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The Golden Assurances of the American Council on Science and Health

Center for Science in the Public Interest

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by Peter Harnik

Center for Science in the Public Interest
Washington, D.C.

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Preface

In the past three years a number of journalists, CSPI members, and others have asked CSPI for information about the American Council on Science and Health. These requests did not come as a surprise, because we, too, had been intrigued by this unusual non-profit organization that billed itself as a "consumer health" group.

The reason that numerous parties were so intrigued by this consumer group was that its views were usually diametrically opposed to those of other consumer groups and health groups. In fact, when it came to health and safety regulations, ACSH was usually aligned with industrial and corporate interests rather than other consumer groups or even government. When a consumer group or governmental agency criticized a particular food additive or other chemical, ACSH was usually not far behind--defending the chemical.

ACSH's views were so friendly to the food, chemical, and other industrial interests that one automatically suspected that the group was financially linked to those interests. But to the surprise of inquirers and to the pleasure of The Wall Street Journal, ACSH claimed for a long time that it did not accept corporate funding that would pose a conflict of interest. Moreover, ACSH's director, Elizabeth Whelan, brandished her Harvard Research Associateship at every opportunity. At long last, it seemed, corporate America had found an untainted, independent defender of its philosophy on food and health matters.

In response to the inquiries and to become informed ourselves, we decided to take a serious, objective look at this peculiar fellow non-profit group. In this report, we look at ACSH's sources of funding, the background of its board members and advisors, and the quality of its scientific reports. To evaluate the reports, a number of highly qualified scientists gave generously of their time to wade through the often tedious reports and prepare brief critiques, which are included in this report. To these

scientists--Thomas Burke, William Castelli, Edward Groth III, Karen Koenig, Bernard Pasternack, Mel Reuber, Martin Rosen, Carl Shy, Theodor Sterling, James Swanson, and Arthur Upton--a word of thanks. I would also like to thank ACSH director Elizabeth Whelan for discussing her views and ACSH's policies and funding with the author of this report, Peter Harnik.

Peter Harnik came to Washington in 1970 to work on a book for the Earth Day organizers, and never left. He was coordinator of Environmental Action and editor of Environmental Action magazine from 1971 to 1977. Since then he has been a free-lance journalist (Washington Post, Chicago Tribune, Bulletin of Atomic Scientists and many others) and consultant to public and private agencies including the Office of Technology Assessment, Solar Lobby, National Consumers League and the Pension Rights Center. He came to this project with no pre-conceived notions about or even knowledge of ACSH, but a good deal of curiosity.

Harnik's curiosity was satisfied by his findings, and I believe the reader's will be also. In brief, Harnik discovered that as a consumer group, ACSH appears to be a consumer fraud; as a scientific group, ACSH seems to arrive at conclusions before conducting studies. Through voodoo or alchemy, bodies of scientific knowledge are transmogrified into industry-oriented position statements. Many of ACSH's advisors and directors work directly or indirectly for the food, chemical, and other industries whose products are the subject of ACSH reports. Much of the organization's funding comes from the companies which make products similar or related to those evaluated in the reports. In short, ACSH appears to be a front for industry, an academic-sounding organization whose positions masquerade as objective and scientific, but which can be counted on to back industry. It is like the proverbial wolf in sheep's clothing.

As industry continues to be lambasted for polluting the environment, poisoning workers, molding children's minds through powerful advertising, and pressuring government officials, corporate leaders have sought ways to buttress their views. One method has been to finance "think tanks" and litigating organizations, such as the Mountain States Legal Foundation (of which

Interior Secretary James Watt is an alumnus), the American Heritage Institute, and American Council on Science and Health. This type of organization has been successful in attracting publicity, if not always in influencing policies, because reporters rarely have dug beneath the veneer of fairmindedness. Consequently, the public has been led to believe that sets of scientific facts were more controversial than they, in fact, were ... and that individual or governmental action would be premature. In X-raying one such organization, it is our hope that the public, and especially reporters, will be inspired to carefully analyze an organization's statements and possible biases. In that way, the public--and the development of public policies--will be best served.

Michael Jacobson
Executive Director
Center for Science in
the Public Interest
January, 1982

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ACSH Background

Early in 1978 a new organization burst upon the public policy scene--the American Council on Science and Health. Self-styled as a pro-consumer organization, it was as different from the existing consumer community as Ralph Nader had been to the old Better Business Bureau in the late 1960s. In fact, nothing quite like ACSH had ever been seen before--an organization that combined an outspoken, aggressive, high-profile style with pointedly status-quo-oriented positions, funded heavily by right-wing foundations and corporations whose products or practices have been under attack, and smoothed over with a thin veneer of "scientific objectivity" by an advisory board of Ph.D.'s, M.D.'s, and others, ranging from the famous to the infamous to the obscure.

Since its inception, the Council has utilized a highly successful operating formula. It chooses a pesticide (such as 2,4,5-T), food additive (such as caffeine), or lifestyle (such as the relationship between diet and hypertension) that is being criticized as a health hazard; does a literature search; publishes a report showing that the substance is safe--or rather that there is no evidence to show that it isn't safe--if used in a reasonable manner by a reasonable person; issues a flurry of press releases ballyhooing the finding; criticizes regulatory agencies for considering restricting the substance; and then directly and indirectly parlays its position into additional financial support both from corporations which want to become disentangled from "consumer-oriented bureaucracies" and from foundations which are philosophically opposed to regulation.

In some respects ACSH seems to be a kind of family affair. The executive director is Elizabeth Murphy Whelan, a 38-year-old epidemiologist who holds a doctorate from Harvard School of Public Health. Among her fellow board members are her father, Joseph Murphy, a New York lawyer; Dr. Frederick Stare, Whelan's former teacher, employer and co-author; and Dr. Robert Olson, a former student of Stare's. The Council's law firm is Thacher, Proffitt and Wood, where Whelan's husband happens to be a partner.

The driving force behind ACSH is Whelan, a perky woman who likes to be photographed holding a can of artificially-sweetened soda or spreading sugar- and fat-rich icing-out-of-a-can on her young daughter's birthday cake. Sitting in her 18th floor Manhattan office with a view of the Hudson River, Whelan rules over a mini-empire that would be the envy of most consumer advocates--plush furnishings, three different offices (in New York City; Summit, N.J.; and Washington, D.C.), a staff of 19, and, supporting it all, a budget that has zoomed from nothing to over three-quarters of a million dollars in just three years.

The guru of the American Council on Science and Health is Fred Stare, former chairman of the Nutrition Department at Harvard's School of Public Health. Stare, who created the department himself in 1942 and built it into prominence largely by attracting huge grants and gifts from such food companies as General Foods, Borden and Kellogg, is perhaps best known for his folksy combativeness, his support of the food industry, and his unique crusade in defense of sugar in the American diet (a viewpoint which Whelan has swallowed lump, bowl and packet).

Both Stare and Whelan are prolific. They've written numerous articles and books, together (Panic in the Pantry, Eat OK--Feel OK!) and individually. They've appeared frequently on TV and radio, and for years hosted their own radio interview show, "Healthline," which Whelan dearly wants to resurrect if she can raise another $100,000 to get it back on the air. Also prolific is board member Dr. Thomas Jukes who frequently takes to the letters-to-the-editor pages of many publications for vitriolic forays concerning chemicals, nutrition, agriculture, wildlife effects, and public interest activists.

Although Whelan rates herself diametrically opposed to such consumer advocates as Ralph Nader, Health Research Group director Dr. Sidney Wolfe, and Center for Science in the Public Interest director Dr. Michael Jacobson--all of whom Whelan labels "anti-technology"--ACSH has directly modeled its high-profile style on these very predecessors. Not only does Whelan sound faintly Naderesque when she speaks ("We don't feel a substance should be banned at the drop of a rat") and when she

titles some of her reports ("New Jersey: Garden State or Cancer Alley?"), but she also gets the kind of media coverage normally reserved for the social critics she so vociferously opposes--the kind of media coverage a corporate public relations director would empty his wallet for. Ironically her ticket to the media is a progression of reports that say, soothingly, "don't worry" at a time when scientists in government, industry, and universities, from Massachusetts to California are identifying links between our modern society and health problems.

ACSH's Funding

Unlike her competitors, adversaries, and predecessor organizations, which scratch around for nickels and dimes, Whelan has struck gold with the American Council. The difference lies with ACSH's sources of funding. While most consumer and scientific groups get the majority of their money from members, small foundations, and the sale of pamphlets, the Council receives the overwhelming majority of its support from corporations and corporate foundations, many of which have a direct or indirect interest in the subject of one or more of the ACSH reports. Only about 10 percent of the ACSH budget stems from membership fees from individual donors.

Some of ACSH's contributors are:

- Coca-Cola Company, Holly Sugar Co., National Soft Drink Association, Pepsico Foundation. As an outspoken defender of both sugar-sweetened and saccharin-sweetened soft drinks, Whelan blames dental cavities on "sticky" sugars (as in dried fruits) and firmly opposes taking what she calls "fun foods" (candy and soda) out of school cafeterias (Dallas Morning News, April 6, 1978, page 7).

- Campbell Soup Fund, Castle and Cooke, Inc., Frito-Lay, Inc., Heinz U.S.A., Hershey Foods Corp., Kellogg Co., Oscar Mayer & Co., Universal Foods Foundation, all companies (or foundations controlled by companies) that produce foods which have been criticized as "junk food" for having

too much sugar, too many additives, too little nutritional value, too much fat, or some other deficiencies. Whelan steadfastly maintains that there is no such thing as a "junk food" and that there is insufficient evidence of a relationship between diet and any disease. She told the Fort Worth Star Telegram on September 25, 1980, "The assignment of foods to the evil categories of junk is very arbitrary. That gorgeous cheeseburger contains ingredients from all of the Basic Four Food Groups, but if you eat it in a fast food restaurant, some people will regard it as junk." She added, "I recommend the permanent retirement of the term junk food."

● International Flavors and Fragrances, Inc., and McCormick and Co., both producers and marketers of artificial flavorings and colorings. The Council published a report stating that diet--specifically the ingestion of food coloring agents--does not lead to hyperactive behavior in children.

● Boise Cascade Corp., Georgia-Pacific Corp., and International Paper Co. Foundation, all huge timber and paper companies (or their wholly controlled foundations) that use vast quantities of herbicides. ACSH published a report exonerating the most controversial herbicide of them all, 2,4,5-T.

● Bethlehem Steel Corp., Chevron USA, Inc., Consolidated Edison Co., General Motors Foundation, Texas Utilities Co., and the United States Steel Foundation, all of which have been cited on numerous occasions by the Environmental Protection Agency for air pollution violations (or are foundations totally controlled by companies so cited). ACSH published a study recommending that certain U.S. air pollution standards be relaxed.

● American Cyanamid Co., Amoco Foundation, Dow Chemical of Canada, Hooker Chemical and Plastics Corp., Mobil Foundation, Monsanto Fund, Shell Companies Foundation, and Tenneco, Inc., all of which are chemical and petrochemical producers (or their wholly controlled foundations). One

of ACSH's most vocal and consistent themes is that cancer, except that from smoking, is overrated as a threat and that the chemical industry is taking a bum rap for its publicly perceived role in raising cancer rates. In a speech at Hillsdale College in 1980, Whelan said,

> Of course we need to keep health-threatening chemicals out of our food, air and water. However, with today's consumer advocates leading the show, we are heading toward not only zero risk, but zero food, zero jobs, zero energy and zero growth. What can we do about changing this state of affairs? How can we become new consumer advocates? One of the more effective ways, in my view, of challenging the popular wisdom is to speak out. Companies and consumer groups alike....
>
> For executives in the chemical industry, the burden falls particularly hard, because they are the most familiar with the relationship between chemicals and our environment. Some companies, like Monsanto and General Foods, have already taken the initiative in this public education concept.

ACSH has published two cancer reports, both largely exonerating chemicals.

Even obscure and innocent-sounding ACSH contributors turn out to have some surprising real or potential conflicts of interest. For instance, the Glenmede Trust Company is actually the administering agency of the Pew Memorial Trust, the $600-million family fortune amassed through the Sun Oil Co. Pittsburgh's Sarah Scaife Foundation, which got ACSH started with grants totalling $125,000, is the foundation growing out of Gulf Oil and Alcoa profits and still heavily based upon Gulf stock. The Rollin Gerstacker Foundation, from which ACSH has received $75,000, was set up by a former chairman of the board of the Dow Chemical Co.; the foundation's current vice president is on the board of Dow, and Dow's President Paul Oreffice is a foundation trustee. (Dow is the largest manufacturer of the herbicide 2,4,5-T,

which the Council found safe.) Finally, the National Chamber Foundation, which contracted with ACSH to produce a report on air pollution and human health, is not an advocate of chamber music but is the tax-deductible sister organization of the National Chamber of Commerce, one of the leading business organizations publicly dedicated to rolling back the nation's pollution control standards.

Altogether, as of May 1, 1981, ACSH reported that it had received contributions from nearly 111 corporations and company and private foundations. (For complete list, see Table, page 7.) (In a mid-August, 1981, interview, Whelan stated that about 30 more gifts had come in since the publication of the original list.) Of the total, all but 13 are companies or company foundations. However, it is important to note that there is no indication of any direct quid pro quo between the money the Council receives and the results of its studies. There is also no indication that the contributors have any say as to what studies are carried out.

Whelan bristles at suggestions that the Council is influenced by industry money. In an interview, she said, "I think it's time that /CSPI director/ Mike /Jacobson/ stop trying to condemn our efforts as an industry front and recognize the fact that the consumer has many voices and we happen to be a different one."

She contends, "Very frequently pro-consumer and pro-industry are synonymous" but adamantly states, "We're not paid off to say anything. If you're a food company you can't trust us." (To substantiate that claim she tells of her ongoing campaign to dissuade the food industry from advertising some of its products as "100% natural." "They /food manufacturers/ don't believe in that," Whelan explains. "They're just trying to boost business by playing to /consumers'/ fears.")

