

Olestra—Is it safe? Should it be taken off the market? Is it an effective weight-loss aid?

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The case

Florence finished filling her plate at the wedding buffet table and looked for a place to sit. She and the bride had been classmates in college, and Florence was hoping to see some of her friends who were her fellow biochemistry majors when she was in college ten years earlier. She took a quick glance around the room and spotted Allen, who had been in her analytical class. She took her plate over to his table to join him.

“Hi Allen! I haven’t seen you in a while! What have you been up to these days?”

“Hey Florence, good to see you!” Allen gave her a quick hug. “Actually, I’ve changed jobs since I talked to you last. I was with a small biotech company in Massachusetts, but two years ago I moved to Cincinnati to be closer to my girlfriend, who decided to go back to medical school. I work for Proctor and Gamble on the Olestra project”.

“Is that stuff safe to eat?” asked Florence. “It seems like I’m always trying to lose weight. But I heard about people who suffered from painful stomach cramps after eating it, so I haven’t been tempted to try it.”

“Are you talking about Olestra?” Theresa, another one of their classmates joined them. “I tried a bag of those Wow chips when they first came out and I got sooooo sick. I’ll never eat an Olestra product again.”

“Of course it’s safe!” replied Allen. “Olestra has undergone more rigorous testing than any other food product on the market now. The company has spent 30 years and \$200 million dollars studying this food additive. We’ve done studies in rats, mice, dogs and rabbits where we fed huge amounts of Olestra to the animals—more than any human would ever consume. And there was no evidence of toxicity.”

“But I also heard that Olestra causes you to lose vitamins, and I’ve been concerned about that,” Florence responded.

“Yes, we know about this. But you would only lose vitamins if you ate them at the same time as a product containing Olestra. Who eats carrot sticks with potato chips? Nobody I know! Besides, we’ve solved that problem by fortifying the Olestra products with certain vitamins. The FDA has reviewed all of our results and says this product is safe. And why not let the marketplace work here? If Olestra really caused huge numbers of people to get sick, no one would buy our products. And our products are selling well.

“I’m going to get another beer—does anyone want anything?” Allen jumped up from the table and went to join the line at the bar.

“So, did you really buy all that stuff that Allen was telling you about Olestra? Sorry, I couldn’t help overhearing your conversation.”

“Hi Sam!” said Florence. “It’s so great to see you! Isn’t this a great wedding reception? What are you doing these days?”

“Well, actually, I’m living in Washington and I’m working for the Center for Science in the Public Interest. We’re a health and nutrition-based advocacy group working to educate consumers on a wide variety of health issues. And we are not fans of Olestra!”

“Well, I’m not either, after my experience. But why aren’t you?” asked Theresa.

“Well, we’ve been getting lots of phone calls at our hotline lately from consumers who have suffered all kinds of gastrointestinal distress after eating chips containing Olestra. Our organization really has tried hard to prevent Olestra from coming to market. Our director, Michael Jacobson, wrote a letter to the FDA urging them not to approve Olestra, but they did anyway. We were pretty upset at CSPI when it happened, but we shouldn’t have been surprised. The advisory committee was stacked with food industry representatives, not health officials. Now Michael’s working to get the FDA to take it off the market. He says that Olestra is the only food additive that has “negative” nutritional benefit. And we’re not alone. The American Public Health Association doesn’t think long term Olestra consumption is a good idea either. Neither does the chair of Harvard’s nutrition department, or the chief of gastroenterology at Johns Hopkins. P & G have done their studies, but we’ve done a few studies of our own. We’ve found that 20% of people who consumed Olestra-containing chips have suffered from some form of gastrointestinal distress.”

“Well, I still don’t think I want to eat this product myself,” said Florence. “But what’s the harm, as long as adults consume small portions of chips in moderation?”

“The harm is that this is the only non-calorie fat replacement that is heat stable,” said Sam. “So even though Olestra is only approved for use in chips, I could envision in the future that the approval might be extended to other fat-containing foods, like French fries. And you know that kids especially eat lots of French fries. It’s hard enough to get kids to eat vegetables anyway—my nephew won’t eat anything green—and if kids consume Olestra, their bodies might be depleted of important vitamins.”

“Shh....Allen’s coming back,” said Theresa. “Let’s talk about something else.”

But Florence was wondering—who was right? Was Olestra really safe? Or was CSPI right to insist that the FDA rescind its approval of the fat substitute?

Background information

Olestra is the generic name (its brand name is Olean) of a product manufactured by the Proctor and Gamble company that is intended to be a fat replacement (1). Chemically, Olestra is a mixture of long-chain hexa-, hepta- and octaesters of sucrose. These sucrose polyesters have many of the physical properties and the “mouth feel” of triacylglycerols but are not digested by pancreatic lipases. Consequently, Olestra passes through the gastrointestinal tract unmetabolized and therefore contributes no calories or energy to the diet. From a food preparation standpoint, Olestra has the unique advantage in that it is heat stable—it does not decompose, even when subjected to the high temperatures of the frying process.

