

January 14, 2009

Via Facsimile (919-855-7123), E-mail, and Priority Mail

Elizabeth Goldentyer, D.V.M.
Regional Director
USDA/APHIS/AC Eastern Region
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

Re: Use of Live Dogs for Advanced Trauma Life Support Courses at the University of Michigan in Ann Arbor

Dear Dr. Goldentyer:

The Physicians Committee for Responsible Medicine (PCRM) requests that the Animal and Plant Health Inspection Service (APHIS) investigate the unlawful use of live dogs in Advanced Trauma Life Support (ATLS) courses at the University of Michigan in Ann Arbor (UM).

We believe that this animal use is a violation of the Animal Welfare Act because the principal investigator provided false information about alternative nonanimal technologies to justify animal use in his IACUC protocol.

UM falls under the statutory definition of a “research facility” and is, therefore, required to comply with the Act. As part of this required compliance, any use of live animals for research, testing, or experimentation must be approved by the research facility’s Institutional Animal Care and Use Committee, which, at UM, is called the University Committee on Use and Care of Animals (UCUCA).

A fundamental goal of the Act is the minimization of animal pain and distress via the consideration of nonanimal alternatives (7 U.S.C. § 2143(a)(3)). To this end, Section 2143 of the Act and Title 9, Section 2.31(d)(1)(ii), of the Act’s implementing regulations require that a principal investigator (PI)—including course instructors—consider alternatives to procedures that may cause more than momentary or slight pain or distress to any animal used for research purposes.

If the PI determines that no alternatives exist, he or she must provide a written narrative to the institution’s UCUCA describing the methods and sources used to determine that alternatives were not available. The written narrative should include adequate information for the UCUCA to assess that a reasonable and good faith effort was made to determine the availability of

alternatives or alternative methods. If a database search or other source identifies a *bona fide* alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative must justify why this alternative was not used.

Human cadavers and the TraumaMan System from Simulab have been approved for use in ATLS courses by the program's national oversight body, the American College of Surgeons (ACS). According to the ACS Subcommittee on ATLS and the Executive Committee to the ACS Committee on Trauma, "an anatomical human body model or manikin may be used in those areas in which the use of live, nonhuman species or human cadavers is cause for significant concern." This 2001 decision (attached) goes on to describe TraumaMan in detail. The Subcommittee on ATLS also recently approved the use of another manikin model—Synman from the Swiss company Synbone—for these courses. **In addition, UM currently owns the TraumaMan System as part of its state-of-the art medical simulation center.** Not only have these nonanimal alternatives been approved by ACS for ATLS courses, but they have been proven more effective in teaching the procedures that make up the surgical skills portion of the ATLS course.

Yet Dr. Richard E. Burney, the principal investigator for this animal use, stated, in his 2006 protocol application for the use of live dogs in UM's ATLS courses, that "manikins have not been shown to be as effective as using live, anesthetized animals," (see page 34 of 49 of the attached protocol application). This is simply untrue. **According to a study published in the November 2002 edition of the *Journal of the American College of Surgeons*, study participants misplaced 30.2 percent of cricothyroidotomies (tracheotomies) when performing the procedure on live dogs compared to only 3.6 percent when using human cadavers (McCarthy; see attached).** In addition, a study published in the February 2003 edition of *Anesthesiology* concludes that "practice on mannequins leads to reductions in cricothyroidotomy times and improvement in success rates" (Wong).

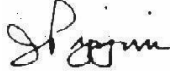
Dr. Burney also stated that the "majority of ATLS courses in the United States use live, anesthetized animals to teach these surgical skills" (see page 34 of 49 of the attached protocol application). This also is untrue. An ongoing 2007-2008 survey by PCRMA has so far received 198 responses from U.S. and Canadian facilities offering ATLS courses (see attached). **The survey has found that 181 of those facilities (more than 90 percent) exclusively use nonanimal models for instruction and the vast majority of those 181 facilities exclusively use the TraumaMan System.**

Dr. Burney acknowledged that the educational research purposes for which live animals are used at UM cause more than momentary or slight pain or distress. **Under section 11.E.10. subsection 1a. of his 2006 protocol application Dr. Burney stated that the dogs will experience the following "adverse affects on [their] mental health and well-being" as a result of their use in ATLS courses: "Fear, anxiety while being restrained for IV catheter placement"** (see page 19 of 49 of the attached protocol application). By providing false statements regarding the availability of alternatives to these procedures that cause distress, Dr. Burney failed to make the required reasonable and good faith effort to determine the availability of such alternatives. Therefore, UCUCA's approval of the use of live dogs in ATLS courses is invalid and in violation of the Animal Welfare Act. See e.g., 9 § 2.31(d)(1)(ii).

Elizabeth Goldentyer, DVM
January 14, 2009
Page 2

Accordingly, the Physicians Committee for Responsible Medicine requests that APHIS investigate this matter to find the University of Michigan in violation of these animal welfare policies.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Pippin".

John J. Pippin, M.D., F.A.C.C.
Senior Medical and Research Adviser

Enclosures