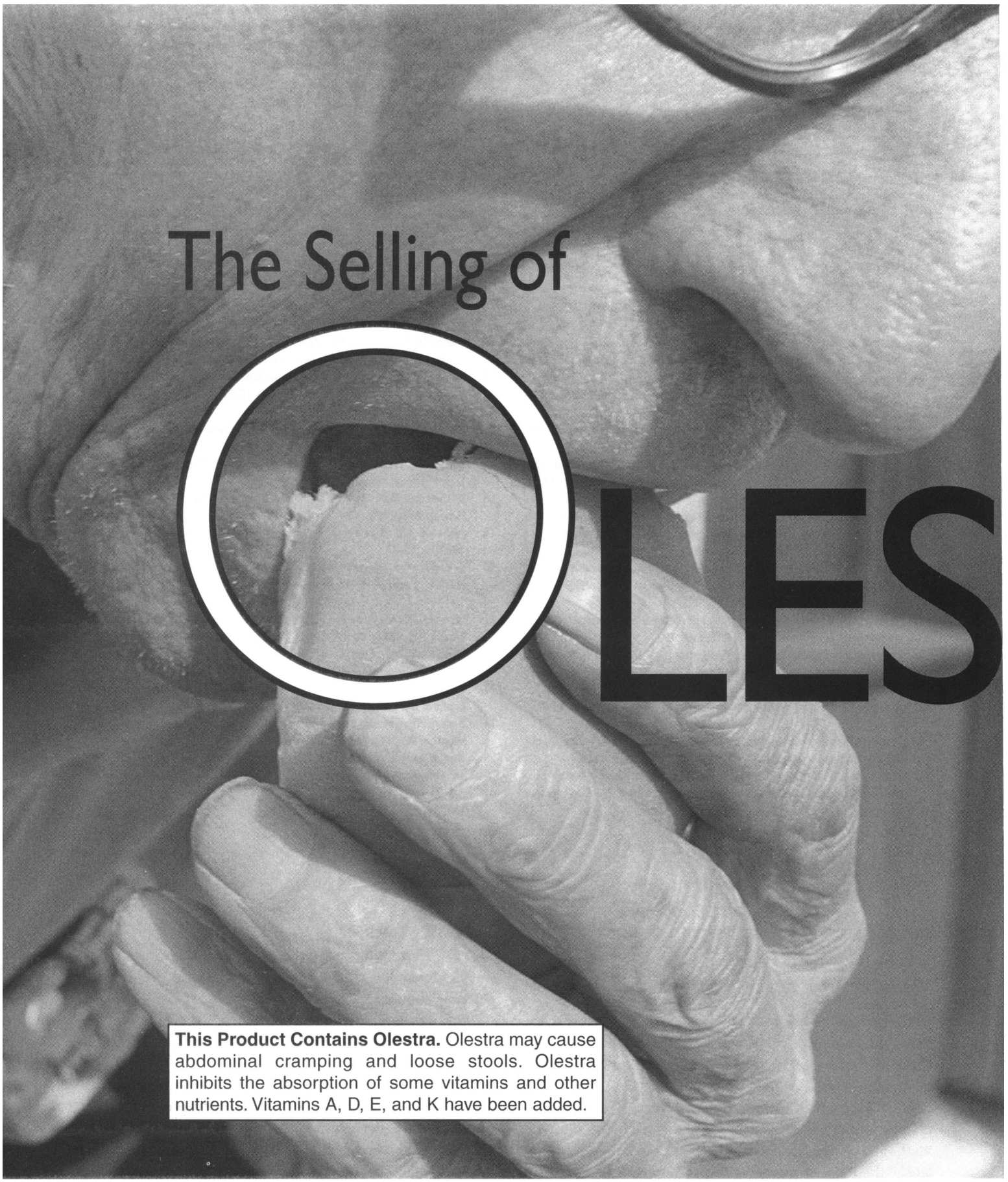
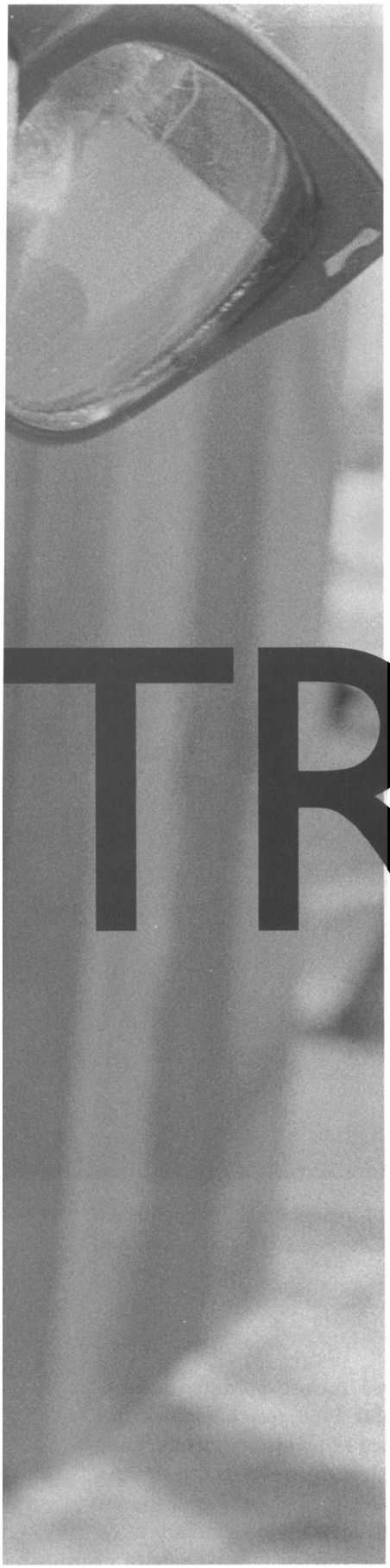

The Selling of
OLESTRA
This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.



