EFFICACY OF LABELING OF FOODS AND PHARMACEUTICALS

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INTRODUCTION

Over the past several decades, the US Congress and regulatory agencies have developed a complex system of informational regulations for food and drugs that goes far beyond indications such as “USDA Approved.” Individual states have also begun to display increasing interest in this issue. California, for instance, has adopted its own warning system for risks of cancer and reproductive toxicity, and many other states are also considering warning measures.

These efforts have diverse objectives. One function is to provide information about beneficial features, such as information about the nutritional value of foods and the medical conditions that pharmaceutical products can address. A second function is to alert the consumers to possible adverse effects of the product, for instance sodium labels for foods, health warnings for cigarettes, and information about adverse reactions to drugs. A third function of warnings is to indicate the particular types of precautions that should be exercised, e.g. cautioning against driving after drinking alcoholic beverages, and against adverse drug interactions.

Examination of food and drug warnings is instructive more generally since these warnings embody all the functions of risk communication mechanisms. Moreover, the presence of the learned intermediary—the physician in the case of prescription medications—provides an interesting variation on the context of risk communication.
Instituting an effective warnings program is different from simply disseminating all that is known about a product. The subsequent sections explore the prerequisites for an effective design of a hazard communication system for food, pharmaceutical products, and cigarettes. Cigarettes, with addictive properties similar to many drugs, have served as the model warnings effort for saccharin, alcoholic beverages, and carcinogenic agents.

The discussion of the rationale for hazard warnings provides a benchmark for judging the efficacy of warnings. I introduce the general issues pertaining to the content, structure, and format of the design of warnings. To be effective, warnings must first be processed by consumers. Finally, I address the effect of warnings on risk perceptions and on consumer behavior.

THE RATIONALE FOR HAZARD WARNINGS

There are a variety of policy options on hazardous products at the local, state, or federal level. At the most extreme, these products could be banned altogether. Second, the product characteristics could be regulated to eliminate certain kinds of risks, for example by banning particular food additives. Third, firms could be permitted to market these products along with an accompanying warning. Finally, there could be no action whatsoever. Consequently, hazard warnings can be viewed as an intermediate policy option between no action and either regulation or proscription of a product.

For hazard warnings to be a potentially attractive policy, there must presumably be some reason to believe that the product is on balance beneficial to some consumers who have been appropriately alerted to its characteristics, otherwise more stringent policy options should be pursued. Food and drugs generally are viewed as raising various issues pertaining to individual welfare, and the key issue is whether the benefits derived from these products exceed the associated costs to the consumers.

The task for hazard warnings is to create an awareness such that consumers will make the decisions that they would have made if they were fully informed. For both the purchase decision and the product use decision, the critical issue is whether expected consumer welfare has been enhanced, based on the true risks associated with the product. These probabilities will not necessarily be those perceived by the consumer. Moreover, it may be the case that the consumer's expected welfare has been raised by a product even though the product lowers the consumer's welfare based on the true probabilities. What matters from the policy standpoint is the consumer's expected welfare using the actual risks associated with the product. The fact that consumers might gladly purchase a product while ignorant of the associated risks does not make a purchase worthwhile.

Figure 1 illustrates the context in which decisions about food and drug
warnings operate. The policy lever in this context is the information provided, which is illustrated at the upper left portion of the diagram. Although the discussion will generally be in terms of hazard warnings, when conceptualizing the role of risk information it is more appropriate to consider the hazard communication system. Prescription drugs, for example, are dispensed by physicians who have access to extensive information compiled in the Physician's Desk Reference regarding the properties of the drugs. This compilation of information draws primarily upon the patient package inserts that accompany pharmaceutical products. The physician also has extensive medical training and continually updates this information both through the medical literature and professional seminars that can be drawn upon to brief the patient regarding the consequences of the drug. The pharmacist also may provide information. What is consequential is not necessarily the specific product label or patient package insert but rather the net informational effect of all sources of information provided to the consumer.

For any information to affect individual beliefs, it must first be processed. The intervening link between the provision of information and its influence
on risk beliefs is an information-processing stage. Individuals must first receive the information, understand it, and then incorporate it in their memory, and ultimately in their decisions (7). Because of cognitive constraints, individuals are limited to the amount of information that they can process from any particular warning. Moreover, some information, such as detailed medical information pertaining to the consequences of certain prescription drugs, requires medical training to interpret it properly.

