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Help Eliminate Animal Suffering: Support Effective Non-Animal Testing Methods

Dear Colleague:

We have enacted landmark legislation to protect the public from harmful chemicals. To carry out these laws, our federal agencies require pesticides and industrial chemicals to be tested to measure their toxicity levels. This is not cruel, this is good policy.

What is cruel, however, is to treat animals like test tubes. While no one is intentionally cruel in crafting measures to protect the public health, unfortunately, that is the result if we are not intentionally aiming to incorporate non-animal test methods.

I doubt any member of Congress believes that an animal should be subjected to pain in a toxicity test if a non-animal test would give an equally accurate result. I hope that you will review the information on the reverse and agree upon the same goal: The U.S. needs to take the lead in developing sophisticated, scientifically sound, non-animal toxicity testing methods.

Why are we still shaving animals' backs and spreading chemicals on their skin (often causing lesions or ulcerations endured with no anesthetics or painkillers) when there are better methods that are more accurate, faster, less expensive and don't require the use of live animals?

The U.S. is a key member of the Organization for Economic Cooperation and Development (OECD). However, we are lagging behind several other member countries with regard to our policies that require or accept data from outdated, inefficient, and cruel test methods.

The five animal tests described on the reverse side of this dear colleague are required or accepted by our federal agencies despite the fact that other OECD member countries have progressed to non-animal methods, often for less cost, less time, and with more relevant and useful results. Protocols are more easily standardized, and the variations among strains and species are no longer a factor.

The question remains: Why do our federal agencies still require or accept animal data for these five tests without implementing or actively seeking alternative methods? Our government has the wherewithal to put the five non-animal methods described here into mainstream regulatory use.

I urge you to join me in working to end the use of unnecessary animal testing when acceptable non-animal methods exist. More research is needed in this field, and we should take these considerations into account when considering future legislation affecting toxicity testing. Both the animals and the American people would be better served by such action.

Thank you for taking this issue under consideration. Reading the information provided is the first step towards implementing highly accurate, humane and cost-saving non-animal testing methods.

Sincerely,

James P. Moran

None of these animal-based test methods currently in use has ever been scientifically validated for its reliability or relevance to human health effects.

Health Effect	What It Is	Animal-based Method	Non-animal Method	Benefits of Non-animal Method
Skin Corrosion (required by DOT and EPA for hazardous substances and pesticides)	Irreversible damage to the skin, including ulceration	Rabbits are locked in full-body restraints, their backs are shaved, and a test chemical is applied. Animals may endure extreme pain as chemicals burn through their sensitive skin for up to 14 days, after which they are killed. No anesthesia or painkillers are given.	EpiDerm™ and EPISKIN™ are comprised of human-derived skin cells that have been cultured to form a 3-D skin model. Corrositex™ consists of a glass vial with a chemical test fluid capped by a membrane. Validated by ECVAM/ICCVAM* and accepted internationally as an OECD** test guideline.	No animal pain or distress. Whereas animal testing can take more than two weeks and cost more than $1,800, EpiDerm™ costs on average less than $800. Corrositex™ takes up to four hours and costs less than $200 per chemical tested.***
Skin Absorption (required by EPA, FDA, OSHA, and ATSDR for chemicals in the workplace)	The rate at which a chemical is able to penetrate the skin	A test chemical is applied to the shaved backs of rats, after which they are confined to small, exposed "metabolism cages" in which they are deprived of sensory stimulation. This can drive animals to destructive behaviors to cope with the stress such as pulling out their fur or circling for hours at a time. They are then killed, and their skin, blood, and excrement are analyzed.	The absorption rate of a chemical through the skin can be measured using excised skin from a variety of sources (e.g. human cadavers). Accepted internationally as an OECD** test guideline.	No animal pain or distress. Tissue-based methods allow researchers to study a broader range of doses, including those at the actual level of exposure that occurs in the occupational or ambient environment, which is <u>not</u> possible with an animal-based method.
Skin Irritation (required by CPSC, EPA, and FDA for household products, pesticides, and pharmaceuticals)	Reversible skin damage	Rabbits are locked in full-body restraints, their backs are shaved, and a test chemical is applied. The wound site is covered with a gauze patch for normally four hours. Over 14 days, effects can include swelling, painful rashes, and lesions. No painkillers are given, and the rabbits must often endure the full-body restraints the entire time. They are then killed.	As in drug clinical trials, human volunteers are used. A chemical is applied to a small area of skin. (The chemical is first determined to be non-corrosive and free of other harmful properties before being considered for human studies.) Accepted by government regulators in Canada.	No animal pain or distress. Researchers who compared the results of rabbit skin irritation tests with human clinical skin patch tests for 65 chemicals found that the animal test was wrong 45% of the time.†
Phototoxicity (required by FDA and NIEHS for pharmaceuticals and other substances)	Inflammatory skin reaction caused by interaction of a chemical with sunlight	A similar body-restraint, shaved-back procedure as above is used, but mice and guinea pigs are the subjects. They are kept restrained for several days while enduring the pain, swelling, and sores that develop on their skin. No anesthesia or painkillers are given. They are then killed.	The 3T3 Neutral Red Uptake Phototoxicity Test is a cell culture method that involves exposing cells to a test chemical in the presence and absence of light. Cell viability is measured by the degree to which they are able to absorb the dye, neutral red. Accepted internationally as an OECD** test guideline.	No animal pain or distress. No animal-based phototoxicity test has been validated or codified into a standardized test guideline, meaning that the protocols can vary widely from laboratory to laboratory, rendering the results virtually uninterpretable. The 3T3 NRU test is the <u>only</u> internationally accepted test for phototoxicity, and costs significantly less to run than its animal-based counterpart.
Pyrogenicity (required by FDA for pharmaceuticals)	Fever and inflammation	Rabbits are locked in full-body restraints, and the test substance is injected into their bloodstream. Effects can range from fever to organ failure to fatal shock. No anesthesia or painkillers are given.	The Human Pyrogen Test uses donated human blood to test for fever-causing contaminants. Validated by ECVAM.*	No animal pain or distress. Variations among strains and species are no longer a factor. The *in vitro* method out-performs the rabbit-based test, and does so at one-fifth of the financial cost and less than one-tenth of the labor cost.††

* ECVAM = European Centre for the Validation of Alternative Methods;
ICCVAM = Interagency Coordinating Committee for the Validation of Alternative Methods
** OECD = Organization for Economic Cooperation and Development, an economic alliance of 30 member countries including the US, EU, Canada, Japan, and Australia.

*** Source: Handbook of Toxicology. CRC Press, 2002.
† Source: *Food & Chemical Toxicology*, Vol.40, pp. 573-92, 2002
†† Source: ECVAM