

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

UNITED STATES OF AMERICA *ex rel.*
MOLDEX-METRIC, INC.,

Plaintiff/Relator,

vs.

3M COMPANY,

Defendant.

CASE NO. 3:16-1533-MBS

**ORIGINAL COMPLAINT FILED IN
CAMERA**

**SEALED PURSUANT TO 31 U.S.C.
§ 3730(b)(2)**

JURY TRIAL DEMANDED

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**INTRODUCTION**

This is an action by *qui tam* Plaintiff/Relator Moldex-Metric, Inc. (“Moldex”), in the name of the United States Government, to recover penalties and damages arising from false statements made by Defendant 3M Company (“3M” or the “Company”) to the Government regarding its dangerously defective dual-ended Combat Arms™ earplugs, which 3M sold to the U.S. military for more than a decade without its knowledge of the defect. Plaintiff/Relator’s claims reveal the protracted fraud perpetrated on the military by 3M, whose dual-ended Combat Arms™ earplugs—which were standard issue in certain branches of the military during foreign conflicts between 2003 and 2015—have likely caused thousands of soldiers to suffer significant hearing loss and tinnitus in addition to exposing millions to the risk caused by 3M’s defective earplugs.¹ The indirect cost to the public of 3M’s fraud has been enormous. In addition to funding the military’s repeated purchases of the defective earplugs from 3M for more than a decade, tax payers must shoulder the massive expense of treating veterans with hearing damage and impairment, which represents the largest ongoing medical cost to the military. Plaintiff/Relator Moldex alleges as follows:

THE PARTIES

1. Moldex is a family-owned business organized and existing under the laws of California with its principal place of business in Culver City, California. It is in the business of designing, manufacturing and selling worker safety products, including hearing protection

¹ As 3M explains in a press release trumpeting its sales of its Combat Arms™ earplugs to the military, “[t]innitus, often referred to as ‘ringing in the ears,’ and noise-induced hearing loss can be caused by a one-time exposure to hazardous impulse noise, or by repeated exposure to excessive noise over an extended period of time.” Ex. 1, 3M Newsroom, *3M Hearing Protection Devices Now Added to the Federal Procurement List* (Aug. 30, 2012), available at http://solutions.3m.com/wps/portal/3M/en_US/3M-Defense-US/Defense/About-3M-Defense/News/ (last visited Apr. 25, 2016).

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products and respirators. In 2011, Moldex introduced a non-linear dual-mode earplug, called BattlePlugs®. Moldex's BattlePlugs® provided the first actual competition to 3M's Combat Arms™ earplugs in the market for non-linear earplugs approved for purchase by the military.

2. 3M Company is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in St. Paul, Minnesota. Among other things, it is in the business of designing, manufacturing, and selling worker safety products, including hearing protectors and respirators. 3M has a dominant market share in virtually every safety product market, including hearing protection. 3M is one of the largest companies in the country.

JURISDICTION AND VENUE

3. This action arises under the False Claims Act, 31 U.S.C. § 3729, *et seq.*

4. Jurisdiction over this action is conferred upon the Court by 31 U.S.C. § 3732(a) and 28 U.S.C. § 3130 in that this action arises under the laws of the United States.

5. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 31 U.S.C. § 3732(a) because Defendant 3M transacts business in this District and can be found within the United States.

6. Venue is also proper because this District has general jurisdiction over 3M due to its extensive, long-standing presence. Defendant 3M operates manufacturing facilities at 1400 Perimeter Road, Greenville, South Carolina 29605-5467, which includes at least two plants. 3M has operated facilities at this location since 1974, and in 2007 began a \$100 million ongoing expansion project. Ex. 3, *History of 3M Greenville*, available at http://solutions.3m.com/wps/portal/3M/en_US/Greenville/Plant/Facility/History/ (last visited May 6, 2016). 3M touts the benefits of its active participation in the Greenville community on its website. Ex. 4, *Community Involvement*, available at

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http://solutions.3m.com/wps/portal/3M/en_US/Greenville/Plant/Community/Involvement/ (last visited May 6, 2016).

7. Venue is also proper because, in addition to the statutory bases, this District has specific jurisdiction over false statements and claims related to 3M's distribution of the Combat Arms earplugs to South Carolinian soldiers. Starting in 2004, all soldiers deployed to Iraq and Afghanistan were issued Combat Arms earplugs. Ex. 5, McIlwain, D. Scott *et al.*, *Heritage of Army Audiology and the Road Ahead: The Army Hearing Program*, AMERICAN JOURNAL OF PUBLIC HEALTH, Vol. 98 No. 12 (Dec. 2008). South Carolina is home to several Army, Air Force, Navy, and Marine military bases from which soldiers were trained and deployed to these combat zones—including Fort Jackson, Shaw Air Force Base, the Marine Corp Recruiting Depot at Parris Island, and the Naval Weapons Station Charleston. With respect to Fort Jackson, for example, 3M was the supplier of Combat Arms earplugs prior to Moldex assuming the contract in 2012.