Olestra has been the subject of intense scientific scrutiny. FDA Commissioner David Kessler referred to Olestra as “one of the most extensively studied food substances to date.” Numerous physiological studies which have examined gastric emptying, pancreatic response, gastric acid and bile acid production,

gut microflora and gut cellular morphology have indicated that the gastrointestinal system treats Olestra as an inert substance. But the mere presence of this inert substance in the small intestine, where the vast majority of micronutrients are absorbed, may have an effect on the absorptions of those micronutrients, and this is a concern. Another concern is the gastrointestinal symptoms that some individuals have reported following consumption of a food product containing Olestra.

Olestra's journey to the marketplace has been a lengthy one. The sucrose polyester compound was synthesized by two Proctor and Gamble chemists in 1968. Their goal, which was unrealized, was to synthesize a compound that would increase fat intake in premature babies. Proctor and Gamble first sought approval for sucrose polyester in 1975 as a cholesterol-lowering drug, but studies indicated that the sucrose polyester did not decrease blood cholesterol levels substantially, so P&G withdrew their application. Further study indicated that the compound might be suitable as a fat replacement, and in 1987 the company petitioned that the FDA approve Olestra as a general purpose fat substitute. Their petition was immediately challenged by the Center for Science in the Public Interest (CSPI), who questioned the safety of Olestra. In August 1990, Proctor and Gamble modified their petition to include only savory snacks. In November of 1995, the FDA advisory panel voted 17 to 5 to approve Olestra, and in January of 1996, The FDA issued its decision to approve the use of Olestra as an ingredient in savory snacks such as corn chips, potato chips, and crackers. Because of the safety concerns raised by CSPI and others, the FDA required that all products containing Olestra be labeled with the following warning: "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." Beginning in April of 1996, Proctor and Gamble licensed the Frito Lay company to use Olestra as an ingredient in its "Max" brand chips (which included Doritos tortilla chips and Ruffles potato chips) which were test-marketed in Cedar Rapids, IA, Eau Claire, WI, and Grand Junction, CO. Later in that same year, Proctor and Gamble test-marketed its own Pringles chips in Columbus, OH and expanded its test market to Indiana the following year. Frito-Lay renamed its chips "Wow" and expanded its test markets to include most of the state of Indiana in 1997. Nabisco test-marketed Wheat Thins and Ritz crackers in Marion, IN and Grand Junction, CO. In the spring of 1998, Frito-Lay began selling its "Wow" product line nationwide.

Olestra-fried chips do have less fat and fewer calories than their full-fat counterparts, but consumers should realize that fat-free does not mean calorie free. A serving of full-fat chips contains 10 grams of fat and 160 calories while a serving of Olestra-fried chips contains no fat and 70 calories. A 2-oz serving of chips contains about 20 grams of Olestra.

In seeking approval for their product, and to demonstrate its safety, P&G conducted literally hundreds of animal and human studies, spent over \$200 million dollars, and has submitted nearly 150,000 pages of data to the FDA (2). As a condition of the approval process, Proctor and Gamble was required to continue to monitor the effect of consumption of Olestra on consumers, and to continue to study its long-term physiological effects. In mid 1997, Proctor and Gamble and CSPI submitted reports of adverse reactions attributed to the consumption of Olestra-containing chips to the FDA. In June of 1998, the advisory committee of the FDA met, reviewed all of the available data, and pronounced Olestra a safe product, stating that there is still "reasonable certainty of no harm". In response, Michael Jacobson, the executive director of CSPI, filed a formal appeal to the FDA to take Olestra off the market. He encourages consumers experiencing gastrointestinal symptoms to call their toll-free hot line at 1-888-OLESTRA. CSPI tracks the calls and reports all accounts to the FDA. If the appeal is denied, CSPI plans to take the FDA to court (3).

Proctor and Gamble continues to insist that their product is safe, and in 1999, the company petitioned the FDA to repeal the warning label requirement. Public health officials, including Walter Willett and Meir Stampfer of Harvard University, continue to discourage the public from consuming products containing Olestra (4). But in August of 2003, the FDA, satisfied with a study they conducted of 3000 people over a six-week period in which there were no differences in GI disturbances between the group that ate Olestra chips and the group that ate full-fat chips, decided that Proctor & Gamble no longer needed to post warnings on their product packages. Products containing Olestra must continue to be fortified with fat-soluble vitamins, but no explanation concerning the reason for their inclusion is required.

