December 14, 2020

The Honorable Annegret Kramp-Karrenbauer Federal Minister of Defence Fontainengraben 150 53123 Bonn Germany

Dear Minister Kramp-Karrenbauer,

We are writing on behalf of PETA U.S. and its more than 6.5 million members and supporters worldwide as well as PETA Germany in response to the Ministry of Defence's reply dated August 3, 2020, signed by Mr. Benner in the office of Dr. Rolf von Uslar (chief of branch FüSK San 1), regarding the use of live animals for trauma training (known as live tissue training, or LTT) in the Bundeswehr. As you know, to date more than 90,000 concerned people have written to the Ministry via our online action alerts to urge the Bundeswehr to switch to more modern and effective non-animal trauma training methods.

Based on the new information described below, we urge the Bundeswehr to end the use of live animals in LTT as part of its trauma training immediately or, at the very least, suspend this practice until the current review of non-animal training methods has been completed, in accordance with the European and German regulations that apply.

LTT Appears to Violate Directive 2010/63/EU and the German Animal Welfare Act

Article 4(1) of Directive 2010/63/EU on the protection of animals used for scientific purposes states, "Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure."¹

The German Animal Welfare Act states, "When deciding whether an animal experiment is indispensable and when carrying out animal experiments, the following principles must be observed: [...] It must be

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¹ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. *Official Journal of the European Union*. L 276/33-79. <u>https://eur-lex.europa.eu/legal-</u> content/EN/TXT/?uri=celex%3A32010L0063.

checked whether the intended purpose can be achieved by other methods or processes."2

Animal experiments cannot be justified as indispensable on the basis of saving time, money, or effort.³ If experimenters don't wish to carry out several non-animal experiments in order to avoid a single animal procedure, the study should be redesigned.⁴

Both EU Directive 2010/63/EU and the German Animal Welfare Act require the explicit assessment – *prior* to the approval of an animal experimentation protocol – of whether the intended purpose can be achieved using a non-animal method achieves satisfactory results or other methods or processes are required.

As you know, PETA U.S. and PETA Germany have been in contact with the Ministry of Defence and the Bundeswehr for years about this troubling matter. On August 3, 2020, the Ministry told us, "[R]esearch into suitable alternatives to live-tissue training is a matter of exceptional urgency to the Minister and all Bundeswehr personnel involved. The alternatives you cited are also being examined."⁵ The Ministry further stated, "[W]e need to maintain live tissue training at present because the Bundeswehr has not yet identified adequate alternative methods."⁶ Separately, the Bundeswehr Medical Service Command recently informed the Bundestag Defense Committee, "A possible replacement for training on living animals (live tissue training) is currently being intensively examined at various levels."⁷ It is important to view these statements in the context of applicable European and German regulations, respectively.

Since the Bundeswehr Medical Service Command acknowledges that it is currently still in the process of intensively examining a possible replacement for LTT, this review has not yet been completed. As such, there is no substantive and comprehensive evidence that a scientifically satisfactory method or experimental strategy that does not use live animals for trauma training is unavailable at the moment. We therefore ask you to reject all use of animals in LTT for trauma training or, at the very least, suspend this practice until the current review of non-animal methods has been completed.

Proven Animal-Free Trauma Training Methods Are Available

As explained above, according to EU and national regulations, animals may be used only as a last resort, i.e., if the intended purpose cannot be achieved by other methods or processes. This is not the case for LTT in trauma training. Again, we refer you to the innovative, animal-free training methods of which we informed you in our letter of August 14, 2019 (see Appendix A).

In its letter to PETA U.S. dated October 1, 2019, the Bundeswehr committed to a "thorough examination"⁸ of the non-animal trauma training methods that we had proposed. When we wrote to you on June 12 to follow up on this matter, we asked that you "please confirm whether each of

² Animal Welfare Act (TierSchG), Section 7a, Art. 2. <u>https://www.gesetze-im-internet.de/tierschg/BJNR012770972.html</u>.