FACTUAL ALLEGATIONS**I. 3M'S DEFECTIVE COMBAT ARMS™ EARPLUGS****3M's dual-ended Combat Arms™ earplugs**

8. 3M's dual-ended Combat Arms™ earplugs, which are non-linear, or selective attenuation, earplugs, were designed to provide soldiers with a single set of earplugs that offer them two options for hearing attenuation depending upon how the plugs are worn. If worn in the

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“closed” or “blocked” position (olive end in), the earplugs are supposed to block sound like traditional earplugs. If worn in the “open” or “unblocked” position (yellow end in), the earplugs are supposed to block, or at least significantly reduce, loud impulse sounds of battlefield explosions, while still allowing the wearer to hear quieter noises such as commands spoken by fellow soldiers and approaching enemy combatants. These earplugs were originally created by a company called Aearo Technologies (“Aearo”). 3M acquired Aearo in 2008 (and thus any liability associated with its past conduct) and hired the employees at Aearo that developed and tested the defective earplugs. These 3M employees were aware of the defects as early as 2000, several years before 3M/Aearo became the exclusive provider of the earplugs to the military.

9. As known to 3M/Aearo at the time it bid for and won the underlying Indefinite-Quantity Contracts (“IQCs”) that made it the exclusive supplier of selective attenuation earplugs to the military between 2003 and 2012, these earplugs have dangerous design defects that can cause them to loosen in the wearer’s ear, imperceptibly to the wearer and even trained audiologists visually observing a wearer, thereby permitting damaging sounds to enter the ear canal by traveling around the outside of the earplug while the user and/or audiologist incorrectly believes that the earplug is working as intended. Because the stem of the dual-ended earplug is too short, it is difficult to insert the plug deeply into some wearer’s ear canals and obtain a proper fit. Specifically, when the earplug is inserted into the ear according to standard fitting instructions, the basal edge of the third flange of the non-inserted end of the earplug is prone to press against some wearers’ ear canals and fold back to its original shape, thereby loosening the seal in their ear canals. The defect has the same effect when either end is inserted because the earplugs are symmetrical. In either scenario, the effect is that the earplug may not maintain a

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tight seal in some wearers' ear canals such that dangerous sounds can bypass the plug altogether thereby posing serious risk to the wearer's hearing unbeknownst to him or her.

10. These dangerous design defects were known to Aearo in 2000 (and later 3M) when it completed testing of the dual-ended Combat Arms™ earplugs. This is evidenced by the fact that when Aearo retested the closed end of the earplug starting in February 2000, as detailed below, its personnel rolled back the non-inserted yellow flanges in order to mitigate the loosening effect of the defect caused by the short stem. Further, the 3M/Aearo scientist who oversaw and documented this testing, and the 3M/Aearo lab technician who conducted the testing, are still employed by 3M to this day.

11. Despite this knowledge, in 2003, Aearo submitted a bid in response to the military's Request for Proposal ("RFP") to supply large quantities of these defective earplugs and entered into an IQC pursuant to which it became the exclusive supplier of earplugs to the military. When it responded to the RFP, Aearo was required to expressly certify that the earplugs complied with the Salient Characteristics of Medical Procurement Item Description ("MPID") of Solicitation No. SP0200-06-R-4202. *See* Ex. 2, Solicitation No. SP0200-06-R-4202. The earplugs did not, however, comply with those Salient Characteristics, which Aearo knew at the time it made its certification. Thus, Aearo's response to the RFP constitutes a false statement or record and each of Aearo's and later 3M's subsequent requests for payment pursuant to the IQC resulting from these false statements or records constitutes a false claim within the meaning of the False Claims Act ("FCA"). Each of Aearo's and 3M's subsequent responses to the military's RFPs and the resulting IQC payment requests constitute additional, distinct false statements and claims by 3M/Aearo for which 3M is now liable.

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II. THE SALIENT CHARACTERISTICS OF THE MILITARY'S RFPs

12. Since 2003, 3M/Aearo has been awarded multiple IQC's in response to RFPs, including but not limited to SP0200-06-R-4202, issued by the military requesting bids to supply non-linear, selective attenuation earplugs. In response to each of these RFPs, 3M/Aearo was required to certify that its dual-ended Combat Arms™ earplugs complied with the Salient Characteristics of the associated MPIDs. The pertinent Salient Characteristics set forth in the MPID, which was uniform across all RFPs, in relevant part, are as follows:

2.1.1. Ear plugs shall be designed to provide protection from the impulse noises created by military firearms, while allowing the wearer to clearly hear normal speech and other quieter sounds, such as voice commands, on the battlefield.

