

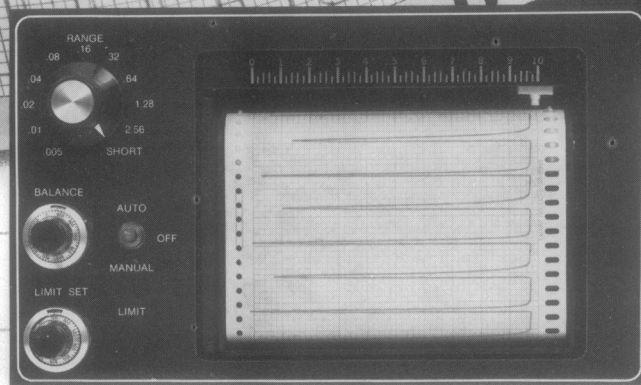
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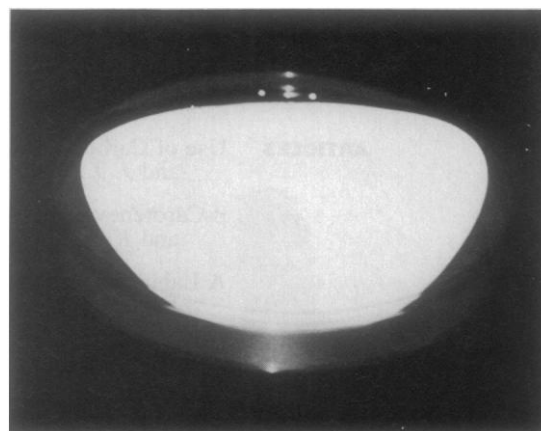
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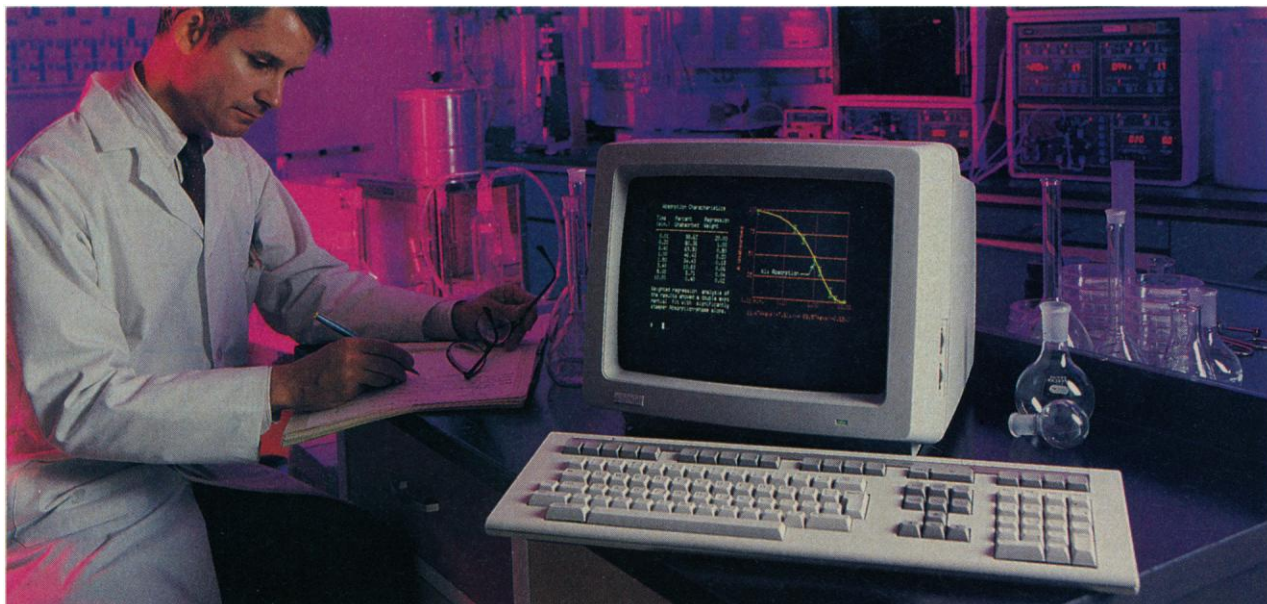
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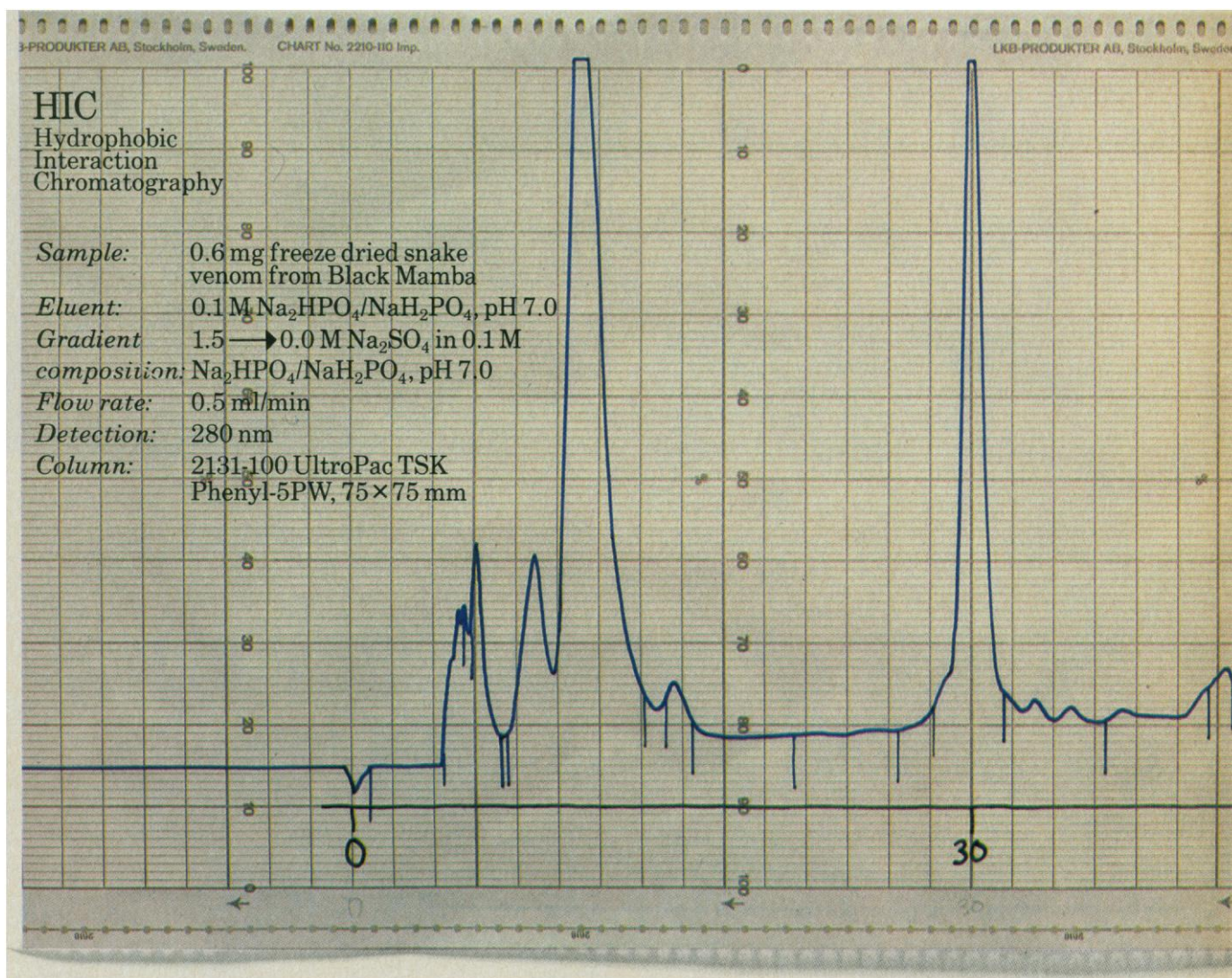