³ VG Hanover ruling, September 30, 2013, Az .: 11 A 3671/11.

⁴ Hirt/Maisack/Moritz, Commentary on the Animal Welfare Act, 3rd edition, 2016, § 7a TierSchG, Rn. 11.

⁵ Ministry of Defence. Letter to PETA U.S., August 3, 2020.

⁶ Ibid.

⁷ Bundeswehr Medical Service Command. Reply to the Bundestag Defence Committee, September 10, 2020.

⁸ Ministry of Defence. Letter to PETA U.S., October 1, 2019.

the non-animal models described above has been evaluated for replacing animal use in LTT and, if so, when each evaluation was conducted, who conducted it, and the result. If any of them have not been evaluated, please explain why not."⁹ In its reply to PETA dated August 3, the Ministry simply noted, "The alternatives [PETA] cited are also being examined,"¹⁰ but it did not give further details in response to the questions we had asked. It is unclear which specific non-animal models the Ministry is evaluating as replacements for LTT.

As long as non-animal training methods are still under review, it is impossible to determine definitively that the Bundeswehr's current use of animals in LTT is indispensable—even though doing so *before* proceeding with the use of animals in experimentation (including LTT) is mandatory under Directive 2010/63/EU and the German Animal Welfare Act. Therefore, we urge you to end all use of animals in LTT for trauma training or, at the very least, suspend this practice until the current review of non-animal methods has been completed.

Furthermore, it is important to note that ignorance of a scientifically satisfactory method or experimental strategy in which no live animals are used – including animal-free methods of which the Ministry may be unaware owing to inadequate literature searches – is *not* listed by Directive 2010/63/EU and the German Animal Welfare Act as a justification for the further use of live animals. Without knowing the full scope of non-animal trauma training methods that the Ministry is evaluating as replacements for animal use in LTT, it is unclear whether the Ministry's search for and evaluation of all possible non-animal trauma training methods are exhaustive and complete.

Researchers at the Bundeswehr Hospital Berlin itself openly admitted in a 2018 study that "training technically demanding maneuvers that require an exact human anatomy ... can currently ... be achieved by [human cadavers]."¹¹

Studies Underscore the Advantages of Using Non-Animal Simulation Models

In our letters to the Ministry dated August 14, 2019, and June 20, 2020, we cited numerous studies showing that non-animal simulation models offer many advantages over using animals in LTT (see Appendix B). In its reply to PETA, the Ministry notably did not refute any of the findings from these studies, which confirm the realism, efficacy, and superiority of animal-free trauma training methods along with the lack of substantive and verifiable evidence that LTT improves patient outcomes.

Classification of LTT as Ethically and Scientifically Unjustifiable

The Bundeswehr Medical Service Command wrote in its recent reply to the Defense Committee of the Bundestag, "An external group of experts, including representatives of the Military Medical Advisory Board, agreed that the Bundeswehr medical service was medically and

⁹ PETA U.S and PETA Germany. Letter to the Ministry of Defence, June 12, 2020.

¹⁰ Ministry of Defence. Letter to PETA U.S., August 3, 2020.

¹¹ Schneider K, Willmund G, Back DA, *et al.* Technische Simulationsmodelle in der notfallchirurgischen Ausbildung—eine Alternative zu Live Tissue Training und humanen Präparaten? *Wehrmedizinische Monatsschrift.* 2018. <u>https://wehrmed.de/article/3582-technische-simulationsmodelle-in-der-notfallchirurgischen-ausbildung-eine-alternative-zu-live-tissue-training-humanen-praeparaten.html.</u>

ethically responsible for the use of animals in military medical research as well as in the medical service training, further education and training."¹²

As we pointed out to you in our letter dated June 12, 2020, independent ethical assessments confirm that LTT is not ethical, given the current availability of non-animal trauma training methods, and there are regulatory, political, and legal precedents in Germany for opposing LTT (see Appendix C).

