### IN THE UNITED STATES BANKRUPTCY COURT FOR THE SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

In re:	) Chapter 11
AEARO TECHNOLOGIES LLC, et al.,1	) Case No. 22-02890-JJG-11
Debtors.	) (Joint Administration Requested)

### INFORMATIONAL BRIEF OF AEARO TECHNOLOGIES LLC

The Debtors in these chapter 11 cases, along with the last four digits of each Debtor's federal tax identification number, are set forth in the *Debtors' First Day Motion for Entry of an Order (I) Directing Joint Administration of Chapter 11 Cases and (II) Granting Related Relief, filed contemporaneously herewith.* The location of the Debtors' service address for the purposes of these chapter 11 cases is: 7911 Zionsville

Road, Indianapolis, Indiana 46268.

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#### I. INTRODUCTION

Debtor Aearo Technologies LLC initiates this voluntary chapter 11 proceeding to equitably and expeditiously resolve all tort claims related to the Combat Arms Earplug, Version 2. Aearo and its corporate parent, 3M Company, have the utmost respect for this nation's military and those who serve our country. Following in the footsteps of prior successful mass tort chapter 11 proceedings, Aearo looks forward to developing a framework to assess, resolve, and provide fair compensation for claims brought by U.S. military servicemembers and veterans. Critically, Aearo's commitment to fair compensation is supported by an uncapped funding agreement from 3M. Restructuring thus offers precisely the efficient and just solution that has eluded the complex and erratic tort claims system that is prologue to this filing.

Aearo turns to chapter 11 in the wake of the failure of the largest MDL in U.S. history to successfully advance the resolution of tort claims related to the Combat Arms earplug. The Combat Arms MDL has become a refuge for more than 230,000<sup>2</sup> unvetted hearing injury claims to languish without scrutiny, as a handful of bellwether trials delivered headline-grabbing verdicts based on a false narrative that frustrated, instead of furthered, settlement and compromise. The Combat Arms MDL now accounts for more than 30 percent of the total number of all cases pending in federal courts.<sup>3</sup> Without mechanisms to assess, stratify, and cull claims with scientific rigor, the MDL structure could neither solve this massive docket in any practical timeframe, nor quell the onslaught of unvetted lawsuits—which shows no signs of abating. In contrast, because

All numbers in this brief relating to filings and claims are Aearo's estimates based on available information and may be subject to modest adjustments depending on dates and data sources.

June 15, 2022 MDL Statistics Report - Distribution of Pending MDL Dockets by Actions Pending, J.P.M.L, avail. https://jpml.uscourts.gov/sites/jpml/files/Pending MDL Dockets By Actions Pending-Jun-15-2022.pdf; at uscourts.gov, https://www.uscourts.gov/sites/default/files/ Nat'l Judicial Caseload Profile, fcms na distprofile0331.2022.pdf; Nat'l Judicial Caseload Profile, uscourts.gov, https://www.uscourts.gov/sites/ default/files/fcms\_na\_distprofile0331.2022.pdf.

bankruptcy tools are designed to do exactly that, the chapter 11 alternative will provide an equitable, timely, and certain ending to this behemoth litigation.

#### A. Overview

More than 20 years ago, Aearo, in partnership and collaboration with the U.S. military and world-renowned researchers, developed the Combat Arms earplug. This revolutionary "non-linear" earplug offered servicemembers hearing protection while preserving lifesaving "situational awareness." For more than a decade, the Combat Arms received accolades from military researchers, scientists in independent labs, and soldiers in the field. In recent years, however, enterprising plaintiffs' lawyers built a cottage industry to identify and recruit U.S. military servicemembers and veterans to sue Aearo and 3M (which acquired Aearo in 2008) for any and all manner of hearing-related conditions, which their lawyers claimed—in a feat of suspended scientific and historical disbelief—lay singularly at the feet of the Combat Arms.

As the number of lawsuits skyrocketed, the federal multidistrict litigation was formed. *In re Combat Arms Earplug Products Liability Litig.*, MDL No. 2885 (N.D. Fla.). Fueled by aggressive advertising and direct outreach by plaintiffs' lawyers, the claims have ballooned from several hundred to more than 280,000 at their peak, and Aearo and 3M still face over 230,000 hearing-injury claims brought primarily by U.S. military servicemembers and veterans. Almost all of the pending cases (more than 99 percent) are centralized for pretrial proceedings in the Combat Arms MDL, which is now the largest MDL in United States history—surpassing all prior MDLs, and eclipsing its contemporary MDLs by orders of magnitude. Reports of not-yet-filed claims in plaintiffs' lawyers' inventory, coupled with statute of limitations tolling for certain military members, suggest that this number could grow to well in excess of the current docket counts.

This colossal docket would stretch the limits of any MDL case management efforts. But the problems here were compounded, as standard MDL early vetting tools (like early medical records production and modest filing requirements) were curtailed or abandoned. This incentivized the filing of unvetted claims, and, together with an accelerated bellwether trial process based on an incomplete record and fictional narratives (all without appellate review), ultimately delivered a few blockbuster verdicts untethered to any comparable compensatory benchmarks. Saddled with untested claims and tainted trial records, any reasonable and timely settlement within the MDL is virtually impossible. According to one plaintiffs' attorney, the claims pose an astonishing exposure risk of "over \$1 trillion." But this speculation is driven by the sheer number of cases—the vast majority of which have never been vetted and are (based on available data) likely non-compensable—and by outsized verdicts and flawed bellwether trial process. Continuing to squander resources in this litigation vortex is neither efficient nor equitable to the claimants themselves.

Where the MDL and tort system broke down, this Court can oversee an efficient global solution. Rather than warehouse hundreds of thousands of claims, each waiting for an uncertain chance to win a lottery verdict at trial, a scientific- and data-driven estimation proceeding grounded in the facts will set the stage to stratify and assess the viability and true value of the claims. And 3M's agreement to provide Aearo uncapped funding for Combat Arms personal injury liability will ensure full compensation is available, unconstrained by Aearo's ability to pay.

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Law Disrupted Podcast, *How a Document Found by a QE Second Year Associate Led to the Largest Mass Tort Litigation in History* (May 11, 2022), available at https://www.law-disrupted.fm/how-a-document-found-by-a-quinn-emanuel-second-year-associate-led-to-the-largest-mass-tort-litigation-in-history/.

### B. Roadmap

Aearo submits this informational brief to describe the historical context of the Combat Arms, to chronicle the confluence of events that doomed any reasonable or equitable resolution in the tort system, and to explain how chapter 11 provides the best solution to resolve claims in an MDL that has spiraled out of control. The following provides a roadmap of the issues.

The Combat Arms earplug revolutionized military hearing protection. Substantial noise exposure and concomitant hearing loss historically have been, and are to this day, ubiquitous facets of military life. The federal government and scientific researchers have long grappled with how to balance protecting servicemembers' hearing against the risks of compromising their ability to hear commands and enemy combatants. Too often, soldiers faced a choice: save their hearing or save their lives. As reflected in the soldiers' adage "better deaf than dead," servicemembers often chose to forego using any hearing protection at all rather than risk vulnerability on the battlefield.

Aearo—working with the military and expert scientists at the French-German Institute de St. Louis (ISL)—developed an innovative earplug that provided an elegant solution to this problem. With the Combat Arms' "non-linear" technology, soldiers for the first time did not have to make a binary choice between protection and awareness; they instead were able to allow certain noises to "pass through," while filtering others. The Aearo-manufactured first generation dual-ended earplug could either provide constant noise reduction (green end) or pass-through filtered protection (yellow end), which reduced loud "impulse" noises like gun fire while allowing soldiers to hear low-level sounds like those that signaled approaching danger. Experts for plaintiffs heralded this new technology as "ingenious," "fantastic," and "novel."

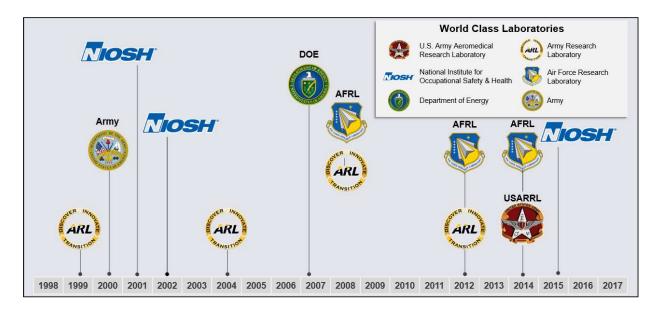


The Combat Arms ushered in a new era of noise protection, setting the stage for other non-linear earplugs. Even so, hearing professionals within and outside of the military recognize that no earplug will fit every single ear; and no single earplug—no matter how advanced—can protect against all levels of noise or auditory traumas no matter how extreme or severe. The goal, as with virtually all safety products, was to *reduce* the risk. The Combat Arms unquestionably did so.

The earplug worked in the lab and in the field. Over the course of more than a decade, world-class military researchers, including the Air Force Research Lab and the Army Research Lab, as well as numerous federal and foreign government organizations and academic institutions, tested the Combat Arms. As sampled below, those independent tests confirmed that the Combat Arms was effective, provided "very good attenuation," and offered noise reduction comparable to later-generation non-linear earplug models.<sup>5</sup>

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Air Force Research Laboratory Report, Wideband Hearing, Intelligibility, and Sound Protection (WHISPr) at 20 (Oct. 2008), D-GEN-1112; see also generally Army Research Laboratory Report, A Comparison of the Single-Sided (Gen II) and Double-Sided (Gen 1) Combat Arms Earplugs (CAE): Acoustic Properties, Human Performance, and User Acceptance (Dec. 2012), D-GEN-0525.



The Army celebrated "finally having a hearing protector that protects without impairing military effectiveness." Military audiologists and soldiers across the globe echoed those sentiments, applauding the effective protection and communication improvement. As one Army audiologist put it, the Combat Arms earplug let soldiers "hear the bad guy."

Plaintiffs' lawyers capitalized on early internal testing documents. After years of successful use and independent testing, plaintiffs' lawyers seized upon an Aearo internal memo produced in an unrelated lawsuit—and testimony from witnesses unfamiliar with the document—to assail the entire history and performance of the Combat Arms. According to plaintiffs' lawyers, that memo showed that the Combat Arms did not reduce or attenuate noise as much as the labelled noise reduction rating ("NRR") of 22 suggested. This "Flange Memo" became the centerpiece of plaintiffs' lawsuits against both Aearo and 3M.

Through a well-orchestrated and well-funded lawyer ad campaign that cut across traditional and social media channels as well as more targeted outlets, plaintiffs' lawyers bombarded servicemembers and veterans with messages that the Combat Arms was to blame for any hearing-related conditions in soldiers who served between 2003 and 2015. Plaintiffs' lawyers'

broad sweep corralled many claimants for whom a basic, pre-filing record review would show normal hearing under even generous authoritative clinical hearing loss standards.

The Combat Arms became the largest MDL in history. The lawyer-advertising onslaught was wildly successful. In April 2019, the Judicial Panel on Multidistrict Litigation formed MDL No. 2885 to "promote the just and efficient conduct of the litigation." By then, the number of potential tag along or related actions in federal courts had grown to nearly 700 cases. Today, the Combat Arms MDL sits as the largest MDL in history, with more than *twice as many claims as the other 191 pending MDLs combined*.

The Judicial Panel on Multidistrict Litigation centralized claims before one judge charged with overseeing consolidated pretrial proceedings, weeding out invalid claims, and ultimately positioning the case for settlement. But commentators have long questioned the capacity of the MDL mechanism to accomplish these tasks in the face of a massive docket of claims, which invites shortcuts and departures from applicable rules and standard practice. Indeed, in the Combat Arms MDL, some of the most basic tools of MDL practice, including medical records releases and production, along with filing requirements, were eliminated or suspended early on, reducing any chance of success an MDL might otherwise offer. Although the MDL judge recognized the need to "test[] the merit of the inventory of cases" and "filter[] out unsupportable claims," plaintiffs' lawyers' purported burdens in accessing military records to support their claims—in the MDL court's own words—"torpedo[ed] the parties' efforts to accomplish an 'early' census of supportable claims."

In re: 3M Combat Arms Earplug Prods. Liab. Litig., 366 F. Supp. 3d 1368, 1369 (J.P.M.L. 2019).

<sup>&</sup>lt;sup>7</sup> See MDL Statistics Report – Distribution of Pending MDL Dockets by Actions Pending (May 16, 2022), U.S. Judicial Panel on Multidistrict Litigation, https://bit.ly/3aoCkDu ("MDL Statistics Report").

<sup>&</sup>lt;sup>8</sup> M. Casey Rodgers, Vetting the Wether: One Shepherd's View, 89 UMKC L.R. 873, at 874 (2021).

<sup>&</sup>lt;sup>9</sup> *Id.* at 876.

As a result, for nearly two years, more than 99 percent of plaintiffs in the MDL had no obligation to produce documents or information substantiating their claims. Predictably (and as the MDL court recognized), "[l]eft unchecked, high volumes of unsupportable claims" "wreak[ed] havoc" on this MDL by, among other things, "clog[ging] the docket" and "frustrat[ing] efforts to assess the strengths and weaknesses of the MDL as a whole." The Combat Arms MDL is now flooded with a massive volume of claims that plaintiffs' leadership conceded are "yet-to-be vetted" and are "being investigated still" by plaintiffs' lawyers. The lawyers' refusal to self-discipline before filing on the front end and the MDL's inability to weed out non-meritorious claims after filing mean there is no end in sight.

The overwhelming majority of claimants have normal hearing. The limited claimantspecific information that is available has exposed serious and systemic problems with most claims.

Based on several hundred claims selected for "wave" discovery, more than 85 percent of plaintiffs had *normal hearing* after they stopped using the Combat Arms—a fact that a proper pre-suit investigation should have revealed and that only underscores the efficacy of the Combat Arms.

And even those with some hearing impairment have other case-ending or significantly valuereducing infirmities, including (i) injury onset *before* Combat Arms use, making causation temporally impossible; (ii) non-noise-related hearing loss; (iii) clear alternative causes; and (iv) contemporaneous records reflecting use of only *non*-Combat Arms hearing protection. The questionable merits of many claims also was exposed, as about 50,000 cases were dismissed either voluntarily or otherwise had their claims dismissed for violations of basic discovery requirements

<sup>&</sup>lt;sup>10</sup> *Id.* at 873.