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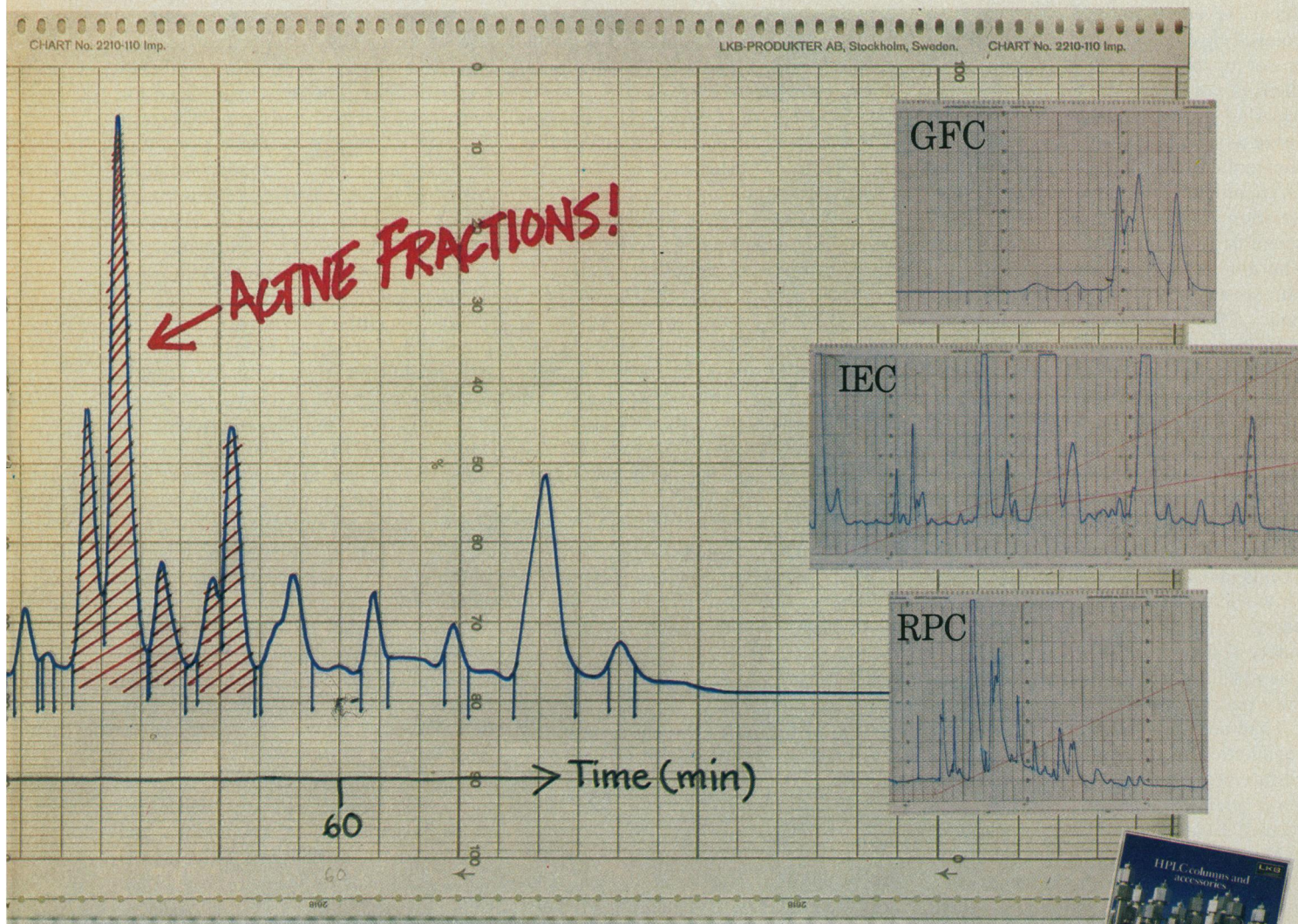
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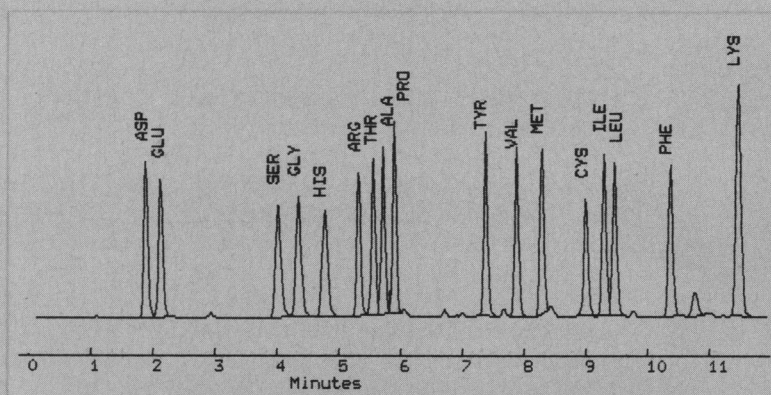
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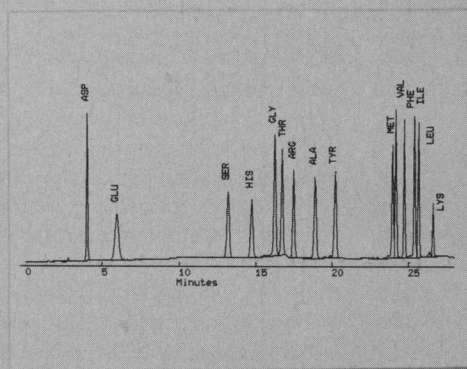
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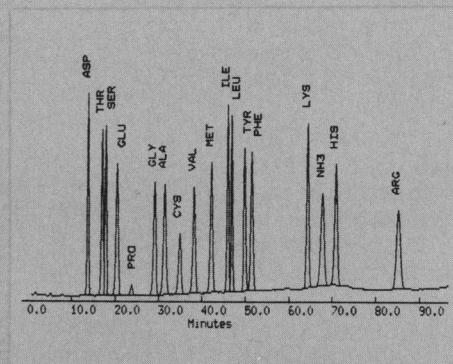


