

Nos. 21-13131, 21-13133, 21-13135

**UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT**

3M COMPANY, *et al.*

Defendants-Appellants,

v.

LUKE ESTES, STEPHEN HACKER, LEWIS KEEFER,

Plaintiffs-Appellees.

On Appeal from the United States District Court
for the Northern District of Florida
Nos. 3:19-md-2885, 7:20-cv-137, 7:20-cv-131, 7:20-cv-104

BRIEF FOR DEFENDANTS-APPELLANTS

COLE CARTER
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000

PAUL D. CLEMENT
Counsel of Record
KASDIN M. MITCHELL
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, NW
Washington, DC 20004
(202) 389-5000
paul.clement@kirkland.com

Counsel for Defendants-Appellants

February 25, 2022

**CERTIFICATE OF INTERESTED PERSONS
AND CORPORATE DISCLOSURE STATEMENT**

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Defendants-Appellants 3M Company, 3M Occupational Safety LLC, Aearo Holdings LLC, Aearo Intermediate LLC, Aearo Technologies LLC, and Aearo, LLC hereby certifies that the following is a complete list of the trial judge(s), all attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of the particular case on appeal, including subsidiaries, conglomerates, affiliates, and parent corporations, including any publicly held corporation that owns 10% or more of the party's stock, and other identifiable legal entities related to a party:

- 3M Company (**MMM**) – Defendant-Appellant
- 3M Occupational Safety LLC – wholly owned subsidiary of Defendant-Appellant 3M Company
- Aearo Holdings LLC – wholly owned subsidiary of Defendant-Appellant 3M Company
- Aearo Intermediate LLC – wholly owned subsidiary of Defendant-Appellant 3M Company
- Aearo Technologies LLC – wholly owned subsidiary of Defendant-Appellant 3M Company
- Aearo, LLC – wholly owned subsidiary of Defendant-Appellant 3M Company
- Aylstock Witkin Kreis & Overholtz – counsel for Plaintiff-Appellee
- Aylstock, Bryan Frederick – counsel for Plaintiff-Appellee

- Barr, Brian H. – counsel for MDL Plaintiffs
- Beall, Charles Franklin, Jr. – counsel for Defendants-Appellants
- Benton, Diana Clough – counsel for Defendants-Appellants
- Bhimani, Jay L. – counsel for Defendants-Appellants
- Bouk, Winston Troy – counsel for MDL Plaintiffs
- Bradley Arant Boult Cummings – counsel for Defendant-Appellant 3M Company
- Branscome, Kimberly O. – counsel for Defendants-Appellants
- Brock, Robert C. – counsel for Defendants-Appellants
- Brown & James – counsel for Plaintiff-Appellee
- Brown, Micah David – counsel for Defendants-Appellants
- Buchanan, David R. – counsel for Plaintiff-Appellee
- Burns, Michael A. – counsel for MDL Plaintiffs
- Buxner, Evan D. – counsel for MDL Plaintiffs
- Carter, Cole T. – counsel for Defendants-Appellants
- Cartmell, Thomas P. – counsel for MDL Plaintiffs
- Castiglia, Craig – counsel for Defendants-Appellants
- Ciresi Conlin LLP – counsel for Plaintiff-Appellee
- Clark Love & Hutson – counsel for Plaintiff-Appellee
- Clement, Paul D. – counsel for Defendants-Appellants
- Cooper, David M. – counsel for Plaintiff-Appellee
- Cornell, Katherine Lindsey – counsel for MDL Plaintiffs
- Czak, Steven C. – counsel for Defendants-Appellants

- DeCamp, Kyle Richard – counsel for Defendants-Appellants
- Dechert LLP – counsel for Defendants-Appellants
- De Paulo, Tabitha J. – counsel for Defendants-Appellants
- Elizabeth, Sierra – counsel for Defendants-Appellants
- Ellis, Robert P. – counsel for Defendants-Appellants
- Esfandiarifard, Saghar – counsel for Defendants-Appellants
- Estes, Luke – Plaintiff-Appellee
- Fields, Barry E. – counsel for Defendants-Appellants
- Fox, Shawn – counsel for Plaintiff-Appellee
- Gibney, Blake – counsel for Defendants-Appellants
- Glass, David M. – counsel for the United States of America
- Gori Julian & Associates – counsel for MDL Plaintiffs
- Gottlieb, Simon – counsel for Defendants-Appellants
- Gunderson, Karl B. – counsel for Defendants-Appellants
- Hacker, Stephen – Plaintiff-Appellee
- Hill, Thomas Larry – counsel for Defendants-Appellants
- Hodge, Leigh Anne – counsel for Defendant-Appellant 3M Company
- Hoekstra, Jennifer M. – counsel for MDL Plaintiffs
- Hutson, Shelley Van Natter – counsel for Plaintiff-Appellee
- Jones, Hon. Gary R. – U.S. Magistrate Judge for the Northern District of Florida
- Karis, Hariklia – counsel for Defendants-Appellants
- Keefer, Lewis – Plaintiff-Appellee

- Kelly, Maxwell H. – counsel for Plaintiff-Appellee
- Kim, Mary H. – counsel for Defendants-Appellants
- Kirkland & Ellis LLP – counsel for Defendants-Appellants
- Kolsky, Joshua M. – counsel for the United States of America
- Kreis, Douglass A. – counsel for Plaintiff-Appellee
- Laminack Pirtle & Martines – counsel for MDL Plaintiffs
- Leach, Garret A. – counsel for Defendants-Appellants
- Leuthauser, Nolan M. – counsel for Defendants-Appellants
- Levin Papantonio Rafferty – counsel for MDL Plaintiffs
- Marlowe, Emily B. – counsel for Plaintiff-Appellee
- Mitchell, Kasdin – counsel for Defendants-Appellants
- Morriss, F. Chadwick – counsel for Defendants-Appellants
- Mostyn Law – counsel for MDL Plaintiffs
- Moore Hill & Westmoreland – counsel for Defendants-Appellants
- Neglia, Ashley E. – counsel for Defendants-Appellants
- Nomellini, Mark J. – counsel for Defendants-Appellants
- O’Callaghan, Orla – counsel for Defendants-Appellants
- Odom, Megan L. – counsel for Plaintiff-Appellee
- Onder Law LLC – counsel for MDL Plaintiffs
- Ozurovich, Allison K. – counsel for Defendants-Appellants
- Pirtle, Thomas W. – counsel for MDL Plaintiffs
- Pulaski Law Firm – counsel for MDL Plaintiffs

- Quinn Emanuel Urquhart & Sullivan LLP – counsel for Plaintiff-Appellee
- Rafferty, Troy Alan – counsel for MDL Plaintiffs
- Rivera, Maria P. – counsel for Defendants-Appellants
- Rodgers, Hon. M. Casey – U.S. District Judge for the Northern District of Florida
- Sacchet, Michael A. – counsel for Plaintiff-Appellee
- Sandman, Patrick P. – counsel for Defendants-Appellants
- Seeger, Christopher A. – counsel for MDL Plaintiffs
- Seeger Weiss LLP – counsel for Plaintiff-Appellee
- Seeley, Caleb A. – counsel for Plaintiff-Appellee
- Tam, Jonathan S. – counsel for Defendants-Appellants
- Tracey Fox King & Walters – counsel for Plaintiff-Appellee
- Tracey, Sean Patrick – counsel for Plaintiff-Appellee
- Van Fleteren, Haley J. – counsel for Defendants-Appellants
- Wagstaff & Cartmell – counsel for MDL Plaintiffs
- Wasdin, Nicholas F. – counsel for Defendants-Appellants
- Wilson, Quinn Robert – counsel for MDL Plaintiffs

Defendant-Appellant 3M Company states that it is a corporation whose shares are publicly traded (NYSE: **MMM**). 3M Company does not have a parent corporation and no publicly held corporation owns 10% or more of 3M's stock.

Defendant-Appellants 3M Occupational Safety LLC, Aearo Holdings LLC, Aearo Intermediate LLC, Aearo Technologies LLC, and Aearo, LLC state that they are wholly owned subsidiaries of Defendant-Appellant 3M Company.

February 25, 2022

s/Paul D. Clement
Paul D. Clement

STATEMENT REGARDING ORAL ARGUMENT

Appellants respectfully request oral argument. This appeal arises from a month-long trial that was the first bellwether trial in the largest-ever multidistrict litigation. It presents MDL-wide dispositive issues and numerous other errors by the district court that may be repeated in future trials absent correction by this Court. Oral argument would assist the Court in resolving these important issues in the context of this important and historic MDL.

TABLE OF CONTENTS

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT..... 1

STATEMENT REGARDING ORAL ARGUMENT..... i

TABLE OF AUTHORITIES..... iv

INTRODUCTION 1

STATEMENT OF JURISDICTION 3

STATEMENT OF THE ISSUES 3

STATEMENT OF THE CASE..... 4

 A. Factual Background..... 4

 1. The Development of the CAEv2 4

 2. Aearo’s Internal Testing of the CAEv2 7

 3. Aearo Relays The Flange-Fold Fitting Tip To The Military..... 9

 4. The Military Develops Instructions for the CAEv2 10

 5. The Military Continues to Use and Test the CAEv2 until 2015 12

 B. Procedural History..... 13

 1. MDL-Wide Summary Judgment Ruling on Appellees’ Government-Contractor Defense 13

 2. The Estes, Hacker, and Keefer Trial 16

SUMMARY OF ARGUMENT..... 25

STANDARD OF REVIEW 28

ARGUMENT 28

 I. The Government-Contractor Defense Preempts Plaintiffs’ Claims 28

A.	The District Court Erred in Finding the Absence of a “Uniquely Federal Interest”	31
B.	Appellants Satisfy <i>Boyle</i> With Respect to Plaintiffs’ Design-Related Claims	33
1.	The military approved reasonably precise specifications for the CAEv2	33
2.	The CAEv2 conformed to the government’s specifications, and Appellants warned the government of known risks.....	37
C.	The Government-Contractor Defense Preempts Plaintiffs’ Failure-to-Warn Claims	40
II.	The CAEv2 Is Exempt From The Noise Control Act.....	45
III.	Numerous Evidentiary Issues Require A New Trial.....	50
A.	The Vietas Letter and <i>Qui Tam</i> Report Are Inadmissible	50
B.	Evidence About Alleged Manufacturing Issues in Mexico Is Inadmissible.....	53
C.	The District Court’s Instruction Regarding Other Lawsuits Was Improper	55
	CONCLUSION	57
	CERTIFICATE OF COMPLIANCE	
	CERTIFICATE OF SERVICE	

TABLE OF AUTHORITIES*

Cases

Ali v. Fed. Bureau of Prisons,
552 U.S. 214 (2008).....47

**Boyle v. United Techs. Corp.*,
487 U.S. 500 (1988)..... *passim*

**Brinson v. Raytheon Co.*,
571 F.3d 1348 (11th Cir. 2009)..... *passim*

Chavez v. Mercantil Commercebank, N.A.,
701 F.3d 896 (11th Cir. 2012).....28

City of Tuscaloosa v. Harcros Chems., Inc.,
158 F.3d 548 (11th Cir. 1998).....28

Dorse v. Eagle-Picher Indus., Inc.,
898 F.2d 1487 (11th Cir. 1990)..... 14, 15, 30, 42

Dowd v. Textron, Inc.,
792 F.2d 409 (4th Cir. 1986).....35

Encino Motorcars, LLC v. Navarro,
138 S.Ct. 1134 (2018).....47

**Harduvel v. Gen. Dynamics Corp.*,
878 F.2d 1311 (11th Cir. 1989)..... 30, 33

Heath v. Suzuki Motor Corp.,
126 F.3d 1391 (11th Cir. 1997).....56

Hudgens v. Bell Helicopters/Textron,
328 F.3d 1329 (11th Cir. 2003)..... 30, 31

In re Agent Orange Prod. Liab. Litig.,
304 F.Supp.2d 404 (E.D.N.Y. 2004).....44

* Citations upon which Appellants primarily rely are marked with asterisks.