Interestingly, the more the American Council on Science and Health is criticized for taking corporate money, the more the group seems to turn to that source. When ACSH got started, Whelan trumpeted the fact that she would not take any money from companies in the food, drug, or chemical industries. For instance, the ACSH 1980 Annual Report states, "ACSH is sup-

ACSH's Current Supporters

The list below identifies foundations, corporations and other organizations that contributed $500 or more to the ACSH operating budget as of May 1, 1981. It does not include institutions which paid honoraria, purchased bulk quantities of ACSH reports, or gave donations since May, 1981. *Reprinted from ACSH annual report.*

Abbott Laboratories Fund
Alliance of American Insurers
Amax Environmental Services, Inc.
Amax Foundation, Inc.
American Cyanamid Company
American Medical Association
Amoco Foundation, Inc.
Amway Corporation
Armco Inc.
ASARCO Incorporated
Ashland Oil, Inc.
Bechtel Power Corporation
Bethlehem Steel Corporation
Boise Cascade Corporation
Bristol-Myers Fund
The Burroughs Wellcome Fund
Campbell Soup Fund
Castle & Cooke, Inc.
Celanese Corporation
Chesebrough-Pond's Inc.
Chevron U.S.A. Inc.
CIBA-GEIGY Corporation
Cities Service Company
The Coca-Cola Company
Consolidated Edison Company of New York, Inc.
The Continental Corporation Foundation
The Continental Group Foundation
Cooper Industries Foundation
Adolph Coors Foundation
Corning Glass Works Foundation
Crystal Trust
Diamond Shamrock Corporation
The Gaylord Donnelley Foundation
Dow Chemical of Canada, Limited
Esmark, Inc. Foundation
Exxon Corporation
FMC Corporation
FMC Foundation
The Ella West Freeman Foundation
Frito-Lay Inc.
General Motors Foundation
Georgia-Pacific Corporation
Rollin M. Gerstacker Foundation
Getty Oil Company
The Glenmede Trust Company
Grace Foundation Inc.
The Hammermill Foundation
Heinz, U.S.A.
H.J. Heinz Company Foundation
Hercules Incorporated
Hershey Foods Corporation
Hoffmann-LaRoche Inc.
Holly Sugar Company
Hooker Chemicals & Plastics Corp
INA Foundation
Institute for Educational Affairs
International Flavors & Fragrances Inc.
International Paper Company Foundation
The J.M. Foundation
Johns-Manville Fund, Inc.
Johnson & Johnson Associated Industries Fund
Kellogg Company
The Esther A. & Joseph Klingenstein Fund, Inc.
F.C. Koch for Charity and David Koch
Koppers Company Foundation
Eli Lilly and Company
Thomas J. Lipton Foundation, Inc.
Loctite Corporation
McCormick & Company, Inc.
Mead Johnson & Company
Mobil Foundation, Inc.
Monsanto Fund
* National Chamber Foundation
National Distillers & Chemical Corp
National Soft Drink Association
Northwood Institute
John M. Olin Foundation, Inc.
Oscar Mayer & Co.
PPG Industries Foundation
Pepsico Foundation Inc.
Pfizer Inc.
Phelps Dodge Foundation
Phillips Petroleum Foundation, Inc.
The Procter & Gamble Company
Rexham Corporation Foundation
The Grace Jones Richardson Trust
Riegel Textile Corporation
Ross Laboratories
St. Joe Minerals Corporation
Sarah Scaife Foundation Incorporated
The Schultz Foundation
Sears, Roebuck and Co.
Shell Companies Foundation
A.O. Smith Foundation, Inc.
SmithKline Corporation
The Stare Fund
The Starr Foundation
Stauffer Chemical Company
The Charles J. Strosacker Foundation
Mary Horner Stuart Foundation
Sunmark Foundation
Tenneco Inc.
Tennessee Eastman Company
Texas Utilities Company
Union Carbide Corporation
United States Steel Foundation, Inc.
Universal Foods Foundation
The Upjohn Company
West Point-Pepperell Foundation, Inc.
Western International Hotels
Westinghouse Electric Corporation

Connected with ACSH in conduct a study on air pollution and human health

ported by grants from public and private foundations, corporations outside the food and chemical industries, associations and institutions, memberships, contributions, and publication sales." This policy was particularly lauded by those supporting the group's approach, including the Wall Street Journal, which, on February 12, 1979, said, "Mrs. Whelan, who intends to make her group as credible and authoritative as possible, says her organization will accept individual contributions from the public and funds from industry unrelated to chemicals or food." (Even then, Whelan's restriction against money from sources "unrelated to chemicals or food" was more myth than fact. For instance, the large Gerstacker Foundation grants were gladly accepted, despite the foundation's board interlocks with the Dow Chemical Co., as was Coors Foundation money, even though the foundation is under the total control of the Coors beer company.)

On September 1, 1980, the Council quietly dropped any restrictions on receiving specific industry money. No press release for this! Since then, any company can contribute to ACSH's version of scientific objectivity and regulatory philosophy, and many do so.

Why the turnaround? Whelan gives three reasons.

"First of all, we had a very diverse list," she says, indicating that her contributors consisted of many different types of corporations--"insurance companies, things like that."

"Second, we were being accused of discrimination by some of the major corporations. We are non-profit, tax-exempt, and it's possibly against the law to turn back contributions."

"Third, it became very complex about what was food and chemicals and what wasn't."

Finally, she said, "We realized that the people who criticized us for /our/ funding /base/ were criticizing us no matter how clean we tried to be. We went to the Scaife Foundation. The Scaife Foundation is as clean as I could ever possibly imagine. Mike /Jacobson/ keeps telling me about how they own Gulf Oil stock--well, so does practically everyone else these

days. ... But they have no association with food chemicals--they're a very wealthy American family. If that isn't accepted as clean then I realized that they would accept nothing as clean. so /I said/ the hell with it--just take money anywhere. And that's what we're doing."

The facts do not bear out Whelan's rationalizations.

Of ACSH's 111 donors, all but 27 have a potential interest in food, drugs, air pollution regulation, or chemicals. Insurance companies, which she frequently cites as part of her list's diversity, comprise only four donors.

As for voluntarily restricting contributions, Washington attorney Gail Harmon explains,

> There is no law against refusing certain contributions. An organization's board of directors has a responsibility to manage the group in a fiscally prudent manner, which could very well include turning down certain types of contributions if they are deemed harmful to the group's activities or image. As for the Internal Revenue Service, it's unheard of that they would revoke a group's tax status based on a policy of refusing certain contributions. The IRS cares about the fairness, accuracy, and lack of bias of a group's published materials, not its sources of money.

On the question of what is and what is not a "chemical company," Whelan is correct in saying that the question is complex; many companies have picked up chemical subsidiaries or established chemical divisions. Nevertheless, there are numerous ways of establishing criteria for acceptable sources of funding--by determining a percentage of a company's earnings from chemical operations and setting a limit, by accepting money only from the thousands of companies without food or chemical subsidiaries, by setting up a blind trust and accepting only anonymous contributions, etc.

As for the last rationalization, that Mike Jacobson would never be satisfied that a contributor is clean enough, the CSPI director has a different recollection. "As I remember it," he said, "it wasn't our group that jumped on the Council back in 1978, it was the press. I didn't even know about the Scaife money until I read about it in the New Jersey papers--they were the ones who were giving more coverage to the source of her funding than to the content of her reports."

ACSH's Scientific Reports

Regardless of the American Council's economic and personnel connections with vested economic interests, the organization's ultimate credibility among the public must hinge on the quality of its scientific reports. Unfortunately, ACSH's scientific prowess--its ability to review complex scientific controversies, analyze the information objectively and completely, and arrive at a reasonable conclusion--leaves much to be desired.

The Center for Science in the Public Interest asked eight scientists, each an expert in a subject covered by major ACSH reports, to read and briefly critique the reports. The experts, and the reports they volunteered to critique, are:

Dr. Arthur Upton (past director of the National Cancer Institute), Dr. Bernard Pasternack, and Ms. Karen Koenig of the New York University Medical Center ("Cancer in the United States: Is There an Epidemic?")

Dr. William Castelli, director of the National Institute of Health's Framingham Heart Disease Epidemiology Study ("Diet and Heart Disease")

Dr. Carl Shy, professor of epidemiology at the University of North Carolina ("Air Pollution and Your Health")

Dr. Edward Groth III, an expert on environmental and food safety policy issues and former staff member of the National Research Council ("Caffeine")

Dr. Theodor Sterling, professor of Computing Science at Simon Fraser University ("The Health Effects of Herbicide 2,4,5-T")

Dr. James Swanson of the University of California-Irvine Medical Center ("Diet and Hyperactivity: Is There a Relationship?")

Dr. Mel Reuber, a consultant in Human and Experimental Pathology and former researcher at the National Cancer Institute's Frederick Cancer Research Center ("Saccharin")

Mr. Thomas Burke and Mr. Martin Rosen of the New Jersey Department of Environmental Protection ("New Jersey: Garden State or Cancer Alley?")

Many of the critiques praised the reports for doing a good job of pulling together a great deal of information on the subjects under review, but without exception the scientists found a wide variety of flaws in the reports--ranging from omissions, misinterpretations, and inconsistencies to more serious factual errors, statistical manipulations, and unsupported conclusions. (The full texts of the critiques are included as an appendix to this report.)

Omissions and inconsistencies are some of the flaws most frequently cited in the critiques. For instance:

- In critiquing the cancer report, Upton, Pasternack, and Koenig indicated a glaring omission: "Because of widespread concern over the safety of a host of industrial products, such as plastics, paints, dyes, solvents, detergents, hair dyes and other cosmetics, it would have been of interest to have included a section on industrial products as possible causes of human cancer." The critiquers also termed ACSH's discussion of diet and cancer "inadequate." Moreover, ACSH's inconsistent use of cancer incidence and mortality data caused bewilderment: "They point out that the mortality data are more reliable than the incidence data, ... /so/ it is puzzling why 10 pages of this 25-page report are devoted to presentation of incidence trends, espe-

cially since no reference is made to them after they are presented."

● In the heart disease critique, Dr. Castelli decried the "gross inconsistencies in the type of data demanded to support various health recommendations." For instance, he pointed out, while ACSH demands almost impossit difficult test protocols for investigating the role of diet in causing heart disease, the group simultaneously accepts as a truism that obesity and smoking are both factors in heart disease--even though "no tightly controlled intervention studies have been done, nor does ACSH deem them requisite for its conclusions." In other words, the epidemiological evidence ACSH accepts for smoking and obesity, it rejects for a high fat diet.

● In the critique of the 2, 4, 5-T report, Dr. Sterling pointed out another major omission: "Most disappointingly, the report leaves out recent results obtained by Swedish studies of railroad and other workers exposed to 2, 4, 5-T and other phenoxy herbicides. Evidence for an increase in cancer levels seems to have been provided by these reports."

● The air pollution report suffers from a significant omission, too, according to Dr. Shy: "... /T/he report fails to mention the uncertainties in our present knowledge, particularly the uncertainties regarding fine particulates, organic aerosols, acid precipitation, and pollutant by-products of newer technologies such as diesel exhaust. We also still know relatively little about the acute and chronic effects on humans of nitrogen dioxide and acid nitrates, and levels of these pollutants are expected to increase over the next 20 years."

● The diet and hyperactivity study contains perhaps the largest omission of all. While implying a comprehensive look at the whole subject, according to Dr. Swanson, it "focuses almost exclusively on the Feingold hypothesis /one particular theory linking hyperactivity with food additives/, ignoring other aspects of children's diets."

Even worse than omissions and inconsistencies are the many outright errors and misstatements that the reviewers uncovered in the ACSH reports. Some examples:

● Dr. Swanson ("Diet and Hyperactivity") found that ACSH "wrongly and arbitrarily" dismissed the results from two key studies and came up with a conclusion about children's improvement rates that are off "by more than an order of magnitude."

● Dr. Sterling ("Health Effects of Herbicide 2, 4, 5-T") was stunned by the ACSH statement that every substance has teratogenic (birth defect-causing) potential if it is used in large enough doses. "It is simply not true," he wrote. "/A non-teratogenic substance/ may kill the experimental dam or female subject if used in too high a dose, but it will not show teratogenic effects."

● Dr. Reuber ("Saccharin") reported that ACSH wrongly claims that key rat studies were improperly designed. In fact, Reuber notes, the two-generation rat studies were specifically recommended by a committee of the National Academy of Sciences and were "within the design limits for carcinogenesis testing set by the National Cancer Institute."

● Dr. Castelli ("Diet and Heart Disease") found numerous errors and misrepresentations, some so severe he labeled them "astounding," "stunning," and "unscientific." For instance, while ACSH claimed that a Finnish cholesterol-lowering diet "did not prove to be a protection against CHD /coronary heart disease/," in reality the Finnish investigators reported, "In men, the use of the cholesterol-lowering diet was associated with considerably and significantly reduced mortality from CHD."

● Drs. Upton and Pasternak and Ms. Koenig ("Cancer in the United States") found ACSH's presentation of cancer incidence improper: "The authors recognize that the recent SEER (Surveillance, Epidemiology and End Results) data are not comparable with the data collected in the earlier National Cancer Survey since the SEER rates are adjusted to a differ-

ent standard population. Yet all these data are presented on the same graphs and the trends in incidence discussed as if the data are comparable."

● Dr. Groth ("Caffeine") had a concise response to the ACSH finding that the incidence of fibrocystic breast disease is not increased by caffeine consumption: "This statement is simply not supported by the evidence."

There is another serious flaw in the ACSH reports which reviewer after reviewer noted and criticized. For reasons that are never explained, ACSH seems to feel that animal testing is not a valid method of determing risk to humans. Here's what some of the scientists said about this surprising attitude:

● Dr. Reuber ("Saccharin") wrote: "The ACSH statement that 'there is no evidence to indicate that saccharin ... causes cancer or any other disease in human beings' is a denial of the value of chronic feeding studies on animals. The whole point of such studies is to develop evidence that a chemical is or is not safe for humans. Every authoritative scientific body that has studied this matter has concluded that if a chemical causes cancer in animals it should be assumed to pose a cancer risk to humans. The ACSH strategy seems to be to deny the value of animal studies and demand human epidemiology studies, knowing that human studies take years to conduct, are inevitably insensitive, and are not appropriate to establish the safety of a food additive."