<sup>&</sup>lt;sup>11</sup> 6/17/2019 CMC Hr'g Tr. at 18-19, MDL Dkt. 469; 3/24/2020 Hr'g Tr. at 66:16-67:7, MDL Dkt. 1027.

or as duplicate claims—all before any merits-based inquiry. But hundreds of thousands of claims still fester unexamined.

The accelerated bellwether trial process further hindered settlement prospects. The MDL bellwether trial process similarly failed to advance any meaningful resolution. Of the 27 cases set for bellwether trials, eight plaintiffs' claims were dismissed before trial, and six trials resulted in complete defense verdicts. Those bellwether trials that resulted in plaintiffs' verdicts provided minimal information about value or resolution.

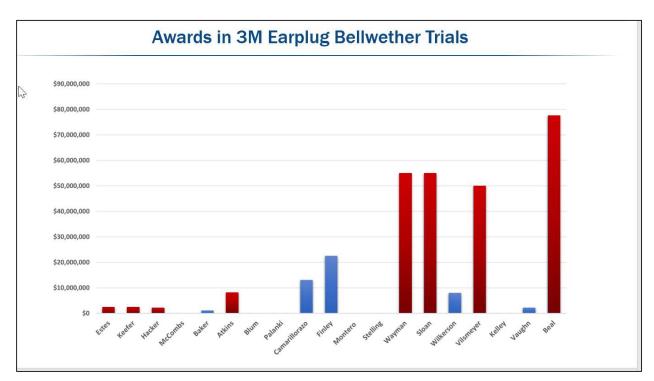
Before the trials began, the MDL court denied Aearo's and 3M's summary judgment motion that the government contractor defense barred plaintiffs' claims, *and* granted plaintiffs' motion for summary judgment against that same defense. As a result, large swaths of evidence regarding the military's role in the design and development of the Combat Arms earplug were excluded from trial. The trial program continued apace (and even expanded) while the key—and dispositive—government contractor defense remained unresolved on appeal. Indeed, the trial pace was unprecedented: 16 trials (involving 19 plaintiffs) in just one year, with some double-tracked as other judges were called in to preside over several trials. The judges to whom the MDL court farmed out some trials questioned the push to try cases while appeals that "could potentially require the parties to relitigate" those same cases were pending. Similarly, the postponement of the depositions of critical ISL scientists involved in the development of the Combat Arms until after the trials defeated the purpose of bellwethers, which is to have trials that are representative and informative.

The compressed trials quickly devolved into a fictional performance—infected with plaintiffs' lawyers' misleading, and at times outright false, representations. Plaintiffs' lawyers'

<sup>12 11/8/2021</sup> Camarillorazo Trial Tr. at 1558:16-20 (statement of Judge Mark E. Walker).

inflammatory trial rhetoric and deliberate barrage of lawyer ads touting verdict amounts had a snowball effect, resulting in verdicts that dwarfed by multiple orders of magnitude any comparable awards across the country for similar claims. Juries rewarded even plaintiffs with mild hearing loss or treatable conditions with tens of millions of dollars in damages. The problem was particularly acute in those cases tried in Pensacola, Florida, where the MDL was venued and where the Estes, Keefer, Hacker, Adkins, Sloan, Wayman, Vilsmeyer, and Beal bellwethers were tried.

The verdicts were already outsized and untethered to reality to begin with. But in the course of one year, the compensatory damages awarded by Pensacola juries for nearly identical injuries increased from \$350,000 in April 2021 to \$50,000,000 in January 2022—nearly *150 times greater*, and the total damages (both compensatory and punitive) awarded to an individual plaintiff increased from \$2,450,000 to \$77,500,000 during that same time period.<sup>13</sup>



The chart below is a modified version of a chart appearing on a plaintiff law firm's blog. See Lawsuit Information

Center Blog, May 2022 Update: Good golly! Beal was awarded \$77.5 million!, https://www.lawsuit-information-center.com/13-million-3m-earplug-verdict.html.

This exponential increase comes on the heels of lawyer-ad saturation coupled with increasingly skewed trial narratives.

Less than two months ago, the MDL court emphasized the inflection point of this litigation. Over the past three years, Aearo and 3M have participated in the MDL, defended bellwether trials, and engaged with plaintiffs' lawyers in multiple rounds of mediation and other settlement discussions, all to no avail. With bellwether trials now complete, the MDL court is on the precipice of remanding thousands of cases back to their transferor courts for trial, and just a few days ago set a non-bellwether case for trial in Pensacola, all while Aearo's appeals remain pending. <sup>14</sup> The brunt of the coming storm will fall not only upon Aearo and 3M, but also on the courts and plaintiffs. Recognizing the "enormous amount of time and resources [that] will be required to accomplish this endeavor, not just from [the MDL court] but from the entire federal judiciary,"15 the MDL court underscored a startling reality: each of the 94 federal districts will face an average of approximately 2,500 cases remanded for trial, and while "some districts will receive many fewer cases and other districts many more," it is "likely no district will be spared the burden." "[T]he amount of judicial resources required to handle this number of cases is staggering." <sup>16</sup> Meanwhile, plaintiffs still will be forced to take their place in line for a trial that may not happen for years, even decades.

In short, the tort system is no longer a viable forum to resolve this litigation, which is instead now a cautionary tale of an MDL that is broken beyond repair. Lawyers, scholars, and judges have long raised questions about the utility of large MDLs to resolve mass tort claims, as aggregations of untested claims have become a magnet for frivolous lawsuits that otherwise may

<sup>&</sup>lt;sup>14</sup> George v. 3M et al., No. 7:20-cv-71963, Dkt. No. 22.

<sup>&</sup>lt;sup>15</sup> MDL Dkt. 3188 at 2.

<sup>&</sup>lt;sup>16</sup> *Id*.

never have been filed and inevitably result in the compensation of claims with little or no merit. The Combat Arms MDL exemplifies these problems, but the extraordinarily high volume of claims and breakdown of traditional case management procedures created a perfect storm that no reasonable settlement could solve.

Restructuring through the chapter 11 process is the only path forward. Against this backdrop and after careful consideration, Aearo has shifted its approach after concluding that chapter 11 presents the only option for achieving a fair, equitable, and expeditious process to resolve these claims. Bankruptcy provides unique jurisdictional and procedural vehicles for consolidating claims, negotiating and voting on global resolution, and ensuring that the scientific and legal merits of claims remain the principal metric for their value. In contrast to the MDL, which (at best) could resolve only a limited number of valid claims, the chapter 11 solution provides a process to establish full and fair compensation for all such claims.

The proposed restructuring path rests on decades of fundamental principles derived from countless other mass tort cases. This Court can ensure the litigation of the core issues through a combination of the automatic stay—which provides a reprieve from the litigation that precipitated this filing—and the Bankruptcy Code's comprehensive process for administering and equitably resolving claims using well-tested tools, including claim objection, litigation, and resolution procedures that focus on the key scientific and factual issues gauged by federal evidentiary rules.

Make no mistake, the chapter 11 cases are not about walking away from responsibilities, and it will not be used to deprive claimants of a fair recovery or deny them their day in court. In this respect, 3M's uncapped financial commitment to Aearo's reorganization—conditioned on Aearo indemnifying 3M against any losses related to Combat Arms claims—is essential. 3M is a co-defendant in nearly every Combat Arms personal injury case, and its liability traces back to

Aearo's alleged conduct. Aearo therefore seeks to confirm the automatic stay applies to 3M and obtain a temporary restraining order and preliminary injunction in favor of 3M. Leaving 3M exposed in the MDL—which stands on the precipice of remanding thousands of cases to dispersed federal courts throughout the country (not to mention pending state court claims)—would directly and immediately undermine this proceeding, relegating this Court to a peripheral function with little control over the central issues in these chapter 11 cases and risking depletion of estate assets.

### II. THE COMBAT ARMS EARPLUG OFFERED A REVOLUTIONARY SOLUTION TO AN AGE-OLD MILITARY PROBLEM.

# A. Balancing Hearing Protection Against "Situational Awareness" Was A Longstanding Military Challenge.

Exposure to massive amounts of loud noises, and concomitant hearing loss or tinnitus (ringing in the ears), was and still is a prevalent part of military service. Historically, however, servicemembers hesitated to wear hearing protection in combat, believing doing so would impede "situational awareness"—the ability to hear critical sounds such as commands or signs of danger—at the risk of their safety or even their lives. The "legacy solution" was for soldiers to "sacrifice their hearing by not wearing hearing protection in an attempt to better monitor the soundscape and communication systems." Army regulations advised that soldiers "should NOT wear hearing protections when they impair necessary hearing," as in "dismounted infantry operations"—*i.e.*, combat. The military viewed "[t]he goal of effectively protecting the hearing of personnel employing small arms in tactical environments ... as a very difficult, *if not impossible*, task."

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<sup>17</sup> K. Conroy & V. Malik, *Hearing Loss in the Trenches: A Hidden Morbidity of World War I*, 132 J LARYNGOL OTOL. 952,955 (Nov. 2018).

Air Force Research Laboratory Report, *Wideband Hearing, Intelligibility, and Sound Protection (WHISPr)*, at 11 (Oct. 2008), D-GEN-1112 ("WHISPr Report").

<sup>&</sup>lt;sup>19</sup> Hearing Conservation Program, *Department of the Army Pamphlet 40-501* (1998) at 6-2(d)2), D-GEN-2170.

WHISPr Report, *supra*, at 11, D-GEN-1112 (emphasis added).

# B. Aearo, In Collaboration And Partnership With The Military And The Institute de Saint-Louis, Developed A Revolutionary Solution.

In an effort to solve this problem, in the early 1990s, ISL—a military research institute established by French and German governments—invented a non-linear, level-dependent "filter," in which low-level sounds can pass through the filter, but sharp "impulse" noises, like gunfire, are diminished. In early 1997, ISL requested assistance from Aearo Company in Indianapolis to develop a non-linear earplug based on ISL's filter and Aearo's existing UltraFit earplug, a premolded, triple-flanged earplug. Around the same time, an Army Research Laboratory representative concluded that the non-linear filter was a good option to protect against "impulse" noises such as gunfire, "especially when one considers that the alternative presently being used is not to wear hearing protection." But he also noted that it provided "essentially no attenuation against high level steady-state noise." For that, the military needed standard linear ear protection. Pascal Hamery, another ISL scientist, devised a two-ended device, with one end using the nonlinear filter and the other end functioning as a traditional earplug.

In December 1997, Dr. Doug Ohlin, the manager of the Army's Hearing Conservation Program and chair of the Defense Department's Hearing Conservation Working Group, indicated that he preferred the two-ended earplug design, which would be easier to dispense in the field than two separate earplugs.<sup>26</sup> Heeding Dr. Ohlin's direction, Aearo and ISL developed and manufactured a two-ended earplug based on the UltraFit. Dr. Ohlin found that initial samples

Aearo Design Drawing No. 4047-A at 4, P-GEN-2976.

<sup>&</sup>lt;sup>22</sup> Armand Dancer & Pascal Hamery, *Nonlinear Hearing Protection Devices* (1998) at 9, D-GEN-2432.

Ltr. from Armand Dancer to Doug Ohlin at 1-2 (Jan. 13, 1997), D-GEN-1020.

Dept. of Defense Hearing Conservation Working Group Mtg. Agenda at 10 (Apr. 9, 1998), D-GEN-1405.

<sup>&</sup>lt;sup>25</sup> Id

<sup>&</sup>lt;sup>26</sup> Notes from Meeting at Aberdeen Proving Ground, Md. at 2 (Dec. 16, 1997), S-GEN-108.

"were at least a quarter of an inch too long," in part because they would not fit in a standard-issue earplug carrier, so he "[took] the liberty in cutting down the samples" himself.<sup>27</sup> Aearo sent Dr. Ohlin samples of a shortened version of the dual-ended earplug in late April 1999.

Dr. Ohlin found the shortened earplugs acceptable, and made a Combat Arms earplug purchase request to the Department of Defense's Joint Readiness Clinical Advisory Board, explaining that the Hearing Conservation Working Group "recommended that a non-linear earplug configured to the specifications of the enclosed production samples be adopted for military use." Dr. Ohlin concluded that, "[i]n the Combat Arms Earplug, we finally have a hearing protector that protects without impairing military effectiveness." 29

Dr. Ohlin asked Aearo to ship the earplugs in bulk—50 pairs in a bag inside a cardboard box—and directed 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."<sup>30</sup> The military later created its own written instructions for the Combat Arms and a "wallet-sized instruction card," which was made available in "large quantities" "to audiologists and hearing technicians throughout the Army."<sup>31</sup>

Email from Doug Ohlin to multiple recipients (Apr. 13, 1999), D-GEN-2377 at 2.

<sup>&</sup>lt;sup>28</sup> Memo. for Staff Director, Joint Readiness Clinical Advisory Board, S-GEN-0002 at 1.

<sup>&</sup>lt;sup>29</sup> *Id.* at 4.

<sup>12/3/2019</sup> Marc Santoro Dep. at 326:15-327:10 (emphasis added). As one military audiologist explained, it would have been "unusual" for the military to rely on a manufacturer's instructions "to educate a soldier on proper use." D-GEN-1136 ¶ 17. Another military audiologist stated that she did not "rely on Aearo or 3M to provide any written instructions to soldiers on the Combat Arms," and that "[w]hen [military audiologists] were responsible for training technicians and hearing conservation officers on how to fit the Combat Arms Version 2, [they] weren't relying on any Aearo or 3M instructions." 6/15/21 Baker Trial Tr. at 317:14-21 (testimony of Lt. Col. Leanne Battler); id. at 336:11-15 (same).

D-GEN-1136 ¶ 15; S-GEN-0071. Aearo also eventually sold relatively small numbers of individually packaged pairs of the Combat Arms, which included individual instructions, in retail stores on Army bases. 12/3/2019 Marc Santoro Dep. at 183:4–184:8. But even in that circumstance, Dr. Ohlin reviewed and approved the retail instructions, suggesting additional language that Aearo adopted. S-GEN-0001.

