

November 11, 2004

To: Alliance for a Healthy Tomorrow
Jeanne Rizzo, The Breast Cancer Fund
Michael Lerner, Commonweal
Ken Cook, Environmental Working Group
Brent Blackwelder, Friends of the Earth
Charlotte Brody, Health Care Without Harm
Damu Smith, National Black Environmental Justice Network
Aimee Boulanger, Women's Voices for the Earth

Dear Founding Members of the Campaign for Safe Cosmetics:

On behalf of the more than 11 million members and supporters of the Alternatives Research and Development Foundation, the American Anti-Vivisection Society, Animal Protection Institute, the Doris Day Animal League, Earth Island Institute, the Humane Society of the United States, People for the Ethical Treatment of Animals, and the Physicians Committee for Responsible Medicine, we are writing to express our concern regarding your recently launched Campaign for Safe Cosmetics and the Environmental Working Group (EWG) report, *Skin Deep*. Specifically, we are concerned with your request that companies sign a pledge to “determine [the] toxicity to living things ... including carcinogens, endocrine disrupters, sensitizers, mutagens, reproductive toxins, developmental toxins and neurotoxins,” which, if carried out using conventional animal-based test methods, would spell suffering and death for many hundreds of thousands of animals in laboratory studies.

Our organizations have a longstanding interest in reducing reliance on the use of animals in toxicity testing through the promotion of more rapid, reliable and relevant approaches that are also more efficient and humane. To this end, we have written in the past to a number of the organizations supporting the Campaign for Safe Cosmetics—in particular EWG. However, our most recent letter to EWG (dated August 3, 2004) has thus far gone unanswered.

As you are no doubt aware, the Food and Drug Administration (FDA), through the 1938 Federal Food, Drug and Cosmetic Act (FFDCA), has very little authority to regulate the cosmetics industry. In fact, the industry has been so successful in avoiding regulation that companies are not required to submit to the agency full safety dossiers for products designated as cosmetic. Just as troubling to the animal protection community is that when the FDA does require data on the safety of cosmetic ingredients, formulations or finished products due to a series of reported injuries, the agency most often conducts the same tests that manufacturers have already performed. This redundant testing results in suffering and death to even more animals with absolutely no “value added” from a public health or consumer protection standpoint. We share the concerns expressed by members of your campaign that, under existing law, safety data generated by manufacturers or their contract labs can be—and are—considered proprietary, and therefore unavailable to the agency and the public.

To make matters worse, when test data indicate that a substance may pose a health hazard, chemical manufacturers consistently argue that animal data are not applicable to humans. One recent example over phthalates illustrates this point very clearly:

“The Cosmetic, Toiletry, and Fragrance Association calls the European regulation ‘unnecessary’ and dismisses research on phthalates for two reasons: Phthalate levels in cosmetics are well within U.S. safety standards and because most studies on the chemicals’ ill effects have been conducted on animals and not humans ... industry insiders say levels of the substance are safe and the outcry is all based on tests of animal subjects that do not translate into human risks.” (*Womens News*, 30 Apr 04)

In its report, *In Harm’s Way*, Physicians for Social Responsibility wrote:

“Our snail’s pace approach to regulation clearly sets children in a minefield of uncertainty and potential harm, where the full extent of current hazards will be unknown for the foreseeable future. Even when there is substantial evidence of hazard, chemicals continue to be inflicted on the unsuspecting public for decades ... Rigid adherence to an inflexible standard for justifying action prevents timely regulatory response to public health threats ... We should not need to identify with certainty exactly how much and through what mechanism a neurotoxic chemical impairs brain development before coming to the conclusion that public health is not protected when the urine of virtually every child in this country contains the residues of these chemicals ... Animal studies of lead, mercury, and PCBs each underestimated the levels of exposures that cause effects in humans by 100 to 100,000-fold. Regulatory decisions that rely largely on toxicity testing in genetically similar animals under controlled laboratory conditions will continue to fail to reflect threats to the capacities and complexity of the human brain as well as important gene-environment interactions.”

It is undeniable that the track record of using animal test results to protect human health is extremely poor, and it is obviously of great concern to us to see yet another campaign launched by the environmental and public interest community calling for yet another endless round of animal testing.

