

BEFORE THE DEPARTMENT OF DEFENSE

In re: Uniformed Services University of the Health Sciences
Wilford Hall Medical Center
and all other DOD components that provide education
for medical students

Docket No. ___

PETITION FOR ENFORCEMENT

Submitted to:

The Honorable Pete Geren
Secretary of the Army
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Washington, DC 20310-0101
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Date:

July 2, 2008

Submitted by:

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A. ACTION REQUESTED

This petition requests that the Secretary of the Army, as the Department of Defense Executive Agent for Veterinary Services, exercise the authority granted by the Animal Welfare Act, 7 U.S.C. §§ 2131–2159 (AWA), Department of Defense Directive 3216.1 ¶ 5.3 (DODD 3216.1), and subparagraph 4c(1) of joint regulation USUHSINST 3203, AFMAN 40–401(I), Army Regulation 40–33, and SECNAVINST 3900.38C, to require that alternative methods to the use of ferrets, gerbils, pigs, snakes, and other animals be considered and used in all medical student courses at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda, Md., Wilford Hall Medical Center at Lackland Air Force Base in San Antonio, and all other DOD components that provide education for medical students.

B. STATEMENT OF GROUNDS

I. Introduction

The current standard of practice for teaching basic sciences, medicine, and surgery to U.S. medical students does not include the use of live animals. According to the schools themselves, 146 of the 154 accredited U.S. allopathic and osteopathic medical schools—more than 90 percent of schools—do not use animals for medical student education. All nine new medical schools opening in the United States between 2007 and 2009 have established non-animal curricula from inception, confirming that this is the current medical education standard of practice. The use of dogs in student courses has already been eliminated by all U.S. medical schools, and the use of other animals is equally unjustified, as explained below.

In response to a 2006 survey regarding the experiences of medical schools that eliminated animal labs, Cornell’s Weill Medical College—ranked 15th among U.S. allopathic medical schools—stated that discontinuing the use of animals had no effect on curriculum success. The school’s survey response added, “This change was made more than 10 years ago . . . Student performance outcomes remain excellent.”

Responding to the same survey, a curriculum administrator at the University of Pennsylvania—ranked 3rd among U.S. allopathic medical schools—stated, “Our curriculum is very successful, providing our students with a strong foundation without using animals.”

Numerous schools eliminated the use of live animals more than a decade ago. Professor Bruce R. Zetter of Harvard Medical School stated in 1996, “We felt it was most important to understand the integrated workings of the body, and since they’re going to be physicians, we wanted that to be the human body.” He also stated, “We asked how in thinking about physiology in the 1990s we could design a course that emphasizes humans and teaches about the heart, and we came up with about 20 different ways.”

Since March 2006, elimination of live animal use has been endorsed by such respected organizations as the American College of Surgeons, the Accreditation Council for Graduate Medical Education, and the American Medical Student Association.

Despite this overwhelming demonstration of the needlessness of live animal use in medical schools, USUHS and other DOD components that instruct medical students continue to kill pigs, Mongolian gerbils, and other animals for “educational” purposes. For example, students use live ferrets for neonatal intubation training during the third-year pediatric clerkship and

live pigs in the third-year surgery clerkship at USUHS in Bethesda, Md., and Wilford Hall Medical Center in San Antonio. These and other live animal labs may be provided for medical students at other DOD facilities as well, and any and all such facilities are included in this petition.

The scientific, economic, and humane benefits of non-animal methods are no longer in doubt (Balls-2000, 2004), and there are numerous validated and widely implemented alternatives to animal-based methods employed by the vast majority of U.S. medical schools. For example, the use of animals for medical student physiology and pharmacology teaching has been replaced in almost all U.S. medical schools with a variety of methods, including a state-of-the-art programmable simulator specifically developed for this purpose—METI's Human Patient Simulator. Despite numerous scientifically and educationally valid alternatives, live pigs are used in the first-year medical student physiology course at USUHS and possibly in physiology and/or pharmacology courses at other DOD components.

The use of ferrets and other small animals for intubation training has been supplanted by lifelike simulators such as Laerdal's BabySim and METI's SimBaby. In addition, the American Academy of Pediatrics (AAP) supports the use of non-animal training models for this purpose. According to AAP life support education specialist Sheila A. Lazier, M.S., "AAP has never advocated the use of live animals in our [Neonatal Resuscitation Program] training. We have always used plastic infant resuscitation mannequins for training exercises."