<i>In re Agent Orange Prod. Liab. Litig.</i> , 517 F.3d 76 (2d Cir. 2008).....	33, 38
<i>In re Int’l Mgmt. Assocs.</i> , 781 F.3d 1262 (11th Cir. 2015).....	45
<i>In re Tylenol (Acetaminophen) Mktg., Sales Pracs. and Prods. Liab. Litig.</i> , 181 F. Supp.3d 278 (E.D. Pa. 2016)	54
<i>Lewis v. Babcock Indus.</i> , 985 F.2d 83 (2d Cir. 1993).....	36
<i>McDonnell v. United States</i> , 136 S. Ct. 2355 (2016).....	48
<i>Quiles v. Sikorsky Aircraft</i> , 84 F. Supp.2d 154 (D. Mass. 1999)	44
<i>Ramey v. Martin-Baker Aircraft Co.</i> , 874 F.2d 946 (4th Cir. 1989).....	35
<i>Reiter v. Sonotone Corp.</i> , 442 U.S. 330 (1979).....	48
<i>Shaw v. Grumman Aerospace Corp.</i> , 778 F.2d 736 (11th Cir. 1985).....	14
<i>Smith v. Marcus & Millichap, Inc.</i> , 991 F.3d 1145 (11th Cir. 2021).....	46
<i>Tate v. Boeing Helicopters</i> , 55 F.3d 1150 (6th Cir. 1995).....	40
<i>United States v. Joseph</i> , 709 F.3d 1082 (11th Cir. 2013).....	28
<i>United Tech. Corp. v. Mazer</i> , 556 F.3d 1260 (11th Cir. 2009).....	52
Statutes	
28 U.S.C. §1291	3

28 U.S.C. §129215
 28 U.S.C. §13323
 28 U.S.C. §14423
 *42 U.S.C. §4902 17, 27, 46, 47
 42 U.S.C. §4907 17, 45

Rules

Fed. R. Evid. 40351
 Fed. R. Evid. 80352

Regulations

40 C.F.R. §211.204-116
 40 C.F.R. §211.204-417

Other Authorities

Black’s Law Dictionary (11th ed. 2019) 32, 46
 Motion to Reconsider Admission of Vietas Letter, *Blum v. 3M Co.*,
 No. 7:20-cv-122, Dkt.88 (N.D. Fla. Oct. 14, 2021) 13, 51
 Order on 3M MIL No. 41 , *Camarillorazo v. 3M Co.*, No. 7:20-cv-98,
 Dkt.89 (N.D. Fla. Oct. 26, 2021)46

INTRODUCTION

This is the first appeal from the sixteen bellwether trials in the largest multi-district litigation (“MDL”) proceedings in history. It will not be the last. Those trials have been permeated by legal and evidentiary errors that distort the verdicts, deprive them of their intended value as representative bellwether outcomes, and require reversal.

The size and importance of this MDL is hard to overstate. More than 280,000 individuals allege defects with the Combat Arms version 2 earplugs (the “CAEv2”) that Appellants designed in consultation with and sold to the military from 1999 to 2015. Those individuals did not sue the military, who procured the CAEv2 and provided the direct instructions for their proper use, for the obvious reason that the military enjoys sovereign immunity from these suits. Instead, they have filed claims against Appellants, complaining about the very product features that the military requested and assailing the absence of instructions that the military insisted it would provide itself. These cases should have never gone to the jury because the complaints about the military’s own design and instructions are preempted by the government-contractor defense. *See Boyle v. United Techs. Corp.*, 487 U.S. 500, 506 (1988). This case falls squarely within the heartland of that defense, and that defense alone should bring this massive and misdirected litigation to an end.

But the errors did not end there. The jury repeatedly heard about Appellants' supposed failure to provide EPA-mandated labels, when the applicable statute expressly exempts equipment designed for combat use. The jury repeatedly heard inaccurate hearsay evidence (that does not remotely qualify for an exception) about a supposed military finding that the CAEv2 was defective, which perfectly illustrates why hearsay is excluded. The jury repeatedly heard about supposed quality-control failures at Appellants' manufacturing facility, even though no plaintiff brought a manufacturing-defect claim. And the jury heard directly from the district court itself, without any testimony or evidence in the record, that many other soldiers had sued Appellants regarding the CAEv2. The combined effect of these errors was not just reversible error, but to render the trial outcomes useless for bellwether purposes. The verdicts reflect not a fair estimate of the worth of these claims, but the wisdom of following precedent, reading statutes and regulations fairly, and excluding inadmissible evidence. This Court should enter judgment for Appellants or, in the alternative, remand for a new trial in which Appellants may present their key defense in a trial that is focused on admissible evidence and to a jury that is correctly instructed on the law.

STATEMENT OF JURISDICTION

The district court had federal subject-matter jurisdiction under 28 U.S.C. §1442(a)(1) and 28 U.S.C. §1332. This Court has appellate jurisdiction under 28 U.S.C. §1291.

STATEMENT OF THE ISSUES

1. Whether the district court erred in denying Appellants' motion for summary judgment on the government-contractor defense and granting plaintiffs' cross-motion.
2. Whether the district court erred in holding that the Noise Control Act's exemption for "any military weapons or equipment which are designed for combat use" applies only to noise-emitting products, and not noise-reducing equipment like the CAEv2.
3. Whether the district court erred in admitting a hearsay statement from an Air Force colonel that the CAEv2 "were found to be defective" and the conclusions of a civil investigation report summarizing the hearsay statements of interviewees, which plaintiffs made a cornerstone of their trial presentation.
4. Whether the district court erred in admitting evidence of alleged quality-control problems at the manufacturing facility for the CAEv2, despite the absence of any manufacturing-defect claim.

5. Whether the district court erred in instructing the jury that there were a “large number” of other, similar claims pending against Appellants.

STATEMENT OF THE CASE

A. Factual Background

1. The Development of the CAEv2

The CAEv2 is the product of collaboration between the U.S. military and Appellants to solve a longstanding problem: battlefields are loud and yet soldiers are reluctant to wear hearing protection in the field. Many soldiers choose to risk hearing damage rather than limit their ability to hear mission-critical sounds such as commands and enemy movement. Indeed, before the introduction of the CAEv2, Army regulations advised soldiers that they “should NOT wear hearing protections when they impair necessary hearing,” as in “dismounted infantry operations.” Ex.8 at 6-2(d)(2)¹.

In the 1990s, the military began seeking out hearing protection devices that would allow soldiers to hear relatively quiet sounds while protecting them against louder and more dangerous noises—a concept known as “nonlinear” hearing protection. In 1995, Army researchers acquired a nonlinear earplug designed at the French-German Research Institute at Saint-Louis (“ISL”). ISL had invented and

¹ Exhibit references are to the exhibits to Appellants’ motion for summary judgment below, Dkt.1071.

patented a unique nonlinear “filter” and inserted that filter into an UltraFit, an existing conventional earplug that was manufactured by the Aearo Company in Indianapolis—later acquired by 3M Company (together, “Appellants”). Ex.10 at 27, 132. The Army researchers concluded that the ISL-designed plug “may be a satisfactory solution.” Ex.10 at 144.

The Army pursued an option like the ISL-designed nonlinear earplug for U.S. military use. A representative of the Army Research Lab, Georges Garinther, visited ISL in 1996 and 1997 and recommended that the Army acquire the earplugs. Ex.1 at 11. Garinther noted, however, that because the nonlinear filter provided “essentially no attenuation against high level steady-state noise” like the noise produced by aircraft and tanks, “it would still be necessary to provide the soldiers with normal earplugs.” *Id.* at 10. This left the Army with three options: issue soldiers separate nonlinear and conventional earplugs; develop an earplug in which the nonlinear filter could be opened and closed; or develop a two-ended device with a nonlinear earplug on one end and a conventional earplug on the other. *Id.*

In December 1997, the manager of the Army’s Hearing Conservation Program and chair of the Defense Department’s Hearing Conservation Working Group—Dr. Doug Ohlin—convened a meeting to discuss the nonlinear-earplug project. He invited Garinther, two lead engineers from ISL, two Army hearing conservation specialists, and Aearo’s chief scientist Elliott Berger. At the meeting, Ohlin stated

that he was unwilling to issue soldiers separate conventional and nonlinear earplugs and was “interested” in a two-ended plug because it would be easier for the Army’s field audiologists to dispense. Ex.2 at 2.

Aearo ultimately developed a two-ended earplug to satisfy the military’s needs and sent Ohlin twenty-five pairs in March 1998. Ex.11. Each end of the earplug featured its own “triple-flange” earplug—the design of Aearo’s longstanding UltraFit—with different colors on each end. Ex.9 at 4.

More than a year later, Ohlin informed Aearo that it needed to shorten the earplugs by approximately one-quarter inch. Ex.4. According to Ohlin, the original length created three problems: the earplugs were too long to fit into the Army’s standard-issue carrying case; parts of the earplugs were exposed to wind noise; and they “st[uck] out too far for the [K]evlar combat helmet.” *Id.* Ohlin described the last problem as a “show stopper if we can’t get the modification.” Ex.5 at 1.

Aearo created a shortened version of the dual-ended earplugs and sent samples to Ohlin for further review. By May 12, 1999, Ohlin deemed the new shortened samples “acceptable,” Ex.3 at 4, and submitted a “Request for National Stock Number (NSN) and Bulk Purchase of Combat Arms Earplug” to the Defense Department’s Joint Readiness Clinical Advisory Board. Ex.9. The request stated that the Hearing Conservation Working Group “has recommended that a non-linear earplug configured to the specifications of the enclosed production samples be

adopted for military use.” *Id.* at 1. The request also included a “[j]ustification” letter from Ohlin providing that, among other things, the earplugs were “compatible with most head gear.” *Id.* at 4.