A practical consequence of these concerns is that excessive information can lead to two problems that have received close attention in the warnings literature (6, 18): label clutter, where too much information in a particular warning can lead to less effective information processing than a more concise warning message; and information overload, when there is a proliferation of warning labels. If everything in the drugstore and supermarket is labeled hazardous, then in effect hazard warnings convey no relative information. Provision of risk information consequently has an important external effect on the efficacy of other risk messages since overuse of very strong warning messages tends to dilute the attention paid to other warnings.

The net effect of the information provided combines with the person's prior beliefs regarding the risk to determine the posterior risk assessment associated with the product. If individuals have very firm initial beliefs or if the risk information is not as convincing, there will be little effect of the information on risk perceptions.

The two key aspects of the warning message are the risk that is conveyed and the informational content associated with this message. In particular, is this message credible when compared to the individual's existing information about the product? Studies of the effect of hazard warning labels for chemical products (19) indicate that information that simply serves as a reminder and does not convey new knowledge about the risk will not alter prior beliefs. Similarly, information that the recipients of the knowledge do not regard as convincing will not alter consumers' prior beliefs concerning the properties of the product.

Once risk beliefs are formed, the individual then assesses the expected utility conferred by the product. This will be done along a variety of dimensions. As is indicated in the bottom panels of Figure 1, the consumer makes two kinds of dichotomous choices—whether to use the product and whether to take precautions. First, will the purchaser choose to exercise the associated precautions? Given this choice of optimal precautions, how does the expected utility associated with purchasing the product compare with the expected utility derived from expenditures on other goods? If, in the consumer's view, expected utility will be raised through product purchase, the product will be bought, where this judgment will be based on the
Pertains to the content of the warning. In particular, what message are we conveying to consumers and what is the specific language used to convey this information? Because individuals have cognitive limitations and limited information processing capabilities, warnings must be conveyed in a manner that can be readily understood and processed. For example, it would make little sense to provide consumers with copies of scientific articles relating to prescription drugs for their own judgments as to the implications of this literature. Instead, drafters of warnings attempt to process the pertinent information to make it accessible to the recipient.

The manner of presentation of the information is also consequential. One aspect of the presentation is the placement of the warning. Is the warning on the product included as part of a package insert, or communicated orally by, for example, a physician? The design of the warning label is another key aspect of the presentation. The structure of the warning component of the label is of consequence, as is its relationship to the other information provided on the label. For example, antidote information that appears at the bottom of labels for hazardous chemicals is seldom read by consumers until after an adverse experience with a product has occurred (6). The overall context in which the warning is presented on the label is also important. If the patient package insert or the label gives detailed directions for use of the product, as is the case for drugs, it may be important to integrate the appropriate precautionary information within the context of product use instructions.

More than simple marketing design, the format of the label is essential to conveying the requisite information and ensuring that it is processed.
Thus, print size, color, and graphic design may affect the efficacy of the warning, although there are diminishing returns. Evidence suggests that once labels have attained a sufficient degree of readability, nuances such as greater print size do not enhance the efficacy of the warning label (6).

Another aspect of the label that affects its effectiveness is the presence of other information. Our limited information processing capabilities prevent us from effectively absorbing the warning message if we are inundated with too much information. In such contexts, consumers may know that products are potentially dangerous, but may not be aware of the specific product risks or how to prevent them.

Because consumers are confronted with a variety of different labels for similar products, standardization is generally desirable. If some companies were to use the word "warning" in situations where others would use "caution," then these words would not have a similar meaning across products. To enable consumers to make judgments for different products, it is desirable to have a uniform warnings vocabulary for language and symbols that can be readily interpreted.

**Food Labeling**

The federal government has two different labeling programs for food. The US Department of Agriculture has authority for grading and inspecting meat as well as food, grains, and nonfood crops. For the most part, the risk-related aspect of this activity consists of prohibiting tainted products from coming to market. The labeling program was designed primarily to indicate differences in character of meat rather than degrees of risk, although the two are not entirely unrelated.