● Dr. Sterling ("Health Effects of 2,4,5-T") also took exception to ACSH's rejection of animal evidence: "Evidence from animal studies, especially from animal systems that are similar to that of human systems, are deemed to present conclusive evidence as to the effects of a particular substance on human systems. Where exceptions appear (i.e., an effect in humans not being reproduced in a particular animal system), that particular animal system usually turns out to function differently than analogous systems in humans. However, the teratogenic and toxic effects of 2,4,5-T have now been demonstrated in so many different animal species that

this combined evidence cannot be denied."

● Dr. Groth ("Caffeine") was startled by the ACSH contention that the studies do not "suggest" that the human fetus is endangered by caffeine. "To say the data don't prove a risk would be accurate. To say they don't suggest one is an extremely conservative judgment. It seems to presume a burden of proof so strict that, given the difficulties in establishing causes for a human birth defect (well described in this report), it seems unlikely to me that ACSH would find that any amount of data were enough to 'suggest' a danger to the human fetus." (Ed. note: For the past year, FDA has been advising pregnant women to avoid caffeine to reduce the risk of birth defects.)

● Dr. Castelli ("Diet and Heart Disease") was even more eloquent in his denunciation of the ACSH approach: "...[T]he group pronounces that 'the results of animal experimentation ... cannot be extrapolated with confidence to humans.' This is a unique position, shared by few investigators. Indeed, if scientists did not consider animal research relevant to man, they would not bother doing it! In fact, certain areas of research would virtually grind to a halt if researchers were forbidden to extrapolate animal findings to man. Further, the ACSH discussion of animal research in the area of diet and coronary heart disease is quite superficial, grossly understating the volume, strength, and consistency of findings to date."

Moreover, the ACSH reports collectively share in a defect which is even more serious than the collection of specific errors, distortions, and omissions. Nearly every report contains conclusions and policy statements that simply do not accurately summarize the contents of the very reports themselves. This is particularly misleading to the unsuspecting reader or journalist, because the policy statements and conclusions are concise enough to be the focus of attention, while the bodies of the reports are long and complex enough to discourage all but the most expert of reviewers. Moreover, ACSH generally reduces its full-length reports to small pamphlet size, eliminating most of the technical material but prominently featuring the conclusions and policy

statements. To illustrate:

● Dr. Groth ("Caffeine") wrote: "In summary, this would have been a relatively good report if it did not contain the 'position statement.' The scientific review is competently done and is both a useful compilation of data and a thoughtful analysis of what we do and don't know. Unfortunately, this work has been shackled with a political statement, prominently featured, which flagrantly contradicts the careful, objective tone of the report itself. I can readily conclude that the body of the report is intended to provide readers with an objective, balanced assessment on which policy judgments might be based. But the position statement seems designed to reassure readers that there is nothing to be concerned about--even if such reassurance comes through distorting or ignoring the facts presented in the report. Even if it were prominently labeled 'editorial opinion,' I find it unfortunate that this statement may gain some credibility, because of the solid research that went into compiling the literature review."

● Dr. Reuber ("Saccharin") wrote: "...[T]he report's major problem is its 'Position Statement,' the summarizing few paragraphs which is all most readers will peruse. From all I can tell, the position statement was written by someone other than Terrence Smith, the report's author, and it may have even been written before the report was completed. Since the vast majority of readers will not plod through 126 tedious but not wholly unbalanced pages, they will assume that ACSH has provided proof for its extremely misleading summary."

● Dr. Groth ("Caffeine") had a remarkably similar comment: "Why ACSH chose to make such a firm statement [about caffeine not increasing the incidence of fibrocystic breast disease], when the review showed how infirm the data are, is a mystery to me. It is almost as if the 'conclusion' paragraphs were written by someone other than the author of the review, since it is difficult to see any connection between the two in this case."

● Dr. Shy ("Air Pollution") stated: "Interestingly, the body of this report is considerably more guarded, cautious, and moderate (often using sweeping, somewhat innocuous statements) than the conclusion, which comes out with irresponsible recommendations for major changes in federal policy."

● Dr. Swanson ("Diet and Hyperactivity") wrote: "While the American Council on Science and Health provides a good review of the literature on the Feingold hypothesis, the report's position statement and conclusion are so inaccurate as to undermine the document's usefulness. ...[This is] particularly unfortunate, because the position statement and the conclusions of the report are repeated in a shorter summary report which has been widely distributed. In the shorter report the literature review--which tempers the extreme view presented in the position statement-- is not presented at all."

In summary, the editorial biases of the American Council on Science and Health appear to significantly interfere with the quality of the group's scientific work. The omissions, misrepresentations, and factual errors always seem to be in the direction that the group wants to take, and in surprisingly many cases opinion seems to be substituted for scientific fact when reality does not match the group's needs.

As Dr. Reuber concluded his saccharin critique, "Anyone can make value judgments about whether saccharin should or should not be allowed. Anyone can try to balance 'perceived' benefits of saccharin to weight-conscious people and diabetics against the chemical's ability to cause bladder cancer in a small fraction of the population. But it is disconcerting to see an alleged 'scientific' organization like ACSH impugn the validity of generally accepted animal studies and pretend that positive human epidemiology studies are crucial to concluding that a chemical is safe in order to arrive at its apparently predetermined conclusion that saccharin is 'safe.'"

(In January, 1982, as this booklet was being completed, ACSH published a new report on alcohol use during pregnancy. In this

report, ACSH acknowledged that drinking less than one ounce of alcohol per day (two drinks) has not been proven safe during pregnancy, but still disputed the Surgeon General's recommendation that pregnant women should abstain from alcohol. Thus, this report appears to have the same thrust as the eight reports reviewed above.)

ACSH's Advisors

A main source of public credibility for the Council is its 62-member board of scientific advisors, consisting mostly of academics from state land grant universities. The list, which is long enough to necessitate an extra page or two in ACSH reports and which is reprinted on virtually every document published by the Council, is designed to look impressive to the casual observer. In fact, a close look at it reveals enough of a pro-industry bias to warm the heart of a junk food salesman. Many of the advisors are consultants to, or have been paid representatives or employees of, corporations in the food, drug, and chemical fields in which ACSH concentrates its work. None of this is indicated in any ACSH literature and is, in fact, often difficult or impossible to ascertain because universities do not require their faculty to reveal outside arrangements and few professors do so voluntarily.

Naturally, the fact that a professor receives an industry grant or does outside consulting for a company does not mean that he or she is dishonest. It is merely far more likely that corporate funds flow to people who are known to share industry's views on a product, a methodology, or government regulation.

What follows is a partial and by no means complete list of the extracurricular affiliations of some ACSH scientific advisors:

● Dr. Roslyn Alfin-Slater, professor of nutrition and biological chemistry at UCLA's School of Public Health, received grants of $33,100 from the Egg Council of California and $4,000 from the California Avocado Advisory Board in 1973. In 1974 she got a grant of $32,500 from CPC International, a leading manufacturer of corn products, such

as starch, sweeteners, and syrups, as well as grocery items, pesticides, and industrial chemicals. She had been a scientific advisor to CPC since 1956.

● Dr. Ernest Briskey, dean of Agriculture at Oregon State University, was for 10 years a high executive at the Campbell Soup Co., culminating as vice-president from 1975 to 1979.

● Dr. Fergus Clydesdale, professor of Food Science and Nutrition at the University of Massachusetts, has received a grant from General Mills. His curriculum vita a few years ago also stated, cryptically, "Have acted and am acting as a consultant to several major U.S. food companies and color instrument manufacturers."

● Dr. Edwin M. Foster, director of the Food Research Institute (F.R.I.) at the University of Wisconsin, was a board member of the Stange Company, a manufacturer of artificial food colors, until it was bought out by McCormick and Co. in early 1981. The F.R.I. is heavily supported by food companies, but refuses to make public its list of contributors.

● Dr. Thomas Jukes, professor of medical physics at the University of California at Berkeley, worked for American Cyanamid, a chemical company, for over 20 years, first in its Lederle Labs division, later as director of chemical research in the agriculture division.

● Dr. John Keller, director of the toxicology division at Research Triangle Institute, has a long history of industry employment, including Hazelton Labs (which tests food additives and other chemicals), the International Resource Development Corp., the American Petroleum Institute (the oil industry trade association), and CIBA-GEIGY (a drug manufacturer).

● Dr. Paul Kifer, head of the Food Science and Technology Department at Oregon State University, was assistant director of corporate research at Ralston Purina until 1973.

He is still a member of a Ralston Purina advisory committee and an advisor to the U.S. Brewers Association.

● Dr. Gilbert Leveille, formerly chairman of the Food Science and Human Nutrition Department at Michigan State University, said in 1975 that he received approximately $3,000 to $4,000 a year in consulting fees and honoraria from unspecified companies. In 1980 he joined General Foods and dropped off the ACSH board.

● Dr. Robert Olson, professor of biochemistry at St. Louis University School of Medicine, consults for the Dairy Council of California and the American Egg Board. He strongly criticized the Senate Select Committee on Nutrition and Human Needs for recommending a general reduction in the intake of high cholesterol foods, such as eggs.

● Dr. Bernard Schweigert, chairman of the Food Science and Technology Department at University of California at Davis, was formerly assistant director of the American Meat Institute Foundation, a sister organization of the powerful trade association representing major meat-packing companies. Although refusing to give specific information, he has written, "I receive honorarial or counseling fees from various public and private agencies ... and provide advice on scientific research and developments within the field of food science."

● Dr. Frederick Stare, chairman emeritus of the Nutrition Department at Harvard School of Public Health, has consulted extensively for the breakfast cereal and sugar industries, receiving retainers from Kellogg, Nabisco, and the Cereal Institute. For many years Stare was a board member of Continental Can Co., the food packaging giant, and he also testified at government hearings on behalf of the Sugar Association, the Cereal Institute, and several food companies.

● Dr. John Todhunter, formerly chairman of the biochemistry program at Catholic University and recently chosen by the Reagan Administration for assistant administrator for toxic substances at the U.S. Environmental Protection

Agency, was employed by the drug company Hoffmann-La Roche from 1976 to 1978.

In addition to those with known ties to companies with vested financial interests in areas the Council has studied (or plans to study), there are a number of other advisors who simply agree with Dr. Julius Coon, who wrote in a letter to Rep. Benjamin Rosenthal in 1975, "[The consumer groups] are completely blind to the possibility that opinions and attitudes of scientists, like myself, which happen to coincide with the interests of industry, can be derived from strictly objective scientific considerations."

Even though ACSH advisors rarely take an industry or a company to task for endangering the health or safety of an individual or for reducing the quality of the environment, Whelan feels her board "includes the whole legitimate spectrum" of public opinion. As for scientists like Harvard's eminent Dr. Matthew Meselson--a longtime critic of chemical and biological warfare--or the University of Illinois' Dr. Samuel Epstein, an outspoken critic of environmental causes of cancer, Whelan says, "I really feel that individuals like that frequently distort data and have an inherent bias. We have no inherent bias. We are not anti-technology."

One of Elizabeth Whelan's most coveted, useful, and publicized affiliations was her appointment as a research associate under Dr. Stare at Harvard University's School of Public Health, an appointment which was terminated on June 30, 1980. However, since the Harvard title provided the kind of credibility she needed to make many of her claims, she was understandably loath to give it up. So she didn't. Time after time, in articles, interviews, radio, and TV shows Whelan identified herself, or had herself identified, as currently connected with Harvard. In her December, 1980, article in Across the Board magazine she wrote, "By the time we moved into the house [Autumn, 1980], I was not only juggling the directorship of the American council ...; the Harvard appointment; [and four other commitments]." In fact, the Harvard appointment had ended several months earlier.

Over a year after she lost her Harvard link, on July 16, 1981,

on the New York television show, "Straight Talk," Whelan was introduced as Director of ACSH and research associate at the Harvard School of Public Health.

When the writer telephoned Harvard's Nutrition Department for a comment, a spokesperson said, "Elizabeth Whelan has no connection with Harvard any more." When told that Whelan was still claiming a Harvard affiliation, Harvard University spokesman Alfred Alcorn chuckled and said, "Half the people in this country claim some kind of connection with Harvard. It's not very professional, but there's not much the university can do."

Another member of Whelan's team is Washington lawyer and lobbyist S. John Byington, one of the more flamboyant and controversial members of the capital's business-government revolving door cadre. Byington, who is listed as ACSH's policy advisor, was formerly chairman of the Consumer Product Safety Commission, a White House deputy special assistant for consumer affairs under President Ford, and the deputy director of the Office of Consumer Affairs in the Department of Health, Education and Welfare.

Despite these seemingly impeccable credentials, Byington is the sort of paper consumer advocate who fits in perfectly with the American Council's veneer of authenticity. Not only had he so alienated consumer organizations by 1976 that Consumer Federation of America Executive Director Carol Tucker Foreman delivered an unusually vitriolic 12-page testimony urging the rejection of his nomination as head of the CPSC, but Byington's own confirmation testimony was sufficiently unconvincing that it took the Senate almost a month and two votes to approve him. He survived as head of the agency only two years, resigning under heavy pressure from Congress for mismanagement, excessive travel and other questionable expenses, lack of adherence to personnel policies, and general agency inaction. When Sen. Wendell Ford (D-Ky.) asked for Byington's resignation from the Consumer Product Safety Commission, he said, "I blame Byington for the inability of the /CPSC/ to act effectively, and I'm concerned that he may have done permanent damage to the agency's credibility." (Every year, under Byington, the Commission's budget was reduced, and only a handful of consumer products were regulated during the period.)

After leaving CPSC in the summer of 1978 Byington reentered the public policy field from the other side, defending variety of companies and industries that were resisting consumer protection regulation. Late in 1978 he held a press conference with Republican fundraiser Barbara Keating to denounce auto air bags. Later, he became lobbyist for the Cellulose Manufacturers Institute in its effort to continue to allow chemically treated cellulose to be used as house insulation.

