Stephen R. Kaufman

MEDICAL RESEARCH MODERNIZATION COMMITTEE

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Statement of Stephen R. Kaufman, M.D., in support HB 873, the Laboratory Animal Bill

As a Chief Resident in ophthalmology at New York University, I strongly support HB 873, which would prohibit the Draize eye irritation test for cosmetic and household products. The Draize test is scientifically unsound and inapplicable to clinical situations. Reliance on this test is in fact dangerous, because the animal data can not be reliably extrapolated to man. Substances "proven" safe in lab animals may in fact be dangerous to people.

I have three years of experience at Bellevue Hospital, an Eye Trauma Center, where I have treated scores of toxic eye injuries in the emergency room. I have never used Draize data to assist the care of a patient. Furthermore, I know of no case in which another ophthalmologist found Draize data useful.

Ocular irritancy testing is often performed in order to label substances accurately as toxic or non-toxic. Here, the Draize test, due to its scientific inadequacies, fails miserably. The Draize test uses rabbits, because they are inexpensive, have large eyes, and are easy to handle. However, the rabbit is an inappropriate and inaccurate model for human ocular damage. There are fundamental anatomical differences between the rabbit and human eyelid, tearing mechanism, and cornea.(1-6)

Consequently, Draize data correlates poorly with actual human experience. Indeed, the limited available human data has demonstrated the inadequacy of the Draize test. Freeberg et al.(7) reported 281 human ocular toxicity exposures to 14 household products, and they compared the findings to Draize test results. The human experiences differed from the Draize results by a factor of up to 250. The closest correlation differed by a factor of 18. Furthermore, the severity of rabbit eye response predicted poorly the degree of human ocular injury. Thus, the Draize test predicts human eye toxicity poorly. Indeed, Griffith and Freeberg wrote:

> The widely used Draize/FHSA rabbit eye irritation test has never been validated against any reported human data base. As an <u>in vitro</u> surrogate for predicting human ocular response to irritants, it has been soundly criticized on both technical and humane grounds...(8)

Elimination of the Draize test in favor of alternatives would encourage greatly the development of alternatives in all areas of toxicity testing. The <u>in vitro</u> technology already allows a battery of tests which compare favorably with the Draize test. Shopsis et al. found a correlation coefficient of .84 for a cytotoxicity assay(9). Leighton et al. have developed a chick

embryo model, which tests for the immune component of irritation(10). The EYETEX system, using a chemical reagent of macromolecular solutes, recorded the same irritancy classification as the Draize test for 61 of 67 tested chemicals, and the other six were within one Draize irritancy classification(11). Noxell Corportation is abandoning the Draize test in favor of the agarose diffusion test(12).

Given the inadequacy of the Draize test and the demonstrated reliability of alternative assays, the Food and Drug Administration should assume the lead in eliminating the Draize test. Hertzfeld and Myers observed:

> ...if all testing were to shift to in vitro assays, then many firms now geared to animal testing would find their labs practically useless...The status quo is a strong motivator for those now profitable firms. Regulatory authorities tend to follow, not lead in accepting new technologies, and they are heavily influenced by the industrial concerns now in place." (13)

Progress in product safety testing will not come from overreliance on outdated animal models. The Draize test has never been and will never be a reliable irritancy assay. As modern technologies are developed, it can no longer be considered a "gold standard." I strongly support animal testing when there are no adequate alternatives. However, if we fail to eliminate the Draize test when compelling scientific evidence supports such a move, then enthusiasm for developments of all alternative technologies will wane.

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Statement of Stephen R. Kaufman, M.D., on the use of animals in educational exercises

As the Vice-Chair of the Medical Research Modernization Committee, a group of over 600 scientists and clinicians, I would like to voice my objection to mandatory use of animals for demonstration purposes. Classroom demonstrations of well-known principles are unnecessary, can confuse students when poorly performed, and lead to an attitude that animals are expendable tools whose use raises no serious moral or ecological considerations.

I did not use animals in either my undergraduate or medical school education, and I do not believe that my training suffered in any way. In fact, medical students who performed optional labs were often confused by inconsistent or inaccurate results due to sloppy technique. Many were distressed when anaesthesia got "light" and the animals clearly suffered.

While the risk to animals is obvious, the dangers to students are more subtle. Biology should teach respect and admiration for living things, but killing animals in classroom exercises does the opposite, particularly when alternatives such as videotapes and computer programs are available. Waste of animals in educational exercises decreases sensitivity to animal concerns among those who pursue a science career. Indeed, such insensitivity among biology instructors has resulted in the waste of millions of animals in classroom demonstrations, and has severely disturbed some ecosystems. Similarly, profligate use of primates in research have devastated monkey, chimpanzee, and gorilla populations.

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