October 30, 2019

The Honorable William P. Barr United States Attorney General c/o Brian Rabbitt, Chief of Staff U.S. Department of Justice 950 Pennsylvania Avenue, NW Washington, DC 20530-0001

Via e-mail:

Dear Attorney General Barr:

Thank you in advance for your time. I am writing to you on behalf of PETA and our more than 6.5 million members and supporters worldwide regarding recent disturbing taxpayer-funded awards issued by the Federal Bureau of Investigation (FBI) and the United States Marshals Service (USMS) for cruel and deadly trauma training drills on animals (otherwise known as live tissue training or LTT), in which live animals are typically shot, stabbed, dismembered and killed.

In light of apparent noncompliance with regulations by LTT contractors used by the DOJ, the availability of superior human patient simulators, the U.S. Coast Guard's decision to end its LTT in favor of non-animal training methods, and President Donald Trump's approval of the new requirement to use simulators "to the maximum extent practicable," we urge you to end the DOJ's use of animals in trauma training.

2019 DOJ Awards for LTT, and Contractor Noncompliance

The USMS awarded \$86,898.00 to The Tactical Development Group, LLC (dba Allegiance) for a contract from May 9, 2019, through September 30, 2019, for USMS Special Operations Group (SOG) Camp Beauregard to undergo "LTT for SOG New Operator Class (NOC) and SOG Mandatory recertification training (MRT)."¹ Per the U.S. Department of Agriculture's (USDA) website that lists registered research facilities that are permitted to conduct regulated activities (including LTT) on animals,² The Tactical Development Group, LLC and Allegiance do not appear to have any active USDA registrations and no indication is given that they are conducting LTT as part of another party's registration. If corroborated, this may violate the federal Animal Welfare Act.

The FBI awarded \$22,594.00 to Assessment and Training Solutions Consulting Corp. (ATSCC) for a contract from June 27, 2019, through August 12, 2019,³ for "Tactical First Responder Training" for the agency's Counterterrorism Division (CTD) Fly Team (FTMU) agents, which involved a "live patient model" (e.g.,



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¹ USASpending.gov. Retrieved from https://www.usaspending.gov/#/award/88015821

² USDA APHIS (2019, October 25) *Listing of Certificate Holders*. Retrieved from <u>https://www.aphis.usda.gov/animal_welfare/downloads/List-of-Active-Licensees-and-Registrants.pdf</u>

³ USASpending.gov. Retrieved from https://www.usaspending.gov/#/award/87385661

animals) being subjected to harmful "battlefield injury scenarios."⁴ In the written "justification" for this award, the FBI stated that "ATSCC is a USDA Class R research facility and for the past 10 years received no adverse action from the USDA."⁵ <u>However, ATSCC has been cited by the USDA multiple times for apparent violations of the federal Animal Welfare Act, including on January 19, 2011 (an "Official Warning"), August 14, 2014, and September 21, 2015. In 2015 following a PETA complaint, Virginia officials issued a cease-and-desist notice to ATSCC's CEO John Janota, stating he could longer use his property to conduct LTT since it isn't zoned for such activities.⁶</u>

Live Tissue Training is Unethical and Unrealistic

A 2018 peer-reviewed study stated, "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

A 2016 study regarding the use of animals in military LTT found "[t]here is a need to replace LTT with other educational methods such as simulation,"⁸ and the authors cite growing concern for animal welfare, the problems with expensive purpose-built laboratories, and the fact that militaries from many countries do not use animals for medical training. Other studies have found that human simulators teach emergency medical procedures as well as or better than animal-based laboratories.^{9,10,11,12,13}

It is ethically wrong to subject live animals to battlefield traumatic injuries, especially when sufficient non-animal training methods exist and are already in use by other military medical programs.

This use of animals is also highly unrealistic for teaching battlefield trauma management, as the use of anesthesia invalidates live animals as realistic "models" for battlefield medical training. Animals under anesthesia do not experience stress or present symptoms of stress, e.g. elevated heart rate and blood pressure, hyperventilation, and more. These are important medical factors that could alter the course and procedures needed for managing trauma such as the speed of blood loss, medications needed, and other countermeasures that trainees need to learn. Intubated pigs attached to assisted breathing machines simply do not mimic actual war and terror victims.

