UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

IN RE: 3M COMBAT ARMS EARPLUG PRODUCTS LIABILITY LITIGATION	Case No. 3:19-md-02885-MCR-GRJ
	Judge M. Casey Rodgers
This Document Relates to All Cases	Magistrate Judge Gary R. Jones

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON THE GOVERNMENT CONTRACTOR DEFENSE

Pursuant to Fed. R. Civ. P. 56 and Local Rule 56.1, Defendants 3M Company, 3M Occupational Safety LLC, Aearo Technologies LLC, Aearo Holding, LLC, Aearo Intermediate, LLC and Aearo, LLC ("Defendants") respectfully, by and through their undersigned counsel, file this motion seeking summary judgment on the government contractor defense. The grounds for this motion are set forth in the accompanying memorandum.

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INTRODUCTION

The Court should grant defendants' motion for summary judgment on the government contractor defense. Plaintiffs base their design defect claim on a design element of the Combat Arms Earplugs version 2 ("CAEv2")—the length of the earplug—that was specifically required by the U.S. military. And the military assumed full responsibility for instructing service members on the proper fitting and use of the CAEv2, preempting any claim based on an alleged failure to warn.

This case presents a classic example of the need for, and purpose behind, the government contractor defense. The U.S. military had a longstanding problem: service members were regularly exposed to very loud noises but often could not (or would not) wear hearing protection because they needed to be able to hear their surroundings. In the mid-1990s, the Army began researching a potential solution: a "non-linear" earplug incorporating a filter designed by the French-German Research Institute of Saint-Louis ("ISL"). The filter allowed lower-level sounds, such as voice commands, to pass through with minimal sound attenuation, but provided increasing attenuation for higher-level sounds, such as gunfire. After testing, the Army concluded that "non-linear earplugs provide acceptable hearing protection, especially when one considers that the alternative presently being used is not to wear hearing protection." (Ex. 1 at P01082.10.)

In December 1997, Army representatives asked Aearo to produce an earplug containing the ISL filter. (Ex. 2 at 2-3.) The military provided various specifications for this product, including that it be (i) dual-ended—*i.e.*, with both conventional and non-linear ends—so that soldiers did not have to carry around two separate sets of earplugs, and (ii) single-sized, because a one-size-fits-most product was easier for the Army's audiologists to dispense. (*Id.*) Most importantly, after Aearo provided initial product samples in 1998, the military directed Aearo to shorten the length of the earplug by approximately 1/4" so that it fit into the military's standard earplug carrying case and would not interfere with a soldier's ability to fasten the helmet chin strap. (*E.g.*, Exs. 3-5.)

The military had valid tactical reasons for wanting a shorter earplug, but that decision created an issue. Aearo discovered during its internal testing that, for certain users who needed to insert the plug deeply to obtain a best fit, the flanges on the opposite end of the dual-ended earplug could come into contact with the user's tragus—the prominence in front of the external opening of the outer ear—and cause the earplug to loosen in the user's ear. The solution to this issue was straightforward: affected users could fold back the flanges on the opposite end as needed to get a good fit. The undisputed evidence shows that (1) Aearo clearly communicated this issue to the military, and (2) the military in turn instructed its audiologists to fold back the flanges as needed when fitting individual service members.

Plaintiffs claim that the CAEv2 is defectively short. But the military concluded otherwise because it dictated the earplug's length and decided to use the product after the flange fold issue was discovered. The Supreme Court has made clear that where, as here, the government makes an informed decision to use a certain design, courts cannot "second-guess" that decision by entertaining state tort suits. *Boyle v. United Techs. Corp.*, 487 U.S. 500, 511 (1988). Summary judgment is therefore warranted.[1]

STATEMENT OF FACTS

A. Hearing Loss And Situation Awareness In The Military.

Hearing loss and tinnitus are "by far the most prevalent service-connected disability among American Veterans." (Ex. 6 at 1.) Hearing protection devices ("HPDs") can help protect soldiers from those injuries, but many soldiers have been reluctant to use them because their situation awareness—the ability to hear their surroundings—would be lost. (*E.g.*, Ex. 7 at 1; Ex. 1 at P01082.3, .9-10; Ex. 9 at 3M_MDL000039902; Ex. 42 at 3M_MDL000055849.) Indeed, the Army's own

[1] Defendants expect to obtain additional evidence in support of the government contractor defense in the future, including over twenty government depositions that have been postponed due to the coronavirus pandemic. The Court declined defendants' request to postpone summary judgment briefing until the conclusion of government discovery. Defendants reserve the right to supplement the arguments made in this brief as discovery continues.

regulations provided that soldiers "[s]hould NOT wear hearing protectors when they impair necessary hearing" in combat. (Ex. 8 at 6–2(d)(2).)

B. The Military Researched And Tested Non-Linear Earplugs.

In the 1990s, military audiologists learned that researchers at ISL had developed a technology that could help reconcile the dueling priorities of hearing protection and situation awareness. (*E.g.*, Ex. 1 at P01082.2-3.) In essence, ISL had invented a cylindrical "filter" that, when inserted into a conventional earplug, provided "non-linear" noise attenuation. (*Id.*; Ex. 9 at 3M_MDL000039902-04.) A "non-linear" earplug allows the wearer to hear relatively quiet sounds, like speech, but provides increasing attenuation for higher level sounds, like gunfire. (*Id.*)

Between 1995 and 1997, Army researchers conducted various tests using non-linear earplugs with the ISL filter. In 1995, Army researcher Dan Johnson tested two non-linear earplugs—an earplug developed by the Army called the "Rucker Plug," and a version of the Aearo "[U]ltrafit" earplug into which the Army had inserted the ISL filter. (Ex. 10 at 3M_MDL000014064.) Johnson concluded that the Ultrafit "performed better" and "may be a satisfactory solution." (*Id.* at 3M_MDL000014157-58.)