Project Design

“Interest groups” have been defined for this case study: Proctor & Gamble scientists, FDA scientists, and consumer groups. Each student in the class will be assigned to one of these interest groups. All students will answer the first set of questions. Each group will give an oral presentation in which the questions posed for their interest group are addressed. Following the presentation, there will be an opportunity for questions.

Due date for the common questions is January 27, 2005. The grade that you will earn for this case study will be based on the following: 20% for the written work (individually prepared), 65% for the group presentation, 10% for your participation in the discussion of the other presentations, and 5% for a “position paper” you will write at the end of the discussions.

Interest groups

All students

Read the following paper:

Kirschner, E. “Fake Fats in Real Food” *Chemical and Engineering News*. April 21, 1997, pages 19-25.

Consult your biochemistry textbooks and Internet resources cited at the end of this case study and any other resources you deem appropriate and answer the following questions:

1. Olestra is prepared by esterifying sucrose with long-chain fatty acids derived from vegetable oils, such as cottonseed oil and soybean oil (see the Appendix for information about the fatty acid content of these oils) (5). The result is a product that consists of a mixture of hexa-, hepta-, and octaesters of sucrose. Use the information in the article to draw the reactants and products of the reactions involved in the production of sucrose polyesters.
2. Compare the structures of the sucrose polyesters you drew with the structure of a typical triacylglycerol found in vegetable oil. How are the structures similar? How are they different?
3. Triacylglycerols are substrates for pancreatic lipases which are secreted into the small intestine and hydrolyze triacylglycerols to monoacylglycerols and free fatty acids. Draw the balanced reaction catalyzed by pancreatic lipase. Study the mechanism of the pancreatic lipase enzyme. Why aren't sucrose polyesters substrates for pancreatic micelles?
4. Products resulting from the digestion of triacylglycerols, along with bile salts, form “mixed micelles”. In addition, other dietary components can be incorporated into the micellar structure. Draw a schematic drawing of a mixed micelle. Identify the lipid products of digestion in your micelle drawing. What dietary components would you expect to be attracted to the micelle? Indicate their location on your micelle drawing. What might happen to these dietary components in the presence of SPE?

P & G Scientists

Read the following papers:

Jandacek, R. J., Kester, J. J., Papa, A. J., Wehmeier, T. J., and Lin, P. Y. T. (1999) “Olestra Formulation and the Gastrointestinal Tract” *Lipids* **34** (8), 771-783.

“A Role for Olestra in Body Weight Management” Eldridge, A. L., Cooper, D. A., and Peters, J. C. *Obesity Reviews* **3**, 12-25.

Answer the following questions:

1. Early formulations of Olestra were liquid at room temperature, but more recent formulations are semisolid.
 - a. Compare the chemical structures of liquid SPE with semisolid SPE and explain why these structural differences lead to changes in melting points of the products.
 - b. Why is Olestra currently made as a semisolid product?
2. Explain the iodine value (IV) scale. Sucrose polyesters with various iodine values are described in Table 2. An SPE product with an IV of 41 would be more desirable than an SPE of either 100 or 22. Explain why.
3. Solid % as a function of temperature is shown for three Olestra formulations in Figure 1 in the article. Discuss how each Olestra formulation was prepared, and describe their physical behavior as a function of temperature as shown in the graph. Which formulation(s) would be desirable? Explain.
4. “Thixotropic area” is the area between ascending and descending curves in Figure 3. Two samples are shown—one has a thixotropic area of essentially zero, whereas a second sample has a thixotropic area of greater than 50 kPa/s. Explain the significance of these data.
5. What is the effect of Olestra on the following: (a) cholecystokinin production (b) pancreatic lipase production and (c) bile acid excretion?
6. What is the effect of Olestra on the absorption of the micronutrients cholesterol, fat-soluble vitamins, and carotenoids?
7. Summarize the metabolic studies carried out as described in the second reference. Did subjects who consumed a diet with some of the fats replaced by Olestra compensate by eating more? Did the subjects lose weight?

FDA Scientists

The data presented here were collected by Dutch scientists at the Unilever corporation in the Netherlands (5). Read the papers, and answer the following questions:

“Sucrose Polyester and Plasma Carotenoid Concentrations in Healthy Subjects” Weststrate, J. A., and van het Hof, K. H. (1995) *Am. J. Clin. Nutr* (1995) **62**: 591-597.

“Decreased Carotenoid Concentrations due to Dietary Sucrose Polyesters do not Affect Possible Markers of Disease Risk in Humans”, Broekmans, *et al.*, (2003) *J. Nutr.* **122**: 720-726.

