UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

IN RE: 3M COMBAT ARMS EARPLUG PRODUCTS LIABILITY LITIGATION	Case No. 3:19md2885
This Document Relates to All Cases	Judge M. Casey Rodgers Magistrate Judge Gary R. Jones

PLAINTIFFS' POSITION STATEMENT

A. INTRODUCTION

This case came to public attention due to a two-year investigation by the Criminal Investigation Command of the Department of the United States Army. As explained more fully below, the Army was tipped off by a *qui tam* relator who stumbled upon evidence of corporate fraud on behalf of 3M Company's ("3M") subsidiarity, Aearo Technologies LLC ("Aearo"). The Criminal Investigation Command found in summary that:

> During the course of this investigation, numerous interviews and record reviews were conducted in reference testing results and contracting process. Interviews of US Government personnel confirmed that had they known about the February 2000 test results (i.e. that the Combat Arms Earplug 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.[1]

As a result of this thorough and robust investigation, it is apparent that hundreds of thousands of U.S. military men and women learned they had been provided an illusion—but only the illusion—of safety when they were told the defendants' Combat Arms Earplugs would protect them. Because of the sheer number of active military personnel needlessly harmed by 3M's

[1] Exhibit 1, Department of the Army, U.S. Criminal Investigation Command Report produced March 20, 2019 (000009)

conduct, hundreds of military personnel have filed lawsuits for the damages they suffered at defendants' hands, and we anticipate tens of thousands more will follow.

Specifically, this case relates to the dual-ended Combat Arms Earplugs (Version 2 CAEv.2), which were designed, manufactured and sold by defendants Aearo and 3M to the United States military from approximately 2003 through 2015. Due to their defective nature, these earplugs placed over one million U.S. men and women serving in the military at risk of significant harm. Of those, tens of thousands have suffered harm in the form of total or partial hearing loss in one or both ears, tinnitus,[2] and other related life-altering effects.

As discussed in more detail below, this case is unique because, at least from what we know right now, much of the defendants' alleged fraudulent conduct appears to have been developed in prior litigations and investigations, including a *qui tam* action prosecuted by the Department of Justice (DOJ) in 2016 based on substantially the same conduct. During its two-year-long investigation, the U.S. Army Criminal Investigation Command conducted numerous interviews and record reviews regarding the allegations. The United States intervened on behalf of Moldex, formally alleging that "3M, and its predecessor Aearo [Technologies, LLC], knew that the CAEv2 was too short for proper insertion in users' ears and, therefore, did not perform as well in certain individuals." The United States also alleged "that 3M did not disclose this information to the

[2] "Tinnitus involves the sensation of hearing sound when no external sound is present. Tinnitus symptoms may include these types of phantom noises in your ears: ringing, buzzing, roaring, clicking, hissing, or humming. The phantom noise may hear it in one or both ears. In some cases, the sound can be so loud it can interfere with your ability to concentrate or hear external sound. Tinnitus may be present all the time, or it may come and go." https://www.mayoclinic.org/diseases-conditions/tinnitus/symptoms-causes/syc-20350156 (visited April 11, 2019). From fiscal years 2006 to 2010, the number of veterans who received new compensation awards for "impairment of auditory acuity" grew by more than 72 percent. 2013- Dougherty et al, blast injuries. https://www.rehab.research.va.gov/jour/2013/506/pdf/page893.pdf . Moreover, "[r]ecent literature has shown that up to 77% of the tinnitus population may present with Psychiatric comorbidities. Among those psychiatric disorders, Anxious and depressive symptoms seem to be the most common complications with tinnitus, with a lifetime prevalence of depression and anxiety significantly higher in tinnitus patients than in the general population." Hu et al. The Correlation of the Tinnitus Handicap Inventory with Depression and Anxiety in Veterans with Tinnitus. International Journal of Otolaryngology, 2015.

United States and delivered the CAEv2 to the United States knowing that the product contained defects that impaired the CAEv2's serviceability."[3] [See Exhibit 1, Settlement Agreement at p. 2.]. Specifically, 3M was charged with violating 31 U.S.C. § 3729: Civil False Claims Act and offenses related to the Qui Tam Investigation. 3M pled "No Contest" to each charged offense.

On July 30, 2018, the U.S. Department of Justice issued a press release announcing that it "has agreed to pay $9.1 million to resolve allegations that it knowingly sold dual-ended Combat Arms Earplugs to the United States military without disclosing defects that hampered the effectiveness of the hearing devices." https://www.justice.gov/opa/pr/3m-company-agrees-pay-91-million-resolve-allegations-it-supplied-united-states-defective-dual. Of that amount, $4,560,000 was restitution.[4] [See Exhibit 1, Settlement Agreement at p. 3). Clearly, an important aspect of this litigation will be what has come before, including the Moldex I and II litigations and the discovery and documents generated in the *qui tam* suit.[5]

B. PRIMARY FACTS

This is a product liability action related to a defective earplug manufactured and sold by the defendants. Aearo developed, marketed, and sold the Combat Arms™ Earplugs – (Version 2 CAEv.2) from approximately 2003 until it was acquired by 3M in 2008. On April 1, 2008, a subsidiary of 3M purchased the stock of Aearo Holding Corp., the parent company of Aearo.[6] Thereafter, Aearo continued to conduct business as a separate operating unit of 3M. Post-acquisition, the Combat Arms™ earplugs have been marketed and sold under the 3M brand.