2.2.2. The sound attenuation of both ends of the ear plugs shall be tested in accordance with ANSI S3.19....

2.4 Workmanship. The ear plugs shall be free from all defects that detract from their appearance or impair their serviceability.

2.5 Instructions. Illustrated instructions explaining the proper use and handling of the ear plugs shall be supplied with each unit....

Ex. 2, Solicitation No. SP0200-06-R-4202 at 41-42.

13. The Environmental Protection Agency ("EPA") has also promulgated regulations pursuant to the Noise Control Act, 42 U.S.C. § 4901, *et seq.*, that govern the testing and attendant labeling of hearing protective devices like the dual-ended Combat Arms™ earplugs. Specifically, 40 C.F.R. § 211.206-1 provides that:

The value of sound attenuation to be used in the calculation of the Noise Reduction Rating must be determined according to the "Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs." This standard is approved as the American National Standards Institute Standard (ANSI-STD) S3.19-1974.

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14. Additionally, 40 C.F.R. § 211.204-4(e) of the EPA regulations requires that certain “supporting information” must accompany hearing protection devices sold in the United States:

The following minimum supporting information must accompany the device in a manner that insures its availability to the prospective user. In the case of bulk packaging and dispensing, such supporting information must be affixed to the bulk container or dispenser in the same manner as the label, and in a readily visible location....
Instructions as to the proper insertion or placement of the device.

Emphasis added.

III. 3M’S DELIBERATELY FLAWED TESTING OF THE EARPLUGS, RESULTING FALSE AND MISLEADING NRRs, AND IMPROPER INSTRUCTIONS FOR USE OF THE EARPLUGS

15. Earplugs like 3M’s are sold with a listed NRR that is supposed to represent the amount of sound attenuation perceived by a test group when tested under certain conditions required by the statutorily required test methodology. The military can only purchase 3M’s dual-ended Combat Arms™ earplugs if they meet the testing standards required by the U.S. Army Public Health Command, Army Hearing Program, or equivalent standards that may be promulgated by other military services. As such, before 3M/Aearo could sell its earplugs to the military, 3M/Aearo had to test them to determine the NRR, which would be included on the product label.

16. In or around January 2000, personnel at Aearo commenced NRR testing on each end of the earplug. Rather than outsource the testing to an independent lab, Aearo chose to conduct the testing at its own E-A-RCAL laboratory (which also is now owned by 3M). Aearo’s personnel selected ten test subjects, some of whom were their own employees, to test the earplug. Aearo’s personnel tested, in no particular order: (1) the subject’s hearing without an earplug inserted; (2) the subject’s hearing with the open/unblocked (yellow) end of the dual-

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

17. Aearo personnel monitored the noise attenuation results of each subject as each test was performed and could stop the test if they did not get the NRR results they wanted, which violated the ANSI S3.19-1974 testing protocol. After eight of the ten test subjects had been tested on both the open and closed ends of the earplug, Aearo personnel decided not to test the last two subjects' hearing with the closed/blocked end of the earplug inserted. At that point, the average of the results for the first eight subjects suggested an NRR of 10.9, which was far below the "22" NRR that 3M/Aearo would have expected for the closed end of the plug. This result was directly attributable to the design defect in the earplugs causing some wearers to receive little or no sound attenuation, due to the imperceptible slip explained above, while others achieved the expected levels of sound attenuation.

18. Aearo personnel apparently liked the low NRRs they were getting from the same test subjects due to the design defect on the open end of the plug, however. As such, Aearo completed testing all ten of the subjects' hearing with the open end of the plug inserted and obtained a facially invalid -2 NRR, meaning the earplug would actually function as a hearing aid by amplifying sound. Aearo personnel reported the -2 NRR as a "0" NRR, which 3M/Aearo has displayed on the packaging of the dual-ended Combat Arms™ earplugs since the product was launched. Since late 2003, 3M/Aearo has touted this rating as an added benefit to the military on the theory that wearers of these earplugs would be able to hear commands from friendly soldiers and approaching enemy combatants, unimpaired, in the same way as if they had nothing in their ears.

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19. After prematurely terminating testing of the closed/blocked end of the earplug, Aearo personnel immediately investigated the cause of the closed/blocked end's implied and unacceptably low NRR and discovered that, because the stem of the earplug was so short, it was difficult to insert the plug deeply into the subject's ear canals and obtain a proper fit, as required by ANSI S3.19-1974, Section 3.2.3. Ex. 8, Acoustical Society of America Standard Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs (ASA STD 1-1975). Furthermore, Aearo personnel discovered that when the olive, closed end of the earplug was inserted into the subject's ear according to standard fitting instructions, the basal edge of the third flange of the yellow, open end of the earplug pressed against the subject's ear canal and folded backwards. When the inward pressure on the earplug was released, the yellow flanges tended to return to their original shape, thereby loosening the earplug, often imperceptibly to the test subject. The dual-ended Combat Arms™ earplugs are symmetrical and thus this problem would be experienced when the plug is reversed as well. The image below illustrates how the basal edge of the earplug interacts with the ear canal.