Byington's most recent foray into the science and health public policy field concerned formaldehyde, a common industrial chemical used in such items as home building products, plywood, mobile homes, permanent-press clothes, air freshener, and mascara. In 1979 a scientific study indicated that formaldehyde is carcinogenic to rats, and the results were made known to the Consumer Product Safety Commission, as required by law. The Commission had the option of banning the substance, regulating its use, or merely requiring a warning label. Shortly thereafter, the Formaldehyde Institute, the industry trade association, hired Byington to represent it.

There is a broad consensus that formaldehyde is a carcinogen; this position is shared by the National Cancer Institute, National Institute for Occupational Safety and Health, National Center for Toxicological Research, and even the Chemical Industry Institute of Toxicology. (The American Council has not done a study on formaldehyde yet, but Whelan said in November, 1981, "I do not believe, from what I've read, that it poses a cancer hazard to human beings.")

One organization that feels there is insufficient evidence to label formaldehyde a carcinogen is the International Agency for Research on Cancer. That finding prompted Dr. Peter Infante, one of the top scientists at the Occupational Safety and Health Administration, to write a highly critical letter in May, 1981. When Byington found out about the scientist's action, he wrote an angry letter to Infante's boss, OSHA head Thorne Auchter, in which he asked, "How do you control members of the bureaucracy who seem to be operating freely within and without government?" Four weeks later, Infante received notice that he was to be fired on grounds of insubordination and misrepresenting the

agency using official stationery.

The event received heavy press attention and even led to a special congressional hearing. In the end Infante was not fired, in what Rep. Albert Gore (D-Tenn.) called "a victory for the integrity of science and for the right of free expression." However, in a sense, Byington got what he wanted--Infante had been sobered by the ordeal, and OSHA may well change its position on formaldehyde altogether.

The American Council has a study on formaldehyde on the agenda for future research. Among ACSH contributors who would probably be pleased with a report exonerating formaldehyde are Allied Chemical, Hercules, Monsanto, Georgia-Pacific, Tenneco, West Point Pepperell, Weyerhaeuser, Dupont, and Occidental Petroleum--each of which manufactures either formaldehyde or urea-formaldehyde resins.

ACSH: A Consumer Group?

When it comes to evaluating the American Council on Science and Health, a key question revolves around the definition of "consumer group." Since there is no official definition of a consumer group--the way, for instance, there are government definitions of political action committees or tax-deductible organizations--there has emerged a general consensus of what such an organization entails.

Esther Peterson, special assistant for consumer affairs under Presidents Johnson and Carter, noted that a group "must represent the consumer" to deserve the label and the key question is who controls the money. "An organization should be very careful about calling itself a consumer group if it's not really controlled by people who are not in a position to make money off its work," she said.

Ralph Nader was more direct. "A consumer group is an organization which advocates the interests of unrepresented consumers. It must either maintain its own intellectual independence or be directly accountable to its membership. In contrast, ACSH is a consumer front organization for its business backers. It has seized the language and style of the existing consumer organizations, but its real purpose, you might say, is to glove the hands that feed it."

The federal government does not appear to have a definition of consumer group, although various agencies have had to grapple with the question because of public hearings, advisory board meetings and other institutional events.

The Food and Drug Administration, according to Pat Kuntze, special assistant in the consumer affairs office, "operates under a fairly open and flexible definition of 'consumer.' We believe that organizations should have the opportunity as well as the responsibility for defining themselves and their purpose. While we do not prohibit consumers or organizations whose consumer orientation may be questionable from participating in our program, we are aware of the differences among organizations and do include this in our assessment of consumer views and concerns relating to agency issues."

However, FDA has actually set a very clear definition in one particular case. For its so-called Consumer Consortium--the group of organizations recommending candidates for agency consumer advisory board members--there is a requirement that not more than five percent of an organization's funding come from industry.

Virginia Knauer, who was President Nixon's consumer advisor, then a consultant to industry, and currently is a Special Assistant to President Reagan, prefers to look at factors other than funding: "While the source of funding may be a factor to be considered in evaluating the findings or proposals of consumer groups, it is by no means determinative. ... Any definition of 'consumer group' that fails to look beyond sources of funding to the actual work of the organization places unfair restrictions on such groups and their members. This could have a chilling

effect on consumer cooperative efforts with business and other groups which I believe can have important benefits for consumers."

Howard Seltzer, the acting director of consumer programs for the U.S. Office of Consumer Affairs, added, "When someone takes a stand as a consumer, it's the stand that matters, not what he calls himself. However, knowing this organization /ACSH/, I personally would be more comfortable if they referred to themselves as something like an 'industrial policy study group.'"

Conclusion

A detailed investigation of the American Council on Science and Health reveals an organization whose activities seem to contradict its oft-repeated claim of being a "consumer health" group. Elizabeth Whelan's claims of honest consumer advocacy have been bought by newspapers as diverse and respected as the Wall Street Journal ("A Health Group Gets a Beating from the Press"), the Chicago Sun-Times ("/ACSH/ is supported by contributions from foundations and individuals and says it gets no industry funds"), and the Atlanta Journal ("A consumer health group says there is no convincing evidence to support banning a controversial herbicide..."). While the group has a strong health-oriented stance on the single non-controversial issue of smoking, ACSH remains opposed to virtually all bona fide, independent consumer protection organizations on four basic, underlying issues.

1. ACSH is outspoken in giving chemicals the benefit of the doubt, with Whelan frequently claiming, "We don't feel a chemical is guilty until proven innocent," and "we don't think a chemical should be banned at the drop of a rat." This position is unprecedented among consumer organizations (not to mention among government agencies), which do press for exhaustive safety tests before allowing a chemical into public use and the environment. Although there is a conceivable "pro-consumer" aspect to Whelan's position (for instance, that many people did have a positive experience with thalidomide), that aspect is adequately represented by the chemical industry, which--like

Whelan--wants less stringent and hence cheaper testing requirements. The question comes to mind: Why is there a need for an "independent" group heavily funded by, but considerably less politically powerful than, the chemical industry itself?

2. ACSH feels that small risks can be essentially dismissed, because the likelihood of any individual being stricken or affected is so tiny. Again, no independent pro-consumer group of which we are aware shares this view; all the others realize that even a small risk spread across a population of 230 million Americans or a world population of over four billion can result in tens of thousands of deaths. While certain risks may be trivial to individuals, they may be quite significant for society at large.

3. ACSH believes that if a chemical poses a particular risk to a specific subgroup of the population--even if the subgroup is virtually impossible to identify in advance--that subgroup should take steps to protect itself rather than inflicting deprivation or higher costs on the whole society. (This stance reaches its ultimate absurdity in the case of salt and hypertension, where ACSH considers the 60 million Americans at risk a subgroup whose problem should not interfere with society at large.) Again, while this is an oft-repeated industry position, ACSH is the only so-called pro-consumer organization to endorse the stance.

4. ACSH apparently believes that cancer is overrated as a threat and a risk. By contrast, virtually all independent pro-consumer organizations we know of believe that rising cancer rates reflect some of the unhealthy excesses of our modern industrial society. Whelan, who expresses anger and terror at the thought that diet soft drinks might be banned or modified, has nerves of steel when she disdainfully rejects "cancerphobia" as unwarranted worrying about an overblown issue. Again, the ACSH position is similar to that of most of the corporations which support the group.

If ACSH, with its $750,000 budget, espouses positions nearly identical to those of its corporate sponsors, with their billions of dollars, their massive public relations and advertising budgets, and squadrons of lobbyists, where does Elizabeth Whelan's prom-

inence and value stem from? Could she possibly have something that Gulf, U.S. Steel, and Monsanto don't?

The answer, of course, is yes. ACSH has three invaluable commodities: a non-profit status, an independent name, and enough novelty to turn the head of even the most cynical reporter.

For journalists that are less than meticulous, ACSH's and Whelan's "independence" and nonprofiting stance assure coverage that corporations or trade associations could never get--coverage like JoAnn Vachule's September 25, 1980, article in the Ft. Worth Star-Telegram which began: "Dr. Elizabeth Whelan's views are an antidote for misinformation that has poisoned Americans' minds about the food they eat." Even hard-working reporters who dutifully point out ACSH's financial and other ties are relentlessly drawn to the novelty of Whelan's positions. The group is kept in the public's eye with headlines like "Health Group Disputes Label of Jersey as a 'Cancer Alley'" and "Consumer Health Advocate Fights 'Ban Everything' Trend."

Besides their direct gifts and grants, the companies in Elizabeth Whelan's life help her in more subtle ways. For one thing, they invite her to speak at their conferences and conventions so they can hear a "pro-consumer" with a comforting message. This not only gets her added press exposure, but also a few dollars to help with the rent. In return, she appears on numerous TV and radio talk shows as the counterpoint to real consumer representatives; the message, explicit or implied, is that legitimate consumer groups can legitimately disagree over public policy--regardless what the vested interests feel. How convenient that Whelan can occasionally substitute for the Calorie Control Council in defending saccharin, the Pork Producers Council in defending hot dogs, and Dow Chemical in defending 2,4,5-T!

How long Whelan's novelty will last is hard to predict. Already there is a growing awareness of the group's modus operandi and a concomitant loss of trust in ACSH by consumer groups and members of the press. On the other hand, ACSH's close ties to industry assure frequent access to business publications, company checkbooks, slick promotion, and easy intro-

ductions from boardroom to boardroom--all valuable assets in the struggle to stay publicly visible and viable.

Ultimately, it seems, ACSH's novelty and value will decline as the defective quality of the organization's scientific work is revealed. If future reports turn out to be as misleading and biased--with pre-conceived conclusions tacked on to exhaustive literature reviews--as the reviewers found the group's first three years' worth of reports, ACSH will be unable to maintain the intellectual underpinning and corporate bankrolling that are necessary for its message.

Critiques

Critique I. "Cancer in the United States: Is There an Epidemic?" by Dr. Arthur Upton (former director of the National Cancer Institute), Dr. Bernard Pasternack, and Ms. Karen Koenig of the New York University Medical Center

The American Council on Science and Health report, "Cancer in the United States: Is There an Epidemic?" examines the time trends in cancer incidence and mortality in the United States and discusses the major risk factors which affect national cancer rates. The authors observe that with the exception of lung cancer, age-adjusted mortality rates for most other cancers have been stable or declining over the past 50 years. Hence, they conclude that there is no epidemic of cancer (aside from lung cancer) in the United States. Most experts would agree with this conclusion.

The authors base their argument on an analysis of mortality trends.[1] They point out that the mortality data are more reliable than the incidence data, and stress that the trends in incidence which they present should be viewed with caution. The incidence data do seem to be subject to several important biases. As screening efforts have intensified and as access to medical care, especially among the elderly, has improved, the proportion of cancers that are diagnosed has increased. In addition, the proportion of diagnosed cancers that are reported by physicians (and are therefore reflected in the incidence figures) has increased over time. This being the case, it is puzzling why 10 pages of this 25-page report are devoted to presentation of the incidence trends, especially since no reference is made to them after they are presented.

Not only is an inordinate amount of space devoted to incidence data, but the presentation of the incidence data is improper.

[1] It is therefore disturbing that the two graphs which present the mortality trends are so poorly printed that the individual cancers cannot be distinguished from one another on the basis of the key.

The authors recognize that the recent SEER data are not comparable with the data collected in the earlier National Cancer Surveys (NCS), since the SEER rates are adjusted to a different standard population. Yet all these data are presented on the same graphs and the trends in incidence discussed as if the data are comparable. This problem could have been avoided by adjusting all rates to the same standard. The authors also (correctly) point out that the SEER data for nonwhites cannot properly be compared with data from the NCS, even if the same standard population is used.[2] Yet they proceed to present and compare these data, ignoring their own advice.

On page 10 and page 20 of the report, the authors state that increased life expectancy in a population results in the occurrence of more cancers, and they imply that this will be reflected in higher age-adjusted cancer rates. While it is true that as people live longer more cancers will occur, age adjustment of rates corrects for differences in the proportion of older people in different populations. If a population ages over time while the cancer rates at specific ages remain the same, the age-adjusted cancer rate will remain the same.

Several comments are in order concerning Part II of the report, "What Causes Human Cancer?" The discussion of diet is inadequate, perhaps because so many questions remain to be answered concerning the role of diet in the production of cancer. Diet could prove to have a major effect on cancers of the stomach and intestines, a significant effect on cancers of the uterus, gallbladder, pancreas and breast, and some effect on cancers of many other tissues.[3] No mention is made of vitamins (e.g., A and E) or micronutrients such as selenium which may enhance or inhibit human carcinogenesis. Neither is the presence in foods of demonstrated or potential carcinogens, such as aflatoxin or nitrite, discussed.

[2] Pollack, E. S. and J. W. Horm. Trends in Cancer Incidence and Mortality in the United States, 1969-76. JNCI, 1980; 64: 1091-1103.

[3] Doll, R. and R. Peto. The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today. JNCI, 1981; 66: 1192-1308.

The authors note that ionizing radiation increases the risk of leukemia and skin cancer. In fact, ionizing radiation can produce cancer at many other, if not all, body sites.

The section on sunlight as a cause of human cancer should have included some mention of melanoma, a relatively rare type of skin cancer which is not uncommonly fatal. Age-adjusted incidence and mortality rates for melanoma are rising fairly rapidly among whites, perhaps as a result of increased sun exposure in the population.

Because of widespread concern over the safety of a host of industrial products, such as plastics, paints, dyes, solvents, detergents, hair dyes and other cosmetics, it would have been of interest to have included a section on industrial products as possible causes of human cancer. The evidence on the human carcinogenicity of these materials remains inconclusive. While it is reasonably certain that large numbers of cancers are not being produced, the difficulty of detecting hazards when the exposures are low-level or limited to a small segment of the population does not allow one to be confident that these materials are safe. Furthermore, many industrial products have been released too recently for any possible carcinogenic hazard to have been detected yet. Research must continue in this area.