[3] Exhibit 2, Settlement Agreement for Qui Tam Action 3:16-CV-01533 dated July 23, 2018 at 2.
[4] *Id.* at 3.
[5] *See id.* at ¶ 6(g) (reserving and not releasing claims for "any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.")
[6] https://s2.q4cdn.com/974527301/files/doc_financials/2014/q4/3MCompany_10K_20150212.pdf.

Plaintiffs used the defendants' Combat Arms™ earplugs while in training and/or deployed on active military duty. The Combat Arms™ Version 2 was the standard issue ear protection for the infantry deployed to Afghanistan and Iraq beginning in 2003, and continuing to approximately 2015. These same earplugs were also offered to the civilian sector and were marketed as 3M Peltor Combat Arms™ Earplugs. The Combat Arms™ Version 2 earplugs were decommercialized and no longer sold to the U.S. military after 2015.

C. PLAINTIFFS' CLAIMS

This story begins with a frivolous patent infringement lawsuit filed by 3M against a small family-owned manufacturer of ear protection devices in California called Moldex-Metric, Inc. (No. 12-CV-1611-JNE-FLN, *3M and 3M Innovative v. Moldex-Metric, Inc.* ("Moldex I").

Moldex developed and sold hearing protection devices called Battle Plugs to the military. [insert hyperlink at p. 32]. As the U.S. Army Criminal Investigation Command subsequently noted, "[w]hile working with APG [Aberdeen Proving Ground], Moldex learned that 3M's Combat Arms Earplugs (CAE.v.2) had several problems. As the CAE.v.2 were dual ended (one olive side and one yellow side), soldiers did not know which end was for which purpose. Moldex learned from a news article that some soldiers would cut the CAE.v.2 in half because of this. Some of the other issues were that the CAE.v.2's filter did not work; on the new versions that encompassed a switch, soldiers could not tell which way to switch the earplugs in order to actuate them; and there was only one size (which did not fit all the soldiers)."[7] [Exhibit 1 at p. 32]. "After Moldex received approval for their Battle Plugs (around 2011), they began taking their Battle Plugs to Trade Shows. While at one of the trade shows 3M noticed Moldex's Earplugs and sued Moldex for patent

[7] Exhibit 1, Department of the Army, U.S. Criminal Investigation Command Report produced March 20, 2019 (000032)

infringement. Moldex advised 3M that its suit was baseless as their earplugs were single sided while 3M's were dual ended." Nevertheless, 3M pursued litigation.

During discovery in the Moldex case, numerous depositions were taken and presumably tens of thousands of pages of documents were produced. Following discovery, both sides filed motions for summary judgment. On the eve of the court considering Moldex's motion for summary judgment, 3M dismissed the lawsuit.

Having spent millions of dollars defending itself in a unsubstantiated patent suit, in 2014 Moldex filed suit against 3M for malicious civil prosecution. *See Moldex-Metric, Inc. v. 3M Innovative Properties Company*, Case No. 14-CV-01821 (D. Minn) ("Moldex II"). Moldex retained the law firms of Quinn Emanuel and Stinson Leonard to represent it. Moldex filed a Slap Motion at the beginning of the litigation, and the Judge ruled in Moldex's favor. As noted in the U.S. Army Criminal Investigation Command's investigation, the "*Slap Motion showed that Moldex had clear and convincing evidence (without discovery) that 3M's patent infringement suit was baseless."*[8] [Exhibit 1 at p. 33]. Discovery was allowed to proceed. Again, numerous documents were produced and numerous depositions were taken that are directly relevant to the claims and defenses in this case. Among the documents produced was one Aearo authored entitled the "Flange Report" that details the fraud in the testing of the Combat Arms™ Earplugs – (Version 2 CAEv.2). Both sides filed for summary judgment, and at the summary judgment hearing, Judge Joan Ericksen advised counsel for 3M, stating that she was beyond trying to decide whether 3M's patent claims were reasonable but instead trying to determine whether they were "ridiculous."[9]

[8] Exhibit 1, Department of the Army, U.S. Criminal Investigation Command Report produced March 20, 2019 (000033)

[9] Exhibit 3, Hearing Transcript for Motions for Summary Judgment (Moldex II) *Moldex Metric, Inc. v. 3M Company, et al.* Cause No. 14-CV-01821-JNE-KMM in the United States District Court for the District of Minnesota, pp.68.

The Judge again ruled in favor of Moldex, finding that "no reasonable litigant could realistically expect success on the merits of 3M's claim that Moldex infringed the '693 Patent. . ."[10] Moldex II ended in a confidential settlement wherein, upon information and belief, 3M paid a substantial sum to end the litigation.

