From: ginnie r. maurer
Sent: Wednesday, December 22, 2004 9:38 AM
To: NIEHS ICCVAM
Subject: In vitro assays

Dr. William Stokes, Director
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Re: November 3, 2004, Federal Register Notice Vol. 69, No. 212 pp. 64081-2

Dear Dr. Stokes:

This letter is in response to a request for comments on Background Review
Documents for four in vitro assays (HET-CAM, BCOP, ICE, and IRE) proposed
for identifying potential ocular corrosives and severe irritants.

I am in favor of these well-established in vitro assays. Non-animal methods are preferred by a majority of Americans who, like me, would like
to see elimination of animal tests especially for such trivial items as cosmetics and household products.

Acceptable alternatives should replace in vivo tests entirely.

The Draize test, for example, has been criticized by the scientific community since it was developed in the 1940s. Dr. Stephen Kaufman of Bellevue Hospital noted that "[t]he Draize test is scientifically unsound
and inapplicable to clinical situations. Reliance on this test is in fact dangerous, because the animal data cannot be reliably extrapolated to man. Substances 'proven' safe in lab animals may in fact be dangerous
to people."

Given the above, why would ICCVAM use such a test. Many of the available
in vitro alternatives to Draize clearly provide adequate information on eye irritation.

Also, I understand Draize testing can vary from lab to lab and even

rabbit to rabbit! The Draize test should be abandoned and replaced with a new set of well-defined standards to which the proposed in vitro replacements can be compared.

Many experts agree that live animal tests actually do a better job of protecting manufacturers than consumers. In fact, many companies perform animal testing simply because their labs and personnel are already geared for them and their legal departments and insurance companies advise continuing to do it in order to shield the company from lawsuits. Even worse, armed with the "animal tested" defense, the very unreliability of many animal tests may provide manufacturers with an easy route to getting virtually any product on the market.

Because of consumer demand to stop animal testing in the U.S. and abroad, hundreds of cosmetics and household-products companies no longer use animal testing and, instead, take advantage of a combination of methods to ensure safety such as maintaining extensive databases of ingredients and formula data and employing in vitro tests and human clinical studies. For example, Avon, which once killed about 24,000 animals annually testing its products, now uses the Irritation Assay System (Eytex and Skintex) along with an in vitro test to assess irritancy levels.

In most cases, non-animal methods take less time to complete, cost less, and are not plagued with issues of species differences. Corrositex, approved by the Department of Transportation as a substitute for the rabbit skin test, assesses corrosivity using a protein membrane designed to function like skin and gives results in just a few hours for as little as $100 per test. TOPKAT, a software package used by the FDA, EPA and the U.S. Army, predicts oral toxicity and skin and eye irritation.

All the above seem sensible reasons for the ICCVAM to be more flexible in its evaluation of in vitro assays and more open to studying companies like Tom's of Maine and researchers like Pharmagene Labs in England.

Consumers know that in vitro tests are already being used safely and

effectively by industry today and want government to take this fact into
consideration.

I urge ICCVAM to take the lead in moving industry forward. A ban of all animal testing of cosmetic and consumer products would be just the incentive needed for serious research and development to end needless animal suffering and make consumer products safer.

As Dr. Coenraad F.M. Hendriksen of the Utrecht University, Netherlands, said: "Less animals make more science, and more science makes better regulations."

Thank you for considering these comments.

Sincerely,

Ginnie R. Maurer