Contact: Donna Krupa
703.527.7357 (office)
703.967.2751 (cell)
djkrupa1@aol.com

DO CIGARETTE ADDITIVES POSE ADDITIONAL RISK TO SMOKERS?

Report details the first approach in the U.S.

(December 27, 2004) Bethesda, MD – The U.S. government does not approve or control the "599 list" of non-tobacco chemical ingredients used to manufacture cigarettes. These additives, such as acetic acid (vinegar), chocolate, vanilla, and menthol are found in everyday foods. Scientists, supported by the U.S. Food and Drug Administration (FDA), generally regard these substances as safe in foods, but the risks for smokers are not known after combustion in cigarettes and inhalation. Can the toxicological effects for smokers be measured? A new report concludes they can.

The Study

The independent, non-profit organization Life Sciences Research Office (LSRO) (www.LSRO.ORG) is conducting a review of how to determine the potential risk of non-tobacco additives for cigarette smokers. In a previous report LSRO concluded that testing added ingredients was feasible. In this latest published report, *Evaluation of Cigarette Ingredients: Scientific Criteria,* LSRO establishes scientific criteria for assessing the impact.

The criteria are based on the work of an expert panel, composed of Alwynelle S. Ahl, Ph.D., D.V.M., Highland Rim Consultancy, Lyles, TN; Carroll Cross, M.D., Professor, Department of Medicine, University of California Davis Medical Center, Sacramento, CA; Shayne Gad, Ph.D., D.A.B.T., President, Gad Consulting Services, Cary, NC; Donald Gardner, Ph.D., F.A.T.S., President, Inhalation Toxicology Associates, Raleigh, NC; Louis Homer, M.D., Ph.D., Medical Director (ret.), Legacy Research Foundation, Portland, OR; Rudolph Jaeger, Ph.D., Principal Scientist, Environmental Medicine, Inc., Westwood, NJ; Robert Orth, Ph.D., President, Apis Discoveries, LLC, Cedar Hill, MO; Emmanuel Rubin, M.D., Chair, Department of Pathology, Anatomy, and Cell Biology, Thomas Jefferson University, Philadelphia, PA; James Schardein, M.S., F.A.T.S., Consultant, Leesburg, FL; and Thomas Slaga, Ph.D., President, AMC Cancer Research Center, Denver, CO. Phillip Morris, USA funded the study.

Methodology

To identify optimum scientific criteria for additive testing, the investigators compared conventional toxicological and regulatory approaches to epidemiological studies. LSRO could not find toxicological tests that predicted the full range of adverse human health

effects. Of particular concern was the difficulty in determining "safe" levels of additives in the context of the obviously unsafe act of smoking. To overcome these problems, LSRO adopted a relative risk approach. Investigators could compare cigarettes containing an ingredient to otherwise identical cigarettes lacking the same ingredient. This approach allows researchers to factor out the adverse health effects, revealing the effects of the additive, if any. This approach focuses on inhalation testing within a smoke matrix, instead of ingestion testing of purified additives.

Findings

The researchers concluded that this approach could establish whether:

(1) the additive, or a pyrolysis product of the additive, did not detectably transfer into cigarette smoke in such a way that smokers might be subject to a change in risk;

(2) the additive did not significantly change the chemistry, physics or biological properties of smoke; and

(3) the additive did not change exposure to cigarette smoke through altered smoking behavior.

If the additive met these three criteria, the expert panel concluded that they would not anticipate that use of the ingredient would increase adverse human health effects. If the additive did not meet one of the criteria, the panel recommended further testing. This could include reducing the amount of ingredient added and retesting or obtaining additional data demonstrating no change in the relative risk of adverse human health effects. The report gives examples.

Conclusions

The purpose of the report was not to create a safer cigarette. The authors state that the primary purpose of additive testing should be to assure the public that the additives do not increase the risk of premature death or illness beyond the levels already associated with smoking. Accordingly, they urge smokers to remember that regardless of the findings from testing, there remain significant risks from smoking even "additive-free" cigarettes.

Next Steps

LSRO will now embark on the next phase of the project, evaluating the impact of individual additives.

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For nearly half a century, the Life Sciences Research Office (LSRO) has provided expert objective scientific opinions and evaluations to governmental agencies and leading corporations in the food, health and bioscience sectors. A non-profit organization originally established in 1962 by the Federation of American Societies for Experimental Biology, LSRO provides independent science-based analysis and advice.

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Editor's Note: A copy of the report is available to the press in pdf format. To receive a copy or schedule an interview, please contact Donna Krupa at 703.527.7357 (office), 703.967.2751 (cell) or djkrupa1@aol.com.

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