In addition to 3M's production of a large number of documents directly relevant to the claims made in the present case, sixteen (16) depositions were taken in either Moldex I or II, including:

3M employees:

- Frank Little, Executive Vice President, 3M Safety & Graphics Business Grup
- Karl Hanson, 3M Patent Attorney
- Brian Myers, 3M Business Director – Personal Safety Division
- Doug Moses, 3M Marketing – U.S. Active Communication's / Military Manager
- Julie Bushman, Executive Vice President - International Operations of 3M Company.
- Eric Levinson, Assistant Chief IP Counsel at 3M Company
- **Elliot Berger**, 3M Division Scientist/Audiologist
- Jeff Hamer: 3M Lab Manager
- Ronald Kieper, Aearo Sr. Acoustic Technician
- **Dr. Douglas W. Ohlin**, 3M Audiologist/Scientist
- Brian McGinley, Global Business Director for 3M

Non-party witnesses:

- Kevin L. Michael, PH.D. (State College PA): President of Michael & Associates, Inc. (Acoustic Lab)
- Walter Pawlowski (FL): President of New Business Dynamics LLC

While most of the documents produced in Moldex II remain under a protective order, one ruling was published without restrictions. It was the information contained within this public ruling that allowed Moldex to approach the government with facts supporting a *qui tam* action filed in the United States District Court for the District of South Carolina on May 12, 2016. *See United States*

[10] *See* Moldex II, Order Granting Moldex's Motion for Partial Summary Judgment, Dkt. 242 at 41.

ex rel. MoldexMetric, Inc. v. 3M Company, 3:16-cv-01533-MBS, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action").

Moldex alleged that (1) the CAEv2 had a design defect which could cause the earplug to imperceptibly loosen in users' ears, thereby rendering the earplugs useless or less effective; (2) that the testing methodology employed by 3M did not comply with required and/or accepted standards; and that (3) the Noise Reduction Rating (NRR) listed on the CAEv2 packaging materials and instructions did not accurately reflect the true characteristics of the CAEv2. Moldex further alleged that 3M and/or its affiliated companies knowingly sold the CAEv2 to the United States military without first disclosing the design defect, flawed testing, and inaccurate NRR rating, which resulted in the submission of false claims.[11] [See Exhibit 2, Settlement Agreement at p. 1-2].

As noted, the U.S. Department of Justice subsequently intervened and took over the *qui tam* litigation. Shortly thereafter, the United States Government announced that it had entered into a settlement agreement with 3M wherein 3M agreed to pay $9,100,000.00 in fines and restitution and enter a plea of No Contest. Of that amount, over $1.9 million was paid to the Relator (Moldex). [See Exhibit 2, Settlement Agreement at p.3] In a press release issued on July 26, 2018, the Department of Justice stated:

> "The Department of Justice is committed to protecting the men and women serving in the United States military from defective products and fraudulent conduct. Government contractors who seek to profit at the expense of our military will face appropriate action...This settlement demonstrates the commitment of the Defense Criminal Investigative Service and our law enforcement partners to hold companies accountable for supplying substandard products, in particular products that could directly impact our service members' health and welfare…"[12]

[11] Exhibit 2, Settlement Agreement for Qui Tam Action 3:16-CV-01533 dated July 23, 2018 at 3.
[12] Exhibit 4, Press Release dated July 23, 2018, https://www.justice.gov/opa/pr/3m-company-agrees-pay-91-million-resolve-allegations-it-supplied-united-states-defective-dual

Much of the discovery and depositions, including the depositions of Dr. Douglas Ohlin and Elliot Berger, will be essential to proving plaintiffs' case. For example, Dr. Douglas Ohlin, who was a former 3M audiologist and former civilian contractor and consultant for hearing conservation at the US Army Center for Health Promotion and Preventative Medicine, is now deceased. This is important, because 3M relies upon Dr. Ohlin's alleged involvement with military's procurement of the Combat Arms™ Version 2 in crafting its government contractor defense to attempt to avoid responsibility in this case.

Through a Freedom of Information Act request, plaintiffs have acquired a partial production of the criminal investigation report related to the DOJ's *qui tam* prosecution.[13] (See Exhibit 1). The report recounts and summarizes many of the documents and testimony reviewed and relied upon by the government in prosecuting the *qui tam* claim against 3M. For example, with respect to the government contractor defense, in particular, it is notable that the investigation report confirms that U.S. Government personnel were unaware of the fraudulent conduct regarding testing of the CAEv2 earplugs. *See infra* pp. 1, 15. Most of the pleadings and exhibits, including affidavits filed in Moldex I and II, were filed under seal or are heavily redacted. Additionally, all the documents and depositions are confidential and are subject to a protective order. The plaintiffs are therefore limited in what background information they can provide the Court at this time with respect to the defendants' fraudulent conduct. Therefore, plaintiffs in this case will be seeking an agreement from defendants and/or Court intervention mandating the immediate production of all documents and depositions from Moldex I and II and the *qui tam* action.[14] Plaintiffs believe the evidence will show there is no validity to any "government contractor defense."