In December 1996, Army researcher Georges Garinther traveled to ISL in France to participate in further testing of non-linear earplugs, including a version of the Ultrafit. (Ex. 1 at P01082.2-7.) Garinther determined that "[t]he non-linear

earplug protected hearing as effectively as the [traditional] earplug that is normally worn by French soldiers." (*Id.* at P01082.4) He provided the results of the testing, and samples of the earplugs used, to Dr. Doug Ohlin, who was the individual responsible for approving new hearing protection devices for the Army. (*Id.* at P01082.6; Ex. 44 (3/3/20 Coleman Tr.) at 281:4-10 (Ohlin was decisionmaker); Ex. 66 (Fallon Decl.) ¶¶ 4-6 (same).)

In November 1997, Garinther returned to ISL for additional testing. (Ex. 1 at P01082.8.) He concluded that "non-linear earplugs provide acceptable hearing protection, especially when one considers that the alternative presently being used is not to wear hearing protection." (*Id.* at P01082.10) He recommended to Ohlin and others that the Army adopt a non-linear earplug. (*Id.* at P01082.11)

C. The Military Worked With Aearo To Develop The CAEv2.

On December 16, 1997, the U.S. military hosted a meeting at Aberdeen Proving Ground, a U.S. military facility, to discuss the development of a new non-linear earplug for the Army. (Ex. 2 at 2-3; Ex. 56 (12/12/19 Berger Tr.) at 8:10-22; 54:22-58:25.) Attendees included Ohlin, Garinther, other Army representatives, ISL representatives, and Elliott Berger, an acoustical scientist with Aearo. (*Id.*) During the meeting, Ohlin requested that Aearo develop an earplug that: (1) incorporated the ISL filter, (2) used Aearo's "Ultrafit" tips, which the government had previously tested with the ISL filter, (3) was dual-ended, with both nonlinear and conventional

ends, so that service members did not need to carry two separate sets of earplugs, and (4) was single-sized, because a one-size-fits-most product was easier for field audiologists to dispense. (Ex. 2 at 2; Ex. 56 (12/12/19 Berger Tr.) at 60:2-61:19, 64:7-10, 81:22-82:24.)

Aearo completed an initial design of the product on March 23, 1998. (Ex. 11; Ex. 56 (12/12/19 Berger Tr.) at 61:20-64:6; Ex. 57 (12/17/19 Knauer Tr.) at 81:24-82:11.) In that design, the overall length of the earplug was 40.34 millimeters, and the tips on each end were 7.72 millimeters apart. (Ex. 11.) Aearo sent samples of the product to Ohlin on March 24, 1998. (Ex. 12 at DOD00000257; Ex. 56 (12/12/19 Berger Tr.) at 65:3-66:11.) The military has not yet provided discovery regarding the steps Ohlin took to evaluate those samples, but [redacted], a military audiologist who worked with Ohlin in that time period, provided the following insights into Ohlin's process:

[redacted]. (Ex. 13 at 234-53.)[2]

2 [redacted]

Similarly, retired LTC Eric Fallon (now at 3M), who took over as the Army Hearing Conservation Program Manager after Ohlin's retirement, testified that: "Ohlin reviewed hearing protection devices, [and] asked manufacturers to make modifications in design when necessary." (Ex. 66 (Fallon Decl.) ¶ 6.)

On April 8-9, 1999, Ohlin directed Brian Myers at Aearo to shorten the earplug by approximately 1/4". (Ex. 4 at 3M_MDL000569995; Ex. 56 (12/12/19 Berger Tr.) at 68:2-70:23) Ohlin sent the same feedback to military audiologists, stating that he "took the liberty in cutting down the samples" himself. (Ex. 3 at DOD00000136; Ex. 5 at 3M_MDL000569956; Ex. 56 (12/12/19 Berger Tr.) at 66:12-68:1.) According to Ohlin, the original length of the earplug created three issues: (1) the samples did not fit into the Army's standard issue carrying case; (2) the flanges were far enough apart that they did not cover the sound port on the stem of the plug, which, Ohlin believed, exposed the plug to wind noise; and (3) the samples stuck out of the ear too far and interfered with the ability to fasten the strap on the Kevlar helmet. (Ex. 3 at DOD00000136; Ex. 4 at 3M_MDL000569995; Ex. 5 at 3M_MDL000569956.) Ohlin described the last problem as a "show stopper if we can't get the modification." (Ex. 5 at 3M_MDL000569956.)

By April 27, 1999, Aearo had shortened the length of the earplug in response to Ohlin's directive. (Ex. 14; Ex. 17 at 0.) In the modified design, the overall length of the earplug was 35.66 millimeters, and the Ultrafit tips on each end were 3.04

millimeters apart. (Ex. 14.) Unlike the original design (left), the modified design (right) fit into the military's standard earplug carrying case.

(Ex. 18 at 20; Ex. 56 (12/12/19 Berger) Tr. at 76:19-79:1.)

By May 12, 1999, Ohlin had determined that Aearo satisfied the government's specifications, and that the company had manufactured "acceptable production samples." (Ex. 3 at DOD00000137.) Ohlin used those production samples to submit a "Request for National Stock Number and Bulk Purchase of Combat Arms Earplugs." (Ex. 9.) Among other things, the National Stock Number ("NSN") request overviews the military's role in developing the product. (*Id.*)

D. The Military Drafted The First Instructions For The CAEv2.

On May 18, 1999, Ohlin sent a letter to the Navy Environmental Health Center regarding the submission of the NSN request. (Ex. 15.) The letter attaches the earliest known instructions for the CAEv2, which were authored by the Army. (*Id.*) The instructions describe when to use each end and how to "tug[ ]" on the earplug

to check for proper insertion. (*Id.*) The letter also attaches promotional materials authored by the Army which note, among other things, that the earplugs were "[c]heap, low tech, easy to maintain, [and] require[d] no batteries." (*Id.*)

E. The Military Tested The CAEv2 Under Worst-Case Impulse Noise Conditions.

Contemporaneously with submitting the NSN request, Ohlin was corresponding with John King, the Army's scientific advisor for Southern Europe, regarding ordering 1,000 pairs of CAEv2 from Aearo. (Ex. 3 at DOD00000138-40.) King, in turn, worked with Garinther and others at the Army Research Laboratory to perform further product testing. (Ex. 16 at 1.) That testing, which concluded by June 30, 1999, determined that CAEv2 provided "acceptable protection" for up to 276 rounds of M16-556 ball ammunition fired under the "worst-case condition" in a closed room. (*Id.* at 4 "Operational Significance"; Ex. 58 (2/26/20 Merkley Tr.) at 84:10-85:11.)