We also have specific concerns with a number of substances that you have singled out for further study – substances about which much is already known and documented. The following are a few examples:

- Your Web site lists hydrogen peroxide, citric acid, aloe vera gel, chamomile extract, glycerin, and sodium chloride (salt) as “unstudied chemicals” (http://www.ewg.org/reports/skindeep/productinfo.php?prod_id=902053 and http://www.ewg.org/reports/skindeep/report/unstudied_ingredients.php).
- At the other end of the hazard spectrum, your Web site lists phosphoric acid as an “unstudied ingredient” (http://www.ewg.org/reports/skindeep/chemhealtheffect.php?chem_id=1630&lookup=1630&ewg_cat=Nail%20Polish#products).

Every time you request a single chronic (repeat-dose) study or a reproductive toxicity study (as, for example, at http://www.ewg.org/reports/skindeep/report/unstudied_ingredients.php), hundreds of animals will have a syringe or a force-feeding tube inserted into their stomachs so that they can be pumped full of the test material. In addition to suffering the effects of toxic

chemicals, hundreds of animals – many of them pregnant – will be subjected to highly stressful handling, restraint devices, and inhumane force-feeding practices. And this will all be done in order to test yet another shade of lipstick, nail polish, or mascara. Given this inevitable fact – that each test you call for translates directly into horrific suffering for animals – we are very concerned to see the apparently haphazard manner in which substances are classified as “unstudied” on your Web site.

The FDA does not require animal testing as the basis for safety substantiation for cosmetics in the United States. Europe has gone a step further by requiring, through the 7th Amendment to the Cosmetics Directive, that *only* non-animal methods be used for cosmetics tested and/or imported into the EU as of 2013. This move by the EU represents a major ethical milestone. The “pledge” you are asking companies to sign, however, will run counter to this trend unless you specify that non-animal alternatives and existing data should provide the information you are seeking. Cruelty-free companies (which tend to use more natural, gentler, and safer ingredients) will be adversely affected as well. We urge you to reconsider the language of your pledge in order to ensure that cosmetics marketed around the world are both safe *and* humane.

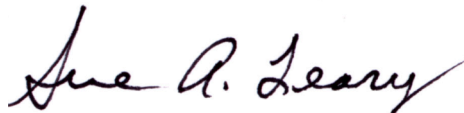
We are requesting that you consider rewording your “Compact with America” to specifically state that non-animal test methods should be used and that existing data should be mined for information on the ingredients of interest. Otherwise, your Campaign for Safe Cosmetics could easily turn into yet another massive animal-testing boondoggle that companies undertake as a public relations exercise, but which does nothing in the long run to actually protect the public from hazardous products.

We look forward to receiving a prompt and positive response to our concerns and thank you for considering this important matter. Questions, requests for further information, and responses should be sent to the attention of Jessica Sandler, Federal Agency Liaison, People for the Ethical Treatment of Animals, 501 Front Street, Norfolk, VA, 23510, tel: 757-622-7382, ext. 8001.

Sincerely,



Jessica T. Sandler, MHS
Federal Agency Liaison
People for the Ethical Treatment of Animals



Sue A. Leary
President
Alternatives Research & Development Foundation



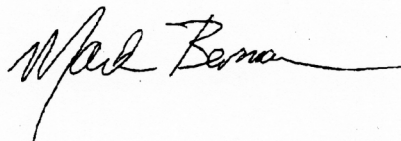
Tina Nelson
Executive Director
American Anti-Vivisection Society



Michelle Thew
Chief Executive
Animal Protection Institute



Sara J. Amundson
Deputy and Legislative Director
Doris Day Animal League



Mark Berman
Director, Marine Mammal Project
Earth Island Institute



Martin L. Stephens, PhD
Vice-President for Animal Research Issues
The Humane Society of the United States



Chad B. Sandusky, PhD
Director of Toxicology & Research
Physicians Committee for Responsible Medicine

cc: Lisa Finaldi, Greenpeace
Karen Johnson, National Organization of Women
+ 57 supporting organizations