Marion Nestle, PhD MPH

OLESTRA

SYNOPSIS

THE PROCTER & GAMBLE Company spent 30 years and an estimated $500 million to bring its non-digestible fat substitute, olestra, to market. The Food and Drug Administration approved olestra as a food additive but requires products containing olestra to carry a warning statement about its potential effects on gastrointestinal function. In obtaining approval for olestra, P&G conducted a lengthy, persistent, and comprehensive campaign to enlist support from members of Congress; FDA staff; and food, nutrition, and health professionals. This campaign raises larger questions about corporate influence on government policies, and the relationships of corporations to health professionals. To address these larger concerns, the author reviews the history of olestra's approval; describes P&G's campaign to obtain support from FDA and Congress, to defend olestra against critics, and to market it to professionals, the press, and consumers; and suggests implications for public health policies.

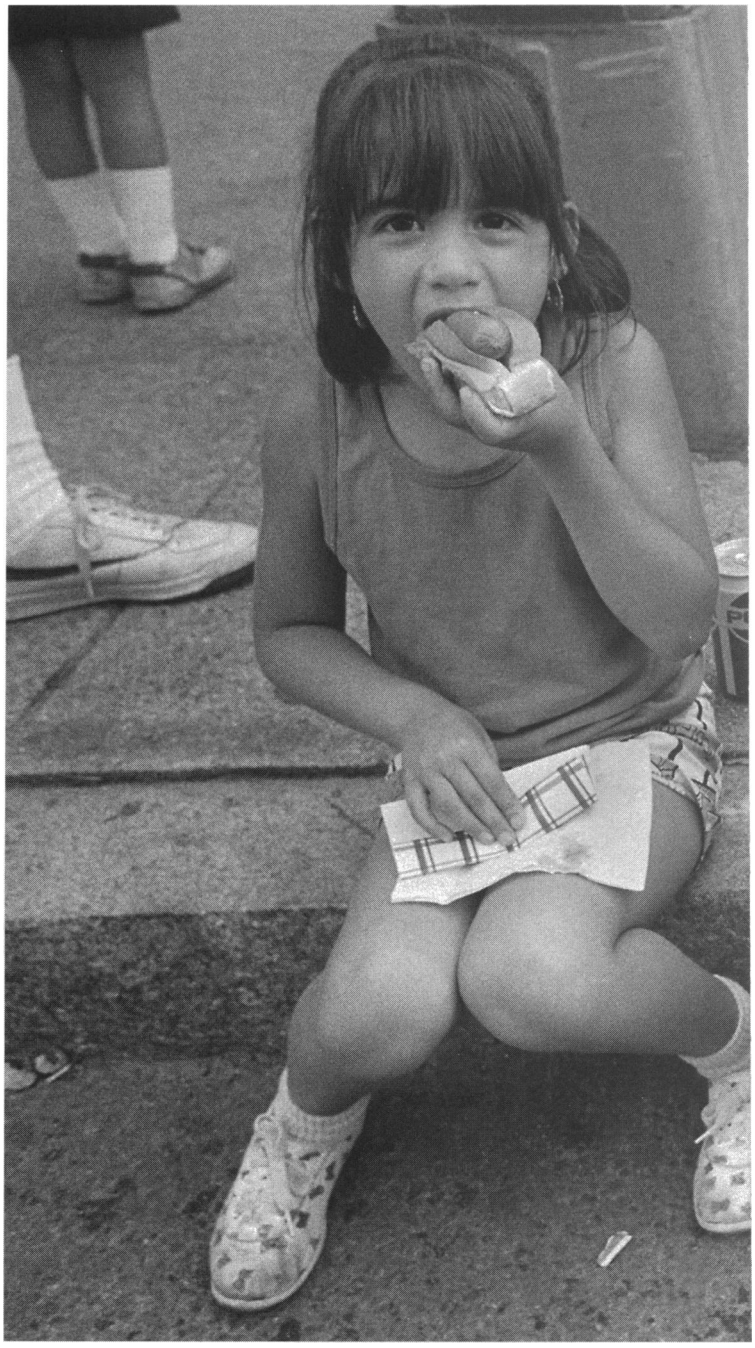
ON JUNE 17, 1998, the Food Advisory Committee of the Food and Drug Administration (FDA) confirmed its earlier judgments that the Procter & Gamble (P&G) company's fat substitute, olestra, was reasonably certain to cause no harm as a food additive and that foods containing this substance should carry a warning statement.[1] This peculiar decision—judging olestra "safe" while alerting consumers to its potential hazards—was only the latest episode in a 30-year struggle to bring olestra to market. The elements of this struggle are useful to review, as they illustrate much larger societal concerns about the relationships of corporations to government and health professionals and the conflicts of interest inherent in such relationships.

P&G's persistence in that struggle is easily understood. Olestra, the company's name for sucrose polyester, retains the sensory and physical properties of natural food fats but is not digested or absorbed by the human body.[2] In theory, substitution of olestra for natural fats could help people reduce their intake of calories, fat, saturated fat, and cholesterol and, therefore, reduce the risk of obesity and related diseases: coronary heart disease, certain cancers, and diabetes.[3] The potential uses of olestra in commonly consumed foods—and the potential economic returns to P&G investors—are enormous.