[13] Exhibit 1, Department of the Army, U.S. Criminal Investigation Command Report produced March 20, 2019 (000001-000267)

[14] Manual for Complex Litigation (4th ed.) §§11.423, 11.455 (advising that when information from other litigation and sources of information is available from public records (such as government studies or reports), or from discovery

Aearo/3M's Fraudulent Testing

The following summary of events and facts are derived in large part from U.S. Magistrate Judge Franklin L. Noel's order entered into Moldex II, under his section entitled "Findings of Fact."[15] [See ORDER from MOLDEX II dated 12/23/15] Additional information comes from the (redacted) report from the U.S. Army Criminal Investigation Command in the criminal investigation against 3M.

The dual-ended Combat Arms™ Earplugs – (Version 2 CAEv.2) were developed for the specific purpose of providing servicemen a single set of earplugs that provide two options for hearing attenuation depending on how they are worn. The earplugs can be worn in an open or "unblocked" position (yellow end in) to block, or at least significantly reduce, loud impulse sounds commonly associated with military service, while still allowing the serviceman to hear quieter noises such as commands spoken by fellow servicemen and approaching enemy combatants. Alternatively, the earplugs can be worn in a closed or "blocked" position (green end in) to block, or at least significantly reduce, all sounds, i.e., operate as ordinary earplugs:

conducted by others in the same litigation, the court should consider requiring the parties to review those materials before undertaking additional discovery. The court may limit the parties to supplemental discovery if those materials will be usable as evidence in the present litigation. Interrogatory answers, depositions, and testimony given in another action ordinarily are admissible if made by and offered against a party in the current action. Similarly, they may be admissible for certain purposes if made by a witness in the current action. Additionally, "[i]t may also be economical for the judges to afford parties in the present litigation access to depositions previously taken in other litigation (see section11.423)−the judges can deem depositions of opposing parties and their employees admissible against parties involved in related litigation under Federal Rule of Evidence 801(d)(2)."

[15] 2015 WL 12780466 (Moldex II) *Moldex Metric, Inc. v. 3M Company, et al.* (D.Minn 2015)

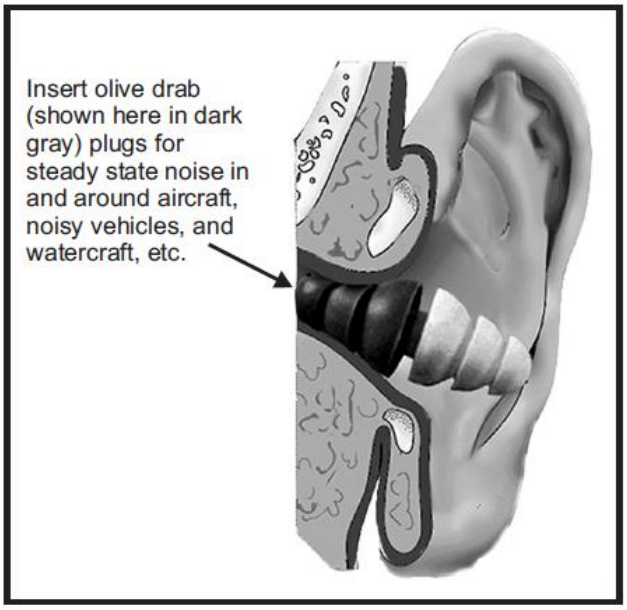
Based on the supposed technological design and qualities of the Combat Arms™ earplugs, defendants won a series of Indefinite-Quantity Contracts ("IQCs") to be the exclusive supplier of selective attenuation earplugs to the U.S. military between 2003 and 2012. To win these IQCs, defendants represented that the Combat Arms™ earplugs would meet specific performance criteria established by the U.S. Government as a prerequisite for bidding on the IQC for earplugs.

The defendants' performance representations were false and they knew they were false. In fact, as early as 2000 the defendants knew the Combat Arms Earplugs were defective and did not work as they represented—years before defendants became the exclusive supplier of selective attenuation earplugs to the U.S. military.

Around January 2000, Aearo began Noise Reduction Rating (NRR) testing on each end of the Combat Arms™ earplug. The NRR is supposed to represent the amount of sound attenuation experienced by a test group under conditions specified by the federal Noise Control Act's testing methodology. Rather than use an independent test lab, Aearo performed its testing in-house at its E-A-RCAL laboratory (also now owned by 3M). Aearo selected 10 test subjects, including some of its own employees. Aearo's test protocol involved testing: (1) the subject's hearing without an earplug; (2) the subject's hearing with the open/ unblocked (yellow) end of the Combat Arms™

earplug inserted; and (3) the subject's hearing with the closed/blocked (green) end of the Combat Arms™ earplug inserted.

Aearo's own employees monitored the test results as the tests were performed, which allowed them to stop the testing at any point if they were not achieving the desired NRR. This violated the ANSI S3.19-1974 testing protocol. In fact, Aearo stopped the test of the green end of the Combat Arms™ earplug inserted after only 8 of the 10 subjects had been tested. At that point, the Combat Arms™ earplugs were failing expectations miserably. Aearo was expecting to achieve an NRR of 22 with the green end inserted, but in fact was on target to receive a 10.9 rating based on the experiences of the first eight subjects. These disappointing results were caused by the design defect described above.