⁴ FBI. *Justification for Limited Competition/Simplified Acquisition*. Retrieved from https://www.fbo.gov/utils/view?id=d11bba8976fb61f688e2bff409e18f84

⁵ FBI. Justification for Limited Competition/Simplified Acquisition. Retrieved from https://www.fbo.gov/utils/view?id=d11bba8976fb61f688e2bff409e18f84

⁶ Mather, M. 2015, November 25. *City leaders: Suffolk land cannot be used for military trauma training without proper permits.* Retrieved from

https://wtkr.com/2015/11/25/city-leaders-suffolk-land-cannot-be-used-for-military-trauma-training-without-proper-permits/

⁷ Rubeis, G., & Steger, F. (2018). Is live-tissue training ethically justified? An evidence-based ethical analysis. *Alternatives to Laboratory Animals*, *46*(2), 65-71.

⁸ Silverplats, K., Jonsson, A., & Lundberg, L. (2016). A hybrid simulator model for the control of catastrophic external junctional haemorrhage in the military environment. *Advances in Simulation*, 1(1), 5.

⁹ Ali, J., Sorvari, A., & Pandya, A. (2012). Teaching emergency surgical skills for trauma resuscitation-mechanical simulator versus animal model. *ISRN Emergency Medicine*, 2012.

¹⁰ Sergeev, I., Lipsky, A. M., Ganor, O., Lending, G., Abebe-Campino, G., Morose, A., ... & Glassberg, E. (2012). Training modalities and self-confidence building in performance of life-saving procedures. *Military medicine*, *177*(8), 901-906.

¹¹ Bowyer, C. M. W., Liu, A. V., & Bonar, J. P. (2005). Validation of SimPL-a simulator for diagnostic peritoneal lavage training. *Studies in health technology and informatics*, *111*, 64-67.

 ¹² Sweet R. (2014). Comparing Live Animal and Simulator Alternatives for Training and Assessing Hemorrhage and Airway Procedures in a Tactical Field Situation [presentation]. Fort Lauderdale, Fla.: Military Health System Research Symposium.
¹³ Savage E. (2014). A Comparison of Two Medical Training Modalities for CAF Medical Technicians: Live Tissue Training and High Fidelity Patient Simulator [presentation]. Fort Lauderdale, Fla.: Military Health System Research Symposium.

Simulating the stressful scenario is equally important from the trainees' perspective, and this can be provided by advanced human patient simulators. A 2018 study states: "High-fidelity simulation offers many advantages, including broad exposure to procedures, their complications, and the opportunity for repetitious learning in a non-clinical setting. The stress of learners undergoing simulation events is a growing field of interest. Proponents of training with live-anesthetized animals argue the associated stress response cannot be equated with inanimate models, and therefore leads to an inferior learning experience with negative implications for future performance. ... A randomized controlled study of 277 army combat medics was performed comparing procedural training and assessment on a live tissue (LT) goat model versus the best-in-class synthetic training models (STM). ... No significant differences were seen for peak stress response of salivary cortisol or amylase, regardless of LT or STM method for training or assessment. In addition, the stress response did not correlate significantly with total performance score. ... Synthetic models can produce a stress response equivalent to that of live tissue during simulation training. This is the largest study to date indicating synthetic models produce a sufficient immersive and realistic experience for trainees. ... Stress inoculation while learning critical medical procedures can be achieved with synthetic models. Training programs may be able to reduce the use of live animals for training without sacrificing educational quality."¹⁴

It is more realistic to train on models that have correct human anatomy and are not intubated or anesthetized, and this can be achieved effectively and ethically using human patient simulation.

Non-Animal Training Methods Are Widely Available and Validated

There are numerous human patient simulators – such as Simulab Corporation's TraumaMan system,¹⁵ Strategic Operations' Cut Suit,¹⁶ CAE Healthcare's Caesar,¹⁷ Kforce Government Solutions' Multiple Amputation Trauma Trainer¹⁸ and Laerdal Medical's cadre of life-like military-focused manikins,¹⁹ and many more – that faithfully replicate human anatomy and physiology and can replace LTT in full.