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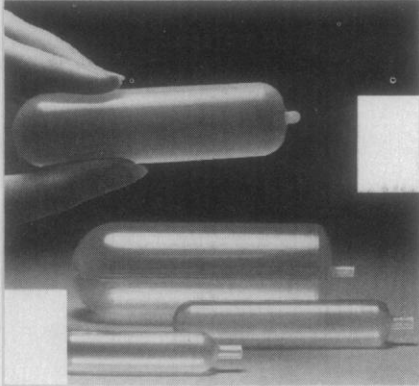
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memorandum. The entire issue of epidemiology is dealt with in one short paragraph in a 16-page memorandum, and the text shows that the authors are not correct.

While I recognize the limits of sensitivity inherent in epidemiology, such data are useful. In particular, for chemicals of long standing and well defined use, epidemiology could tell if a critical situation exists. If formaldehyde were a potent human risk, this would show up epidemiologically. There does not appear to be any relationship, based on the existing data base for humans, between exposure and cancer. Real human risk could be considered to be low on such a basis.

The text clearly states that, while the epidemiology does not rule out the existence of a low-level risk, neither does it support the existence of a high level of risk. The only passing consideration given this issue in a lengthy memorandum indicates that it was neither a critical nor central issue.

Ashford *et al.* further state that "incoming EPA officials had determined their policy on formaldehyde long before any 'decision-making process' had been completed. . . . J. Todhunter himself has testified that when he arrived at EPA in July 1981 he was informed that the agency would take no regulatory action on formaldehyde." This testimony refers to discussion (concerning the career staff's view regarding emergency regulation of formaldehyde) with Warren Muir, then head of EPA's Office of Toxic Substances. Muir was a career employee in charge of TSCA administration and most certainly not an "incoming official," as he had been head of the Office of Toxic Substances at EPA under the Carter Administration.

Ashford *et al.* also state that, on the basis of "substantial" but unspecified evidence, "Todhunter met on several occasions with John Byington, attorney for the Formaldehyde Institute, and Len Guarraia, then a director of the American Industrial Health Council." The record (2) has well established that such meetings with these gentlemen—the latter of whom was not even professionally involved with formaldehyde—did not occur when the 10 February memorandum was being prepared. Unfortunately for all so maligned, the "substantial" evidence relied on by the authors is a supposed—but highly inaccurate—list of "meetings" compiled by former congressional staffer Lester O. Brown. Brown has since left the employ of Congress after admitting to being responsible for improper alteration of transcripts of EPA oversight hearings held in the summer of 1982 (3).

The authors' views are at odds with

those of interested federal agencies (save CPSC) regarding formaldehyde and with court decisions on this substance (4). It is, of course, the authors' prerogative to disagree. The errors noted above do not, however, build a strong case for the authors' point of view.