1. Describe the experimental design of the study described in the first paper. At what meal were the subjects given the margarines, and why?
2. The results of the plasma analyses are shown in Table 3 in the article. What were the results for the individuals on the “high dose” study? What additional information is given in Figure 1?
3. What were the results for individuals on the “low dose” study? What additional information is given in Figure 2?
4. What conclusions would you make about this study?
5. Compare the absorption of fat-soluble vitamins in the presence and absence of SPE (ie, revisit Question 4 under the “All Students” category). Why is the effect of SPE consumption on β -carotene and lycopene absorption of such concern?
6. What are some of the limitations of the study design?
7. The short term study described in the first paper was followed up by a longer term study, described in the second paper. Describe how this study was carried out. What were the results of this study?

Consumer Groups

Read the following papers:

Blackburn, H. (1996) *New Engl Jour Med* **334**, 984-986.

Levine, J., *et al.* (2003) *American Journal of Public Health* **93**, 664-669.

Satia-Abouta, J., *et al.* (2003) *Nutrition* **19**, 754-759.

Glade, M. J. (2003) *Nutrition* **19**, 813.

1. What questions should consumers ask regarding the use of Olestra?
2. Did Henry Blackburn believe that testing of Olestra was adequate? What are his concerns? Compare the standard of approval for drugs vs. food additives.
3. What might the potential concerns be for physicians whose patients are taking the anticoagulant drug warfarin?
4. There are quite a few “phytochemicals” in fruits and vegetables. Romaine lettuce contains lutein, spinach contains zeaxanthin, tomatoes contain lycopene and carrots contain β -carotene. Are these compounds added to products containing Olestra? What effect may long-term consumption of Olestra have on the absorption of these compounds? What are the consequences to public health?
5. Will consuming Olestra products help people lose weight? (Did the introduction of artificial non-caloric sweeteners like Aspartame lead to weight loss in the general population?)
6. How would you respond to Proctor and Gamble’s claim that the gastrointestinal side effects experienced by Olestra users are similar to those individuals who consume a high fiber diet?
7. How do authors’ financial relationships with the food industry affect their published positions (ie, were P&G scientists more likely to be supportive of Olestra than non-P&G scientists?) Describe the study that was done by Levine, *et al.*
8. Describe the study carried out by Satia-Abouta, *et al.* Did this study find that consuming Olestra lead to weight loss?
9. In the conclusion of the Satia-Abouta paper, the authors state “An important area for future research would be to investigate consumers’ beliefs about fat-modified foods and understand how they are incorporated into the diet.” How did Michael J. Glade respond to this statement?

Appendix

Table 1: Fatty acid content of fats and oils (percentages) (from Snyder, C. H. (1998) *The Extraordinary Chemistry of Ordinary Things*, John Wiley & Sons, NY, NY, page 407.)

Fat or Oil	Iodine value ¹	14:0	16:0	18:0	16:1	18:1 (oleate)	18:2 and 18:3	C > 20
cottonseed oil	103-111	1	23	1	2	23	48	
corn oil	110-130	1	10	3	2	50	34	
olive oil	80-88		7	2		85	5	
palm oil	50-60	1	40	6		43	10	
peanut oil	90-100		8	3		56	26	7
safflower oil	145		4	3		17	76	
soy bean oil	120-135		10	2		29	57	

References

Web sites

1. This is Proctor and Gamble's product web site: <http://www.olean.com/>
2. Check out this web site for space-filling, rotatable models of glycerol, fatty acids, triacylglycerols, and sucrose polyesters. The web site author is Daniel Berger of the Science Department of Bluffton College in Bluffton, Ohio. <http://www.bluffton.edu/~bergerd/chem/olestra.html>.
3. A good overview of the Olestra story can be found at <http://www.american.edu/projects/mandala/TED/olestra.htm>.
4. The Center for Science in the Public Interest has information about Olestra on its website. <http://www.cspinet.org/olestra/>
5. The Institute of Food Science and Technology is the independent professional qualifying body for food scientists and technologists. Olestra is featured on their web site as a "hot topic". <http://www.ifst.org/hottop13.htm>
6. The Institute of Shortening and Edible Oils has a web site that contains useful information. The home page is located at <http://www.iseo.org/iseo/index.htm>. Chapters 6 and 7 have particularly good information about the physical characteristics of fats and oils at http://www.iseo.org/iseo/ffo_6-7.htm.

¹The iodine value refers to the number of grams of iodine that will react with 100 grams of the fat or oil.

Print resources

1. Peters, J. C., Lawson, K. D., Middleton, S. J., and Triebwasser, K. C. (1997) *Journal of Clinical Nutrition*, **127**, Number 8S, pages 1539S-1546S.
2. Raber, L. *Chemical and Engineering News*, November 20, 1995, page 11.
3. Kaolin, J. *E Magazine*, September/October 1996, pages 42-43.
4. Blackburn, H. (1996) *New Engl Jour Med* **334**, 984-986.
5. Weststrake, J. A., and van het Hof, K. H. (1995) *Am. J. Clin. Nutr* (1995) **62**: 591-597.