The reasons for the long delay in FDA approval are also readily apparent. Olestra raises at least two health concerns that have been difficult to resolve: first, olestra might be expected to behave in the body like mineral oil, with similar laxative effects and interference with the absorption of fat-soluble nutrients, and, second, as a replacer of cooking fat, olestra could be consumed in large amounts. P&G's many studies of the effects of olestra have been of short duration and, therefore, unable to address the long-term risk of gastrointestinal problems or nutrient depletion. Under current laws, petitioners must demonstrate that food additives are safe before the FDA grants approval; Congress has not granted the FDA a mandate or funds for independent evaluation of additives under review. Furthermore, because the laws do not require P&G to demonstrate long-term improvements in caloric balance or chronic disease risk, any benefits of olestra also remain uncertain.

With questions about long-term safety and benefits unresolvable at present, the FDA approved olestra but required a warning notice. Unlike drugs, which also are approved on the basis of limited testing by manufacturers and require warnings of side effects, olestra needs no doctor's prescription. Unlike other food additives that carry warning notices, such as sulfites or artificial sweeteners, olestra is the first "macro-additive": a 1 oz serving of chips contains up to 10 g of olestra. In contrast, diet soft drinks contain only milligram amounts of artificial sweeteners. On quantitative grounds alone, olestra raises unprecedented public health and regulatory issues.[4]

To demonstrate the safety and potential efficacy of olestra, P&G invested upwards of a half billion dollars in research, development, and activities targeted to the FDA, professional societies, health scientists, practitioners, and consumers. P&G also worked to convince a reluctant Congress to extend protection on a key olestra patent. The company's comprehensive and persistent campaign to bring olestra to market deserves attention as an especially visible example of the ways large corporations gain support for their products from government agencies and health professionals. The olestra campaign also highlights larger concerns about conflicts of interest that may result from corporate funding of government and professional activities and the difficulties of maintaining independence faced by health professionals engaged in alliances and partnerships with industry.



Regulatory Issues

P&G researchers discovered sucrose polyester accidentally during an unsuccessful 1968 search for fats that could be more easily digested by premature infants.[5] Conventional fats are composed of glycerol attached to three fatty acids. P&G scientists replaced glycerol with sucrose (table sugar), which can attach to up to eight fatty acids. The resulting larger molecule cannot be broken down by

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human or bacterial enzymes in the digestive tract and is not absorbed across the intestinal wall to any appreciable extent. Because its fatty acid composition can be adjusted to give it the viscosity, cooking properties, and taste of natural fats and oils,[2] olestra can be used to prepare a wide variety of snack foods, restaurant foods, and home-cooked meals.[5] The potential for olestra to be consumed in much larger quantities than any other food additive explains the FDA's regulatory predicament. Food additives are usually consumed in tiny amounts but tested in animals at hundred-fold higher levels; this method could not be used to determine whether olestra affected intestinal function or depleted fat-soluble nutrients because animals could not eat that much. Thus, P&G needed to develop different safety testing methods and the FDA needed to establish new regulatory standards;[4] over the years, they "learned together" how to approach these tasks.[6,7]

FDA. The regulatory history of olestra began in 1971, when P&G obtained its first patent and met with the FDA to explore approval of olestra as a food additive. Over the next few years, P&G studies found that substitution of olestra for natural fats caused a decrease in blood cholesterol levels; however, to market olestra as cholesterol-lowering, the company would have to obtain approval of it as a drug. P&G filed a drug petition in 1975. Under FDA regu-

lations, drug approval required at least a 15% reduction in blood cholesterol. When the studies could not demonstrate this great a reduction, P&G abandoned its drug approval strategy and began preparations to petition the FDA for approval of olestra as a food additive.

The company was encouraged in this approach when, in 1984, the FDA tacitly permitted Kellogg's to claim that its high fiber cereals helped reduce the risk of cancer, which suggested that P&G would be able to make health claims for olestra.[7]

Three years later, P&G petitioned the FDA to permit substitution of olestra for up to 35% of the fat used in home cooking and up to 75% of that used for commercial purposes. Because the petition did not include table spreads and ice cream, P&G presented the request as "a conservative first step."[5] The FDA, however, viewed the potentially vast scope of uses as posing safety issues that required further testing. To expedite approval, P&G then narrowed its request just to use of olestra in savory (salty and spicy) snacks.[7]

Over the years, P&G submitted 150 animal and human studies and 150,000 pages of data[8] on the effects of olestra on absorption and excretion of drugs, vitamins, carotenoids (plant precursors of vitamin A that have antioxidant properties), and minerals and on hormone levels, intestinal function, and certain gastrointestinal diseases.[4] Late in 1995, the FDA provided a summary of this information and a substantial critical analysis[9] to a subcommittee of the FDA Food Advisory Committee and to the Committee itself. Both recommended approval of olestra, although some Committee members sharply dissented.[10,11] On January 24, 1996, the FDA announced approval of olestra for use in savory snacks provided that P&G formulated it to meet certain specifications for composition and stiffness, and that users fortify their products with fat-soluble vitamins A, D, E, and K and include a warning notice on packages. Recognizing that P&G planned to conduct post-market surveys of consumer responses to olestra, the FDA also announced that it would review new data in 30 months and reconsider approval at that time.[4]


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Current food additive regulations do not demand demonstration of absolute safety but only "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[4] In practice, the rules do not require P&G to demonstrate, *nor is the FDA permitted to consider*, whether olestra might actually be beneficial. As explained by then–FDA Commissioner David Kessler, questions about whether olestra might make sense or contribute to the nutritional health of the nation were irrelevant to the FDA's approval processes.[12]

In June 1998, the FDA asked the Food Advisory Committee to evaluate whether P&G's post-market studies had raised any significant public health concerns and to advise the agency about changes that might be needed in labeling requirements. The Committee reviewed data presented by P&G scientists and sponsored researchers and listened to testimony from about 30 individuals, at least half of them supported by or otherwise connected to P&G. The Committee also heard testimony from representatives of the Washington, DC–based consumer advocacy group, the Center for Science in the Public Interest (CSPI) and independent scientists about reported and potential adverse effects. Most of the Committee members again viewed such concerns as minor and voted to reaffirm their original decisions,[1] thus concluding a matter that had required substantial FDA attention for 27 years.