Despite stopping the test on the green end of the Combat Arms™ earplug, Aearo had the remaining two test subjects complete the test with respect to the yellow end of the Combat Arms™ earplugs only because Aearo liked the low NRR rating the test was indicating to that point. After completion, however, testing of the yellow end resulted in an NRR of -2, which falsely suggested

that the earplugs actually amplified sound. Aearo thus knew that the test was inaccurate and needed to be repeated. Instead, Aearo changed the -2 NRR to a 0 NRR, and used that rating on its labels.

After prematurely stopping the NRR test of the green end of the Combat Arms™ earplug, Aearo investigated the disappointing test results and discovered that because the stem of the earplug was so short, it was difficult to insert the earplug deep enough into the wearer's ear canal to obtain a proper fit as required by ANSI S3.19-1974, Section 3.2.3.[16] Aearo also discovered that when the green end of the Combat Arms™ earplug was inserted into the ear using the standard fitting instructions, the basal edge of the third flange of the yellow end pressed against the wearer's ear and folded backward. When the inward pressure of the earplug was released, the yellow flanges tended to return to their original shape, thereby loosening the earplug, often imperceptibly to the wearer. And, because the Combat Arms™ earplug was symmetrical, this same problem occurred when the earplug was reversed.

One witness interviewed by the U.S. Army Criminal Investigation Command in its investigation, a Supervisory Audiologist, Occupational Audiology Division, Navy and Marine Corps Public health Center, plainly "stated that 3M should have told the US Government about the slippage issues with the CAE. . . . [he] stated that the US Government would not have found out any of the issues regarding slippage through their own testing nor were they looking for that issue during the test."[17] [See Exhibit 1 at P. 248].

Aearo then manipulated the test protocol by instructing the test subjects to fold the flanges on the non-inserted end of the earplug back before inserting it into the ear. Using the manipulated

[16] Acoustical Society of America Standard Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs (ASA STD 1-1975)).

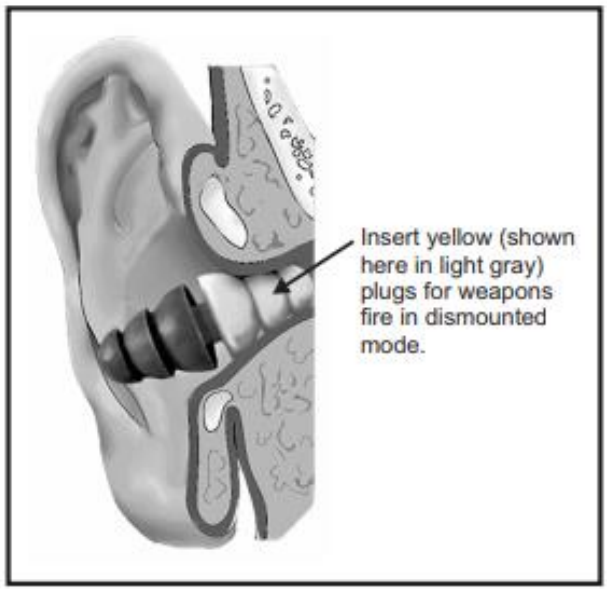
[17] Exhibit 1, Department of the Army, U.S. Criminal Investigation Command Report produced March 20, 2019 (000248)

fitting instructions, Aearo re-tested the green end of the Combat Arms™ earplugs starting in February 2000.[18] During this re-test of the green end, test subjects folded back the yellow flanges of the earplug (essentially elongating the too-short defective stem) to allow them to insert the earplugs deeper into their ears to obtain a proper fit. Because the yellow flanges were folded back, the basal edge of the third flange no longer pressed against the subject's ear canal, and thus did not cause the earplug to loosen during the testing. Using this manipulated test protocol, Aearo achieved a 22 NRR on the green end of the Combat Arms™ earplug.

Due to the symmetrical nature of the Combat Arms™ earplugs, the design defect that affected the fit of the green end similarly affected the fit of the yellow end. The fact that Aearo's testing of the yellow end resulted in a -2 NRR meant that the earplugs did not provide a proper fit (as required by ANSI S3.19-1974, Section 3.2.3) between the ear canal of at least some of the subjects and the earplugs. As a result, some subjects had large standard deviations across trials on the yellow end test, which suppressed the NRR rating.

[18] Exhibit 5, E-A-RCAL Attenuation Test Report dated January 25, 2000.

Nevertheless, Aearo did not re-test the yellow end using the manipulated fitting instructions like it did on the green end, i.e., folding back the flanges on the green end of the earplug before inserting the yellow end into the ear. Aearo did not re-test the yellow end because it knew that it would not be able to obtain a 0 NRR (much less the facially invalid -2 NRR) and further knew the 0 NRR was a major selling point to the U.S. military. An accurate NRR for the yellow end, which would have been higher than 0, would have rendered the Combat Arms™ earplug less attractive to the U.S. military because the military would have known that the earplugs would impair communication.