F. Aearo Conducted REAT Tests On The CAEv2.

Although the CAEv2 was initially developed with and for the military, the government did not preclude Aearo from subsequently selling the product to the general public. Pursuant to regulations promulgated by the EPA, manufacturers of civilian HPDs are required to perform product testing to a particular American National Standards Institute ("ANSI") standard, and use the results of that testing to calculate a Noise Reduction Rating ("NRR") for inclusion on the product label. (Ex.

19.) The statute enabling the EPA regulations—the Noise Control Act—carves out "any military … equipment which are designed for combat use" from the "product[s]" subject to the EPA regulations, and thus there was no requirement that Aearo perform EPA testing and labeling in connection with the earlier sales to the military. *See* 42 U.S.C § 4902(3)(B)(i).

In particular, the EPA regulations require "real ear attenuation at threshold" ("REAT") testing pursuant to ANSI S3.19 1974, under which protocol (i) human test subjects sit in a sound proof room, (ii) an experienced experimenter inserts the earplugs into the test subjects' ears to achieve a "best fit," and then (iii) the experimenter plays tones of different frequencies to determine the quietest sounds the subjects can hear with and without the earplugs. (*Id.*; Ex. 20 at 3M_MDL000011408-11; Ex. 59 (11/13/19 Berger Tr.) at 200:23–201:8; Ex. 60 (12/19/19 Kieper Tr.) at 128:8–129:3.) The NRR is calculated by subtracting two standard deviations from the mean attenuation for ten subjects. (Ex. 19; Ex. 60 (12/19/19 Kieper Tr.) at 128:8–129:3.)

Aearo conducted the first REAT tests on the CAEv2 between December 1999 and January 2000. (Exs. 21-22.) Aearo employee Ronald Kieper performed the testing while Berger supervised. (Ex. 60 (Kieper 12/19/19 Tr.) at 111:25–112:10.) Aearo performed a separate REAT test on each end of the CAEv2: test number

213015 involved the green (conventional) end, and test number 213016 involved the yellow (non-linear) end. (Exs. 21-22.)

The initial results for the '015 test were unusually variable, with certain users reporting attenuation values that were lower than the standard Ultrafit earplug. (Ex. 21; Ex. 61 (3M_MDL000186637 ("Ex. 61 (10/8/15 Berger Tr.)")) at 109:6-110:15; Ex. 24 at 3M_MDL00005286.) The combination of increased variability and lower mean attenuation resulted in an estimated NRR of 10.9 through eight subjects. (Ex. 21)[3] Berger stopped the test after eight subjects to investigate the cause of the variability. (Ex. 61 (10/8/15 Berger Tr.) at 106:6-13, 109:6-110:15; Ex. 59 (11/13/19 Berger Tr.) at 214:13-215:4; Ex. 24 at 3M_MDL00005286.)[4] Upon investigation, Berger and Kieper determined that certain test subjects had experienced a fitting issue. Essentially, when Kieper needed to insert the plug deeply to get a "best fit" (per the test protocol) for some users, the bottom flange on the opposite end of the earplug could contact the user's tragus and cause the earplug to loosen in the user's ear. (Ex. 24 at 3M_MDL000005286.) Because this was occurring in a silent, soundproof test room, the loosening was imperceptible to the

[3] Because NRR ratings are calculated by subtracting two standard deviations from the mean attenuation, variability between tests in either direction will result in a lower NRR.

[4] Neither the EPA regulations nor the ANSI standard prohibits stopping a test prior to completion.

test subjects, and they proceeded to participate in the test without the "best fit" required under the protocol. (*Id.*; Ex. 59 (11/13/19 Berger Tr.) at 241:14-243:14.)

The solution to this issue was straightforward. For those users who needed to insert the earplug deeply to achieve a best fit, the flanges on the opposite end could be folded back upon themselves, so they would not interact with the users' tragus. (Ex. 24 at 3M_MDL000005286; Ex. 59 (11/13/19 Berger Tr.) at 237:15-239:10, 358:15-18.) Aearo ran a second test on the green end using this fitting technique for at least one of the ten test subjects: test number 213017. (Ex 23 at 3M_MDL000195519, 24.)[5] That test showed lower variability, moderately higher mean attenuation, and a resulting NRR of 21.7. (*Id.*) Aearo summarized its findings in a memorandum titled "How Folding the Flanges Back Affects REAT Results of the UltraFit Earplug End of the Combat Arms Plug" (the "Flange Memo"), which explains that the product was "too short for proper insertion" on an S3.19 1974 REAT test without "changing the fitting technique" as described above. (Ex. 24 at 3M_MDL00005286; Ex. 59 (11/13/19 Berger Tr.) at 289:7-23.) When Aearo subsequently labeled the product for civilian markets, it used the NRR from the '017 test, and included the following fitting tip on the packaging: "Fitting is … improved

[5] The handwritten notes accompanying the 213017 test report state that "[i]f subj's data are variable, fold flanges back on additional test," and the subsequent comments reference folding back the flanges for one test subject. (Ex. 23 at 3M_MDL000195524; *see also* Ex. 59 (11/13/19 Berger Tr.) at 411:2-412:2)

if the sealing rings of the outward directed plug are rolled back upon themselves." (Ex. 25 at 3M_MDL000425527.)

G. Aearo Informed The Military Of The Flange Fold Issue And The Results Of Its Internal Testing.

Discovery from the government is ongoing in this case. For example, defendants have taken only two of the 32 depositions requested from the government to date. Even still, the undisputed evidence is clear that Aearo informed the military of the flange fold issue and the results of its internal testing.

