' willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals." *Varig Airlines*, 476 U.S. at 808.

The Supreme Court set forth a three-part test for determining when a state law claim for design defects in military equipment falls within the "scope of displacement" by federal common law; in other words, when preemption is necessary to protect the federal policies underlying the discretionary function exception to the FTCA. See id. at 512. Under Boyle, liability for design defects in military equipment cannot be imposed on federal contractors under state law where: (1) the government approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the contractor warned the government about the dangers in the use of the equipment that were known to the contractor but not to the government. See id. The first two requirements ensure that the government contractor defense is available only when the imposition of state tort liability would frustrate the "discretionary function" exercised when government officials specify designs for military equipment. See id. The third requirement incentivizes contractors to disclose known design defects so that the government may make informed procurement decisions. See id. at 512-13. Together, the three requirements limit the scope of the government contractor defense to those circumstances "where the government has actually participated in discretionary design decisions, either by designing a product itself or approving specifications prepared by the contractor." *Harduvel*, 878 F.2d at 1316.

B. Uniquely Federal Interest

The first question that must be answered is whether the dispute in this litigation implicates interests that are "uniquely federal" within the meaning of *Boyle. See* 487 U.S. at 507. *Boyle* is unequivocal in its determination that "the procurement of equipment by the United States is an area of uniquely federal interest," *see id.*, and this litigation is nothing if not about the government's procurement of equipment. Its genesis is in the United States military's desire for, and ultimate purchase of, a hearing protection device that it believed would protect service members from loud impulse noises while at the same time allowing them to hear commands and other lower-level environmental sounds, thereby improving situational awareness on the battlefield. One might assume this would be the end of the "uniquely federal interest" analysis—if only it were that simple.

The complication here is that the parties' dispute concerns a design defect and, at the time Aearo designed the CAEv2, it had no procurement contract with the Army. Nor did it have one when it redesigned the earplug to fit in the Army's carrying case.²² Even after the Army began using the CAEv2, there was no contract establishing, adopting, or even describing the design of the product. *See In re Agent*

²² Again, it was not until July of 1999 that the Army placed its first purchase order for the CAEv2 using a National Stock Number, *see* CAEv2 SKU data, PX47, ECF No. 1072-50 at 4, and not until years later, in 2006, that it awarded Aearo an indefinite quantity contract, *see* Solicitation/Contract/Order for Commercial Items, PX37, ECF No. 1072-40.

Orange Prod. Liab. Litig., 517 F.3d 76, 83 (2d Cir. 2008) (government contracts for purchase of allegedly defective chemical defoliants "required that the chemicals be nearly 100% pure and that they be combined in roughly equal proportions"). In other words, at no time did Aearo perform work for, or on behalf of, the United States under a contract with the Army that contained a design component for the CAEv2. *See Harduvel*, 878 F.2d at 1316 (contractor must "act under the authority and direction of" the United States to be entitled to immunity under the government contractor defense). Plaintiffs strenuously urge the Court to reject the government contractor defense on this basis.²³ Not surprisingly, Defendants strenuously resist.

The Court has wrestled with the question of whether the federal government's interest "in getting [its] work done" as delineated in *Boyle*, 487 U.S. at 504, is sufficiently implicated when there is no government contract with a design component requiring contractor performance. After considerable deliberation, the Court concludes it is not. The Supreme Court has long made clear that federal common law preemption is limited to a few narrow areas—where "the authority and duties of the United States as sovereign are intimately involved" or "the interstate or

²³ Plaintiffs also argue, based primarily on *In re Hawaii Fed. Asbestos Cases*, 960 F.2d 806 (9th Cir. 1992), that no uniquely federal interest is involved in this litigation because Defendants sold a "feature-identical" version of the CAEv2 to civilian users on the commercial market. In response, Defendants insist that commercial use of the CAEv2 does not render the government contractor defense inapplicable. Because this Order resolves the uniquely federal interest question on other grounds, it does not address the merits of Plaintiffs' commercial availability argument.

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 28 of 56 Page 28 of 56

international nature of the controversy makes it inappropriate for state law to control." *See Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 641 (1981). *Boyle* further identified two categories of dispute where the authority and duties of the United States as sovereign are sufficiently involved to justify federal preemption—the "obligations to and rights of the United States under its contracts" and the scope of "civil liability of federal officials for actions taken in the course of their duty." *See Boyle*, 487 U.S. at 504-05.

The *Boyle* decision is predicated on the existence of a federal government procurement contract and, in terms of its discussion of the uniquely federal interest present in that case, the Court speaks only in terms of contract.²⁴ More specifically, *Boyle* speaks of contract performance and the civil liability that may arise *from that performance*, such that it can be said that the contractor's *performance* is "sufficiently related to the [government] contract" to warrant federal preemption. *See id.* at 505. Indeed, nothing explicit or implicit in the *Boyle* holding extends its

²⁴ See Boyle, 487 U.S. at 505 ("The [Boyle] case does not involve an obligation to the United States under its contract, but rather liability to third persons. That liability may be styled one in tort, but it arises out of performance of the contract—and traditionally has been regarded as sufficiently related to the contract to that until 1962 Virginia would generally allow design defect suits only by the purchaser and those in privity with the seller."); see also id. at 504-05 ("[Tort liability] aris[ing] out of the performance of [a federal government] contract" intersects with the government's "uniquely federal interests" under its contracts); id. at 505 ("[T]he civil liability of federal officials for actions taken in the course of their duty" and cases involving "an independent contract or performing its obligations under a procurement contract" both "implicate[] the same interest in getting the Government's work done"); id. at 505-06 ("[T]he reasons for considering these closely related areas to be of 'uniquely federal' interest apply as well to the civil liabilities arising out of the performance of federal procurement contracts.").

application to private companies designing products or otherwise operating without a government contract. It cannot be seriously argued that the "authority and duties of the United States as sovereign are intimately involved" in a private controversy surrounding the design of a product where no aspect of that design was the subject of a procurement contract with the government. See Texas Indus., 451 U.S. at 641. Without a contract, the government has not "validly conferred" any "authority" on a private company to "carry out [a] project" on its behalf or otherwise "get[] [its] work done." See Boyle, 487 U.S. at 505-06 (citing Yearsley v. W.A. Ross Constr. Co., 309 U.S. 18, 20-21 (1988)).²⁵ Moreover, the uniquely federal interests underlying the creation of a federal common law defense in the context of federal procurement contracts in Boyle-in particular, the cost and availability of government contracts, see id. at 505-simply do not exist in the absence of a government contract. The costs of potential liability to third-parties cannot be passed along to the government where it has no contractual relationship with a private company in connection with the design of a product. See id., 487 U.S. at 512 ("It makes little sense to insulate the [g]overnment against financial liability for the judgment that a particular feature of military equipment is necessary when the

²⁵ Although the contractor in *Yearsley* enjoyed an agency relationship with the government, this distinction was not material to the *Boyle* majority's holding that civil liabilities arising from a contractor's performance under a government procurement contract, like those that arise from performance under a government performance contract, implicate a uniquely federal interest. *See Boyle*, 487 U.S. at 506.