Congress. By 1988, P&G's first patent had expired, and three key patents were due to lapse in 1994.[13,14] Arguing that the FDA's lengthy regulatory review had jeopardized its $200 million research investment, P&G, which is headquartered in Ohio, induced its local Congressmen (four out of five of whom received campaign funds from P&G[15]) to help the company revive the original patent and extend the others for 10 years following FDA approval. Although Congress generally opposes private patent extensions because they inhibit competition, both Houses introduced such legislation in the 1991–1992 sessions and held Judiciary Committee hearings on these bills.[6,14] Furthermore, Congress demanded a General Accounting Office (GAO) investigation of the FDA approval process for olestra; the GAO's report attributed the delay to P&G's indecisiveness about whether to pursue approval as a drug or additive and to the FDA's lack of regulatory precedents.[7] Because patent laws require extension requests to be filed before expiration dates, Congress did not agree to revive the expired patent. Instead, it passed amended bills to extend the three remaining patents until the end of 1997,[16] but these bills defaulted when Congress adjourned without taking final action.

Similar bills introduced during the 1992-1993 sessions and numerous further hearings eventually culminated in passage of a generic law granting limited extensions on patents for products under lengthy regulatory review.[17] The law did not specifically refer to olestra, but its net effect was a two-year extension on one patent until January 25, 1996, with the possibility of an additional two-year extension if the FDA approved olestra by that date.[13,18] In what appeared to be anything but coincidence, the FDA announced approval of olestra on January 24, 1996.[4] Thus, a seemingly arcane patent issue preoccupied the Congressional judiciary committees for nearly three years; resulted in a four-month GAO investigation of the FDA's procedures; led to an Act of Congress designed to benefit a particular company; and gave the FDA the appearance of collusion with the corporate interests of a product under regulatory review.

Opponents. Some scientists and consumer groups have opposed olestra on safety grounds for more than a decade (see "Effects of Olestra in Humans," page 517). The most organized opposition has come from CSPI, which first challenged the safety of olestra in a response to P&G's 1987 food additive petition.[19] In preparation for the 1995 meeting of the Food Advisory Committee, CSPI provided a detailed analysis of P&G-sponsored studies that found olestra to deplete carotenoids and fat-soluble vitamins and to cause significant gastrointestinal disturbances. On that basis, and because olestra appeared to be associated with precancerous liver lesions in animals, CSPI asked the FDA to deny approval.[9]

SOME POTENTIAL USES OF OLESTRA, ACCORDING TO THE PROCTER & GAMBLE COMPANY

Snack foods	Restaurant foods
Potato chips[a]	French fries
Corn chips[a]	Fried chicken
Cheese puffs[a]	Fried fish
Crackers[a]	Onion rings
Doughnuts	
Pastries and pies	Table spreads
Cakes and cookies	Margarines[b]
Ice cream[b]	Cheeses[b]

Home use
Fried chicken
Grilled meats and vegetables
Sauteed meats and vegetables
Baked desserts and snacks

SOURCE: Reference 5
[a]Use of olestra in savory (salty and spicy) snacks was approved by the FDA on January 24, 1996 (see Reference 4).
[b]Not included in P&G's 1987 petition to the FDA, which excluded uses in table spreads and ice cream

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Studies conducted or supported by P&G, however, invariably conclude that olestra poses no health risks,[20] but the company obviously has a vested interest in producing such results. CSPI has criticized these studies on methodological grounds.[9] That the FDA cannot require confirmation by disinterested investigators troubles critics,[11] especially when the studies suffer from small sample sizes, short time spans, and other problems (see page 517). Indeed, the few studies conducted by Unilever, a competitor of P&G, indicate that high doses of olestra cause gastrointestinal problems in 15% to 30% of recipients[21] and that a dose of just 3 g significantly reduces blood levels of fat-soluble vitamins and carotenoids,[22] raising concerns that olestra might increase risks for heart disease, stroke, cancer, and macular degeneration.[23] A more recent study has confirmed such effects.[24] Despite such findings, and the 6600 anecdotal complaints of gastrointestinal problems filed with the FDA by the time of the meeting (Personal communication, Thomas Wilcox, MD, Medical Officer, FDA, July 27,1998), the Food Advisory Committee decided that because critics could not *prove* that carotenoid losses were harmful, the P&G data were acceptable and the gastrointestinal concerns could be handled by retaining the warning notice.[1]

Although CSPI did not change this outcome, its actions encouraged the FDA and Congress to be more cautious and the public to be more aware of issues related to olestra. Investigative reports state that in response to this opposition, P&G hired Washington's "most feared and vilified" private investigation firm to obtain information that might undermine CSPI's credibility[25] and placed media stories critical of CSPI in publications with financial connections to the company. For example, a *Reader's Digest* article characterizing CSPI as the "food police"[26] failed to mention that P&G is the magazine's third largest advertiser and had spent $1 million on advertising in that particular issue alone.[27]

Marketing Campaign

P&G's actions against CSPI were components of an extraordinarily thorough campaign to enlist government, journalists,[15] and nutrition, food, and health professionals in efforts to promote olestra's value and safety (see page 518).