### C. Extensive Testing By The Military And Other Independent Laboratories Confirmed That The Combat Arms Worked In The Lab.

1. The Military Extensively Tested The Combat Arms And Confirmed That It Worked As Expected.

A "noise reduction rating," or "NRR," is a single number that gives an indication of the overall noise attenuation (protection) offered by an earplug.<sup>32</sup> Generally speaking, the higher the NRR, which is calculated based on real ear attenuation threshold ("REAT") testing, the greater the attenuation the device provides. Through its own testing, Aearo found the NRR for the Combat Arms was 22. But for non-linear hearing protection, it is also necessary to perform impulse testing, which assesses the performance of a non-linear device when exposed to loud impulse noises, and localization testing, which assesses how well the user is able to maintain situational awareness.

The military does not rely on a manufacturer's testing or NRRs, but instead does its own testing using state-of-the-art methods, and it considers its own testing to be the strongest evidence of a hearing protection device's efficacy.<sup>33</sup> Indeed, the Navy's guidelines require it to *disregard* a manufacturer's testing when assessing any hearing protection product.<sup>34</sup>

World-class military laboratories tested the Combat Arms, some several times, using multiple testing methods, including through REAT tests, impulse tests, and localization tests. Each of these tests confirmed that the product performed as intended. Significantly, both the Army

See 40 C.F.R. § 211.207. The EPA requires manufacturers of hearing protection devices—*except* those designed for use in combat—to label their products with an NRR. See id. § 211.206-1.

D-GEN-3094 at 49-50 (Feb. 26, 2016 Air Force Instruction 48-127 citing "AFRL ANSI measured values utilizing ANSI S12.6 [the current standard]" as the "most preferred" method for selecting attenuation values for hearing protection devices); D-Gen-788 (Mar. 2006 USACHPPM technical guide on Personal Hearing Protection Devices, stating all "approved" hearing production devices "have been tested for attenuation characteristics in accordance with (IAW) the ANSI, S12.6-1997 [the current standard], as well as for durability and toxic effects").

Navy Medical Dept. Hearing Conservation Program Procedures (Sept. 15, 2008), D-GEN-3095 at 18-19 ("Remember, when investigating any hearing protection product assure they have been evaluated by an approved laboratory. An approved lab is defined as one that meets general industry accreditation standards and is not affiliated with a manufacturer or product." (emphasis added)).

Research Laboratory ("ARL") and the Air Force Research Laboratory ("AFRL") conducted extensive testing on the Combat Arms.

Army Research Laboratory Testing. The ARL concluded that the Combat Arms' REAT test results "compared very well with design specifications," and that "[p]redicted values of impulse noise attenuation were good, to within 15% of the experimental values." The ARL also found that the Combat Arms "functioned as intended to protect against impulsive noise." <sup>36</sup>

Air Force Research Laboratory Testing. The AFRL similarly found that the Combat Arms "provide[d] very good attenuation" and "seems to work as advertised." The AFRL even tested the Combat Arms against other non-linear earplugs, the SureFire Sonic Defenders and the Moldex Battleplug. The Combat Arms beat the competition. At the highest sound level tested, both ends of the Combat Arms had better attenuation than the Battleplug and SureFire Sonic Defenders. Defenders.

Army Research Laboratory Report, *Modeling of Acoustic Pressure Waves in Level-Dependent Earplugs* (Sept. 2008), D-GEN-246 at 4.

Army Research Laboratory Report, U.S. Marine Corps Level-Dependent Hearing Protector Assessment: Objective Measures of Hearing Protection Devices (Jan. 2014), D-GEN-3567 at 20.

WHISPr Report, *supra*, D-GEN-1112 at 30, 81. One of the lead Air Force researchers and authors on the 2008 report was Richard McKinley, who is now a paid expert for plaintiffs suing Aearo and 3M. His paid expert opinions are markedly different from those he offered as a government employee whose task was to fairly evaluate the Combat Arms.

Air Force Research Laboratory Report, Continuous and Impulsive Noise Attenuation Performance of Passive Level Dependent Earplugs (Oct. 22-26, 2012), D-GEN-3729.

<sup>&</sup>lt;sup>39</sup> *Id.* at 15.

#### 2. Other Well-Respected Laboratories Tested The Combat Arms.

The U.S. Department of Energy, 40 NIOSH, 41 ISL, 42 and the Canadian government 43—among others—also tested the earplug and confirmed that it was effective and worked as intended. Even a laboratory hired by a *competitor* tested the Combat Arms and found that it worked as designed. Years before any personal injury claims, in March 2012, Moldex, a competitor earplug manufacturer, hired the nationally accredited Michael & Associates Lab to test the Combat Arms earplug to develop evidence to use against Aearo in a patent dispute. Despite having every incentive to find that the earplug was ineffective, the Michael Lab found the opposite: the Combat Arms worked *even better* than advertised. The Michael Lab found that the closed end of the Combat Arms earplug had an NRR of 23—higher than the NRR of 22 that Aearo found in its own testing and put on the label. 44

### D. Real-World Experience Confirmed That The Combat Arms Earplug Worked In The Field.

Real-world experience confirmed what researchers found in the lab. Military field studies found that soldiers almost unanimously reported that the Combat Arms was more comfortable than

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<sup>40</sup> Idaho Nat'l Laboratory (a U.S. Dept. of Energy Nat'l Laboratory), Hearing Protection Evaluation for the Combat Arms Earplug at Idaho National Laboratory (Mar. 2007), D-GEN-347 at 20 ("non-linear attenuation of impulse noise levels, using the Combat Arms earplug, provides adequate protection ... while allowing necessary verbal communications during [combat] exercises").

Email from William Murphy to multiple recipients (Oct. 23, 2001), D-GEN-1750 (confirming that the Combat Arms performed as designed in protecting against impulse noise); Nat'l Institute for Occupational Safety and Health ("NIOSH"), Hearing Loss Prevention Section, *Attenuation Measurements of Passive Linear and Nonlinear Hearing Protectors for Impulse Noise*, D-GEN-1121 (same).

<sup>&</sup>lt;sup>42</sup> See ISL, Evaluation of Hearing Protection Devices and a Flight Helmet when Undergoing Noise Stimulations (Dec. 18, 2012), D-GEN-1116 (tests showing that the Combat Arms protected against impulse noises and offered more protection than the SureFire Sonic Defender, and at least as much protection as the Battleplug).

<sup>&</sup>lt;sup>43</sup> Defence Research and Development Canada, *Sound Attenuation of the Indoor/Outdoor Range E-A-R Plug* (2004), D-GEN-106 at 4 (concluding that "the observed outcomes suggest that the manufacturer's specifications were a good predictor of outcome").

Michael & Assocs., Inc., Hearing Protective Device Test Report Number Q2558A (Mar. 28, 2012), D-GEN-0250; D-GEN-0248 at 4.

their current earplug, allowed them to hear speech better, and attenuated loud noises just as well.

And when compared to much more expensive electronic devices, soldiers ranked the Combat Arms near the top in every single category, including "situational awareness" and "durability."<sup>45</sup>

Feedback from the battlefield was equally positive. In a survey of 950 soldiers returning from Iraq, 86% found the Combat Arms to be "beneficial in combat operations" and 70% felt the Combat Arms "protect[ed] their ears as well as improve[d] communication ability in noise." One soldier in Iraq wrote that the "Combat Arms Earplugs ... work great in this environment .... [T]hey probably made the difference between eardrum/hearing damage and not, they definitely allow you to mentally recover very quickly, so you are able to deal with your 'situation' vs. standing around like a stunned mullet for awhile."

Trained military audiologists were impressed with the Combat Arms based on their own experiences and those of the soldiers with whom they worked. For example, Lieutenant Colonel Leanne Battler, an Army audiologist, testified that she used the Combat Arms "[e]very year for seventeen years" and had "excellent hearing" and no tinnitus.<sup>48</sup> Battler fit "thousands" of soldiers with the Combat Arms, and not one ever complained that the Combat Arms failed to protect their hearing.<sup>49</sup> Battler explained that the Combat Arms was "cutting-edge technology; for the first time, soldiers were ... wanting the hearing protection; they had great things to say about it," and testified that she "[a]bsolutely" "believe[d] that the earplug, the Combat Arms earplug, Version 2,

<sup>&</sup>lt;sup>45</sup> P-GEN-00782; WHISPr Study, *supra*, D-GEN-1112.

<sup>46</sup> U.S. Army Research Laboratory, *Improved Combat Arms Earplug QRI Status* (June 26, 2006), P-GEN-01011 at 4.

<sup>&</sup>lt;sup>47</sup> D-GEN-0125; see also P-GEN-00071 at 23.

<sup>&</sup>lt;sup>48</sup> 9/10/20 Leanne Battler Dep. at 125-126.

<sup>&</sup>lt;sup>49</sup> *Id.* at 172:23-173:3.

helped improve situational awareness, survivability and lethality."<sup>50</sup> Others shared Battler's view,<sup>51</sup> and their experience was not just anecdotal.

#### III. STRUCTURAL PROBLEMS DOOMED THE MDL FROM THE OUTSET.

Decades of testing and overwhelmingly positive results in the lab and in the field showed that the Combat Arms worked. Nonetheless, plaintiffs' lawyers seized on an internal Aearo document to build claims against Aearo and 3M alleging product defects and inadequate warnings. The initial spate of lawsuits later ballooned into a massive and unmanageable MDL. Bolstered by millions of dollars in advertising spend by plaintiffs' lawyers, the MDL became the largest in history, surpassing at its apex more than 280,000 individual plaintiffs, and consisting of more than 230,000 plaintiffs today.

It soon became clear that the MDL was too large to manage. The problem was exacerbated by the suspension of customary procedures to vet mass tort claims. Approximately 110,000 active plaintiffs still have their claims languishing on an "administrative" docket. And of the approximately 124,000 plaintiffs on the active docket, only 1,500 or so have been required to produce basic discovery, including medical records. This leaves more than 230,000 claims that remain completely unvetted. Critically, once modest safeguards were imposed, a substantial portion of claimants (thus far, about 50,000) dropped out of the MDL, voluntarily or involuntarily.

### A. Plaintiffs' Lawyers Constructed Litigation Around The "Flange Report."

In the face of overwhelming scientific evidence that the Combat Arms worked, and that the military understood how the earplug performed, plaintiffs' lawyers built their case around an early testing report known as the "Flange Memo," authored by Aearo researcher Ron Kieper. The

<sup>&</sup>lt;sup>50</sup> *Id.* at 82-84.

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For example, military audiologist Lieutenant Colonel John Merkley testified that he wore the Combat Arms while deployed to Iraq and that it worked for him. 2/26/21 John Merkley Dep. at 197:1-198:17.

memo described interrupting the first REAT test before it was completed, after testing the plug on only eight people. Kieper halted the test to investigate unexpectedly variable results—largely due to aberrantly low attenuation on one (out of three) trials in each of two users, and aberrantly *high* attenuation from another user. He hypothesized that for some users, the opposing flanges (*i.e.*, the flanges on the side of the plug not inserted into the ear) may have come in contact with the outer ear anatomy and prevented deep insertion or caused the earplug to loosen after insertion. <sup>52</sup> Kieper concluded that some users could therefore achieve a better fit by folding back the flanges of the opposing end of the earplug. Kieper then completed a full REAT test a few weeks later, in which records indicate one user out of ten did in fact fold back the opposing flanges. The results of that full REAT test led to a calculated NRR of 22.

At trial, plaintiffs treated the Flange Memo as a "smoking gun" document, incorrectly arguing that it showed that the Combat Arms was too short, that the NRR of 22 was fraudulent, and that the military was unaware of problems with the earplug.

First, the claim that the plug—having been shortened at the military's request—was too short is belied by the mountain of testing conducted by the military itself and other independent laboratories. By the time Kieper stopped the test, the Combat Arms had been tested on only eight people. Since then, dozens of tests have shown that the Combat Arms works. Not one of them indicated that the earplug was too short.

Second, the NRR of 22 was accurate. There could be no better proof that the NRR of 22 was legitimate than the testing performed by the Michael lab, an expert hired by Aearo's

Aearo Co., How Folding the Flanges Back Affects REAT Results of the UltraFit Earplug End of the Combat Arms Plug (July 10, 2000), D-GEN-0115 ("Flange Memo").

competitor and adversary in litigation, which determined that the NRR of the Combat Arms was 23, even higher than Aearo's results.

Third, the military was well aware of the option for some users to fold back the earplug's opposing flanges to get a better fit. Aearo's retail packaging for the Combat Arms—which was provided to the military—included the following fitting suggestion: "[f]itting is ... improved if the sealing rings of the outward directed plug are rolled back upon themselves." <sup>53</sup>



Aearo also discussed the flange fold option directly with Dr. Ohlin, who passed that information on to military audiologists. The current manager of the Army Hearing Program testified that, as early as 2001, Dr. Ohlin told a gathering that included "most of the Army['s] audiologists" that, "if you needed to, you could fold back the flange on the earplug to get a good fit."<sup>54</sup> A fact sheet that was distributed throughout the Army provided additional instructions on proper insertion and fit, including the ability to fold back the flanges if necessary to "enhance proper insertion."<sup>55</sup> The military's own written instructions for the Combat Arms included a

S-GEN-0083; see also Email chain involving Doug Ohlin and others (Dec. 9-13, 2005), D-GEN-1903.

<sup>&</sup>lt;sup>54</sup> 2/26/2020 John Merkley Dep. at 98:2-3, 106:21-107:1.

U.S. Army Center for Health Promotion and Preventive Medicine ("USACHPPM"), *Just the Facts: The Combat Arms Earplug*, S-GEN-0070 at 3; 4/27/2021 *EHK* Trial Tr. at 305:11-23.

picture of the Combat Arms with the flanges folded back and the following statement: "[f]or very large ear canals, fold opposing plug back."



