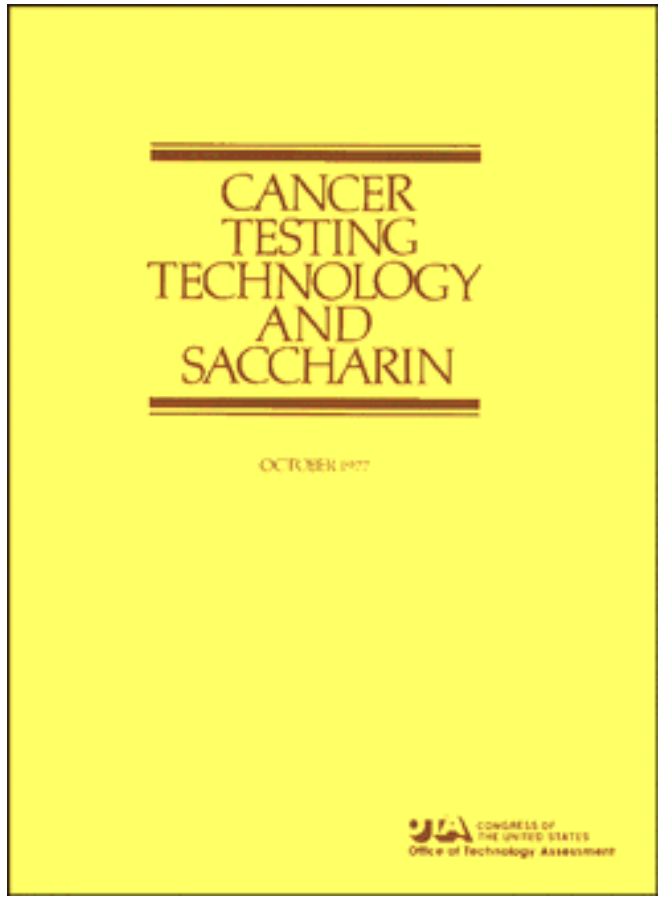
Cancer Testing Technology and Saccharin

October 1977

NTIS order #PB-273499



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Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, D.C. 20510

DANIEL DE SIMONE
ACTING DIRECTOR

OCT 17 1977

Committee on Human Resources
U. S. Senate
Washington, D. C. 20510

Gentlemen:

On behalf of the Board of the Office of Technology Assessment, we are pleased to forward the results of the assessment requested by your Committee.

This report provides a balanced and impartial analysis of issues related to the proposal by the Food and Drug Administration to prohibit the use of saccharin in foods. We hope that this analysis will serve as a useful resource not only for the current debate, but also for the continuing evaluation of the broader issues that it discusses.

Sincerely,

Edward M. Kennedy
Chairman

Sincerely,

Larry Winn, Jr.
Vice Chairman

Enclosure

FOREWORD

This assessment of cancer-testing technology and saccharin was requested by the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources. The study was performed as part of an evaluation by the Congress of the proposed ban on saccharin by the Food and Drug Administration.

The "Delaney Clause" of the Food, Drug, and Cosmetic Act prohibits the use of any food additive that has been shown to cause cancer when ingested by humans or animals. Since saccharin has been shown to cause cancer in laboratory animals, the FDA must ban its use.

Because saccharin is the only non-nutritive sweetener currently available to the American public, its ban has been widely criticized. The debate has prompted questions about the validity of the technology for testing whether a substance causes cancer, as well as the failure to consider the benefits as well as risks of a substance in determining whether it should be prohibited.

The Office of Technology Assessment was requested specifically:

(1) To assess the capacity of current testing methodology to predict the carcinogenic potential of chemicals consumed by humans, with special reference to the validity of extrapolating from results of animal tests to possible human effects.

(2) With respect to that assessment, to evaluate and quantify insofar as possible the potential risks that saccharin consumption might cause cancer in humans.

(3) In view of current methods for measuring health benefits of dietary behavior, to evaluate the potential health benefits, including any psychological benefits, of saccharin available to the general public and to diabetics and other groups with special medical problems.

(4) To assess the potential availability of alternative artificial sweeteners.

In the report, chapter 1 introduces the current debate over cancer-testing technology, saccharin use, and Government regulation. It also explains the scope of the assessment and presents a summary of the findings and conclusions. Chapter 2 examines testing methods and guidelines. Chapter 3 summarizes the results of animal, short-term, and human studies of the carcinogenicity of saccharin. Chapter 4 discusses possible benefits of saccharin, and Chapter 5 evaluates the potential availability of alternative sweeteners. The appendixes contain detailed data on the findings of animal and short-term tests, including the results of short-term tests commissioned by OTA for this assessment.

As an addendum to this report, the results of two epidemiological studies on the relationship between artificial sweetener consumption and human bladder tumors are summarized. Complete studies have not been made available to OTA, and these results were not available when a draft of this report was forwarded to the requesting subcommittee for hearings on June 7, 1977.

This assessment was conducted by staff of the OTA Health Program, with assistance from an advisory panel and consultants. Joyce C. McCann, a member of the advisory panel, coordinated the short-term tests for the study and was the Principal author of appendix II. The report was also reviewed *by the* OTA Health Advisory Committee, chaired by Frederick C. Robbins. This report is a synthesis and does not necessarily represent the views of any of the individuals involved in its preparation.

DANIEL DeSIMONE
Acting Director

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