2. Aearo’s Internal Testing of the CAEv2

Later in 1999, Aearo decided to sell the CAEv2 on the civilian market. To create a commercial label, Aearo conducted “real-ear-attenuation-at-threshold” (REAT) testing and calculated a “Noise Reduction Rating” (NRR) for the CAEv2. In a REAT test, the experimenter fits a human subject with the device, attempting to obtain the “best fit” possible for each subject. Ex.20 at 11. The experimenter determines the subject’s ability to hear certain sounds at certain volumes, with and without hearing protection. *Id.* The goal is to measure the amount of attenuation provided, and the NRR can be calculated after attenuation levels have been recorded for ten subjects, participating in three trials each. Ex.60 at 128:8-129:3.

Aearo’s first REAT test on the nonlinear end of the earplug produced an NRR of -2, which was consistent with the company’s expectation that it would attenuate little to no sound at low levels. Ex.22. Aearo expected an NRR in the range of 20 for the conventional end, based on the company’s experience with the UltraFit. Ex.59 at 214:19-25. But a few of the subjects had unusually variable results. Ex.21. After eight subjects had been tested, the NRR was just 10.9. *Id.* Aearo decided to end the test and investigate the source of the variability. Ex.59 at 214:13-215:4.

On the next REAT test of the CAEv2, the experimenter used a technique on at least one of the subjects called the “flange fold,” where he folded back the flanges on the opposing end of the earplug to obtain a better fit.² Ex.24 at 2. The results were less variable on this second test, yielding an NRR of 21.7, which was within the expected range. *Id.*; Ex.23.

Elliott Berger and the experimenter contemporaneously documented their conclusions about the testing in an internal report known in this litigation as the “flange report.” Ex.24. The report began by noting that the “Combat Arms earplug was shortened, at the request of the military.” *Id.* at 2. Berger and the experimenter determined that the CAEv2’s shorter length caused fitting issues for some subjects during the first test, which led to the observed variability. Because the stem was “so short,” “it was difficult ... to insert the plug deeply into some subjects’ ear canals.” *Id.* Additionally, because the earplug’s shortening had brought its two ends closer together, the bottom edge of the opposing flanges sometimes contacted the outside of the subject’s ear before the experimenter could fully insert the earplug. *Id.* When the experimenter finished inserting the earplug, the opposing flanges would return to their normal shape, which would partially withdraw the inserted end from the subject’s ear canal. *Id.* In the soundproof test chamber, where subjects can hear

² The experimenter’s contemporaneous notes indicate that he folded back the flanges for only one subject. Ex.23 at 8.

only the testing sounds, that partial withdrawal—or “loosen[ing]”—was “imperceptibl[e]” to the subjects. *Id.*; Ex.59 at 241:14-243:14.

Consistent with these conclusions, Aearo included a fitting tip on the label for the civilian version of the CAEv2 advising users that “[f]itting is ... improved if the sealing rings of the outward directed plug are rolled back upon themselves.” Ex.25 at 2.

3. Aearo Relays The Flange-Fold Fitting Tip To The Military

Aearo told the military about the flange-fold fitting tip and the reasons for it. Elliott Berger informed Doug Ohlin of “the fact that the shortened earplug was creating a problem in the initial test and ... the work we had done to try and resolve that problem to get optimum performance for labeling purposes.” Ex.59 at 297:13-22. Berger also explained to Ohlin that “rolling back the flanges would be important for some people,” *id.* at 337:8-18, and asked whether “this additional type of instruction” would be “acceptable to the military.” *Id.* at 305:10-20. Berger shared the flange-fold tip with others in the military. In 2001, an Army audiologist reached out to Berger, at Ohlin’s recommendation, for information about the CAEv2. *See* Ex.28. Berger responded with a copy of the retail instructions, which included the flange-fold fitting tip, and the report from Aearo’s second test of the CAEv2, which noted that the experimenter used the flange-fold technique. *See* Exs.29, 25, 23.

Ohlin determined that the flange-fold technique was acceptable and passed it along to military audiologists. As early as 2001, Ohlin told a gathering including “most of the Army audiologists” that “if you needed to, you could fold back the flange on the earplug to get a good fit.” Ex.58 at 98:2-3, 106:21-107:1. The military audiologists implemented Ohlin’s advice. For example, one audiologist instructed technicians who issued earplugs to soldiers 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 at ¶9.

4. The Military Develops Instructions for the CAEv2

The military insisted on providing its own in-person training for the first several years it used the CAEv2. Aearo shipped the CAEv2 to the military in bulk—50 pairs in a bag in a cardboard box—and the military specified that the bulk packages should *not* include instructions. Ex.62 at 326:15-18. Ohlin told Aearo “not to include instructions in th[e] box” because “[h]e felt that personal training was the most effective way to train the soldiers.” *Id.* at 326:22-327:10. As one of the military audiologists explained, it would have been “unusual” for the military to rely on a manufacturer’s instructions for a premolded earplug. Ex.66 at ¶17.

In August 2004, however, some military audiologists began to express concern that soldiers did not know when to use which end of the earplugs. *See* Ex.38.

Ohlin notified Aearo of the issue, and Aearo proposed shipping the CAEv2 in individual packages that included instructions. *See id.* Ohlin expressed concern about the “cost of individual packaging.” *Id.*

The military ultimately chose to create its own instructions rather than obtaining written instructions from Aearo. Ohlin notified Aearo that his office had been asked to create a “wallet-sized instruction card” for the CAEv2 and that he was planning to print approximately 200,000 copies. Ex.39. Ohlin’s wallet card included a picture of the CAEv2 with one set of flanges folded back and provided the instruction that “[f]or very large ear canals, fold opposing plug back.”



Ex.41.

Appellants separately sold relatively small numbers of individually packaged pairs of the CAEv2 in retail stores on Army bases. Ex.62 at 183:4-184:8. The instructions contained in these individual packages included the flange-fold tip that appeared on the civilian packaging. Ex.43. Ohlin reviewed and approved these

retail instructions in 2005, after suggesting additional language that Aearo adopted.
Id.

5. The Military Continues to Use and Test the CAEv2 until 2015

Military laboratories repeatedly tested the CAEv2 between 2001 and 2015 and never documented any defects in the product's design. *See* Exs.7, 45-52. On the contrary, the Air Force Research Laboratory concluded after a REAT test that the CAEv2's conventional end "provide[d] very good attenuation" and the product "seems to work as advertised." Ex.7 at 71, 20. Those results were consistent with numerous tests across the country—by the military and others—concluding that the CAEv2 was effective. *See* Exs.7, 45-52.

The military continued to use the CAEv2 until 2015. By that time, Appellants had introduced three subsequent versions of the Combat Arms earplugs—which the military still uses today—and version-2 sales had accordingly declined. 4/21/21 Tr. at 71:23-72:4; D-Gen-107. In 2016, a competitor company filed a *qui tam* action against 3M, after it obtained the flange report in unrelated patent litigation, and alleged that 3M and Aearo had withheld the report findings from the military. *See* P-Gen-10 at 6–7. Although 3M denied the allegations, it settled the lawsuit for \$9.1 million in July 2018 rather than continue with costly litigation. *Id.* The Justice Department issued a press release explaining that "the claims resolved by the settlement were allegations only, and there has been no determination of liability."

Motion to Reconsider Admission of Vietas Letter, *Blum v. 3M Co.*, No. 7:20-cv-122, Dkt.88-2 (N.D. Fla. Oct. 14, 2021).

B. Procedural History

Shortly after DOJ announced the settlement, plaintiffs' lawyers began advertising for personal-injury clients who developed hearing loss or tinnitus in the military from 2000 to 2015. In April 2019, the Judicial Panel on Multi-District Litigation consolidated hundreds of federal cases for pretrial proceedings before Judge Rodgers in the Northern District of Florida. Dkt.1.

Plaintiffs' master MDL complaint alleged that the CAEv2's defective design caused imperceptible loosening and that Appellants concealed the flange report's findings regarding potential fitting issues and the purported need "to fold back the opposing flanges of the earplug." Dkt.704 at ¶174. Plaintiffs asserted numerous design-defect and failure-to-warn claims, along with related negligence, warranty, and misrepresentation claims.

1. MDL-Wide Summary Judgment Ruling on Appellees' Government-Contractor Defense

After months of discovery, the parties filed cross-motions for summary judgment on Appellants' government-contractor defense. Dkt.1071, 1072. That defense provides that "[l]iability for design defects in military equipment cannot be imposed" when the government "approve[s] reasonably precise specifications," the product "conform[s] to those specifications," and the manufacturer warned the

government of known risks. *Boyle*, 487 U.S. at 512. The defense seeks to protect the government’s “uniquely federal interest” in disputes involving its “procurement of equipment,” even where the “litigation is purely between private parties.” *Id.* at 507.

The district court denied Appellants’ motion and granted plaintiffs’ motion for summary judgment. Dkt.1280. After recognizing that “this litigation is nothing if not about the government’s procurement of equipment,” the court inexplicably rejected the government-contractor defense at the threshold by holding that the government lacked any “uniquely federal interest” in the CAEv2 because the earplugs were procured via purchase order rather than through a procurement contract specifying the product’s design features. *Id.* at 26. Additionally, the court held that Appellants could not satisfy *Boyle*’s first prong because they did not send drawings or plans with “‘detailed, precise, [or] quantitative’ information” about the product design—although the court acknowledged that the head of the Army’s hearing conservation program reviewed physical samples, requested changes, and reviewed revised samples before approving them for purchase. *Id.* at 39-40 (quoting *Shaw v. Grumman Aerospace Corp.*, 778 F.2d 736, 745 (11th Cir. 1985), *abrogated by Boyle*, 487 U.S. at 513)).

With respect to plaintiffs’ failure-to-warn claim, the district court held that “[p]ursuant to *Dorse* [*v. Eagle-Picher Indus., Inc.*, 898 F.2d 1487, 1489 (11th Cir.

1990)]”—a one-sentence, per curiam decision—“the government contractor defense preempts failure-to-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.” *Id.* at 49-50 (emphases added). Because there was “no contract, formal specification, or incorporated publication in which the Army forbade Aearo from fulfilling any state law duty to warn or instruct” or “dictated the specific warnings to be given,” the court held that Appellants could not invoke the defense. *Id.* at 51. In the alternative, even if the “more relaxed” *Boyle* standard applied, the court held that Appellants could not prove that the military “exercised its discretion as to warnings.” *Id.* at 52-53. Although the court acknowledged that the military “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,” that directive did not “preclude Aearo from affixing warnings to the *outside* of the boxes.” *Id.* at 53-54 (emphasis added).