1. Elliott Berger Informed Doug Ohlin.

During his 2015 deposition, Elliott Berger testified:

> Q. Now, what was the justification for doing a retest? Was it the change in fitting procedures?
>
> A. As I said, we looked at the original results. We found that multiple subjects were highly variable. …
>
> We also discussed this at the time with the military because we were doing this to meet the customer requirements. The Army was unhappy with the original design, not for any reason having to do with the plug, but because it wouldn't fit in a carrying case that they were using. And so they had asked us to shorten the earplug to fit in this carrying case and we discussed the ramifications with them, the need for changing the fitting instructions and the problems that that created.
>
> …
>
> Q. You discussed with them the fact that you were folding back the flange to test the plug?
>
> A. Yes.

...

Q. When did you talk to Mr. Ohlin about this?

A. At the time it was occurring.

Q. In 2000?

A. Yes.

(Ex. 61 (10/8/15 Berger Tr.) at 109:6-110:15.)

In 2019, Berger further testified that:

- He told Ohlin about "the fact that the shortened earplug was creating a problem in the initial test and that the work we had done to try and resolve that problem to get optimum performance for labeling purposes would require this fold-back instruction." (Ex. 59 (11/13/19 Berger Tr.) at 297:13-22.)
- "This entire development project was discussed with [Ohlin], and the issues from shortening it to how it affected our testing were reviewed." (*Id.* at 298:4-7.)
- He told Ohlin "that the 017 test had been conducted by rolling back the flanges," and that "rolling back the flanges would be important for some people and that it was something that we were doing on the most recent test." (*Id.* at 334:7-13, 337:8-18.)
- He discussed with Ohlin whether proceeding with the flange fold instruction was "acceptable to the military." (*Id.* at 305:10-20.)

2. Ohlin Told Military Audiologists About The "Flange Fold" Issue.

Per Defense Department regulations, military audiologists (or medically trained technicians working at their direction) are responsible for fitting individual service members with pre-molded earplugs, like the CAEv2. (Ex. 26 at 6.6.7; Ex. 58 (2/26/20 Merkley Tr.) at 24:21-26:4.) To do so, they perform two in-person tests:

(i) a "visual inspection" to observe the position of the flanges in the service member's ear, and (ii) a "tug test" to "make sure that [the service member] felt the suction and that the earplug didn't just come out of the ear." (*Id.* at 33:5-36:15.) Additionally, military audiologists meet annually to "get instruction from leadership" and "get an update … on … what was new that [they] needed to pay attention to." (*Id.* at 105:10-107:5.)

Beginning at least as early as 2001, Ohlin gave the following instruction to military audiologists on how to fit the CAEv2: "if you needed to, you could fold back the flanges on the earplug to get a good fit." (*Id.* at 97:15-99:14.) Ohlin did not limit this advice to any particular group of soldiers or any particular size ear canal. (*Id.* at 98:13-99:2.) After receiving Ohlin's "flange fold" instruction, the audiologists implemented it into the fitting procedures performed with individual service members. (*Id.* at 99:15-20, 107:21-113:4.) Thus, according to the Chief of the Army Hearing Program, LTC John Merkley: "If [a service member's] earplug was the Combat Arms Version 2, their training would have included the option to fold back the flanges as needed to get a good fit." (*Id.* at 123:8-12.)

LTC Fallon agreed:

> With respect to the dual-ended Combat Arms earplugs, I instructed technicians that, if they believed the bottom edge of the opposing flange was preventing them from inserting the earplug far enough into a soldier's ear canal, they should roll back the opposing flanges and try again. (Ex. 66 (Fallon Decl.) ¶¶ 9-11.)

[redacted] (Ex. 27 at 3.)

Military audiologists also understood *why* they were given the flange fold instruction. For example, military audiologist [redacted]—who worked directly with Ohlin at the time CAEv2 was shortened (Ex. 3 at DOD00000136)—stated that "[redacted]" and that, as a result, "[redacted]." (Ex. 44 (3/3/20 Coleman Tr.) at 424:17-425:6.) Like Ohlin, [redacted] did not limit the flange fold instruction to any particular size ear canal. (*Id.* 426:18-427:4.)

3. Berger Sent Aearo's Internal Test Reports And Civilian Instructions To The Government.

Berger also corresponded with other military audiologists regarding Aearo's internal testing. In August 2001, an Army audiologist named Mark Little (who at the time was doing a fellowship at NIOSH) contacted Berger and requested information on the CAEv2. (Ex. 28; Ex. 56 (12/12/19 Berger Tr.) at 84:25-88:13.) On September 18, 2001, Berger sent Little a letter enclosing three attachments: (i) a package for the consumer version of the product, which contained the "flange fold" fitting instruction; (ii) ISL test data; and (iii) Aearo's internal test reports for the '016 and '017 REAT tests, which describe, among other things, the flange fold fitting technique used on the '017 test. (Exs. 29-33; Ex. 56 (12/12/19 Berger Tr.) at 88:16-

103:3.) On September 25, 2001, Little sent Berger an email stating that he "received [the] mailing and will make use of the instructions." (Ex. 34; Ex. 56 (12/12/19 Berger Tr.) at 103:4-104:10.) Little specifically asked Berger if "the sealing rings of the outward facing plug that were rolled back upon themselves during fitting, as per the instructions, stay this way in the ear or should they be unrolled??" (*Id.*) Berger responded: "they should stay that way." (*Id.*)

4. Aearo Provided Attenuation Specifications To The Military.

In 2003, the Defense Logistics Agency ("DLA"), which oversees military procurement for the DoD, decided to develop a Medical Procurement Item Description (MPID) for the CAEv2 and other "equal" dual-ended earplugs. DLA worked with Aearo to develop the MPID, and asked Aearo to provide input on the "salient characteristics" of an "equal" product, including minimum mean attenuation. (Ex. 35 at P1355.1, 3.) The attenuation specifications Aearo provided were *below* the results of the '015, '016, and '017 tests. (*See* Ex. 36 at P0498.1; Exs. 21-23.) In other words, when the military asked Aearo how the product performed, Aearo provided attenuation specifications consistent with (and, indeed, below) all of its internal testing, *including* the '015 test, on which the flanges were *not* folded back.