Although it now appears that a large proportion of cancers are related to lifestyle factors, this does not relieve government of a major responsibility in cancer prevention, as is implied in the final statement of the report. Government regulation of the tobacco industry is certainly indicated, as are restrictions on cigarette advertising and, if passive smoking proves to be related to lung cancer, prohibition against smoking in public places. Also, despite the fact that a small percentage of total cancer appears to be due to occupational exposures, government must continue to be on the lookout for occupational carcinogens, for at least two reasons: 1) Carcinogenic effects are most easily seen among the people who are most heavily exposed, and these are generally occupational groups; 2) Once recognized, occupational hazards are usually fairly easy to control. If we hope to prevent cancer, government, industry, and private citizens must all participate in the effort.

Critique II. "Diet and Heart Disease" by Dr. William Castelli, director of the National Institute of Health's Framingham Heart Disease Epidemiology Study

During the past two decades, more than twenty expert committees worldwide have studied the problem of coronary heart disease (CHD) and recommended dietary changes to help reduce the enormous toll that this disease takes annually in Western nations. In the U.S., coronary heart disease is the leading cause of death, accounting for about 40 percent of mortality. Every eighth man 40-44, every sixth man 45-49, every fifth man 50-54, and every fourth man 55 or older gets a heart attack within the next 14 years.

Based on epidemiological findings linking high blood cholesterol to increased risk of CHD, and carefully controlled experiments showing that saturated fat and cholesterol increase the blood cholesterol level, a consensus has emerged that reduction of saturated fat and cholesterol is recommended as an important preventive measure. A range of other human studies as well as animal experiments add strong support to this conclusion.

The American Council on Science and Health (ACSH) stands virtually alone in its position that current knowledge does not warrant the recommendations for reduced fat and cholesterol intake that have been issued by such prestigious bodies as the World Health Organization, the U.S. Surgeon General's office, the International Society of Cardiology, the Task Force on Arteriosclerosis of the National Heart, Lung and Blood Institute, and many others (1-5)*. Beneath the ACSH's veneer of scientific reasoning is a report riddled with inconsistency, misrepresentation, errors, omissions of important facts, and ambiguity.

* The only other noteworthy report taking exception to the diet-heart recommendations was prepared by the Food and Nutrition Board (FNB) of the National Research Council. It should be noted that Robert Olson, author of the FNB report, sits on the Board of Directors of the ACSH. Two of the remaining five FNB members who worked on its report, Alfred Harper and Roslyn Alfin-Slater, are on the ACSH Board of Advisors.

Inconsistency

Nothing is more glaring in this report than the gross inconsistencies in the type of data demanded to support various health recommendations. The ACSH strongly endorses weight control, a suggestion applauded by almost all. However, to be perfectly honest, the evidence favoring weight control consists of epidemiological information showing that obesity increases the risk of heart disease and studies indicating that obesity affects risk factors such as blood cholesterol and blood pressure. No tightly controlled intervention studies are available to show that obese individuals who lose weight fare better than obese individuals who remain obese. ACSH does not even suggest that such a clinical trial is necessary before advocating weight control, yet the group demands such evidence for the issue of fat and cholesterol restriction. ACSH also ignores the simple fact that obesity is not as strong a risk factor for CHD as high blood cholesterol, high blood pressure, and smoking (6).

Similarly, ACSH concludes, as do most scientists, that cigarette smoking contributes to CHD. This conclusion, too, is based almost wholly on epidemiological information. Again, no tightly controlled intervention studies have been done, nor does ACSH deem them requisite for its conclusions. The same inconsistency applies to the ACSH endorsement of exercise and control of diabetes.

Yet where they were willing to use only epidemiological data to justify losing weight and stopping smoking to reduce the risk of CHD, they were unwilling to accept the much greater amount of epidemiological, clinical, and laboratory evidence demonstrating that blood cholesterol levels correlate well with the risk of CHD. Moreover, in its flair for selectivity, ACSH informs us that "the average cigarette smoker in the U.S. has a 70% greater chance of developing CHD than non-smokers." No corresponding data for blood cholesterol levels are given. Such data show that white males aged 30-59 with cholesterol levels of 250-274, which are quite common in the U.S., have a 160 percent greater chance of suffering a major coronary event than men with cholesterol levels of 175 or less (7).

Throughout its report, ACSH takes pains to discuss flaws, both real and imagined, in studies that support recommendations for reduced fat and cholesterol consumption. Yet the group cavalierly touts several laughable studies purporting to show that eggs, a high-cholesterol food, do not affect blood cholesterol level. Suddenly, the extremely cautious evaluation--indeed, often nit-picking--that characterizes ACSH's approach to studies supporting the diet-heart relationship disappears even though these particular egg studies have been severely criticized by the National Heart, Lung and Blood Institute and the American Society of Clinical Nutrition (8, 9). One can only conclude that ACSH is either grossly ignorant of scientific thinking or wholly willing to overlook any criticism that challenges its preconceived goal of denying the diet-heart relationship.

Finally, ACSH is inconsistent in its position that no dietary changes should be advocated until fully tested in unfeasible controlled studies. Such an approach not only overlooks natural experiments the world over showing that individuals eating balanced diets lower in fat and cholesterol suffer no known untoward effects, but also misses the plain fact that the current American diet has never been tested in the manner that ACSH demands for diets lower in fat and cholesterol.

Misrepresentations

ACSH reports that "under usual conditions of the American diet, about 20 percent of the cholesterol metabolized daily is exogenous" (i.e., the result of external influences, such as diet). This statement is probably technically correct for ingestion of dietary cholesterol, but not true when you consider all the other aspects, such as saturated fat and dietary fiber, as well as exercise, that influence cholesterol levels. It is also basically irrelevant and highly misleading. The issue at hand is not the origin of the cholesterol metabolized daily by the liver and other body tissues, but rather the origin of the cholesterol in the blood. Studies have found the average adult blood cholesterol level in Japan to be about 150 mg/dl, while the U.S. average approximates 220 mg/dl, and the East Finland value is about 270 mg/dl. Such findings indicate that exogenous factors (particularly diet) can account for 30 to 50 percent of the blood cholesterol level, not the 20 percent figure implied by ACSH. However, while ACSH misleads the

reader with its 20 percent figure, it should be noted that even a seemingly small 20 percent increase in blood cholesterol substantially raises the risk of CHD. The Framingham Study found that men with a cholesterol level of 260 mg/dl had about twice the CHD risk of men with a level of 220 mg/dl (the difference between 260 and 220 is roughly 20 percent).

ACSH states that the cholesterol-lowering diet tested in two Finnish mental hospitals "did not prove to be a protection against CHD." This statement is simply not factual. It misrepresents the findings and conclusions of the Finnish investigators who reported, "In men, the use of the cholesterol-lowering diet was associated with considerably and significantly reduced mortality from CHD."

Relating the findings of the Los Angeles Veterans Study, ACSH reports only that the cholesterol-lowering diet resulted in "no significant difference in death from myocardial infarction." This stunning misrepresentation was created by excluding sudden death from CHD and atherothrombotic brain infarctions (a type of stroke) from the analysis. As all three diseases result from atherosclerosis, the investigators considered them together and reported a striking reduction of atherosclerotic events in the group fed the cholesterol-lowering diet. By narrowing the issue to include only part of the picture, ACSH takes advantage of the fact that statistical significance declines as the numbers one is working with decrease.

In addition to misrepresenting the results of these studies, the ACSH exaggerates the importance that scientists place on this type of research. Indeed many scientists have been impressed with the positive results observed, given that the cholesterol-lowering diets in these studies were introduced rather late in life, often to men with quite elevated blood cholesterol levels. Thus, there is the problem of "too little, too late;" to be more specific, how much benefit can be expected from lowering a cholesterol level of 300 to 260, when even the lower value carries high risk? Even if a late-life intervention study yields negative results, the findings cannot be extrapolated to the benefits of changes introduced earlier in life. Unfortunately, studies with younger subjects are unfeasible, due to the cost of following the subjects 10

to 30 years into the ages when heart attacks begin to strike.

While ACSH fails to note the unfairness of extrapolating data from late-life changes to the issue of early-life changes, the group pronounces that "the results of animal experimentation ... cannot be extrapolated with confidence to humans." This is a unique position, shared by few investigators. Indeed, if scientists did not consider animal research relevant to man, they would not bother doing it! In fact, certain areas of research would virtually grind to a halt if researchers were forbidden to extrapolate animal findings to man. Further, the ACSH discussion of animal research in the area of diet and CHD is quite superficial, grossly understating the volume, strength, and consistency of findings to date, and failing to even mention the swine model, one of the more important species. The effect of cholesterol-raising diets on animal atherosclerosis has been so well-established that one can state with fair certainty that only about three groups of animals can eat the American diet with impunity: namely, the dog, the cat, and the rat.

The Council also unfairly insinuates that cholesterol-lowering diets increase cancer risk by pointing to the higher cancer rates observed among subjects in the L.A. study who consumed the cholesterol-lowering diet. The ACSH adds that a pooling of data from this study and four similar trials revealed the "cancer factor" (i.e., increased cancer risk among subjects on the cholesterol-lowering diet) in one other study. This discussion grossly misrepresents the research by neglecting to even mention three relevant points: most importantly, that the combined results of the five studies showed no excess cancer risk from the cholesterol-lowering diets; second, the one additional study that ACSH claims to show higher cancer rates from cholesterol-lowering diets involved seven cancer deaths among men on the test diet and five cancer deaths among the controls (these results hardly reached statistical significance, a standard invoked as essential by another section of the ACSH report); third, ACSH conveniently ignores the results of one of the five studies that shows significantly more cancer deaths among controls than in subjects on the cholesterol-lowering diet. ACSH is terribly one-sided in its discussion. Moreover, it is unfair and unscientific to evaluate current public health recommendations calling for reduced total fat

intake by using the above five studies, since these diets principally replaced saturated fat with polyunsaturated fat, retaining a fairly high total fat intake.

In studies that examined the relationship between serum cholesterol levels and cancer, nine out of seventeen did not find a relationship between low cholesterol levels and cancer. In the studies that did appear to find a correlation between low cholesterol and cancer, such factors as lower body weights, colitis and other colon disorders that themselves lead to a higher risk of cancer, smoking, and other factors may be confounding the results. In fact, cancer itself is known to lower cholesterol levels; therefore, in some of the cases, undiagnosed cancer may be responsible for the apparent relationship. Animal studies have never found a relationship between lowered cholesterol levels and increased cancer risk; it has also been demonstrated in animals that cancer lowers cholesterol levels. Population groups that eat a relatively small amount of saturated fat and cholesterol generally have much lower cholesterol levels than typical Americans and have less than half the rate of cancer, virtually no heart attacks, and a relatively long life span.

Errors and Omissions

According to the ACSH, "Animal studies involving species similar to man such as non-human primates have shown that atherosclerotic plaques will regress when the total serum cholesterol is reduced. But no studies in humans have shown similar results" (emphasis added). ACSH shows astounding ignorance of important work demonstrating plaque regression in humans resulting from lowering of blood cholesterol (10, 11).

ACSH also misses important research regarding the Eskimos, who have low CHD rates despite a diet moderately high in fat. These people show a high HDL to LDL ratio that seems to result from their high intake of eicosopentanoic acid from fish. As high levels of HDL-cholesterol are associated with reduced risk of CHD, the Eskimo experience is not the mystery that ACSH would lead us to believe. Likewise, in reporting several uncontrolled studies observing reduced blood cholesterol when whole milk was consumed, ACSH neglects to mention that a greater and more

rapid lowering of blood cholesterol occurred in subjects drinking skim milk. Such findings, while hardly conclusive, support recommendations to favor lowfat dairy products, but owing to ACSH's selective reporting, one would never know.

The report errs further by proclaiming that "margarines made from hydrogenated corn oil are high in saturated fatty acids." Actually, the process of hydrogenation can produce anything from slight to major changes in fatty acid composition. Retail margarines are actually quite low in saturated fat, containing roughly one-third as much as butter. Still another error is the ACSH statement that "trans fatty acids /a type of fat that has shown inconsistent effects on blood cholesterol/ do not occur normally in oils or fats." Dairy and meat fats do contain naturally-occurring trans fatty acids, though in smaller amounts than most margarines and shortenings (12-14).

Conclusions

Some of the concepts embraced by ACSH are not unreasonable. However, the Council's reasoning fails because the group does not appreciate the realistic implications of the concepts it espouses. ACSH agrees, for instance, that individuals at high risk of CHD should receive professional advice, which regularly includes diet modification. Were ACSH to translate the notion of "high-risk" into numbers, it would become obvious that a majority of Americans are at high risk for CHD. About half of American adults have a blood cholesterol level above 220, the amount generally regarded as a maximum desirable level. Moreover, many with levels below 220 are young adults whose levels will likely rise with age, meaning that a level of 220 can be excessive if observed in a young adult. If people who are above desirable weight and those with a family history of CHD are added, it becomes evident that the high-risk individual is not a medical rarity, but rather the average American.

Similarly, ACSH sums up its dietary advice with the vague assurance that "moderation, variety, and balance" are the keys to a good diet. "Moderation," however, is never defined, and it appears that ACSH has given little thought to the meaning of the word. Which diet, one might ask, embodies the meaning of

the word "moderation:" the current American diet containing almost 40 percent of its calories from fat, 500 mg cholesterol per day, and almost 20 percent of calories from refined sugar--or the diet proposed by many health authorities: 30 percent of calories from fat, 300 mg cholesterol, and 10 percent of calories from refined sugar? The answer is obvious, and in the final analysis reveals the absurdity of the ACSH position.

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Critique III. "Air Pollution and Your Health" by Dr. Carl M. Shy, professor of Epidemiology, University of North Carolina

The report "Air Pollution and Your Health" prepared by the American Council on Science and Health presents a misleading, biased picture of the public health consequences of air pollution. In general, the positive evidence obtained from human population studies is largely discounted as irrelevant to today's air pollution levels. This is hardly the case, since there is a continuum of response in the population to most hazardous agents, varying from adverse effects on susceptible individuals at low concentrations to widespread morbidity and even mortality at high concentrations.