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 30 of 56 Page 30 of 56

[g]overnment produces the equipment itself, but not when it *contracts* for the production.") (emphasis added). In short, shielding a private company from civil liability in such circumstances would stretch *Boyle* well beyond its reasonably conceivable scope, and the Court declines to do so here.

This decision is consistent with the decisions of federal appellate courts, including the Eleventh Circuit, recognizing the significance of the performance of a government contract under Boyle. See Hudgens v. Bell Helicopters/Textron, 328 F.3d 1329, 1335 (11th Cir. 2003) ("A close relationship [must] exist[] between the contract duty imposed by the federal government and the state law duty that application of the government contractor defense will preempt."); see also In re Hanford Nuclear Reservation Litig., 534 F.3d 986, 1000 (9th Cir. 2008) ("The [government contractor] defense allows a contractor-defendant to receive the benefits of sovereign immunity when a contractor complies with the specifications of a federal government contract."); Bailey v. McDonnell Douglas Corp., 989 F.2d 794, 797 (5th Cir. 1993) ("The government contractor defense, as formulated [] by the Supreme Court in *Boyle*, generally immunizes government contractors from civil liability arising out of the performance of federal procurement contracts."); Carley, 991 F.2d at 1120 ("A private contractor who is compelled by a contract to perform an obligation for the United States should, in some circumstances, share the sovereign immunity of the United States."); In re Joint E. & S. Dist. N.Y. Asbestos

Litig., 897 F.2d 626, 628 (2d Cir. 1990) ("[In Boyle], the [Supreme] Court limited the [government contractor defense] to when a state tort law duty poses a 'significant conflict' with the duties imposed under a federal contract."). Even the two government contractor defense cases cited by Defendants for the proposition that no written design contract is required by the government contractor defense involved federal policy interests that arose in connection with the respective contractors' performance of obligations under a government procurement contract containing a design component. In Brinson v. Raytheon Co., for example, the plaintiff's design defect claim arose from the defendant's performance of a government contract for the design of a single-propeller aircraft. See 571 F.3d 1348 (11th Cir. 2008). The Agent Orange litigation involved government contracts for the purchase of allegedly defective chemical defoliants; however, those contracts prescribed a "design" for the defoliants by requiring them to be "a mixture of two different herbicides . . ., nearly 100% pure and . . . combined in roughly equal proportions."²⁶ See 517 F.3d at 83. Defendants have identified no authority-none-in which a defendant having no

²⁶ Defendants make much of the Second Circuit's statement in *Agent Orange* that "a conflicting, express contractual duty [i]s [not] required for the contractor defense to preempt state law." 517 F.3d at 96. However, this statement was not directed at the "uniquely federal interest" prong of the *Boyle* test. Rather, the court was observing that the *Boyle* Court framed the "significant conflict" prong "broadly" in terms of "federal policies and interests and the exercise of federal discretion, in the face of contrary state law." *See id.* While that observation was critical to the "significant conflict" analysis in *Agent Orange* because the defendants were "not rely[ing] on a contractual duty to demonstrate the required *conflict* between federal interests and state law," *see id.* at n.18 (emphasis added), it did not bear on whether that case implicated a uniquely federal interest.

design obligation to the federal government nevertheless enjoyed the benefit of the government's sovereign immunity pursuant to *Boyle*.

Returning to the undisputed record and as already discussed, Defendants had no contractual relationship with the Army regarding the design of the CAEv2. True, the Army liked the dual-sided, non-linear design of Aearo's earplug and believed it would improve military readiness. Indeed, it is not too much to say that the Army wanted Aearo's earplug, and, at one point, even went so far as to make clear that it would not commit to purchasing the earplug unless it could be stored inside a military carrying case and worn underneath a Kevlar helmet.²⁷ But, the design already existed—it came into existence without any input from the Army, and Aearo's subsequent actions changing the length of the CAEv2's stem were not compelled by the terms of any government contract. And none of the Army's purchase orders (or the much later IQC) included a design component. Thus, Aearo was never "performing [any] obligation under a procurement contract" with the Army when it came to the CAEv2's design. See Boyle, 487 U.S. at 505. Consequently, the uniquely federal interests that *Boyle* sought to protect are not implicated in this litigation. Stated differently, whatever federal interests there may be in a products liability dispute between private parties arising from the CAEv2's

²⁷ Nothing in *Boyle* or its progeny even hints that federal preemption would be recognized, must less state tort law displaced and federal sovereign immunity extended, in the case of a private company acting on the mere hopeful anticipation that the government might buy its product.

design, those interests are not "uniquely" federal within the meaning of *Boyle*. For these reasons, Plaintiffs are entitled to summary judgment on the government contractor defense.

C. Significant Conflict

Even assuming Defendants had shown that a uniquely federal interest is implicated in this litigation, "that [would] merely establish[] a necessary, not a sufficient, condition for the displacement of state law." *See id.* at 507. As already discussed, Plaintiffs' state law claims must also present a "significant conflict" with federal policies or interests to warrant displacement by federal common law. *See id.* Here, Plaintiffs assert claims for negligence and strict product liability based on design defect and failure-to-warn theories, as well as various other state law claims. For the reasons that follow, the government contractor defense either does not apply or fails on the merits, in light of the relevant law and the evidentiary record.

