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I. INTRODUCTION

For more than a decade, federal health regulatory agencies have devoted major attention to controlling human exposure to substances believed capable of causing cancer. These efforts have evoked a broad spectrum of criticism; government has been accused of both indolence in the face of an incipient epidemic[1] and reckless distortion of science to support restrictions on substances that present only trivial risks.[2]

A central object of regulatory concern has been the safety of the food supply. At least since the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act),[3] with its famous Delaney Clause,[4] the Food and Drug Administra-

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1. *See, e.g.*, ENVIRONMENTAL DEFENSE FUND & R. BOYLE, MALIGNANT NEGLECT 3 (1979) (attributing the "cancer epidemic" in part to government's failure to recognize that most cancers are environmentally caused and the failure to take preventive measures).

2. *See, e.g.*, E. EFRON, THE APOCALYPTICS: CANCER AND THE BIG LIE (1984) (arguing that "regulatory science" is devoid of logic, *id.* at 293, is unable to differentiate between carcinogens and noncarcinogens, *id.* at 308, and that regulation, therefore, is based upon a "no-safe-dose theory," which holds that a substance is not safe if it contains even the smallest amount of a carcinogen, *id.* at 335).

3. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040, *amended by* Food Additives Amendment Act of 1958, Pub. L. No. 85-929, 72 Stat. 1764 (codified as further amended at 21 U.S.C. §§ 301-392 (1982)).

4. 21 U.S.C. § 348(c)(3)(A) (1982). The Delaney Clause provides in pertinent part:

> [N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal . . . .

Id. See generally Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 MICH. L. REV. 171, 178-84 (1978) (discussing the origin and interpretation of the Delaney Clause).

tion (FDA) has sought, with mixed success, to identify food constituents that pose cancer risks and to eliminate them from food. The Environmental Protection Agency (EPA), which is responsible for setting permissible pesticide levels in food, has displayed similar concern for the elimination of carcinogenic residues in foods that comprise important parts of the American diet. I do not propose here to evaluate the success of the FDA's and the EPA's efforts to prevent the addition of hazardous chemicals to the food supply. While that is certainly an important issue, this Article explores the potentially greater challenges to regulation presented by recent assessments suggesting highly significant associations between traditional foods and cancer incidence.[5] This Article does not identify all the relevant issues or exhaust analysis of those it does address; the objective is to sketch the broad contours of future debate.

To dramatize the novel regulatory problems that these recent assessments pose, it is useful to summarize the basic features of current food safety regulation. First is the implicit assumption that traditional foods, and particularly those eaten with minimum processing, are safe. Man's "contributions" to foods—artificial ingredients, chemicals used in production, preservation, and packaging, and accidental industrial contaminants—are the main source of risk. Second, current regulation generally assesses food constituents individually, and in isolation. To be sure, the FD&C Act, like its predecessor,[6] permits the FDA to curb the sale of complete foods that pose risks to health, but this authority rarely has been invoked, and the modern regulatory tools—essentially forms of licensure—are geared to controlling individual ingredients, such as food and color additives, and contaminants, such as pesticide residues, animal drugs, or environmental chemicals. Regulators assess whether a specific substance, as found in food, might cause harm. The relevant data come from tests of that substance alone; the assessment of safety focuses on the capacity to harm living organisms, the relationship between that capacity and dosage, and the

5. For illustrative purposes, I rely primarily on the Report of the Committee on Diet, Nutrition, and Cancer of the National Research Council, published under the title *Diet, Nutrition, and Cancer* (National Academy Press 1982) [hereinafter cited as NRC Report]. This report is not the only important study of the problem, but it is the most comprehensive and balanced. For a list of other recent reports and recommendations concerning dietary practices and disease prevention, see Hutt, *Regulatory Implementation of Dietary Recommendations*, 36 FOOD DRUG COSM. L.J. 66, 167-168 (1981).

6. Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

levels at which humans are likely to be exposed. Almost no attention is given to how a substance may interact with other substances in the food, to the effects of other foods, or to relative risks posed by other frequently encountered food constituents.