### B. The Combat Arms MDL (Like Many Other MDLs) Became A Magnet For Unvetted Claims.

MDLs now account for over 62% of the cases pending in the federal court dockets,<sup>56</sup> the overwhelming number of which involve mass torts.<sup>57</sup> The "MDL has ascended as the most important federal procedural device to aggregate (and settle) mass torts."<sup>58</sup> But there are increasing

As of September 30, 2021, 629,588 cases were pending in federal courts. Table C, U.S. District Courts—Civil Cases Commenced, Terminated, and Pending During the 12-Month Periods Ending September 30, 2021, Judicial Business of the United States Courts, Annual Reports of the Director, Administrative Office of the United States Courts, available at https://www.uscourts.gov/sites/default/files/data\_tables/jb\_c\_0930.2021.pdf. As of that same date, 391,953 actions were pending in and subject to MDL proceedings. United States Judicial Panel on Multidistrict Litigation, Statistical Analysis of Multidistrict Litigation Fiscal Year 2021, available at https://www.uscourts.gov/sites/default/files/data\_tables/jb\_s20\_0930.2021.pdf.

See, e.g., Bolch Judicial Institute, Guidelines and Best Practices for Large and Mass-Tort MDLs (Duke Law School, 2d ed. 2018) ("Not only is the overall number of actions in MDLs growing, these actions are becoming more concentrated in a small number of mass-tort MDLs, primarily products liability, and particularly pharmaceutical and health-care cases. Of the MDLs pending in August 2018, 90% of them were consolidated in only 24 MDLs—predominately product liability.").

M. Thomas, Morphing Case Boundaries in Multidistrict Litigation Settlements, 63 EMORY L.J. 1339, 1346-47 (2014). The MDL device is lauded as "a 'once-in-a-lifetime' opportunity for the resolution of mass disputes by bringing similarly situated litigants from around the country, and their lawyers, before one judge in one place at one time." E. Fallon, et al., Bellwether Trials In Multidistrict Litigation, 82 TUL. L. REV. 2323, 2339 (2008); see

concerns over the MDL process in the mass torts space. The combination of advertising-induced filing of masses of unvetted claims and a preordained expectation of settlement often create a high-volume cudgel that inflates settlement value, or—as is the case with the Combat Arms MDL—precludes any reasonable settlement.

The MDL Subcommittee of the Advisory Committee on the Civil Rules recognized that there "seems to be fairly widespread agreement among experienced counsel and judges that in many MDL centralizations—perhaps particularly those involving claims about personal injuries resulting from use of pharmaceutical products or medical devices—a significant number of claimants ultimately (often at the settlement stage) turn out to have unsupportable claims, either because the claimant did not use the product involved, or because the claimant had not suffered the adverse consequence in suit… ."<sup>59</sup> The MDL court recognized these problems in a law review symposium on MDLs, penned while presiding over the Combat Arms MDL:

A reported twenty to fifty percent of those cases involve plaintiffs with unsupportable claims. In the products liability context, unsupportable claims are often a result of a plaintiff having not used the relevant product and/or having not suffered the injuries alleged, or, in some cases, the applicable statute of limitations having run. MDLs have no built-in, uniform mechanism for efficiently filtering out these sorts of claims. The procedural safeguards used effectively in one-off cases (e.g., federal pleading standards, discovery obligations, case-specific motions for summary judgment, and Rule 11 sanctions) are difficult to employ at scale in the MDL context, where the volume of individual cases in a single MDL can number in the hundreds, thousands, and even hundreds of thousands. ... [T]he sheer volume of unsupportable claims in some MDLs can grossly distort the true merit and size of the litigation. 60

also Manual for Complex Litigation § 20.132 (2004) (MDLs "bring before a single judge all of the federal cases, parties, and counsel comprising the litigation" and "therefore afford a unique opportunity for the negotiation of a global settlement"); H. Erichson & B. Zipursky, *Consent Versus Closure*, 96 CORNELL L. REV. 265, 270 (2011) (MDL "creates the perfect conditions for an aggregate settlement").

Fed. Rules Adv. Cmm. Nov. 1, 2018 Agenda Book 140, 142, available at https://www.uscourts.gov/sites/default/files/ 2018-11\_civil\_rules\_agenda\_book\_0.pdf.

Judge M. Casey Rodgers, Vetting the Wether: One Shepherd's View, 89 UMKC L. REV. 873, 873-74 (2021). As another experienced federal MDL judge observed, "the evolution of the MDL process toward providing an alternative dispute resolution forum for global settlements has produced incentives for the filing of cases that

Critically, these unintended MDL consequences may have the perverse effect of "prevent[ing] plaintiffs with trial-worthy claims from timely getting their day in court." The Combat Arms MDL exemplified and increased these concerns by multiple orders of magnitude.

1. Plaintiffs' Lawyers Engaged In An Expansive And Targeted Ad Campaign.

Plaintiffs' lawyers launched an extensive marketing campaign that led to the filings of hundreds of thousands of Combat Arms lawsuits. The content of those ads evolved over time to capture headline-grabbing verdicts, which, together with intense media coverage, further incentivized filings and saturated the airwaves and internet feeds reaching prospective bellwether-trial jury pools.

Records suggest that, between January 2019 and May 2022, plaintiffs' lawyers spent nearly \$25 million on television advertising alone, airing more than 120,000 advertisements during nationally and locally broadcast television programming. Lawyers spent untold millions more to solicit claimants through radio spots, direct emails, and targeted social media outreach to servicemembers and veterans. And law firm websites and podcasts, infomercials, and YouTube and other online videos furthered the reach of the litigation advertising machine.

otherwise would not be filed if they had to stand on their own merit as a stand-alone action." *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, MDL No. 4:08-md-02004 (CDL), 2016 WL 4705807, at \*1 (M.D. Ga. 2016) (Land, C.J.).

<sup>&</sup>lt;sup>61</sup> H. Rep. No. 115-25, at 2 (2017) (italics omitted).









The advertisements promised that servicemembers may be entitled to substantial or significant financial compensation,<sup>62</sup> and many were inaccurate or misleading. In some cases, they falsely suggested that 3M had already agreed to settle or had paid out millions of dollars for personal injury claims. In others, lawyers inaccurately suggested that 3M had admitted the Combat Arms were defective, and at times, they even pictured the wrong version of the earplugs.<sup>63</sup>





Kenneth S. Nugent, P.C., 3M Earplugs Attorney Georgia | 3M Combat Arms Earplugs Lawyer, https://www.youtube.com/watch?v=WOeiN-ip1sM.

<sup>63</sup> Miller & Zois, Attorneys at Law, 3M Earplugs Lawsuits Settlement Value Predictions, youtube.com/watch?v=KkiXsvLONn0.

In addition, CAMG (an ad agency that works only with law firms) produced a 30-minute infomercial that has played in markets and across the U.S. on various cable channels. Show host Tony Noakes and Dr. Wendy Walsh used a talk-show style set to urge potential plaintiffs to call a provided phone number to sign up for legal representation."<sup>64</sup> The infomercial presents Dr. Walsh as an authority on Combat Arms design and hearing injury. But it does not disclose that Dr. Walsh is not a medical doctor (nor an expert in the military, earplugs, or hearing issues), but instead is "a self-help expert" in "the science of love,"<sup>65</sup> or that Noakes is a paid actor.<sup>66</sup>



<sup>&</sup>lt;sup>64</sup> 3M Earplugs Infomercial, *available at* https://vimeo.com/431941540.

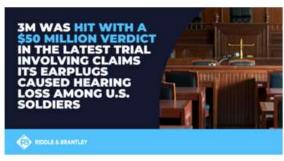
<sup>65</sup> See drwendywalsh.com ("[Dr. Walsh is] a self-help expert who helps you help yourself. Through her unique lens of evolutionary psychology and attachment theory and backed by science, Dr. Wendy Walsh shines a light on love, marriage, parenting, and workplace dynamics. With a core believe [sic] that healthy human connection is critical in order for humans to flourish, Dr. Wendy shows us how interpersonal relationships hold the keys to our mental and physical health, thriving in the workplace, and even our ability to reproduce. Dr. Wendy reveals the gameboard of life, giving you the freedom to make the best choices for your personal circumstances.").

<sup>&</sup>quot;Tony Noakes is an actor and cinematographer, known for *The Dentist* (1996), *Breakaway* (1996), and *JAG* (1995)." https://www.imdb.com/name/nm0633450/.

As trials began, the placement and timing of the ads were tailor-made for jury pools. The ads were disproportionately run in or targeted to Pensacola, Florida, where the MDL is venued and where most of the bellwether trials took place.<sup>67</sup> They touted increasingly outsized jury verdicts:<sup>68</sup>









#### 2. The Unvetted Claims Continue To Bloat The MDL Docket.

Case numbers predictably skyrocketed. In November 2019, the number of cases stood at about 2,700. The number of cases ultimately peaked at more than 280,000, making the Combat Arms MDL the largest in history.<sup>69</sup>

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Although it is only the 57th largest media market out of the 210 local television media markets in the United States, the Mobile, Alabama–Pensacola, Florida media market received more Combat Arms advertising spend than all but 12 local markets.

Miller & Zois, Attorneys at Law, \$110 Million Verdict in 3M Earplugs Bellwether Trial, https://www.youtube.com/watch?v=4h7-g58SJBs.

<sup>69 11/22/2019</sup> Hr'g Tr. at 4, MDL Dkt. 840; see also Nov. 19, 2019 MDL Statistics Report - Distribution of Pending MDL Dockets by Actions Pending, U.S. Judicial Panel on Multidistrict Litigation, available at https://www.jpml.uscourts.gov/sites/jpml/files/Pending\_MDLs\_by\_Actions\_Pending-November-19-2019.pdf. Thousands of these claims are duplicates, where a single plaintiff is named in two or more separate complaints, reflecting the lack of any meaningful vetting.

Indeed, data provided by the Judicial Panel on Multidistrict Litigation shows that, as of June 15, 2022, the MDL had more than *twice* as many claims as the other 191 pending MDLs *combined*.<sup>70</sup> The Combat Arms MDL has become so large that for the last two years, in his annual report on the federal judiciary, the Chief Justice has singled out the "unusually large number of filings" associated with the MDL and has reported two separate sets of data detailing the annual number of civil filings in the U.S.—one set that includes this MDL, and one that does not.<sup>71</sup>

### 3. The MDL Court Suspended Basic Vetting Requirements.

As they recruited more and more potential claimants, plaintiffs' lawyers were able to file and maintain an avalanche of unvetted claims at virtually no expense. Plaintiffs' leadership conceded in mid-2019 that many of the claims in the litigation were then "yet-to-be vetted," and—almost a year later—admitted that "the vast majority" of claims that had yet to be transitioned to the active docket "are being investigated still" by counsel. To this day, counsel for the vast majority of plaintiffs have yet to obtain and evaluate basic records regarding the plausibility of the pending claims.

A year and a half after creating the administrative docket, the MDL court began to dismantle it. In August 20, 2021, the MDL court ordered 1,358 of the more than 250,000 thenremaining cases on the administrative docket to transfer to the active MDL docket, only then triggering basic filing requirements.<sup>74</sup> Since then, the MDL court has periodically, typically once

See June 15, 2022 MDL Statistics Report - Distribution of Pending MDL Dockets by Actions Pending, U.S. Judicial Panel on Multidistrict Litigation, available at https:jpml.uscourts.gov/sites/jpml/files/Pending\_MDL\_Dockets\_By\_Actions\_Pending-Jun-15-2022.pdf.

See, e.g., Chief Justice Roberts, 2021 Year-End Report on the Federal Judiciary at 8.

<sup>&</sup>lt;sup>72</sup> 6/17/2019 CMC Hr'g Tr. at 18-19, MDL Dkt. 469.

<sup>&</sup>lt;sup>73</sup> 3/4/2020 Hr'g Tr. at 66:16-67:7, MDL Dkt. 1027.

<sup>&</sup>lt;sup>74</sup> MDL Dkt. 1876 at 1-2, 4.

every month or two, ordered groups of cases to transition to the active docket. To date, the Court has ordered nearly 140,000 cases to transition to the active docket, but there are still approximately 110,000 active cases sitting on the administrative docket with no requirement to file a claim on the active docket.

#### a. Basic Data And Medical Records Requirements Were Suspended.

A standard case management tool in large MDLs is the requirement that each plaintiff provide basic factual information and discovery regarding their claims. Plaintiff fact sheets or responses to initial census questions, for example, "provide information useful for case management" that, among other things, can "help to uncover cases that should not have been centralized in the first instance." Similarly, "requiring the collection of plaintiffs' medical records (in personal injury cases) ... is another straightforward way that a transferee judge can encourage a robust exchange of key information at a relatively early stage." In fact, medical records "can help defendants verify the answers provided in" fact sheets and census responses "and can shed light on the potential causes of the plaintiffs' injuries."

Recognizing the importance of medical records in early vetting of plaintiffs' claims, MDL courts across the country have required basic access to records at the outset of the litigation, before full-fledged discovery. Virtually all of the top ten largest MDLs nationwide require the production of medical records and/or the authorization of medical release forms in early stages of the case.<sup>79</sup>

See MDL Dkt. 1915 (Sept. 3, 2021) (Transition Order #2); MDL Dkt. 2652 (Jan. 31, 2022) (Transition Order #3);
 MDL Dkt. 2825 (May 22, 2022) (Transition Order #4); MDL Dkt. 2989 (Apr. 14, 2022) (Transition Order #5);
 MDL Dkt. 3069 (May 3, 2022) (Transition Order #6); MDL Dkt. 3204 (June 15, 2022) (Transition Order #7).

<sup>&</sup>lt;sup>76</sup> Bolch Judicial Institute, *Guidelines and Best Practices for Large and Mass-Tort MDLs* (Duke Law School, 2d ed. 2018) at 10 ("BEST PRACTICE 1C(v)"); *see also id.* ("Fact sheets are one of the most useful and efficient initial mechanisms for obtaining individual discovery in large mass-tort MDLs.").

<sup>&</sup>lt;sup>77</sup> *Id.* at 11.

<sup>&</sup>lt;sup>78</sup> *Id*.