In contrast, the US Food and Drug Administration (FDA) has exercised substantial influence over hazard warnings and nutrition labeling, as well as legal authority over advertising for food. The *Federal Food Drug and Cosmetic Act*, enacted in 1938, gave the FDA authority to determine the amount of food additives that could be present in food, where these additives were to be presumed unsafe unless it could be demonstrated that they were central to the product. In 1958, the act was amended to include carcinogens. Substances shown to cause cancer in either animals or humans were deemed unsafe. This stipulation, known as the Delaney Clause, has turned out to be a quite stringent requirement given the increased ability to identify low-risk carcinogens (5).

In 1973 the FDA issued regulations pertaining to nutrition labeling. These regulations, which became effective in 1975, required that all products for which a nutrition claim was being made had to bear a label providing nutrition information. In addition, the regulation specified that the upper portion of the label must provide information concerning serving size,
calories, and nutritional breakdown, whereas the lower portion of the label gave information pertaining to the US Recommended Daily Allowance (USRDA) of various nutrients.

In 1992 this labeling system was amended in several ways: serving sizes were standardized to promote comparability; information pertaining to calories from fat, dietary fiber, saturated fat, and cholesterol was added; and the percent of USRDA was restricted to pertain only to more salient nutrients, such as Vitamin C and calcium. In each case of the FDA food nutrition labels, it is noteworthy that a standardized vocabulary was established by the agency as well as a standard format for presenting the information to facilitate comparisons across products regarding their nutritional value.

One of the more controversial labeling efforts now administered by the FDA pertains to hazard warnings for saccharin. After a Canadian study reported the development of tumors in rats that had been fed saccharin, the FDA attempted to implement the Delaney Clause by banning saccharin as a food additive. This action aroused substantial public debate, particularly since there were competing risks (5, 15). Use of saccharin decreased obesity, and therefore had beneficial effects on heart disease and other health outcomes. The compromise solution is that in 1977 Congress passed the Saccharin Study and Labeling Act, which mandated a standard warning label to appear on products containing saccharin: "Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals."

**Cigarettes and Alcoholic Beverages**

Perhaps the best known warning labels mandated by Congress are those for cigarettes. In particular, cigarette packages and cigarette advertising have borne a series of warning labels over the past three decades. The development of these warnings is summarized in Table 1. The cigarette warning effective in 1965 required that consumers be apprised that "smoking may be hazardous to your health." This warning was then strengthened in 1969 to indicate that "smoking is dangerous to your health." In 1984 these warnings were expanded to include a series of four rotating warnings alerting consumers to cigarette-related risks of cancer, health risks generally, pregnancy, and carbon monoxide, among other risks.

Congress has followed a similar approach with respect to alcoholic beverages in mandating an on-product warning. Beginning November 14, 1990, Congress required that alcoholic beverage containers bear the following warning: "GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages
impairs your ability to drive a car or operate machinery, and may cause health problems.”

**Drug Labeling**

Drug labeling regulations began with the enactment of the *Pure Food and Drug Act* in 1906, which specified that drug labels could not make “false or misleading” statements and that all addictive substances (including alcohol) must be indicated on the drug label. These requirements were expanded in 1938 with the passage of the *Federal Food, Drug, and Cosmetic Act*, which required that all drugs include information about how to use the product, how long a product could be used, and warning information about unsafe dosages. In addition, beginning in 1938, a distinction was made between nonprescription drugs, which could be purchased by general consumers, and prescription drugs, for which a physician’s prescription was necessary. The introduction of the role of the learned intermediary, the physician, was to ensure that dangerous drugs were not used indiscriminately. After the thalidomide tragedy in Europe in which babies with severe birth defects were born to mothers who had used this drug, the FDA requirements were strengthened with amendments to the *Federal Food, Drug, and
Cosmetic Act, passed in 1962. Under these amendments, the FDA classified drugs based on both their safety and efficacy, and it required that warning labels include information pertaining to the active ingredients, the indications and directions for use, the mechanism of drug action, as well as potential adverse effects of the drug.

The quantity of information to be conveyed to consumers, however, was too unwieldy to be compressed into a single warning label. Moreover, it was desirable for product manufacturers to convey additional information to physicians to enable them to prescribe drugs more appropriately. To achieve this objective, the FDA developed requirements on patient package inserts (PPIs). These inserts provide more detailed information to product users and are compiled annually in the Physician's Desk Reference. The warning information included in the PPI is based on information submitted to the FDA by the manufacturer, where the actual warning language is drafted in house by the FDA, primarily by pharmacologists and physicians. Because of the centralized manner in which the warnings are issued, the pharmaceutical warnings program serves as perhaps the best model of a standardized warnings vocabulary.

