

September 7, 2010

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7 pages via email to: [betty.j.goldentyer@usda.gov](mailto:betty.j.goldentyer@usda.gov)

Dear Dr. Goldentyer:

On behalf of People for the Ethical Treatment of Animals (PETA) and our more than 2 million members and supporters, I am writing to request an investigation into what we believe to be serious violations of the Animal Welfare Act (AWA) related to the use of cats and pigs in invasive and deadly medical training exercises in the Survival Flight course at the University of Michigan (UM) (34-R-0001). **As we outline in this complaint, valid alternatives to the use of animals are available for these procedures and are already in use to teach the same skills in other courses at UM. Based on documentation we have reviewed, we do not believe that these non-animal methods were adequately sought and considered by the principal investigator nor did he provide an adequate justification for the continued use of animals, in violation of the AWA.**

#### Background

Documents obtained by PETA through the Freedom of Information Act (FOIA) indicate that as many as 12 cats and 16 pigs are used each year in a Survival Flight course for nurses at UM (Protocol #09505) led by faculty member Mark Lowell. Records indicate that cats are used for pediatric endotracheal intubation training and pigs are used for training in emergency medical procedures including intraosseous access, venous cutdown, tube thoracostomy, pericardiocentesis, cricothyroidotomy, and cardiac puncture. According to UM documents, cats used in this course are frequently killed and pigs, due to the invasive nature of the procedures, are always killed at the completion of the course. Alternatives to the use of animals for these trainings are available, have been shown in peer-reviewed studies to be superior to animal use and are already used to teach these skills at UM. The Principal Investigator has provided no evidence that the use of animals is superior to these alternatives.

#### Concerns regarding the failure to use alternatives to cats for pediatric intubation training

There are substantial animal welfare and pedagogical concerns associated with the use of animals for endotracheal intubation that—for ethical, legal and educational reasons—weigh heavily in favor of replacing animals with humane alternatives.



**PETA**

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THE RIGHTS OF ALL ANIMALS

As you are aware, the AWA states that alternatives<sup>1</sup> must be sought for procedures that "cause more than momentary or slight pain or distress to the animals" [9 C.F.R. §2.31(d)(ii)]. Research shows that endotracheal intubation is the single most painful procedure that human neonates routinely undergo in the course of hospitalization,<sup>2</sup> and the *Guide for the Care and Use of Laboratory Animals* recommends assuming "that procedures that cause pain in humans also cause pain in animals."<sup>3</sup> Therefore, it should be assumed that endotracheal intubation causes more than "momentary pain" in other animals. Intubation training, which involves repeatedly forcing a hard plastic tube down the cats' windpipes, can cause bleeding, swelling, and scarring in the tissues of the throat. It also has the potential to cause pneumothorax, subcutaneous emphysema, and even death.<sup>4</sup>

The approved protocol further indicates that each cat used in the Survival Flight course is subjected to this painful procedure as many as 30 times during each session and—in most situations the cats are killed.<sup>5</sup> According to the protocol approved by the UCUCA, additional adverse effects include—postintubation stridor, which is described as an expected adverse effect, as well as anesthetic death, endotracheal perforation, and need for euthanasia.<sup>6</sup> Even routine procedures such as transportation and handling have been shown to cause statistically significant elevations of physiological stress indicators in animals in laboratories.<sup>7</sup>

Protocol #09505 attempts to justify the use of cats by stating that “cats provide an excellent model for endotracheal intubation of the infant or small child,”<sup>8</sup> but does not cite any literature to support such a claim. **Indeed, the relevant scientific literature shows that simulation methods are *pedagogically superior to the use of animals for this training and for this reason, non-animal methods are now the standard of practice in this area.***

Research has repeatedly found that those who learn intubation for children and adults through the use of simulation technology exhibit greater proficiency than those who are trained with animals or even human patients. Modern simulation technology for pediatric airway training has proved to be a valid training<sup>9</sup> tool and offers accurate anatomy, repeatability, objective feedback, and assessment capabilities, which are

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<sup>1</sup> According to the USDA's *Animal Care Resource Guide* Policy #12, "Alternatives or alternative methods are generally regarded as those that incorporate some aspect of replacement ... of animal use .... These include methods that use non-animal systems ... to partially or fully replace animals ...."