Numerous studies also validate the use of various non-animal trauma training methods:

Human Worn Partial Task Surgical Simulator (Cut Suit)

• A 2015 review article found that 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" and "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. The Cut Suit is regularly being upgraded and in the near future will be equipped with specific in-line flow sensors that will permit an accurate calculation of simulated blood loss during different procedures and situations and with different surgeons."²⁰

¹⁴ Keller, J., Hart, D., Rule, G., Bonnett, T., & Sweet, R. (2018). The physiologic stress response of learners during critical care procedures: live tissue vs synthetic models. *Chest*, *154*(4).

¹⁵ Simulab Corporation. *TraumaMan Surgical Simulator*. Retrieved from http://www.simulab.com/product/surgery/open/traumaman-system

¹⁶ Strategic Operations. Surgical Cut Suit. Retrieved from <u>http://www.strategic-operations.com/products/surgical-cut-suit</u>

¹⁷ CAE Healthcare. CAE Caesar. Retrieved from https://caehealthcare.com/patient-simulation/caesar/

¹⁸ Trauma F/X Solutions. Retriever from <u>https://traumafx.net/home/</u>

¹⁹ Laerdal Medical. *Military Training Solutions*. Retrieved from <u>http://www.laerdal.com/us/military</u>

²⁰ Kirkpatrick, M. A. W., LaPorta, A., Brien, S., Leslie, T., Glassberg, C. E., McKee, J., ... & Tien, C. H. (2015). Technical innovations that may facilitate real-time telementoring of damage control surgery in austere environments: a proof of concept

• A 2017 study stated, "Remote damage control resuscitation (RDCR) endeavours to rescue the most catastrophically injured, but has not focused on prehospital surgical torso hemorrhage control (HC). ... A surgical simulator was customized with high-fidelity intraperitoneal anatomy, a "blood" pump and flowmeter. A standardized HC task was to explore the simulator, identify "bleeding" from a previously unknown liver injury perfused at 80 mm Hg, and pack to gain hemostasis. Ten surgeons performed RDCR laparotomies onboard a research aircraft, first in 1g followed by 0g. The standardized laparotomy was sectioned into 20-second segments to conduct and facilitate parabolic flight comparisons, with "blood" pumped only during these time segments. A maximum of 12 segments permitted for each laparotomy. ... Performing laparotomies with packing of a simulated torso hemorrhage in a high-fidelity surgical simulator was feasible onboard a research aircraft in both normal and weightless conditions."²¹

High-Fidelity Human Cadaver Models

- The "Major Incident Surgical and Trauma Teams" (MISTT) Trauma Course, held at Queen Elizabeth Hospital Birmingham (UK) and supported by the UK National Health Service, states that, "Delegates will benefit from a three day cadaveric course, focusing on damage control of all cavities and extremities in Trauma, together with two days of discussion, lively debate and case studies."²² In private communication with the PETA Foundation, the MISTT Trauma Course confirmed that it "do[es] not use any cadaveric or anaesthetised models, tissue or other samples derived from animals" and that they are going to be "using silicone anatomical models such as supplied by TraumaSimU Ltd," which is the Surgical Anatomical Model (SAM).²³ Regarding the SAM model, Surgeon Vice Admiral Alasdair Walker (former Surgeon General of the UK Defence Medical Services) and his colleagues in the Royal Army Medical Corps and the Royal Navy stated 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"²⁴
- A 2018 study from the U.S. Navy Trauma Training Center stated: "[O]ur military trauma training site now utilizes a novel ventilated and pressurized cadaver model for training and evaluation of forward surgical teams (FST). FSTs attend a 4-day damage control course including didactics and cadaveric dissection focused on trauma exposures, damage control vascular and orthopedic procedures. A capstone half-day simulation pairs the perfused cadaver model with conventional simulation to involve the entire surgical team in four sequential surgical scenarios that involve the chest, abdomen, and extremities, as well as airway management and resuscitation. Initial evaluations support the use of this novel perfused cadaver model for the training and evaluation of military FSTs. Preliminary data highlights the utility for open

²² The MISTT Trauma Course. Retrieved from <u>https://www.mistt.co.uk</u>

comparative evaluation of the importance of surgical experience, telepresence, gravity and mentoring in the conduct of damage control laparotomies. *Canadian Journal of Surgery*, *58*(3 Suppl 3), S88.