Nee MDL Statistics Report, https://bit.ly/3aoCkDu (listing MDLs by number of claims). The MDL court has likewise required screening information in a different MDL over which it presided. In In re Abilify Products

- *C-Qur Mesh* MDL: "Each Plaintiff in a case filed or transferred into this MDL" is required to provide, "contemporaneous with the submission of a [Plaintiff Profile Form]," "all medical records in their possession, custody, or control" that relate to the mesh implant, care, and treatment, as well as "authorizations for the release of medical, insurance, employment, Medicare/Medicaid, military, income," and other records. <sup>80</sup>
- Juul Labs, Inc. MDL: Every personal injury plaintiff must complete a plaintiff fact sheet that "include[s] document requests and a variety of written authorizations for the release" of medical and other records.<sup>81</sup>
- Xarelto MDL: Plaintiffs were required to produce documents and an executed medical records authorization within 60 days of "the date ... each Plaintiffs' case is filed" or "transferred to [the MDL] Court."<sup>82</sup>
- Cook Medical IVC MDL: In addition to extensive profile and fact sheets, all plaintiffs are required to produce, within 30 days of joining the MDL, "hard copies or electronic files of all medical records in their possession," including "records that support product identification and the alleged injury," along with authorizations for medical, insurance, and employment and other records. 83
- Roundup MDL: Plaintiffs were required to list extensive information on a fact sheet, including "all healthcare providers where you have received treatment over the last 25 years for any type of cancer" or for "conditions, procedures, or medications" identified elsewhere on the form (including issues like eczema, ulcers, smoking, diabetes, and obesity)—along with executed medical, employment, tax, and other authorizations. 84
- *Proton-Pump Inhibitor* MDL: All plaintiffs are required to complete a 25-page fact sheet and produce medical or other records substantiating "use of the PPI product," as well as all pharmacy and insurance records related to purchase of the product, all medical records related to the product, and "all documents" relating to alleged injuries, "including but not

Liability Litigation, MDL No. 2734, the same MDL court required plaintiffs to provide "more detailed information" and "supporting documentation." Judge M. Casey Rodgers, *Vetting the Wether: One Shepherd's View*, 89 UMKC L. REV. 873, 875 (2021). The result "was a high rate of voluntary dismissals of cases." *Id.* "This experience underscores the importance of an early vetting process in some litigation." *Id.* at 876.

Fourth Am. CMO No. 3G, In re: Atrium Medical Corp. C-QUR Mesh Prods. Liab. Litig., No. 16-md-2753-LM (D.N.H. Aug. 3, 2017), Dkt. 1098-1.

<sup>61</sup> CMO No. 8 at 2, In re Juul Labs Inc. Marketing, Sales Pracs., and Prods. Liab. Litig., No. 19-md-2913 (N.D. Cal. Oct. 2, 2019), Dkt. 406. That order was later expanded to require all personal injury plaintiffs both (i) to produce "all medical records in counsel's possession" and (ii) to request and produce medical records that were not already in their possession regarding any medical treatments for injuries allegedly caused by JUUL use. In re Juul Labs Inc., Dkt. 2928 at 8.

<sup>82</sup> CMO No. 1, In re: Xarel (Rivoroxaban) Prods. Liab. Litig. (E.D. La. May 4, 2015), Dkt. 891 at 4.

<sup>&</sup>lt;sup>83</sup> CMO No. 2, In re: Cook Medical, Inc. IVC Filters Mktg., Sales Practices, & Prods. Liab. Litig., No. 1-14-ml-02570-RLY-TAB (S.D. Ind. Dec. 16, 2016); see also Fourth Am. CMO No. 4, Cook Medical, Inc., Dkt. 13046 at 2.

<sup>&</sup>lt;sup>84</sup> In re: Roundup Prods. Liab. Litig., No. 3:16-md-02741-VC (N.D. Cal. Oct. 4, 2016), Dkt. 1918.

limited to, medical bills, medical records, hospital records, rehabilitation center records, treatment center records, employment records," and to give record authorizations. 85

• *Pinnacle Hip Implant* MDL: Required production of medical records and medical records authorizations for all plaintiffs. 86

Consistent with standard practice, the Combat Arms MDL court initially ordered that "[e]ach Plaintiff must complete and serve on Defendants," under penalty of perjury, "answers to the Initial Census Questions" along with certain personnel and medical records. Plaintiffs' lawyers agreed to produce a number of documents alongside the initial census form, including "[a]ny audiograms or other hearing tests performed on Plaintiff outside of the military," "[r]ecords relating to any disability benefits Plaintiff applied for and/or received as a result of hearing loss, tinnitus or other hearing injury," and military records related to the plaintiff's service and audiological exams. 88

But on November 22, 2019, the MDL court suspended all obligations on the vast majority of plaintiffs to provide information about their claims, citing "the difficulty in obtaining records from the military." For almost two years, most plaintiffs were not required to provide *any* records or essential information about their claims. Initial census form obligations remained suspended until July 2021. Even when the court reinstated *some* initial census form obligations, it eliminated the requirement that the initial census questions be answered under penalty of perjury. 91

<sup>&</sup>lt;sup>85</sup> CMO No. 9, *In re: Proton-Pump Inhibitor Prods. Liab. Litig.*, No. 2:17-md-02789 (D.N.J. Aug. 4, 2017), Dkt. 119-1 at 29, 30.

<sup>&</sup>lt;sup>86</sup> CMO No. 5, *In re: DePuy Orthopaedics Inc.,Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-md-2244-K (N.D. Tex. May 24, 2011), Dkt. 151.

Pretrial Order No. 18, MDL Dkt. 775 at 2-6.

Pretrial Order No. 18, MDL Dkt. 775-2.

<sup>&</sup>lt;sup>89</sup> 11/22/2019 Hr'g Tr. at 4:18-19, MDL Dkt. 840; Case Management Order No. 6, MDL Dkt. 836.

<sup>90</sup> Pretrial Order No. 81 at 1, MDL Dkt. 1848.

Id. at 2; see also Bolch Judicial Institute, Guidelines and Best Practices for Large and Mass-Tort MDLs (Duke Law School, 2d ed. 2018) at 10 (to serve their intended purpose, fact sheets "should be deemed a form of discovery

As for basic medical records, while the MDL court expected that the initial production deadline would be "redefine[d]" due to government burden, recognizing that the records were "need[ed] to move this litigation forward," the ensuing order instead indefinitely "suspended" the production of medical records "until further order." No "further order" was ever issued, however. As a result, the vast majority (more than 99 percent) of plaintiffs in the MDL remain under no obligation to produce *any* medical records, regardless of how easy they are to access.

There is accordingly an extremely small volume of records and little reliable data available to determine whether most plaintiffs ever suffered any hearing injury, let alone an injury that could be attributable to the Combat Arms. On July 12, 2022, the Defense Health Agency agreed to produce certain audiograms for plaintiffs. But producing audiograms will take time, while representing only a fraction of the hearing and medical records necessary to assess the merits of each claim.

# b. <u>Until Very Recently, Most Cases Were Exempt From Basic Filing Requirements.</u>

Standard practice in all federal cases, including MDLs, requires plaintiffs to comply with basic requirements for filing a claim, including, for example, modest filing fees. These requirements act as a "gatekeeping" mechanism to ensure non-meritorious claims do not burden

governed by the relevant Federal Rules of Civil Procedure, requiring the same level of completeness and verification").

<sup>&</sup>lt;sup>92</sup> 11/22/2019 Hr'g Tr. at 4:25-5:5, MDL Dkt. 840.

<sup>&</sup>lt;sup>93</sup> Case Management Order No. 6, MDL Dkt. 836 at 1.

On June 15, 2022, Aearo moved for an order requiring plaintiffs' counsel to access and produce medical records available online through the MyHealtheVet and TRICARE portals. There has been no ruling on this motion as of the time of this filing.

Federal law is clear that the district court "shall require ... a filing fee of \$350" whenever any party "institute[s] any civil action, suit or proceeding." 28 U.S.C. § 1914 (emphases added). The Local Rules of the MDL court likewise require that "a party who files or removes a civil case must simultaneously either pay any fee required under 28 U.S.C. § 1914 or move for leave to proceed in forma pauperis under 28 U.S.C. § 1915." N.D. Fla. Loc. R. 5.3; see also http://www.flnd.uscourts.gov/fee-schedule (requiring filing fee of \$402 for a civil case).

the judicial system or defendants or, by their large number, make settlement more difficult. A critical purpose of this filing requirement, for instance, is to "act[] as a threshold barrier, albeit a modest one, against the filing of frivolous or otherwise meritless lawsuits." *In re Diet Drugs*, 325 F. Supp. 2d 540, 541 (E.D. Pa. 2004).

But approximately 110,000 Combat Arms MDL claims remain exempted from these requirements. On December 6, 2019, the court created an "administrative docket" and declared that "[a]ll cases placed on the inactive administrative docket will be subject to the jurisdiction of the Court." While the court required plaintiffs on the administrative docket to submit short-form complaints, <sup>97</sup> it suspended other basic requirements for initiating a case in federal court: "No filing fee is required while a case remains on the inactive administrative docket." Thus, all that was required to file a case was a short-form complaint naming the plaintiff and identifying alleged injuries from a list of check-the-box options.

4. Even Modest Vetting Substantially Reduces The Number Of Claims.

History confirms that a significant portion of claimants in the MDL are unable or unwilling to comply with even the minimal requirements that are standard MDL practice. Once obligations to comply with basic filing requirements, serve unverified census forms, and produce proof of military service were imposed, dismissals began rolling in.

First, thus far nearly 140,000 plaintiffs have been required to transition their claims off of the court's administrative docket. More than 18,000 of those plaintiffs have already chosen to dismiss their claims rather than comply, and thousands more missed the deadline to transition and are subject to dismissal. When put to the "test" of filing a claim on the active docket and producing

<sup>96</sup> Pretrial Order No. 20 at 2, MDL Dkt. 864.

<sup>&</sup>lt;sup>97</sup> See id. ¶ 3; Admin. Dkt. 3 ¶ 4.

<sup>&</sup>lt;sup>98</sup> Pretrial Order No. 20 ¶ 4, MDL Dkt. 864; Admin. Dkt. 3 ¶ 5.

basic information and records that can be obtained for free, plaintiffs' lawyers declined to prosecute thousands of cases.

Second, only 1,500 of the claims on the active docket have been ordered to produce discovery, including medical records, depositions, and disclosure of experts. Of those, hundreds have been unable or unwilling to do so, resulting in 249 dismissals early on. Again, when required to substantiate claims with basic information, plaintiffs' lawyers have abandoned a significant number of claims.

### C. Data Indicate That The Overwhelming Majority of Claims Are Unsupported.

In the absence of any vetting requirements, the vast majority of MDL plaintiffs have yet to produce any discovery. The MDL court did, however, order three "waves" of 500 plaintiffs each to begin producing discovery. Notably, more than a quarter of plaintiffs in "Wave 1" voluntarily dismissed their claims or were transferred to another wave. Of the 500 plaintiffs who were ordered to provide discovery in Wave 1, 126 were either unable or unwilling to do so. Wave 1 discovery is now complete and shows that the vast majority of claims are highly implausible, even under plaintiffs' lawyers' flawed theories of liability.

1. Most Plaintiffs Have No Proof That They Ever Used The Combat Arms.

The Combat Arms was just one of the many earplugs the military offered to soldiers, including hand-formed "foamies"; single flange, triple flange, and quad flange earplugs; Etymotic's SureFire Sonic Defenders, Moldex's Battleplugs; and versions 3 and 4 of the Combat Arms (which are not at issue in the MDL).



When the Combat Arms earplugs were on the market, the military spent hundreds of millions of dollars on hearing protection devices. The Combat Arms accounted for just a fraction of the total hearing protection units purchased by the military. The military's Combat Arms purchases in 1999 amounted to a mere \$10,000. In 2000 and 2001, respectively, the military purchased only \$89,360 and \$64,480 worth of Combat Arms. The military purchased Combat Arms in greater numbers in 2003 and 2004, but they were still a small portion of the total hearing protection devices purchased by the military. Even as the military's Combat Arms purchases increased, there were many bases at which Combat Arms earplugs were not available, largely due to supply constraints. For instance, the Hearing Conservation Manager at Fort Benning, Georgia

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Plaintiffs in the bellwethers frequently mischaracterized documents discussing the Combat Arms' market share in the smaller non-linear earplug sub-segment to argue that the Combat Arms had a monopoly on hearing protection devices purchased by the military. Because the Combat Arms was the first non-linear earplug, within this small niche, which represented only a fraction of the total purchases of hearing protection devices purchased by the military, Aearo initially had a large share. But market dominance in this small sub-segment was short lived, and the Combat Arms' share of the military's level-dependent purchases was quickly diminished by the launch of the Combat Arms version 3 in 2007 and version 4 in 2009, as well as the launch of the Sonic Defender in 2009 and the Moldex Battleplug in 2011—all of which are level-dependent earplugs.

from 2004 to 2008 testified that the base "opted not" to issue the Combat Arms to soldiers "and chose to go with a standard earplug instead of the Combat Arms Earplug." <sup>100</sup>

Even when Combat Arms earplugs were available, military records demonstrate that the majority of plaintiffs used hearing protection other than the Combat Arms. As part of its Hearing Conservation Program, the military conducts frequent audiograms, usually once per year, to monitor soldiers' hearing. In connection with those tests, the military documents the hearing protection devices issued to, and used by, each soldier. Specifically, the form used to document a soldier's first military audiogram (known as a "reference audiogram") includes a section titled "Personal Hearing Protection"—"Type Issued." The form used for later annual or pre- or post-deployment audiograms contains a section titled "Type of Personal Hearing Protection Used." Within these sections, both forms list several standard options that can be selected, including "single flange," "triple flange," "hand formed earplug," "ear canal caps," and "noise muffs." The audiogram forms also include the options "other" and "none." When "other" is selected, the forms contain a field in which the type of hearing protection used can be entered manually. Military audiogram records produced by Wave 1 plaintiffs identify a number of "other" devices,

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<sup>12/14/2020</sup> Kevin Hannah Dep. at 34:23-35:2; see also 10/6/2020 Melissa Leccese Dep. at 19:6-18, 20:20-25 (triple flange earplugs, not Combat Arms, were standard issue at Fort Campbell, Kentucky between 2006 and 2010); 2/6/2011 Bettina Rogers Dep. at 30:8-9 (Fort Knox, Kentucky "never had supply of" Combat Arms between 2011 and 2019); 11/24/2020 Andrew Toyama Dep. at 70:22-23 (audiology technician at Schofield Barracks, Hawaii from 2012 to 2014 "never had [the Combat Arms] available to distribute"); 11/13/2020 Jimmy Conforme Dep. at 79:10-14 (Army medic and audiology technician at Fort Stewart, Georgia did not fit soldiers with the Combat Arms between 2005 and 2010).

