Authors' Financial Relationships With the Food and Beverage Industry and Their Published Positions on the Fat Substitute Olestra

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The Procter and Gamble (P&G) indigestible fat substitute olestra was approved as a food additive by the Food and Drug Administration (FDA) in 1996 with the proviso that olestra-containing products carry a warning statement about the additive's potential negative effects on gastrointestinal function and nutrient absorption.¹ Since that time, concerns about laxative effects and nutrient depletion have continued to be debated in the medical and nutrition literature and in the lay press.^{2–5}

P&G conducted an extensive marketing campaign for olestra, both before and after approval. The campaign included financial support of health professionals through "research grants, travel funds, honoraria, educational materials, samples, and meals."6 Industry support of health professionals is controversial because such relationships may pose a conflict of interest. For example, physicians' financial relationships with the pharmaceutical industry have been shown to be associated with their positions on the safety of calcium-channel antagonists.⁷ Other studies examining potential conflicts of interest related to pharmaceutical industry support have demonstrated similar results.⁸⁻¹⁰

Although a single study examines what nutrition professionals know and think about the food industry's marketing efforts in elementary schools,¹¹ the extent to which support by the food and beverage industry influences the opinions and behavior of health professionals appears not to have been studied. The debate about the safety and efficacy of olestra in assisting with weight loss provides such an opportunity. We designed our study after that of Stelfox et al.⁷ to examine whether authors' financial interactions with the food and beverage industry are related to their published positions regarding olestra. *Objectives.* This study examined the association between authors' published positions on the safety and efficacy in assisting with weight loss of the Procter & Gamble (P&G) fat substitute olestra and their financial relationships with the food and beverage industry.

Methods. Journal articles about olestra, and their authors, were classified as supportive, critical, or neutral with respect to its use. Authors not known to have industry affiliations were surveyed about their financial relationships.

Results. Supportive authors were significantly more likely than critical or neutral authors to have financial relationships with P&G (80% vs 11% and 21%, respectively; P < .0001). All authors disclosing an affiliation with P&G were supportive.

Conclusions. Because authors' published opinions were associated with their financial relationships, obtaining noncommercial funding may be more essential to maintaining objectivity than disclosing personal financial interests. (*Am J Public Health.* 2003; 93:664–669)

METHODS

Study Questions

We asked 2 questions: (1) Are authors who support or whose research findings support the use of olestra more likely than neutral or critical authors to have financial relationships with P&G? (2) Are authors who support the use of olestra more likely than neutral or critical authors to have financial relationships with *any* food or beverage company or trade group? To answer these questions, we examined authors' financial relationships with P&G and with other food and beverage companies and trade groups and compared them with their published positions.

Selection and Review of Articles

We identified authors by reviewing materials on olestra written by health professionals and published between 1996 (the year olestra was approved by the FDA) and September 1999. Relevant materials (reports and reviews of original research, commentaries, editorials, and letters to the editor) were identified using the MEDLINE database and the indexes of the journals of the American Dietetic Association and the Society for Nutrition Education (the major applied-nutrition journals). Of the 72 articles identified, only $67^{2-4,7,12-74}$ were included in the study, because it was later determined that 5 articles⁷⁵⁻⁷⁹ did not concern the safety and efficacy of olestra.

The articles were reviewed and classified as supportive, neutral, or critical with respect to the use of olestra by criteria defined as follows:

Supportive: Emphasizes safety/efficacy; recommends use; criticizes authors questioning safety/efficacy.

Neutral: Concludes that there is insufficient information to assess safety/efficacy; makes no recommendations about use; equitably assesses opposing views.

Critical: Emphasizes concerns about safety/ efficacy; recommends alternatives; criticizes authors emphasizing safety/efficacy.

The articles were first assessed by 2 raters independently (J.L. and J.G.), 1 of whom did and 1 of whom did not make a conscious effort to ignore authors' stated affiliations. When the independent rankings of the first 2 raters were compared, there were 19 discrepancies (for only 1 article the difference was supportive vs critical; for 2 it was supportive vs neutral, and in the 16 remaining cases, one of the reviewers rated the article

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either supportive or critical and the other was undecided between the same rating and neutral). All but 4 of these minor discrepancies were resolved by having both raters reread the articles. The articles then were submitted to a third rater (D.H.) who had no prior contact with either the articles or the other raters' ratings. The articles were sent to this rater with all indications of authors' affiliations removed. In the undisputed cases, the latter ratings agreed with the original 2 raters in all but 5 cases; in those cases, the original ratings were determinant. In the 4 originally disputed cases, the third rater agreed with one or the other of the original raters, and her ratings were accepted as final.