5. Ohlin Included The "Flange Fold" Instruction On The Military's Instructional Materials.

The military began purchasing larger quantities of CAEv2 earplugs. Per the military's orders, Aearo shipped the product in bulk, without instructions. (Ex. 62 (12/3/19 Santoro Tr.) at 326:19-21; Ex. 63 (10/18/19 Myers Tr.) at 248:17-25; Ex. 58 (2/26/20 Merkley Tr.) at 129:4-10; Ex. 66 (Fallon Decl.) ¶ 16.) Ohlin told Aearo that, rather than having soldiers rely on written instructions, military personnel would personally instruct soldiers on how to fit the earplugs. (Ex. 62 (12/3/19 Santoro Tr.) at 326:22-327:10; *see also* Ex. 26 at 6.6.7) For example, former Aearo employee Marc Santoro testified:

> Q. Did [Ohlin] tell you not to include instructions in that box?
>
> A. He did.
>
> Q. Did he indicate why he didn't want instructions in that box?
>
> A. He felt that personal training was the most effective way to train the soldiers, and that the military audiologists were going to take on that responsibility of individually training every solider.
>
> Q. Did you follow Mr. Ohlin's requests?
>
> A. Yes.
>
> Q. And why is that?
>
> A. Doug was the one that pretty much dictated how we were to provide hearing protection to the military.

(*Id.* at 326:11-327:10 (emphasis added).)

Ohlin further told Aearo that the cost of packaging the earplugs with individual user instructions would outweigh the benefits. (Ex. 38.)

Instead, in 2004, the military created its own written training materials for the CAEv2. First, the U.S. Army Center for Health Promotion and Preventive Medicine ("CHPPM") created a "wallet card" that could be distributed to service members at the time they were fitted with the earplugs. (Exs. 39-41; Ex. 58 (2/26/20 Merkley Tr.) at 126:7-13.) The wallet card includes a picture of the CAEv2 with the flanges folded back and a bullet that reads: "[f]or very large ear canals, fold opposing plug back." (Ex. 41.)[6] Second, CHPPM created a two-page overview called "Just the Facts" that was provided to military audiologists. (Ex. 42; Ex. 58 (2/26/20 Merkley Tr.) at 126:19-128:10.)

6. Ohlin Reviewed Aearo's Civilian "Flange Fold" Instruction.

In 2005, Aearo began marketing individually packaged pairs of the CAEv2 as the "Combat Arms Earplugs." (Ex. 64 (10/17/19 Moses Tr.) at 128:4-129:2; Ex. 62 (12/3/19 Santoro Tr.) at 183:4-184:8.) Before Aearo finalized the packaging, Brian

[6] Discovery is ongoing regarding why CHPPM included the limitation "for very large ear canals" on the wallet card, and whether that was based on the military's own analysis of those soldiers most likely to deeply insert the earplug. In any event, it is clear that Aearo did *not* so limit its guidance to Ohlin, and also that Ohlin's instructions to military audiologists were *not* limited to any particular size ear canal. (Ex. 59 (11/13/19 Berger Tr.) at 350:7-351:12; Ex. 65 (12/10/19 Berger Tr.) at 211:4-213:1; Ex. 58 (2/26/20 Merkley Tr.) at 98:13-99:14.)

Myers sent Ohlin the proposed instructions, which included the "flange fold" fitting tip that was included on civilian packaging (and previously sent to Mark Little in 2001). (Ex. 43 at 1, 3.) Ohlin reviewed the instructions and made certain suggested edits, including that individuals with small ear canals might experience discomfort using the CAEv2 and should consider a single-sided product as an alternative. (*Id.* at 1) Aearo adopted Ohlin's edits. (*Id.*)

H. The Military Tested The CAEv2 And Understood How It Performed.

In addition to the testing it performed during product development, the government extensively tested the CAEv2 between 2001 and 2015. (Exs. 7, 45-52.) Among other things, the military performed: (i) laboratory REAT tests on humans, like the testing performed internally at Aearo (Exs. 7, 48-49, 51-52); (ii) real-world field testing on humans, in which soldiers' hearing was measured before and after firing weapons while wearing the CAEv2 (Ex. 46); (iii) impulse noise tests, in which the CAEv2 was inserted into a specialized mannequin and exposed to high level explosions (Ex. 45, 47-50); and (iv) speech intelligibility and localization precision testing, in which service members wore the yellow end of the earplug while listening to speech or determining the direction of incoming sounds (Ex. 49). One military REAT test determined that the CAEv2 "compared very well with [its] design specifications." (Ex. 48 at 19.) Another, done *without rolling back the flanges*, concluded that the green end of the CAEv2 provides "very good attenuation" and

"should provide for a safe exposure level for the average user in many noise environments up to 105 dB." (Ex. 7 at 19-20; Ex. 58 (2/26/20 Merkley Tr.) at 448:17-451:16.) These tests "show that the plug provides reasonable attenuation or good attenuation under a variety of different circumstances." (Ex. 58 (2/26/20 Merkley Tr.) at 452:12-18) More importantly, these tests put the military on notice of exactly how the product performed, including during REAT testing on humans.

I. The CAEv2 Meets The Military Sound Attenuation Specification, With Or Without The Flanges Folded Back.

DLA updated the MPID in 2006. (Ex. 53 at P0692.2.) The updated MPID included the same attenuation specification as the original MPID. (Ex. 55 at 3M_MDL000000055.) ***The CAEv2 meets the attenuation specification at every frequency with or without the flanges folded back***—that is, whether measured using the '015 test that was stopped after eight subjects after the product "loosened" without folding back the flanges, or the completed '017 test, on which the flanges were folded back for at least one subject.

Frequency	MPID Green-End Spec	213015 Test Result	213017 Test Result		MPID Yellow-End Spec	213016 Test Result
125	>25dB	30.5	32.7		0-10dB	4.7
250	>25dB	29.3	31.8		0-10dB	4.2
500	>25dB	30.3	33.0		0-10dB	6.0
1000	>25dB	27.5	32.0		5-15dB	9.5
2000	>30dB	30.6	34.5		10-20dB	16.7
4000	>35dB	36.7	38.9		10-20dB	16.3
8000	>40dB	41.2	43.3		10-25dB	17.2

(Ex. 55 at 3M_MDL000000055; Exs. 21-23.)