1. Design Defect Claims

To receive the benefit of the government contractor defense with respect to Plaintiffs' design defect claims, Defendants must satisfy all three requirements of the *Boyle* "significant conflict" test. *See Hudgens*, 328 F.3d at 1334-35. As discussed more fully below, Defendants have failed to marshal evidence that would enable a reasonable jury to find in their favor on the first requirement; namely, that

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 34 of 56 Page 34 of 56

the government approved reasonably precise specifications for the CAEv2.²⁸ Accordingly, Plaintiffs are entitled to summary judgment on the government contractor defense with respect to their design defect claims.

The first element of the *Boyle* test requires evidence of: (1) the existence of reasonably precise specifications for the design feature in question and (2) government approval of those specifications. *Brinson*, 571 F.3d at 1351. Because this element focuses on whether and to what extent federal discretion was exercised over allegedly defective design features, see id., the approved specifications must address the particular features at issue in the litigation in reasonable detail and the government's approval must follow from its "substantive review or evaluation" of those features; it cannot be a "mere bureaucratic rubber stamp" of the overall product. Trevino v. Gen. Dynamics Corp., 865 F.2d 1474, 1479-80, 1486 (5th Cir. 1989); see also Gray v. Lockheed Aeronautical Sys. Co., 125 F.3d 1371, 1377 (11th Cir. 1997), abrogated on other grounds by Gray v. Lockheed Aeronautical Sys. Co., 155 F.3d 1343 (11th Cir. 1998). "Where the government merely approves imprecise or general guidelines, the contractor retains the discretion over the important design decision and enjoys no immunity against liability based on the Boyle defense."

²⁸ Because the Court finds that Defendants cannot meet the first element of the *Boyle* threepart test, this Order does not address the remaining two elements (i.e., conformance and warning of known dangers).

Gray, 125 F.3d at 177; *see also Brinson*, 571 F.3d at 1352 ("[G]eneral narrative requirements can not rise to the level of 'reasonably precise specifications.'").

There are two broad categories of cases in which courts have found that the government meaningfully exercised its discretion over reasonably precise design specifications.²⁹ First, a written government contract and/or applicable federal government publication incorporated into a contract may explicitly dictate a product's design requirements with reasonable precision. See Hudgens, 328 F.3d at 1331, 1335-36 (Army technical manuals incorporated by reference into service contract dictated reasonably precise maintenance procedures); Glassco v. Miller Equip. Co., Inc., 966 F.2d 641, 643 (11th Cir. 1992) (written contract with design "specifications exceed[ing] 11 pages in length, exclusive of detailed drawings" was reasonably precise). Second, the government and the contractor may engage in a "continuous back and forth" as to the content of a design, during which the government manifests its substantive review and approval of a reasonably specific design for the allegedly defective feature. See Brinson, 571 F.3d at 1352; Harduvel, 878 F.2d at 1320. In this second category of cases, substantive review and approval has been demonstrated with evidence that the government examined detailed

²⁹ Evidence that the government knew of and investigated an alleged design defect, mandated a specific remedial action, and continued reordering the same product without any change to its design is also relevant to the inquiry into whether the government approved reasonably precise specifications for a product feature. *See Brinson*, 571 F.3d at 1353-56; *Agent Orange*, 517 F.3d at 94. There is no such evidence in this litigation.

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 36 of 56 Page 36 of 56

descriptions, drawings and blueprints for the design of the product feature at issue, *see Harduvel*, 878 F.2d at 1320, that the government and the contractor engaged in "extensive negotiations" and "exchange[s] of views" about the design, *see Kleemann v. McDonnell Douglas Corp.*, 890 F.2d 698, 701 (4th Cir. 1989), and/or that the government tested or otherwise quantitatively analyzed the particular product feature during the design and production phases, *see Brinson*, 571 F.3d at 1352; *Getz v. Boeing Co.*, 654 F.3d 852, 863 (9th Cir. 2011).

This litigation clearly does not fall within the first category of cases as it is undisputed that the United States Army did not enter into a contract with Defendants for the design and development of the CAEv2. The Army never issued a request for design proposal for the new earplug, *see Brinson*, 571 F.3d at 1349, there was no competitive bidding process during which the Army established design details for a new earplug from interested contractors,³⁰ *see Maguire v. Hughes Aircraft Corp.*, 912 F.2d 67, 71 (3d Cir. 1990), and there was no comprehensive statute, regulation or federal government publication dictating the Army's design criteria, *see Hudgens*, 328 F.3d at 1335-36. In short, there was no formal "provision of up-front

³⁰ Viewing Aearo's notes from the meeting in December 1997 at Aberdeen Proving Ground in the light most favorable to Defendants, it appears that Aearo and government officials discussed the possibility of the military initiating a competitive bidding process in early 1998. *See* Aearo Aberdeen Meeting Notes, D2, ECF No. 1071-3 at 4. Significantly, however, a dual-ended design for the CAEv2 already existed at that time. *See id.* at 3 ("[ISL] ha[s] applied for patent on 2-ended plug."); *see also infra* note 33. Therefore, at most, the meeting participants could only have been contemplating bids for the purchase (as opposed to the design) of the product. In any event, it is abundantly clear from the record that no bidding process materialized until years later.

specifications" prescribed by the Army for the design of the CAEv2.³¹ *See* Def. Opp., ECF No. 1088-12 at 22. The question thus becomes whether reasonably precise specifications for the allegedly defective design features—that is, for the positioning of the earplug's flanges and/or for the length of the stem—were later provided by or to Army officials, such that meaningful review and approval could follow during "back and forth" discussions about the content of the product's design. *See Harduvel*, 878 F.2d at 1320-21. In other words, does this litigation fall within the second category of cases in which the government is deemed to have approved a design? Based on the undisputed facts in the evidentiary record, the answer is no.