Appellants sought permission to immediately appeal this case-dispositive ruling, *see* 28 U.S.C. §1292(b), before the parties expended tremendous resources on numerous arguably unnecessary bellwether trials. The district court denied the motion. Dkt.1329.

In subsequent proceedings, the district court made clear that its ruling on the government-contractor defense meant not only that Appellants could not present the defense to the jury, but that Appellants would be limited in arguing about the military's role in the design of the earplug. The court limited the arguments Appellants could make about the government's role to the point of forcing Appellants to provide a counterfactual version of events to the jury, admonishing that “[y]our client was the designer and the only designer of this plug.” 3/15/2021 Tr. at 75:9-18. The court reiterated at a pretrial conference: “[I]t’s not going to be suggested to the jury, they’re not going to be told, it’s not going to be argued to them, witnesses are not going to get into that the government was responsible for the design. That is not going to happen. You can take it up with the Eleventh Circuit, but it’s not going to happen in this courtroom.” 3/17/21 Tr. at 141:20-142:1.

2. The Estes, Hacker, and Keefer Trial

For the first bellwether trial, the district court consolidated—over Appellants’ objection—the cases of plaintiffs Estes, Keefer, and Hacker. Dkt.1583.

1. Before trial, Appellants moved for summary judgment on plaintiffs’ negligence per se claims, which alleged that Appellants had violated federal regulations requiring them to provide instructions and an NRR label with every pair of CAEv2. The federal regulations at issue were promulgated by the U.S. Environmental Protection Agency (“EPA”), pursuant to the Noise Control Act. 40

C.F.R. §§211.204-1, 211.204-4(e). That Act vested in EPA the authority to “by regulation designate any product” that (1) “*emits* noise capable of adversely affecting the public health or welfare” or that (2) is “sold wholly or in part on the basis of its effectiveness in *reducing* noise.” 42 U.S.C. §4907(a)(1)-(2) (emphases added). The Act defines “product” as “any manufactured article or goods or component thereof,” but provides an “except[ion]” for “any military weapons or equipment which are designed for combat use.” 42 U.S.C. §4902(3).

Appellants argued that—as Aearo believed in the late 1990s—the exemption for “any military weapons or equipment which are designed for use in combat” applied to the CAEv2 and thus exempted them from the EPA’s regulations. The district court did not dispute that the earplugs fall within the ordinary meaning of “equipment” or even that they were “designed for use in combat,” but nevertheless held that they fell outside the exemption for “equipment ... designed for use in combat.” The district court invoked the *noscitur a sociis* canon, according to which a word is “known by the company it keeps,” reasoning that because weapons “emit rather than reduce noise, ‘equipment’ is subject to the same meaning.” *Estes*.Dkt.53 at 23-24. The court then denied Appellants’ motion for summary judgment.

Plaintiffs fully embraced that ruling—and the district court enforced it enthusiastically—from the beginning to end of the trial. The issue featured in plaintiffs’ opening statements, where they argued that “things had already gone

wrong” with the CAEv2 because “the EPA requires a certain type of testing to be done on every earplug that’s manufactured or sold in the United States of America”—testing that Appellants concededly did not undertake before they sold the first few thousand pairs of the CAEv2 to the military (because they thought the statutory exemption applied). 3/30/21 Tr. at 45:24-46:3. When Elliott Berger tried to explain that Aearo did not “creat[e] labels for the military, because we didn’t believe that was necessary,” 4/20/21 Tr. at 236:2-4, the court *sua sponte* instructed the jury that it could not “consider his testimony as an accurate statement of any laws, any EPA regulations, or anything of that sort.” *Id.* at 244:11-12; *see also* 4/13/21 Tr. at 269:24-270:3 (court asking plaintiffs’ expert if he “underst[oo]d that it was a mandatory requirement ... for the manufacturer” to label the CAEv2); 4/27/21 Tr. at 208:3-4, 15-16 (overruling objection to plaintiffs’ question asking Appellants’ design expert whether, “[a]ssuming it is required that there actually be EPA labeling on the product that’s sold to the military,” it would be “unreasonable for a manufacturer not to do that before ... going in the ears of soldiers”); 3/30/21 Tr. at 244:1 (plaintiffs’ design expert testifying that there was no testing “in accordance with the EPA requirements”).

The district court went further and included a jury instruction on the applicability of the EPA labeling requirements. The court expressly instructed—over Appellants’ objection, 4/27/21 Tr. at 363:5-7—that the EPA labeling regulations

“apply to the testing and labeling of all hearing protection devices, including those sold to the military.” 4/29/21 Tr. at 61:15-17. The court went on, “These regulations provide that certain information must be included with each and every device sold, whether packaged individually or in bulk. In deciding whether 3M failed to exercise ordinary care in any of these respects, you should consider what 3M knew or should have known and whether it acted reasonably.” 4/29/21 Tr. at 84:15-20. Plaintiffs’ counsel were quick to exploit that instruction, arguing in closing that “[t]he Judge has instructed you ... Berger is not right.” *Id.* at 132:22-24. Labeling is “required”— “[e]ven in the military, and it has to be on each and every device sold.” *Id.* at 132:24-25.

2. Numerous trial errors reinforced the legal errors concerning the government-contractor defense and the NCA.

Vietas letter and DOJ qui tam report. With Appellants hamstrung in their ability to explain the government’s extensive role in designing the CAEv2 and limiting direct warnings to servicemembers, Plaintiffs filled the evidentiary gap with two highly prejudicial hearsay statements by government officials, a July 2019 letter from Air Force colonel Jay Vietas and a DOJ summary from the *qui tam* litigation instigated by a 3M competitor. The Vietas letter advised that the CAEv2 should be removed from the Air Force’s inventory and included the highly prejudicial (and inaccurate) double-hearsay statement on the ultimate issue in this case, that the

CAEv2 “were found to be defective.” P-Gen-2586. The district court agreed that the letter was hearsay, but allowed the jury to “consider this document for what the Air Force knew or did not know in regards to the plugs.” 4/12/21 Tr. at 304:2-3.

The DOJ report summarized interviews with military officials about whether they knew about Appellants’ test results and whether that information was material to their purchase decision. *See* P-Gen-10. The vast majority of the interviews were of procurement officials with no expertise in hearing protection. *Id.* at 7-8. One of the few interviews with military audiologists confirmed they were aware “if the earplug touched one part of the ear (the Tragus) it could push out of the ear ... [s]o their office recommended that personnel flip the first flange back.” *Id.* at 258.

The summary of the investigation stated: “Interviews of US government personnel confirmed that had they known about the February 2000 test results (i.e., that the CAE was too short for proper insertion in the users’ ears and, therefore, did not perform well in certain individuals) on the CAE they may not have purchased the items.” *Id.* at 7. Appellants moved to exclude the report and underlying interview notes as hearsay. Dkt.1664 at 6-7. The court excluded the interview notes, but ruled the summary of the notes constituted a “factual finding” from a government

investigation, and thus qualified for the public-records exception in Rule 803(8). Dkt.1693 at 5-6.

Plaintiffs *repeatedly* referenced and relied on these documents throughout the trial to argue that the government had determined the CAEv2 was defective and that Appellants had concealed that defect from the military. During opening statements, plaintiffs' counsel claimed "the Air Force has issued a letter that you'll get to see today that shows ... they need to pull it off their shelves, and that the plug is defective." 3/30/21 Tr. at 48:17-19. And they claimed that the *qui tam* report "made a factual conclusion that the military did not know, and that [Appellants] did not share; that the plug did not work." 3/30/21 Tr. at 84:19-21; *see also id.* at 48:8-11. Plaintiffs used the Vietas letter with three of their live witnesses, *see* 4/1/21 Tr. at 126:4-127:1; 4/2/21 Tr. at 233:14-234:6; 4/12/21 Tr. at 303:20-304:4, and the *qui tam* report with four live witnesses, *see* 4/2/21 Tr. at 227:15-229:2; 4/12/21 Tr. at 301:14-303:4; 4/16/21 Tr. at 239:18-240:20; 4/20/21 Tr. at 76:17-78:9—none of whom had any personal knowledge of either document. Plaintiffs also incorporated the "found to be defective" phrasing into witness exams—for example, asking plaintiff Estes whether a different earplug he had used "was determined to be defective by the military," 4/6/21 Tr. at 88:10-11, and asking one of their experts whether another earplug had "ever been found to be defective ... by the U.S. military." 4/13/21 Tr. at 31:19-20. Then, plaintiffs referenced the Vietas letter no

less than six times during their closing argument, claiming that “[t]he Air Force believed the plug to be defective so much so they had to issue a recall.” 4/29/21 Tr. at 225:1-3; *see id.* at 112:14-18, 127:4-5, 141:20-22, 233:16-18, 236:11-13. And they used the *qui tam* report to argue for high punitive damages, telling the jury “[w]e know the Department of Justice investigations don’t do anything” because they did not prompt Appellants to issue a recall. 4/29/21 Tr. at 135:7-11.

Manufacturing issues. With little evidence to support their actual claims, plaintiffs introduced a slew of evidence about alleged quality-control problems at the Mexican facility that manufactured the CAEv2. That evidence centered on a device called the “acoustic resistance checker”—or “ARC box” for short—which Appellants’ manufacturing facility used to test the nonlinear end of each CAEv2 earplug. *See* 4/26/21 Tr. at 285:23-286:5. The Mexico facility had trouble properly calibrating the ARC boxes when it first began using them, which led Aearo to issue a series of waivers adjusting the permissible range of ARC-box readings.³ One

³ Aearo eventually discovered that the calibration issue stemmed from the altitude difference between the Mexico facility and Aearo’s laboratory in Indianapolis, where the ARC boxes were originally calibrated. *See* 4/26/21 Tr. at 301:22-302:14.

waiver indicated that 80% of all CAEv2 were failing the test. *See* 4/26/21 Tr. at 298:18-299:2.

Appellants moved in limine to exclude all evidence related to “alleged manufacturing defects or failed quality control in the manufacturing process for the CAEv2” as irrelevant and unduly prejudicial, for the rather obvious reason that plaintiffs asserted no manufacturing-defect claims. The district court nonetheless found the evidence “relevant to Plaintiffs’ claims ‘that Defendants’ overall quality assurance process for the CAEv2 was substandard.’” Dkt.1695 at 18-19.