J. The CAEv2 Helped The Military Advance Its Hearing Conservation Mission.

According to LTC Merkley, the CAEv2 worked well, with or without the flanges folded back. Ex. 58 (2/26/20 Merkley Tr.) at 197:1-11, 452:20-453:1.) He treated service members in Iraq and "those that didn't use a plug had hearing loss, and those that did use a hearing protector, like the CAEv2, did not." (*Id.* at 453:9-14, 195:6-19.) Similar "success stories" written by other military audiologists make clear that CAEv2 worked well in their experience, too. (*Id.* at 179:9-188:20, 453:4-8.)

ARGUMENT

The federal government contractor defense ensures that, when the government makes an informed decision to use a certain product design, courts do not "second-guess" that decision by entertaining state-law tort suits. *See Boyle*, 487 U.S. at 511. The defense plays a particularly important role in protecting *military* procurement decisions, which "often involve[] not merely engineering analysis but judgment as to the balancing of many technical, military, and even social considerations, including specifically the trade-off between greater safety and greater combat effectiveness." *Id.* Juries should not, and as a matter of federal law cannot, reweigh the many factors the military considered and declare that, in hindsight, the military made a mistake and approved a product that was defective.

I. The Government Contractor Defense Preempts Plaintiffs' Design Defect Claims.

In the context of a design defect claim, the government contractor defense has the following three elements: (1) "the United States approved reasonably precise specifications," (2) "the equipment conformed to those specifications," and (3) "the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States." *Id*. at 512. Importantly, this analysis "depends only" on whether "the elements are met with respect to the particular product feature upon which the claim is based." *In re Katrina Canal Breaches Litig.*, 620 F.3d 455, 460 (5th Cir. 2010) (emphasis added). There can be no dispute that all three elements are met with respect to the allegedly defective design feature in this case—the length of the CAEv2. Although couched in various terminology, the design defect allegations in the complaint all relate to interaction of the opposite-end flanges due to the length of the CAEv2. (*See e.g.*, Dkt. 704 (Master Long Form Compl.) ¶¶ 107, 265.)

A. The Government Approved Reasonably Precise Specifications.

The first element of the defense is met when the allegedly defective design results from a "continuous back and forth" between the government and the contractor. *Brinson v. Raytheon Co.*, 571 F.3d 1348, 1355 (11th Cir. 2009). Put more precisely, a contractor meets the first element if it "incorporated" the government's specifications "into a design that the government subsequently

reviewed and approved." *Harduvel v. Gen. Dynamics Corp.*, 878 F.2d 1311, 1320 (11th Cir. 1989). The CAEv2 easily satisfies that standard.

In December 1997, the military requested that Aearo develop a new non-linear earplug that: (1) incorporated the ISL filter, (2) used Aearo's "UltraFit" tips, which the government had previously tested with the ISL filter, (3) was dual-ended, so that service members did not need to carry two separate sets of earplugs, and (4) was single sized, because a one-size-fits-most product was easier for field audiologists to dispense. (Ex. 2 at 2; Ex. 56 (12/12/19 Berger Tr.) at 60:2-61:19, 64:7-11, 81:22-82:24.) After Aearo sent initial production samples, Ohlin directed that Aearo shorten the earplug to its allegedly defective length so that it fit into the military's carrying case and fit under the helmet chin strap. (Exs. 3-5.) Aearo shortened the earplug in response to that directive, and Ohlin determined the modified design was "acceptable." (Ex. 3 at DOD00000137.) The military thereafter tested the earplug under "worst case condition[s]," and decided to move forward with using it. (Ex. 16; Ex. 58 (2/26/20 Merkley Tr.) at 83:20-84:9.) There is thus no doubt that, as Ohlin confirmed, "***the combat arms earplug has been 'evaluated and specified by the U.S. Armed Forces***.'" (Ex. 54 (emphasis added).)

The Eleventh Circuit has held that far less government involvement satisfies the first *Boyle* element. For example, in *Harduvel v. Gen. Dynamics*, the plaintiffs alleged that a fighter aircraft's electrical system had failed because wires were

packed too closely together and wore one another down. 878 F.2d at 1319. The court held that the defendant had satisfied the first *Boyle* element because the military had conducted "independent review and analysis" of the plane's electrical system, even though it had ***no*** role in designing the system in the first place. *Id*. at 1320.

Similarly, in *Brinson v. Raytheon*, the contractor had designed and patented the product—an automatic "rudder trim system" for a single-propeller aircraft—without any involvement from the government. 571 F.3d at 1350. But as the Eleventh Circuit emphasized, what matters is whether "the design feature in question was considered by a Government official." *Id.* at 1355 (quoting *Boyle*, 487 U.S. at 512). That consideration can take place after the contractor has designed, manufactured, and even begun to sell a product. *Id.*

Here, far beyond the level of involvement in *Harduvel* and *Brinson*, the military was the driving force behind the CAEv2's creation. It researched and tested the ISL filter, directed that Aearo develop a dual-ended product incorporating that filter, instructed that the product be shortened after Aearo provided initial samples, and approved and tested its final length. That level of involvement is *more than* sufficient to satisfy *Boyle*, and thus summary judgment is warranted on the first element.

B. The CAEv2 Conformed to the Government's Specifications.

"To demonstrate the second *Boyle* condition, a contractor must show that the equipment at issue conformed to precise, government-approved specifications." *Brinson*, 571 F.3d, at 1357. "[W]here the procurement process involves [a] continuous exchange between the contractor and the government, the process itself becomes persuasive evidence of the product['s] conformity to precise specifications." *Id.* The CAEv2 meets the second element, too.

It cannot be disputed that the CAEv2 conforms to the specifications provided by Ohlin to Aearo, including Ohlin's directive that Aearo shorten the CAEv2 to its allegedly defective length. In Aearo's original design, the overall length of the earplug was 40.34 millimeters, and the tips on each end were 7.72 millimeters apart. (Ex. 11.) Aearo subsequently shortened the length of the earplug approximately 1/4" in response to Ohlin's request. (Ex. 14; Ex. 17 at 0; Ex. 3 at DOD00000136; Ex. 4 at 3M_MDL000569995; Ex. 5 at 3M_MDL000569956; Ex. 56 (12/12/19 Berger Tr.) at 66:12-68:1.) After review, Ohlin determined the modified design was "acceptable," and the military moved forward with testing and using the earplug. (Ex. 3 at DOD00000137; Ex. 16) Plaintiffs do not allege CAEv2 was subsequently manufactured to a different length than that which Ohlin approved, and thus defendants are entitled to summary judgment on the second *Boyle* element.