DD 2215 Reference Audiogram Form, *available at* https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2215.pdf.

DD 2216 Hearing Conservation Data Audiogram Form, *available at* https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2216.pdf.

DD 2215 Reference Audiogram Form, *available at* https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2215.pdf; DD 2216 Hearing Conservation Data Audiogram Form, *available at* https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2216.pdf.

including the Combat Arms, the Surefire Sonic Defender, Peltors, communications earplugs (CEPs), Elvex Quattro earplugs, and custom musician earplugs.

Military audiology technicians testified that when reporting for their audiograms, soldiers themselves identified the hearing protection device they used or were issued, which the technicians input onto the relevant form. <sup>104</sup> If a soldier did not know the name of his or her hearing protection device, staff could help: "[W]e always had some to show them ... if they couldn't remember the name, they knew the color or ... some other identifying factor." <sup>105</sup> If a soldier used more than one type of earplug, he or she could choose multiple options on the form. <sup>106</sup>

These forms therefore provide a reliable record of a soldier's hearing protection over time. Military records produced so far demonstrate that few plaintiffs reported using the Combat Arms. Nearly three quarters of Wave 1 plaintiffs have *no record* of *ever* using the Combat Arms earplug, including more than 65 percent of plaintiffs who affirmatively reported using *different* hearing protection.<sup>107</sup> These records fail to support<sup>108</sup> (and instead contradict) certain claims of Combat Arms use.

Other use claims are also implausible. For example, some plaintiffs claim use of Combat Arms before their military bases ever issued these earplugs, or during periods of extremely low

See, e.g., 11/24/2020 Andrew Toyama Dep. at 83:11-14 ("I believe it gave a list of types of hearing protection devices, and then the patient would need to state which one they were using."); 11/13/2020 Jimmy Conforme Dep. at 63:10-16 ("[S]o once they give me that form, all that, once I put them in the booth and start the test, I will input all that stuff in the software. All those questionnaires that they answer, I have to answer for them on the—on the software.").

<sup>2/6/2011</sup> Bettina Rogers Dep. at 58:9-12; 103:15-20; see also 2/11/2021 Roberto Gonzalez Dep. at 52:19-22 ("[W]e have different pictures that show what the hearing—different type of hearing protection. We have them circle which one they're using....").

<sup>&</sup>lt;sup>106</sup> 11/13/2020 Jimmy Conforme Dep. at 70:4-19; 133:23-134:3.

These numbers are conservative since, in later years when the Combat Arms versions 3 and 4 were available, noting "Combat Arms" on the form did not necessarily mean the servicemember used the Combat Arms version 2.

See 2/11/2021 Roberto Gonzalez Dep. at 115:6-7 ("If it doesn't say Combat Arms Earplug [on the audiogram form], that means that they were using something else ....").

sales, while others claim that they were issued Combat Arms while stationed at military bases that did not issue those earplugs.

### 2. Most Plaintiffs Have No Hearing Loss.

The limited discovery available in the MDL shows that the vast majority of plaintiffs, most of whom claim hearing loss as their primary injury, have normal hearing by accepted clinical standards. Such claims thus fail because they cannot prove injury.

The gold standard test of a person's hearing is the "pure tone audiogram." An audiogram measures the person's hearing "thresholds" (*i.e.*, the softest sound the person can hear most of the time) for tones of various frequencies (*i.e.*, pitches). Thresholds are measured in "decibels," abbreviated as "dB," which reflect sound intensity. The lower the threshold, the softer the sound the person can hear, and the better the hearing. Thresholds at various frequencies (usually 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz or 4000 Hz) are averaged into a "pure tone average," or "PTA."

Using these measurements, the World Health Organization ("WHO") developed criteria for determining whether, and to what degree, an individual has hearing loss. "To standardize the way in which severity of hearing loss is reported," the WHO "adopted a grading system based on audiometric measurements." The WHO grades hearing loss according to PTA as follows:

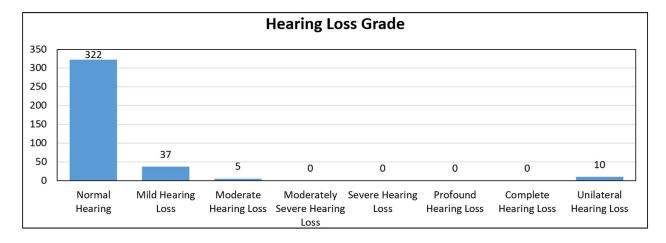
- Less than 20 dB is "normal hearing." 110
- 20 dB to less than 35 dB is "mild hearing loss."
- 35 dB to less than 50 dB is "moderate hearing loss."

<sup>&</sup>lt;sup>109</sup> WHO, World Report on Hearing at 37 (2021).

The WHO's method is conservative, measuring the "onset of mild hearing loss" at 20 dB, equivalent to a very soft whisper. *Id.* This approach contrasts with the American Medical Association and numerous other organizations, including the military and plaintiffs' own experts, all of whom have concluded that mild hearing loss begins at a PTA of 25 dB. *See, e.g.*, Dennis A. Colucci, *AMA Hearing Loss / Tinnitus Guidelines* (Feb. 2016); American Accademy of Otolaryngology Committee on Hearing and Equilibrium, and the American Council of Otolaryngology Committee on the Medical Aspects of Noise, *Guide for the Evaluation of Hearing Handicap*, JAMA Vol. 241, No. 19 (May 11, 1979), at 2058; NIOSH, *Inquiring Ears Want to Know: A Fact Sheet about Your Hearing Test*; OSHA Standard No. 1904.10, *Recording Criteria for Cases Involving Occupational Hearing Loss*; U.S. Navy and Marine Corps Public Health Center, *Technical Manual NMCPHC—TM 6260.51.99-2* (Sept. 2008), at 14; U.S. Air Force Instruction No. 48-127 (May 10, 2013) at 33.

- 50 dB to less than 65 dB is "moderately severe hearing loss."
- 65 dB to less than 80 dB is "severe hearing loss."
- 80 dB to less than 95 dB is "profound hearing loss."
- 95 dB or greater is "complete or total hearing loss/deafness." 111

The Wave 1 plaintiffs' audiograms indicate that the vast majority of plaintiffs had normal hearing by these standards during their alleged periods of Combat Arms use. The chart below shows the number of plaintiffs who fall into each WHO category, using data from the first audiogram immediately following each plaintiff's last claimed Combat Arms use (or, for those plaintiffs who have not produced audiograms post-dating the claimed use period, the latest-in-time audiogram)<sup>112</sup>:



As reflected in the chart, after they allegedly stopped wearing the Combat Arms earplug, *more than 85 percent* of Wave 1 plaintiffs had *normal hearing* under the WHO's methodology. People with normal hearing under the WHO standard should experience "no problem hearing sounds" in "a quiet environment," and "no or minimal problem hearing sounds" in "a noisy environment." <sup>113</sup>

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WHO, World Report on Hearing at 38 (2021). The WHO's criteria also define "unilateral" hearing loss as hearing of less than 20 dB or better (i.e., normal hearing) in one ear, and 35 dB or worse in the other ear. *Id.* at 38.

Where the next audiogram was not until many years after a plaintiff's alleged use of the Combat Arms ended, the data reflect the latest-in-time audiogram during claimed Combat Arms use.

WHO, World Report on Hearing at 38 (2021).

The American Medical Association employs its own method for categorizing hearing impairment, generating a hearing handicap score, with a score of zero indicating no impairment at all. Applying the AMA method to the Wave 1 plaintiffs results in hearing handicap scores of zero for more than 88 percent of Wave 1 plaintiffs.

3. The Few Plaintiffs With Some Hearing Loss Have Clear Alternative Causes.

Less than 15 percent of the remaining Wave 1 plaintiffs had some hearing loss during their claimed Combat Arms use period based on the conservative WHO criteria. Of that small group, over 70 percent have only mild hearing loss, meaning that they "do[] not have problems hearing conversational speech" in "quiet" environments, and "may have difficulty" hearing speech in "noisy" environments. Only 10 percent have moderate hearing loss. According to the WHO, these individuals "may have difficulty" with speech in "quiet" environments, and likely will have difficulty in "noisy" environments. And 19 percent of those with some hearing loss have unilateral hearing loss (*i.e.*, normal hearing in one ear but hearing levels of 35 dB or greater in the other). 117

Of course, product use and injury alone are not enough to prove a personal injury case. A personal injury plaintiff must also prove causation, *i.e.*, that their injury was caused because the product failed to work as intended. As to the few Wave 1 plaintiffs with (mostly very mild) hearing loss, however, the evidence reflects that other factors likely caused their injuries. Many of them have types of hearing loss that are not caused by noise exposure but instead by other medical issues. Several have conductive hearing loss, which, unlike "sensorineural" hearing loss, is not

See generally W. Dixon Ward, The American Medical Association/American Academy of Otolaryngology Formula for Determination of Hearing Handicap, AUDIOLOGY 22:313-324 (1983).

WHO, World Report on Hearing at 37 (2021).

<sup>&</sup>lt;sup>116</sup> *Id*.

<sup>&</sup>lt;sup>117</sup> *Id*.

caused by noise exposure, but by the blockage of sound through the external ear or middle ear, preventing full sound from reaching the inner ear. These plaintiffs have, among other things, conditions like Eustachian tube dysfunction, scarring from ruptured eardrums, and otosclerosis (abnormal bone growth inside the ear). In addition, several of the Wave 1 plaintiffs have a family history of hearing loss or other medical issues that can cause hearing loss, such as Meniere's disease.

Other potential causes of hearing loss in the plaintiff population abound. As just one example, more than 50 percent of the Wave 1 plaintiffs with some hearing loss were exposed to significant noise while not wearing any hearing protection.

#### IV. THE COMBAT ARMS MDL IS BROKEN BEYOND REPAIR.

The Combat Arms cases exceed the limits (and exemplify the shortcomings) of the MDL process as a means for consolidating, managing, and resolving mass torts. As of June 15, 2022, the Combat Arms claims accounted for over 30 percent of the total number of cases pending in federal courts. Resolving such a massive docket of claims in the absence of any structural mechanisms to assess, stratify, and cull claims is neither feasible nor fair. These cases cannot be reasonably settled based on the extant record, and the bellwether trial process has done nothing to help. The looming remand of hundreds and then thousands of "wave" cases to courts across the country will only add to a backlog of trial cases in federal court.

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June 15, 2022 MDL Statistics Report - Distribution of Pending MDL Dockets by Actions Pending, J.P.M.L. avail. at https:jpml.uscourts.gov/sites/jpml/files/Pending\_MDL\_Dockets\_By\_Actions\_Pending-Jun-15-2022.pdf; Nat'l Judicial Caseload Profile, uscourts.gov, https://www.uscourts.gov/sites/default/files/fcms na distprofile0331.2022.pdf.

### A. Tainted MDL Bellwether Trials Frustrated, Instead Of Furthered, Settlement.

The goal of bellwether trials is to "produc[e] reliable information about other cases centralized in that MDL proceeding." The rushed Combat Arms bellwethers fell well short of that goal and resulted in knowingly incomplete and unsettled trial records that provided little reliable information about the merits of the 230,000 claims in the MDL.

Of the 27 bellwether plaintiffs, eight were dismissed before trial and six resulted in trial victories in favor of Aearo—meaning 14 out of 27 bellwether plaintiffs did not recover. Those bellwether trials that resulted in plaintiffs' verdicts did not provide representative data or meaningfully inform settlement, as the MDL court gutted defenses and barred key evidence in the 16 bellwether cases (some with multiple plaintiffs), which were tried in an unprecedentedly compressed time span—an average of one trial per month. The frenetic bellwether cadence, coupled with the cascading effects of substantial evidentiary errors and false narratives, tainted the trials from the start.

1. Plaintiffs' Lawyers Made Inflammatory And Prejudicial Statements And Arguments.

Plaintiffs' lawyers in the bellwether trials repeatedly packed their opening statements and closing arguments with irrelevant, overwrought, and highly prejudicial rhetoric designed to inflame the jury. Aearo's objections to these inflammatory statements were denied.

Fed. Jud. Ctr., Bellwether Trials in MDL Proceedings: A Guide for Transferee Judges 3 (May 15, 2019); *id.* at 4, 18; Bolch Judicial Institute, Guidelines and Best Practices for Large and Mass-Tort MDLs (Duke Law School, 2d ed. 2018) at 18; Manual for Complex Litig. § 22.315 (4th ed. 2004)

See Burgus (Case No. 7:20-cv-007) Dkt. 11; Garcia (Case No. 7:20-cv-072) Dkt. 16; Hensley (Case No. 7:20-cv-093) Dkt. 59; King (Case No. 7:20-cv-132) Dkt. 21; Lopez (Case No. 7:20-cv-060) Dkt. 24; McNeal (Case No. 7:20-cv-066) Dkt. 24; Rowe (Case No. 7:20-cv-026) Dkt. 30; Taylor (Case No. 7:20-cv-071) Dkt. 24; Blum (Case No. 7:20-cv-122) Dkt. 119; McCombs (Case No. 7:20-cv-094) Dkt. 157; Montero (Case No. 20-cv-067) Dkt. 132; Palanki (Case No. 3:19-cv-2324) Dkt. 135; Stelling (Case No. 20-cv-143) Dkt. 176; Kelley (Case No. 7:20-cv-153) Dkt. 173.