This narrow focus is dictated largely by practical considerations. To predict, much less measure, interactions among food substances is almost impossible. Further, even if measurement techniques were available, regulators ordinarily could not afford to use them. Finally, even if time were not a constraint and data were not expensive to obain, the intellectual task of calculating the effects of the several thousand substances found in food in a multitude of combinations would be beyond the capacity of every regulatory (and scientific) institution in the country.[7]

Recent studies of the relationship between diet and disease are beginning to challenge the established regulatory framework. These studies suggest that substances in food *do* contribute to disease—and to cancer specifically. They also suggest that the real culprits are not few and foreign, but are ubiquitous and occur naturally in many agricultural commodities. The foods providing the greatest concentrations of risk-increasing material comprise important parts of popular diets and represent major products of American agriculture. Moreover, some dietary constituents appear to be useful in *preventing* cancer, but these substances are found in foods of modest economic significance and popularity. Finally, the risk of disease for individuals is linked closely to lifetime dietary patterns rather than to occasional encounters with individual toxicants. Under these circumstances, a regulatory regime geared to identifying individual toxicants and removing them from the food supply may seem ill-suited or at least inadequate. If diet-induced cancer is of concern, the government must devise more effective means with which to deal with the problem.

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7. The historical origins of federal regulation of foods and drugs also help explain the FDA's current focus. In 1906, when the first federal food and drug statute was enacted, federal authority was viewed narrowly and was confined, as a matter of constitutional theory, to goods as they moved across state lines. It was logical, therefore, for the FDA to emulate the usher at the movie theater, checking each would-be patron for a ticket—one at a time. It is worth emphasizing, however, that the prevailing single constituent focus of food safety regulation is reinforced by the threshold assumption that the dietary risks of real concern are those posed hy substances added to food by man.

II. The Nexus Between Diet and Cancer

Scientists interested in disease prevention have studied the relationship between dietary components and cancer for many years. Recent assessments by the National Research Council (NRC) and others do not break new scientific ground, but rather evaluate and summarize the work of many researchers extending over a long period. Nonetheless, the assessments have captured attention because of their broad coverage and the prominence, and presumed objectivity, of their sources. This Article will not survey all of these assessments but will simply focus on the most notable: the 1982 report by the NRC entitled *Diet, Nutrition, and Cancer* (NRC Report).[8]

The NRC Report cautions that current understanding of the relationship between diet and cancer is neither complete nor refined, and in fact is scarcely more sophisticated than the understanding of the relationship between smoking and cancer that prevailed in the early 1960's. The task of relating dietary patterns to cancer incidence has proved difficult. Regulators have only crude information about what foods, and particularly in what quantity, individuals actually eat. Additionally, according to the Report, most foods are complex mixtures of largely unknown composition. Nonetheless, several studies of human population groups have revealed strong associations between dietary patterns and the risk of developing specific types of cancer. According to the NRC Committee on Diet, Nutrition, and Cancer (NRC Committee), the evidence suggests that diets high in fat or containing cured or smoked foods tend to increase the risk of cancer, while diets containing large quantities of certain fruits and vegetables may decrease cancer incidence.[9] These general conclusions from epidemiological studies have been supplemented by laboratory investigations designed to elucidate the mechanisms by which dietary components may influence the process of carcinogenesis.

The NRC Committee's findings can be summarized under the following headings.

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8. *See supra* note 5.

9. A more recent National Cancer Institute report, in addition to echoing these conclusions, suggests that diets high in fiber may reduce cancer risk. *See* Office of Cancer Communications, National Cancer Institute, *Cancer Prevention and Research Summary: Nutrition* 6-8 (May 1984); *see also* U.S. Department of Health and Human Services, Cancer Prevention (1984) (recommending a "generous intake" of dietary fiber to help protect against the increased risk of several cancers that are attributable to diet).