The USUHS medical student course in diagnostic parasitology and medical zoology uses live Mongolian gerbils to train students how to diagnose filariasis. Yet medical students can easily learn to diagnose filariasis microscopically using fixed samples. Students can also learn to identify filarial worms by viewing videos and photographs of living specimens. Both of these methods meet the objectives of animal use in this course. This course also uses live snakes for a "venomous reptile demonstration." Because the animal is used strictly for identification purposes, videos and/or color photographs would easily serve the same purpose.

The use of pigs, goats, and other animals for surgery skills training in U.S. medical schools has been replaced with a variety of simulators including bench models, laparoscopic and vascular surgery simulators, and simulators such as Simulab's TraumaMan, METI's SurgicalSIM, and Laerdal's SimMan for training in trauma and emergency settings. The American College of Surgeons and the Accreditation Council for Graduate Medical Education have endorsed simulation-based surgery training without animals.

Further, there is substantial medical education literature validating and recommending the use of simulation and other alternatives for animal use in medical education (Sachdeva-2008; Reznick-2006; Aggarwal-2006; McGaghie-2006; Issenberg-2005; Goodrow-2005; Gordon-2004; Balcombe-2004a; Tan-2002; Euliano-2001), including articles from the military setting addressing such issues as trauma and casualty training (Bowyer-2008, Anderson-2007, Ritter-2005, Liu-2003, Moses-2001, Kyle-undated).

Simulation training programs are now prominent in DOD educational and military readiness training, as reflected in internal and peer-reviewed publications and on DOD Web sites including but not limited to the following: http://www.usuhs.mil/apg/sim_lab.html; http://airforcemedicine.afms.mil/idc/groups/public/documents/webcontent/knowledgejunction.n.hcst?functionalarea=CSTARS&doctype=subpage&docname=CTB_035119; and <http://simcen.usuhs.mil>. In addition, numerous civilian and military media sources have

reported on the prominence of medical simulation within DOD training programs (Hanson-2007, Herndon-2007, Marine Corps Bases Japan, U.S. Army Medical Department, WUSA 9). Thus, it is improper for DOD components to continually approve the use of live animals in their medical education programs when alternatives are widely available and educationally valid.

II. Live Animals in Medical Education Courses Experience Pain and Distress

The use of animals in medical education courses inherently and unavoidably causes pain, distress, and suffering to those animals. Factors resulting in the inherent suffering of animals used in medical education include the manner in which animals are housed, transported, and used by medical schools.

Notwithstanding the problem of under-reporting of pain and distress, deaths associated with animal housing, transport and usage, and the nature of many experiments themselves, including stress and distress arising from everyday laboratory living conditions, create an even greater incentive for replacing the use of animals in medical education. A recent literature review reported on the effects of common laboratory routines, including handling animals and moving or cleaning cages, on physiological markers of stress. The authors related that animals exhibited rapid, pronounced, and statistically significant elevations of physiological stress indicators such as heart rate, blood pressure, and a variety of hormone levels in response to these daily perturbations. The elevations typically ranged from 20 percent to 100 percent or more above baseline, usually lasting 30 to 60 minutes or longer. The data indicate that significant fear, distress, and physical stress are predictable consequences of standard laboratory procedures, and that these phenomena not only cause animal suffering, but also may distort physiological measures and scientific outcomes (Balcombe-2004b).

This tendency for stress is compounded by standard laboratory housing conditions, which impose unnatural levels of confinement and commonly deprive the occupants of opportunities to engage in essential natural behaviors, including exploring, foraging, nesting, hiding, and, in many cases, social interaction with other members of their own species (Olsson-2002; Hurst-1999).

Additionally, the presence or likelihood of animal pain and distress associated with the described medical education purposes is confirmed by the fact that USDA inspectors enforcing the AWA routinely and regularly inspect such animal uses at medical schools, produce reports of those inspections, and identify and require correction of non-compliances that are common for this use of animals.