In the *McCombs* trial, for instance, plaintiff's lawyers insinuated that Aearo was grateful to Osama Bin Laden because it profited from the September 11 terrorist attacks: "Seven days after 9/11, war profiteering. Thank you, Osama." In the *Vilsmeyer* trial, counsel falsely argued that Aearo was preoccupied with selling the Combat Arms earplug immediately after the 9/11 attack: "And they *sell, sell, sell. That's what 3M does a week after 9/11. Dollar signs in their eyes*. Soldier safety, no way." In the *Adkins* trial, plaintiff's counsel referenced the 9/11 attacks to suggest that the Afghanistan war was a "money train for [Aearo]." These were not isolated statements. Plaintiffs' lawyers frequently demonized Aearo and its witnesses in a ploy to inflate verdicts, even in several trials that did not involve claims for punitive damages:

- Plaintiffs' lawyers argued that Aearo was "okay with Elliott Berger monkeying with these tests" because, "[f]or over 30 years, he's been instrumental. The last 10 years, from 2000 to 2010, he's brought in a billion dollars to the company. You'll put up with a lot for a billion dollars. Apparently 3M will." 124
- "There's going to be happiness in the camp because they were not held responsible for what they did to Mr. Vilsmeyer in an amount of money that's appropriate to balance the harm with their conduct. And that's going to happen. Or there's another future where you listen to the objective evidence ... [a]nd you find for the plaintiff in a fair and reasonable amount that will let 3M know that they can't do this. Enough is enough." 125

Plaintiffs' lawyers used other misleading and inflammatory analogies, including implicitly comparing wearing the Combat Arms earplug to a car "going 60 miles an hour" hitting "a little girl [who] goes off chasing a ball." This analogy was in keeping with the theme—irrelevant

<sup>&</sup>lt;sup>121</sup> 5/28/2021 *McCombs* Trial Tr. at 53:22-23.

<sup>&</sup>lt;sup>122</sup> 3/14/2022 *Vilsmeyer* Trial Tr. at 237:6-21 (emphasis added).

<sup>&</sup>lt;sup>123</sup> 9/20/2021 *Adkins* Trial Tr. at 63:22-25.

<sup>&</sup>lt;sup>124</sup> 3/14/2022 *Vilsmeyer* Trial Tr. at 152:5-10.

<sup>&</sup>lt;sup>125</sup> 3/14/2022 *Vilsmeyer* Trial Tr. at 218:9-219:1 (emphasis added).

<sup>&</sup>lt;sup>126</sup> 1/24/2022 Sloan-Wayman Trial Tr. at 123-124.

and unsupported by any evidence—that children may have been harmed by the Combat Arms. <sup>127</sup> Despite the fact that the plaintiff was not a minor, the MDL court denied a mistrial motion because "Kids do wear this earplug ... depending on how you define kids." <sup>128</sup>

Finally, and perhaps most egregiously, plaintiff's counsel in one trial—over Aearo's objection—read a text message from plaintiff's counsel's father that was neither in evidence nor admissible: "I have a father who served 30 years in the Air Force, and he sent me a text. And it says, '[h]ope you picked a good jury and made headway helping your client. Sad and upsetting when a prominent American company gouges the military ... and screws the GIs." The court overruled Aearo's motion to strike the irrelevant and inadmissible comment.

2. Plaintiffs' Lawyers Falsely Told Juries That The Air Force Found The Combat Arms Earplugs To Be Defective.

In July 2019, years after the last Combat Arms sale, an Air Force colonel named Jay Vietas wrote an internal letter stating that the Combat Arms should be removed from the Air Force's inventory. Colonel Vietas's letter also included a highly prejudicial statement on the ultimate issue in this case: that the Combat Arms "were found to be defective." Colonel Vietas confirmed in sworn deposition testimony that he was not speaking on behalf of the military when he wrote the letter: He "wasn't in a position" to speak on behalf of any other branch of the military, and thus his opinion did not "relate to the other services in any way, shape or form." 132

<sup>&</sup>lt;sup>127</sup> 1/21/2022 *Sloan-Wayman* Trial Tr. at 164:9-16.

<sup>&</sup>lt;sup>128</sup> *Id.* at 242:1-6.

<sup>&</sup>lt;sup>129</sup> 5/28/2021 *McCombs* Trial Tr. at 148:7-13.

<sup>&</sup>lt;sup>130</sup> *Id.* at 148:12-19.

<sup>&</sup>lt;sup>131</sup> P-GEN-02586.

<sup>&</sup>lt;sup>132</sup> 9/27/2021 Jay Vietas Dep. at 39:1-8.

More importantly, Colonel Vietas confirmed that he was not aware of "any studies, testing, or analyses to support the statement that Combat Arms earplugs were found to be defective." Instead, the "sole basis" for the statement in his letter that the Combat Arms was "found to be defective" was a "press release" from a *qui tam* litigation settlement—in which the government *did not* find the earplug to be defective and in which "there ha[d] been no determination of liability" on the part of Aearo. 134

Over Aearo's objections, plaintiffs' lawyers introduced the Air Force letter into evidence and made it a cornerstone of their trial presentation. They read the letter during opening statements, and showed it to nearly every witness they called—even though none of those witnesses had any personal knowledge of the letter or its context. Plaintiffs' lawyers falsely told juries that the letter shows that "[t]he Air Force d[id] their own investigation," and "determined that they're defective." Attempting to undermine the Air Force's *actual* testing of the Combat Arms earplugs, plaintiffs' lawyers used the letter to support bold and inflammatory statements about there being "something [Aearo] cannot escape": "[T]hey're trapped by ... the Air Force investigation." According to plaintiff's counsel, "the box that [Aearo is] in is that the ... Air Force already looked at all of this when they concluded this was a defective product." 138

<sup>&</sup>lt;sup>133</sup> *Id.* at 29:6-15.

<sup>&</sup>lt;sup>134</sup> *Blum* Dkt. 88 at 2.

See, e.g., 3/28/2022 Kelley Trial Tr. at 223:7-10; 6/7/2021 Baker Trial Tr. at 61:24-62:14; 6/8/2021 Baker Trial Tr. at 196:16-199:20, 208:10-209:8; 6/9/2021 Baker Trial Tr. at 323:17-324:19; 6/10/2021 Baker Trial Tr. at 271:19-272:2; 6/11/2021 Baker Trial Tr. at 303:9-304:7; 6/15/2021 Baker Trial Tr. at 95:7-97:23; 6/17/2021 Baker Trial Tr. at 58:3-59:18.

<sup>&</sup>lt;sup>136</sup> 3/28/2022 Kelley Trial Tr. at 223:7-10; 4/18/2022 Vaughn Trial Tr. at 168:1-4.

<sup>&</sup>lt;sup>137</sup> 6/18/21 *Baker* Trial Tr. at 137:6-10.

<sup>&</sup>lt;sup>138</sup> *Id.* at 139:3-5 (emphasis added).

But none of that was true. And plaintiffs' lawyers, who attended and had access to the Vietas deposition, knew it. There was no Air Force "investigation" other than the myriad tests demonstrating that the Combat Arms worked. The Air Force never "concluded" that the Combat Arms "was a defective product." 139

3. The Empirical And Exculpatory Michael Lab Testing Was First Limited And Then Excluded.

Plaintiffs' lawyers repeatedly argued that the Flange Memo showed that Aearo's NRR of 22 was "rigged" and fraudulent and insisted that the NRR could not be and had never been replicated:

- "What we are going to see in that evidence—I showed you the slide—they never got a 22 ever again, and they hid it." 140
- "There was other testing that was performed on this plug. And when you look at that testing done by 3M, you see very quickly that other tests of the plug confirm that they never got another 22. And they never got another 22 because that's the one that they had to cheat on to get." 141

The Michael Lab testing—testing by an independent laboratory paid for by a competitor showing a *higher* NRR of 23—refutes these false statements. The MDL court agreed that the Michael testing was "very probative" evidence. At plaintiffs' lawyers' insistence, however, the court first limited and then eliminated the Michael Lab report entirely from the bellwether trials. 143

<sup>&</sup>lt;sup>139</sup> *Id*.

<sup>&</sup>lt;sup>140</sup> 9/20/2021 *Adkins* Trial Tr. at 79:7-9 (emphasis added).

<sup>&</sup>lt;sup>141</sup> 10/18/2021 *Blum* Trial Tr. at 76:12-17.

<sup>&</sup>lt;sup>142</sup> 5/3/2021 *McCombs/Baker* Pretrial Tr. at 20:12-20; *Baker* Dkt. 118 at 3; *see also* 10/21/2021 *Blum* Trial Tr. at 65:19-20; 10/21/2021 *Blum* Trial Tr. at 137:9-12.; MDL Dkt. 2244 at 2.

<sup>&</sup>lt;sup>143</sup> See MDL Dkt. 1454 at 2; Baker Dkt. 118 at 3.

4. Plaintiffs' Lawyers Told A Fictionalized And Incomplete Development And Design Story

The rushed pace of trial resulted in the exclusion of key defense evidence because discovery was incomplete, while critical—potentially dispositive—pre-trial rulings had not been reviewed by the appeals court.

## a. <u>Key ISL Depositions Were Deferred Until After The Trials.</u>

Long before the first bellwether trial, Aearo sought to depose the two key ISL scientists, Dancer and Hamery.<sup>144</sup> After administrative delays, the French Ministry of Justice authorized the depositions to take place in October 2021. Despite finding that Aearo's "pursuit of the Hamery and Dancer depositions was diligent," the MDL court delayed the depositions, reasoning that they would "unfairly prejudice Plaintiffs by potentially requiring extensive modifications to their trial work product." The court thus "permit[ted] the depositions to go forward" only "after the bellwether trials are complete." <sup>146</sup>

Plaintiffs' lawyers took advantage of this evidentiary vacuum by advancing a counterfactual narrative about ISL's involvement and views on the Combat Arms. They told the bellwether juries that ISL had no role in the design of the two-ended stem, and—after bolstering ISL's Dancer as the "world leader in earplugs and acoustics" argued ISL was critical of the Combat Arms design. None of that was true. But because the ISL depositions were taken only after the bellwether process was complete, there was no way for Aearo to correct the fiction, leaving juries with a false impression about ISL's role in, and view of, the design of the Combat Arms.

<sup>&</sup>lt;sup>144</sup> See MDL Dkt. 1288; MDL Dkt. 2201 at 3.

<sup>&</sup>lt;sup>145</sup> *Id.* at 4.

<sup>&</sup>lt;sup>146</sup> *Id.* at 5.

<sup>&</sup>lt;sup>147</sup> MDL Dkt. 2201 at 3; 3/15/22 Wilkerson Trial Tr. at 259:1-3.

## b. <u>The Military's Role Was Downplayed By An Order Barring Aearo's</u> Government Contractor Defense.

Early in the litigation, Aearo moved for summary judgment on all of plaintiffs' claims based on the "government contractor defense," which bars certain lawsuits against manufacturers if the government made an "informed, discretionary decision" about a design or the warnings associated with it. The military asked Aearo to develop a dual-ended earplug, reviewed samples, requested design changes, and approved the final design. Further, the military asked Aearo *not* to provide instructions for using the Combat Arms, because the military preferred to train its own soldiers. Later, when the military decided to use written instructions, it drafted its own. The military plainly made an "informed, discretionary decision" about the Combat Arms earplug's design and warnings, such that the government contractor defense applied and should have barred every claim in the MDL.

The MDL court not only denied Aearo's summary judgment motion, it also granted plaintiffs' counter-motion and precluded Aearo from even arguing that defense to a jury. Based on this ruling, the MDL court then excluded evidence about the government's role in the product's design and development. The MDL court insisted that Aearo "was the designer and the only designer of this plug." The court directed that "it'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." The court also

<sup>&</sup>lt;sup>148</sup> Boyle v. United Techs. Corp., 487 U.S. 500, 506-07 (1988).

<sup>&</sup>lt;sup>149</sup> 3/15/2021 Wilkerson Trial Tr. at 9:9-18.

<sup>3/17/2021</sup> *EHK* Trial Tr. 141:20-25, 142:1; *see also* 3/15/21 *EHK* Trial Tr. at 75:15-18 ("There is not going to be a suggestion that the government made a mistake here. Your client was the designer and the only designer of this plug."); 4/13/2021 *EHK* Trial Tr. at 156:17-18 ("[The military] didn't develop the plug. I'm not going to let you argue that.").

admonished Aearo that the mere "idea that the military collaborated in the development and design of the plug is too close to violating [its] summary judgment order."<sup>151</sup>

The MDL court also repeatedly "remind[ed]" the jury that the "military did not design this plug"—and interrupted a core witness who began discussing the military research that led to the Combat Arms. In the final jury instructions, the MDL court reiterated that "the United States has no legal responsibility for the design of the [Combat Arms Earplug Version 2]." Plaintiffs' lawyers capitalized on these rulings at trial. In opening statements, they argued that "the government did not design this product." And their witnesses followed suit, with Aearo unable to cross-examine them with the truth.

## B. Appellate Review Cannot Cure The Systemic Problems In The MDL.

The absence of interlocutory relief from most MDL court judgments on threshold dispositive issues means there is rarely appellate review of core issues. As Congress reported, some "MDL judges have issued questionable rulings on pivotal issues that are not subject to immediate appellate review, including the admissibility of expert evidence and the appropriateness

<sup>9/20/2021</sup> Adkins Trial Tr. at 1613-15. The court also excluded records confirming the military's (and ISL's) involvement in the development of the Combat Arms, including ones documenting that the military "in partnership with" ISL "introduced a new earplug from an American manufacturer specifically designed for the dismounted soldier or marine." D-GEN-1095.

<sup>4/15/2021</sup> *EHK* Trial Tr. at 203:2-3 ("I remind you that the military did not design this plug."); *see also* 4/20/2021 *EHK* Trial Tr. at 178:4-6 ("I would remind you that the military hard no responsibility for the design of this earplug.").

<sup>4/29/2021</sup> *EHK* Trial Tr. at 52:23-25; *see also, e.g.*, 11/3/2021 *Camarillo* Trial Tr. at 530:7-8 ("[T]he military is not responsible for the design of the earplugs.").