A. Overall Contribution of Diet to Cancer Risk

The uncertainties that plague efforts to quantify the role of other environmental factors affecting cancer incidence also encumber estimates of the contribution of diet. A 1981 study by Doll and Peto[10] stated with some confidence that a substantial portion of cancers in both men and women could be attributed to dietary factors, and found support in the literature for estimates ranging from ten to seventy percent.[11] They offered their own assessment that dietary changes eventually might result in a thirty-five percent reduction in deaths from cancer.[12] The NRC Committee also found convincing evidence that dietary patterns influence the incidence of most types of cancer. The Committee, however, did not offer quantitative estimates of the contribution of dietary patterns or specific food constituents to overall cancer risk or attempt to forecast the percentage reduction in incidence that might result from dietary changes.[13]

B. Dietary Risk Factors for Cancer

1. Caloric Intake

Human evidence suggesting that total caloric intake may be a risk factor for cancer is indirect; that is, the evidence is primarily based on demonstrated associations between body weight or obesity and cancer. Laboratory animals on restricted diets exhibit a lower incidence of tumors than those on unrestricted diets, but this observation is difficult to interpret because the lower incidence might be the result of a reduction in the intake of some specific nutrient, such as fat. Thus, neither epidemiological evidence nor animal studies currently permit a confident conclusion about assessment of the effect of total calories on the risk of cancer.[14]

2. Fats and Cholesterol

Epidemiological studies repeatedly have shown a direct correlation between dietary fat levels and the occurrence of several cancers, especially breast, prostate, and colorectal cancer. Although the NRC Committee noted that total dietary fat frequently corre-

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10. Doll & Peto, *The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today*, 66 J. NAT'L CANCER INST. 1192 (1981).
11. *Id.* at 1226-35, 1258.
12. *Id.* at 1235.
13. NRC Report, *supra* note 5, at 2-9 to -10, 18-10 to -11.
14. *Id.* at 4-4 to -5.

lates with saturated fat, it could not identify specific components of fat as being responsible for the elevation in risk. The relationship between fat consumption and cancer risk is corroborated by animal studies. The NRC Report concluded that, of all the dietary components studied, the combined human and experimental evidence is most suggestive of a causal relationship between fat intake and cancer occurrence.[15]

3. Protein and Carbohydrates

Epidemiological studies have suggested possible correlations between protein intake and several cancers, but the literature is more limited than the studies on the role of dietary fat. Because there is a high correlation between levels of protein and fat in the diets of most Western countries, the existing studies are difficult to interpret. A few laboratory experiments suggest that the relationship between cancer and protein consumption is similar to the link between cancer and dietary fat. The NRC Report concluded, however, that although it is not yet possible to draw a firm conclusion, high protein intake *might* be associated with certain cancers.[16] Neither human nor animal studies permit a conclusion about the role of carbohydrates in cancer incidence.[17]

4. Non-Nutritive Substances

In addition to fats, proteins, and carbohydrates, a variety of non-nutritive substances are natural constituents of human foods. These include certain molds, nitrates and nitrites, and toxins synthesized naturally by plants to ward off bacteria, fungi, and predators. While a number of these substances are carcinogenic in laboratory animal experiments, the NRC Committee found insufficient evidence that any non-nutritive substance makes a significant contribution to human cancer risk.[18]

5. Alcohol

The NRC Committee found numerous reports implicating specific alcoholic beverages as risk factors for cancers of certain sites. In several Western countries excessive beer drinking has been associated with colorectal cancer. Limited evidence also shows that ex-

15. *Id.* at 5-17 to -21.
16. *Id.* at 6-11.
17. *Id.* at 7-4 to -5.
18. *Id.* at 12-23 to -25.

cessive alcohol consumption causes hepatic injury and cirrhosis, which may be precursors of liver cancer. In addition, convincing evidence establishes that alcohol, when consumed in large quantities, acts synergistically with cigarette smoking to increase the risk of cancers of the mouth, larynx, esophagus, and respiratory tract.[19]