PROCESSING WARNING INFORMATION

For hazard warning information to have an effect on risk perceptions and individual decisions, it must first be received and processed by the intended recipient, a requirement that may not always be met in practice. As the examination of the processing of warning information below indicates, exposure to the information is seldom complete, and even labels written for a general audience may not always be fully understood. Thus, how the warning message is conveyed and whether it will reach the intended recipient are of paramount concern.

Nutrition Labeling

The performance of various nutrition labeling programs has been mixed. Here it is useful to distinguish the performance of on-product warnings from that of in-store point-of-purchase displays.

In a study of nutrition labeling for the US Food and Drug Administration, Heimbach (3) assessed the extent to which individuals process the sodium content listings given on food labels. This study found that only one fourth of all respondents recalled a sodium content listing. Moreover, only forty percent of all respondents recalled reading an ingredient listing on food products. In each case, fewer than half of the consumers read the health-related information provided on food products.

These results may not reflect the long-term effect of the nutrition labeling
effort. This study, performed in February 1983, may have been undertaken prematurely since the FDA only began encouraging food manufacturers to voluntarily label the sodium contents of their products in 1982. Moreover, salt and sodium content listing is not necessarily of substantial interest to many consumers, since the degree to which these substances pose a health risk varies and only a minority of the population is on a sodium-restricted diet. A recent study of the effect of fiber content in cereals found that this nutritional information, which is of broad concern, did affect consumption patterns (3a).

Even if consumers process the information, there is no assurance that it will be used. The degree to which consumers actually take advantage of this information in making their purchase decisions is sometimes low. Evidence suggests that few consumers comprehend nutrition labels and use the information in making their purchase decisions.

Interestingly, Heimbach (2) found that many consumers had trouble comprehending the nutrition information even after it was processed. For example, consumers had difficulty dealing with the percentage and ratio information and in calculating the number of servings needed to supply 100 percent of the USRDA for a particular nutrient. Moreover, technical terms such as “polyunsaturated fat” and “hydrogenated,” and even “carbohydrates” pose difficulties for consumers. Other studies have found similar results, as there is often a confusion between salt and sodium.

Point-of-purchase displays have also been used to convey information about nutrition. The nutrition point-of-purchase displays examined by Russo et al (12) had little impact on the purchasing behavior of consumers of positively valued nutrients. In contrast, information on ingredients that are considered “bad”—in particular, the amount of sugar added to breakfast cereal—was processed by consumers and significantly affected their behavior.

The point-of-sale study by Muller (10) examined the effect of a matrix that gave nutrition information by brand. This study had more favorable findings, as brand-by-nutrient information increased the nutritiousness of the products that consumers purchased.

### Drug Information

A study for the Rand Corporation by Kanouse et al (4) assessed the degree to which patients read the drug leaflets accompanying prescription drugs. The structure of the study tended to produce an overstatement of the degree to which individuals read information provided to them about drugs. In particular, when the 2000 volunteer participants received their prescription drugs at the pharmacy, they were given a leaflet concerning the risks posed by the drug and told that they would be called about the information contained in the leaflet.
Notwithstanding these instruction that should have produced more diligent information processing than would normally happen, only 69–74 percent of the subjects claimed to have read the leaflets. Furthermore, only 45–54 percent of the participants in the study kept the leaflet.¹

Other studies of PPI information processing have surveyed current users of oral contraceptives to ascertain the degree to which they have processed the risk information. The study by Morris, Mazis, & Gordon (8) indicated that 88 percent of current users of oral contraceptives claim to have read the PPI. However, the degree to which subjects could recall specific information provided on the insert was less. Of current users of oral contraceptives, 69 percent could correctly recall information on usage of the drug, and only 50 percent could correctly recall information on common reactions to the drug.

This study did not include analysis of whether the respondents actually read the PPI or the extent to which individuals who did not receive the PPI could have answered the factual questions correctly without the PPI based on what their doctor had told them. Thus, there were no adequate experimental controls.

The study of aspirin warnings by Morris & Klimberg (9) suggests that, overall, roughly half of all consumers of aspirin process the risk information included on the product label. Only 25 percent of all aspirin users surveyed were aware of the Reye's syndrome warnings, 53 percent were aware of the contraindications against flu and aspirin usage, and 40 percent could spontaneously recall Reye's syndrome.