<sup>2</sup> Simons SH, van Dijk M, Anand KS, Roofthoof D, van Lingen RA, Tibboel D. Do we still hurt newborn babies? A prospective study of procedural pain and analgesia in neonates. *Arch Pediatr Adol Med* 2003;157:1058–64.

<sup>3</sup> Office of Laboratory Animal Welfare. *Guide for the care and use of laboratory animals*. Washington (DC): National Academies Press; 1996.

<sup>4</sup> Hofmeister EH, Trim CM, Kley S, Cornell K. Traumatic endotracheal intubation in the cat. *Vet Anaesth Analg* 2007;34(3):213–6.

<sup>5</sup> Protocol #09505. Page 19.

<sup>6</sup> Protocol #09505. Page 20-21.

<sup>7</sup> Balcombe JP, Barnard ND, Sandusky C. Laboratory Routines Cause Animal Stress. *Contemp Top Lab Anim Sci* 2004; 43(6):42–51.

<sup>8</sup> Protocol #09505. Page 12.

<sup>9</sup> Overly FL, Sudikoff SN, Shapiro MJ. High fidelity medical simulation as an assessment tool for pediatric residents' airway management skills. *Pediatr Emerg Care* 2007;23:11–5.

the cornerstones of effective, evidence-based medical training and not present in animal-based training laboratories.<sup>10,11</sup>

Adams *et al* compared the intubation proficiency of medical care providers who had both completed Neonatal Resuscitation Program (NRP) and Pediatric Advanced Life Support (PALS) training and who then had either undergone additional training using didactics and manikins or a cat intubation laboratory.<sup>12</sup> The study found that those who did the additional manikin training instead of animals were “significantly more successful on the first attempt at intubation” and overall. The manikin group had a 92% overall success rate while the animal group had a 77% overall success rate. The study concludes that “training on mannequins allows for greater concentration by the trainee on technique. Without the urgency to place the tube, which is felt when practicing on animals or humans, the trainee is much more open to suggestions and corrections.”<sup>13</sup> Similarly, another study found that pediatricians who were trained using a cat intubation laboratory had only a 65% overall intubation success rate.<sup>14</sup> Participants’ discomfort with the use of animals has been noted in the medical education literature as well.<sup>15</sup>

Another inherent and insurmountable obstacle presented by animal use for intubation training is the “drastic differences between the oropharyngeal anatomy of human infants and cats.”<sup>16</sup> Compared to human babies, cats have larger, sharper teeth; a proportionately larger tongue; more copious salivation; a smaller anterior larynx; dome-shaped arytenoid cartilage; and a larger epiglottis; and elongated jaws and snouts. Research has noted that the drastic anatomical differences between the oropharyngeal anatomies of cats and humans make the former a poor model for pediatric-intubation training.<sup>17</sup>

Conversely, simulation manikins are specifically created to faithfully reproduce the anatomy and physiology of human children. High-fidelity manikins—such as Laerdal’s SimNewB or SimBaby—can be programmed to mimic a wide range of physical and physiological responses that are experienced by human infants who are having difficulty breathing which insures that trainees will have the opportunity to address conditions such as laryngospasm which cannot be produced on demand when using a live animal. State-of-the-art simulators have the ability to produce realistic heart, lung, and vocal sounds, have actively dilating pupils, exhibit appropriate chest movements, can demonstrate a wide range of lifelike responses to combinations of important parameters such as heart rate, ECG, SPO<sub>2</sub>, NIBP, ETCO<sub>2</sub>, and respirator rate. An article in *Advances in Neonatal Care*, detailed how SimBaby “breathes, cries, cough,

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<sup>10</sup> Maran NJ, Glavin RJ. Low- to high-fidelity simulation—a continuum of medical education? *Med Educ* 2003;37(suppl 1):22–8.