6. Substances Created in Cooking and Processing

A chemical that is mutagenic to bacteria or other test organisms generally is regarded as potential carcinogen. Mutagens are produced when meat or fish is charred at high temperatures. Smoking of foods and charcoal broiling result in the deposition of mutagenic and carcinogenic compounds on the surface of food. The NRC Report concluded that it is not yet possible to assess whether these by-products of processing are likely to contribute significantly to cancer incidence in the United States. The Report, however, cited epidemiological evidence from other countries indicating tbat populations which frequently consume salt-cured or smoked foods have a greater incidence of certain cancers, particularly of the esophagus and stomach.[20]

7. Food Additives and Chemical Contaminants

The NRC Committee noted that nearly 3000 substances intentionally are incorporated in processed foods and another 12,000 man-made chemicals occasionally are detected in some foods. In addition, low levels of a large group of environmental contaminants may be present in a variety of foods. While some of these various substances have been found carcinogenic in animal studies, the Committee found little evidence that additives or contaminants contribute significantly to the overall risk of cancer among Americans.[21]

C. Possible Inhibitors of Carcinogenesis

While the NRC Report raised troubling questions about some familiar dietary components of the United States food supply, it

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19. *Id.* at 11-1 to -7.

20. *Id.* at 17-1 to -6.

21. *Id.* at 14-29; *see also* Doll & Peto, *supra* note 10, at 1235-37. These authors suggest that chemical additives are not a significant source of cancer risk and that some additives *might* even protect against cancer. The authors mention both indirect effects, such as saccharin's potential reduction of risk-elevating obesity, *id.* at 1235, and direct effects, such as antioxidants' inhihiting the formation of carcinogens and thereby reducing the risk of stomach cancer, *id.* at 1237.

also found that other dietary elements may *reduce* the risk of cancer.

1. Dietary Fiber

Both epidemiological and experimental studies have examined the hypothesis that high fiber diets protect against colorectal cancer. The NRC Committee found no "conclusive" evidence that dietary fiber exerts a protective effect in humans.[22] A more recent report of the National Cancer Institute (NCI), however, is less equivocal.[23]

2. Vitamins

A growing body of epidemiological evidence demonstrates an inverse relationship between the risk of cancer and the consumption of foods high in vitamin A, such as liver, or in its precursors the carotenoids, such as, many green and yellow vegetables. Most of the data are insufficient to determine whether the protective effects result from carotenoids, vitamin A itself, or some other constituent of these foods. Laboratory evidence shows that vitamin A and many of its synthetic analogues are able to suppress chemically induced tumors.[24]

The data on vitamin C are less convincing. The preventive effects observed in epidemiological studies have been tied to the consumption of foods rich in vitamin C, rather than to consumption of the vitamin itself. Nonetheless, the consumption of foods containing vitamin C is associated with a lower risk of cancers of the stomach and esophagus.[25]

3. Minerals

A number of minerals have been suspected of playing a role, some as inhibitors, in carcinogenesis. The NRC Committee, however, concluded that the data are insufficient to support any conclusions about the role of such common minerals as iron, zinc, copper, molybdenum, iodine, arsenic, cadmium, and lead.[26] The Report did note that limited epidemiological studies and labora-

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22. NRC Report, *supra* note 5, at 8-5.
23. *See supra* note 9.
24. *Id.* at 9-6 to -7.
25. *Id.* at 9-10.
26. *Id.* at 10-1 to -25. The FDA has characterized selenium as an animal carcinogen. *See* 39 Fed. Reg. 1355 (1974).

tory experiments suggest that selenium may protect against risk.[27]

D. The NRC Committee's Interim Dietary Guidelines

While the NRC Committee emphasized the primitive nature of current understanding of the link between diet and cancer in humans, it offered some guidelines for a risk-reducing diet that it believed is consistent with good nutritional practices:

(1) The consumption of both saturated and unsaturated fats should be reduced. A decrease from the current average level of forty percent of total calories to thirty percent was characterized as a prudent goal.

(2) Fruits, vegetables, and whole grain cereal products should be included in significant proportions in all diets.

(3) Consumption of food preserved by salt curing, salt pickling, or smoking should be minimized.