Plaintiffs made extensive use of the manufacturing evidence at trial. They questioned three of their live witnesses about the quality-control testing, *see* 3/31/21 Tr. at 65:22-74:9; 4/1/21 Tr. at 208:24-226:17; 4/16/21 Tr. at 218:20-232:14; 235:25-236:18, 285:2-289:8. One of those witnesses was a putative expert in “the field of government procurement [and] government contracting,” 4/16/21 Tr. at 192:23-193:4, who concededly lacked any expertise on the “ARC boxes and testing down in Mexico,” *id.* at 218:20-23, but who was permitted to testify that Appellants had “violated” their obligations regarding quality-control testing. *Id.* at 219:10-15. Plaintiffs also played five deposition videos with testimony about the testing, including three hour-long videos that were devoted exclusively to that topic. *See* 4/6/21 Tr. at 149:8-156:13; 4/8/21 Tr. at 203:19-213:19; 4/15/21 Tr. at 229:15-271:14; 4/16/21 Tr. at 137:17-172:13; 4/19/21 Tr. at 24:12-64:4. Appellants even

lodged a cumulativeness objection, given the hours upon hours of testimony elicited about the manufacturing evidence. *See* 4/16/21 Tr. at 12:2-3.

Other lawsuits. Finally, during trial, the district court erroneously instructed the jury that it had “heard evidence” that “a large number of soldiers” have “made complaints about the CAEv2 and how it worked for them in terms of issues with fit and hearing-related problems.” 4/22/21 Tr. at 110:20-23; 297:11. The fact that other soldiers had sued 3M regarding the CAEv2 was not in the record. The court had rejected plaintiff’s request for judicial notice, 4/27/21 Tr. at 394:18-395:5, and the only witness to testify about it said in response to plaintiffs’ question (and over Appellants’ objection) that he “d[id]n’t know what that number is,” 4/28/21 Tr. at 109:17, although he “would not be surprised that it’s a large number” given the number of litigation advertisements he had seen. *Id.* at 108:2-3. The witness’s rank speculation was the only basis for the court’s instruction.

3. The jury, confronted with this wealth of irrelevant and highly prejudicial evidence, instructed that Appellants failed to perform testing and provide warnings required by the EPA, and deprived of Appellants’ government-contractor defense and evidence about the military’s role in the earplugs, found for plaintiffs Estes, Hacker, and Keefer on all claims. The jury awarded a total of \$830,500 in compensatory damages and \$6.3 million in punitive damages. *Estes*.Dkt.184; *Keefer*.Dkt.186; *Hacker*.Dkt.202.

SUMMARY OF ARGUMENT

The trial in this case was shot through with legal and evidentiary errors that require reversal and rob the verdict of any use as a meaningful bellwether outcome. But this case careened off the rails long before the trial. These state-law claims never should have seen a jury because they are preempted by the government-contractor defense. Rather than grant summary judgment to defendants on that defense and bring this sprawling MDL to a prompt end, the district court erroneously granted summary judgment to *plaintiffs* and then went a step further and prevented defendants from even presenting the jury with an accurate picture of the government's critical role in the design of the CAEv2 and the absence of direct supplier-to-soldier instructions for use. And to make matters worse, the district court coupled its erroneous government-contractor ruling with a construction of the NCA that defies its plain text and common sense. As with the government-contractor error, the district court's error went beyond depriving Appellants of a valid legal defense; it was used to give the jury a wholly distorted view of a company that withheld mandatory warnings, when the military could not have been clearer that it wanted to do the instructing itself, freed from any potentially contradictory guidance that could accompany the product. In lieu of admissible evidence of the government's pervasive role, the district court allowed the jury to consider highly prejudicial hearsay and evidence of irrelevant manufacturing issues. The result was

a jury that heard a distorted version of reality largely scrubbed of the government's pervasive involvement. Having been treated to a version of *Hamlet* without the Prince, the jury's verdict cannot stand and is useless as a bellwether outcome.

I. The district court erred on the government-contractor defense by 180 degrees. Rather than grant summary judgment for Appellants, it granted summary for the plaintiffs and then for good measure limited Appellants' ability to fully explain the government's role at trial. Correctly understood, the government-contractor defense plainly preempts plaintiffs' state tort-law claims. Aearo did not decide to shorten the CAEv2 or dispense with instructions on its own motion. Instead, it is undisputed that the director of the Army Hearing Program, Dr. Doug Ohlin reviewed initial prototypes, asked that Appellants shorten the earplugs to accommodate military needs, reviewed revised prototypes, approved the CAEv2's final design, and told Appellants not to include any instructions with the product because the military would instruct the soldiers on its own. This case falls squarely within the government-contractor defense. The district court reached the opposite conclusion only by imposing limits on the defense that have no basis in law or logic and by erroneously drawing unreasonable inferences in *plaintiffs'* favor when deciding *plaintiffs'* motion.

II. The district court's erroneous interpretation of the NCA wrongly deprived Appellants of summary judgment on plaintiffs' negligence per se claims and

fundamentally skewed the trial. The NCA presumptively gives EPA regulatory authority over both noise-emitting and noise-reducing products, but expressly exempts “any military weapons or equipment which are designed for combat use.” 42 U.S.C. §4902(3)(B)(i). That exemption unmistakably covers noise-emitting “military weapons” and (at least) noise-reducing military “equipment...designed for combat use.” That makes eminent sense, as the prospect of the EPA second-guessing military judgments about noise-levels of combat weaponry *or* the appropriate earplugs for the battlefield is not a happy one. The district court’s misguided ruling is contrary to the plain language of the NCA, resulted in an erroneous jury instruction, and distorted the evidence and arguments presented at trial.

III. Numerous evidentiary errors compounded the problem and substituted irrelevant and inadmissible evidence for the critical evidence of the government’s role excluded in the wake of the district court’s erroneous legal rulings. The court allowed plaintiffs to make extensive use of an Air Force letter that includes the demonstrably false statement—which all agree is hearsay—that the CAEv2 “were found to be defective.” On top of that, the district court admitted a statement from a *qui tam* investigation that “[i]nterviews of US government personnel confirmed that had they known about the February 2000 test results ... they may not have purchased the items,” even while acknowledging that the underlying interviews were inadmissible hearsay. The court admitted hours of testimony and many documents

relating to alleged quality-control problems at Appellants' manufacturing facility, even though no plaintiff alleged injury caused by a manufacturing defect. And the court instructed the jury that many other soldiers had brought similar suits against Appellants in the absence of any actual evidence supporting that assertion in the trial record. The resulting verdict cannot stand.

STANDARD OF REVIEW

This Court “review[s] *de novo* a district court’s rulings on cross-motions for summary judgment, and the facts are viewed in the light most favorable to the non-moving party on each motion.” *Chavez v. Mercantil Commercebank, N.A.*, 701 F.3d 896, 899 (11th Cir. 2012).

The Court “review[s] *de novo* whether the district court misstated the law in its jury instruction[s].” *United States v. Joseph*, 709 F.3d 1082, 1093 (11th Cir. 2013). “Rulings on the admissibility of evidence are reviewed for abuse of discretion,” but “[a] district court by definition abuses its discretion when it makes an error of law.” *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 556 (11th Cir. 1998).

ARGUMENT

I. The Government-Contractor Defense Preempts Plaintiffs’ Claims.

The government-contractor defense should have put an immediate end to this sprawling and misdirected litigation. The military not only approved the design of the CAEv2—it *introduced* and *required* the very feature plaintiffs claim rendered the

product defective. When Appellants learned that the military's decision to shorten the earplug might cause fitting issues, it provided the military with a technique that resolved the problem. And when the military told Appellants not to include instructions with the CAEv2 shipments because it would instruct soldiers itself, Appellants obliged. In sum, Appellants provided the military with exactly the product and absence of directions it wanted, and plaintiffs should not be able to second-guess the military's judgment through this litigation.

This case falls squarely within the federal defense first recognized in *Boyle*. There, the Supreme Court declared that the federal government has a “uniquely federal interest[]” in disputes involving the government’s “procurement of equipment,” even where the “litigation is purely between private parties and does not touch the rights and duties of the United States.” *Id.* at 504-06 (quotation marks omitted). That interest can preempt state tort law where a “significant conflict” exists between the interest and the state law. *Id.* at 507. A significant conflict exists, and thus “[l]iability for design defects in military equipment cannot be imposed,” “when (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. That rule prevents plaintiffs from evading

principles of sovereign immunity by redirecting a complaint about government designs and decisions at third-party suppliers.

The Court expressly recognized that the “selection of the appropriate design for military equipment” is a “discretionary function” that involves “the balancing of many technical, military, and even social considerations, including specifically the trade-off between greater safety and combat effectiveness.” *Id.* at 511. Accordingly, the first two prongs of the “significant conflict” test “[en]sure that the suit is within the area where the policy of the ‘discretionary function’ would be frustrated—*i.e.*, they [en]sure that the design feature in question was considered by a Government officer.” *Id.* at 512. The third prong—government knowledge of any dangers known to the supplier—is a prudential requirement to remove any “incentive for the manufacturer to withhold knowledge of risks.” *Id.*

This Court has repeatedly applied the defense to bar tort claims involving products sold by private defendants to the government. *See, e.g., Harduvel v. Gen. Dynamics Corp.*, 878 F.2d 1311 (11th Cir. 1989); *Brinson v. Raytheon Co.*, 571 F.3d 1348 (11th Cir. 2009). The defense displaces not just design-defect claims, but any state tort claims where a plaintiff attempts to hold a private party liable for conduct reviewed and approved by the government. *See, e.g., Hudgens v. Bell Helicopters/Textron*, 328 F.3d 1329 (11th Cir. 2003) (“service contract”); *Dorse*, 898 F.2d 1487 (failure-to-warn claims).

A. The District Court Erred in Finding the Absence of a “Uniquely Federal Interest.”

The district court’s ruling on the government-contractor defense was fundamentally flawed from the start. According to the court, the “first question” it had to answer was whether “this litigation implicates interests that are ‘uniquely federal’” and thus can preempt state law. Dkt.1280 at 26. That should have been a straightforward inquiry because the Supreme Court and this Court have unequivocally held that “the procurement of equipment by the United States is an area of uniquely federal interest.” *Brinson.*, 571 F.3d at 1351 (quoting *Boyle*, 487 U.S. at 507); *see also Hudgens*, 328 F.3d at 1333 (same). The district court forthrightly recognized that “this litigation is nothing if not about the government’s procurement of equipment.” Dkt.1280 at 26. The entire “genesis” of this litigation, the court explained, 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.” *Id.* The existence of a uniquely federal interest here should have been an open-and-shut case.

The district court, however, perceived the analysis as not so “simple,” because the military acquired the CAEv2 by “purchase order” rather than a “procurement contract containing a design component.” *Id.* at 31-32. That distinction was

dispositive, the court reasoned, because *Boyle* was “predicated on the existence of a federal government procurement contract” and spoke “only in terms of contract.” *Id.* at 28.