Each author was assigned a classification based on the classification of the article. Authors of more than 1 article were assigned a single classification. Authors classified as neutral on the basis of 1 article but as supportive or critical on the basis of another were classified as supportive or critical, respectively. No author was found to be supportive in 1 article and critical in another.

Survey Instrument

A survey instrument based on the questionnaire of Stelfox et al.⁷ was developed to examine the authors' financial relationships with food and beverage companies and trade groups. The questionnaire was sent to the authors of all the identified articles, excepting those whose mailing address was a food company or industry group. Authors whose food industry affiliations were known were not surveved, because their financial relationship was obvious. Major food and beverage companies and trade groups, many of which were known to have previous or ongoing financial relationships with health professionals, were listed alphabetically on the questionnaire. For each of the organizations listed, authors were asked whether they had received any of 5 types of funding in the past 6 years: (1) a scholarship or research grant, (2) travel expenses to attend a conference, (3) an honorarium to speak at a conference, (4) support to organize an educational program, or (5) employment or consultation. The authors were also asked whether they had equity in any of the companies.

The addresses of as many authors as possible were obtained from the articles. For the addresses that could not be so obtained, a search was made for recent articles by the same author that might carry an address, and various Web sites were searched. The names of authors with missing addresses were also submitted to a colleague with experience in such searches for long-term epidemiological studies. If all else failed, questionnaires for coauthors were sent to first authors on the same study with a request to forward. The survey questionnaire was mailed to 102 authors with a cover letter explaining the purpose of the study.

Statistical Analysis

The rate of response to the survey was analyzed according to the authors' ratings (supportive, neutral, or critical). Responses were coded according to the indication of at least 1 relationship with P&G or with any food and beverage company or trade group. The data analysis included the survey respondents and the authors who were not sent a questionnaire because of a known food industry affiliation. Logistic regression was used to determine whether a significant relationship existed between an author's rating and the presence of financial support. The results are reported as χ^2 values and P values. A series of logistic regressions was also performed for each type of financial support. In addition, χ^2 and Spearman's r analyses were performed to examine whether a significant relationship existed between a survey respondent's rating and the number of financial interactions reported.

RESULTS

Classification of Authors

The study included 67 articles (35 reports of original research, 7 review articles, 17 commentaries/editorials, and 8 letters to the editor) (Table 1). Thirty-eight (57%) were classified as supportive, $^{3,12-48}$ 16 (24%) as neutral, $^{2,49-63}$ and 13 (19%) as critical. $^{4,7,64-74}$ Thirty-five (52%) of the 67 articles carried acknowledgments of P&G support or identified at least 1 author as affiliated with P&G. Of these, 83% were classified as supportive, 17% as neutral, and none as critical.

From 67 articles, we identified 148 authors. Each author was assigned a classification based on that of his or her articles; 101 were classified as supportive, 22 as neutral, and 25 as critical. Of the 102 authors surveyed, 58 were classified as supportive, 21 as neutral, and 23 as critical. Of the authors who were not sent a questionnaire because of a food industry mailing address, all 40 authors affiliated with P&G were classified as supportive; 3 of the 5 authors with other food industry affiliations were classified as supportive, and 2 were classified as critical. A mailing address could not be obtained for 1 author classified as neutral.

Response Rates for the Survey

Questionnaires were sent to the 102 authors included in the study who had non-food industry mailing addresses. Twelve questionnaires were "returned to sender" because of noncurrent addresses, and 1 author was deceased. Sixty-three (71%) of the remaining 89 authors responded; of these, 1 classified as supportive did not complete the questionnaire. A total of 62 authors (70%) completed the survey. This percentage was consistent across all 3 classifications. That is, 32 (70%) of the 46 respondents supportive of olestra completed the survey, as did 14 (70%) of the 20 neutral authors and 16 (70%) of the 23 critical authors. The consistency of the response rates suggests that nonresponses are highly unlikely to have altered the results. The final sample consisted of 107 authors (62 survey respondents and the 45 with food industry mailing addresses who were not sent the survey).

Study Questions

Our first question—whether authors who supported the use of olestra were more likely than neutral or critical authors to have financial relationships with P&G—was answered affirmatively. Eighty percent of the supportive authors had at least 1 financial interaction with P&G, compared with 21% of neutral authors and 11% of critical authors (Table 2).

