June 12, 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 People for the Ethical Treatment of Animals (PETA)—which has more than 6.5 million members and supporters around the world—and PETA Germany in reference to the response that Dr. Rolf von Uslar of the German Ministry of Defence sent to PETA on October 1, 2019, regarding the use of animals in live tissue training (LTT) for Bundeswehr military surgeons. As we stated in our letter of August 14, 2019, LTT does not offer a realistic or relevant representation of the human condition. In addition to the evidence that we have already provided, we hope you will be interested in the more recent pertinent research that we describe below, which confirms the superior efficacy of non-animal trauma training methods and the lack of substantiation that using LTT results in improved patient outcomes.

As such, we strongly urge you to reconsider your position and end the Bundeswehr's use of LTT in favor of widely available nonanimal trauma training methods that are already used to train thousands of troops by the nearly three-quarters of NATO member states that don't use animals for military medical training.¹

Again, we want to refer to the Ministry of Defence's letter to PETA dated March 17, 2017: "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." Given that only a small number of animals are used for LTT, there is no compelling justification for using any.

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¹Gala 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.

https://www.researchgate.net/publication/230767180_Use_of_Animals_by_NATO_C ountries in Military Medical Training Exercises An International Survey.

Regarding the Bundeswehr's use of LTT—in what Dr. Jens Diehm of the German Ministry of Defence told PETA in a letter dated September 5, 2018, was "for training surgeons in preparation for operations abroad, i.e. highly qualified medical specialists, to perform life-saving emergency surgical procedures,"—we presented you with the following non-animal trauma training methods in our letter of August 14, 2019:

- 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."²
- 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.³ and also mentioned in a 2018 study from the 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."⁴
- 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."⁵

As described in its letter to PETA dated October 1, 2019, the Bundeswehr committed to a "thorough examination" of these non-animal trauma training methods that we proposed in our August 14, 2019, letter. We ask that you please confirm whether *each* of 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.

In our letter of August 14, 2019, we also summarized numerous findings that underscore the advantages of using non-animal simulation models. In short, they are able to provide a realistic adrenergic response in trainees. A 2018 study found that "[h]igh-fidelity simulation offers many advantages, including broad exposure to procedures, their

³Major Incident Surgical and Trauma Teams The MISTT Trauma Course. <u>https://www.mistt.co.uk/index.html</u>.

²Kirkpatrick 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. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4467498/.

 ⁴Polk TM, Grabo DJ, Minneti M, *et al.* 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 Surgeons.* 2018;227(4 Supp 2):E40. <u>https://www.journalacs.org/article/S1072-7515(18)31238-9/fulltext.</u>
⁵Naumann 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.

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."⁶ In addition, we cited a 2018 study from Ulm University that 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."⁷

We can now complement these findings with recent studies that highlight the utility and suitability of non-animal trauma training methods:

- 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 teams."⁸
- 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."⁹ The use of this approach in

⁶Keller 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. https://journal.chestnet.org/article/S0012-3692(18)31402-8/fulltext.

⁷Rubeis G, Steger F. Is live-tissue training ethically justified? An evidence-based ethical analysis. *Altern Lab Anim.* 2018;46(2):65-71. <u>https://www.ncbi.nlm.nih.gov/pubmed/29856644</u>.

⁸Hoang 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.

⁹O'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>.

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 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)."¹⁰ 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."11

Further, we wish to remind you of important regulatory, political, and legal precedents in Germany for opposing LTT:

- In 2010, PETA persuaded German regulators to block applications repeatedly from U.S. Army Europe to conduct LLT with U.S. servicemembers stationed in Germany on the grounds that such invasive and lethal exercises would violate the German Animal Welfare Act.¹²
- In 2011, a Thuringia plenary report from your political party, the Christian Democratic Union of Germany (CDU), described LTT as "the mutilation of living animals without there being a scientific need for it."¹³
- On October 2, 2012, a chief justice of an administrative court in Gera (Thuringia) issued a news release (regarding court proceedings 1 K 584/11 Ge) stating that a trauma training contractor "is prohibited from training paramedics for war zones and other crisis areas on anesthetized pigs inflicted with injuries typical of war prior to the training" and that Thuringia's State Office for Food Safety and Consumer Protection

¹⁰Mackenzie 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. ¹¹Directive 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. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF.

¹²Montgomery N. Germany again shoots down U.S. Army Europe's live-tissue training. *Stars and Sripes*. October 28, 2010.

https://www.stripes.com/news/germany-again-shoots-down-u-s-army-europe-s-live-tissue-training-1.123395.

¹³Christian Democratic Union. Aktueller Plenarbericht der CDU-Fraktion: Alle Themen und Debatten im Überblick. Neues von Maik Kowalleck. 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>.

"is of the opinion that such tests on animals are not necessary, according to the Animal Welfare Act, especially as alternative methods of training are available, e.g. on dummies, or manikins, which can be used to practice the treatment of injuries in a realistic manner."¹⁴

Based on the information above, the availability of non-animal training methods, the lack of evidence that LTT results in improved patient outcomes, and the established precedents against LTT in Germany, we again urge the Bundeswehr to fulfill its ethical, scientific, and legal responsibilities and end its use of LTT. Switching to state-of-the-art, non-animal trauma training methods provides a great opportunity for the Bundeswehr to show leadership in innovative, high-tech solutions for medical training issues.

You may contact me via e-mail at <u>ShalinG@peta.org</u>. Thank you for your consideration. I look forward to your response.

Sincerely yours,

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Encl.: PETA's letter to Annegret Kramp-Karrenbauer dated August 14, 2019

¹⁴Amelung B. Presserklärung vom 2. Oktober 2012 zum Verfahren 1 K 584/11 Ge. Gera Administrative Court. October 2, 2012.

http://www.thovg.thueringen.de/webthfj/webthfj.nsf/6C447206B6A89D0FC1257A8D003148C1/\$File/288 03840.pdf?OpenElement.