²¹ Kirkpatrick, A. W., McKee, J. L., Tien, H., LaPorta, A. J., Lavell, K., Leslie, T., ... & Franciose, R. (2017). Damage control surgery in weightlessness: A comparative study of simulated torso hemorrhage control comparing terrestrial and weightless conditions. *Journal of trauma and acute care surgery*, 82(2), 392-399.

²³ The MISTT Trauma Course. Private correspondence with PETA Foundation. 2019, October 16.

²⁴ Naumann, D. N., Bowley, D. M., Midwinter, M. J., Walker, A., & Pallister, I. (2016). High-fidelity simulation model of pelvic hemorrhagic Trauma: the future for military surgical skills training?. *Military medicine*, *181*(11-12), 1407-1409.

vascular, thoracic and other high acuity/low volume procedures critical to combat casualty care." 25

Advanced Human Patient Simulators

- A study published in 2014 by a U.S. Air Force team in the journal *Military Medicine* compared the self-efficacy reported by military trainees taught emergency procedures on human simulators versus live animals and found equivalent results in both groups, concluding that "if the goal for trainers is to produce individuals with high self-efficacy, artificial simulation is an adequate modality compared with the historical standard of live animal models."²⁶ The author published a separate letter in the journal, stating, "We have entered into an age where artificial simulator models are at least equivalent to, if not superior to, animal models. [T]he military should make the move away from all animal simulation when effective equivalent artificial simulators exist for a specific task. For emergency procedures, this day has arrive."²⁷
- A 2015 study found that a human patient simulator is as effective as animal use during LTT in teaching trauma injury management to military medical technicians, and the researchers "found no difference in performance between medics trained on simulators versus live tissue models."²⁸
- A 2015 study by one of the research teams that are part of the U.S. Combat Casualty Training Consortium stated that they "assembled a 'Frank N. Stein' model representing the best of commercially available simulation. ... For Airway, the SimMan 3G head/neck was selected as the nasopharyngeal airway and cricothyrotomy model. For chest tube and needle decompression, the Strategic Operations Cut Suit was selected. For hemorrhage, the KGS MATT was chosen as the only model that contained both junctional and amputation wounds with animatronics. An actor was trained and a platform was created to allow the head and arms of the actor to wear the cut-suit above the platform, with the actor's torso and legs below the MATT legs on the platform. Frank was dressed appropriately and moulage was applied to face, wounds, and amputated stump. ... The actor could be switched out for the SimMan head/neck/torso for airway interventions. ... The emulation of a complex airway and hemorrhage patient was successful, providing a realistic full body simulation requiring placement of nasopharyngeal airway, chest seal, needle and tube thoracostomy, cricothyrotomy, tourniquet, amputation stump dressing, and junctional wound packing. ... Over 1000 trainees have been trained or assessed with this model."29

U.S. Coast Guard End LTT, President Trump Mandates Non-Animal Training Methods

In 2017, the U.S. Defense Health Agency criticized the use of animals in military trauma drills as being

²⁵ Polk, T. M., Grabo, D. J., Minneti, M., Kearns, M. J., Inaba, K., Benjamin, E. R., & Demetriades, D. (2018). Initial Report on a Damage Control Surgery Course for Military Forward Surgical Teams Utilizing a Novel Perfused Cadaver Model for Training and Evaluation. *Journal of the American College of Surgeons*, 227(4), e40.

²⁶Hall, A. B., Riojas, R., & Sharon, D. (2014). Comparison of self-efficacy and its improvement after artificial simulator or live animal model emergency procedure training. *Military medicine*, *179*(3), 320-323.