Professionals. P&G garnered support from health professionals through efforts targeted to organizations, publications, and individuals. The company gave grants to orga-

Key Events in the History of Approval and Marketing of Olestra

1968	Procter & Gamble (P&G) researchers develop sucrose polyester (olestra), conduct animal studies.
1971	P&G meets with FDA, obtains first patent.
1973	P& G initiates human feeding studies, conducts further animal studies.
1975	Olestra found to reduce blood cholesterol levels, P&G petitions FDA for drug approval.
1977	U.S. Senate report *Dietary Goals for the United States* (Reference 68) recommends fat restriction to reduce chronic disease risk.
1984	Kellogg's high fiber cereals advertise their connection to cancer prevention, leading to some relaxation of FDA restrictions on food-related health claims.
1987	Further P&G studies fail to demonstrate sufficient reductions in blood cholesterol to permit FDA approval of olestra as drug. P&G petitions FDA for food additive approval. Center for Science in the Public Interest (CSPI) and other critics object to approval on safety grounds.
1988	Initial olestra patent expires; three others due to expire in 1994. *Surgeon General's Report on Nutrition and Health* identifies fat reduction as nutrition priority.
1989	FDA requires additional safety tests for olestra.
1990	P&G resubmits petition for approval of olestra as food additive, restricting its request to approval for use in savory snacks. Nutrition Labeling and Education Act permits certain health claims on food labels.
1991	Congress considers bills to revive the expired olestra patent (H.R. 2805) and to extend three others for 10 years after FDA approval (H.R. 5475, S. 1506), holds hearings, asks the General Accounting Office (GAO) to report on reasons for FDA delays.
1992	GAO report attributes approval delays to P&G's indecisiveness and to unprecedented regulatory requirements. Congress holds patent hearings, adjourns without taking action.
1993	Olestra patent bills reintroduced (S. 409, H.R. 3379). Congress enacts P.L. 103-179 permitting certain generic patent extensions that extend one olestra patent until January 25, 1996, with two further years possible with FDA approval.
1994	Dietary Supplement and Health Education Act permits health claims for dietary supplements.
1995	CSPI issues *White Paper* opposing FDA approval of olestra. FDA Food Advisory Committee recommends approval. Frito-Lay obtains exclusive supply agreement for limited term after start of national marketing.
1996	FDA approves olestra for use in savory snacks on January 24; requires warning notice, addition of fat-soluble vitamins. P&G begins test marketing, brands olestra Olean, petitions FDA for less explicit warning notice. CSPI petitions FDA for more prominent warning notice, petitions Federal Trade Commission to halt deceptive olestra advertising.
1997	P&G, Frito Lay, and Nabisco conduct further market tests.
1998	P&G and Frito Lay announce nationwide release of Olean products. FDA Food Advisory Committee reaffirms olestra approval with warning notice.

The food industry spends about $10 billion annually on direct media advertising, a level of spending no Federal agency could ever hope to match.

nizations to develop educational materials and to hold conferences on olestra and related topics. It sponsored focus groups and booths at annual meetings and paid publication costs for special issues of professional journals.[20,28] For example, a P&G official sits on the board of the International Life Sciences Institute, which sponsored a 1997 conference funded in part by P&G; proceedings of the conference were published through the New York Academy of Sciences.[29] P&G also is one of many corporate sponsors of several professional journals that have published articles about olestra.

The company has supported scientists, educators, and practitioners through research grants, travel funds, honoraria, educational materials, samples, and meals. Since 1996, it has mailed educational brochures and samples of olestra chips to tens of thousands of physicians, nurses, and dietitians and sent its research summaries to thousands more.[30] P&G officials personally visited professionals perceived as influential, and the company recruited dozens of paid consultants, among them two former Secretaries of Health and Human Services and many prominent researchers and clinicians,[31] who wrote articles, testified, or appeared in commercials supporting olestra.[32]

Such actions raise questions of conflict of interest, especially when financial relationships are not disclosed. One former DHHS Secretary, for example, appears in a promotional videotape without revealing his consulting relationship. Other materials also display or quote spokespersons whose connections with the company are not stated.[33]

Disclosure would provide a more complete basis for critical judgment. The website of the American Dietetic Association (ADA) contains a series of fact sheets sponsored by corporations. The olestra fact sheet emphasizes benefits, does not mention the warning notice, and dismisses effects on carotenoid absorption as insignificant.[34] Because the fact sheet fully discloses P&G sponsorship, one would not expect it to be balanced. Even so, the website does not mention the $100,000 reportedly donated by P&G to the ADA over the last decade.[30] Disclosure might also prevent embarrassing situations such as that involving the American Medical Association, which was negotiating for an $800,000 health education grant from P&G in the same month that it issued a statement supportive of olestra.[35]