That novel holding finds no support in *Boyle* or the countless cases that have applied it. To be sure, *Boyle* was “predicated on the existence of a ... procurement contract,” *id.*, but not in some technical sense. A purchase order, no less than a lengthy design contract with detailed specifications, qualifies as a “procurement contract” in the sense *Boyle* used the term. *See* Black’s Law Dictionary (11th ed. 2019) (“procurement” is “[t]he act of getting or obtaining something”).

Appellants are aware of no court—ever—that has held that a *written* procurement contract *with express design specifications* is necessary to invoke the government-contractor defense. Moreover, such a requirement could not be squared with this Court’s decision in *Brinson*, which applied the government-contractor defense based on “post-design, post-production evidence” demonstrating that the military made an “informed, discretionary decision” to continue using the component at issue despite its alleged defects. 571 F.3d at 1353, 1356. This Court did not even mention whether the component’s specifications were included in the original procurement contract. That is because that fact is immaterial under *Boyle*, which focuses on conflicts between “federal policies and interests and the exercise of federal discretion” and “contrary state law,” without regard to whether the conflict

stems from express contractual specifications or a federal direction to dispense with warnings or adjust a product to ensure compatibility with other military equipment. *In re Agent Orange Prod. Liab. Litig.*, 517 F.3d 76, 96 (2d Cir. 2008).

B. Appellants Satisfy *Boyle* With Respect to Plaintiffs’ Design-Related Claims.

The district court’s alternative holding that plaintiffs’ design-defect claims fail to satisfy *Boyle*’s first prong was equally misguided. In fact, Appellants readily satisfy all three prongs, entitling them to summary judgment.

1. The military approved reasonably precise specifications for the CAEv2.

Undisputed evidence makes clear that the military “approved reasonably precise specifications” for the CAEv2. *Boyle*, 487 U.S. at 512. That requirement “ensure[s] that ‘the design feature in question was *considered* by a Government official.’” *Brinson*, 571 F.3d at 1355 (quoting *Boyle*, 487 U.S. at 512) (emphasis in *Brinson*). And it is satisfied where the product’s design “was a result of ‘continuous back and forth’” between the government and manufacturer. *Harduvel*, 878 F.2d at 1320. The key inquiry is whether the government’s “approval, if given, was meaningful,” such that the government “considered” the design feature before deciding to use the product. *Brinson*, 571 F.3d at 1355-56.

There is overwhelming undisputed evidence that the military “considered” the CAEv2’s design features and gave “meaningful approval” before purchasing them.

Id. at 1355. The military gave Appellants significant guidance on the design from the outset, before the company even began work on the earplug. Specifically, the military knew from its own research that it would have to choose between distributing separate conventional and nonlinear earplugs, acquiring a single-ended earplug that could switch between conventional and nonlinear modes, or acquiring a two-ended earplug with separate conventional and nonlinear ends. *See* Ex.1 at 10. The military discussed these options with Appellants in 1997, when Ohlin expressed that he was interested in the two-ended option. *See* Ex.2 at 2. Appellants then created two-ended samples and sent them to Ohlin for his review. Ex.11.

Ohlin spent more than a year with Appellants' samples, ultimately concluding that they were too long in light of other combat-related concerns. Ohlin conveyed that the earplugs needed to be shortened so that they would fit in the Army's carrying case, cut down on wind noise, and avoid interference with the soldiers' helmets. Ohlin emphasized that the helmet concern would be a "show stopper." Ex.5 at 1. In response, Appellants created new, shortened samples and sent them to Ohlin for further review. Ohlin determined that the shortened samples were "acceptable" and began the process of securing them for order, requesting a "National Stock Number" and recommending them for bulk purchase. Ex.9 at 1. The military first purchased the CAEv2 a few months later.

These undisputed facts make crystal clear that the military decided it wanted the CAEv2 to be double-ended, reviewed Appellants' samples, decided they were too long, reviewed shortened samples and determined they were "acceptable," and only then approved the CAEv2 for purchase. The absence of blueprints or schematics does not change that outcome. The CAEv2 may not be as complicated as a helicopter, but its ultimate design—and particularly its length—are just as much a product of the government's review and approval as in *Boyle* or this Court's cases finding the defense applicable.

The district court nevertheless found the military's approval lacking, holding that Appellants could satisfy the first prong of *Boyle* if and only if they sent the military drawings or written descriptions reflecting "detailed, precise, or quantitative information" about the design. Dkt.1280 at 39-40. The physical product samples, the court reasoned, were not enough. But *Boyle* does not require that the manufacturer provide drawings, plans, or written descriptions. To the contrary, numerous courts of appeals have applied the government-contractor defense where plans, drawings, and descriptions were *not* provided—including in cases cited favorably in *Brinson*. See *Ramey v. Martin-Baker Aircraft Co.*, 874 F.2d 946, 950 (4th Cir. 1989) (explaining that in *Dowd v. Textron, Inc.*, 792 F.2d 409 (4th Cir. 1986), the military's decision to *continue* using helicopter rotor system amounted to sufficient approval, even though the military had never "developed or approved the

specifications for the component at issue”); *Lewis v. Babcock Indus.*, 985 F.2d 83, 85 (2d Cir. 1993) (military adequately approved design of manufacturer’s cables by reordering them after learning they could corrode, where military had dictated only “dimensions and strength”). If the government sufficiently “considered” the design features at issue in *Dowd* and *Lewis*, then *a fortiori* the military sufficiently “considered” the design features here. *Brinson*, 571 F.3d at 1355.

Nor would there have been any reason for Appellants to provide the military with drawings or a written design description, when they had furnished physical prototypes that gave Ohlin all the information he needed about the CAEv2. Indeed, Ohlin not only reviewed the product samples, but requested modifications. That back-and-forth confirms that the product samples allowed the military to meaningfully review the CAEv2’s length and other design features. It also belies the district court’s suggestion that the military merely “rubber stamped” the design. Dkt.1280 at 40. Reviewing the design for over a year before identifying three problems created by the length and then insisting that the manufacturer go back to the drawing board because the current design is a “show stopper” is no “rubber stamp[.]” The military’s consideration of the CAEv2’s design readily satisfies *Boyle*’s first prong.

2. The CAEv2 conformed to the government’s specifications, and Appellants warned the government of known risks.

Although the district court did not reach the remaining *Boyle* prongs, Appellants are entitled to summary judgment on them as well. The relevant facts are beyond dispute, and the equities strongly favor resolving this case-dispositive issue now. Appellants have already been forced to defend against fourteen plaintiffs in eleven trials in less than a year—with more to come. The Court should decide in this appeal whether more trials are necessary.

The undisputed record makes abundantly clear that Appellants satisfy the second and third prongs. As to the second, there can be no dispute that the CAEv2 “conformed to precise, government-approved specifications.” *Brinson*, 571 F.3d, at 1357. Plaintiffs have never suggested that the CAEv2 earplugs sold to the military had a different length or varied in any material respect from the final production samples approved by Ohlin, and for good reason, as no evidence would support that claim. Moreover, “where the procurement process involves [a] continuous exchange between the contractor and the government,” as here, “the process itself becomes persuasive evidence of the product[’s] conformity to precise specifications.” *Id.*

The record is just as clear on the third prong, that Appellants “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.” *Boyle*, 487 U.S. at 512. To satisfy this prong,

a manufacturer must show that it informed the government of all dangers that were “substantial enough to influence [its] decision.” *In re Agent Orange*, 517 F.3d at 99.

Plaintiffs’ attorneys commenced this litigation because they thought they had found a document—the flange report—recording fitting issues that defendants kept from the military. This theory has never been viable. Aearo told the military about the flange report’s conclusions: that the shortened nature of the two-sided CAEv2 could cause fitting issues and that the issues could be resolved by folding back the opposing flanges before insertion. The author of that report, Elliott Berger, has repeatedly testified that he told the military “rolling back the flanges would be important for some people and that it was something [Aearo] w[as] doing on the most recent test.” Ex.59 at 297:13-22, 337:8-18. A slew of military documents and testimony corroborate that testimony. In 2001, Berger sent an Army audiologist the report from Aearo’s second CAEv2 test, which notes that the experimenter used the flange-fold technique. *See* Exs.29, 25, 23. The message plainly got through: when the *military* created its wallet card in 2004, it included a picture of the CAEv2 with the opposing flanges folded back and advised soldiers with “very large ear canals” to “fold the opposing plug back.”

In the face of this evidence, plaintiffs insist that the warning was insufficient because the flange report observed fitting issues in subjects with “medium and larger” ear canals, yet the wallet card advised folding back the flanges only in “very

large” ear canals. Ex.24 at 2; Ex.41 at 1. But the wallet card is not the sum total of Appellants’ warnings or the evidence that the military received and implemented them. The manager of the Army Hearing Program testified that Ohlin instructed “most military audiologists” that “if you needed to, you could fold back the flange on the earplug get a good fit.” Ex.58 at 98:2-3, 106:18-107:2. Ohlin’s instruction did not “limit [the advice] to one particular size ear canal.” *Id.* at 99:4-8. And a former manager of the Army Hearing Conservation Program stated that he instructed his technicians to try “roll[ing] back the opposing flanges” “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.” Ex.66 at ¶9. While he told technicians the issue was “particularly likely to occur with soldiers who had large ear canals,” he did *not* tell them the issue “would only occur with soldiers who had large ear canals.” *Id.* at ¶10-11. This evidence leaves no doubt that the military knew the opposing flanges of the CAEv2 could cause fitting issues for some individuals and that the issues could be resolved by folding back the opposing flanges before insertion.⁴

* * *

⁴ In the face of this evidence, plaintiffs later argued that the flange report established that “the flanges *had* to be folded to ensure the CAEv2 worked”—i.e., the technique was needed for *everyone*. Dkt.1089 at 31. But that sweeping claim lacks any foundation. Even on the first test documented in the flange report, in which no flanges were folded back, the CAEv2 exceeded the government’s mean attenuation expectations at every frequency. *Compare* Ex.21 at 5, *with* Ex.55 at 44.

With the third and final prong of *Boyle* satisfied, the government-contractor defense entitles Appellants to summary judgment on plaintiffs' design-defect and related claims. Plaintiffs cannot fault Appellants for supplying the military with the product it determined, after years of research and review, would best protect soldiers' hearing in the field while balancing other military-readiness needs.

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

For similar reasons, the government-contractor defense displaces plaintiffs' failure-to-warn claims. The three-part *Boyle* test, "modified to the failure-to-warn context," requires Appellants to show 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." Dkt.1280 n.44 (citing *Tate v. Boeing Helicopters*, 55 F.3d 1150, 1157 (6th Cir. 1995)).

