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SACCHARIN BENEFITS

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POTENTIAL BENEFITS

As part of this study, the OTA was asked “to evaluate the potential health benefits, including psychological benefits, of saccharin availability to the general public and to diabetics and other groups with special medical problems.”

Many Americans use saccharin, like to use it, and want to continue using it. Its use is widely perceived to result in health benefits, but the claim that saccharin use is essential for the continued health of any segment of the population has not been tested,

Except for the formulation of some drug products, the uses of saccharin are identical to those of the entire class of non-nutritive sweeteners. In contrast to the assessment of the specific risk of cancer from saccharin ingestion, this inquiry stops at the point of identifying *potential* benefits. Although conclusions can be reached on the existence of the risk of cancer, if not on its magnitude, no conclusions can be reached on either the existence or magnitude of benefits.

No scientific data were found to prove or to disprove that use of a non-nutritive sweetener leads to any health benefits. As it is noncaloric and nonfermentable, an artificial sweetener would not promote the health problems associated with excessive calories and fermentable acid formation characteristic of sugar. But the benefits of using non-nutritive sweeteners rest primarily with the avoidance of sugar and not in the use of the sweetener itself.

The proclivity to ingest sweet substances is an innate biological characteristic of newborn animals and humans. It appears to be alterable, and such alterations induced by cultural practices may increase or decrease this proclivity. The preference for a particular level of sweetness is an individual matter, but beyond a certain level this preference becomes an aversion. Too much sweetness is avoided as much as lower levels of sweetness are desired. At an appropriate concentration in foods, sweetness might be used to increase adherence to certain dietary practices that could result in improvement or maintenance of health.

The benefits of a non-nutritive sweetener such as saccharin are unusually difficult to assess, in large part because it has become integral to the diet of many Americans and, in part, because of the absence of controlled studies on its effectiveness in any particular situation. Indeed, benefits may be identified only through the response to the removal of non-nutritive sweeteners from the food supply.

Potentially profound social consequences and the possibility of emotional, unpredictable, and even irrational responses may follow any attempt to change well-established dietary practices. Three contemporary factors may increase the emotional

responses to the removal of non-nutritive sweeteners: (1) its relationship to weight control in a society preoccupied with body weight; (2) the innate biological desire for sweet foods, supported by a culture accustomed to sweets; and (3) the current heightened concern with civil liberties and personal freedom that has produced strong pressures for permitting people to choose even potentially harmful personal practices, such as smoking.

Potential benefits were identified by answering the question: Who would be at risk if non-nutritive sweeteners were not available? Potential benefits derive from the use of saccharin in diets designed to avoid sugar and maintain sweetness for the following groups of people:

1. diabetics,
2. those requiring long-term, low-calorie diets,
3. the obese and those concerned with avoiding obesity, and
4. those particularly susceptible to dental caries.

Additionally, because of its sweetness, lack of bulk, and chemical inertness, saccharin has been included in some drugs to disguise their unpalatable taste. Thus, saccharin is also of potential benefit to:

5. those who must take certain drugs.

No scientific evidence is available to show that saccharin is indispensable for the diets of any of the first four groups of users; For those people, sugar is a problem, and saccharin provides sweetness. The use of sugar can be reduced without any substitute for its sweetness. However, because sweetness is a desired quantity in our society, retention of a sweetening agent may be a psychological benefit.

Another view suggests that the *removal* of saccharin is a potential benefit. According to this view, the ready availability of saccharin has fostered a greater craving for sweets than would have occurred in its absence, and its removal might reduce this craving and decrease the likelihood of other persons developing it. If so, long-term benefits in decreased consumption of nutritive and non-nutritive sweeteners would outweigh short-term risks and inconveniences.

Diabetics. Weight control and avoidance of sugar are important components in the treatment of adult-onset diabetes. No evidence, other than anecdotal testimonials, is available to support the contention that use of non-nutritive sweeteners leads to these desired consequences.

Nonetheless, access to artificial sweetness might be considered an important factor in complying with prescribed diet therapy. In fact, according to the Interim Regulations on Saccharin (21 CFR 121.4001), saccharin at present is supposedly used only for "a valid special dietary purpose . . . in accord with current special dietary food regulations and policies or if the use or intended use is for an authorized technological purpose other than calorie reduction."

Juvenile-onset diabetes presents many of the same dietary problems, which are, if anything, complicated by peer pressure. Many of the social activities of a young diabetic's peer group center around the consumption of sweet snacks and beverages. The availability of foods sweetened with saccharin enables diabetics to participate in these activities as equals. If such products became unavailable, young diabetics would be able to participate only at some risk to their health, or elect not to participate and perhaps suffer from a feeling of being excluded or different. Saccharin-sweetened

snacks may be an important psychological benefit for young diabetics. The criteria for determining if saccharin is useful for weight control and for diabetes management would be difficult to define in areas in which cultural pressures are important, such as in the management of the juvenile-onset diabetic.

Persons with low-calorie requirements. Persons on long-term, low-calorie diets must exercise careful management. If a food, such as sugar, lacking in vitamins and minerals (micronutrients) constitutes a sizable percentage of total calorie intake, the remaining food may not contain adequate amounts of essential nutrients. Substitution of a non-nutritive sweetener for sugar could permit the consumption of greater amounts of foods containing micronutrients.