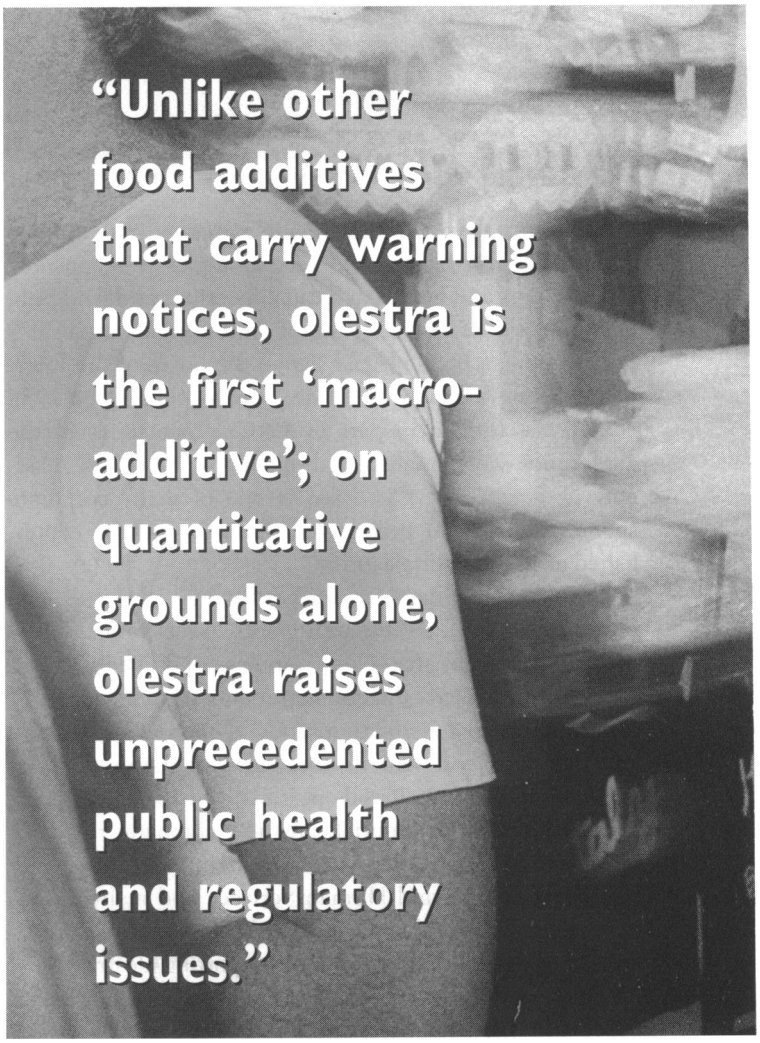
Even though recipients of corporate funding do not inevitably support corporate interests, financial connections give the appearance of conflict of interest.[36] People who accept P&G funds may believe olestra beneficial and the arrangement unlikely to influence their critical judg-

ment.[32] My own experience suggests that even as a nutritionist holding an independent opinion on olestra, it is virtually impossible to avoid some sort of financial relationship with P&G unless one systematically refuses all speaking invitations, travel reimbursements, honoraria, or meals from outside parties. I am not a P&G consultant, yet I spoke at a P&G–sponsored press luncheon for a report I edited[3] and later gave a similar talk at a P&G conference on olestra[5] (meals and travel expenses, $1000 honorarium). Since then, I have discussed product development at meals hosted by P&G officials, explained my views of olestra to company staff ($500 honorarium), and co-chaired a session and was lead author of a report[37] from a P&G-sponsored conference on fat-modified foods[28] (travel and meals, $4000 honorarium). Because I do not accept honoraria from food companies, I had P&G write the checks to my department's scholarship fund or to CSPI. P&G staff also have been unfailingly gracious in responding to requests for information or materials. Given such courtesy and generosity, it may seem churlish to express criticism.

Media and consumers. Once olestra was approved, savory snacks containing it could be marketed. To do so, P&G sold exclusive rights to the Frito-Lay company in exchange for an "eight-figure" investment in a new manufacturing plant.[38] To launch the test-marketing of the new products, P&G worked with "a raft" of public relations agencies,"[39] some of them employing well-connected former advisors to President Clinton.[40] P&G or Frito-Lay officials personally visited media outlets,[41] and the companies distributed hundreds of thousands of free samples,[42] recruited and trained dietitians, collected testimonials from satisfied customers, ran tour buses, hired cheerleaders, and did Christo-like wrappings of supermarkets in olestra banners,[39] actions reported to have resulted in "gobs" of free publicity and sales of 28 million servings by mid-1997.[30]

Campaign costs. P&G's investment in selling olestra can only be estimated, but it appears to have been at least $500 million.[43] During 1993 patent hearings, P&G officials reported expenditures of $200 million for olestra research and development;[14] other sources report estimates of $160 million[38,39] to $250 million[42,44] for the olestra processing plant and $5 million to $10 million for test marketing olestra in Columbus, Ohio,[39,45,46] and the less publicized costs of the three other test markets. In addition Frito-Lay was reported to have spent $7.4 million,[45] and P&G $22 million,[47] on advertising olestra products in just the *first quarter* of 1998. To these costs must be added expenditures for the 700,000 acres of land used for growing soybeans and cotton to produce olestra's fatty acids,[44] and the purchase of sugar raw materials.

Such astounding expenditures must be understood in context. In 1996, P&G earned $35.3 billion in revenues and spent $3.25 billion to advertise its full line of products, of which $30 million was spent just for pre-olestra Pringles potato chips.[46] The same year, Americans bought 5.5 billion pounds of salty snacks worth $13 billion.[42] Olestra chips would not have to capture a very large share of this market to recoup P&G's investment. Indeed, company officials predict annual revenues of $400 million[44] to $500[42] million by 1999. If the FDA approves olestra cooking oil, P&G also could enter the billion-dollar annual markets for fried snack and restaurant foods.[48] Whether the company will achieve its financial goals, however, is uncertain. Although more than 100 million bags of olestra snacks were reported sold from the February 1998 launch through July 1998, tracking data showed that sales in one of the early test markets fell markedly immediately following the end of a media blitz that accompanied the launch and have continued to decline ever since.[45]



POLICY IMPLICATIONS

P&G spent $500 million or more to introduce olestra into a highly competitive food marketplace already glutted with calories and food products. In 1995, the U.S. food supply provided 3800 kilocalories per day (kcal/day)—500 kcal higher than in 1970 and vastly above needs—for every man, woman, and child.[49] People can choose healthful diets from this supply at low cost and do not need any new food products[50] beyond the approximately 240,000 already on the market.[51] The relationship between food choices and health is well established.[3] Dietary guidelines recommend that people consume more grains, fruits, and vegetables, smaller amounts of high-fat meat and dairy foods, and even smaller amounts of processed foods high in fats, sugars, and salt.[52,53] Such guidelines are meant to be followed as a total dietary pattern.[54] Olestra addresses just the fat component of that pattern; its use in snacks might help some people reduce calories and fat—and, perhaps, body weight and certain chronic disease risk factors—but it might also interfere with the benefits of fruits and vegetables. Its food sources are also high in salt. Marketing olestra chips as health foods because