To begin with, there is no evidence that the Army ever issued or received "detailed, quantitative" descriptions or drawings of the individual component parts of the CAEv2, or of how those parts should or would be integrated together into a finished product. *See Kleemann*, 890 F.2d at 703 (citing *Shaw v. Grumman*

³¹ See Email from Douglas Ohlin to Marion Burgess, dated March 14, 2006, PX53, ECF No. 1072-56 ("There is no DOD specification for the [C]ombat [A]rms [E]arplug."); see also Deposition transcript of Dr. Douglas Ohlin in *Moldex-Metric, Inc.*, 12-cv-611 (D. Minn.) dated April 24, 2013, PX9, ECF No. 1072-11 at 16 ("I don't know of any specification for the Combat Arms Earplug.") and 24 ("I know of no specification for the Combat Arms Earplug."); Deposition transcript of Timothy McNamara dated March 11, 2020, PX18, ECF No. 1072-21 at 26 ("I don't remember seeing" any formal military specifications for the CAEv2); Deposition of Lorraine Babeu dated March 10, 2020, PX23, ECF No. 1072-26 at 7-9 (agreeing that she had never seen a military specification prescribing the "size" and "characteristics" for the CAEv2); Deposition of D. Garrard Warren, III, PX34, ECF No. 1072-37 at 36 (stating that he was not aware of a DOD specification for the CAEv2 at any point in time when he was president" of Aearo); Deposition of LTC John A. Merkley, PX 43, ECF No. 1072-46 at 7 (testifying that he found no DOD or Army specification for the CAEv2).

Aerospace Corp., 778 F.2d 736, 745 (11th Cir. 1985), *abrogated on other grounds by Boyle*, 487 U.S. at 513). Aearo had design drawings for the device,³² as well as lengthy and detailed descriptions of the designs and dimensions for the earplug and its component parts.³³ The problem for Defendants is that none of these design details were ever shared with Army officials.³⁴ And rather than engaging with the Army on the specifics of how the CAEv2 would be configured, Aearo simply "put together the parts in a way [it] thought could work for the military." *See* Berger Deposition dated December 12, 2019, D56, ECF No. 1072-57 at 21.

It is true, as Defendants argue, that Dr. Ohlin and other military officials were "interested in" a dual-ended version of the earplug integrating ISL's non-linear filter and Aearo's Ultrafit tips.³⁵ *See* Aearo Aberdeen Meeting Notes, D2, ECF No. 1071-

³² See, e.g., Drawing of dual-ended earplug, D11, ECF No. 1071-12; Drawings of dualended earplug and its components, D14, ECF No. 1071-15.

³³ See United States Patent No. 4,867,149, dated September 19, 1989 (multiple flange earplug), PX3, ECF No. 1072-5; United States Patent No. 5,936,208, dated August 10, 1999) (dual-ended earplug), PX6, 1072-8; United States Patent No. 6,068,079, dated May 30, 2000 (acoustic valve capable of selective and non-linear filtering of sound), PX2, ECF No. 1072-4.

³⁴ Defendants conceded this fact during oral argument. *See* Oral Argument Transcript dated June 15, 2020, ECF No. 1199 at 23-24.

³⁵ The source of this information is a set of notes taken by Aearo's Elliott Berger at a meeting with representatives of his company, ISL and the Army at Aberdeen Proving Ground in December 1997. *See* D2, ECF No. 1071-3. Again, the notes reflect that the dual-ended design already existed at that time. Moreover, the notes show that Dr. Ohlin was simply choosing one of the three options "propose[d]" to the Army at the time, which were: "1) original openable/closable concept[;] 2) 2-ended plug, w/nonlin end=yellow, closed end=red[;] 3) two separate earplugs, one=nonlin and one=UltraFit." *See* D2, ECF No. 1071-3 at 4. Of those, according to Berger, Dr. Ohlin said the United States Army would be "interested in [the] 2-ended plug" because it would be "easier to dispense" and "less labor-intensive . . . to use." *See id.* at 4. Nothing in Berger's notes suggested, and nothing else in the record supports, that detailed design drawings or

3 at 4. But the Army's mere expression of an interest in an existing technology cannot constitute government approval of reasonably precise specifications under *Boyle*, particularly where it was not preceded, accompanied or followed by receipt and meaningful review of the product's underlying design details. *See Brinson*, 571 F.3d at 1351 ("[The first *Boyle* condition] is meant to ensure that a government officer considered and approved 'the design feature in question.'"). Somewhat relatedly, it is also true that the IQCs issued by the government to Aearo years later (which, again, included the MPID) were for "double-ended, swept-back triple-flange earplugs . . . incorporating a passive non-linear technology." *See* P37, ECF No. 1072-40 at 44-45. However, this too falls short of the *Boyle* standard. General narrative descriptions of this nature "can not rise to the level of reasonably precise specifications." *See Brinson*, 571 F.3d at 1352 (citing *Gray*, 125 F.3d at 1378).

Equally insufficient is Defendants' argument that the Army received something "far better" than design drawings when Aearo provided it with production samples for the CAEv2, which Dr. Ohlin found acceptable.³⁶ *See* Oral Argument Transcript dated June 15, 2020, ECF No. 1199 at 24. The government contractor

descriptions for the various proposed "solutions" were shown to the military at that time, or that the Army ever saw and approved the meeting notes.

³⁶ The exact date that the Army received the second production sample is not clear from the record. The new design drawings depicting the shortening of the CAEv2's stem are dated April 27, 1999. *See* D14, ECF No. 1071-15. On May 12, 1999, Dr. Ohlin reported to a colleague that Aearo had already "got[ten] back to [the Army] with acceptable production samples." *See* Ohlin Email to Belva Hoffman, D3, ECF No. 1071-4 at 4.

defense requires more than the government's acceptance of a contractor's product there must be "substantive review and evaluation of the contractor's design choices," Trevino, 865 F.2d at 1486, which cannot occur if the government never receives and reviews any "detailed, precise [or] quantitative" information about a product's design, see Shaw, 778 F.2d at 745. It is undisputed that Dr. Ohlin never received the existing detailed design drawings or descriptions, and there is no evidence that he evaluated the second production sample in any meaningful way. The Court may not speculate about what he may or may not have done to evaluate that sample. See Marshall v. City of Cape Coral, Fla., 797 F.2d 1555, 1559 (11th Cir. 1986) ("Inferences based upon speculation are not reasonable, and may not defeat a motion for summary judgment.") (internal marks omitted). At most, the evidentiary record establishes that Dr. Ohlin "rubber stamped" the second production sample and, thereafter, the Army began purchasing and using it. "Boyle clearly indicates that such 'approval' would be insufficient." See Trevino, 865 F.2d at 1482; see also Gray, 125 F.3d at 1377 ("A finding that the military approved the specifications" requires more than a tacit approval: the approval must be meaningful, not a mere formality.").