The second question was whether authors who supported olestra were more likely than neutral or critical authors to have financial relationships with any food and beverage company or trade group. The answer was, once

Type of Article	No. of Articles (%)					
	Total	Supportive	Neutral	Critical		
Research						
P&G ^a	25	19 (76)	6 (24)	0 (0)		
Other ^b	7	3 (43)	3 (43)	1 (14)		
No industry ^c	3	2 (67)	1 (33)	0 (0)		
Total	35	24 (69)	10 (29)	1 (3)		
Review						
P&G ^a	6	6 (100)	0 (0)	0 (0)		
Other ^b	0	0 (0)	0 (0)	0 (0)		
No industry ^c	1	0 (0)	1 (100)	0 (0)		
Total	7	6 (86)	1 (14)	0 (0)		
Commentary						
P&G ^a	3	3 (100)	0 (0)	0 (0)		
Other ^b	1	0 (0)	0 (0)	1 (100		
No industry ^c	13	2 (15)	5 (38)	6 (46)		
Total	17	5 (29)	5 (29)	7 (41)		
Letter						
P&G ^a	1	1 (100)	0 (0)	0 (0)		
Other ^b	0	0 (0)	0 (0)	0 (0)		
No industry ^c	7	2 (29)	0 (0)	5 (71)		
Total	8	3 (38)	0 (0)	5 (62)		
Total						
P&G ^a	35	29 (83)	6 (17)	0 (0)		
Other ^b	8	3 (38)	3 (38)	2 (25)		
No industry ^c	24	6 (25)	7 (29)	11 (46)		
Total	67	38 (57)	16 (24)	13 (19)		

TABLE 1—Analysis of Articles by Type of Article, 1996-1999

Note. P&G = Proctor & Gamble.

^aArticles with at least 1 P&G author or acknowledged P&G support.

^bArticles with at least 1 non-P&G food industry author or acknowledged non-P&G food industry support.

^cArticles with no acknowledged food industry authors or support.

TABLE 2—Authors With Financial Relationships With the Food and Beverage Industry, 1996–1999

	No. of Authors (%)				
	Total (n = 107)	Supportive (n = 75)	Neutral (n = 14)	Critical (n = 18)	χ^2
No food industry	20	3 (4)	7 (50)	10 (56)	28.7*
P&G	65	60 (80)	3 (21)	2 (11)	39.6*
Any food industry	87	72 (96)	7 (50)	8 (44)	28.7*

Note. Includes survey respondents and authors with known food industry affiliations (n = 107). P&G = Proctor & Gamble. *P < .0001.

again, yes. Ninety-six percent of the supportive respondents, compared with 50% of neutral authors and 44% of critical authors, had financial relationships with at least 1 member of the food and beverage industry (Table 2). Associations between the authors' published positions on the safety and efficacy of olestra and their financial relationships with the food and beverage industry were analyzed across 6 categories of funding (Table 3). A clear, consistent association was found on 3 of the 6 categories—honoraria for speeches, research grants, and employment or consultation. The association was strongest for research grants and employment or consultation. All 40 authors who were listed on the articles as affiliated with P&G were classified as supportive.

The number of financial interactions with the food and beverage industry, which could be assessed only for survey respondents, was significantly associated with authors' positions on the safety and efficacy of olestra (Spearman's r=.43, P=.001); respondents classified as supportive reported the greatest number of financial interactions (Table 4). In addition, 50% of the supportive respondents reported 2 or more of the 6 types of interactions, compared with 14% of the neutral respondents and 12% of the critical respondents.

DISCUSSION

Food and beverage companies and trade groups employ nutrition researchers. The industry also sponsors the research of nutrition investigators, and nutrition academics consult for food companies.⁸⁰ The extent to which such widespread financial support influences research results and opinions has not been investigated. Our study, which examined the relationship between food and beverage industry funding and health professionals' conclusions about P&G's fat substitute olestra, was undertaken to begin to fill that gap. The findings demonstrate a strong association between authors' published opinions about the safety and efficacy of olestra and their financial relationships with the food and beverage industry. Supportive authors were much more likely than critical authors to have financial relationships with P&G and were also more likely to have financial relationships with any food and beverage company or trade group. These findings are similar to those of Stelfox et al.⁷ The types of support that appear to be most influential are research funding and employment or consultation.