<sup>11</sup> Issenberg BS, Mcgaghie WC, Petrusa ER, Gordon DL, Scalese RS. Features and uses of high-fidelity medical simulations that lead to effective learning: a BEME systematic review. *Med Teach* 2005;27:10–28.

<sup>12</sup> Adams K, Scott R, Perkin RM, Langa L. Comparison of intubation skills between interfacility transport team members. *Pediatr Emerg Care* 2000;16(1):5–8.

<sup>13</sup> Adams, et al.

<sup>14</sup> Falck AJ, Escobedo AJ, Baillargeon JG, Villard LG, Hall CA. Proficiency of pediatric residents in performing neonatal endotracheal intubation. *Pediatrics*. 2003;112:1242-7.

<sup>15</sup> Waisman Y, Amir L, Mor M, Mimouni M. Pediatric Advanced Life Support (PALS) Courses in Israel: Ten Years of Experience. *IMAJ* 2005;7:639-642.

<sup>16</sup> Tait C. On the differences between a child and a kitten. *J Emerg Nurs* 2010; 36(1):78-80.

<sup>17</sup> Katzman GH. On teaching endotracheal intubation. *Pediatrics* 1982;70:656.

hiccoughs [and] can be programmed to exhibit cyanosis, stridor, retractions, wheezing, and even a pneumothorax.”<sup>18</sup>

Officials at the Heartland Regional Medical Center in St. Joseph, MO, with whom PETA worked to replace the use of cats in their PALS course, have stated that the manikins they purchased to replace the cat intubation laboratory are, “the closest we've seen to a representation of a live situation.”<sup>19</sup>

**There is no scientific data available to suggest that the use of animals is educationally superior, or even equivalent, to manikins and high-fidelity human patient simulators for pediatric or neonatal intubation training.**

Two of the more frequently cited papers on the use of animals for pediatric-intubation training do not include any data on intubation success rates.<sup>20,21</sup> In addition, several years after the Jennings *et al* article was published, response article appeared in *Pediatrics* stating that because of the anatomical differences between kitten and human neonates, “transference of the intubation skill to a clinical situation with a human neonate has been less than satisfactory.”<sup>22</sup> Conversely, Adams *et al* and others<sup>23</sup> have found that intubation skills learned on simulators do transfer to the bedside. It should also be noted that the aforementioned articles on animal intubation were written 18 to 35 years ago. The sophistication and fidelity of manikins and simulators have progressed leaps and bounds since that time.

Because of the pedagogical and animal welfare concerns associated with the use of animals for pediatric intubation training, and in light of the availability of effective non-animal training methods, **the American Heart Association (AHA), the American Academy of Pediatrics (AAP), and the Emergency Nurses Association (ENA), which sponsor the most widely offered pediatric and neonatal life support training courses—all of which include intubation training—exclusively endorse the use of manikins rather than animals for all aspects of life support training.**

In a January 2009 memo sent to all of its training facilities across the country, **the AHA stated that it, “does not require or endorse the use of live animals in any of its training courses”** and distanced itself from facilities that continue to do so.<sup>24</sup> Additionally, Dr. Robert E. O’Connor, former chair of the AHA Emergency Cardiovascular Care Committee, has recently stated in a letter to PETA that, “The use of lifelike training manikins for PALS courses is the standard accepted norm and that —the AHA

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<sup>18</sup> Stokowski LA. Dartmouth welcomes SimBaby. *Adv Neonat Care*. 2005;5:237-9.

<sup>19</sup> For Once PETA May Be Right. *St. Joseph News-Press*, 19 Oct. 2009.