Each factor is satisfied here. The absence of supplier-to-soldier instructions regarding the CAEv2 was plainly a deliberate decision of the military, reflecting the exercise of its "discretion" to train soldiers directly rather than rely on information from the manufacturer. *Id.* at 1280. Ohlin expressly told Appellants "not to include instructions" in the box with shipments of the CAEv2 because 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 soldier.” *Id.* at 326:19-327:3. Ohlin then made providing individual-box-instructions impossible by expressly directing Appellants to ship the CAEv2 earplugs in bulk with “50 pair in a plastic bag, with nothing else in there, inside a box.” Ex.62 at 326:16-18. When the military later decided it wanted to distribute written instructions to supplement that direct instruction, Appellants offered to provide them, but the military chose to draft its own wallet card. *See* Ex.38.

Under these circumstances, the absence of instructions is directly attributable to the military, just as if the military had told a contractor not to replace a part or put a guard on a rotor. These facts indisputably establish that the military “considered” whether to obtain written instructions from Appellants and affirmatively instructed them not to provide any. *Brinson*, 571 F.3d at 1355 (quoting *Boyle*, 487 U.S. at 512)). And because the military directed Appellants *not* to provide any instructions, and Appellants obliged, there can be no serious question that Appellants’ actions conformed to the government’s wishes. Plaintiffs may not “second-guess[.]” that considered military judgment, which—just like the design decisions—involved “the balancing of many technical, military, and even social considerations.” *Boyle*, 487 U.S. at 511. And for all the reasons that Appellants satisfy the third *Boyle* prong with respect to the design features of the CAEv2, they satisfy the third prong here. *See supra* at pp.37-38.

The district court reached the opposite conclusion only by applying an idiosyncratic and unduly more-demanding standard. According to the district court, the *Boyle* framework does not apply to failure-to-warn claims; instead, the government-contractor defense preempts those 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.” Dkt.1280 at 49-50 (emphasis added). The district court gleaned that outlier standard from this Court’s one-sentence per curiam decision in *Dorse*, 898 F.2d at 1489, affirming “based upon” the “appended” district court opinion. But the district court in *Dorse* announced no such novel standard. To the contrary, it held that *Boyle* provides a “guide[]” in failure-to-warn cases, even if the three-part test is not strictly transferable. *Id.* The court then went on to conclude that the elements of the government-contractor defense were lacking there, noting, among other things, that the defendant’s contract “d[id] not contain any prohibition against health warnings on the product.” *Id.* That reasoning far from supports the district court’s insistence that the defense applies to failure-to-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.” Dkt.1280 at 49-50 (emphasis added).

At any rate, whether applying a modified version of *Boyle* or the more stringent so-called “*Dorse*” test, the result here is the same. The military expressly told Appellants not to provide instructions and effectively foreclosed individual instructions by insisting on bulk shipments of the CAEv2, so that it could later instruct the soldiers in person. And when the military decided to provide written instructions for individual sets of earplugs, it refused Appellants’ offer to develop instructions and used its own wallet card instead. Plaintiffs’ failure-to-warn claims thus seek to impose a duty on Appellants to provide instructions with the earplugs, which is in direct conflict with the military’s command “affirmatively prohibit[ing]” that conduct.

The district court’s final effort to justify its grant of summary judgment to plaintiffs only serves to demonstrate the lengths the district court was willing to go to deprive Appellants of a government-contractor defense. The court acknowledged that the military “told [Appellants] 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,” Dkt.1280 at 53-54 (emphasis added), but held that the directive “did not preclude [Appellants] from affixing warnings to the *outside* of the boxes.” Dkt.1280 at 54 (emphasis added). That reading of the record is, at best, implausible. Perhaps the military would not have minded instructions on the outside of bulk shipment boxes, but only because they would have been utterly useless in

providing instruction or warning to individual soldiers and thus could not have interfered with the military's stated preference for providing its own instructions directly to servicemembers. That the bare possibility of providing useless instructions on the outside of a bulk shipment box was a strike against Appellants' government-contractor defense is a sure sign the district court was not applying a valid test, and was drawing inferences in *plaintiffs'* favor rather than defendants'.

* * *

With judgment properly entered in favor of Appellants on the government-contractor defense, this entire litigation should come to an end. Plaintiffs' warranty, negligence per se, and misrepresentation claims all "boil down to claims of design defect ... and failure to warn." *Quiles v. Sikorsky Aircraft*, 84 F. Supp.2d 154, 165 n.2 (D. Mass. 1999); *see also In re Agent Orange Prod. Liab. Litig.*, 304 F.Supp.2d 404, 408 (E.D.N.Y. 2004). At bottom, plaintiffs have two arguments in this litigation: that the design of the CAEv2 created fitting issues, and that Appellants failed to provide adequate instructions for fitting the CAEv2. The government-contractor defense precludes both.

At the very least, Appellants are entitled to a new trial. The district court amplified the effect of its erroneous government-contractor ruling by using it as a basis to severely distort the evidence before the jury and to hamstring Appellants' trial presentation, declaring that Appellants were "the only designer of this plug" and

that “witnesses are not going to get into that the government was responsible for the design.” 3/15/2021 Tr. at 75:9-18; 3/17/21 Tr. at 141:20-142:1. There can be no serious question that forcing Appellants to defend this case without that defense had a “substantial prejudicial effect” on their trial presentation. *In re Int’l Mgmt. Assocs.*, 781 F.3d 1262, 1266 (11th Cir. 2015). Even if some element of the government-contractor defense were missing, there was still no proper basis for forcing Applicants to litigate this case with one hand tied behind their backs and with the major player reduced to a supporting role in the *dramatis personae*. The Court should enter judgment in favor of Appellants on all claims, but at a minimum should vacate the jury verdict and order a new trial.

II. The CAEv2 Is Exempt From The Noise Control Act.

The district compounded its mistaken approach to the government-contractor defense by ignoring the plain text of the Noise Control Act and allowing plaintiffs repeatedly to label Applicants as law-breakers, despite a clear exemption for military equipment. EPA has promulgated labeling regulations pursuant to the statutory mandate of the NCA, which charges EPA with “designat[ing] any product” that “emits noise capable of adversely affecting the public health or welfare” or that is “sold wholly or in part on the basis of its effectiveness in reducing noise.” 42 U.S.C. §4907(a)(1)-(2). EPA thus has authority to regulate both noise-*emitting* and noise-*reducing* “product[s].” The NCA defines “product” broadly as “any manufactured

article or goods or component thereof.” *Id.* §4902(3). Thus, the NCA would presumptively reach military “products” whether they emit noise (like weapons) or reduce noise (like the CAEv2), but the NCA expressly exempts, among other things, “any military weapons or equipment which are designed for combat use.” *Id.*

That exemption fits the Combat Arms Earplugs version 2 to a tee. The product was specifically designed for the unique challenges for hearing-protection devices in combat—hence, its name—and sold to the military for that purpose. Here, the district court did not dispute that an earplug falls within the ordinary meaning of “equipment,” which is defined as “articles or implements used for a specific purpose or activity.” Black’s Law Dictionary (11th ed. 2019). And it did not seriously dispute that the earplugs were “designed for combat use.” The entire reason the military recruited Appellants to develop the earplug was to find a solution for soldiers who were under-utilizing hearing protection to facilitate situational awareness in combat. As the district court correctly acknowledged in another part of this MDL, “the CAEv2 earplug was a hearing protection device designed specifically for combat.” Order on 3M MIL No. 41 , *Camarillorazo v. 3M Co.*, No. 7:20-cv-98, Dkt.89 (N.D. Fla. Oct. 26, 2021) at 2. That should have been the end of the matter. *See Smith v. Marcus & Millichap, Inc.*, 991 F.3d 1145, 1161 (11th Cir. 2021) (“[O]ur analysis begins with the language of the statute,” “[a]nd where the statutory language provides a clear answer, it ends there as well.”)).

The surrounding text and statutory context only confirm that the CAEv2 is “equipment” within the combat-use exemption. First, Congress placed the modifier “any” before “military weapons or equipment,” which has “an expansive meaning,” and certainly warns against carving out a species from the genus of equipment. *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219 (2008) (quotation marks omitted). Second, the exemption for military “equipment” is in contradistinction from presumptively included “products,” which include both noise-emitting and noise-reducing devices. The Supreme Court has warned courts off interpreting exemptions narrowly, and emphasized that they should, like other text, be interpreted fairly. *See Encino Motorcars, LLC v. Navarro*, 138 S.Ct. 1134, 1142 (2018). Moreover, absent some contrary indication, the scope of an exemption is informed by the scope of its accompanying prohibition, and a one-sided exemption (noise-producing only) from a two-sided prohibition (noise-producing or reducing) is neither fair nor plausible absent some textual indication that the exemption is one-dimensional.

The district court eschewed all of these textual indicators in favor of the *noscitur a sociis* canon. According to the district court, because the exemption covers “any military weapons or equipment which are designed for combat use,” 42 U.S.C. §4902(3), the *noscitur a sociis* canon requires the court to interpret “equipment” in light of the word “weapon.” Because weapons only *emit* noise, the

district court reasoned, the term “equipment” must be limited to the subset of equipment that emits noise.

That is, with all due respect, a complete misapplication of the *noscitur a sociis* canon. First, the canon teaches that “a word is known by the company it keeps,” *McDonnell v. United States*, 136 S. Ct. 2355, 2368 (2016) (quotation marks omitted), and it requires a meaningful amount of company to have significant interpretive force. That is why the Supreme Court expressly declined to apply it in *Reiter v. Sonotone Corporation*, 442 U.S. 330 (1979), when interpreting the phrase “business or property” in the Clayton Act. The Court held that “property” should be given its “naturally broad and inclusive meaning,” expressly rejecting that the term should be limited to “property related to one’s business.” *Id.* at 338. “That strained construction,” the Court observed, “would have us ignore the disjunctive ‘or’ and rob the term ‘property’ of its independent and ordinary significance.” *Id.* at 338-39.

But even if the *noscitur a sociis* canon could apply to some other disjunctive pair, it cannot apply where, as here, the surrounding text provides strong reasons to interpret the two disjunctive terms as having different characteristics. When interpreting an exemption to a general authorization that expressly covers two different things (both noise-emitting products and noise-reducing products) one would naturally expect a disjunctive exemption to be two-dimensional as well. And that is exactly how the military combat exemption works, as it expressly exempts

both noise-emitting weapons and equipment, which logically covers (at least) the other half of the waterfront when it comes to military combat products. Indeed, the harder interpretive question would seem to be whether “equipment” covers noise-emitting military equipment *in addition to* noise-reducing military equipment, as that would risk rendering the reference to “weapons” superfluous, as weapons would seem to be the ultimate in noise-emitting military equipment. The better reading is that both noise-emitting and noise-reducing military equipment are exempted (especially given the word “any”), but the one thing that seems most obviously exempted is noise-reducing military equipment, and the prototypical example of noise-reducing equipment “designed for combat use” is the CAEv2.