The report reviews but fails to place in perspective the air quality changes and resulting public health benefits achieved over the past 15 years. In the decades of the 1940s, 1950s and early 1960s, air pollution levels periodically were high enough to exert a marked increase in morbidity and mortality, and these consequences were well documented in Great Britain, the U.S., Japan and several other countries. Between 1965 and 1980, levels of sulfur dioxide and particulates showed a pronounced decline in the most polluted cities of the above countries, from concentrations that averaged 300 to 500 micrograms per cubic meter ($\mu g/m^3$) to 60 to 80 $\mu g/m^3$, about a five-fold decrease. These changes were accompanied by an apparent cessation of episodes of excess mortality due to stagnant air masses. Further, there is now little difference in sulfur dioxide and particulate levels between

urban and rural areas, or between different cities, and as a consequence it is difficult any longer to detect a consistent pattern of excess acute or chronic respiratory disease in urban areas. Some recent epidemiologic studies of air pollution show no differences in morbidity patterns between areas of contrasting air pollution levels; other studies continue to show some disease excess in the slightly more polluted communities, but the magnitude of the difference in adverse health effects is much smaller than was consistently demonstrated 20 years ago.

This evidence needs to be placed in perspective. It suggests that we have achieved a very desirable health-related improvement in sulfur dioxide/particulate air quality. At the same time, since it is not clear that all adverse health effects have been eliminated at present air concentrations, and since adverse effects are highly likely at levels three to four times those now measured, any relaxation of existing standards would move us in the direction of a return to widespread adverse health consequences.

Based on these considerations, I disagree with the report's summary statement that "most research indicates that, at the levels we experience today even in urban areas, sulfur oxide and particulate matter pollution do not pose a threat to human health." As mentioned, some current studies continue to find evidence of air pollution-related health effects. More importantly, the report fails to mention the uncertainties in our present knowledge, particularly the uncertainties regarding fine particulates, organic aerosols, acid precipitation, and pollutant by-products of newer technologies such as diesel exhaust. We also still know relatively little about the acute and chronic effects on humans of nitrogen dioxide and acid nitrates, and levels of these pollutants are expected to increase over the next 20 years.

Interestingly, the body of this report is considerably more guarded, cautious, and moderate (often using sweeping, somewhat innocuous statements) than the conclusion which comes out with irresponsible recommendations for major changes in federal policy.

In my opinion, present air quality standards are appropriate

for protecting public health. But there is no reason to imply, as the report does imply, that present standards are unnecessarily stringent or overly protective. A relaxation of standards would increase the probability that public health would be adversely impacted.

Critique IV. "Caffeine" by Dr. Edward Groth III, former staff member of the National Research Council

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Before I get down to the ACSH report itself, I would like to make some general comments about scientific review documents, such as this one on caffeine. In my opinion, all reviewers have some biases. It's impossible simply to catalogue the evidence that's been published; one also has to decide what evidence is important, what is good and not so good data, what the evidence--in part, or as a whole--means as far as health hazards go. These choices require judgments that are scientific in nature, but also subjective. Beyond that, reviewers also tend to make policy and value judgments. For instance, anyone who has reviewed the caffeine issue has an opinion as to what level of concern about the possible health effects is warranted. That concern is only partly related to how good the scientific evidence is. It's more closely tied to one's personal philosophy about when to start worrying in the face of incomplete, inconclusive data.

It's useful for reviewers to have opinions; readers need some interpretations of the data, as well as recapitulations of them. Potential problems of bias in reviews can be divided into two groups: The opinions stated may be independent of (or contradicted by) the scientific evidence, but may appear without careful study to be valid on the basis of all the amassed data. (The "This guy must know what he's talking about, since he read all those papers" effect.) Or, on the other hand, the reviewer's opinions may lead to the selected citation of evidence, the slanting of interpretations to support pre-ordained conclusions. Of the two, the former is the lesser problem, since a reader can always come to his/her own conclusions, as long as the summary of evidence is fair and accurate.

In this case, the report from ACSH avoids the second kind of

problem. I found this review to be quite solid, and worthy of the terms balanced and objective. Some of the discussions are excellent; for instance, the section on teratogenic hazards contains a very good summary of reasons why it is virtually impossible to establish a causal relationship between a chemical teratogen and human birth defects.

Not that the review could not have been better. The section on effects on the central nervous system omits much discussion of the potential for behavioral effects in children. I found this odd, since the sections on exposure clearly identify children who drink caffeinated soft drinks as a group potentially at high risk of effects. Other sections were somewhat dated. The discussion of methylxanthines in fibrocystic breast disease omits Minton's later report, which increased the data base from 47 to 121 cases. (This didn't change the picture much, but the data have been out for at least a year.)

I also found a number of areas in which the report could have been better done. Perhaps, no generalist should be expected capable of doing an expert job on such a diversity of topics! Nevertheless, there were a few areas where I felt the analysis was insufficient:

(1) Assessment of exposures from soft drinks uses averaging techniques which obscure what may be significant. Although per capita intake averaged over 24-hour periods may fall below levels known to have stimulant effects, it is not uncommon for a child (or an adult) to have two or more servings of caffeinated soft drinks within the space of a few hours. Given the rapid uptake of caffeine and its several-hour half-life in the body, it is plausible that realistic examination of intake--rather than averaging it out over the whole day which may be more appropriate for some other sources--would lead to another conclusion. That is, some soft drink users may get stimulant doses.

(2) Likewise, the assessment of exposure from soft drinks

paid too little attention to the distribution of exposure. The section on coffee looked especially at high-intake groups--90+ and 99+ percentiles. The same approach is called for in examining caffeine in soft drinks, since here too it is those with the highest intake who are most in need of assessment of potential health impacts.

(3) The definition of a "toxic" dose seems arbitrary and unscientific. It is stated that 600 mg/day seems to be a toxic level. (At this point, the reference is to acute toxic reactions, a significant fact that I will refer back to in later comments.) That designation is rather precise--and in fact it is highly unlikely that any single dose represents a sharp division between "safe" and "toxic" intakes. Estimates by varied authors have defined anything from 200 to 750 mg/day as the "excessive" level of intake. There is frequent reference in this document to the wide variation in sensitivity to caffeine among different humans. It is inconsistent with that valid, documented observation to try to designate any one dose as the "threshold of toxicity." Obviously, that mythical boundary will be very different for different individuals.

There are other points in the review itself with which I might take issue, but in general, I found the scientific summary well done. This is a useful compilation, and an objective and reasonably insightful critical appraisal of how good or bad the data are on most points.

Despite that, I had some big problems with this report. They don't arise from its presentation of facts, but rather from the opinions presented, which do not always fit the facts that have been well summarized.

There are two types of opinion statements in the document. The most important is the "Position Statement," on pages 2 and 3. I will deal with this shortly. Other mostly opinion statements appear as wrap-up lines at the ends of sections. These might distort the sense of what is known, if one read only these passages, or give them more weight than they deserve.

Not all the wrap-up lines are out of keeping with the data presented, but a couple of them are quite misleading in my judgment:

(1) On the risk of birth defects: "/Studies/ do not suggest that the human fetus is endangered..."

At best, this tells only half the truth. The facts (as summarized in a lengthy review) certainly do not establish that caffeine is not a hazard to the human fetus. The vast amount of animal data, plus evidence presented (also in this report) about relatively large numbers of pregnant women who consume large doses of caffeine (several cups of coffee per day), is large enough to "suggest" a hazard to a great many scientists. The suggestion is just that--not a proven fact. The dilemma arises from the difficulty of learning how real the suggested risk is in reality. A lot of research effort is being carried out in pursuit of that "suggestion."

To say the data don't prove a risk would be accurate. To say they don't suggest one is an extremely conservative judgment. It seems to presume a burden of proof so strict that, given the difficulties in establishing causes for a human birth defect (well described in this report), it seems unlikely to me that ACSH would find that any amount of data were enough to "suggest" a danger to the human fetus.

(2) On caffeine and benign breast lumps: "...the incidence of ... fibrocystic breast disease /is not/ increased by caffeine consumption."

This statement is simply not supported by the evidence. It is a flat rejection of the hypothesis that caffeine and other methylxanthines may be factors in the etiology of fibrocystic breast disease. The section that presents the evidence is quite objective: It reviews the limited data, gives the theoretical basis for suspecting caffeine may in fact play a role, cites the limited, nonrandom nature of the data, and calls for further research--better designed clinical trials, and epidemiology, to resolve the question. The fact is, the question is not resolved. We can't say caffeine does cause breast lumps. Neither can we say that

it does not.

Why ACSH chose to make such a firm statement, when the review showed how infirm the data are, is a mystery to me. It is almost as if the "conclusion" paragraphs were written by someone other than the author of the review, since it is difficult to see any connection between the two in this case.

The most seriously flawed part of the report is the short "position statement," noted earlier. This section--placed prominently at the start of the report, where it is likely to be taken as a summary (especially since the report has no actual summary), read preferentially, quoted (as in ACSH's press release on caffeine), and in general given disproportionate weight--is, like the shorter statements just mentioned, barely connected at all to the scientific review the report offers.

It is clear that ACSH's position is that people should not be concerned about caffeine. They feel that there is not enough adequately documented evidence of harm to justify efforts to reduce or restrict caffeine exposure.

That is an opinion, and they have a right to their opinion. But I feel it largely discredits what is a generally sound and thoughtful review of the scientific data, because some of the statements in the "position statement" are simply out of keeping with the facts presented and the tone of the body of the report.

For instance, the position of ACSH is that caffeine as generally consumed is not a serious threat to the health of most Americans. That widely-quotable statement is excessive in its vagueness, and it omits or distorts several important conclusions of the report:

- The position statement makes no reference to the possible effects of caffeine in children. If this is not a major concern of the report, it is nonetheless an issue given serious attention in the report's text.

- The position statement does warn about sensitive individuals, but gives no guidance as to how many there may be, who they

are, or how safe it may be for them to use caffeine.

● The position statement cites 300 mg/day as the level below which caffeine is "generally consumed." It then cites 600 mg/day as a level above which caffeine may cause health problems (emphasis added).

This is a severe distortion of the facts that the report presents. First, exposure estimates reviewed in the text indicate that 30 percent of adults who drink coffee drink enough to get doses greater than 500 mg/day, so the "average" intake of 300 mg/day or less certainly excludes a large fraction of the population! The same review says 10 percent of the population consumes more than 1,000 mg/day. This is ignored as well in the position statement.

In addition, the designation of 600 mg/day as a cutoff level below which no health impact is said to be likely is grossly misleading. The arbitrary nature of this designation was discussed in my earlier comments. Moreover, you will recall that the 600 mg/day dose is one (high) estimate of the dose needed to produce acute toxic effects. Most of the research that the report reviews is concerned with much more subtle, possibly chronic effects--not always readily seen as "toxic." There are few good dose-response data, but surely some effects, such as disturbed sleep, can occur at doses far below 600 mg/day.

● The position statement says there is "no scientific evidence" linking caffeine with human birth defects. The report itself devotes considerable space to a review of the human studies, some of which suggest a possible link, none of which are solid enough to establish one.

The facts are that there is a lot of evidence related to the issue of human birth defects and what it all means is not clear yet. To say, "No evidence exists," is deceptive in that it leads readers to think the case is much weaker than it actually is.

In summary, this would have been a relatively good report, if it did not contain the position statement. The scientific review is competently done and is both a useful compilation of data and a thoughtful analysis of what we do and don't know.

Unfortunately, this work has been shackled with a political statement, prominently featured, which flagrantly contradicts the careful, objective tone of the report itself. I can readily conclude that the body of the report is intended to provide readers with an objective, balanced assessment on which policy judgments might be based. But the position statement seems designed to reassure readers that there is nothing to be concerned about--even if such reassurance comes through distorting or ignoring the facts presented in the report. Even if it were prominently labeled "editorial opinion," I find it unfortunate that this statement may gain some credibility because of the solid research that went into compiling the literature review.

Critique V. "The Health Effects of Herbicide 2,4,5-T" by Dr. Theodor Sterling, professor of Computing Science, Simon Fraser University

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I reviewed the literature on toxic and teratogenic effects of 2,4,5-trichlorophenoxyacetic acid and 2,3,7,8-tetrachlorodibenzo-p-dioxin repeatedly during the last decade (as one of the members of the NAS/NRC Committee to advise the Administrator of EPA in 1970 and 1971, for the Royal Commission Hearings on herbicides and pesticides in 1974, to the Assembly Committee on Natural Resources of the State of Wisconsin in 1975, and for a number of legal briefs). I am familiar with the literature and reports relating to the toxic quality of these substances. I therefore appreciate the full extensiveness of the report "The Health Effects of Herbicide 2,4,5-T" by the American Council on Science and Health.

For the most part this review is extensive, although some studies that ought to have been critically evaluated are not, and others that ought to have been included are missing. There are also a number of minor errors that indicate that much may have been copied from other reviews in the report (for instance, the

Advisory Committee on which I served and to which the report refers, is cited repeatedly but by various names, most of them incorrect.).

The major conclusion appears to be summarized in the report's "Position Statement" on page 2. "No scientific reports presented to date have shown any convincing relationship between the traditional use of 2,4,5-T and adverse health effects in humans."

This statement is of the type usually made by industry spokesmen who defend the use of a particular substance which has been found to be toxic. Such assertions are objectionable and certainly inaccurate.

The report itself lists the demonstrated toxic teratogenic effects of 2,4,5-T and TCDD (dioxin) repeatedly and often. Evidence from animal studies, especially from animal systems that are similar to that of human systems, are deemed to present conclusive evidence as to the effects of a particular substance on human systems. Where exceptions appear (i.e., an effect in humans not being reproduced in a particular system), that particular animal system usually turns out to function differently than analogous systems function in humans. However, the teratogenic and toxic effects of 2,4,5-T have now been demonstrated in so many different animal species that this combined evidence cannot be denied. Further, such effects have been demonstrated at almost any dose and any technical purity of experimental materials used.

