Cruelty Free INTERNATIONAL

February 28, 2018

Senator Michael Sirtokin
Chair, Senate Committee on Economic Development, Housing and General Affairs
Vermont State House
Montpelier, VT 05633-5301
Sent via email: msirotkin@leg.state.vt.us

RE: Response to Ruth Blauwiekel University Veterinarian, The University of Vermont concerns on S.161.

Dear Senator Sirotkin.

Thank you for hearing S. 161 in your committee last Thursday. As you are aware, S.161 seeks to prohibits the use of vertebrate animals in nonmedical research testing when a scientifically valid alternative to the animal test is available. The language of S.161 is modeled after existing laws in California, New York and New Jersey which have been in effect for over 10 years. These laws have not negatively impacted the numerous Universities in these states that use animal in research.

In the written testimony from Ruth Blauwikele DVM University Veterinarian at the University of Vermont (UVM) it was argued that S.161 is "redundant with federal regulations that govern the utilization of animals in a research setting." The Animal Welfare Act and existence of Institutional Animal Care and use Committees (IACUCs) were provided to suggest that the use of alternatives to avoidable animal testing is already required by federal law. However, this is not the case.

The AWA only applies to facilities that use species covered by that Act which excludes most animals used in testing namely rats, mice, and birds. In addition, the requirement for IACUC oversight only applies to institutions that receive federal funding or that transport covered animals in interstate transport. The Public Health Service Policy also mentioned by UVM, does cover all animals but, only applies to research conducted with funding from the National Institutes of Health. Therefore, institutions or private companies which only use rats, mice, and birds or do not receive federal funding are not subject to the AWA or Public Health Service Policy.

Moreover, even when facilities do fall under the AWA and related laws and regulations, those using animals are only bound only to "consider" alternatives to painful or lethal experiments but are not *required* to use available alternatives.

In addition, the USDA has long documented problems with the implementation and effectiveness of IACUCs. In 2000, a USDA survey on the effectiveness of IACUC regulations found that some IACUCs did not ensure that unnecessary or repetitive experiments would not be performed on laboratory animal[1]

[1] 2000, USDA Employee Survey on the Effectiveness of IACUC Regulations
https://www.aphis.usda.gov/animal_welfare/downloads/iacuc/iacucaugust.pdf

The survey concluded that *"IACUCs seem to be doing well at functions related to setting up the administrative structure and developing the process but not as well at monitoring and follow through."* In 2005 and 2014 USDA's Office of Inspector General found that failure to search for alternatives to painful procedures and to document the availability of alternatives were among the most common violations by research facilities[2] [3]

The UVM also stated that AWA applied to private companies developing safety data on products for the purposes of FDA approval and referenced the October 2015 FDA guidance document "Product Development Under the Animal Rule Guidance for Industry." This document is irrelevant to this issue and simply restates that AWA regulations apply to the animal tests described in the document – this did not represent new regulations or broader more comprehensive regulations. The document also notes that," In general, FDA's guidance documents do not establish legally enforceable responsibilities."

S. 161 already excludes testing done for drugs and medical purpose and by doing so, excludes the bulk of products regulated by the FDA. The remaining products governed by the FDA and potentially covered by the bill are cosmetics for which alternatives are plentiful and are not commonly, if ever, tested by Universities like UVM. The other items targeted by S.161 are household products which are not regulated by the FDA. It is also important to restate that S. 161 only required that alternatives be used when they exist. If an alternative does not exist, then the animal test may be used.

The examples of research projects presented by UVM would seem to fall under the medical exemption and/or represent protocols that likely do not have a viable alternative and, as such, would not be impacted by the bill. Other states including California, home to UC Davis and many other Universities, has a similar law in place for 18 years and has a robust research program in all areas noted by UVM.

While it is highly unlikely that S. 161 would have any impact on the activities of UVM, if greater clarification is needed to alleviate concerns presented by Dr. Blauwiekel, I am happy to assist in working toward that goal.

Thank you for your consideration.

Sincerely,

Monica Engebretson
North America Campaign Manger
Cruelty Free International.

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[2] 2005, OIG Audit Report APHIS Animal Care Program Inspection and Enforcement Programs https://www.usda.gov/oig/webdocs/33002-03-SF.pdf

[3] 2014, OIG Audit Report APHIS Oversight of Research Facilities https://www.usda.gov/oig/webdocs/33601-0001-41.pdf