Furthermore, in a September 9, 2020, report issued by a NATO Human Factors and Medicine Research Task Group – in which Germany is listed as one of the core members – the authors openly admit that there are numerous ethical and other issues associated with LTT, including the following:

- LTT "[r]equires [a] [v]eterinarian and trained technician to monitor anaesthesia," which undermines the realism of this training, since these personnel would obviously not be present on the battlefield when the trainees treat human trauma-injury victims.
- LTT involves using "[a]naesthetized" animals, whereas on a battlefield, injured humans may be conscious, terrified, and moving around while medical treatment is administered.
- For LTT, the "[a]natomy [of animals is different from humans] (landmarks are slightly different)," which makes the skills learned on pigs difficult to translate or apply to human patients.
- The animals used for LTT are "not as large as humans," which makes the skills learned on pigs difficult to translate or apply to human patients.
- For LLT, there is a high "[c]ost and infrastructure [required] to house" animals.
- There are "[e]thical questions/concerns about proper use and care of animals."
- The "[s]imulation [of human traumatic injuries using wounded animals is] limited by maintenance of anaesthesia (e.g., staff must be nearby monitoring)."¹³

Clearly, these issues contradict the Ministry's argument that the use of animals in LTT is "medically and ethically responsible."

Request for Action

The Ministry of Defence responded to PETA in 2017, stating, "The training of 18 surgeons per year for the entire Bundeswehr requires a maximum of twelve pigs. ... [It] is our ultimate goal to abandon live tissue training entirely as soon as suitable simulation models are available. ... We are open to a further exchange of ideas and conversations regarding this topic"¹⁴

It is unacceptable for any animal still to be used and killed for the Bundeswehr's LTT, given the information presented in this letter and the enclosed appendices and considering the context of German and EU regulations that mandate the use of non-animal methods that are already widely available and in use by militaries in other peer nations.

¹² Bundeswehr Medical Service Command. Letter to the Bundestag Defence Committee, September 10, 2020. ¹³ NATO STO. Technology alternatives for medical training: Minimizing live tissue use. Final report of Task Group HFM-242. Published September 2020. <u>https://www.sto.nato.int/publications/STO%20Technical%20Reports/STO-</u> <u>TR-HFM-242/\$\$TR-HFM-242-ALL.pdf</u>.

¹⁴ Ministry of Defense. Letter to PETA, March 17, 2017.

The Ministry of Defence has not shown that its use of animals in LTT in the context of trauma training is indispensable. As such, we urge your office to prohibit all current and future use of animals for LTT in accordance with Directive 2010/63/EU and the German Animal Welfare Act.

You may contact me via e-mail at <u>ShalinG@peta.org</u>. Thank you for your consideration. Please respond by November 30, 2020.

Sincerely yours,

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Anne Meinert Campaigner, Animal Experiments PETA Deutschland e.V.

Enclosures: Appendix A: Proven Animal-Free Trauma Training Methods Are Available Appendix B: Studies Underscore the Advantages of Using Non-Animal Simulation Models Appendix C: Classification of LTT as Ethically and Scientifically Unjustifiable

Appendix A: Proven Animal-Free Trauma Training Methods Are Available

- Researchers at the Bundeswehr Hospital Berlin openly admitted in a 2018 study that "training technically demanding maneuvers that require an exact human anatomy ... can currently ... be achieved by [human cadavers]."¹⁵
- The Human Worn Partial Task Surgical Simulator (Cut Suit) is a "realistic surgical training tool that allows for the simulated performance of actual surgical procedures. In addition to perfused extremities, the Cut Suit also has perfused internal organs that may be accessed through the abdominal wall and can be incised to bleed and repaired or excised to control hemorrhage."¹⁶
- High-fidelity human cadaver models are used in the Major Incident Surgical and Trauma Teams (MISTT) Trauma Course held at the Queen Elizabeth Hospital Birmingham in the U.K.¹⁷ and are mentioned in a 2018 study from the U.S. Navy Trauma Training Center, which states, "Preliminary data highlights the utility for open vascular, thoracic and other high acuity/low volume procedures critical to combat casualty care."¹⁸
- High-fidelity simulation models include the surgical anatomy model (SAM), whose use was described by representatives of the U.K.'s Royal Army Medical Corps and Royal Navy in a 2016 study: "During damage-control surgery using the SAM, the materials and anatomical details have simulated human blast injury with fidelity that may be superior to cadaveric and animal models."¹⁹