Beer and Cigarette Warnings

Examination of the processing of warnings for beer and cigarettes is useful because these warnings programs are at quite different stages of development. Cigarette warnings are well established, and these warning messages are well understood, although many consumers do not continue to read the warning information in advertising and on the product once they have already seen it repeated several times. Nevertheless, there is striking awareness of the basic content of these messages as, for example, between 99 and 100 percent of all respondents have heard that “cigarette smoking is dangerous to a person’s health” and that “cigarette smoking will most likely shorten life.”

The experience with the alcoholic beverage warnings program is much shorter, and evidence regarding receipt of that information is more sketchy. Scammon, Mayer, & Smith (13) found that as of July 1990, awareness

¹These ranges in response are attributable to the variation in percentages according to which of the three leaflets used in the study was given to the subjects. The study analyzed three different drugs.
of the alcoholic beverage warning in a survey of Utah consumers had reached 35 percent, but since 73 percent of the respondents indicated that their alcoholic beverage consumption did not exceed one drink per month, and in many cases was zero, it is difficult to generalize upon these results because of the state’s high Mormon population. These various studies suggest that conveying the warning message to consumers is a critical link that cannot be ignored in designing an effective risk communication system.

THE EFFECT ON RISK PERCEPTIONS

Although it is clearly important that hazard warnings provide accessible and comprehensible information, the risk perceptions formed must also be accurate. One can view this as posing a more refined question about the processing of risk information. Not surprisingly, this issue has been much less thoroughly examined than the actual receipt of the risk information.

However, information does exist in two different contexts in which risk information has been assessed relatively precisely. The cigarette experience provides a substantial data base on which to make judgments. The trends in the Gallup poll responses on lung cancer risk perceptions reflect the provision of hazard warnings. Before hazard warnings were in place in 1958, 45 percent of all respondents believed that cigarette smoking was one cause of lung cancer. In a 1969 survey, after the first two sets of cigarette warnings had been in place, this awareness figure had risen to 70 percent. By 1977, awareness of lung cancer risks from smoking had gone up to 81 percent (16). However, the effect of hazard warnings per se is difficult to isolate from the extensive public information campaigns about cigarette smoking. Moreover, awareness of these risks does not necessarily imply that risk perceptions are accurate. One could, for example, be aware of the risk of fatality from automobile crashes but believe that these risks are only one chance in a trillion per year.

A more instructive set of information about risk perceptions pertains to the level of the risk assessment. These figures are quite striking. Overall, individuals believe that 43 out of 100 smokers will get lung cancer because they smoke and that 54 out of 100 smokers will die of some smoking-related cause, such as lung cancer or heart disease (16). These figures exceed the “true” estimated risks of smoking, which as of 1991 were 0.06–0.03 for the lung cancer mortality risk and 0.23–0.46 for the total mortality risk of smoking (16). The amount of expected life lost by smokers also exceeds scientific estimates.

The potential mismatch between the warning information and the underlying risk associated with the product is illustrated in the warnings language under California’s Proposition 65. This proposition, enacted in 1986, requires
that risk information be provided on hazardous exposures that pose a lifetime cancer risk of at least 1/100,000. Products above the cancer-risk threshold are Liquid Paper, mantles for Coleman lanterns, and snuff. There is also a requirement about risks of reproductive toxicity. Coffee and soft drinks with caffeine are among many products above this risk threshold. The full effect of these warnings has yet to become apparent because of a series of legal challenges to Proposition 65. However, examination of the risk perceptions that would be induced by the warning language is of great interest since other states are considering similar measures. In particular, Proposition 65-type measures have been proposed in Hawaii, Illinois, Missouri, New York, Ohio, Oregon, and Tennessee, and a measure is under study in the legislature of Massachusetts (17).

The warning language mandated under Proposition 65 for carcinogens is: "WARNING: The State of California has determined that this product is dangerous to your health." This warning was patterned after the cigarette warning, but cigarettes pose a lifetime cancer risk that is approximately 10,000 times greater than the warnings threshold in Proposition 65. Not surprisingly, given the similarity of the warning language to the 1965 cigarette warning, many consumers believe that the product in question is just as risky as cigarettes. In particular, 21 percent of all Illinois respondents examining products bearing this warning believe the product would have a risk level between zero and that posed by one 12-ounce saccharin cola for which the estimated lifetime risk is 1/2500, 44 percent estimate that the Proposition 65 product poses a risk between one saccharin cola and one pack of cigarettes, and 35 percent of all respondents believe that the risk is between that of one and five packs of cigarettes. Overall, respondents believe that the Proposition 65 warning poses the same average risk as do 0.58 packs of cigarettes, or a lifetime risk in excess of 1/10. This perceived risk is 10,000 times greater than the warnings risk threshold under Proposition 65.