(4) Alcoholic beverages should be consumed, if at all, in moderation.[28]

E. Implications of NRC Committee Findings

The NRC Committee did not purport to conduct new studies of the relationship between diet and cancer; rather, it attempted to summarize the findings of hundreds of individual researchers. But even if the Committee's broader conclusions were already latent in the literature, the NRC Report gave the conclusions visibility and the imprimatur of the nation's most prestigious scientific body. The Report suggests that the capacity of the traditional American diet to contribute to cancer is a significant public health problem that might not be addressed by current regulatory strategies. What has traditionally been viewed as a problem of "pollution control"—the reduction or elimination of toxicants added to food by man—now appears to be a problem of individual dietary patterns, which are influenced powerfully by religion, tradition, and commerce.[29] The Report thus reveals that effective governmental ef-

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27. NRC Report, *supra* note 5, at 10-7.

28. *Id.* at 1-14 to -16.

29. The comparison to environmental regulation yields some insights into the current difficulties of food safety regulation. Congressional efforts to regulate food safety can be analogized to other programs, such as the EPA's regulation of air pollution under the Clean Air Act, that rely on a combination of ambient air quality standards designed to protect health and locally devised emissions limits that may reflect a weighing of feasibility or other offsetting constraints. The FD&C Act can be viewed as a series of health driven limits on "emission" of "pollutants" inte food that are not calibrated to any articulate standards of

forts to reduce diet-related cancer will be constrained not only by the limitations of science, such as in the capacity to test for carcinogenesis or to detect contaminants, but also by the unwillingness or inability to control commercial activities or individual autonomy.

One should not overlook the many uncertainties in the Committee's findings, which are stressed repeatedly in its Report. The Committee drew on a vast array of published studies, which inevitably prove to be of unequal quality. These studies' findings often are expressly equivocal or later contradicted and are subject to qualifications that accompany even the best investigations into the causes of human cancer—qualifications that are inherent in retrospective epidemiology and animal toxicology. No member of the Committee would claim that it had found evidence demonstrating "beyond a reasonable doubt"—perhaps not even by "a preponderance"—the strongest causal associations that it reported, including the link between cancer incidence and dietary fat.

Persistent uncertainties may not, and probably should not, impede all governmental action. What action is appropriate depends not only on the strength of evidence of risk but also on the nature of the governmental action contemplated. Less convincing evidence might suffice to justify changes in government programs that provide food for individuals, for example, members of the armed services, than to support FDA-mandated modifications in the composition of commercially marketed foods. Similarly, requirements of information on the labels of foods might not require the level of evidence necessary to justify banning a traditional ingredient.

The NRC Report also holds implications for private entities, including consumers, producers, and food merchandizers. Individuals may be inclined, and surely are entitled, to alter their personal diets based on the Committee's conclusions. Perhaps a more important effect will be commercial efforts to exploit the NRC findings in formulating and promoting foods and meals. Such private initiatives in turn will pose questions for government regulators—principally the FDA and the Federal Trade Commission (FTC)—that are responsible for preventing misrepresentation of foods in labeling and advertising.

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diet quality, save for the unstated assumption that a traditional diet of natural foods is risk free. The NRC Report can be viewed as undermining this "standard" of diet quality. The Report surely demonstrates the necessity for devising and articulating standards of food or, better, diet quality.

III. Implications for Affirmative FDA Regulation

The implications of the NRC Report for the FDA's regulation of food labeling, food quality or composition, and food safety are this Articles' specific concern. To assess these implications requires some understanding of the agency's current authority.[30] The FDA regulates the labeling of all non-meat and non-poultry foods marketed in the United States,[31] theoretically including foods sold in restaurants and to institutions such as schools and hospitals. In practice, however, the agency is concerned primarily with the information provided with foods sold for consumption in the home. The 1938 FD&C Act mandates that the labels of all foods contain certain information, such as net weight and statement of ingredients; authorizes the FDA to prescribe detailed label information for special classes of foods, such as nutritional supplements; and forbids label statements that are "false or misleading in any particular."[32] The Act also specifies that, in assessing whether statements in labeling are misleading, the FDA or a court may take into account material information that is omitted.[33] Together, these provisions empower the FDA to require any food label to bear just about any information that the Agency believes necessary to inform consumers about the food's important characteristics—presumably including its capacity to reduce or increase the risk of disease.[34] The FD&C Act also gave the FDA authority to prescribe "standards of identity" for foods. Designed to assure that consumers were not cheated by the sale of processed foods, such as mayonnaise or fruit preserves, the Agency's early standards took the form of detailed recipes.[35] At one time the FDA identity stan-