The teratogenic properties of these substances, demonstrated over and over in animal studies, are highly specific to 2,4,5-T and TCDD and comprise: cleft palate, rib and vertebrae abnormalities, limb abnormalities, kidney malformation, resorption of fetus, and fetal growth retardation. All these observations have been summarized and included in the ACSH Report. (The only one deleted is observations on inadequate ossification in newborn experimental offspring.) These are precisely the types of disorders found in studies of human populations exposed to 2,4,5-T and other phenoxy herbicides.

What other kind of evidence must be presented to prove

adverse effects in humans? The only test that has not been included is the purposeful exposure of pregnant women to 2,4,5-T. Does ACSH advocate such a test?

Moreover, the position statement does not clarify what is meant by "traditional." In 2,4,5-T's short history, its traditional use has evolved from hand-application to truck-spraying to small agricultural planes to civilian and military helicopters. Which tradition does ACSH endorse?

For these major reasons I would discount the position statements and conclusions reached by ACSH as nonsensical and contrary to accepted scientific standards of inference. The overwhelming evidence linking 2,4,5-T and TCDD to various toxic and teratogenic effects is so strong that if another chemical had been involved, one not as ubiquitously used for agriculture, forest management, and right-of-way clearance, that chemical would long have been banned from public use.

A number of other comments are relevant to this report.

It is simply not true that any substance has teratogenic potential if it is used in large enough dose. This assertion has been a favorite device among industry spokesmen. In fact, I thoughtlessly made that statement myself in a Science article some years ago where the baselessness of that statement was brought to my attention by my colleagues. There is no evidence that a non-teratogenic substance will become so in exceedingly high doses. It may kill the experimental dam or female subject if used in too high a dose, but it will not show teratogenic effects. As there is no evidence for that statement, and as the ACSH Report so frequently refers to it as a truism, it might be proper to ask ACSH to deliver documentation and referneces demonstrating that substances that are not teratogenic get to be that way when administered in high doses.

ACSH also discusses the possibilities that dioxins are created as the natural result of combustion. In my 1974 review of the literature presented to the Royal Commission Hearings in Vancouver, I reviewed some of the evidence that combustion of wood sprayed with 2,4,5-T could lead to the formation of TCDD. Inter-

estingly, at the time that possibility was heatedly denied in a separate brief by Dow Chemical and by scientists working for them. More to the point, whether combustion by itself forms TCDD or not, it is a fact than an unusually and inexplicably high concentration of TCDD is found around Dow's 2,4,5-T production plant in Midland, Michigan.

The work done by Dr. Kociba, a toxicologist working for Dow Chemical who is testing for a threshold value of a detectable effect on animals of TCDD exposure, is taken as the centerpiece around which animal experiments are discussed. Unfortunately, Dr. Kociba's experiment contains a major flaw which has been the subject of a number of reviews. While dose-response curves for a number of toxic effects are clearly visible in Dr. Kociba's data, they are hidden by the use of statistical tests which ignore the dose-response effect altogether. Rather, he uses a statistical strategy which compares the lowest dose of exposure to the control group. Because of an inadequate number of animals and because the overall regression of dose and effect is ignored, a level of statistical significance was not achieved. However, the data published by Dr. Kociba in 1978 clearly show dose response effects and furnish evidence that if a threshold exists for the effects of TCDD, it is certainly way below the value used in Dr. Kociba's experiments.

As ACSH points out, the human studies which exist now do represent a number of problems. However, in their totality they also are convincing.

Unfortunately, two of the studies cited by ACSH--that by Cutting for the U.S. Army in Viet Nam and that of the explosion of the Hoffmann-La Roche factory in Seveso, Italy--are useless. The former is unusable because Cutting took most of his information from hospitals in Saigon which serviced a population that had not been exposed to 2,4,5-T; as for the latter, incidents surrounding the Seveso catastrophe have been so distorted and so much data from them has been suppressed that no clear picture has emerged of whether or not there has been an increase in spontaneous abortions or malformations in the area exposed to the dioxin cloud.

On the other hand, the study by Meselson (and by the Committee appointed by the American Association for the Advancement of Science) clearly demonstrated an increase in the kind of teratogenic effects found in animals by searching in the records of hospitals that served populations exposed to by-products of spraying operations. I might also add that the Viet Nam studies by Dr. Tung and his associates have been given less credit than they deserve. Dr. Tung is a competent investigator and the fact that he operates out of North Viet Nam ought not to carry more weight than the fact that the American Council on Science and Health operates out of the U.S.

Most disappointingly, the report leaves out recent results obtained by Swedish studies of railroad and other workers exposed to 2,4,5-T and other phenoxy herbicides. Evidence for an increase in cancer levels seems to have been provided by these reports.

The Alsea 2 study is fundamentally sound from an epidemiological perspective. This study, initiated by women residents of Alsea County, Ore., in desperation because of the failure of U.S. health agencies to attend to their problems, has been done with the professionalism which is perfectly acceptable epidemiology. I, for one, find the statistical analysis of that report quite adequate and convincing.

In view of the failure of U.S. health agencies to mount an epidemiological study similar to Alsea, that report remains the best evidence in this country so far. Those who have over the years been involved in the aborted efforts by various groups to motivate U.S. health agencies to study the problems adequately have become impressed by the apparent inability by responsible U.S. health agencies to mount a concerted attack on problems related to dioxin exposures and with the concentrated effort of Dow Chemical Corporation to prevent public hearings or to see large-scale population studies implemented. The Alsea data need to be accepted as the best available; combined with the evidence from Swedish studies they form a convincing reason for cancellation of the registration of 2,4,5-T, any product containing TCDD, and perhaps most phenoxy herbicides.

In conclusion, while this report gives the impression of being even-handed, it is in fact a careful selection of those studies and findings which underscore the points ACSH would like to make. Needless to say, this is not the way a careful scientist--one who weighs each piece of information on its merits and thereby reaches a conclusion--usually operates.

Critique VI. "Diet and Hyperactivity: Is there a Relationship?" by Dr. James Swanson, University of California-Irvine Medical Center

In 1973, Dr. Ben Feingold, a pediatric allergist at California's Kaiser-Permanente Medical Center, proposed a hypothesis that artificial food dyes, flavors, and certain other additives, and constituents of natural foods contribute to behavioral problems in a large percentage of hyperactive children. On the basis of this theory, he created an additive-free dietary regimen, the Feingold Diet, which he and many parents have claimed results in a striking reduction of hyperactivity in previously affected children.

Since 1975, a number of studies have been carried out to test the hypothesis under controlled scientific conditions.

The report by the American Council on Science and Health, although entitled "Diet and Hyperactivity," focuses almost exclusively on Feingold's recommendations, ignoring other dietary factors that might influence behavior. The report summarizes comprehensively the research published through 1978 on the Feingold hypothesis; however, there is as much controversy of interpretation of the data from these studies as there was about the Feingold Diet itself before the research was done. The ACSH "Position Statement" and the "Conclusion" sections add to this controversy by presenting the extreme view that the observed beneficial effects of the Feingold Diet are due primarily to a placebo effect (i.e., patients improved largely because they thought the diet would make them improve). Not only is this view far from universally accepted, but, more seriously, it is inconsistent with the data reviewed in the body of the ACSH report itself.

There are two ways of evaluating the Feingold hypothesis. One is to utilize total-diet studies, whereby everything the test subjects eat is controlled by researchers, with one group receiving an additive-free diet and the other a diet containing the usual complement of additives. Since psychological factors are so strong in an area such as this, it's important that all tests be conducted "double-blind" so that neither participants nor investigators know during the course of an experiment who is getting which diet. (The second method, the challenge experiment, is described below.)

How Many Children Respond Positively to the Feingold Diet?

Double-blind total-diet studies have been carried out by Conners and his colleagues (Pediatrics 58, 154, 1976) and by Harley and co-workers (Pediatrics 61, 818, 1977). The Conners study reported that during the additive-free phase of the experiment "four or five" of the 15 children were seen as "improved by both parents and teachers," for an improvement rate of between 26.7 and 33.3 percent. (Four children fell into the most extreme category of response; a total of five children fell into the two top categories of response.) Four out of 36 of the children in the Harley study were rated by both parents and teachers as improved on the Feingold Diet relative to the placebo diet, for an improvement rate of 11.1 percent. These figures for the percent of children who responded to the diet are more than an order of magnitude greater than stated in the ACSH conclusion, which claims: "The current evidence indicates a few hyper-kinetic children, on the order of a fraction of one percent, may experience adverse reactions to one or several of the large number of artificial food colors and thousands of artificial flavors."

Moreover, ACSH dismisses too readily the many additional children in the controlled trials who appear improved to parents, but not to teachers. Yet parents' ratings obtained under double-blind conditions are actually the most appropriate measure for judging Feingold's claim, which is simply that from 30 to 50 percent of the hyperactive children tried on the diet will improve in the eyes of the parent. ACSH fails to acknowledge that the parents' evaluations in Harley's excellent double-blind study clearly confirm this prediction, in that 36.1 percent of the school-aged

children were judged by their mothers to have benefited from the additive-free diet, and 46.7 percent were so judged by their fathers. Furthermore, by ignoring all trials where teachers could not be present to notice behavioral changes, ACSH leaves out Harley's remarkable finding that, for preschool children, 100 percent of their mothers (10 out of 10) and 57 percent of their fathers detected improvement during the Feingold Diet phase. These results back Feingold's additional point that the younger the child, the more rapid and complete the response.

ACSH discards all the positive data from the total diet experiments largely because of a complicating factor that appeared in both the Harley and Conners studies. The advantage of the Feingold diet over the placebo was observed mainly in those trials where the Feingold phase followed the placebo, and not in those where the order was reversed. ACSH states that this order effect "attenuates the efficacy of the Feingold Diet," suggesting that the observed changes were mostly just a matter of biased responses by participants who hadn't noticed much happening in the first phase of the study and so assumed the "real" treatment was going to come second.

But a closer examination of the data reveals that the order effect is not statistically significant in the Conners report; nor does it necessarily invalidate the positive responses in the Harley study. In that study, participants were led to believe that their diets were being changed 6-8 times in all, and so would have no way of knowing when the critical switch took place. Moreover, even when the additive-free diet was given first, children clearly benefited from it relative to their behavior on their usual (pre-test) diets, while no such improvement was seen when the placebo came first. The order effect, then, was due to the fact that children improved when given the Feingold diet at any time, but did not deteriorate when switched to the placebo afterward.

When the results are seen in this light, they suggest the following points:

(1) Since Harley's placebo diet was as elaborate and demanding as the additive-free variant, yet the placebo diet alone triggered no changes in behavior, there is little support for

ACSH's hypothesis that the Feingold Diet may work predominantly because of "changes in family dynamics and/or placebo effects of the entire Feingold therapeutic regimen."

(2) The fact that behavior remained improved when children were switched from the additive-free to the placebo phase of the experiment may simply reflect a carryover effect of the 4 weeks on the Feingold Diet.

What conclusions may be drawn from the data about the percentage of hyperactive children who respond to the Feingold Diet? The percent of positive responses in the double-blind total-diet studies reviewed above is similar to that reported on the basis of Feingold's uncontrolled clinical experience (30-50 percent). Then one might conclude that either the double-blind conditions, which were among the most expensive and extensive ever tried, were completely ineffective in hiding the two diet conditions, and despite all precautions a placebo effect occurred which was the same as the one presumed to be operating in Feingold's clinical practice; or the Feingold Diet works independent of a placebo effect. ACSH assumes the former to be the case; the reader can decide whether this judgment is warranted by the evidence.

How Much Do Children Improve on the Feingold Diet?

The ACSH report argues that the children who do show evidence of responding to the Feingold Diet do not express this response in ways that could be detected by the battery of objective neuropsychological tests used in the Harley study to supplement the overall parent and teacher ratings. But according to the Feingold hypothesis, some of these tests would not have been expected to register a change. Feingold cautions that the initial improvement caused by the diet is in the child's behavioral pattern, followed by improved muscular coordination, and only months or years later by improved perception and cognition (learning skills). Certainly 4 weeks of diet treatment could not be considered sufficient to elicit changes in IQ or in the other cognitive-perceptual tests employed by Harley.

However, the 4-week period is long enough so that behavioral responses should become evident. Yet, as the ACSH report cor-

rectly notes, objective tests for behavioral changes also revealed no significant difference between the Feingold Diet and the placebo diet. Even the overall parent-teacher ratings suggested that the magnitude of the Feingold Diet's effect is not large, and is best described as "moderate improvement." Apparently, within a 4-week trial period most patients do not reach the level of "marked improvement" claimed by Feingold.

Response to Food Dyes in Challenge Experiments

The second method used for investigating Feingold's hypothesis is simply to administer a controlled amount of one type of additive--in this case, a typical mix of artificial food dyes in food or in a capsule--to a test group of children on an additive-free diet and to measure how much the subjects respond as accurately as possible. This is called a challenge experiment.

The challenge experiments are well reviewed in the ACSH report. But it is important to remember that the response to the food dyes does not test the whole Feingold Diet, since a challenge with only one of the substances removed from the diet may result in only a partial reoccurrence of symptoms affected by the treatment.

As ACSH points out--and my own study in 1980 confirmed this--the behavioral response to food dyes is limited, and only a sensitive laboratory test can monitor the effect. Since many hyperactive children, even under double-blind conditions, respond favorably to the Feingold Diet but are not clearly affected by food dyes, then it is important to consider the possibility that the dyes are not the primary additives in foods which create the problems. The role of preservatives and artificial food flavors, which have not been subjected to challenge experiments, cannot be discounted. Regrettably, ACSH seems to dismiss the entire Feingold Diet on the basis of limited response to food dye challenges, instead of recommending further study of the remaining additives which are also removed in the total-diet studies.