Image from J.G. Casali, *et al.*, *A field investigation of hearing protection and hearing enhancement in one device: For soldiers whose ears and lives depend upon it*, 11 NOISE & HEALTH JOURNAL 42, 69-90 (2009).

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20. Aearo personnel then determined that in order for a test subject to obtain proper plug insertion, the flanges on the opposite, non-inserted end of the earplugs had to be folded back prior to insertion into the test subject's ear.

21. Once it had identified the design defect of the earplugs, Aearo decided to retest the olive, closed end of the earplug starting in February 2000 using different fitting instructions. Ex. 9, 3M's Answer to First Amended Complaint in *Moldex-Metric, Inc. v. 3M Company, et al.*, No. 14-cv-1821-JNE-FLN (D. Minn.), ¶¶ 35-36. During this retest of the closed end, Aearo personnel folded back the yellow flanges on the open end of the earplug (essentially elongating the too-short defective stem) to allow the experimenter to insert the closed end of the plug deeply into the subject's ear in order to obtain a proper fit. *Id.* Furthermore, as the yellow flanges were folded back during this retest, the basal edge of the third flange of the yellow, open end of the earplug no longer pressed against the subject's ear canal, and thus did not cause the earplug to loosen during the testing. *Id.* As a result of using this manipulated fitting procedure during the retest, as 3M/Aearo was aware before it sold the earplugs to the military, Aearo's personnel achieved a "22" NRR on the closed end of the dual-ended Combat Arms™ earplug. *Id.*

22. As explained above, due to the symmetrical structure of the dual-ended Combat Arms™ earplug, the design defects that affect the fit of the earplug on the closed end of the earplug also impact the fit on the open end. It is facially obvious from the -2 NRR test data Aearo obtained on the open end of the earplug that multiple test subjects were not properly fitted with the open end, as required by ANSI S3.19-1974 Section 3.2.3. During Aearo's testing of the open end, there was not a proper seal between certain of the subjects' ear canal and the earplug, thereby allowing noise to bypass the earplug filter and go directly into the ear canal. As a result, certain test subjects had large standard deviations across trials on the open end test, which

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artificially drove down the NRR to -2 in the open position. 3M/Aearo knew before selling the earplugs to the military that, notwithstanding these facially unreliable testing results, it did not go back and retest the open end of the earplug using the “modified” fitting procedure, *i.e.*, folding back the flanges on the olive, closed end of the earplug prior to inserting the yellow, open end into the ear.

23. The reasoning for this inaction is clear: 3M/Aearo wanted a very low NRR on the open end of 3M’s Combat Arms™ earplug (like the rounded up “0” NRR it previously obtained) so that the military would be more likely to buy it. If the open end of the plug were fitted securely into the test subjects’ ears using the modified fitting procedure, the NRR would have been much higher on the open end of the earplug and hence less marketable to the military as an earplug that supposedly would allow soldiers to hear commands and approaching combatants.

24. 3M/Aearo also knowingly used the deliberately flawed retest of the closed end of the earplugs to sell dual-ended Combat Arms™ earplugs to the military with a “22” NRR in the closed position. 3M/Aearo includes standard instructions for “proper use” of the earplugs in the packaging for the earplugs as required by the EPA, Noise Control Act, and the MPID. *See* Ex. 10, Combat Arms Earplugs Instructions. 3M’s/Aearo’s standard instructions for “proper use” of its Combat Arms™ earplugs do not instruct wearers to fold back the flanges before inserting the plug into the ear. *Id.* Instead, 3M/Aearo improperly instructs wearers to simply insert the earplugs as-is into the ear canal. *Id.* By failing to instruct wearers of the dual-ended Combat Arms™ earplug to fold back the flanges on the open/unblocked end of the plug before inserting the closed/blocked end of the plug into their ears (which is necessary to achieve the “22” NRR and avoid the defect associated with the short stem), 3M/Aearo falsely overstates the amount of hearing protection provided by the closed end of the plug. 3M’s/Aearo’s packaging and

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marketing of such earplugs with a labeled NRR of “22” thereby misleads the military, and has likely caused thousands of soldiers to suffer significant hearing loss and tinnitus in addition to exposing millions more to the risk caused by 3M’s/Aearo’s defective earplugs.