30. See Hutt, *supra* note 5, for a comprehensive examination of the FDA's authority, and the authorities of the FTC and the USDA as well.

31. *See* 21 U.S.C. §§ 321 (m), (n), 343 (1982). *See generally* R. Merrill & P. Hutt, Food and Drug Law ch. II (1980) (discussing the regulation of food labeling).

32. 21 U.S.C. § 343 (1982).

33. *Id.* at § 321(n).

34. This conclusion may overstate the scope of the FDA's authority to prescribe the content of food labels. Its ability to force affirmative disclosures—as distinct from its ability to prevent misleading statements—is hinged to the claims that a manufacturer makes about a food, expressly or implicitly in its name or in the purpose for which it is promoted. For example, the Agency has retreated from mandating nutrition labeling on all foods, preferring instead to require such labeling only when a nutritional claim is made or implied and to prescribe a standard format for nutritional labeling when it is undertaken voluntarily. *See* R. Merrill & P. Hutt, *supra* note 31, at 265-68 (quoting 38 Fed. Reg. 2125 (1973)).

35. 21 U.S.C. § 341 (1982). For a discussion of the FDA's food standard program, see Merrill & Collier, *"Like Mother Used To Make": An Analysis of FDA Food Standards of Identity*, 74 Colum. L. Rev. 561 (1974).

dards covered approximately fifty percent of all foods sold in the United States. While the standards stabilized the composition of basic foods, they also deterred the marketing of substitutes—including some formulations that reduced traditional constituents precisely to serve a perceived health need, for example cholesterol free eggs. In the early 1970's, the FDA instead began to prescribe "common or usual names" for substitutes for many traditional foods—names that incorporated disclosure of compositional information believed to be important to consumers. With judicial confirmation of this alternative approach,[36] the FDA now can claim authority to prescribe the composition of virtually any food, through a standard of identity, or to mandate disclosure, as part of the name, of important information about the composition of unstandardized foods.

The final weapon in the FDA's arsenal is the authority to prevent the sale of unsafe foods.[37] The Agency's power to condemn any food that contains an "added" material rendering the food potentially hazardous betrays the statute's preoccupation with foreign constituents. The Agency also may condemn foods whose natural constituents render them "ordinarily injurious" to health—a rarely invoked standard that historically has been assumed to impose a heavy burden to prove likelihood of harm. Both of these original provisions of the 1938 Act probably were aimed at food constituents that threatened immediate harm, such as poisons, rather than at long-term hazards. Later amendments, inspired by concern about such hazards, have authorized the FDA to demand premarket testing of, and to issue licenses for, constituents used to make fabricated foods or utilized in food production in ways that make their entry into foods likely. These foreign constituents include food additives, color additives, animal drugs, packaging materials and other "indirect" additives, and pesticide residues, which comprise most of the substances man might "add" to food. The only other man-made constituents are environmental contaminants, for which the FDA can set tolerance levels.[38]

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36. *See* American Frozen Food Inst. v. Mathews, 413 F. Supp. 548 (D.D.C. 1976), *aff'd sub nom.* American Frozen Food Inst. v. Califano, 555 F.2d 1059 (D.C. Cir. 1977) (per curiam).

37. *See generally* Merrill, *supra* note 4, at 184-241 (discussing the regulatory standards that the FDA applies in determining whether to ban food constituents).