Moreover, the defect in the Combat Arms™ earplugs is more likely to manifest itself during military activities than in a lab where the NRR tests are performed over the span of just a few minutes and the head of the test subject remains virtually motionless during the test. Servicemen, on the other hand, may wear the earplug for an extended period of time and are more active than test subjects in a lab. Because the defect was imperceptible to the wearer, the design defect went undetected for more than a decade by the U.S. military and those who wore them. It

is thus not surprising that hearing damage is now the largest ongoing medical cost the military incurs each year.[19]

In 2003, Aearo submitted a bid in response to the U.S. military's Request for Proposal ("RFP") to supply large quantities of Combat Arms™ earplugs. The RFP required bidders to certify that the earplugs complied with the Salient Characteristics of Medical Procurement Item Description ("MPID") of Solicitation No. SP0200-06-R-4202. In its bid, Aearo certified the Combat Arms™ earplugs complied with the Salient Characteristics of MPID, even though Aearo knew that certification to be false.

> The pertinent Salient Characteristics of MPID in each RFP, in relevant part, were:
>
> 2.1.1. Ear plugs shall be designed to provide protection from the impulse noises created by military firearms, while allowing the wearer to clearly hear normal speech and other quieter sounds, such as voice commands, on the battlefield.
>
> 2.2.2 The sound attenuation of both ends of the ear plugs shall be tested in accordance with ANSI S3.19....
>
> 2.4. Workmanship. The ear plugs shall be free from all defects that detract from their appearance or impair their serviceability.
>
> 2.5. Instructions. Illustrated instructions explaining the proper use and handling of the ear plugs shall be supplied with each unit....[20]

Aearo knew that its test protocol did not comply with ANSI S3.19, but nevertheless certified that its testing was fully compliant with the U.S. military's specifications. Aearo also falsely certified that it provided accurate "instructions explaining the proper use and handling of

---

[19] (David E. Gillespie, *Researchers Evaluate True Effects of Hearing Loss for Soldiers* (Dec. 16, 2015), available at https://www.army.mil/article/160050/researchers_evaluate_true_effects_of_hearing_loss_for_soldiers last accessed Jan. 16, 2019). The VA thus spends more than $1 billion per year to treat hearing damage suffered by more than 800,000 servicemen. (*Id.*; *see also* Kay Miller, *Hearing loss widespread among post-9/11 veterans*, The Center for Public Integrity (Aug. 29, 2013),available at https://publicintegrity.org/national-security/hearing-loss-widespread-among-post-9-11-veterans (last visited Jan. 16, 2019) ("The most-widespread injury for [post-9/11] veterans has been hearing loss and other auditory complications.... Hearing maladies cost more than $1.4 billion in veterans' disability payments annually, according to first year 2010 data from the Hearing Center of Excellence, a part of the Department of Defense.")).

[20] (Exhibit 6. Solicitation No. SP0200-06-R-4202, at 41-42).

the ear plugs." Aearo knew when it did so that its own testing had revealed a design defect that needed modified fitting instructions to ensure a proper fit that would deliver the promised NRR. At no time did Defendants disclose the modified fitting instructions to achieve appropriate hearing protection to the U.S. military—even after winning the bid.

Pursuant to Section 2.4 of the MPID, Aearo was required to certify that the "ear plugs shall be free from all defects that detract from their appearance or impair their serviceability." (Ex. 6 at 41-42). Despite Aearo knowing since 2000 that its Combat Arms™ earplugs suffered from a design defect, Aearo certified to the U.S. military that its earplugs had no defects. Based on its facially invalid test results, Aearo falsely reported to the U.S. military that the yellow end of its Combat Arms™ earplugs had a 0 NRR, which would allow servicemen to freely communicate with their fellow servicemen and avoid any impairment to hear enemy combatants.

Aearo also certified that the green end of its Combat Arms™ earplugs had a 22 NRR, even though Aearo did not disclose the modified fitting instructions necessary to achieve the hearing protection afforded by a 22 NRR.[21] Nothing in these fitting instructions disclosed that it was necessary to fold back the flanges of the opposite end to ensure a proper fit and achieve the promised NRR. By failing to provide this disclosure, Aearo falsely overstated the amount of hearing protection afforded by the green end of the earplug and overstated the benefits of the yellow end of the earplug. As noted by members of the military interviewed by the U.S. Army Criminal Investigation Command for their investigation:

> The '"imperceptible loosening" of the earplug has unknown consequences. Per the test results the flanges should always have been pulled back. Again, the manufacturer should have informed the military of this problem, so that the military could [have] advised the solders of the slippage problem. The manufacturer's failure to inform the military made a difference in how the military dealt with the soldiers. Because of the manufacturer's failure to inform, the U.S Government doesn't know what it is really receiving. If they (the US Government) would have

[21] Exhibit 7. Combat Arms Earplugs Instructions.

> known of the slippage issue, they would have insisted on the instructions saying the same (flanges must always be folded back). They said that there was no practical way that soldiers could determine the size of their ear canals (small, medium, large, etc.)."[22]
>
> [See Exhibit 1 at P. 244]

Based on Aearo's false representations, its bid was the prevailing bid and Aearo entered into the first of a series of IQCs later that year making it the exclusive provider of selective attenuation earplugs to the U.S. military. In response to additional RFPs in subsequent years, defendants re-certified that the Combat Arms™ earplugs met the MPID criteria, even though they knew that to be false. In total, the U.S. military purchased enough Combat Arms™ earplugs to provide one pair to every serviceman deployed each year in major foreign engagements from 2003 through 2015.[23]

It is important to note that based on the U.S. Army Criminal Investigation Command's Investigation Report, testing conducted on the CAE.v.2 in 2004 and 2006 were stopped due to fitting problems. There is no evidence plaintiffs have seen thus far that indicates the U.S. military was aware of the abandoned test from 2004 and 2006.