III. The Use of Live Animals in Medical Education Violates DOD Regulations Because Scientifically Valid Alternatives to Animal Use Exist

DODD 3216.1, which governs the use of animals in all DOD activities, mandates the consideration of animal testing alternatives whenever scientifically valid or equivalent results can be attained. DODD 3216.1 ¶ 4.4. The Directive operates concomitantly with applicable federal statutes, regulations, and publications on the “acquisition, transportation, housing, control maintenance, handling, protection, treatment, care, use and disposal of animals,” including the AWA. *Id.* ¶ 4.1.

To implement DODD 3216.1, several DOD components jointly promulgated a regulation regarding the use of animals in DOD programs. This regulation (“Joint Regulation”), issued as USUHSINST 3203 by USUHS, AFMAN 40–401(I) by the U.S. Air Force, Army Regulation 40–33 by the U.S. Army, and SECNAVINST 3900.38C by the U.S. Navy, states, “Alternative methods to the use of animals **must be considered and used** if such alternatives produce scientifically valid or equivalent results to attain the research, education, training, and testing objectives.” Joint Regulation ¶ 5b (emphasis added). By requiring the **consideration and use** of alternatives, the Joint Regulation is more stringent than DODD 3216.1, which requires only the consideration of alternatives. As mandated by DODD 3216.1, “[i]n the case of differences between standards of care and use of animals . . . the most stringent standard shall apply.” DODD 3216.1 ¶ 4.13. Therefore, DOD components are bound by the explicit language of the Joint Regulation, which requires alternative methods to animal use to be employed.

A wide variety of validated methods have been adopted by nearly all U.S. medical schools, demonstrating the widespread acceptance by medical school faculty and administrators of the use of non-animal teaching methods for student education. USUHS currently owns and utilizes many of these non-animal teaching methods at its own National Capital Area Medical Simulation Center (NCAMSC).

In addition, medical simulation has been widely embraced by many DOD components. The Marine Corps teaches basic combat casualty care to medics using the First Responder Emergency Device human patient simulator. The Air Force uses the Center for Sustainment of Trauma and Readiness Skills simulation program to sharpen the trauma skills of medical personnel. Wilford Hall Medical Center operates its own simulation center, allowing instructors to teach critical care and resuscitative skills (Hanson-2007, Herndon-2007, Marine Corps Bases Japan, U.S. Army Medical Department, WUSA 9). And the DOD, especially NCAMSC, has been on the forefront of validating the efficacy of simulation technologies for military use (Ritter-2005; Bowyer-2008).

Thus, the curricula of USUHS and other DOD components that use live animals in medical education despite the availability of scientifically valid alternatives do not comport with the responsibilities mandated by the Joint Regulation.

IV. The Use of Live Animals in Medical Education Also Violates the Animal Welfare Act Because Such Use Is Not Unavoidable for the Conduct of Scientifically Valuable Research

DOD components also are bound by the mandates of the AWA. The AWA defines a “federal research facility” as a “department, agency, or instrumentality of the United States which uses live animals for research or experimentation.” 7 U.S.C. § 2132(o). As agencies or instrumentalities of the United States, the DOD components meet this definition due to their use of live animals for military and medical research and medical education programs.

To assure the consideration and implementation of alternatives to procedures likely to produce pain or distress in animals, AWA regulations require each facility’s Institutional Animal Care and Use Committee (IACUC) to ensure that the “principal investigator [for any proposed activity involving animals] has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals.” 9 C.F.R. § 2.31(d)(1)(ii); *see*

also 9 C.F.R. § 2.37 (applying section 2.31 to federal research facilities). If no such alternatives are available, the principal investigator must “[provide] a written narrative description of the methods and sources . . . used to determine that alternatives were not available.” 9 C.F.R. § 2.31(d)(1)(ii). To go forward with a procedure that causes pain or distress to an animal, the principal investigator must provide a “rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.” 9 C.F.R. § 2.31(e)(2). The principal investigator also must provide a “description of procedures designed to assure that discomfort and pain to animals will be **limited to that which is unavoidable for the conduct of scientifically valuable research.**” 9 C.F.R. § 2.31(e)(4) (emphasis added). In other words, such procedures must be unavoidable—and not **merely** preferred, customary, easier, or less expensive.

