

September 24, 2007

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VIA FACSIMILE [(202) 228-2981]

Senator Richard Burr
United States Senate
217 Russell Senate Office Building
Washington, DC 20510

Dear Senator Burr:

The North Carolina Biosciences Organization (NCBIO) and its North Carolina Medical Device Forum (NCMD) wish to express their serious concern about language related to the Animal Welfare Act (AWA) that was included in the House-passed Farm Bill (HR 2419) as it is pending in the Senate. Specifically, we urge against the inclusion of language in the Farm Bill that would amend the AWA to further limit the use of live animals in the training of health care professionals in connection with medical devices. This change in existing law threatens patient safety, physician training and professional education, and continued medical innovation.

The AWA currently provides appropriate controls the use of animals for training of training professionals and physicians. Under the AWA, all animal research facilities to have an Institutional Animal Care and Use Committee (IACUC), which is responsible for the evaluation and approval of all protocols involving animal use. The IACUC is accountable for evaluating the justification for animal use, number of animals used, value of scientific outcomes of the proposed use, potential for pain and distress, and oversight of post approved protocol compliance. No research or education using animals may proceed without IACUC approval. As part of their oversight charge, IACUCs regularly review protocols and conduct facility inspections.


NCBIO supports the policies the AWA and our members have adopted stringent company policies and procedures to ensure full compliance with the law. We strive to develop alternative training models to allow us to reduce, refine, and replace the

use of animals to train medical professionals. Medical device manufacturers and research facilities that use animals in the testing of the technology or training in the use of the device have a company IACUC to review protocols prior to animal use and ensure compliance with the AWA. Compliance with the AWA is assessed through annual site inspections by the USDA.

In addition to surgeons and other health care providers, all professionals involved in the training of medical personnel, including sales representatives for medical device manufacturers, must undergo a comprehensive educational program to be able to train a surgeon on the unique details of a medical device and the related procedure. Surgeons regard them as the expert training and technical support professionals on the proper and safe operation and implantation technique for the device. These training professionals must maintain access to live-animal straining option to ensure fundamental patient safety. This is also essential for veterinarian training professionals for the care of animal health and welfare.

These essential training needs are provided for under current law in a way that appropriately balances patient safety and animal welfare. We ask you to oppose the additional legislative language in HR 2419 that would restrict such training and threaten patient safety, physician training and professional education, and continued medical innovation.

Sincerely,



Samuel M. Taylor
President.