EFFECTS OF OLESTRA IN HUMANS AND CRITICISMS OF STUDIES

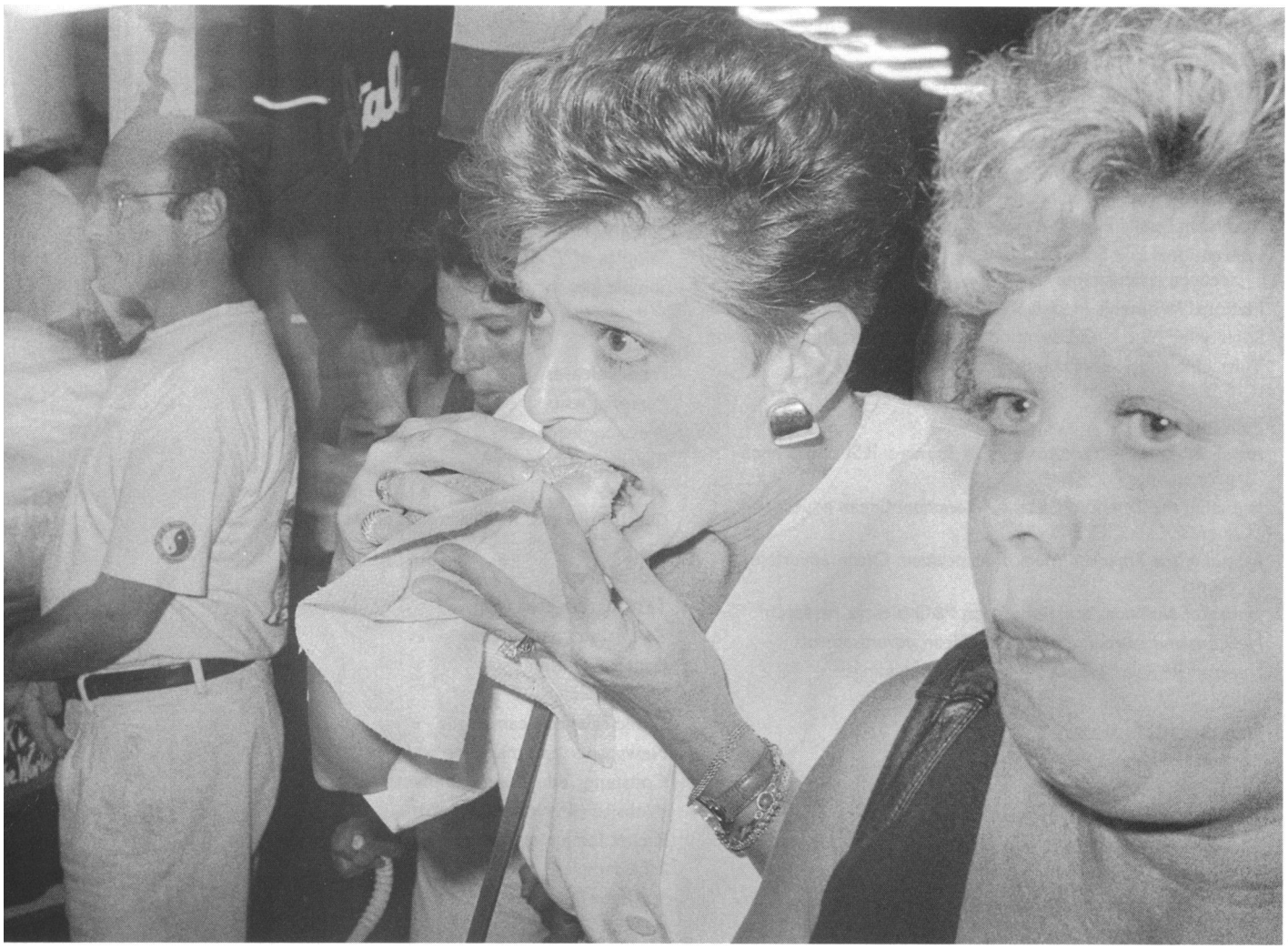
PHYSIOLOGICAL EFFECTS:

- Gastrointestinal problems (pain, gas, diarrhea, leakage) in some people
- Reduced absorption of fat-soluble vitamins
- Reduced absorption of carotenoids
- Uncertain effects of reduced absorption on disease risks
- Efficacy in inducing weight loss or reducing risk factors unknown

CRITIQUES OF SCIENTIFIC STUDIES CONDUCTED BY P&G:

- Duration too short
- Doses too low (unlike usual food additive testing)
- Numbers of subjects insufficient
- Statistical power inadequate
- Insufficient focus on frequent users
- Lack of confirmation by independent investigators

SOURCES: References 4,9,11,21-24.



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they are low in fat misses the point that the best health outcomes are associated with healthy dietary *patterns*, not just eating or avoiding one or another single dietary factor.

Moreover, olestra foods may be fat-free but they are not calorie-free; they save only about half the calories of natural fat products. And experience with artificial sweeteners suggests that olestra will have little impact on overall fat intake. In 1970, manufacturers produced enough artificial sweeteners to replace the sweetness of 5.8 lb of sugars per capita per year; by 1995 they produced enough to replace nearly 25 lb. During these years, the supply of caloric sugars *increased* from 122 lb to 150 lb per capita per year.[49] Some individuals who use artificial sweeteners may reduce sugar intake, but most do not; some may, for example, rationalize that consuming diet soft drinks justifies eating foods high in sugar.[55] If olestra indeed reduces inhibitions about eating salty snacks[42,56] or encourages deliberate misuse to induce laxative effects,[57] people may well increase their intake of these products and therefore their caloric intake. Given the uncertainties about olestra's long-term effects, the lack of evidence for long-term benefits, the adequacy of the present food supply, and the pressing need to find ways to feed the world's growing population, P&G's Herculean efforts to develop and market olestra can be considered an astonishing waste of human, land, food, and economic resources.[58] Whether the efforts will prove worthwhile to stockholders remains to be seen.