<sup>&</sup>lt;sup>154</sup> 3/30/2021 *EHK* Trial Tr. at 59:20; *see also* 9/20/2021 *Adkins* Trial Tr. at 49:3-4 ("I want you to understand something, though. The plug was Aearo's design.").

See, e.g., 11/4/2021 Palanki Trial Tr. at 819:15-16 ("Aearo design[ed] the Combat Arms 2."). Focusing on the Flange Memo, plaintiffs' lawyers also argued that Aearo broke the law by failing to comply with EPA regulations requiring certain testing and labeling, which were promulgated pursuant to the Noise Control Act. But the Noise Control Act expressly exempts "equipment ... designed for use in combat." Even though the Combat Arms was clearly "designed for use in combat," the MDL court ruled that the exemption did not apply. Plaintiffs' lawyers were again allowed to argue a fiction: that Aearo was a serial law-breaker. See, e.g., 6/7/2021 Baker Trial Tr. at 36:19-25; 3/30/2021 EHK Trial Tr. at 45:24-46:17; 6/18/2021 Baker Trial Tr. at 53:24-54:2; 6/9/2021 Baker Trial Tr. at 26:5-17, 29:1-2.

of multi-plaintiff trials."<sup>156</sup> "Indeed, MDL courts have sometimes forced defendants to proceed with consecutive trials without the benefit of appellate review, even though the same judicial errors will likely be repeated."<sup>157</sup> And "if the information gathered" for settlement purposes "is a result of uncorrected legal errors, then any resulting settlement is tainted."<sup>158</sup> Legal commentators have similarly observed that, because "interlocutory rulings generally are not subject to immediate appeal, the trial judge presiding over an MDL lacks any meaningful appellate supervision."<sup>159</sup> This is a problem because "[a] single [MDL] trial-court decision can implicate hundreds, or even thousands, of individual lawsuits. As a result, MDL decisions can have an exaggerated influence both for the parties to MDL proceedings and for the evolution of the law."<sup>160</sup>

Here, the lack of appellate review was especially impactful. Pre-trial rulings—including most notably the order striking the government contractor defense and applying EPA's testing and labeling regulations to the Combat Arms—had a monumental influence in shaping the MDL and the bellwether trials. Aearo sought interlocutory review by the appeals court before the bellwether trials, but its request was denied. <sup>161</sup>

Thus, Aearo was forced to defend itself in *16* bellwether trials (involving 19 plaintiffs) before the appellate court could consider Aearo's appeal, which is still unresolved today. The frantic trial pace required enlisting eight other federal district court judges from across the Eleventh Circuit, who tried ten cases over a span of just 27 weeks (with several trials taking place

<sup>&</sup>lt;sup>156</sup> H.R. Rep. No. 115-25, at 36 (2017) (Judicial Comm. Report).

<sup>&</sup>lt;sup>157</sup> *Id*.

<sup>&</sup>lt;sup>158</sup> *Id*.

A. Pollis, The Need for Non-Discretionary Interlocutory Appellate Review in Multidistrict Litigation, 79 FORDHAM L. REV. 1643, 1646 (2011).

<sup>&</sup>lt;sup>160</sup> *Id.* at 1648.

<sup>&</sup>lt;sup>161</sup> MDL Dkt. 1329.

simultaneously). As one of those judges put it: "[I]t's odd to me, and I understand you're trying to move the cases, but you do all these bellwether trials where the initial bellwether trial carries with it 20 major potential appellate issues that could potentially require the parties to relitigate 30 cases." 162

The bellwether trials themselves resulted in numerous additional rulings that are now on appeal. As rushed as the bellwether process was, however, the post-trial motions have stagnated. Aearo has filed eleven of them in total, but only four have been decided fully (two in August 2021, one just last week, and one yesterday). As a result, there are currently seven sets of post-trial motions pending, the oldest of which has been pending for seven months. Until Aearo obtains a ruling on these motions, the appeals process cannot even begin. Meanwhile, as of this filing, hundreds or thousands of discovery deadlines loom in the next several months, as does potential remand of many cases for trial to federal courts throughout the country. None of the appeals would have been decided in time to stem the tide or provide controlling authority for key issues in these cases. And in any event, appellate review of those trials would come in the context of incomplete discovery and trial records.

# V. CHAPTER 11 PROVIDES THE ONLY EFFICIENT, EQUITABLE, AND EXPEDITIOUS RESOLUTION OPTION HERE.

The Combat Arms MDL is a recent and extreme example of the systemic shortcomings of traditional litigation, including MDLs, in certain mass tort contexts. At this point, the Combat Arms tort claims morass simply cannot be sorted out in the MDL or in the traditional tort system. This "elephantine mass" of claims is akin to those that introduced the era of asbestos bankruptcy cases. Dating back to the *Johns-Manville* asbestos bankruptcy in the 1980s, tools uniquely

<sup>&</sup>lt;sup>162</sup> 11/8/2021 Camarillorazo Trial Tr. at 1558:16-20.

<sup>&</sup>lt;sup>163</sup> Norfolk & Western Ry. Co. v. Ayers, 538 U.S. 135 (2003); Ortiz v. Fibreboard Corp., 527 U.S. 815, 821 (1999).

available in chapter 11 have offered "a structured system to manage multiple liabilities and ha[ve] provided a forum for companies with massive liabilities to attempt to do so." These procedures have evolved and improved over time, providing the tools required to rationally and efficiently resolve mass tort claims against debtors and related third parties.

As explained below, chapter 11 protection and procedures—which extend to Combat Arms litigation against 3M as well—will facilitate the measurement of liability and fair compensation by legal and scientific merits. Chapter 11 is the only expeditious path forward to full, fair, and final resolution and compensation of Combat Arms claims.

# A. 3M's Participation And Funding Commitment Are Essential To A Successful Reorganization And To An Expeditious And Equitable Resolution.

Aearo is a wholly-owned indirect subsidiary of 3M. As explained above, Aearo developed and designed (in collaboration with the U.S. military and ISL) the Combat Arms and began manufacturing and selling the earplugs in the early 2000s. In 2008, 3M acquired Aearo, and in 2010, Aearo's earplug sales business was transferred upstream to 3M. The companies continued producing and selling the Combat Arms until 2015. Throughout the entire time the Combat Arms was sold, the earplug design remained exactly the same, as did the instructions and labelling provided to the military.

Although the first Combat Arms lawsuit was not filed until December 2018, that lawsuit—and the more than 280,000 that followed—was predicated on design and instruction decisions that occurred years before the 3M acquisition. Plaintiffs' design defect and failure-to-warn claims were built around the so-called "Flange Memo," which was written in 2000. And of the

Report of the National Bankruptcy Review Commission 315 (Oct. 20, 1997).

See Decl. of John R. Castellano in Support of the Debtors' Ch. 11 Petitions and First Day Motions ("Castellano Decl.") ¶ 8 (filed concurrently).

approximately \$31 million in lifetime sales of the Combat Arms, the vast majority (approximately 80 percent) occurred before 3M's acquisition. Not surprisingly, throughout the MDL proceedings and trials, Aearo and 3M were together referred to as "Defendants," including on jury verdict forms assessing liability and damages.

As explained in Aearo's contemporaneous first day filings, the automatic stay applies to 3M. Among other things, 3M shares insurance and an identity of interests with, and has indemnification rights against, Aearo for these claims. Under both Sections 362(a) and 105(a), the Code authorizes a stay of litigation as to 3M, which is essential to an evenhanded, efficient, and expeditious resolution here. Aearo's reorganization efforts would be thwarted if litigation were allowed to proceed apace against 3M, Aearo's financial sponsor and indemnitee.

3M's financial contribution is essential to a successful reorganization, which will promptly, fully, and fairly compensate servicemembers and veterans (as well as the relatively small number of civilians). 3M has agreed to fund both these chapter 11 cases and a subsequent claims trust. This funding is indispensable to the creation and implementation of a claims trust that will efficiently review and fairly compensate tort claims, and otherwise satisfy the requirements necessary to qualify for section 105(a) relief. 168

# B. The Bankruptcy Code Provides Powerful Tools To Deal With Mass Tort Claims That Cannot Be Fairly Or Fully Resolved In Traditional Litigation.

#### 1. Centralization of Claims

As a gating issue, chapter 11 provides mechanisms to centralize Combat Arms claims to allow an efficient, consistent, and evenhanded approach to assessment and resolution. The Court

<sup>&</sup>lt;sup>166</sup> See Castellano Dec. ¶ 22.

<sup>&</sup>lt;sup>167</sup> See Castellano Decl. ¶¶ 7, 12, 34-49.

<sup>&</sup>lt;sup>168</sup> Castellano Decl. ¶¶ 12, 45-49.

has the power to extend the stay to enjoin litigation against certain-Debtors under Section 105(a) of the Bankruptcy Code. As is routinely done in mass-tort chapter 11 cases, as part of its first day pleadings, Aearo is moving for an order holding that the automatic stay should be applied to Combat Arms-related actions against Aearo's parent, 3M, which has committed to provide uncapped funding to resolve Aearo's Combat Arms liability claims and which will be primary benefactor of any settlement trust. Centralization will encourage the coordinated adjudication and resolution of all Combat Arms tort claims in this Court, or if appropriate in the case of liquidation of personal injury claims, in the District Court for the Southern District of Indiana.

#### 2. Consensual Resolution Track

Despite extensive settlement efforts, and the assistance of several court-appointed mediators, it is clear that the parties have materially divergent views as to the scope of liability and metrics for compensation. Aearo nonetheless remains steadfastly committed to reaching a consensual resolution, through negotiations with any committee formed to represent claimants. A chapter 11 plan may "provide for the settlement or adjustment of any claim or interest belonging to the debtor or the estate." Indeed, compromises are favored because they "minimize costly litigation and further parties" interests in expediting the administration of the bankruptcy estate." As soon as the committee is formed, Aearo will stand ready to negotiate.

#### 3. Parallel Claims Estimation Procedures

In parallel with consensual plan negotiations, Aearo will propose (and work with the Court and interested parties to develop and implement) a schedule and protocol to estimate the aggregate

<sup>&</sup>lt;sup>169</sup> 11 U.S.C. § 1123(b)(3)(A), (b)(6).

<sup>&</sup>lt;sup>170</sup> In re MF Global Inc., 466 B.R. 244, 247 (Bankr. S.D.N.Y. 2012).

amount of liability for plan purposes. The estimation procedures will categorize and value the claims in aggregate, by collecting and analyzing (through empirical data and reliable methodologies) crucial information regarding, among others, product identification, hearing function, and alternative causes.

As in prior successful mass tort bankruptcies, such an estimation *cannot* be premised on speculation about settlements or judgments that might have arisen out of tainted litigation records in the tort system. Instead, any estimation procedures should include rigorous procedures for stratifying and assessing evidence of and severity of hearing loss, use of other non-Combat-Arms hearing protection devices, circumstances and timing of noise exposure, alternative causes for any alleged hearing injuries such as combat trauma, and other relevant facts.

Moreover, where liability is disputed, it must be determined in accordance with non-bankruptcy law, including substantive law where applicable. The procedural mechanisms for resolving disputed claims, however, must remain grounded in the Federal Rules of Evidence, including Rules 702 and 703. This Court is thus empowered to resolve summary judgment and *Daubert* motions. The proposed restructuring path here rests on well-tested principles derived from successful mass tort bankruptcies, which have encouraged the litigation of core, cross-cutting issues, that have the potential to resolve or inform all or substantial parts of the litigation. Aearo will be seeking a full and conclusive valuation of its liabilities for the benefit of all valid claims.

<sup>11</sup> U.S.C. § 502(b)(1); In re Dow Corning, 215 B.R. 346, 348-52 (Bankr. E.D. Mich. 1997).

Order Estimating Aggregate Liability [ECF No. 3296], In re Garlock Sealing Technologies, LLC, Case No. 10-31607 (GH) (Bankr. W.D.N.C. January 10, 2014); In re W.R. Grace & Co., 355 B.R. 462, 482-83 (Bankr. D. Del. 2006) (employing an estimation proceeding to dispute liability for groups of claimants whose exposure was scientifically insufficient to establish causation); In re Dow Corning, 215 B.R. 346, 352-55 (Bankr. E.D. Mich. 1997) (holding that the bankruptcy court is to assess claim validity and may estimate any allowed claims); In re Babcock & Wilcox Co., No. CIV.A. 00-0058, 2000 WL 422372, at \*4-5 (Bankr. E.D. La. Apr. 17, 2000) (adjudicating motions for summary judgment on threshold liability issues).

However, during the estimation litigation and even through any estimation trial, Aearo will continue negotiations to reach a consensual resolution.

#### 4. Global Resolution

Aearo's ultimate objective is to confirm a plan of reorganization that resolves all Combat Arms-related claims against Aearo and 3M. That plan would have two cornerstones.

The first would be a settlement trust for Combat Arms claims funded by Aearo, including from an uncapped commitment by 3M that will ensure sufficient resources to pay the true value of all claims filed against it. The trust would have fair procedures to pay claimants who meet specified criteria to establish values of their claims. Plaintiffs would no longer have to wait for years or decades to have their claims resolved, would have greater certainty with respect to the compensation they will receive, and would not have to undergo time consuming and costly discovery, trials, and other litigation. And the "staggering" burden that the MDL court recently predicted would befall other federal courts throughout the country upon remand will be averted. Meanwhile, Aearo and 3M will be able to resolve the claims against them on a scientific basis based on a fair and complete evidentiary record. The settlement trust will be backstopped by a funding commitment from 3M that will not be capped, ensuring that Aearo and its affiliates will have access to sufficient funding to pay the fair value of all legitimate claims.

The second cornerstone would be a permanent channeling injunction and a third-party release of 3M. This injunction would require that all Combat Arms-related claims be brought only against the settlement trust, and not the reorganized Aearo entities or their non-debtor affiliates. The injunction would apply to all potential Combat Arms plaintiffs.

Through these twin pillars, this reorganization would achieve both fairness and finality in the Combat Arms litigation.

Indianapolis, Indiana Dated: July 26, 2022

#### /s/ Jeffrey A. Hokanson

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