38. *See generally* Merrill & Schewel, *FDA Regulation of Environmental Contaminants of Food*, 66 VA. L. REV. 1357 (1980) (focusing on the FDA's standards and procedures for determining acceptable contamination levels in foods *unintentionally* contaminated with potentially hazardous substances).

This battery of regulatory authorities gives the FDA both comprehensive control over all substances advertently added to foods and reasonably effective authority over the marketing of foods that become contaminated with hazardous substances. Although the regulatory scheme does not function perfectly, it does not display major gaps, and, at least in theory, the scheme permits the FDA to prescribe, *ex ante*, the conditions of use of virtually all added substances and conditions of sale of foods containing them. Even so, as one contemplates regulatory action to implement the most cogent findings of the NRC Report, the current system seems ill-fitting for at least four reasons. First, as previously noted, the current system focuses on the safety of added constituents individually rather than on their collective effects. Second, although the FDA makes informed assumptions about likely dietary exposure in deciding whether or on what terms to license ingredients, the Agency generally does not attempt to alter the consumer dietary patterns that might have health significance. Third, the regulatory system generally contemplates binary responses from the FDA; a substance either is permitted or it is not. The Delaney Clause[39] makes this structure explicit for any additive found to cause cancer in man or animals. Finally, the system correspondingly places little reliance on consumers to protect themselves; the FDA's decisions to allow foods to be marketed are understood as confirming the fundamental safety of those foods. In short, the system is designed to set "emission limits" for foreign toxicants in foods, not to convey information that would enable consumers to control the long-term risks associated with dietary choices.

Perversely, the current system for setting "emission limits" for food constituents embodies criteria that appear to be the reverse of those implied by the NRC Report. The law applies the most stringent test—freedom from any risk of harm—to food and color additives, whose contribution to cancer incidence the NRC Committee was unable to discern.[40] As a corollary, the law applies the most relaxed standard—forbidden only if "ordinarily injurious"—to unprocessed foods of natural origin, many of which include high levels of constituents that pose a cancer risk which the Committee ranked the highest.[41]

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39. See *supra* note 4 for text of Delaney Clause.

40. *See supra* text accompanying note 21.

41. The NRC Committee's assessment surely is not the final word on the issue of which food constituents pose the greatest risk. Bruce Ames, a distinguished scientist in the field, has speculated that the major culprits may be substances produced by nature to pro-

This apparent anomaly[42] can be explained, however, wholly apart from the difference between the time of enactment of the key statutory provisions and the recent confirmation of the relationship between diet and cancer. Broadly speaking, the Act's diverse safety criteria reflect not differing assessments of the risks posed by various categories of added constitutents, but perceived differences in our capacity or willingness to limit human exposure to them. Theoretically, regulators easily could assure that consumers are not exposed to a hazardous *ingredient* by making it a crime to add the substance to food.[43] It is usually more difficult, however, to limit exposure to an industrial by-product whose presence in food is discovered only after a sizeable segment of the food supply is contaminated, for example, the polychlorinated biphenyl (PCB) contamination of fish caught in the Great Lakes.[44] And it may be even more difficult to limit exposure to substances found naturally in the unprocessed products of American agriculture. Consequently, the present law's apparent ordering of risks betrays the legislature's ranking of benefits.[45]

IV. Opportunities and Impediments

While the FDA will encounter difficulties if it seeks to implement the findings of the NRC Report, the major impediments do not reflect deficiencies in the current law but more practical difficulties. The practical difficulties include the preliminary character of the Committee's findings, the continuing uncertainty surrounding the link between diet and cancer, and, most significantly, the resistance of both American agriculture and consumers to dramatic changes in dietary patterns. These obstacles become obvious as one considers the Report's basic messages:

(1) The major dietary risk factors are not chemicals added by

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tect plants from disease and predators. *See* Ames, *Dietary Carcinogens and Anticarcinogens*, 221 Sci. 1256 (1983).

42. The current law is criticized in *Food Safety in the United States, Report of the Committee for a Study of Saccharin and Food Safety Policy*, Institute of Medicine and National Research Council, National Academy of Sciences (March 1979).