25. 3M/Aearo also has continued to sell the dual-ended Combat Arms™ earplugs to the military with a “0” NRR in the open position and with standard fitting instructions, which is false and misleading for the same reasons. Given the symmetrical nature of the earplugs, the defective stem issue that causes the earplug to imperceptibly loosen when the closed end is inserted also causes the plug to loosen when the open end is inserted. As a result, soldiers who wear the plug with the yellow end inserted desiring to block out dangerous impulse noise while still being able to hear voice commands or approaching combatants are at risk of serious hearing impairment. When the seal between the earplug and the soldier’s ear canal is broken, dangerous impulse noise can bypass the filter on the open end leaving the soldier with no hearing protection at all. 3M/Aearo would not have achieved a facially invalid -2 NRR if this were not the case.

26. In sum, as 3M/Aearo was aware prior to selling the earplugs to the military, testing procedures and fitting instructions were unlawfully manipulated to obtain the NRRs it wanted on both ends of the dual-ended Combat Arms™ earplug, and 3M/Aearo has continued to use these inaccurate NRRs to market the earplugs to the military for more than ten years without disclosing the design defect in the plugs. The closed end provides a “22” NRR only if inserted using non-standard instructions for use that 3M/Aearo does not disclose to purchasers (*i.e.*, the military) nor end user wearers (*i.e.*, soldiers). This grossly overstates the noise protection offered by this end of the plug in violation of ANSI S3.19, EPA regulations, 40 C.F.R. § 211.201, *et seq.*, and the NCA, 42 U.S.C. § 4901, *et seq.* Meanwhile, the open end of the earplug’s “0” NRR

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is based on facially unreliable test data derived from tests in which the earplugs were not fitted properly in the subjects' ears.

IV. FALSE CERTIFICATIONS TO THE MILITARY

27. Although 3M/Aearo was aware when it first bid for the IQCs to supply its Combat Arms™ to the military that testing of the earplugs violated ANSI S3.19-1974, 3M/Aearo certified to the military that the testing complied with that testing standard. In response to the military's RFPs, 3M/Aearo were required to certify that testing of the earplugs was done in accordance with ANSI S3.19-1974, and thus each response by 3M/Aearo would constitute a false statement or record within the meaning of the FCA.

28. 3M/Aearo was further required to certify in response to each RFP that it provided accurate "instructions explaining the proper use and handling of the ear plugs." As discussed above, 3M/Aearo was aware at the time it bid for the IQCs that personnel folded back the flanges of the yellow, open end of the earplug when testing the closed end and did not similarly manipulate the fit of the earplugs when testing the open end. Yet, despite knowing that its flawed testing involved steps to manipulate the fit of the earplug, 3M's/Aearo's instructions for use of the earplugs do not instruct, and never have instructed, the wearer to fold back the flanges on the open end of the plug before inserting the closed end of the plug into their ears (which is necessary to achieve the "22" NRR and avoid the defect associated with the short stem). Ex. 10, Combat Arms Earplugs Instructions. Since it first began supplying the earplugs to the military, 3M's/Aearo's instructions instead have provided standard fitting instructions for inserting the earplug on both ends. *Id.* These use instructions are, therefore, facially inadequate. Certification to the contrary is a false statement for purposes of the FCA and has put soldiers at risk of suffering serious hearing impairment on the battlefield.

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29. Pursuant to Section 2.4 of the MPID, when responding to the RFPs, 3M/Aearo also was required to certify that “[t]he ear plugs shall be free from all defects that detract from their appearance or impair their serviceability.” Ex. 2, Solicitation No. SP0200-06-R-4202 at 42. As explained above, 3M/Aearo knew as early as 2000 that its dual-ended Combat Arms™ earplugs were designed with too short a stem, which causes the plugs to imperceptibly loosen in the wearer’s ear when the flanges are not rolled back. Despite this knowledge, 3M/Aearo marketed and sold the defective earplugs to the military over a period of more than a decade with fitting instructions that do not instruct the purchaser/wearer to roll back the flanges, all the while being required to certify that the earplugs were free of defects. Further, soldiers moving around on the battlefield are even more likely to experience the harmful effects of the earplug’s defects than are test subjects during an NRR test, because NRR tests typically only last a few minutes and are performed in a laboratory setting where the subject’s head remains virtually motionless during testing. Thus, such defects place thousands of soldiers at risk of suffering hearing damage or impairment.

V. THE ENORMOUS DAMAGE TO THE GOVERNMENT AND PUBLIC RESULTING FROM 3M’S FRAUD

30. The impact of 3M’s fraud cannot be overstated. In addition to the cost borne by the military for its repeated purchases of the defective earplugs, 3M’s fraud has likely contributed to the enormous medical costs associated with treating returning combat soldiers impaired by significant hearing damage and impairment. Given the imperceptibility of the defect, wearers would not have been able to detect whether the earplug had come loose. Similarly, given how imperceptible it is, military personnel, including trained audiologists, fitting the plugs and observing a wearer with the plugs inserted also likely could not perceive the

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defect. 3M was thus able to perpetrate its fraud on the military for more than ten years at enormous cost to the public.