JOHN A. TODHUNTER

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References

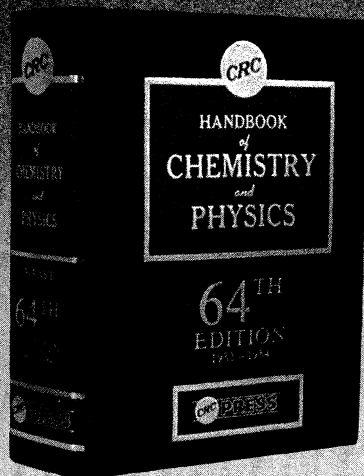
1. J. A. Todhunter, in *Safety Evaluation and Regulation of Chemicals*, F. Homburger, Ed. (Karger, New York, 1983), p. 1; *Reg. Toxicol. Pharmacol.* 3, 163 (1983).
2. U.S. Congress, Committee on Science and Technology, *Review of the Scientific Basis of the Environmental Protection Agency's Carcinogenic Risk Assessment of Formaldehyde* (Government Printing Office, Washington, D.C., 1983).
3. U.S. House of Representatives, Committee on Ethics and Standards, *Investigation of Alleged Improper Alteration of House Documents* (HR 98-544, Government Printing Office, Washington, D.C., 1983).
4. *Gulf South Insulation vs. CPSC* (No. 82-4218, 5th Cir. Ct., 1983); *Borden et al. vs. Commissioner of Public Health* (Superior Court, Commonwealth of Massachusetts, Nos. 38,508-38,473; 41,840; 49,725; 46647, 1982).

Ashford *et al.* argue that, in the areas where the law is unspecific or science uncertain, it is established practice to use "science policy"—a body of prudent assumptions and decision strategies for handling insufficient data—to fill the gap. Such a body of received assumptions has come into being for the regulatory treatment of carcinogens, and Ashford *et al.* charge that EPA administrators under President Reagan have sought to change this existing "science policy" without valid scientific reasons, and also without adequately exposing whatever justification they thought they might have to review by scientists and the public.

The latter criticism is unfortunately valid and is emblematic of the general unease shown by the Reagan Administration in dealing with the scientific and technical community. But the former criticism is arguable. "Science policy" is derived, after all, for the general case, and it does not seem wise to blindly apply its settled assumptions where evidence is available casting doubt upon or flatly contradicting them. Such is the case with formaldehyde.

1) Formaldehyde, unlike most carcinogens identified in animal cancer tests, is not a synthetic industrial chemical but a normal metabolite in human biochemistry with an elaborate enzymatic system already in place for handling it. This suggests that our bodies are capable of handling it safely as long as exposure is not much higher than the amounts the body itself manufactures.

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plies that harmful effects (including cancer) seen at high, saturating doses almost certainly cannot be manifest in proportion at low, physiologically normal doses. In fact, the Chemical Industry Institute of Technology inhalation study in rats shows just this behavior. The incidences and doses were as follows for squamous cell carcinoma of the nasal passages, the only tumor seen in significant numbers (males and females calculated together): 0 of 232 at 0 part per million (ppm), 0 of 236 at 2.0 ppm, 2 of 235 at 5.6 ppm, and 103 of 232 at 14.3 ppm (1). This is a solidly nonlinear dose response of high order, and it shows that the standard practice of assuming, when data are lacking, a linear dose response for purposes of human risk estimation is clearly inappropriate here. (Science policy is, after all, supposed to fill gaps, not override available data.)

3) Mice, when tested in parallel under identical conditions with comparable numbers of animals at risk, did not develop a significant incidence of tumors of any sort. It is true that the general "science policy" presumption has been that even "well conducted" negative animal studies "will not be said to detract from well-established positive evidence for other species," and this is defensible when one tries to make sense out of a large mass of wayward bioassay data carried out in many different laboratories with differing degrees of statistical power and with nonuniform methods of tumor classification. But this general presumption is validly controvertible in cases where, as here, the doses, exposure times, statistical sensitivity, and criteria for tumor evaluation are perfectly comparable in the two bioassays. The only salient difference between the two tests is the choice of species, and hence the discordant results between two taxonomically close relatives tested under identical conditions does raise the question of how much confidence we are obliged to place in generalizing the cancer verdict in rats to the taxonomically quite distant species called humans.

Given that formaldehyde is as ubiquitously useful as it is, wise regulatory rule-making would not, I believe, apply "science policy" so rigidly as to override the above facts. But such a clear departure from accepted practice should, without doubt, be aired before the scientific community and the public.

WILLIAM R. HAVENDER

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Berkeley, California 94707*

References

1. J. A. Swenberg *et al.*, *Carcinogenesis* 4, 945 (1983).

In Wildavsky's letter, the nature of science, science policy, and procedural consistency in decision-making are confused. He sets up "straw men" and attributes to us positions that we do not take.

We argue neither for nor against more regulation. Rather we criticize OSHA and EPA for departing from their previously articulated positions on matters of science policy without following the proper administrative procedures for doing so. Further, we criticize the Fifth Circuit Court of Appeals for violating the principles of judicial review by substituting its own judgment on issues of science policy for that of the CPSC.

Nor do we suggest that science policy provides agencies with carte blanche to regulate at will. In situations where an agency's statutory mandate requires it to make regulatory decisions in the face of scientific uncertainty, however, the agency will necessarily be making science policy determinations. As the courts have long recognized, basing regulatory action on science policy determinations violates neither good science nor good law. While proper identification and understanding of issues of science policy demand a working knowledge of the underlying scientific principles, the ultimate resolution of these issues must rest on determinations of social policy. The formulation of social policy, within the confines of a congressional mandate, is precisely the function society has assigned to the regulatory agencies.