In the meantime, the history of olestra suggests the need for rethinking certain public health policies:

FDA regulatory processes. The FDA approved olestra because P&G's research found it safe, the Advisory Committee judged gastrointestinal effects to be trivial, and critics could not prove demonstrable harm from depletion of fat-soluble nutrients. The shift of the burden of proof from industry to critics highlights weaknesses in the current regu-

SELECTED PROCTER & GAMBLE COMPANY–SPONSORED ACTIVITIES IN SUPPORT OF OLESTRA

NUTRITION, FOOD, AND HEALTH PROFESSIONALS

Organizations

American Council on Science and Health: educational grant
American Diabetes Association: educational grant
American Dietetic Association: educational grant, website, and print materials
American Heart Association: conference
American Public Health Association: booth at annual exhibit
International Life Sciences Institute (ILSI): corporate and conference sponsorship
National Women's Health Resource Center: educational grant
Society for Nutrition Education: focus groups at annual meeting
Tufts University: conference grant

Publications

Annals of the New York Academy of Sciences: ILSI conference proceedings[29]
Journal of the American Dietetic Association: Olean advertisements
Journal of the American Medical Association: Olean advertisements
Journal of Nutrition: supplement on P&G olestra research[20]
New England Journal of Medicine: Olean *advertisements*
Nutrition Reviews: Tufts conference proceedings[28]

Individual professionals

Research grants
Consulting funds
Travel to conferences
Travel to FDA hearings
Honoraria
Educational brochure for physicians, nurses, dietitians
Research bibliographies, articles, and summaries
Personal visits and consultations
Educational materials: pamphlets, illustrations, information kits
Website information on research and clinical effects
Videotapes
Office displays
Olestra oil samples (to chefs)
Olestra dinners
Samples of Wow! chips and Pringles
Sample kits for classes and groups

MEDIA

Press releases
Personal visits
Press conferences
Research summaries
Samples
Olestra dinners: food editors and writers

CONSUMERS

Test market campaigns
Television commercials
Print advertisements
Videotapes
Public relations campaigns
Newspaper and magazine articles
Consumer education pamphlets
Website (**www.olean.com**)
Packet for junior high and high school students
Free samples
Toll-free information number

latory system. In the case of olestra, research by independent investigators would have been highly desirable, especially since P&G's study designs may have been "years behind" current clinical and epidemiologic methods for evaluating risk, as suggested by one member of the FDA Advisory Committee.[11] If the FDA were adequately funded or if petitioners were required to provide funds to the FDA to conduct or sponsor high quality research by independent investigators, the agency would not need to work hand-in-glove with industry to regulate new products.[6,7] Congress should revise the statutes to increase the FDA's research authority and funding, not cut them, as has been Congressional practice for the past several years.[59]

Health and nutritional claims. A relaxing of regulatory restrictions encouraged P&G to seek approval of olestra as a food additive. In 1990, Congress required the FDA to permit food package labels to claim some health benefits beyond meeting nutritional needs (for example, low-fat foods could be labeled as contributing to reduced risk of heart disease or cancer). In 1994, Congress permitted greater flexibility in health claims made for dietary supplements.[60] In seeking the same flexibility for foods, manufacturers have developed thousands of products for which they can make health and nutritional claims; they view creation of such "functional foods" as a prime strategy for corporate growth.[61] Because the eat-less-fat message is so well recognized by the public, potato chips and sugared cereals can appear to be healthy just because they are low in fat. The FDA should be granted greater authority to regulate health and nutrition claims on package labels, not less.

Nutrition education. One of the reasons that nutrition guidelines are not routinely followed may be that products such as olestra chips and fat-free cookies lull people into a false sense of dietary security. Another likely reason is that funding for nutrition education cannot compete with the $30 billion annual advertising expenditures of food companies.[51,54] The National Cancer Institute, for example, allocated just $2 million—distributed over *five years*—to the educational component of its otherwise brilliant Five-A-Day campaign to increase fruit and vegetable consumption.[62] Demonstration projects prove that advertising can promote healthful dietary changes.[63] Yet, although higher funding levels would certainly improve campaigns to promote recommended dietary patterns, no Federal agency will ever be able to allocate as much to educational efforts as P&G and Frito-Lay spend to advertise olestra chips. These realities call for more creative policy approaches that extend well beyond education to encompass a broader range of Federal food and nutrition programs: agricultural supports, food regulations, food assistance programs, nutrition services and training, and food and nutrition monitoring and research.[64,65]

Industry-professional relations. In nutrition as in other fields, alliances with industry may be viewed as "the only way" for academics to fund research[66] and for practitioners to reach the public with nutrition messages.[67] As the olestra case illustrates, such alliances inevitably raise questions of conflict of interest. Health organizations and individuals who accept industry funding should be acutely aware of the potential hazards of such relationships and take every possible precaution to avoid compromising their independence and integrity.

These suggestions, of course, run precisely counter to current trends in Congress, Federal agencies, and professional societies that promote alliances with industry and, directly or indirectly, favor corporate interests over those of public health. The olestra case is not the first such example, nor will it be the last, but it is one that especially well illustrates the need for vigilance in keeping public health goals at the forefront of national food, nutrition, and health policies.

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