That leaves only the fact that Dr. Ohlin conveyed to Aearo that the initial production sample for the CAEv2 was one-quarter of an inch too long to fit in the

Army's earplug carrying case,³⁷ and then sent an email relaying additional concerns about wind noise and interference with the Kevlar helmet's chinstrap. According to Dr. Ohlin, the latter concern was a "showstopper"—i.e., a dealbreaker. This shows that not only did the Army *not* exercise design discretion, but also gave Aearo complete freedom to decide whether and how to proceed. Also, it is worth emphasizing that what we are talking about here is no more than two short emails one email from Aearo's Brian Myers to Dr. Ohlin, and one email from Dr. Ohlin responding to Myers—in which Dr. Ohlin's concerns are described in the most general of terms.³⁸ These messages, themselves, do not amount to government

³⁷ There is no evidence of a prior communication from Dr. Ohlin to Aearo on this issue. However, considering the record in the light most favorable to Defendants, the Court reasonably infers that at some point between March 24, 1998-when Aearo's Richard Knauer sent 25 initial production samples of the CAEv2 to Dr. Ohlin, see D12, ECF No. 1071-13-and April 8, 1999when Aearo's Brian Myers advised Dr. Ohlin, via email, that the company believed it could probably shorten the plug by the one-quarter inch required to fit the military's current container, see D4, ECF No. 1071-5, Dr. Ohlin conveyed the problem to Aearo. The Court may not infer anything about what exactly Dr. Ohlin said at the time, however. See Marshall, 797 F.2d at 1559 ("Inferences based upon speculation are not reasonable, and may not defeat a motion for summary judgment."). Interestingly, the record shows that Dr. Ohlin initially had a different solution for the problem. On April 6, 1999, Dr. Ohlin submitted a formal request to the Staff Director, Joint Readiness Clinical Advisory Board for the Army, seeking a one-quarter inch increase in the height and width of the current earplug carrying case in order to accommodate the CAEv2. See PX72, ECF No. 1089-6. Dr. Ohlin attached detailed "specification drawing[s] [for the case] from an initial supplier" to that request. See id. at 4-5. Two days later, it was Myers who volunteered to shorten the plug as an alternative solution. See D4, ECF No. 1071-5. Myers said that the plug's "designer [would] look at this" after returning from vacation and he requested a sample storage container to "help ... expedite the redesign." See id. at 2. There is no evidence that Myers or the designer ever spoke any further with Dr. Ohlin about the redesign. Instead, shortly after Myers' email, Aearo supplied new production samples to the Army.

³⁸ See Emails between Brian Myers and Dr. Ohlin dated April 8-9, 1999, D4, ECF No. 1071-5. Other than this email exchange, there is no evidence the Army and Aearo ever communicated about wind noise and the Kevlar helmet again. Myers also was copied on an email from Dr. Ohlin to an Army colleague, Belva Hoffman, on April 12, 1999, which conveyed the

approval of reasonably precise design specifications for several reasons. First, because Aearo and the Army had no contractual relationship at this stage, nothing Dr. Ohlin said during that period can reasonably be construed as the Army imposing a mandatory duty or obligation on Aearo. Stated differently, absent a contract, no reasonable jury could conclude that Dr. Ohlin or the Army made Aearo do anything. See Brinson, 571 F.3d at 1351 ("Stripped to its essentials, the military contractor defense is available only when the defendant demonstrates with respect to its design and manufacturing decisions that the government made me do it."); KBR, Inc., 744 F.3d at 348 ("[N]o 'uniquely federal interest' warrants preemption when the federal government has little or no control over a contractor's conduct.") (quoting *Boyle*, 487 U.S. at 509-10). Dr. Ohlin's statements certainly conveyed that Aearo's production sample would not meet the Army's needs, but they did not direct Aearo to do anything.

Second, the messages were not "reasonably precise" regarding either of the design features at issue in this litigation, i.e., flange positioning and stem length. There is no evidence that Dr. Ohlin's communications about the plug's overall size referenced either of these two features. And why would they? Regarding the size of the plug, Dr. Ohlin—and thus, the Army—was undisputedly concerned only with

same three concerns about the production sample (i.e., carrying case, wind noise, Kevlar helmet). *See* D4, ECF No. 1071-6 at 2.

whether the plug could be stored inside a carrying case and worn underneath a Kevlar helmet.³⁹ Aearo was left to figure out *how* to modify the CAEv2's design to achieve these objectives. This fact is significant because the record reflects there were multiple ways to modify the length of the earplug,⁴⁰ and it is undisputed that Aearo had sole discretion over the method chosen. *See Gray*, 125 F.3d at 1377 ("[R]easonably precise specifications . . . means that the discretion over significant details all critical design choices will be exercised by the government."); *In re Katrina Canal Breaches Litig.*, 620 F.3d 455, 464-65 (5th Cir. 2010) ("By providing only general instructions regarding the compaction method, the [government] ensured [the contractor] would have significant discretion over the method chosen . . . [which] is not protected by the [defense]."). Of course, this is not to say that the Army could not later exercise policy discretion to approve reasonably precise

³⁹ In point of fact, it appears from the record that Aearo did not even shorten the stem by one-quarter of an inch. The design drawing for the first production sample indicates that the original length of the CAEv2 was 1.588 inches (40.34 millimeters). *See* D11, ECF No. 1071-15 at 10. The design drawing for the second production sample reflects a new length of 1.404 inches (35.66 millimeters). *See id.* at 11. By the Court's calculation, the stem thus was only shortened by 0.184 inches (4.68 millimeters). There is no evidence that Aearo shared this information with Dr. Ohlin or that he discovered it on his own. However, it is undisputed that the second production sample did fit the military carrying case and that Dr. Ohlin deemed it acceptable.

⁴⁰ See, e.g., Elliott Berger Deposition dated December 12, 2019, D56, ECF No. 1071-57 at 18 (agreeing that the Army could have asked that the plugs be designed with flanges of different sizes); Richard Knauer Deposition dated December 17, 2019, PX57, ECF No. 1071-58 at 8 (describing how Aearo modified certain Ultrafit tips by "cut[ting] them down to certain lengths") and 8-9 (acknowledging that triple-flange tips "can come in more than one size"); Letter from Drs. A. Dancer and P. Hamery to Elliott Berger dated July 25, 1997, PX93, ECF No. 1089-27 at 2-3 (describing two earplugs "made from a perforated classical Ultrafit plug of which the tip ha[d] been shortened").