¹⁵ Schneider K, Willmund G, Back DA, Maaz A, Peters H, Lieber A, Hauer T. Technische Simulationsmodelle in der notfallchirurgischen Ausbildung—eine Alternative zu Live Tissue Training und humanen Präparaten? *Wehrmedizinische Monatsschrift*. 2018. <u>https://wehrmed.de/article/3582-technische-simulationsmodelle-in-der-notfallchirurgischen-ausbildung-eine-alternative-zu-live-tissue-training-humanen-praeparaten.html</u>.

¹⁶ Kirkpatrick AW, LaPorta A, Brien S, *et al.* Technical innovations that may facilitate real-time telementoring of damage control surgery in austere environments: A proof of concept comparative evaluation of the importance of surgical experience, telepresence, gravity and mentoring in the conduct of damage control laparotomies. *Can J Surg.* 2015;58(3 Suppl 3):S88-S90. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4467498/</u>.

¹⁷ Major Incident Surgical and Trauma Teams. The MISTT trauma course. <u>https://www.mistt.co.uk/index.html</u>.
¹⁸ Polk TM, Grabo DJ, Minneti M, Inaba K, Benjamin ER, Demetriades D. Initial report on a damage control surgery course for military forward surgical teams utilizing a novel perfused cadaver model for training and evaluation. *J Am Coll Surg*. 2018;227(4 Supp 2):E40. <u>https://www.journalacs.org/article/S1072-7515(18)31238-9/fulltext</u>.

¹⁹ Naumann DN, Bowley DM, Midwinter MJ, Walker A, Pallister I. High-fidelity simulation model of pelvic hemorrhagic trauma: The future for military surgical skills training? *Mil Med*. 2016;181(11):1407-1409. https://www.ncbi.nlm.nih.gov/pubmed/27849473.

Appendix B: Studies Underscore the Advantages of Using Non-Animal Simulation Models

- A 2018 study found that "[h]igh-fidelity simulation offers many advantages, including broad exposure to procedures, their complications, and the opportunity for repetitious learning in a non-clinical setting" and that "[s]ynthetic models can produce a stress response equivalent to that of live tissue during simulation training." At that time, this was the largest study indicating that "synthetic models produce a sufficient immersive and realistic experience for trainees."²⁰
- A 2020 study published in *Trauma Surgery & Acute Care Open* examined the training of U.S. Navy and U.S. Army surgical teams involving the above-mentioned Cut Suit. The authors found that simulation training enhances team performance, i.e., "improves surgical procedures and processes." The paper concludes, "High fidelity surgical simulation equipment such as the ... "Cut Suit" combined with highly realistic replicated settings will allow surgical trauma teams to improve their life-saving skills and teamwork communication to maximize successful patient outcomes. High fidelity, highly realistic, immersive and stress-provoking surgical trauma training is now an option to improve the readiness and capabilities of trauma teams."²¹
- A 2016 study in the *Journal of the Royal Army Medical Corps* states that the Danish LTT course (which is similar to the Bundeswehr's course) uses pigs, whose anatomy differs from that of humans: "Training courses based on animal models (Exercise Surgical Training Denmark) and cadavers (the Military Operational Surgical Training course) have been used extensively to prepare surgeons for deployment in recent conflicts. However, they are expensive and provide a one-off opportunity to practice advanced techniques in models that are either anatomically incorrect (pigs) or have altered tissue characteristics with no vascular perfusion (cadavers). [Instead, a]bdominal multivisceral organ retrieval [in clinical settings] is the ultimate laparotomy and takes the surgeon to parts of the retroperitoneum and thorax otherwise not seen during standard surgical training. ... From April 2012 to April 2013, there were 2748 retrievals carried out by the 8 UK abdominal retrieval teams. The number of retrievals has increased by 50% between 2010 and 2014, and it is predicted to increase by a further 50% by 2020."²² The use of this approach in Germany as an alternative to LTT for training and maintaining the skills of military surgeons is feasible.
- In addition, a 2019 study in the *Journal of Surgical Education* states that the purported benefits of LTT to patient outcomes are unsubstantiated: "[N]o published evidence from prospective controlled trials exists suggesting that surgical skills training courses change trauma patient outcome, or improve performance of the skills taught, when performed in the real-world operating room. ... Published evidence of course training benefit was not identified for many established courses including: Definitive Surgical Trauma Skills, Emergency Management of Battlefield Injuries, Endovascular Skills for Trauma and