²⁷Hall A. (2014). Letter to the editor. Military Medicine; 179(7): vii.

²⁸ Savage, E. C., Tenn, C., Vartanian, O., Blackler, K., Sullivan-Kwantes, W., Garrett, M., ... & Tien, H. C. (2015). A comparison of live tissue training and high-fidelity patient simulator: a pilot study in battlefield trauma training. *Journal of Trauma and Acute Care Surgery*, *79*(4), S157-S163.

²⁹ Reihsen, T., Speich, J., Ballas, C., Hart, D., & Sweet, R. (2015). Creation of a multi-trauma patient using current technology based simulators. *Academic Emergency Medicine*, 22.

"outdated and cost-prohibitive"³⁰ and "not anatomically accurate".³¹ In 2017, U.S. Coast Guard Commandant Admiral Paul Zukunft told the U.S. Congress that the use of animals for military trauma training is "abhorrent" and that the Coast Guard "will move to a simulation [training model] . . . For us it will be the right thing to do to prepare our Coast Guard members who may be deployed to theaters where they may encounter traumatic injuries."³² As such, the Coast Guard became the first branch of the U.S. military to end the use of animals for trauma training altogether.³³

Last year, President Donald J. Trump has signed the bipartisan John S. McCain National Defense Authorization Act (H.R. 5515), which includes a game-changing, first-of-its-kind restriction that requires the Department of Defense (DOD) to use medical-simulation technology in trauma-skills training "to the maximum extent practicable" before resorting to harming animals in the deadly drills.³⁴ This new provision will force the Pentagon to focus on more effective, ethical, and economical human-simulation technology as the new gold standard of trauma training, rather than the decades-old practice of shooting, stabbing, dismembering, and killing thousands of pigs and goats each year, which will now be a secondary or non-essential element.

Conclusion

The DOJ should replace its use of LTT with superior and more cost-effective human simulation models. Such a move would bring the DOJ in line with growing medical consensus and the best practices of the nearly three-quarters of fellow NATO nations that do not use animals for military medical training.³⁵

You can contact me at <u>ShalinG@peta.org</u>. Thank you, and we look forward to your response.

Sincerely yours,

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Shalin G. Gala Vice President, International Laboratory Methods Laboratory Investigations Department

cc: The Honorable Donald Washington, Director, USMS (Carole O'Brien, Procurement Executive, USMS (Carole O'Brien, Procurement)) The Honorable Christopher Wray, Director, FBI (Carole O'Brien, Procurement)) Paul Courtney, Chief Acquisition Officer, FBI (Carole O'Brien, Procurement))

³⁰ Defense Health Agency. 2016 stakeholder report. Retrieved from <u>https://health.mil/Reference-Center/Reports/2017/06/08/Defense-Health-Agency-2016-Stakeholder-Report</u>

³¹ Defense Health Agency SBIR/STTR programs. 2017, May 16. *Seed Funding Health Technologies*. Retrieved from <u>https://www.sbir.gov/sites/default/files/Master%20Health%20Technologies.National%20SBIR.pptx</u>

³² Seck, H. H. 2017, May 18. *Ending "abhorrent" live tissue training was right: Coast Guard*. Military.com. Retrieved from <u>http://www.military.com/daily-news/2017/05/18/ending-abhorrent-live-tissue-training-was-right-coast-guard.html</u>

³³ Seck, H. H. 2018, March 20. *Coast guard puts permanent end to wounding animals for training*. Military.com. Retrieved from <u>https://www.military.com/daily-news/2018/03/20/coast-guard-puts-permanent-end-wounding-animals-training.html</u>

³⁴ Crist, C. 2018, October 11. *Doctors move away from using live animals for trauma surgery training*. Reuters. Retrieved from <u>https://www.reuters.com/article/us-health-trauma-training-animals/doctors-move-away-from-using-live-animals-for-trauma-surgery-training-idUSKCN1ML2LE</u>

³⁵ Gala, S. G., Goodman, J. R., Murphy, M. P., & Balsam, M. J. (2012). Use of animals by NATO countries in military medical training exercises: an international survey. *Military medicine*, *177*(8), 907-910..