In 2001, a major study⁸¹ concluded that nondisclosure of personal financial interests is a significant problem in scientific and medical literature. However, nondisclosure is not at the heart of the problem identified in our TABLE 3—Authors' Financial Relationships With the Food and Beverage Industry, by Type of Support, 1996–1999

	No. of Authors (%)				
Type of Funding	Supportive (n = 32)	Neutral (n = 14)	Critical (n = 16)	χ^2 (P)	
Travel funding ^a					
P&G	2 (6)	0 (0)	2 (13)	0.63 (P=.43)	
Any food industry	7 (22)	1 (7)	3 (19)	5.1 (P=.02)	
Speaker funding ^a					
P&G	3 (9)	0 (0)	0 (0)	9.5 (<i>P</i> =.002)	
Any food industry	8 (25)	1 (7)	1 (6)	11.4 (P=.0007)	
Education funding ^a					
P&G	1 (3)	0 (0)	0 (0)	3.5 (P=.06)	
Any food industry	2 (6)	0 (0)	1 (6)	1.9 (P=.17)	
Research funding ^a					
P&G	15 (47)	1 (7)	0 (0)	27.1 (P<.0001)	
Any food industry	22 (69)	5 (36)	4 (25)	15.4 (P=.0001)	
Equity ^a					
P&G	1 (3)	1 (7)	0 (0)	0.22 (P=.64)	
Any food industry	3 (9)	1 (7)	0 (0)	7.0 (<i>P</i> =.008)	
Employment or consultation ^b	(n = 75)	(n = 14)	(n = 18)		
P&G	44 (59)	1 (7)	1 (6)	42.5 (P<.0001)	
Any food industry	55 (73)	3 (21)	5 (28)	30.2 (P<.0001)	

Note. P&G = Proctor & Gamble.

^aIncludes only survey respondents (n = 62).

^bIncludes survey respondents and authors with known food and beverage industry affiliations (n = 107).

TABLE 4—Number of Financial Interactions Reported by Survey Respondents, 1996–1999 (n = 62)

No. of Financial Interactions	Supportive	Neutral	Critical
0	3	7	10
1	11	2	2
2	7	3	2
≥3	11	2	2

Note. $\chi^2 = 17.3$ (*P* = .008); Spearman's *r* = .42 (*P* = .001).

study. In the case of olestra, P&G openly sponsored an entire issue of *The Journal of Nutrition* devoted to olestra studies authored by P&G scientists.^{30–41} The food industry's open support of nutrition scientists goes as far back as 1918, when the National Dairy Council began enlisting the support of nutrition researchers such as E.V. McCollum of Johns Hopkins University and H.C. Sherman of Columbia University.⁸² No conflict of interest was found at the time, because milk was considered a basic food that nutritionists would be recommending anyway. The possibility for such conflict is more obvious when research support involves products such as sugared breakfast cereals and olestra, whose use is more controversial.

One critic⁸⁰ believes that a "just say no" approach to such financial relationships is unlikely to be used and that a "pragmatic compromise" would include balancing risks and benefits and disclosing all sponsorship relationships. That approach is similar to the one recommended by Stelfox et al.,⁷ who described a process for disclosing conflicts of interest. What our study suggests, however, is that disclosure of conflicts of interest does little more than warn the reader and that noncommercial funding sources are essential. Eighty-three percent of the articles that acknowledged P&G support or a P&G-affiliated author were classified as supportive, and none were classified as critical. Forty authors

disclosed their affiliation with P&G, and all 40 were supportive of olestra. Because the regulation of food products is the responsibility of the FDA, which neither funds nor conducts research relating to those products, it seems unlikely that the balance of available research funding will change in the near future. In such an environment, journal readers seeking to answer questions about the safety and usefulness of food products need to exercise exceptional caution.

Limitations of the Study

Authors who disclosed their food industry affiliations (most were employed by P&G) were not sent questionnaires, so their other financial relationships could not be determined. In addition, this study cannot rule out the possibility that the causality of the relationship implied by the results—that authors' opinions were influenced by their financial relationships with the industry—is not reversed. Food and beverage companies may well seek out relationships with researchers and practitioners whom they know to be supportive of their products.

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Contributors

J. Levine conceived the study, contributed to its design, was responsible for data acquisition, and did most of the article preparation. J.D. Gussow contributed to the design of the study and article preparation. All authors contributed to the analysis and interpretation of the data and critical revision of the article; D. Hastings focused on analyzing and rating the articles; A. Eccher did the statistical analyses.

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Human Participant Protection

The study was approved by the institutional review board for the protection of human subjects in research

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