C. The Government Was On Notice Of The Consequences Of Shortening The Product's Length.

The third element of the contractor defense requires that "the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States." *Id*.

1. Because The Product Provided Sufficient Attenuation Without the Flanges Rolled Back, There Was No "Danger" To Warn Of.

Plaintiffs allege that Aearo concealed the results of its '015 test and the "danger" that the product was "too short for proper insertion" absent folding back the flanges. As detailed in the charts above, however, the '015 test shows that the CAEv2 provided mean attenuation above the minimum levels the military required, even without the flanges folded back. (Ex. 55 at 3M_MDL00000055; Exs. 21-23) Because the CAEv2 met the military's attenuation specification—***with or without the flanges folded back—***there was no "danger" that required a *Boyle* warning. To conclude otherwise would imply that the mean attenuation levels specified by the military were, in fact, dangerously low, or that the military should have used a different metric for its specification—precisely the sort of "second-guess[ing]" *Boyle* forbids. 487 U.S. at 511; *see also Lewis v. Babcock Indus., Inc.*, 985 F.2d 83, 89 (2d Cir. 1993) ("Whether or not these decisions were ill-advised … it is not our role to second-guess the Air Force's judgment.").

2. Aearo Warned the Military of Any Known "Dangers."

In any event, the undisputed evidence is clear that Aearo ***did*** tell the government about the results of its internal testing, including the fitting issues that occurred as a result of the military's decision to shorten the product's length. Among other things:

- Elliott Berger told Ohlin "that the shortened earplug was creating a problem in the initial test" and "that the 017 test had been conducted by rolling back the flanges." (*E.g.*, Ex. 59 (11/13/19 Berger Tr.) at 297:13-22, 334:7-13, 337:8-18.)
- Military audiologists were aware that "[redacted]" and, as a result, [redacted]" (Ex. 44 (3/3/20 Coleman Tr.) at 424:17-425:6.)
- Ohlin instructed military audiologists to fold back the flanges on the opposite end of the earplug as needed to get a good fit. (Ex. 58 (2/26/20 Merkley Tr.) at 97:15-99:20; 107:21-113:4; Ex. 66 (Fallon Decl.) ¶ 11; Ex. 27 at 3.)
- Berger sent a government audiologist: (i) Aearo's '016 and '017 test reports, which make clear that Aearo folded back the flanges for at least one test subject on the '017 test; and (ii) a version of the civilian instructions that included the flange fold fitting tip. (Exs. 29-33; Ex. 56 (Berger 12/12/19 Tr) at 88:16-103:3.)
- Ohlin included a picture of the CAEv2 with the flanges folded back on the wallet card, along with a version of the flange fold instruction. (Ex. 41.)
- Ohlin reviewed and commented on Aearo's civilian instructions that included the flange fold instruction. (Ex. 43.)
- Aearo provided DLA with attenuation specifications consistent with (and, indeed, below) *all* of its internal testing, including the '015 test. (Ex. 35 at 1, 3; Ex. 36 at 1; Exs. 21-23.)

On this record, it cannot reasonably be disputed that Aearo put the military on notice that, due to the military's decision to shorten the earplug, some users may need to roll back the opposing flanges in order to get a best fit.

3. The Military Was On Notice Of Any "Dangers" From Its Own Testing And Use.

Even if Aearo had not disclosed the findings from its internal testing, the third *Boyle* element would still be met because a contractor has no duty to warn of "dangers" otherwise "known ... to the United States." *Boyle*, 487 U.S. at 512. Courts around the country have recognized that, in light of the extensive testing the military performs on combat equipment, its knowledge of a product's characteristics is often equal to (or greater than) that of the manufacturer. *In re "Agent Orange" Prod. Liab. Litig.*, 304 F. Supp. 2d 404, 435 (E.D.N.Y. 2004) (collecting cases). These cases are on point here.

For example, *Zinck v. ITT Corp.* involved night vision goggles that the military had subjected to repeated "field tests." 690 F. Supp. 1331, 1332–33, 1337–38 (S.D.N.Y. 1988). The court reasoned that this testing "alerted [the military] to the goggles' limitations." *Id.* The court also noted that the military had been "using this equipment in flight missions for four years prior to the crash," and accordingly "would have become aware of any limitations or dangers." *Id.* Thus, the court held, although the record on summary judgment "may point to knowledge on the part of

[the defendant] of these dangers," it also "clearly establishes superior knowledge on the part of the Government, which nevertheless continued to use the equipment." *Id.*

Similarly, *Haltiwanger v. Unisys Corp.* involved a letter sorting machine the government subjected to "extensive testing" and thereafter used for years. 949 F. Supp. 898, 900-01, 905 (D.D.C. 1996). The court reasoned that the government's testing made it "independently aware" of any product limitations. *Id.* at 904-05. Moreover, the court held, "[r]egardless of articles and studies regarding the machinery, actual, real-world use of the equipment is the best means by which to truly understand its nature as well as its shortcomings," and thus "[a]cceptance and continued use of a product, especially where the government agency participated in the design process, reflects a cognizance of any risks involved." *Id.*

The same is true here. The military tested the product under "worst case condition[s]" shortly after Aearo provided "acceptable production samples." (Ex. 16 at 4; Ex. 3 at DOD00000137.) Numerous branches of the military thereafter used the product for over a decade, during which time it was continuously tested under a variety of different conditions. (Exs. 7, 45-52.) Like *Zinck*, this testing included a "[f]ield [s]tudy," in which soldiers fired weapons in full combat uniform after running an obstacle course. (Ex. 46 at 6.) It also included laboratory REAT tests on humans (Exs. 48-49, 51-52), including REAT testing done *without folding back the flanges* like the allegedly concealed '015 test done at Aearo. (Ex. 7 at 19-20; Ex. 58

(2/26/20 Merkley Tr.) at 448:17-451:16.) The military's extensive use and testing of CAEv2 put it on notice of the product's capabilities and limitations, in the real world as well as under laboratory conditions.