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 44 of 56 Page 44 of 56

specifications for Aearo's design choice. *See Boyle*, 487 U.S. at 513 ("The design ultimately selected may well reflect a significant policy judgment by the [g]overnment officials whether or not the contractor rather than those officials developed the design."). But that is a separate question from whether the Army, in those messages, established reasonably precise specifications, which did not happen.⁴¹ *See Harduvel*, 878 F.2d at 1316 ("[T]he government . . . participate[s] in discretionary design decisions[] either by designing a product itself or approving specifications prepared by the contractor."). On this record, even viewed in the light most favorable to Defendants, no reasonable jury could conclude that Dr. Ohlin's communications created reasonably precise specifications for the design of the CAEv2 or its allegedly defective features.

Based on the foregoing, Defendants' argument that meaningful government approval occurred here stumbles right out of the gate. Without evidence that the Army created or received detailed descriptions or drawings of the CAEv2's design, or of the design for the product features at issue in this litigation (which, again, undisputedly existed), it cannot reasonably be said to have "substantive[ly] reviewed" and approved Aearo's design choices. *See Trevino*, 865 F.2d at 1486. In this respect, the design and development process for the CAEv2 could not be more

⁴¹ Consequently, even if Dr. Ohlin had voiced these concerns from the start—the need to fit in a carrying case and underneath a Kevlar helmet—the result would be the same.

different from government contractor defense cases in which courts found that a "continuous back and forth" between the government and the contractor demonstrated meaningful approval of reasonably precise specifications as a matter of law.

Harduvel v. Gen. Dynamics Corp., for example, involved an alleged design defect in the electrical system for a fighter aircraft. See 878 F.2d at 1318. The United States Air Force had initiated the design process for the aircraft by soliciting proposals from interested contractors. See id. at 1320. The Air Force then "extensive[ly] reviewed" the winning contractor's proposed design by "examining specifications, drawings, and blueprints" for the aircraft, and assigning a specific group of engineers to review the electrical system's design. *Id.* It further evaluated the designs during three formal reviews prior to the start of production. *Id.* Even after production began, the Air Force continued reviewing, modifying and approving "design and production methods" for the aircraft, including the electrical system. *Id.* Based on the Air Force's extensive involvement, the Eleventh Circuit concluded that the Air Force and the contractor designed the electrical system through a "cooperative back-and-forth" process. Id. at 1321.

The Eleventh Circuit found similarly "exhaustive" government involvement in the design and development of a training aircraft for the Air Force in *Brinson v*. *Raytheon. See* 571 F.3d at 1356. There, the allegedly defective feature of the

aircraft—an automatic rudder trim system (operated by a "trim aid device," or "TAD") incorporated Teflon-lined pushrods that could bend and fracture under stress, causing the entire TAD system to fail—was originally designed and patented by the contractor without government input. See id. at 1350. Nevertheless, there was "ample" evidence that the contractor's design was subsequently "considered, reviewed and approved" by the Air Force. See id. at 1355, 1357. For starters, the Air Force "always had the design drawings" for the TAD and all other systems in the aircraft. See id. at 1354 n.6. Air Force engineers demonstrably reviewed and approved those drawings and, after production began, government engineers compared the "engineering drawings and work instructions" with the assembled rudder system (of which the TAD was a component) to ensure the aircraft conformed to the design requirements. See id. at 1354-55. There were "numerous meetings" about the TAD during the aircraft's development phase and "direct, hands on participation" by Air Force officials in the "installation and interfacing" of the TAD. See id. at 1355 n.8. Finally, the evidence established that the military later became "specifically aware of the design defect at issue" (*i.e.*, that some Teflon-lined pushrods showed evidence of bending) and responded by ordering that the pushrods be replaced with new, but otherwise identical, Teflon-lined pushrods. See id. at 1355. That order "reflect[ed] an informed, discretionary decision on how to address a known problem." See id. at 1356. Taken together, this evidence-that is, the

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 47 of 56 Page 47 of 56

"extensive and 'continuous back and forth" development process, and the military's selection of a remedy for the defect that it deemed appropriate—demonstrated the government's meaningful review and approval of reasonably precise specifications for the automatic rudder trim system and its components. *See id.* at 1356-57.

And so it goes in government contractor defense jurisprudence around the country. See, e.g., Getz, 654 F.3d at 862-63 (Army "carefully scrutinized, tested, and made necessary changes to" the contractor's "lengthy and detailed design specifications" for the allegedly defective components of an aircraft); Oliver v. Oshkosh Truck Corp., 96 F.3d 992, 996, 998-99 (7th Cir. 1996) (Marine Corps participated "extensive[ly]" in design and development of a military supply vehicle, made "hundreds" of design changes, and had "substantive input" in the configuration of the allegedly defective fuel and exhaust system); Stout v. Borg-Warner Corp., 933 F.2d 331, 335 (5th Cir. 1991) (Army "reviewed, evaluated, tested and approved detailed design drawings" of the product at progressive stages of the development process, including "over fifty pages" of drawings of the allegedly defective component); Kleemann, 890 F.2d at 701-03 (Navy "performed extensive review of detailed design drawings submitted by" the contractor, participated in regular "design review meetings[,]" and required government approval of all design changes). The common thread woven through all of the "continuous back and forth" cases-aside from the existence of a government contract for the design or

development of *something*, of course—is receipt and substantive review of detailed design descriptions, drawings and/or blueprints by government officials. *See, e.g., Harduvel*, 878 F.2d at 1320. Its absence in this litigation dooms the government contractor defense.