However, even food dyes themselves should not be discounted as quickly as ACSH attempts to do. First of all, it appears that the amount of food dye used in most of the experiments is on the

low side, not taking into account the full amount of dye a child is likely to be exposed to in an average day. Second, if only a small subset of the population is sensitive to additives in the diet (and the ACSH report seems to accept this possibility), then statistical limitations make it difficult or impossible to demonstrate treatment differences when only small groups are used for study, as has been the case in the past. Larger samples or more studies of individual changes must be obtained. Finally, the challenge food combines all nine food dyes, diluting the effect of only one dye (such as FD&C Red #3) that may have greater effects than others. The ACSH report does not comment on any of these important questions. (After the ACSH report was published, a careful challenge study demonstrated clearly that food dyes caused behavioral changes in one or two children out of a group of twenty-two (Science, Vol. 207, pp. 1487-9, 1980).)

Summary

While the American Council on Science and Health provides a good review of the literature on the Feingold hypothesis, the report's position statement and conclusion are so inaccurate as to undermine the document's usefulness. The primary inaccuracy is that the report presents a gross underestimate of the percentage of subjects in controlled experiments who have shown a favorable response to the Feingold Diet. Specifically, the position statement says: "The symptoms of the vast majority of the children labeled 'hyperactive' are not related to salicylates, artificial food colors or artificial food flavors in their diet." ACSH indicates that less than one percent of children might respond to the Feingold diet.

This inaccuracy is particularly unfortunate because the position statement and the conclusions of the report are repeated in a shorter summary report which has been widely distributed. In the shorter report, the literature review--which tempers the extreme view presented in the position statement--is not presented at all.

A balanced view of the literature should acknowledge that a significant percentage of the hyperactive subjects who have been

tried on the diet under controlled conditions have shown a favorable response, but that the magnitude of the response has been limited. It should also acknowledge that the specific response to food dyes (only a few of the additives restricted by the Feingold Diet) seems to be a small but dose-related pharmacological response, but that questions about average daily intake of food dyes, effects of individual food dyes on neurotransmitters, and specific effects of individual food dyes on behavior are still unanswered.

The report of the American Council on Science and Health does not present this type of balanced view of the status of the Feingold hypothesis.

Critique VII. "Saccharin" by Dr. Mel Reuber, former researcher, National Cancer Institute's Frederick Cancer Research Center

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The American Council on Science and Health makes the statement that saccharin has been in use for 80 years and that all this human experience, as well as testing, has not documented any risk of cancer or other life-threatening disease. ACSH "recommends that saccharin be recertified as a safe substance. . . . There is no evidence to indicate that saccharin, at current levels of use, causes cancer or any other disease in human beings."

In actual fact, the scientific community--including the Food and Drug Administration, National Academy of Sciences, National Cancer Institute, and Office of Technology Assessment--has concluded that saccharin is a weak carcinogen. This conclusion is based on both animal studies and on human epidemiology. Saccharin did not come into large-scale public use until around 1960, and it did not become ubiquitous in diet soda drinks until cyclamate was banned in the early 1970's. Between 1915 and 1955, saccharin use remained limited in the general population. It was primarily used by diabetics as an additive in canned vegetables and as a substitute for the sweet taste of sugar in other foods and beverages. Although 38 million Americans now use saccharin on a regular basis, half of them have used it for less than five years, and only 5 million have used it regularly for 15 years or more.

As has been shown with other substances, this could very well be a time period too short to register an increase in cancer deaths, which may take twenty or more years to become evident.

As most scientists (but apparently not those associated with ACSH) recognize, epidemiology is almost always too insensitive a tool to identify chemicals that do not cause massive amounts of cancer in human populations. For that reason, most scientists are satisfied with results from animal carcinogenicity studies. Because of the great public debate over saccharin, numerous epidemiological studies have been conducted. Most involved small numbers of subjects and could not detect modest increases. Some of the studies suggested that saccharin was safe, while others did not. The biggest and best study was sponsored by the National Cancer Institute, and the results were reported shortly after the ACSH report was published. The NCI report concluded:

> However, an excess risk was seen among subjects who used table top AS /artificial sweeteners/ or diet drinks heavily (6 or more daily servings of table-top AS, or 2 or more daily servings of diet drink), particularly among subjects who consumed both forms at those higher levels. . . ."

The design and details of the animal carcinogenicity studies are presented fairly well, although ACSH is annoyingly selective in choosing the experts it quotes as well as what they say. They rely particularly on the soft drink industry-financed Calorie Control Council and on the Council's consultant, Dr. Bernard Oser.

ACSH makes a big point about the fact that the National Academy of Sciences, which originally rejected earlier studies showing saccharin's carcinogenicity, reversed itself in 1978 to endorse those findings after studying the results of the famous Canadian rat experiment. Presumably, the fact that the NAS changed its position renders it incompetent and unbelievable.

At the same time, ACSH leaves out the rather interesting

story of why the NAS failed to be concerned about saccharin. At first, when experimental rats were fed the substance and developed bladder tumors, researchers attributed them to kidney stones. When that was proven wrong, the scientists blamed the tumors on parasites that lived in the bladder. Next, the parasites, too, were ruled out and the researchers claimed that a saccharin impurity--OTS--was the culprit. Finally, the Canadian study, which was designed to consider the effects of OTS, confirmed the carcinogenicity of saccharin itself. It was then that the NAS reversed its earlier stand.

ACSH accepts the fact that saccharin induces cancer of the urinary bladder in rats. However, it dismisses the NAS and Office of Technology Assessment reviews, because it claims they were improperly designed. The report (p. 3) states that "...the accuracy and reliability of the two-generation carcinogenesis design has not been verified." Using Dr. Oser and the Calorie Control Council as critics, ACSH lets the reader draw his or her own conclusion as to the validity of the charge. In fact, the design--a two-generation study, in which saccharin was fed to pregnant rats as well as their offspring--was specifically recommended by an NAS committee and (as mentioned by ACSH) was within the design limits for carcinogenesis testing set by the National Cancer Institute.

The ACSH statement that "there is no evidence to indicate that saccharin ... causes cancer or any other disease in human beings" is a denial of the value of chronic feeding studies on animals. The whole point of such studies is to develop evidence that a chemical is or is not safe for humans. Every authoritative scientific body that has studied this matter has concluded that if a chemical causes cancer in animals it should be assumed to pose a cancer risk to humans. The ACSH strategy seems to be to deny the value of animal studies and demand human epidemiology studies, knowing that human studies take years to conduct, are inevitably insensitive, and are not appropriate to establish the safety of a food additive.

In general, the ACSH report summarizes the studies about saccharin quite competently. However, it has several flaws which are then compounded by a highly misleading position statement.

One flaw is that the report does not adequately discuss the development of neoplasms in animals in organs other than the urinary bladder. Benign and malignant neoplasms at all sites were significantly increased in mice and rats ingesting the higher doses of saccharin. These neoplasms were present in the reproductive and hematopoietic systems, and to a lesser extent in the lungs, vascular system and squamous epithelium. Neoplasms in some organs developed with the lower doses of saccharin. Lymphosarcomas of the lung were significantly increased in rats given 0.01% saccharin. Saccharin also causes chronic renal disease in rats. (Environ. Health Perspectives 25, 173-200 (1978))

Another failing is that the section on risks and benefits is rather one-sided. Saccharin's use by diabetics is cited as a benefit, but there are medical doctors who tell their diabetic and obese patients that it is better to drink an occasional sugary soft drink and cut out sugar somewhere else in their diet than to ingest saccharin. And since when is it necessary to have sweet dental preparations or pills in order to get children to use these products? (Sweet, candy-like pills have even been implicated in child poisonings, and might be considered a risk rather than a benefit.)

The report also suffers from the insertion of snide, irrelevant editorial comments, like about the number of lung cancer patients who carry matches, or such as: "Because it is considered to be an unavoidable contaminant and thus an inevitable risk (like getting out of bed) ...."

However, the report's major problem is its "Position Statement," the summarizing few paragraphs which is all most readers will peruse. From all I can tell, the position statement was written by someone other than Terrence Smith, the report's author, and it may have even been written before the report was completed. Since the vast majority of readers will not plod through 126 tedious but not wholly unbalanced pages, they will assume that ACSH has provided proof for its extremely misleading summary.

Anyone can make value judgments about whether saccharin

should or should not be allowed. Anyone can try to balance "perceived" benefits of saccharin to weight-conscious people and diabetics against the chemical's ability to cause bladder cancer in a small fraction of the population. But it is disconcerting to see an alleged "scientific" organization like ACSH impugn the validity of generally accepted animal studies and pretend that positive human epidemiology studies are crucial to concluding that a chemical is safe in order to arrive at its apparently predetermined conclusion that saccharin is "safe."

Critique VIII. "New Jersey: Garden State or Cancer Alley?" by Thomas Burke and Martin Rosen, New Jersey Department of Environmental Protection

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"New Jersey: Garden State or Cancer Alley? A report by the American Council on Science and Health" is, in the author's words, "an attempt to set forth the current knowledge about New Jersey's high cancer rates." The "knowledge" presented consists of three main items: 1) that information within the National Cancer Institute report, U.S. Cancer Mortality by County: 1950-1969, which indicated that New Jersey had some of the highest cancer mortality rates in the nation, 2) the discovery and official response to the cancer cluster which occurred in Rutherford, and 3) a series of studies analyzing the geographic distribution of specific cancer mortality rates within the New Jersey region and the significant correlations between environmental factors possibly related to cancer causation and these mortality rates.

Although the report's conclusions are never really clearly stated, the implied contention seems to be simply as follows: Because the causative relationship between cancer and various environmental factors, especially pollution, has not been established, it is not cost-effective, or even reasonable, to regulate public exposure to these factors. The assumption is that "dangerous lifestyle factors" are more significant in terms of producing cancer than are the "involuntary" factors, such as air or drinking water contamination; therefore, any regulation is over-regulation. Since there are no proven health benefits resulting from the imposition of environmental quality standards, why bother with them?

The response to this argument is obvious. True, it is not proven that low levels of toxic materials in the air we continually breathe or the water we drink daily have any serious, long-term health effects, especially in terms of individual carcinogenic risk. But does that mean it is more reasonable to do nothing, do we sit back and wait for proof, perhaps in the form of rapidly increasing mortality rates? Simply because we do not know, it is prudent that we prevent any unnecessary exposure that might suggest a public health risk. It is very cavalier to speak of economic benefits and reduced costs to the consumer, but cost-benefit analysis has not yet been able to (and may never) quantify the value of a human life or the suffering of an individual or a family due to the ravages of cancer. As the report itself indicates, the available data on New Jersey's high cancer mortality rates is limited and inconclusive. Does that necessarily mean "it /the data/ provides little support for specific prevention and control measures?" Or does it instead suggest, simply because it is limited and inconclusive, that we cannot afford to take potentially dangerous risks with the public's welfare?

Although direct proof indicating a causal relationship between environmental exposure (i.e., air and water) and cancer incidence is not yet available, there is indirect evidence to lend credence to the above response and make it more than just a moral viewpoint. The correlation studies, mentioned earlier, described groups of counties which have similar patterns of cancer mortality. One of these groups is the urban-industrial core, including the state's most highly developed counties and characterized by the highest cancer mortality rates. If one looks at mortality rates in the New Jersey region and compares them with national trends it is apparent that although the regional rates are still higher the gap has narrowed during the time period 1950-1975. As the New Jersey Department of Environmental Protection wrote in 1981,

> Unfortunately, this is in large part due to increasing cancer mortality rates for the rest of the country, not decreasing rates for our region. It is possible that as the rest of the country has become more industrialized in the last 30 years, its cancer rates have come

to reflect those found in our predominantly industrial region.[1]

It is entirely plausible that those areas of the country experiencing increased industrialization, as reflected in rapid growth rates, have made the same "mistakes" as the older, industrialized areas presently exhibiting high mortality rates. Because these are new growth areas, the need, or perhaps desire, for strict environmental regulations is not yet apparent. Until one of the secondary impacts of rapid industrialization, i.e., adverse health effects, is recognized, there may be little motivation to require more than minimal standards; in fact, lenient regulations could be a contributing factor to these areas' rapid development.

Though they have not yet received the attention cancer has, there are other public health threats, perhaps even more serious, posed by exposure to toxic materials. Unfortunately, ACSH ignores these threats in its analysis. Environmentally-induced cancer has been a focus of research in New Jersey over the past five years, because data showed mortality from this disease was far above national averages. If the data had not been available or analyzed, the problem may have been overlooked but would have still existed. There are toxic pollutants either known to be, or suspected of being, human carcinogens. However, these substances, as well as a wider array of contaminants, have other deleterious properties, including acting as mutagens and teratogens. Unfortunately, the data for these health effects are very scarce and the true impact of environmental toxins is not yet known. But the need to determine these interactions is of paramount importance. The consequences of the genotoxic compounds, that is, those damaging genetic material, go beyond a single lifetime and could influence birth defects and physical and mental disabilities over several generations. Thus, although cancer is of vital public interest, because of the emotional issues associated with this disease, it has perhaps received more attention than other health issues which have a much longer time frame

[1] NJ Department of Environmental Protection. 1981. Trends in Cancer Mortality in the New Jersey-New York-Philadelphia Region 1950-1975. March, 1981, p. 34.

and, therefore, are far more costly. Even if cancer was not the concern it is today, there are other equally important reasons to minimize public exposure to toxic contamination.

Control of toxic discharge and emissions may not mean zero release, although any exposure, however small, is regarded as an addition to the total carcinogenic risk; economic realities will just not allow 100 percent control. Yet shifting resources to control exposure to only those factors which have "known tangible health benefits" is a short-sighted and potentially dangerous approach. We concur that some emphasis must be placed on reducing exposure through changes in lifestyle, that personal responsibility is important. But there is also a social responsibility to minimize the threat of involuntary exposure. Just as each individual must protect himself whenever possible, it is the obligation of government to protect the public it serves. It is with this understanding of its responsibility that the State of New Jersey has been conducting an extensive program of air, water, and industry monitoring which has revealed widespread public exposure to toxic and carcinogenic substances. We cannot wait until all the facts are in; we must act on the assumption that environmental contamination does pose a threat (as much evidence does seem to indicate), because the costs, both economic and social, of being wrong would be too great for any society to bear.