The actual risk perceptions generated by this measure will depend in part upon its implementation. However, the basic message is that conveying warning information does not necessarily ensure accurate probability assessments. When the level of risk perceptions is a potential concern, and not simply awareness of a potential consequence of the product, care must be exercised to ascertain that the risk perceptions generated are accurate. Language appropriate in one context may fail to convey risks of a different character.

BEHAVIORAL RESPONSES TO WARNINGS

Hazard warnings aim to provide information that will alter individual behavior either in respect to the purchase of the product or its use. Although this is the intended outcome, examining changes in behavior does not
necessarily provide a perfect indication of the efficacy of the warnings. If individuals were fully informed before receiving the warning information, then no change in behavior would be expected. Similarly, if the warnings provide an excessively adverse portrayal of the product and its risks, then there will be a response, but this response may not necessarily be commensurate with the level of risk.

_Tetracycline Warnings_

An interesting example of the effect of hazard warnings on the market for drugs is that for tetracycline. Although tetracycline is a beneficial drug, it can cause tooth staining in young children. Although the discoloration of children's permanent teeth is only cosmetic, the drug has been the subject of widespread litigation. Moreover, the FDA mandated warnings for tetracycline to alert physicians and potential consumers to the risk of permanent discoloration, beginning in April 1963.

An instructive test for the efficacy of this warning is the extent of the market response, as measured by prescribing practices that reflect the influence of the warning. Figure 2 gives the trends in physician mentions (i.e. prescriptions and refills of prescriptions) per 1000 population for two groups—age group 0-8, the specific targets of the FDA warning, and age group 9 and above. If the pattern of drug use for those affected by the warning was not influenced by the provision of the warning information, then it would have been expected to follow the same kind of trend as the use of tetracycline for the age group 9 and above. As illustrated in Figure 2, the use of tetracycline continued to increase throughout the 1960s for the older age group. However, for the age 0-8 group, the trend flattened out in 1963 when the warning was first given, and decreased steadily thereafter. Use of tetracycline declined from approximately 400 mentions per 1000 population in 1963 to under 100 mentions per 1000 population in 1975. Use of tetracycline in the younger age group did not decline to zero because tetracycline continues to be an effective drug in treating many diseases, such as Rocky Mountain spotted fever and lyme disease. Thus, physicians must make a tradeoff between the risk of the adverse effect of tooth discoloration and the beneficial effects of the drug. However, the shift in the consumption pattern for the drug is evidence of an effect of the warning on physician behavior.

The analysis of tetracycline and other products considered below rests on common features: the level of consumption of a product observed after the warnings and how this differed from what would have been observed had the warnings not been in place. It is not sufficient to ascertain whether consumption of the product has dropped. It may have been that the warnings were effective in a situation in which consumption was growing, but that the nature of the influence was to decrease the rate of growth, even though
it may not have decreased the rate of growth by so much that a decline was observed. Thus, the appropriate test is not whether consumption of the labeled product has decreased but rather whether consumption is less than it would have been in the absence of the warning.

Caution is needed in drawing conclusions about the efficacy of the warning based on such studies. If there is no effect on consumption, this is an indication that warnings did not influence behavior, but it does not necessarily imply that consumers are misinformed. One situation in which warnings would have no effect is when they do not provide any new information that alters consumers' beliefs. If these beliefs were accurate initially, the warnings would serve no useful purpose. In addition, the existence of an effect on consumption is not necessarily an outcome to which one should attach a value judgment. If the goal of the warning was to decrease consumption of the product, an outright ban would be more effective. The existence of some effect of the warning suggests that the warning did play a constructive role in terms of fulfilling its intended purpose, but the magnitude of the effect alone is generally not sufficient to determine whether this effect is too little or too great.