31. The military has paid millions of dollars over the past ten plus years to purchase the defective earplugs and, unbeknownst to it, when issuing the earplugs to combat soldiers, was putting their hearing at risk. Hearing loss is a significant ongoing healthcare issue for the Department of Veteran Affairs (“VA”). Data collected by the VA indeed shows that as many as 52% of combat soldiers return from foreign conflicts with significant hearing damage, which represents the largest ongoing medical cost of the military. Ex. 12, David E. Gillespie, *Researchers Evaluate True Effects of Hearing Loss for Soldiers* (Dec. 16, 2015), available at http://www.army.mil/article/160050/Researchers_evaluate_true_effects_of_hearing_loss_for_soldiers/ (last accessed May 4, 2016). A 2015 article, for example, estimates that the VA spends more than \$1 billion per year to treat hearing loss for more than 800,000 veterans. *Id.*; see also Ex. 6, Kay Miller, *Hearing loss widespread among post-9/11 veterans*, The Center for Public Integrity (Aug. 29, 2013), available at <https://www.publicintegrity.org/2013/08/29/13283/hearing-loss-widespread-among-post-911-veterans> (last visited Apr. 25, 2016) (noting that “[t]he most-widespread injury for [post-911] veterans has been hearing loss and other auditory complications” and that “[h]earing maladies cost more than \$1.4 billion in veterans disability payments annually, according to fiscal year 2010 data from the Hearing Center of Excellence, a part of the Department of Defense.”).

32. The military likely purchased, at a minimum, one pair of 3M’s Combat Arms™ earplugs for each deployed soldier annually involved in certain foreign engagements between 2003 and 2015. See Ex. 5, McIlwain, D. Scott *et al.*, *Heritage of Army Audiology and the Road*

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Ahead: The Army Hearing Program, AMERICAN JOURNAL OF PUBLIC HEALTH, Vol. 98 No. 12 (Dec. 2008).

33. In 2006, the military entered into an IDQ with 3M/Aearo pursuant to which 3M/Aearo supplied 10,000 packages (50 pairs per package = 500,000 pairs), an estimated annual quantity of 15,000 packages (750,000 pairs), and estimated maximum of 45,000 packages (2,250,000 pairs) of 3M's/Aearo's Combat Arms™ earplugs. Ex. 11, Award Notice, 65 – Plug, Ear, Combat Arms, Dbl-Ended, 50 Pair (Dec. 19, 2006). According to the award notice for this IDQ, 3M/Aearo was guaranteed at least \$9,000,000 in sales of the earplugs in 2006. *Id.*

34. 3M's/Aearo's dual-ended Combat Arms™ earplugs were sold to the military beginning in late 2003 and continued to be sold directly and indirectly by 3M to the military until late 2015 when 3M discontinued the earplugs. Ex. 7, Discontinuation: 3M Combat Arms Earplugs Version 2 (Nov. 17, 2015). However, the defective earplugs were not recalled (and thus are likely still used by soldiers) and continue to be sold by others.

COUNT I
False Claims Act – Presentation of False Claims
31 U.S.C. § 3729(a)(1)(A)

35. Plaintiff/Relator Moldex re-alleges and incorporates by reference the allegations contained in paragraphs 1-34.

36. Defendant 3M, by and through its predecessor Aearo, and their officers, agents, supervisors, and employees, knowingly presented or caused to be presented to the United States Government false claims for payment or approval of multiple IQCs awarded under Solicitation Nos. SP0200-06-R-4202, SP0200-07-D-4103, and related solicitations for the supply of 3M's dual-ended Combat Arms™ earplugs to the military. Such false claims are in violation of 31 U.S.C. § 3729(a)(1)(A).

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37. In 2003, and several times since then and through 2015, 3M/Aearo was awarded several IQCs in response to the military's RFPs to supply large quantities of its Combat Arms™ earplugs to the military pursuant to which 3M/Aearo became the exclusive supplier of earplugs to the military. When it responded to these RFPs, 3M/Aearo was required to expressly certify that the earplugs complied with the Salient Characteristics of the MPID of the RFP. The earplugs did not, however, comply with those Salient Characteristics. Thus, every contract awarded as a result of these RFPs represents a false claim. Plaintiff/Relator is currently unaware of the specific number of such false claims, but will prove such number at trial.