The Court recognizes that the CAEv2 is not a technically complex item of military hardware, such as an F-16 fighter aircraft, see Harduvel, 878 F.2d at 1313; MK-48 transport vehicle, see Oliver, 96 F.3d at 995, or the diving chamber of a submarine, see Trevino, 865 F.2d at 1476. But neither was the leather lineman's belt in *Glassco*, which, again, involved design specifications approximately "11 pages in length." See 966 F.2d at 643. The Boyle requirement of meaningful government approval of reasonably precise specifications had to be met there, see id., just as it must be met in *all* cases where a contractor seeks the benefit of the government's sovereign immunity, see Harduvel, 878 F.2d at 1316. Here, at the very least, there were nearly thirty pages of "detailed, precise and [] quantitative" design descriptions and drawings of the CAEv2 and its component parts that could have been provided to Army officials for review and approval, but were not. See Shaw, 778 F.2d at 745. Even Aearo's shortening of the earplug's stem resulted in a new design drawing that could have been reviewed and approved by the Army, but was not.

The Court's analysis of the first *Boyle* element in the context of this record thus ends where it began: there is no evidence that the Army ever created or received

detailed, quantitative descriptions or design drawings showing the component parts of the CAEv2, or describing how those parts should or would be integrated together into a finished product. Thus, it cannot be said that the Army "actually participated in discretionary design decisions [for the CAEv2], either by designing [the] product itself or approving specifications prepared by" Aearo.⁴² *See Harduvel*, 878 F.2d at 1316. The Army did not participate in any way in Aearo's decision on how to position the CAEv2's flanges or how to shorten the plug to fit the Army's carrying case. Instead, the undisputed material facts establish that those discretionary design decisions, which are the basis for the design defect claims in this litigation, were made by Aearo alone. Accordingly, the type of significant conflict contemplated in *Boyle* is not present on this record, and the government contractor defense is not available to Defendants.

2. Failure-to-Warn Claims

The Eleventh Circuit extended the government contractor defense to failureto-warn claims in *Dorse v. Eagle-Picher Indus., Inc.*, 898 F.2d 1487, 1489 (11th Cir. 1990). Pursuant to *Dorse*, the government contractor defense preempts failure-to-

⁴² Perhaps the Army *should* have exercised discretion over reasonably precise design specifications for the CAEv2 before purchasing it in bulk and issuing it to service members. However, the Army's *failure* to exercise discretion is not a basis for insulating Aearo from civil liability under *Boyle*. *See Trevino*, 865 F.2d at 1487 n.13; *see also Hudgens*, 328 F.3d at 1335 (quoting *Boyle*, 487 U.S. at 512) ("The reasonable precision requirement ensures that the government contractor defense is limited to its proper scope by requiring 'that the design feature in question was considered by a [g]overnment officer, and not merely the contractor itself.").

warn claims only where a federal government contract affirmatively prohibits a warning or contains specific warning requirements that significantly conflict with those required by state law. *See id.*; *see also In re Joint*, 897 F.2d at 631. The defense fails as a matter of law if the contractor can "comply with both its [federal] contractual obligations and the state-prescribed" duty to warn. *See Dorse*, 898 F.2d at 1489-90. The Eleventh Circuit has not retreated from this standard, and in fact has reaffirmed it. *See Glassco*, 966 F.2d at 644 (reversing grant of summary judgment on government contractor defense as "inconsistent with *Dorse*" where district court applied three-part *Boyle* test to failure-to-warn claim).⁴³ *Dorse* thus is binding and dispositive.

Plaintiffs allege Defendants failed to warn or instruct of the following risks and dangers of using the CAEv2 as intended: (1) that the CAEv2 loosens imperceptibly in a user's ears, thereby allowing damaging sounds to bypass the earplug and enter the ear; (2) that Aearo's testing subjects did not follow standard fitting instructions, but rather used a reconfigured method of folding back the opposing flanges before inserting the device into their ears; (3) that following Defendants' standard instructions for insertion of the CAEv2 would not achieve the 22 Noise Reduction Rating and would thereby pose a serious risk to users; and (4)

⁴³ This Court obtained and reviewed the district court's summary judgment order. *See Glassco v. Miller Equip. Co., Inc.*, No. 5:90cv294-ELN, ECF Nos. 32-33 (N.D. Ala. Jan. 7, 1991).

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 51 of 56 Page 51 of 56

that Defendants did not adequately or properly test the CAEv2. *See* Master Long Form Complaint, ECF No. 704-1 at 55-60. In response, Defendants have identified no contract, formal specification, or incorporated government publication in which the Army forbade Aearo from fulfilling any state law duty to warn or instruct of these alleged risks or dangers inherent in the use of the CAEv2 or otherwise dictated the specific warnings to be given. Consequently, "the state-imposed duty of care that is the asserted basis of [Aearo's] liability (warning of the danger) is not 'precisely contrary' to the duty imposed by" any contract the company had with the Army. *See Dorse*, 898 F.2d at 1489. Consistent with *Dorse*, the government contractor defense thus fails as a matter of law with respect to Plaintiffs' failure-towarn claims.

Instead of meaningfully acknowledging *Dorse* and grappling with its undeniable implications for this litigation, Defendants essentially ignore it, and invite this Court to do the same, by simply furnishing a different legal standard—a version of *Boyle's* three-part test for significant conflicts in design defect cases, adapted for the failure-to-warn context by other circuits—and applying that standard to Plaintiffs' failure-to-warn claims. *See* Def. Mot., ECF No. 1071-68 at 39-40. However, in *Dorse*, the Eleventh Circuit expressly considered and declined to extend *Boyle's* three-part test to failure-to-warn claims, *see* 898 F.2d at 1489 ("[T]he three-part test [adopted by the Supreme Court in *Boyle*] is necessarily limited to design

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 52 of 56 Page 52 of 56

defect cases."), deciding instead to be guided solely by "*Boyle's* two-pronged analysis"—namely, the "threshold requirement" that a case involve an area of uniquely federal interest, and the need for a significant conflict to exist between "an identifiable federal policy and the operation of state law." *See id.* at 1489. The existence of a significant conflict depends only on whether "the state-imposed duty of care that is the asserted basis of the contractor's liability (warning of the danger) is [] 'precisely contrary' to the duty imposed by [a] government contract." *See id.* This Court is bound by *Dorse*, period. *See Johnson v. DeSoto Cty. Bd. of Comm'rs*, 72 F.3d 1556, 1559 n.2 (11th Cir. 1996) ("[D]istrict courts must follow the holdings of their courts of appeals and the Supreme Court.").