4. Plaintiffs' Alternative Arguments Are Without Merit

Given the body of evidence showing that the military was on notice of the flange fold issue, plaintiffs have pivoted to two alternative arguments. Neither has merit.

First, plaintiffs argue that Aearo should have advised the military that *all* users needed to roll back the flanges to obtain an adequate fit. This assertion has no basis in the record. The handwritten notes accompanying the '017 test report indicate that the flanges were folded back only "[i]f [the] subj's data [were] variable," and that only *one* test subject required that technique to get a best fit. (Ex. 23 at 3M_MDL000195524.) In any event, even assuming that the flanges were folded back for *everyone* on the '017 test, the undisputed evidence demonstrates that such action is not necessary for all users. For example:

- Test subjects on the '015 test achieved attenuation values above the MPID specification without rolling back the flanges. (Exs. 21, 55 at 3M_MDL00000055.)
- REAT testing performed by the military found that, even *without folding back the flanges*, the CAEv2 provides "very good attenuation" that "should provide for a safe exposure level for the average user in many noise environments." (Ex. 7 at 19-20; Ex. 58 (2/26/20 Merkley Tr.) at 168:6-11; 448:17-451:16 ("Q. So, Mr. Hobbs is testing the earplug in human ears

without rolling the flanges back, and they are working? A. Yes, it appears so.")

- LTC Merkley testified that the CAEv2 worked well *without folding back the flanges.* (Ex. 58 (2/26/20 Merkley Tr.) at 197:1-199:10; 452:20-453:1.)

Plaintiffs cannot survive summary judgment by arguing that Aearo should have given the *erroneous* warning that *all* users must fold back the flanges.

Second, plaintiffs have pointed to the absence of evidence that the *Flange Memo itself* was shared with the government. But that is irrelevant, because it is undisputed that the *information in the Flange Memo* was communicated to the government, and that the government understood and acted on that information. *See supra* at Section G. Indeed, in light of the information Ohlin provided to military audiologists, LTC Merkley testified about the Flange Memo as follows:

> Q. But if … the central issue in the [Flange Memo] was that for some people folding back the flanges could benefit them to get a good fit, that was information you already had, right?
>
> A. Yes. … I was made aware of it in 2001 or thereabouts.
>
> (Ex. 58 (2/26/20 Merkley Tr.) at 459:16-460:5.)

There is no requirement under *Boyle* that a warning take any particular form, and thus plaintiffs cannot survive summary judgment by quibbling about the precise manner the government learned of the flange fold issue here.

II. The Government Contractor Defense Preempts Plaintiffs' Failure to Warn Claims.

In addition to their design-defect claims, Plaintiffs allege that Defendants negligently failed to instruct soldiers to roll back the flanges before insertion. It is well established that the government contractor defense also applies to failure-to-warn claims. *See Dorse v. Eagle–Picher Indus., Inc.*, 898 F.2d 1487, 1489 (11th Cir. 1990); *Ripley v. Foster Wheeler LLC*, 841 F.3d 207, 211 (4th Cir. 2016). Adapted for the failure-to-warn context, the three elements of the defense are:

> (1) the United States exercised its discretion and approved the warnings, if any; (2) the contractor provided warnings that conformed to the approved warnings; and (3) the contractor warned the United States of the dangers in the equipment's use about which the contractor knew, but the United States did not.

Tate v. Boeing Helicopters, 55 F.3d 1150, 1157 (6th Cir. 1995). Because the third element of the defense is the same for the design defect claims, only the first two elements require independent discussion.

The undisputed evidence shows that the military ordered Aearo to ship the product in bulk, ***without instructions***, because the military did in-person training with every service member. (Ex. 62 (12/3/19 Santoro Tr.) at 326:19-21; Ex. 63 (10/18/19 Myers Tr.) at 248:17-25) Indeed, in-person fit and training was ***required*** by DoD policy. (*See* Ex. 26 at 6.6.7, 6.6.9; Ex. 58 (2/26/20 Merkley Tr.) at 24:21-26:19.) And because Berger had discussed the flange-fold instruction with Ohlin, and Ohlin in turn relayed that instruction to military audiologists, the training that

was given "included the option to fold back the flanges as needed to get a good fit." (Ex. 58 (2/26/20 Merkley Tr.) at 123:8-12.) Plaintiffs cannot now "second guess" those decisions under *Boyle*. *See Tate*, 55 F.3d at 1157.

CONCLUSION

The evidence developed to date is clear and unambiguous: the military not only asked Aearo to develop earplugs using the ISL filter, but also specified and approved detailed product requirements, including the allegedly defective length. The military accepted and used the earplugs fully aware of the "fit" issues related to the shorter length. Under *Boyle*, Defendants cannot, as a matter of law, be liable to service members who used earplugs designed, manufactured and delivered as the military directed. Defendants respectfully request that the Court enter summary judgment on all claims brought by plaintiffs who used CAEv2 purchased by the military.

DATED: April 1, 2020

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1(B)

Pursuant to Local Rule 7.1(B), counsel for Defendants certify that they contacted counsel for Plaintiffs regarding the relief requested in the foregoing motion. Plaintiffs do not consent to the relief requested.

CERTIFICATE OF COMPLIANCE WITH LOCAL RULES 7.1(F) & 56.1

I HEREBY CERTIFY that this brief complies with the word limit of Local Rules 7.1(F) and 56.1, and contains 7,999 words, excluding the parts exempted by those Rules.

DATED: April 1, 2020

/s/ Kimberly Branscome
Kimberly Branscome

CERTIFICATE OF SERVICE

I, Kimberly Branscome, hereby certify that on April 1, 2020, I caused a copy of the foregoing to be filed through the Court's CM/ECF system, which will serve all counsel of record.

DATED: April 1, 2020

/s/ Kimberly Branscome
Kimberly Branscome