Defendants continued to sell the Combat Arms™ earplugs to the U.S. military until approximately December 2015, at which time the earplugs were discontinued.[24] Not surprisingly, defendants' misrepresentations to the United States military about the alleged benefits and protections provided by the Combat Arms™ earplugs meant that hundreds of thousands U.S.

---

[22] Exhibit 1, Department of the Army, U.S. Criminal Investigation Command Report produced March 20, 2019 (000244)

[23] *See* McIlwain, D. Scott *et al.*, *Heritage of Army Audiology and the Road Ahead: The Army Hearing Program*, AMERICAN JOURNAL OF PUBLIC HEALTH, Vol. 98 No. 12 (Dec. 2008)).

[24] Exhibit 8. Discontinuation: 3M Combat Arms Earplugs Version 2 (Nov. 17, 2015)). Defendants did not recall the earplugs despite discontinuing them due to the design defect.

military personnel were sent into combat unprotected, resulting in tens of thousands of veterans (plaintiffs) suffering total or partial hearing loss and tinnitus.

D. ANTICIPATED DEFENSES BY AEARO AND 3M

Based on notice of removals filed by defendants in various jurisdictions, including Minnesota, Delaware and Indiana, plaintiffs anticipate Aearo and/or 3M will raise the "government contractor defense" and the "enemy combatant activities" defense instead of the defense of denial. Plaintiffs will argue that defendants cannot meet their burden to prove either defense.

1. Government Contractor Defense

The government contractor defense is an affirmative defense, and defendants bear the burden to establish that (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. *Boyle v. United Techs. Corp.*, 487 U.S. 500, 512 (1988). Moreover, *Boyle* crucially holds that "[w]hether the facts establish the conditions for the defense is a question [of fact] for the jury." *Id.* at 514.

After a review of just the U.S. Army Criminal Investigation Command's redacted version of the criminal investigation report, it is difficult to imagine how defendants can credibly rely on the government contractor defense. Still, based on prior filings, plaintiffs have good reason to believe defendants will assert that "military generally made a discretionary determination regarding the requirements and design of the CAEv2's benefits against the alleged risks."[25] Even the limited facts plaintiff currently posess indicate this will be a wasted argument.

[25] Aearo's Notice of Removal, 1:19-CV-00590-UNA [Doc #1].

Among other things, plaintiffs allege injuries arising from defendants' defective design of the ear plugs and their failure to properly warn soldiers about the defective condition of the earplugs or their proper use. Any allegation by defendants that the U.S. military was warned about the dangers of the earplugs is belied by at least the U.S. Army Criminal Investigation Command's criminal investigation report (which will become part of the record). What seems to be an uncontroverted fact is that defendants knowingly submitted false and misleading testing data, claims for which they recently agreed to pay $9.1 million to resolve with the United States Government. This fraud is the opposite of adequately warning the government about the defective nature of the CAEv2 earplugs.

2. Combatant Activities Defense

Prior pleadings suggest the defendants will also raise the combatant activities defense, which immunizes the government from claims arising out of combat activities. Defendants will be unable to meet their burden for this defense—for several reasons. First, defendants cannot colorably assert that they were combatants, much less engaged in combatant activities. Courts have readily rejected the availability of the combatant activities defense for private contractors, ruling that application of a combatant activities defense to private contractors improperly extends sovereign immunity to private actors, and conflates the judicially-created government contractor defense and the legislatively-mandated combatant activities exception:

> [T]his Court declines to endorse such a defense for private contractors based solely on the fact that Defendants were operating in a combat zone. **This Court can find no persuasive authority for the conclusion that the combatant activities exception preempts state tort law claims. The combatant activities exception to the FTCA is an explicit legislative preservation of sovereign immunity, while the government contractor defense is a judicially recognized affirmative defense...**. Private contractors are not entitled to sovereign immunity unless they are characterized as government employees, which Defendants are not. *Foster v. Day & Zimmermann, Inc*., 502 F.2d 867, 874 (8th Cir.1974) ("The doctrine of sovereign immunity may not be extended to cover the fault of a private corporation,

> no matter how intimate its connection with the government."). There is no express authority for judicially intermixing the government contractor defense and the combatant activities exception; nor is there authority for bestowing a private actor with the shield of sovereign immunity. Until Congress directs otherwise, private, non-employee contractors are limited to the government contractor defense and *Boyle*'s preemption analysis. Unless they qualify as employees or agents of the Government, private contractors may not bootstrap the Government's sovereign immunity.

McMahon v. Presidential Airways, Inc., 460 F. Supp. 2d 1315, 1330 (M.D. Fla. 2006), aff'd, 502 F.3d 1331 (11th Cir. 2007).