As set forth above, the use of live animals in medical education inherently causes pain and distress to the animals. Yet USUHS and other DOD components continue to use live animals in educational courses despite the widespread availability of scientifically and educationally valid alternatives to procedures that cause pain or distress to animals. Any reasonable and good-faith effort to identify alternatives to procedures that cause pain or distress to animals used for medical education will identify validated, widely available alternatives that are extensively employed by the vast majority of medical schools. Therefore, it is not possible for a course instructor’s written narrative—describing either the search for alternatives or the procedures to be used—to demonstrate that alternatives are not available, *see* 9 C.F.R. § 2.31(d)(1), and that animal use for this purpose “is unavoidable for the conduct of scientifically valuable research,” *see* 9 C.F.R. § 2.31(e)(4). Thus, USUHS and other DOD components using live animals violate the AWA because such use is not unavoidable for the conduct of scientifically valuable research.

V. **The Joint Regulation, DODD 3216.1, and the AWA Authorize the Secretary of the Army to Instruct DOD IACUCs to Deny Requests for the Use of Live Animals in Medical Education**

As the heads of federal research facilities, the DOD component heads must enforce and implement DODD 3216.1, the Joint Regulation, and the AWA. Additionally, the Secretary of the Army, as the DOD Executive Agent for Veterinary Services, must implement the Joint Regulation at all regulated DOD components. Joint Regulation ¶ 4c(1).

DOD component heads bear the ultimate responsibility to make decisions regarding the use of animals at their facilities. Joint Regulation ¶ 5a. The Joint Regulation requires them to “[e]stablish appropriate mechanisms to implement and monitor compliance with this regulation and other applicable Federal statutes, policies, and guidelines,” such as the AWA. *See id.* ¶¶ 4b(1), 6b. This responsibility includes designating oversight offices to receive reports of protocol suspensions and significant deficiencies. *Id.* ¶ 4b(3)(a)–(b). DOD component heads also must support and ensure development of animal care and use training programs for their IACUCs and certificate programs involved in the care, use, and treatment of animals. *Id.* ¶ 4b(4).

The AWA similarly delegates the authority to take corrective action at federal research facilities to the head of the agency conducting the research. 7 U.S.C. § 2143(c); 9 C.F.R. § 2.37(b). Accordingly, DOD component heads must oversee the delegation to their facilities’ IACUCs of the duties to investigate, inspect, and report violations. 7 U.S.C. § 2143(c). The

IACUCs report to the DOD component heads, further establishing the important decision-making role of these officials regarding the use of live animals. *See* 9 C.F.R. § 2.37(a).

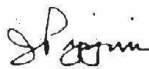
The Joint Regulation mandates alternative methods to live animal use at DOD components whenever alternative methods are scientifically valid or can achieve equivalent results to attain research, education, training, and testing objectives. Joint Regulation ¶ 5b. Further, the AWA allows the use of live animals in medical education only if such use is “unavoidable for the conduct of scientifically valuable research.” *See* 9 C.F.R. § 2.31(e)(4). Given the widespread acceptance and prevalence of animal use alternatives in furthering the objectives of medical education, all DOD components involved in medical student education are required to use these scientifically valid alternatives to live animal use in their medical education curricula. Because the use of animals is not scientifically justified, the Secretary of the Army must require the DOD component heads to institute corrective action.

C. CONCLUSION

DOD components regulated by the Joint Regulation must employ alternative methods to animal use whenever the results would be scientifically valid. Because widely validated and accepted non-animal alternatives for teaching physiology, pharmacology, pediatrics, parasitology, medical zoology, surgery, and other medical school topics are available and implemented at more than 90 percent of U.S. allopathic and osteopathic medical schools, there is no adequate or good-faith justification for the use of live animals for educational purposes. Such uses necessarily cause pain and distress that is not “unavoidable for the conduct of scientifically valuable research.”

To effectuate consistent and meaningful enforcement that comports with the language, intent, and mandates of DODD 3216.1, the Joint Regulation, and the AWA, the Secretary of the Army must exercise his broad enforcement powers to ensure that DOD component heads instruct IACUCs at all DOD components to deny all protocol requests for the use of animals to teach physiology, pharmacology, pediatrics, parasitology, medical zoology, surgery, and other topics in their curricula.

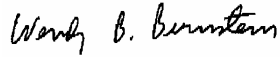
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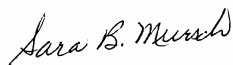
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