38. The Salient Characteristics required earplugs designed “to provide protection from the impulse noises created by military firearms, while allowing the wearer to clearly hear normal speech and other quieter sounds, such as voice commands, on the battlefield.” MPID Section 2.1.1. To meet this requirement, and in violation of ANSI S3.19-1974, as it was aware prior to supplying the earplugs to the military, 3M/Aearo took advantage of a known design defect during testing of the open/unblocked end of the earplugs by not rolling back the flanges on the opposite end prior to insertion. This resulted in an improper fit and a false NRR of -2, which 3M/Aearo have reported as an NRR of “0” and continually used to market the earplugs to the Government. Correcting for the known design defect, as it was aware before it sold the earplugs to the military, 3M/Aearo tested the closed/blocked end of the earplugs by rolling back the flanges on the opposite end prior to insertion to achieve a false NRR of “22” which 3M/Aearo knew was not accurate without instructions to roll back the flanges but nevertheless used the 22 NRR without such instructions to market the earplugs to the Government. 3M/Aearo were required to certify to the military that its earplugs had an accurate, properly tested NRR of “0”

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when worn in the open/unblocked position and an accurate, properly tested NRR of “22” when worn in the closed/blocked position.

39. The Salient Characteristics of the MPID required testing of the earplugs in compliance with ANSI S3.19-1974. MPID Section 2.2.2. 3M’s/Aearo’s testing failed to comply with ANSI S3.19-1974 because it initially tested only eight subjects on the closed end in contravention of the requirement to test no less than ten subjects on both ends. Additionally, as 3M/Aearo was aware prior to selling the earplugs to the military, 3M’s/Aearo’s testing failed to comply with ANSI S3.19-1974 because reported NRRs included test results from subjects for which 3M/Aearo knew there was not an adequate fit, thus making the result invalid. 3M/Aearo was nonetheless required to certify to the military that its testing of the earplugs complied with ANSI S3.19-1974 as required by the Solicitation.

40. The Salient Characteristics of the MPID also required that 3M/Aearo supply to the military earplugs that were “free from all defects that detract from their appearance or impair their serviceability.” MPID Section 2.4. 3M/Aearo knew as early as 2000 that its dual-ended Combat Arms™ earplugs were defectively designed with too short a stem that caused the plugs to imperceptibly loosen in the wearer’s ear when the flanges were not rolled back prior to insertion. 3M/Aearo was required to certify to the military that the earplugs were free of defects.

41. The Salient Characteristics of the MPID further required the provision of accurate “instructions explaining the proper use and handling of the ear plugs.” MPID Section 2.5. 3M’s/Aearo’s instructions for use of the earplugs do not instruct the wearer to fold back the flanges on the non-inserted end before inserting the other end of the plug into their ears (which 3M/Aearo knew was necessary to achieve the “22” NRR and avoid the defect associated with the short stem). 3M’s/Aearo’s instructions instead provide standard fitting instructions for inserting

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the earplug on both ends and are, therefore, inadequate to ensure a proper fit. 3M/Aearo was nonetheless required to certify to the military that the instructions for “proper use” of the earplugs are complete and accurate.

42. Each false statement alleged in this Count was knowingly presented, made, or used as the term “knowingly” is defined in 31 U.S.C. § 3729(b). The falsely obtained and reported NRR ratings, failure to comply with ANSI S3.19-1974, design defects requiring special fitting instructions, and the failure to provide such instructions were known to 3M/Aearo at least by 2000 when testing of the dual-ended Combat Arms™ earplugs was completed. 3M/Aearo therefore had actual knowledge of the falsity of its claims at the time it made them, but exercised deliberate indifference and reckless disregard toward such falsity in seeking payment under the IQCs awarded in connection with the RFPs.

43. 3M’s/Aearo’s false representations in being awarded the IQCs in response to the military’s RFPs were material to the Government’s decision to purchase the dual-ended Combat Arms™ earplugs. 3M’s/Aearo’s products were not eligible for such contracts unless they complied with the Salient Characteristics of the MPID. But for false certifications of compliance, the Government would not have awarded the contracts to 3M/Aearo and paid 3M’s/Aearo’s claims pursuant to the IQCs. 3M’s/Aearo’s actions therefore had a natural tendency to influence, or were capable of influencing, the payment or receipt of money.

44. As a result of required certifications, the Government did in fact award several IQCs for the purchase of dual-ended Combat Arms™ earplugs to 3M/Aearo, 3M’s/Aearo’s requests for payment under each of which constitutes a claim to the Government within the meaning of the FCA.

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45. The United States has been damaged as a result of 3M's/Aearo's violations of the FCA because it has received a product inferior to that which it specified and for which it paid. In addition to damages directly associated with the contractual cost of the earplugs, the United States has been damaged by the large and ongoing medical costs associated with treating veterans who likely suffered hearing damage and impairment as a result of the defective earplugs.

WHEREFORE, Plaintiff/Relator Moldex demands compensatory and multiple damages, costs, attorney fees, and such other legal and equitable relief as the Court may provide, including, but not limited to, exclusion or debarment.