Finally, we do not, as Wildavsky suggests, argue that an agency is bound to accept the views of scientists on questions of science policy. Our position is simply that when a majority viewpoint on a science policy issue has evolved within the relevant scientific community, the agency should not depart from that viewpoint without acknowledging its departure and articulating a reasoned justification for taking a contrary view. The role of the courts is to ensure that the agency's position on such issues—whether or not consistent with that of the scientific community—is arrived at by a reasoned decision-making process.

Todhunter's comments are inconsistent with our article, with his own prior statements, and with the TSCA. We address them in the order presented.

Certainly, we do not contend that Todhunter ignored *all* evidence of formaldehyde carcinogenicity in his memorandum of 10 February 1982. Our article does state, however, that this memorandum failed to address certain key empirical data contrary to its author's assessment of the significance of the human

cancer risk posed by exposure to formaldehyde. We, and others, have documented these factual omissions in detail in other publications (1, 2).

We do not contend that Todhunter's memorandum wholly ignores the possibility that formaldehyde poses a significant cancer risk to humans. Indeed, as we note in our article, Todhunter's own informal risk assessment—that "there may be human exposure situations . . . which may not present carcinogenic risk of significance"—necessarily implies the possibility of significant human risk.

Nor do we quibble with Todhunter's position that "significance" refers to "probability." Our article quite clearly states our opinion that "significance," in the context of section 4(f) of TSCA, "pertains to the likelihood of occurrence." We *do* quibble, however, with Todhunter's disregard of the word "may" in section 4(f). That section of TSCA is triggered whenever (3)

there *may* be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer [emphasis added].

In law, science, and everyday usage, "may" refers to possibility. As we suggest in our article, a threshold determination under section 4(f) may fairly be said to require only a "credible possibility" of significant risk. At this point, the agency is directed by the plain language of the statute to give serious, immediate consideration to the propriety of taking regulatory action under one or more of the various provisions of sections 4, 5, 6, and 7 of TSCA. If Todhunter disagrees with this framework, his quarrel is with Congress, not with us.

With regard to Todhunter's reliance on the then-available epidemiological studies of formaldehyde, we can only refer him back to his own language. That language—both in the 10 February memorandum and in his current response to our article—indicates that Todhunter treated these studies as evidence that the human risk of formaldehyde was not "critical," "potent," or "high-level." Yet a number of methodological inadequacies—such as small sample size and poor exposure documentation—renders them unsuitable for this purpose. Most evaluators, including the International Agency for Research on Cancer (IARC), the CPSC, and even EPA's own Office of Toxic Substances, declined to rely on the available epidemiology in their analysis of formaldehyde carcinogenicity (1).

Todhunter's suggestion that his initial EPA discussions on formaldehyde were with Warren Muir appears to be at odds with his congressional testimony. In a

hearing before Representative Florio's subcommittee, Todhunter testified as follows (4, p. 27):

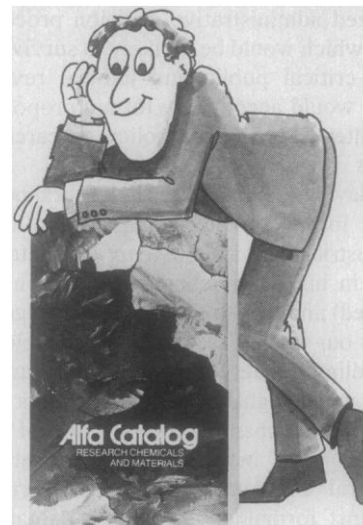
When I arrived at the agency, before I ever met with Dr. Hernandez, I was briefed by Dr. Mueller and Mr. Clark, who was at the time the acting assistant administrator, and was informed that the Agency at the time had no intention of regulating formaldehyde. . . ."

Had the discussions been with Muir, one would think that Todhunter's testimony would have reflected this fact. Indeed, the Office of Toxic Substances, when headed by Muir, had recommended that section 4(f) be deemed to have been triggered for formaldehyde.

Similarly, Todhunter's statements regarding meetings with Byington and Guarraia are difficult to reconcile with his congressional testimony. In response to questioning from Representative Mofat, Todhunter testified that "I know I had breakfast with Mr. Byington at least once, possibly twice during January" (4, p. 29), only days before the completion of the 10 February memorandum. Further, the same congressional testimony indicates that a "planning calendar" submitted by Todhunter lists several scheduled meetings with Guarraia in December, January, and early February. If these meetings were merely the product of a staffer's overactive imagination, that fact is certainly not evident from Todhunter's testimony. Guarraia was then a director of the American Industrial Health Council (AIHC) and director for government relations for the Synthetic Organic Chemical Manufacturers Association (SOCMA). Both AIHC and SOCMA have strong ties to the Formaldehyde Institute. AIHC is an industry research and lobbying group and, until 1979, the Formaldehyde Institute was part of SOCMA, where it was known as SOCMA's "Formaldehyde Task Force." All three organizations maintain their offices in Scarsdale, New York, and as of April 1983 shared the same phone number (1).

Finally, Todhunter's reliance on a Massachusetts Superior Court decision [his reference (4)] is ill founded. While a Superior Court judge did overturn the state's ban on urea-formaldehyde foam insulation in 1982, the Massachusetts Supreme Judicial Court reversed the lower court's decision in April 1983 and reinstated the ban on the use of urea-formaldehyde foam insulation (5).