The district court’s contrary holding infected the whole trial. It stripped Appellants of any defense against the accusations that they did not test and label the CAEv2 according to the EPA’s requirements. Meanwhile, plaintiffs seized on the district court’s erroneous ruling in their opening statement, arguing that “things had already gone wrong” with the CAEv2 because Appellants had not done the testing that would be needed for the labeling (even though it did not apply to the CAEv2). 3/30/21 Tr. at 45:24-46:3. Plaintiffs falsely asserted: “Mr. Berger knows and 3M knows, an EPA label ... should be placed on all hearing protections. There is no exceptions for the U.S. military. You don’t get a free pass simply because you sell them to the military.” *Id.* at 66:20-24. Plaintiffs then cross-examined Appellant’s

experts, over Appellants' objection, about whether failing to follow the law was unreasonable. 4/27/21 Tr. at 208:3-18. And when Berger tried to explain that Appellants "didn't believe" complying with the EPA regulations "was necessary," 4/20/21 Tr. at 236:2-4, the court interjected that the jury could not consider that testimony "as an accurate statement of any laws, any EPA regulations, or anything of that sort." *Id.* at 244:11-12. Indeed, the district court expressly *instructed* the jury to consider Appellants' purported failure to follow the EPA regulations when considering whether Appellants used "ordinary care" in testing and labeling the CAEv2. 4/29/21 Tr. at 84:1-17. The jury thus started its deliberations from the premise that Appellants broke the law, which undoubtedly tainted the jury's deliberations on every claim.

III. Numerous Evidentiary Issues Require A New Trial.

Throughout trial, and over Appellants' repeated objections, plaintiffs' counsel introduced irrelevant and highly prejudicial issues. Each of those errors supports a new trial, and their cumulative effect compels one and rendered the verdicts here (and in follow-on trials infected by the same repeated errors) useless as representative bellwether outcomes.

A. The Vietas Letter and *Qui Tam* Report Are Inadmissible.

There can be no serious dispute that the Vietas letter and the *qui tam* report—and their respective double-hearsay statements that the CAEv2 "were found to be

defective” and “may not have [been] purchased” if the government knew about Appellants’ testing—never should have been admitted.

The district court recognized that the “found to be defective” statement in the Vietas letter was double hearsay, but nevertheless allowed the jury to consider it “for what the Air Force knew or did not know in regards to the plugs,” as if that were a non-hearsay purpose. 4/12/2121 Tr. at 303:25-304:2-3. But the statement sheds light on what the Air Force “knew or did not know” about the CAEv2 only if it is *true* that the military found the CAEv2 to be defective. And the military never did.

Even if that statement were not inadmissible (it is manifestly hearsay) and were somehow minimally relevant (it manifestly is not), the unfair prejudice of admitting it would still be undeniable. *See* Fed. R. Evid. 403. The letter effectively communicates that the military already weighed in on the ultimate issue in this trial. It implies that an internal military investigation found the CAEv2 to be defective—a proposition that is demonstrably false.⁵ Indeed, that is exactly the inference plaintiffs invited the jury to draw throughout the trial. *See supra* pp.19-22.

⁵ Appellants took Col. Vietas’s deposition in Minnesota state-court litigation involving the CAEv2. His testimony underscores all the reasons the hearsay is inadmissible. He testified that the “sole basis” for his statement that the CAEv2 “were found to be defective” was a “press release” announcing that the Department of Justice had settled the False Claims Act claims against 3M. *Blum.Dkt.88-1* at 30:15-25, 35:9-16, 49:14-23. That press release, in turn, contained the critical disclaimer that the settlement resolved “allegations only” and that “there has been no determination of liability.” *Blum.Dkt.88-2*.

The district court likewise recognized the hearsay character of the *qui tam* report, but nevertheless admitted the summary of the investigator's interviews on the ground that it was a factual finding and thus satisfied the public-records exception. Fed. R. Evid. 803(8). But the summary simply repeated the interviewees' statements, which the district court correctly excluded as "inadmissible hearsay within hearsay." Dkt.1693 at 8. If the underlying statements are excluded, then so must be the investigator's summary of those statements. Placing "otherwise inadmissible hearsay statements by third-parties into a government report does not make the statements admissible." *United Tech. Corp. v. Mazer*, 556 F.3d 1260, 1278 (11th Cir. 2009).

Indeed, the district court's decision to admit the summary but exclude the underlying notes resulted in the worst of both worlds for Appellants, who were unable to point out that the notes showed that the military audiologists interviewed *were* aware that the flange-fold technique could be used to resolve fitting issues. P-Gen-10 at 257.

The prejudicial effect of these errors was magnified by the district court's erroneous ruling related to the government-contractor defense. This case should have never gone to the jury because both the alleged defect and the absence of direct supplier-to-soldier instructions were a product of military decisions. But the district court sent it to the jury anyway and limited Appellants' efforts to give the jury a fair

view of the military's involvement and knowledge. The district court then allowed the plaintiffs to fill that artificial gap with hearsay evidence that should have never been admitted and gave the jury a skewed view of what the government knew and when they knew it. The product of that profoundly distorted trial cannot be allowed to stand.

B. Evidence About Alleged Manufacturing Issues in Mexico Is Inadmissible.

A new trial is warranted in light of the district court's improper admission of an array of evidence relating to alleged quality-control issues in the manufacturing process for the CAEv2. There is no manufacturing-defect claim in these cases, or in the MDL more generally. The district court acknowledged as much, explaining, "I didn't let [the evidence] in because I thought there was a manufacturing defect claim." 4/26/2021 Tr. at 358:24-359:4. The court nonetheless permitted the plaintiffs (and most bellwether plaintiffs to date) to elicit hours of testimony and admit a slew of documents suggesting that there were "chronic" problems at Aearo's manufacturing facility in Mexico, and that as many as 80% of CAEv2 failed Aearo's internal quality-control tests.

The district court's rationale does not withstand scrutiny. The court explained that it saw the manufacturing evidence as "relevant to the operation of the lab. So you have a lab in Indianapolis that oversaw all of the quality control for this earplug, and in my opinion ... it's relevant how that lab dealt with these quality issues."

4/26/2021 Tr. at 358:12-16. But the ARC box testing was performed in Mexico, not in Indianapolis. Whether a different group of people at a different facility in a different country struggled with a different sort of test is in no way a reflection of the quality of the testing Appellants conducted in Indianapolis.

Moreover, even if the manufacturing evidence did somehow bear on the professionalism of the Aearo laboratory a thousand miles away in a different country, Rules 403 and 404(b)(1) would bar its admission. According to the district court's rationale, the plaintiffs could introduce the ARC-box evidence to show that Appellants' "overall quality assurance process for the CAEv2 was substandard." Dkt.1695 at 18-19. In other words, the plaintiffs could introduce evidence of supposed quality-control failures in *manufacturing*, even though the plaintiffs do not claim those problems affected them in any way, to suggest there were *also* quality-control failures in *designing* the CAEv2.

That conflates the timeline (the CAEv2 was obviously designed before it was manufactured) and is precisely what the evidentiary rules prohibit. Plaintiffs simply may not introduce otherwise irrelevant manufacturing issues to prove that Appellants *generally* had poor quality control. *See, e.g., In re Tylenol (Acetaminophen) Mktg., Sales Pracs. and Prods. Liab. Litig.*, 181 F. Supp.3d 278, 299 (E.D. Pa. 2016) (excluding evidence of quality-control issues at manufacturing facility because "plaintiff asserts a design defect claim, not a manufacturing defect

claim”). It is understandable why plaintiffs want to focus on this irrelevant and highly prejudicial evidence (and inject the false notion that U.S. servicemembers were given equipment manufactured in substandard fashion in Mexico), but that is not how the Federal Rules of Evidence work.

C. The District Court’s Instruction Regarding Other Lawsuits Was Improper.

Finally, in yet another example of the errors that permeated this trial, the district court instructed the jury that there are a “large number of soldiers who have made complaints about the CAEv2 and how it worked for them in terms of issues with fit and hearing related problems”—even though this highly prejudicial evidence was not in the record. 4/28/21 Tr. at 110:21-23. The court correctly agreed that it could not take judicial notice of the number of claims, 4/27/21 Tr. at 394:18-395:5, and the only witness who was asked testified that he “d[id]n’t know what that number is.” 4/28/21 Tr. at 109:17. That witness did add that he “would not be surprised that it’s a large number” in light of the advertisements his family had seen on TV, *id.* at 108:2-3, but that rank speculation does not support the court’s instruction that “there are a large number of soldiers who have made complaints about the CAEv2 and how it worked for them in terms of issues with fit and hearing-related problems.” *Id.* at 110:8-111:8. That instruction should have been grounds for an immediate mistrial, *see Keefer*:Dkt.181 (denying Appellants’ timely motion

for mistrial), and it is certainly grounds for a new trial. *See, e.g., Heath v. Suzuki Motor Corp.*, 126 F.3d 1391, 1396 (11th Cir. 1997).

* * *

These errors—individually and collectively—require a new trial. They are regrettably only the tip of an iceberg. The trial was replete with erroneous and highly prejudicial rulings that prevented Appellants from having a fair trial and gave the jury a skewed version of reality. The errors run the gamut from refusing to admit the plaintiffs’ own filed complaints as a party admission, 3/17/21 Tr. at 107:14-25; to excluding a public record (helpful to Appellants) because of the possibility, unsupported by any evidence, that although Ohlin signed the government report, he may not have drafted it, *id.* at 136:20-137:16; D-Gen-1095; to redacting and excluding positive feedback from the military about the CAEv2, D-Gen-1663, D-Gen-0272, *Keefe*.Dkt.122-1 at 73; to admitting the price different private-equity buyers paid to acquire Aearo, despite the clear prohibition on that evidence under Kentucky law, *e.g.*, 4/2/21 Tr. at 49:22-52:13; Dkt.1664 at 19. Those errors permeated this three-plaintiff, month-long trial, and they are being replicated over and over again in these bellwether trials, where the jury hears inadmissible and inaccurate hearsay, rather than anything approaching an accurate picture of the military’s role in shortening the plugs and prohibiting instructions. The plaintiff

verdicts that result from such trials are deeply flawed and useless as bellwether outcomes. This Court's intervention is sorely needed.

CONCLUSION

For the foregoing reasons, the Court should reverse the judgment of the district court, or at a minimum vacate the judgment and remand for a new trial.

Respectfully submitted,

COLE CARTER
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000

s/Paul D. Clement
PAUL D. CLEMENT
Counsel of Record
KASDIN M. MITCHELL
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, NW
Washington, DC 20004
(202) 389-5000
paul.clement@kirkland.com

Counsel for Defendants-Appellants

February 25, 2022

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 12,966 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and 11th Cir. R. 32-4.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman type.

February 25, 2022

s/Paul D. Clement
Paul D. Clement

CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Paul D. Clement
Paul D. Clement