²⁰ Keller J, Hart D, Rule G, Bonnett T, Sweet R. The physiologic stress response of learners during critical care procedures: Live tissue vs synthetic models. *Chest*. 2018;154(4):229A. <u>https://journal.chestnet.org/article/S0012-3692(18)31402-8/fulltext</u>.

²¹ Hoang TN, LaPorta AJ, Malone JD, *et al.* Hyper-realistic and immersive surgical simulation training environment will improve team performance. *Trauma Surg Acute Care Open.* 2020;5(1):e000393. https://tsaco.bmj.com/content/5/1/e000393.

²² O'Reilly D, Lordan J, Streets C, Midwinter M, Mirza D. Maintaining surgical skills for military general surgery: The potential role for multivisceral organ retrieval in military general surgery training and practice. *J R Army Med Corps*. 2016;162(4):236-238. <u>https://pubmed.ncbi.nlm.nih.gov/26243807/</u>.

• Resuscitative Surgery, Emergency War Surgery Course (EWSC), Military Operational Surgical Training, Specialty Skills in Emergency Surgery and Trauma, Surgical Training for Austere Environments, or Surgical Trauma Response Techniques"—all of which, according to the paper, "used live tissue (usually porcine)."²³ Article 4(1) of Directive 2010/63/EU on the protection of animals used for scientific purposes calls for scientific judgment on whether a given method or testing strategy will achieve results in a satisfactory manner. The lack of substantive and verifiable evidence that LTT improves patient outcomes means that it fails the standard set by the Directive of using a "scientifically satisfactory method."²⁴

²³ Mackenzie CF, Tisherman SA, Shackelford S, Sevdalis N, Elster E, Bowyer MW. Efficacy of trauma surgery technical skills training courses. *J Surg Educ.* 2019;76(3):832-843. https://www.sciencedirect.com/science/article/abs/pii/S1931720418305506?via%3Dihub.

²⁴ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the Protection of Animals Used for Scientific Purposes. *Official Journal of the European Union*. L 276/33-79. <u>http://eur-lex.europa.eu/Lex.UriServ/Lex.UriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF</u>.