Havender raises technical issues regarding the scientific determination of formaldehyde's carcinogenicity and risk assessment. We did not in our article express our opinion on this subject—we focused on legal process and science policy concerns. However, Havender's



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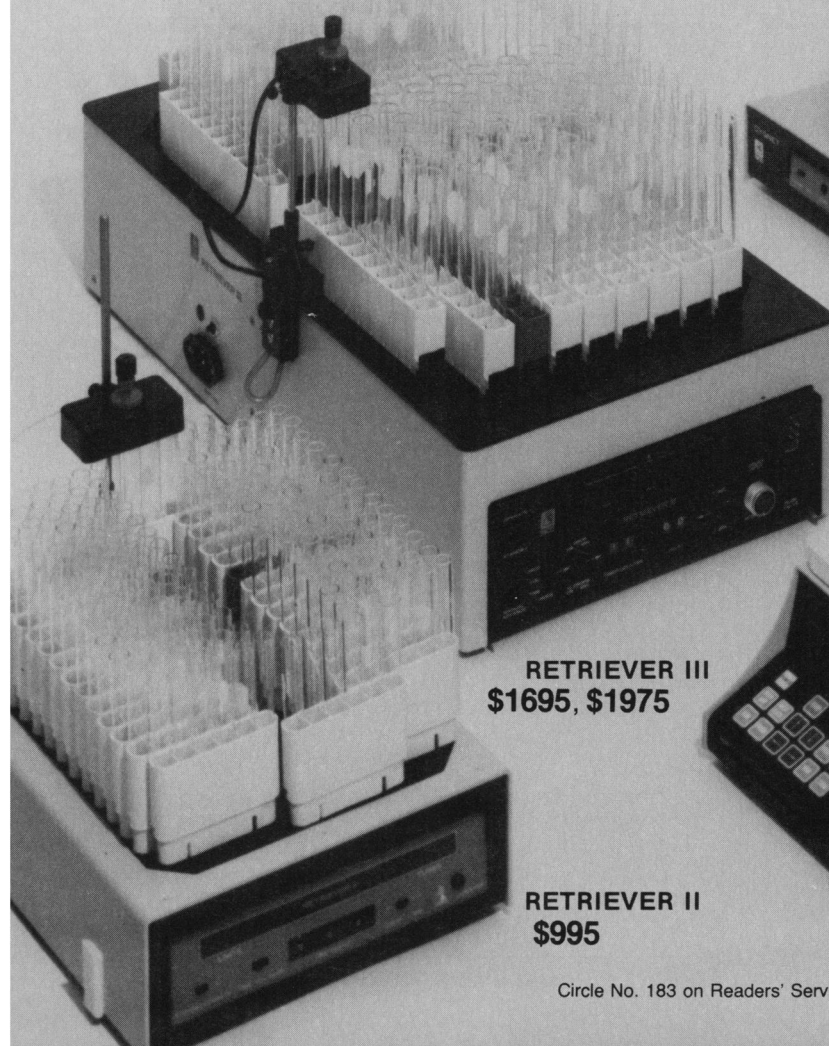
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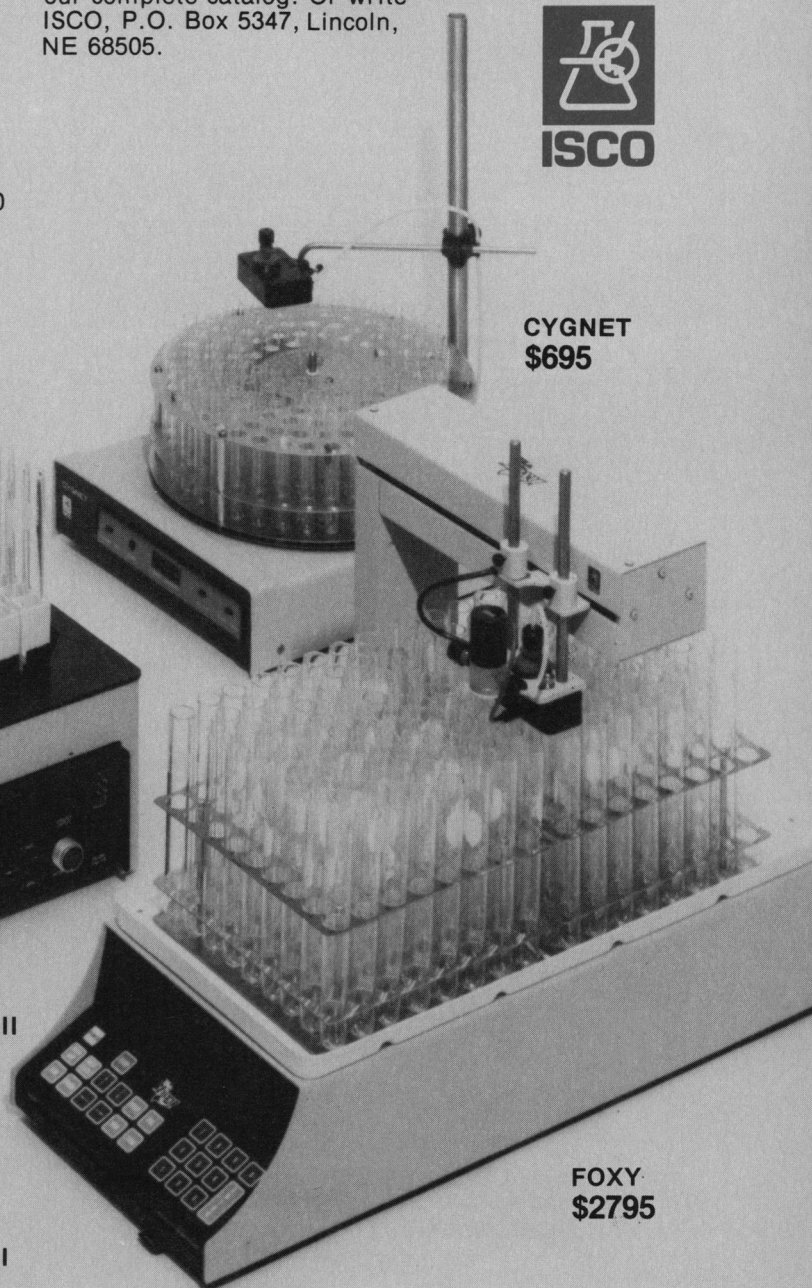
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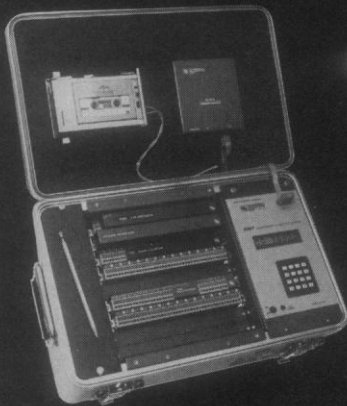
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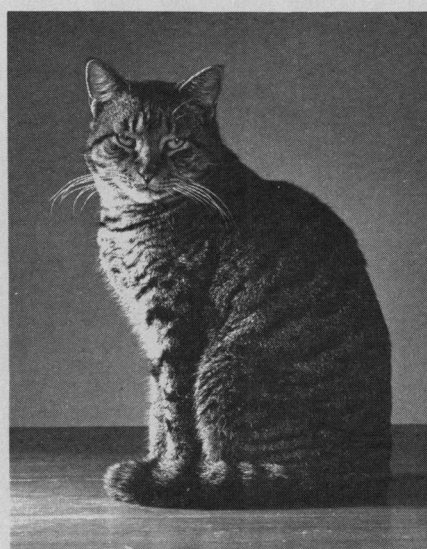
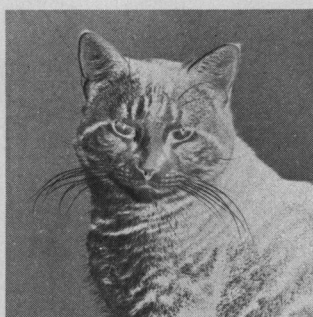
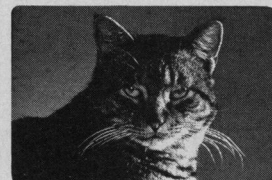
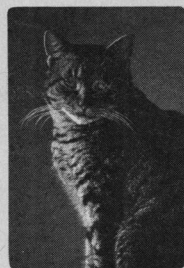
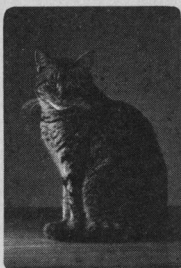
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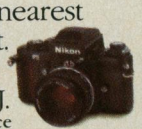
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The Budget for Social Science Research