Sovereign immunity does not extend to private contractors like the defendants here. In *Foster*, the plaintiff alleged a defective grenade exploded in his hand during a training exercise at Ft. Benning, Georgia. *Foster v. Day Zimmermann, Inc.*, 502 F.2d at 874. Defendants asserted that as suppliers of government munitions, they were entitled to the protections of government immunity. *Id*. The court summarily rejected the defendant's sovereign immunity defense. *Id*.

Such holdings make sense because the combatant activities exception is narrowly construed to shield military combat decisions from state law regulation. *Saleh v. Titan Corp*., 580 F.3d 1, 8-9 (D.C. Cir. 2009). Where contract employees are under the direct command and exclusive operational control of the military chain of command such that they are functionally serving as soldiers, preemption ensures that they need not weigh the consequences of obeying military orders against the possibility of exposure to state law liability. *Id*. Put differently, it is the military chain of command that the FTCA's combatant activities exception serves to safeguard.[26]

---

[26] As aptly explained by the court in *McMahon v. General Dynamics Corp.*,

> tort law does not "lose[] its salutary capacity to encourage care, punish negligence and spread the cost of accidents, simply because the customer happens to be the government. Indeed, where the purchaser and the person likely to be injured are not the same, it may be more important to give the latter a voice and a means of recourse. The tort system, here as elsewhere, can help enforce the highest standard of care in the production of the equipment upon which our servicemen and servicewomen rely...."

Here, the CAEv2 was developed over several years and was not being delivered to the front line on an emergent basis. Moreover, the CAEv2 was not only sold to the military, it was sold for commercial use. That also removes claims against defendants from the combatant activities defense, because "this preemption doctrine is limited to combat equipment with no civilian counterpart." *Id*. at 1491.

E. PLAINTIFFS' CLAIMS

Based on plaintiffs' review of the various complaints filed thus far in this litigation, the claims asserted generally include: (1) strict liability – design defect; (2) strict liability – failure to warn; (3) negligence; (4) breach of express warranties; (5) breach of implied warranties; (6) fraudulent misrepresentation; (7) fraudulent concealment; (8) negligent misrepresentation; (9) fraud; and (10) violation of consumer protection laws.

F. STATUS OF MOTIONS, DECISIONS, LEGAL ISSUES AND OTHER IMPORTANT EVENTS

It is plaintiffs' understanding that cases have been filed in the state courts in Delaware, Indiana, Minnesota, Georgia and Philadelphia. Based on conversations with defense counsel, all of those cases have been removed or are in the process of being removed. Plaintiffs also understand that motions to remand have been filed in Minnesota and Delaware. Those motions remain pending.

Other important events in this case include plaintiffs' intent to immediately seek production from defendants (whether by agreement or court order) of the discovery in their possession related to the Moldex I and II litigations. Obtaining such information from the start is consistent with Federal Rule of Civil Procedure 1. There is no reason to re-plow old ground just for the sake of

933 F. Supp. 2d 682, 692 (D.N.J. 2013) (citing *Bentzlin*, 833 F. Supp. at 1493–94).

being adversarial. Therefore, until a more fulsome protective order can be negotiated between the parties, plaintiffs believe it prudent and efficient to immediately enter into a limited protective order for the specific purpose of allowing defendants to turn over without delay the documents and any other discovery (e.g. deposition and other transcripts) they produced and/or obtained in the Moldex I and II litigations. In the meantime, plaintiffs will continue their efforts to obtain un-redacted versions of the government's *qui tam* investigation from the relevant federal agencies and/or courts. Obtaining this prior discovery from Moldex I and II should significantly move the ball and focus the litigation in an efficient manner from the start.

Another legal issue may include the legal effect of 3M's financial settlement (including restitution) and pleas entered in the *qui tam* action. In that action, 3M was charged with violating 31 U.S.C. § 3729: Civil False Claims Act and other offenses related to the *qui tam* Investigation. 3M pled "No Contest" to each charged offense. Based on a plea of "No Contest," there is a question whether those pleas have *res judicata* or collateral estoppel implications in this case, thereby potentially foreclosing 3M's ability to re-litigate the same charged conduct here.

G. STATUS OF ANY RELATED CASES PENDING IN STATE OF FEDERAL COURT

Apart from the aforementioned cases pending in state courts, plaintiffs understand that all federal court cases have been stayed pending transfer to this MDL court.

To date, the only substantive discovery that has taken place is that requested and produced in the Moldex I and II litigations, as well as the discovery obtained by the U.S. Government in its prosecution of the *qui tam* action against 3M. Various plaintiffs have served discovery in individual cases prior to the coordination of this litigation, but no documents have yet been produced in response to those requests.

Date: April 12, 2019

Respectfully Submitted,

/s/ Bryan F. Aylstock

Bryan F. Aylstock, FL Bar No. 78263
Douglass A. Kreis, FL Bar No. 129704
Neil D. Overholtz, FL Bar No. 188761
Caitlyn Prichard Miller, FL Bar No. 126097
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
baylstock@awkolaw.com
dkreis@awkolaw.com
noverholtz@awkolaw.com
cprichard@awkolaw.com
17 East Main Street, Suite 200
Pensacola, FL 32502
Phone: (850) 202-1010
Facsimile: (850) 916-7449