<http://www.newspressnow.com/news/2009/oct/19/our-opinion-once-peta-may-be-right/>

<sup>20</sup> Jennings PB, Alden ER, Brenz RW . A teaching model for pediatric intubation utilizing ketamine-sedated kittens. *Pediatrics* 1974;53(2):283–4.

<sup>21</sup> Powell DA, Gonzales C, Gunnels RD. Use of the ferret as a model for pediatric endotracheal intubation training. *Lab Anim Sci* 1991;41(1):86–9.

<sup>22</sup> Katzman.

<sup>23</sup> Mayo PH *et al*. 2004. Achieving house staff competence in emergency airway management: Results of a teaching program using a computerized patient simulator. *Crit Care Med* 32: 2422-2427.

<sup>24</sup> American Heart Association. Message from AHA ECC Program: PETA Inquiries re: use of live animals in PALS course. 27 January 2009.

recommends that any hands-on intubation training for the AHA PALS course be performed on lifelike human manikins.<sup>25</sup>

The AAP's life-support education specialist has explicitly stated that the AAP "has never advocated the use of live animals" in the Neonatal Resuscitation Program (which includes intubation training) and that it has "always used plastic infant resuscitation mannequins for training exercises."<sup>26</sup>

Likewise, the Michigan Student Nursing Association (MSNA) has recently passed a resolution opposing the use of animals for training nurses.

**UM has already deemed simulators to be an effective mode of pediatric intubation training and uses them—not animals—to teach this skill in its own PALS course for physicians, nurses, and allied health professionals.<sup>27</sup> It is incongruous that the very same skill would be taught with the use of cats in the University-sponsored Survival Flight course when the PALS course has clearly demonstrated that it can be effectively taught with simulators and/or task trainers.**

This issue was summed up succinctly in a recent issue of the *Journal of Emergency Nursing*, in which Cindy Tait, RN, MPH, one of the original developers of the AHA's PALS course and president of Southern California's largest medical training facility wrote, "The bottom line is that there is no need to traumatize and harm animals to teach [intubation], especially when highly effective non-animal methods are the accepted standard of practice and readily available to instructors."<sup>28</sup>

#### Concerns regarding the failure to use alternatives to pigs for surgical trauma training

According to Protocol #09505, 16 pigs are used per year in the Survival Flight course for procedures including venous cutdown, cardiac puncture, pericardiocentesis, tube thoracostomy (chest tube insertion), cricothyroidotomy, and intraosseous access. Due to the invasive nature of these procedures, the pigs are killed at the conclusion of each course offering.

The list of procedures performed on pigs in the Survival Flight Course is nearly identical to the list of procedures performed in the American College of Surgeons' (ACS) Advanced Trauma Life Support (ATLS) course, for which simulation methods have been approved as a complete replacement for animal use since 2001. The ATLS course includes tube thoracostomy, pericardiocentesis, peritoneal lavage, tracheostomy, and intravenous cutdown. Comparative research has repeatedly shown that models like Simulab's TraumaMan are pedagogically superior to the use of animals for teaching the skills included in the ATLS course<sup>29,30</sup> which also constitute the majority of procedures covered by the pig laboratory in the Survival Flight course. Today, nonanimal methods like TraumaMan are employed exclusively in

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<sup>25</sup> American Heart Association. Letter to PETA. 3 Feb. 2009.

<sup>26</sup> Lazier S. Personal e-mail to PETA. 3 Aug 2005.

<sup>27</sup> University of Michigan. ACLS / PALS Courses.

[http://www.med.umich.edu/umcsc/education/acls\\_pals\\_courses.html](http://www.med.umich.edu/umcsc/education/acls_pals_courses.html)

<sup>28</sup> Tait.

<sup>29</sup> Block EF, Lottenberg L, Flint L, Jakobsen J, Liebnitzky D. Use of a human patient simulator for the advanced trauma life support course. *Am Surg* 2002; 68(7): 648-651.