Nonetheless, and in an abundance of caution, even if *Dorse* could be read to encompass a "more relaxed" test for significant conflict, *see Graves v. 3M Co.*, --- F. Supp. 3d ----, 2020 WL 1333135, at *4 (D. Minn. 2020), which the Court does not believe it can, the Court would still find that Defendants have failed to satisfy the first element as a matter of law.⁴⁴ The first element would require evidence that government officials exercised discretion and substantively approved certain

⁴⁴ The three-part *Boyle* test, modified to the failure-to-warn context, generally requires a showing that: (1) government officials exercised discretion and substantively approved certain warnings; (2) the contractor provided warnings that conformed to the approved warnings; and (3) the contractor warned the government of the dangers in the equipment's use about which the contractor knew, but the government did not. *See Tate v. Boeing Helicopters*, 55 F.3d 1150, 1157 (6th Cir. 1995) (*"Tate I"*); *Oliver*, 96 F.3d at 1003-04.

Case 3:19-md-02885-MCR-GRJ Document 1280 Filed 07/24/20 Page 53 of 56

warnings for a product. See, e.g., Tate v. Boeing Helicopters ("Tate I"), 55 F.3d

1150, 1157 (6th Cir. 1995); Oliver, 96 F.3d at 1003-04. The government exercises

discretion as to warnings where it is

both knowledgeable and concerned about the contents of the proposed warnings before granting its approval. The government is sufficiently knowledgeable when it has a complete enough understanding of the proposed warnings to reasonably recognize which hazards have been thoroughly addressed and which have not. The government is sufficiently concerned when it demonstrates a willingness to remedy or require the remedy of any inadequacies it finds in the proposed warnings. Where government knowledge and concern are exhibited through [a continuous back and forth] review process, it may be fairly said that the government has decided which warnings should and should not be provided to end users.

Tate v. Boeing Helicopters ("Tate II"), 140 F.3d 654, 658 (6th Cir. 1998).

Defendants have not even attempted to explain how the record demonstrates that the Army exercised its discretion as to warnings. To begin with, Defendants do not suggest that the alleged absence of adequate warnings for the CAEv2 resulted from a "continuous back and forth" with the Army. *See* Def. Opp., ECF No. 1071-68 at 39-40; Def. Reply, 1101-6 at 15-17. Instead, they argue only that they were complying with the military's "*directive* not to provide instructions." *See* Def. Reply, ECF No. 1101-6 at 17. This argument fails. There is no evidence—none—that the Army prohibited Aearo from warning of alleged dangers inherent in the use of the CAEv2. At most, according to two Aearo employees, Dr. Ohlin told the company not to include instructions inside the boxes for bulk shipments of the

earplug because military audiologists would provide in-person training to each service member.⁴⁵ But that "directive" did not preclude Aearo from affixing warnings to the outside of the boxes, an alternative that was later expressly contemplated in the MPID.⁴⁶ Nor did it prevent Aearo from providing adequate warnings with individual blister packs of the CAEv2. Finally, while Dr. Ohlin's statements may have addressed the *placement* of instructions in bulk shipments, they reflect no exercise of discretion as to the *type* and *content* of any warnings that "should and should not be provided to end users." *See Tate II*, 140 F.3d at 658. In short, on this record, Defendants simply cannot show that the Army substantively approved (or rejected) certain warnings for the CAEv2.

Because Defendants have failed to produce evidence sufficient to satisfy the test for significant conflicts in failure-to-warn cases under any interpretation of *Dorse*, the government contractor defense is unavailable to them as a matter of law with respect to the failure-to-warn claims in this litigation. Accordingly, Plaintiffs'

⁴⁵ See Santoro Tr., D62, ECF No. 1071-63 at 13-14; Myers Tr., D63, ECF No. 1071-64 at 6-10.

⁴⁶ See MPID, PX37, ECF No. 1072-40 at 45 ("Illustrated instructions explaining the proper use and handling of the ear plugs shall be supplied with each unit. Instructions shall be printed in permanent black or navy blue ink on a suitable sheet of paper which shall be placed inside the unit package prior to sealing. As an alternate, instructions may be printed on a suitable, clearly visible location on the unit container in permanent black or navy blue ink.") and 46 ("Illustrated instructions for use, as specified [above], shall be supplied with each unit.").

motion for summary judgment on the government contractor defense as to the failure-to-warn claims is granted.

3. Remaining Claims

Finally, Plaintiffs have moved for summary judgment on the government contractor defense as to their negligence, warranty, misrepresentation, fraud, gross negligence, negligence *per se*, and consumer-protection claims. Defendants concede that the defense applies only to design defect and failure-to-warn claims. *See* Def. Opp., ECF No. 1088-12 at 39. Therefore, Plaintiffs' motion is granted with respect to their remaining claims.

IV. Conclusion

Federal common law preempts and displaces state tort law under *Boyle* only in "area[s] of uniquely federal interest" where a "significant conflict exists between an identifiable federal policy or interest and the operation of state law." *See* 487 U.S. at 507. Because no aspect of the design for the CAEv2 was ever the subject of a procurement contract with the Army, the design defect claims in this litigation do not implicate a uniquely federal interest. However, even if the Army's interest in the CAEv2's design was "uniquely federal," there is no evidence that the Army "actually participated in discretionary design decisions, either by designing [the CAEv2] itself or approving specifications prepared by" Aearo. *See Harduvel*, 878 F.2d at 1316. As a result, on this record, no significant conflict exists between a discretionary decision of the Army and Aearo's alleged state tort law duty of care with regard to the design of the CAEv2, and thus adjudicating the design defect claims in the litigation will not require the Court to second-guess any discretionary policy decision by the Army. Accordingly, displacement of state law is not warranted. *See Boyle*, 487 U.S. at 508 ("[C]onflict there must be."). The same is true with respect to Plaintiffs' failure-to-warn claims.

Plaintiffs are entitled to judgment as a matter of law on the government contract defense as to all of their claims.

Accordingly:

- 1. Defendants' Motion for Summary Judgment on the Government Contractor Defense, ECF No. 1071-68, is **DENIED**.
- 2. Plaintiffs' Motion for Summary Judgment on the Government Contractor Defense, ECF No. 1072, is **GRANTED**.

SO ORDERED, on this 24th day of July, 2020.

M. Casey Rodgers

M. CASEY RODGERS UNITED STATES DISTRICT JUDGE