In the President's proposed budget for fiscal year 1985, funding for research in the social and behavioral sciences is scattered among nearly 40 agencies, programs, or departments. Their budgets reflect many of the same forces that shaped other federal budgets—legal mandates, a belief in the importance of certain areas of federal expenditure, a desire to reduce the federal deficit, and, this year, the inevitable appeal to the electorate.

What is missing is a sense of the scientific and economic benefits of an integrated, collaborative national research program in the social and behavioral sciences and a budget strategy that takes these benefits into account. Although it is not surprising that mission and basic research activities should be different, it is inefficient for a research program in one federal agency to emphasize an aspect of the research enterprise that is being dismantled in another part of the government.

In the fiscal 1985 budget, there is strong support for the development of scientific databases at the National Science Foundation; at the same time, there are plans to discontinue, for want of funds, the Department of Labor's National Longitudinal Surveys, one of the most productive and scientifically important longitudinal databases in the nation. Programs in the Alcohol, Drug Abuse, and Mental Health Administration to examine the medical and social problems of alcoholism and drug abuse receive sizable increases, but research programs in the Office of Human Development Services that, if well managed, would deal with some of the human effects of these factors are very nearly decimated. In education, too, the Administration's rhetorical emphasis on improving the education of American youth is undercut by its inconsistent budget proposals over the past several years.