**Cigarette Warnings**

Figure 3 illustrates trends in cigarette consumption as a function of time and indicates the three different warning eras. The 1965 and 1969 warnings were generally associated with a flattening in the consumption of cigarettes,
and the 1984 warning was associated with a decline in consumption. If only the effects of the warnings are examined, the conclusion would be that these warnings were instrumental in dampening cigarette consumption.

However, the situation with cigarettes was not a pure controlled experiment in any sense. Numerous other sources of information also affected the trend in cigarette smoking. The landmark report on smoking issued by the Department of Health, Education, and Welfare in 1964 and the ensuing public debate were undoubtedly influential in driving the tapering-off of cigarette consumption in the mid-1960s. Moreover, the Surgeon General has issued annual reports on cigarette smoking over the past two decades, and there have been many other smoking-related actions. For example, in 1971 cigarette advertising was banned on television and radio.

Numerous econometric studies have attempted to isolate the effect of the hazard warnings from other informational events that may have affected consumption (16). Some evidence is presented in the literature that the warnings had an effect on market purchases of cigarettes, but the contemporaneous nature of the informational events makes it difficult to attribute a specific extent of this decline in smoking to the hazard warnings as distinct from other sources of information.

**Saccharin Warnings**

A market-based approach has also been used to assess the effect of saccharin warnings on consumption of products containing saccharin. The saccharin

![Figure 3](https://www.annualreviews.org/aronline)

*Figure 3* Trends in US per capita cigarette consumption, 1900–1989.
warning label went in place in early 1978, although news coverage of the risks associated with saccharin had begun in early 1977. Although the studies of saccharin have had some difficulty in disentangling the influence of the warning label from the surrounding publicity, overall there does seem to be evidence of an effect of the warning label on consumption of products containing this chemical. Schucker et al (14) found that diet soft drink sales grew faster during the period before the warnings were in place. In particular, the average annual growth rate in diet soft drink sales was 17.2 percent in 1975–1977, as compared to 1.8 percent in 1978. Sales of regular soft drinks continued to grow at an annual rate of 3–6 percent. In a subsequent study with additional data, Orwin, Schucker, & Stokes (11) concluded that to the extent that the effect of the public information in the warning label could be isolated, the evidence suggested that the warning label reduced sales of saccharin soft drinks by 4 percent and media coverage by 17 percent.

**Heart Disease Information**

A more narrowly focused study of the effect of warnings on behavior examined a program at Stanford University to provide information regarding heart disease (1a). The study aimed to alert consumers to the risks associated with smoking, excessive weight, diets high in saturated fat and cholesterol, and a lack of exercise. The Stanford physicians sought to disseminate information to a large number of consumers through distribution of a booklet on heart-related risks and a cooking guide for low-fat recipes.

The test in this instance focused on the effect of the information on patients’ diets, exercise, smoking habits, weight, plasma cholesterol concentrations, egg consumption, and general knowledge. Based on these various criteria, there was evidence of a statistically significant effect of the program in the direction intended by the researchers.

**Experimental Evidence**

Controlled field experiments using alternative labels have also been used to assess the efficacy of warnings in other contexts. For example, researchers have assessed the effect of hazard warning labels for products such as toilet bowl cleaner, insecticide, workplace chemicals, and bleach by using this approach (6, 18). By undertaking experiments in which different samples were given alternative labels, it is possible to control for different aspects of the information provided and to test for their influence. This research technique is useful in ascertaining the effect of hazard warnings, assuming that the warning information is processed in the same manner as it would be in an experimental study, but it may tend to overstate the degree to which consumers will receive information since, as was noted above, not all warning information is processed by the intended recipients.
CONCLUSION

The role of food and drug warnings is clearly a central concern in the market for these products. Both food and drugs are potentially risky consumer products with both beneficial and possibly adverse effects on individual health. Given the consequences to individual mortality and morbidity that might occur from use of these products, it is not surprising that government has been active in mandating warnings.

Not coincidentally, the first sets of warnings for which the specific language was mandated by Congress were for cigarettes, saccharin, and alcoholic beverages. Moreover, perhaps the most well-developed long-standing federal warnings effort is the warning system for prescription drugs administered by the Food and Drug Administration. This program is in many respects a model of a well-run warning system. The FDA has maintained a standardized warnings vocabulary across labels for different products and producers. As a result, the warning language is comparable, as is the format in which the information is conveyed to the recipient groups. Since consumers benefit not only from the warnings themselves but also from the provision of information to them by the learned intermediary, the physician, this medical context has a well-developed risk communication network.