Appendix C: Classification of LTT as Ethically and Scientifically Unjustifiable

- An independent, peer-reviewed study published by German scientists has shown that the use of animals in such trauma training is ethically unacceptable. The researchers concluded, "A close examination of the evidence base for the presumed advantages of LTT showed that it is not superior to simulation-based methods in terms of educational benefit. Since credible alternatives that do not cause harm to animals are available, we conclude that LTT on animal models is ethically unjustified."²⁵
- A plenary report by the Christian Democratic Union Thuringia describes LTT as the "mutilation of living animals without there being any scientific need for this."²⁶
- PETA U.S. successfully persuaded German regulators to block repeated applications by U.S. Army Europe to conduct LLT with US service members stationed in Germany, on the grounds that such invasive and lethal exercises would violate the German Animal Welfare Act.²⁷
- Gera Administrative Court declared in 2012 in case 1 K 584/11 Ge that it is legally forbidden to train medical personnel who are deployed in warzones and other crisis areas using "anesthetized pigs that were previously supposed to have been inflicted with typical war injuries." In addition, the competent licensing authority, the Thuringian State Office for Consumer Protection, was of the opinion that "such animal experiments are not necessary within the meaning of the Animal Welfare Act. In particular, there are alternative training options, such as on dummies, i.e., training dummies on which the treatment of injuries can easily be practiced in a realistic manner. This was confirmed by the experts questioned by the Chamber."²⁸
- Animal-free methods are available and are already used by almost three-quarters of all NATO countries in their military medical training programs.²⁹ This represents independent assessments by various experts worldwide underscoring that non-animal training methods can replace the use of animals in LTT. (You'll see that Germany was originally included in this study as a nation that does not use animals for military medical training, based on written statements that the Bundeswehr made to PETA U.S. in 2010. However, in 2017, Lieutenant General Dr. Michael Tempel in the Bundeswehr Medical Service Command wrote to PETA U.S. at the direction of former Minister Ursula von der Leyen to "formally apologise for the misunderstandings in [the military's] communication so far with regard to

²⁵ Rubeis G, Steger F. Is live tissue training ethically justified? An evidence-based ethical analysis. *Aging Lab Anim.* 2018;46(2):65-71. <u>https://www.ncbi.nlm.nih.gov/pubmed/29856644</u>.

²⁶ Kowalleck M. Current plenary report of the CDU parliamentary group: An overview of all topics and debates. Maik-Kowalleck.de. October 14, 2011. <u>https://www.maik-kowalleck.de/lokal_1_1_203_Aktueller-Plenarbericht-der-CDU-Fraktion-Alle-Themen-und-Debatten-im-Ueberblick.html</u>.

²⁷ Montgomery N. Germany again shoots down U.S. Army Europe's live-tissue training. *Stars and Stripes*. October 28, 2010.

https://www.stripes.com/news/germany-again-shoots-down-u-s-army-europe-s-live-tissue-training-1.123395. ²⁸ Amelung B. Gera Administrative Court. Press release from October 2, 2012, on case 1 K 584/11

Ge. http://www.thovg.thueringen.de/webthfj/webthfj.nsf/6C447206B6A89D0FC1257A8D003148C1/\$File/2880384 0.pdf?OpenElement.

²⁹ Gala SG, Goodman JR, Murphy MP, Balsam MJ. Use of animals by NATO countries in military medical training exercises: An international survey. *Mil Med*. 2012;177(8):907-910. <u>https://www.piscltd.org.uk/wp-content/uploads/2014/10/use-of-animals-by-nato-countries-in-military-medical-training-exercises-military-medicine-aug-2012_-gala-et-al.pdf</u>.

- this particular form of training,"³⁰ acknowledging that the Bundeswehr does, indeed, participate in LTT.)
- The Polish military replaced its use of animals in trauma training drills in 2013 with modern, superior simulation models after hearing from PETA U.S.³¹
- The U.S. Coast Guard became the first branch of the U.S. military to end all use of animals in LTT a practice that then-Commandant Adm. Paul Zukunft described before a U.S. House of Representatives committee as being "abhorrent" after the agency reviewed available non-animal training methods.³²

³⁰ Ministry of Defence. Letter to PETA U.S., March 17, 2017.

 ³¹ PETA U.S. PETA campaign prompts Polish military to end deadly animal labs. Press release, November 20,
 2013. <u>https://www.peta.org/media/news-releases/peta-campaign-prompts-polish-military-end-deadly-animal-labs/</u>.
 ³² Hodge Seck H. Coast Guard puts permanent end to wounding animals for training. Military.com. March 20, 2018. https://www.military.com/daily-news/2018/03/20/coast-guard-puts-permanent-end-wounding-animals-training.html.