COUNT II
False Claims Act – Use of False Statements
31 U.S.C. § 3729(a)(1)(B)

46. Plaintiff/Relator Moldex re-alleges and incorporates by reference the allegations contained in paragraphs 1-45.

47. As described above, Defendant 3M, by and through its predecessor Aearo, and their officers, agents, supervisors, and employees, knowingly made, used, or caused to be made or used false records or statements material to the United States Government's payment or approval of the false claims pursuant to multiple IQCs awarded under Solicitation Nos. SP0200-06-R-4202, SP0200-07-D-4103 and related solicitations for the supply of dual-ended Combat Arms™ earplugs to the military. Such false records or statements are in violation of 31 U.S.C. § 3729(a)(1)(B).

48. Each false record or statement alleged in this Count was knowingly presented, made, or used as the term "knowingly" is defined in 31 U.S.C. § 3729(b). The falsely obtained and reported NRR ratings, failure to comply with ANSI S3.19-1974, design defects requiring

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special instructions, and the failure to provide such instructions were known to 3M/Aearo before it was awarded the IQCs in response to each RFP. 3M/Aearo therefore had actual knowledge of the falsity of its claims at the time it made them, but exercised deliberate indifference and reckless disregard toward such falsity in seeking payment under the IQCs awarded in connection with the RFPs.

49. These required false statements in response to RFPs were material to the Government's decision to award 3M/Aearo the IQCs to purchase the dual-ended Combat Arms™ earplugs and its payments to 3M/Aearo. 3M's/Aearo's products were not eligible for such contracts unless they complied with the salient characteristics of the MPID. But for false certifications of compliance, the Government would not have awarded the contracts to 3M/Aearo and paid 3M's/Aearo's claims pursuant to the IQCs. 3M's/Aearo's actions therefore had a natural tendency to influence, or were capable of influencing, the payment or receipt of money.

50. As a result of these required fraudulent statements, the Government did in fact award several IQCs for the purchase of dual-ended Combat Arms™ earplugs, the RFP underlying each of which constitutes a false record or statement to the Government within the meaning of the FCA.

51. The United States has been damaged as a result of 3M's/Aearo's violations of the False Claims Act because it has received a product inferior to that which it specified and for which it paid. In addition to damages directly associated with the contractual cost of the earplugs, the United States has been damaged by the large and ongoing medical costs associated with treating veterans who likely suffered hearing damage and impairment as a result of the defective earplugs.

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WHEREFORE, Plaintiff-Relator Moldex demands compensatory and multiple damages, costs, attorney fees, and such other legal and equitable relief as the Court may provide, including, but not limited to, exclusion or debarment.

COUNT III
False Claims Act – Conspiracy
31 U.S.C. § 3729(a)(1)(C)

52. Plaintiff/Relator Moldex re-alleges and incorporates by reference the allegations contained in paragraphs 1-51.

53. Defendant 3M, by and through its predecessor Aearo, and their officers, agents, supervisors, and employees, conspired to defraud the United States Government in order to get false or fraudulent claims paid by the United States Government pursuant to multiple IQCs awarded under Solicitation Nos. SP0200-06-R-4202, SP0200-07-D-4103 and related solicitations for the supply of its dual-ended Combat Arms™ earplugs to the military. In furtherance of this conspiracy, 3M/Aearo and certain of its employees took substantial steps, as set forth above, to effect the objects of the conspiracy alleged herein. Such conspiracy is in violation of 31 U.S.C. § 3729(a)(1)(C).

54. At all relevant times, 3M/Aearo knew about, advanced, and conspired in directing and perpetuating the fraudulent conduct.

55. As a result of 3M/Aearo conspiring to submit required false, fraudulent claims pursuant to the IQCs to the United State Government, the United States Government paid 3M/Aearo based on these false claims.

56. The United States has been damaged as a result of 3M's/Aearo's violations of the FCA because it has received a product inferior to that which it specified and for which it paid. In addition to damages directly associated with the contractual cost of the earplugs, the United

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States has been damaged by the large and ongoing medical costs associated with treating veterans who likely suffered hearing damage and impairment as a result of the defective earplugs.

WHEREFORE, Plaintiff/Relator Moldex demands compensatory and multiple damages, costs, attorney fees, and such other legal and equitable relief as the Court may provide, including, but not limited to, exclusion or debarment.

COUNT IV
Unjust Enrichment

57. Plaintiff/Relator Moldex re-alleges and incorporates by reference the allegations contained in paragraphs 1-56.

58. By reason of the United States Government's payments pursuant to multiple IQCs awarded under to Solicitation Nos. SP0200-06-R-4202, SP0200-07-D-4103 and related solicitations for the supply of dual-ended Combat Arms™ earplugs to the military, 3M/Aearo received monies to which it was not entitled and has thereby been unjustly enriched to the detriment of the United States Government in an amount to be determined at trial.

WHEREFORE, Plaintiff/Relator demands compensatory damages, costs, attorneys fees, and such other legal and equitable relief as the Court may provide.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues triable by jury.

Date: May 11, 2016

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