In contrast, other federal warnings programs are far less structured. In the case of occupational safety and health regulations pertaining to risk communication, there is no specification whatsoever regarding the content and structure of the warnings that must be provided other than that hazardous chemicals must be labeled adequately. Similarly, even in the case of pesticide warnings that must undergo approval by the US Environmental Protection Agency (EPA), there is no effort to standardize the structure and content of warning labels for comparable products manufactured by different companies, as is done for prescription drugs and nutrition labeling.2

Notwithstanding the comparative success of the food and drug warnings efforts, there remain open issues, both with respect to policy and research. Consumers do not always process the information provided, and if the information is not received it will not have the intended effect. In addition, even when the information is processed and there is an effect on market behavior, the resulting risk perceptions are not necessarily always accurate

2For example, comparison of the warning labels for household bleach across different manufacturers reveals stark differences. Some products, such as Clorox, include warning language only at the bottom of the warning label, whereas others, such as the Brite brand made by the Kroger company, integrate the risk information more prominently as part of the directions for use.
nor the decisions well-chosen. The recurring research issue that must continue to be addressed is whether these warnings promote the kinds of choices that consumers would make if they were accurately informed of the risks of the product and made sound decisions based on this information.
CONTENTS

EPIDEMIOLOGY AND BIOSTATISTICS

Sharing Statistical Data in the Biomedical and Health Sciences: Ethical, Institutional, Legal, and Professional Dimensions, *Stephen E. Fienberg* 1

Scientific and Ethical Issues in the Use of Placebo Controls in Clinical Trials, *Pamela I. Clark and Paul E. Leaverton* 19

Latino Outlook: Good Health, Uncertain Prognosis, *William A. Vega and Hortensia Amaro* 39

The Effects of Mustard Gas, Ionizing Radiation, Herbicides, Trauma, and Oil Smoke on US Military Personnel: The Results of Veteran Studies, *Tim A. Bullman and Han K. Kang* 69

ENVIRONMENTAL AND OCCUPATIONAL HEALTH

The Impact of the Americans with Disabilities Act on Employment Opportunity for People with Disabilities, *Mary Richardson* 91

Acute Respiratory Effects of Particulate Air Pollution, *D. W. Dockery and C. A. Pope III* 107

Wood Smoke: Emissions and Noncancer Respiratory Effects, *Timothy V. Larson and Jane Q. Koenig* 133


Interpretation of Low to Moderate Relative Risks in Environmental Epidemiologic Studies, *John F. Acquavella, Barry R. Friedlander, and Belinda K. Ireland* 179


PUBLIC HEALTH PRACTICE

The Maturing Paradigm of Public Health, *Abdelmonem A. Afifi and Lester Breslow* 223

(Continued) vii
Changing Public Health Training Needs: Professional Education and the Paradigm of Public Health, Harvey V. Fineberg, Gareth M. Green, James H. Ware, and Bernita L. Anderson 237

Healthy People 2000 and Community Health Planning, Mark W. Oberle, Edward L. Baker, and Mark J. Magenheim 259


The Re-emergence of Tuberculosis, John D. H. Porter and Keith P. W. J. McAdam 303

BEHAVIORAL ASPECTS OF HEALTH

Efficacy of Labeling of Foods and Pharmaceuticals, W. Kip Viscusi 325


Child Abuse, Andrea M. Vandeven and Eli H. Newberger 367

Job Strain and Cardiovascular Disease, Peter L. Schnall, Paul A. Landsbergis, and Dean Baker 381

HEALTH SERVICES

Rationing Alternatives for Medical Care, Charles E. Phelps 413

Managed Care Plans: Characteristics, Growth and Premium Performance, Robert H. Miller and Harold S. Luft 437

Underinsured Americans, Alan Monheit 461

Health Status of Vulnerable Populations, Lu Ann Aday 487

Health Services in Head Start, E. Zigler, C. S. Piotrkowski, and R. Collins 511

Methods for Quality of Life Studies, Marsha A, Testa and Johanna F. Nackley 535

Technology Assessment and Public Health, Elaine J. Power, Sean R. Tunis, and Judith L. Wagner 561

INDEXES

Subject Index 581

Cumulative Index of Contributing Authors, Volumes 6-15 591

Cumulative Index of Chapter Titles, Volumes 6-15 595