<sup>30</sup> Pandya A, Ali A. The role of TraumaMan in the Advanced Trauma Life Support course. *Can J Surg* 2009; 52 (Suppl.):S3-S19.

nearly 95% of ATLS courses across the U.S. **Indeed, in February 2009, the University of Michigan Health System announced that the school had ended the use of animals in ATLS and now employs TraumaMan to teach the course.**<sup>31</sup>

Intraosseous access and cardiac puncture are the only two skills included in the Survival Flight course that are not amongst the skills taught within ATLS. However, intraosseous access is included in both the AHA's Advanced Cardiovascular Life Support (ACLS) course and Pediatric Advanced Life Support (PALS) course. The AHA's aforementioned position against animal use for training courses applies to ACLS as well as PALS. **As with ATLS, UM already teaches intraosseous access in these courses using non-animal methods.**

With respect to cardiac puncture, a recent paper in the *Journal of Trauma* noted that existing training programs that focus on operative trauma use animal models and that there is a need for programs that focus on human anatomic structures since real life practitioners will be treating humans, not pigs.<sup>32</sup> The researchers from the University of Texas Southwestern Medical Center found that their human cadaver based program "improved participants' self-confidence in operative skills required for surgical exposure of human anatomic structures for trauma."<sup>33</sup> This is relevant to the current discussion because, among other things, the course covered cardiac injuries.

The protocol attempts to justify the use of pigs by claiming that the pig "has been a standard animal model for the teaching of surgical skills for many years" due to the "similarity between the swine model and the human."<sup>34</sup> The Principal Investigator provides no scientific evidence to support these assertions and these claims fail to acknowledge that manikins such as TraumaMan and other task trainers faithfully replicate human anatomy, are endorsed as replacements for animal use by leading medical professional organizations and are the current standard of practice for teaching all of the skills included in UM's Survival Flight course.

Given that UM's Graduate Medical Education Committee has already determined that TraumaMan can effectively meet the educational objectives of ATLS and task trainers are already used to teach intraosseous access at UM and it is incongruous for UM to claim that TraumaMan and other non-animal methods could not meet the needs of the Survival Flight course.

## **Conclusion**

Based on the information above, it is clear that cats and pigs used in the Survival Flight course exercises experience significant pain and suffering and that alternatives to the use of animals are effective and available; indeed, they are already in use on the UM campus. **Given the existence of effective and widely employed non-animal methods, it is simply not possible—as required by the AWA—for a course instructor's written narrative to demonstrate that alternatives to the use of animals are not available [see 9 C.F.R. Section 2.31 (d)(1); Section 2.32 (c)(5)(ii)] and that the use of animals for this**

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<sup>31</sup> U-M Ends Practice of Training Surgeons on Live Dogs. The Detroit News. 26 Feb 2009.

<sup>32</sup> Gunst M, O'Keeffe T, Hollett L, et al. Trauma operative skills in the era of nonoperative management: The Trauma Exposure Course (TEC). *Journal of Trauma* 2009; 67(5): 1091-1096.

<sup>33</sup> Gunst, et al.

<sup>34</sup> Protocol # 09505. Page 32.

**purpose “is unavoidable for the conduct of scientifically valuable research” [see 9 C.F.R. Section 2.31 (e)(4)]. As we have demonstrated, the author of the protocol provided no evidence of the superiority of animal use over the alternatives available.** The use of animals for the Survival Flight course represents a staggering failure on the part of both the training instructor and the UCUCA.

We urge you to undertake a full investigation into the use of live animals for medical training purposes at UM and any underlying issues that such an investigation might expose. If noncompliance is found, we urge you to take swift and decisive action that includes citing UM for violations of the AWA, issuing an Official Warning, levying fines against UM, and suspending its USDA registration.

I look forward to hearing from you and can be contacted at 860-882-2492 or [JustinG@peta.org](mailto:JustinG@peta.org). Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to be 'JG', with a large loop at the end.

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