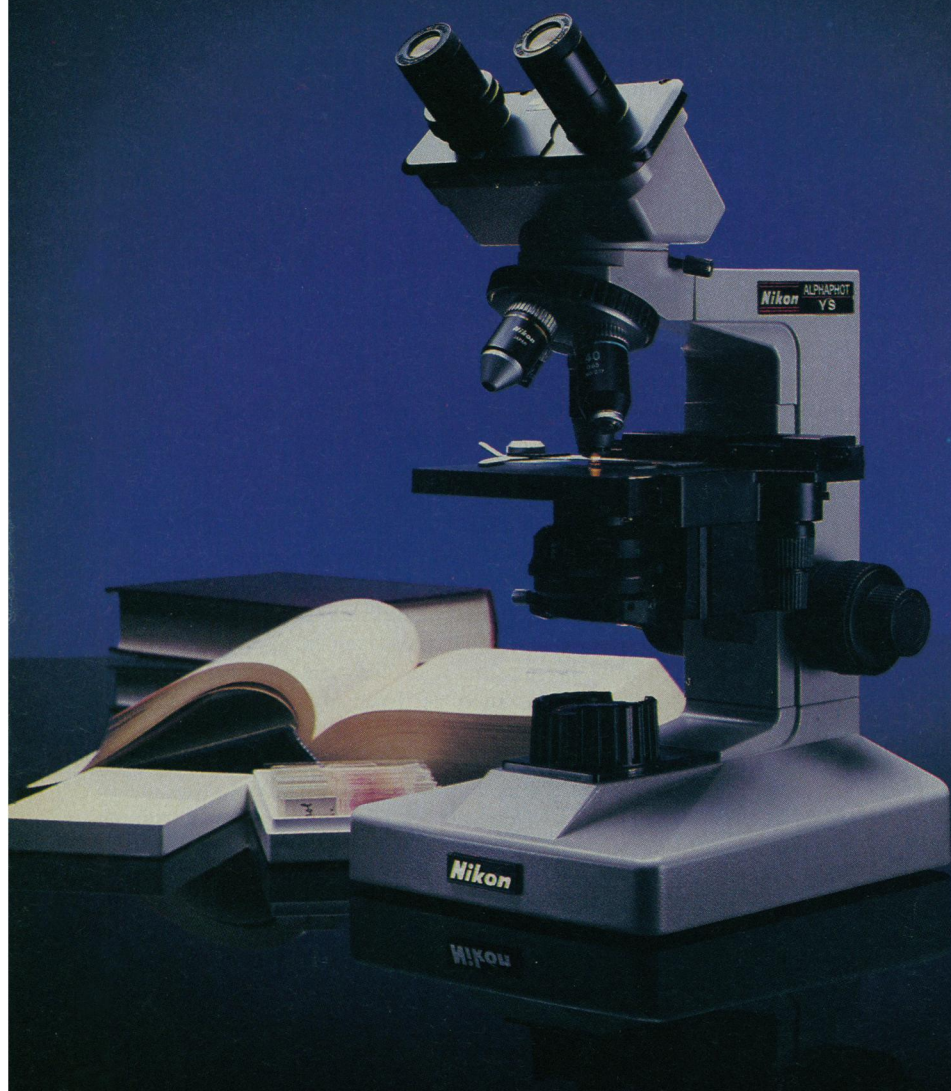
In general, the fiscal 1985 proposals for social and behavioral science research continue the patterns established by this Administration in the last 2 years. There are, once more, modest increases in support for basic research. Research budgets in mission agencies dealing with topics of importance to the Administration, such as defense or alcohol and drug abuse, are granted increases, while research programs dealing with social services or social policy are generally slated for budget cuts. Finally, certain research and training programs are again not funded, including programs in the Office of Juvenile Justice and Delinquency Prevention, clinical training at the National Institute of Mental Health, and international education and foreign language studies in the Department of Education. In the past, Congress has consistently reestablished funding for agencies with zero budgets. A similar situation may well occur in fiscal 1985.

The larger issue raised by this budget and its recent predecessors is whether the combination of uncoordinated and, at first glance, almost capricious budget changes imposed on social and behavioral science research programs over the past several years is wise. The cumulative effect of the 50 to 75 percent budget cuts of fiscal 1981 and 1982, combined with the uncertainty on a year-to-year basis of the future of specific federal research programs, may be less important for the dollars that are not spent than for the consequent depletion of important national scientific resources. One resource that is being eroded is the strength and vitality of the research community. A second is the corps of able and experienced federal social science research administrators, many of whom are leaving their positions because of low esteem and budget uncertainty.

At a time when the federal budget deficit is expanding rapidly, it is difficult to argue for special purpose or special interest funding increases. However, the interest of the social and behavioral science community coincides with the national interest. A modest amount of coordinated intelligence when research budgets are being set and when research projects and databases are under consideration would go a long way toward achieving economies and improving the federal research enterprise in this area.—ROBERTA BALSTAD MILLER, *Executive Director, Consortium of Social Science Associations, Washington, D.C. 20036*

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You will be notified in **October** about acceptance, conditional acceptance, or non-acceptance of your proposal. Further information will be provided at that time. If accepted, your preliminary program with confirmed speakers is due in **November**, and your final program copy, suitable for publication, is due in **January**.

 <div style="clear: both;"></div> <p>Annual Meeting Los Angeles 24-29 May 1985</p>	<p>PROPOSED SYMPOSIUM</p> <p>Submit not later than 1 August 1984</p>	<p>Return this form to: AAAS Meetings Office 1101 Vermont Ave., N.W. Washington, D.C. 20005 Telephone: (202) 842-9530</p>
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PRINCIPAL ARRANGER (who will receive correspondence):

TELEPHONE _____
(Area Code) (Number)

NAME _____ AFFILIATION _____

MAILING ADDRESS _____
(Street) (City & State) (Zip Code)

CO-ARRANGER (if applicable):

TELEPHONE _____
(Area Code) (Number)

NAME _____ AFFILIATION _____

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(Street) (City & State) (Zip Code)

TITLE OF SYMPOSIUM _____

SPONSORSHIP (AAAS Section, Office, or Affiliate **only**) _____ No. of 3-hr. Sessions _____

- | | |
|---|---|
| <p>1. Speaker _____
Affiliation _____
Topic _____</p> <p>2. Speaker _____
Affiliation _____
Topic _____</p> <p>3. Speaker _____
Affiliation _____
Topic _____</p> | <p>4. Speaker _____
Affiliation _____
Topic _____</p> <p>5. Speaker _____
Affiliation _____
Topic _____</p> <p>6. Speaker _____
Affiliation _____
Topic _____</p> |
|---|---|

**PLEASE ATTACH SYNOPSIS OF OBJECTIVES OF
PROPOSED SYMPOSIUM (APPROXIMATELY 200 WORDS).**