Saccharin is not essential for management of such dietary problems. Other alternatives are available, such as taking vitamin and mineral supplements or eating foods other than sugar.

The obese and those concerned with avoiding obesity. A strong case has not been made for the effectiveness of any single aid in the treatment or prevention of obesity. One can argue either that the availability of non-nutritive sweeteners has not prevented the occurrence of obesity or that the prevalence and severity of obesity would have been greater in their absence. The impact on human behavior of removing non-nutritive sweeteners from the food supply is not known. If persons now using them shift to sugar, their calorie intake may increase with predictable consequences; if they do not shift to sugar, these consequences will not ensue. Neither animal nor human data permit conclusions as to which of these consequences is most likely to occur. An increase in weight, however, might have more than simple cosmetic consequences. If large, it would lead to increased risks of hypertension, diabetes, hyperlipidemia, and associated cardiovascular diseases.

Persons might shift from a non-nutritive sweetener to sugar in order to satisfy their desire for sweet food and drink, a satisfaction to which they have become accustomed. Also, adolescents might consume soft drinks containing sugar because of peer pressure.

Persons particularly susceptible to dental caries. The essential elements in dental caries are the presence of acid-producing bacteria, fermentable sugars, and susceptible teeth. Controlling or preferably eliminating one or more of these factors would minimize the incidence of caries. Simple saccharides, especially sucrose, are particularly cariogenic (cause caries) when added as a sweetener in snacks and beverages that come in frequent contact with the tooth surface.

Almost everyone is susceptible to a moderate amount of dental caries. However, some people with dry mouth conditions and some adolescents succumb to a rampant type of dental decay when they use sugar. This dental condition is defined as "a suddenly appearing, widespread, rapidly burrowing type of caries resulting in early involvement of the pulp and affecting those teeth or dental surfaces usually regarded as immune to ordinary decay" (19). Rampant dental caries are found in about 10 percent of the population, particularly in the New England and Northwest sections of the country.

Non-nutritive sweeteners, if used to substitute for all the sugar in the diet, probably would help patients control rampant caries. But with the exception of this one group of people, total substitution of all sugar in all foods and beverages would not be feasible.

Partial substitution of sugar by non-nutritive sweeteners may have some effect on dental caries, but the magnitude of such an effect is difficult to predict. As long as some sugar remains in the diet and if foods containing sugar are eaten frequently during the day, the potential for cariogenic, acidogenic bacterial plaques to form on the tooth surface is present and the effect possible.

Because non-nutritive sweeteners cannot be fermented by the oral flora, they are not cariogenic. However, adequate data on the correlation between use of non-nutritive sweeteners and dental caries do not exist. Neither positive nor negative results have been reported with respect to the role of non-nutritive sweeteners in preventing caries.

Persons who must take certain drugs. Many drug products are sweetened artificially to increase palatability without increasing bulk. Palatability may be relevant in patient compliance with prescribed drug therapy. Because of its pleasing taste, a sweet additive can make medicinal more acceptable. In addition, saccharin is the best sweetener known in terms of chemical inertness, which is important for maintaining the stability of a drug product.

If non-nutritive sweeteners were unavailable, which drugs would be affected? If some drugs cannot be formulated without them, which of these drugs are medically necessary? If drugs can be formulated only with considerably altered taste, how would this taste affect patient compliance in following prescription regimens? Assessing the benefits of non-nutritive sweeteners in drugs requires a review of drug safety and efficacy.

REGULATING SACCHARIN AS A DRUG

The FDA proposal to ban saccharin as a food additive also includes proposals to allow it as a single-ingredient, over-the-counter (OTC) drug and to ban it as a non-medical ingredient in drugs. The latter proposal would remove saccharin as an inactive ingredient in drugs unless it affords an overriding benefit: "If saccharin is included as a pharmaceutical aid, an adequate showing that there are not technically feasible alternatives to saccharin, or an adequate showing that the drug product containing saccharin provides a substantial health benefit that would not be available without the use of saccharin" must be made.

Because there is no "Delaney clause" for determining the safety of drug products, the conditions under which they are used would be relevant. Safety and efficacy are separate criteria, and the Food and Drug Administration balances the benefits of a drug product against its risks.

A general test for whether saccharin benefits users of certain drugs would be based on 1) whether the therapeutic component of the drug product is efficacious, and 2) whether no technological alternatives are available for saccharin as a component of such drug products. Because certain fluoridated dentifrices and other fluoridated oral health preparations are considered drug products, these products would also be included in such determinations.

Efficacy of drug products must be shown through "substantial evidence," which is defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified to evaluate the effectiveness of the

drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof” (21 U.S.C. Section 505(d)). These criteria address the question of the benefits of saccharin or any other non-nutritive sweetener for weight reduction and management of diabetes.

Because present use of saccharin falls under food additives and not drug regulations, the supposed restriction of use for “a valid special dietary purpose” is not enforced, and saccharin is widely available. If saccharin were removed as a food additive and classified as an over-the-counter drug, this restriction not only would be more strictly enforced, but its validity would first have to be proven. Though difficult, tests to meet the criterion of “substantial evidence” could be developed to see whether saccharin does lead to measurable benefits in weight reduction and weight maintenance.