43. By use of the term "easily" I mean that such regulation would not confront technological obstacles. It could confront political obstacles, however, as the FDA's aborted effort to ban saccharin has demonstrated.

44. It can be argued that these cases reveal no difference in principle—that is, that control of any food constituent is limited only by our willingness to pay the cost. This insight of economics, however, does not refute the observation that the current law's categories reflect congressional perceptions of differing "benefits."

45. *See, e.g.*, Pape, *Legislative Issues in Food Safety Regulation*, in Social Regulation: Strategies for Reform (1982).

man but inherent constituents of traditional and popular foods.

(2) The major risks stem from lifelong ingestion of classes of foods rather than short-term exposure to a few easily identified foods. Moreover, foods are not categorizable as "dangerous" or "safe," but as "better" or "worse" in their contribution to cancer risk. Thus, moderation and substitution are more practical guides to behavior than banning or abstinence. Correspondingly, risk reduction requires individual daily attention to dietary choices rather than one-time decisions about which foods to eat or to avoid.

(3) Most siguificantly, the NRC Report suggests that the aggregate consumption of food constituents—both those associated with increased risk and those believed to be protective—influences the risk of cancer. This last message has profound implications, for it suggests that regulators must shift their focus from the safety of individual foods to the composition of diets. Diet-induced cancer should be viewed as a novel problem of behavior modification rather than a traditional problem of market regulation.

A. Regulation of Food Composition

1. Assuring Additive Safety

While the NRC Committee found little evidence that added chemicals have contributed to cancer incidence, this conclusion simply may refiect the overall success of regulation in preventing the introduction of toxic additives and in curtailing the sale of dangerously contaminated foods. It does not support an argument for abandoning premarket screening of the safety of new compounds or the monitoring of foods for industrial residues.

2. Controlling Food Composition

One ought not neglect tlie composition of individual foods in assessing opportunities for effective regulatory intervention. If the amount of fat in foods comprising major sources of calories for Americans could be reduced by twenty-five percent, and consumers did not substitute new higher-fat foods, one could expect a significant reduction in cancer incidence. If protein were confirmed as an independent cancer risk factor, reductions in protein levels likewise could lower risk. Conceivably, reductions in risk also might be achievable through the *addition* of constituents that provide a pro-

tective effect.[46] Because the association between dietary fat and cancer incidence appears well established, that relationship provides a useful example.

Assuming that a twenty-five percent reduction in dietary fat is the goal, the FDA should have two objectives. First, it should seek opportunities to mandate reductions in the amount of fat in individual foods. Second, it should eliminate requirements that impede reductions undertaken voluntarily by food producers. The Agency has the legal authority to pursue both objectives. Under section 401 of the FD&C Act,[47] the FDA is empowered to promulgate mandatory standards of identity prescribing the composition—including the amount of fat—of products sold as particular foods, such as mayonnaise.[48] Furthermore, the Agency surely may amend existing standards of identity that mandate minimum levels of overall fat or fat of a particular origin, for example butter fat—requirements which are often based on the assumption that fat is an index of product quality.

The FDA would encounter problems in the pursuit of each of these objectives. First, reducing fat might alter the palatability of some foods and thus cause consumers to substitute other high fat foods. The Agency might hear claims of product degradation, and resulting deception, from consumers who prefer the immediate enjoyment of the traditional food to the much more remote benefits of reduced risk. Furthermore, experience suggests that food producers and ingredient suppliers would vigorously resist signficiant changes in existing standards of identity—even changes merely *permitting* reductions in fat.[49] A standard of identity that sets a minimum level of fat for a food traditionally has assured manufacturers that they will not face competition from diluted products

46. The NRC Committee does not recommend the use of supplemental vitamins A or C or other possibly protective nutrients, but rather endorses the foods in which they occur naturally on the prudent ground that the effects observed may be attributable to other constituents. NRC Report, *supra* note 5, at 144, 147.

47. 21 U.S.C. § 341 (1982). *See generally*, Merrill & Collier, *supra* note 35 (discussing the costs and benefits of food standards).

48. Compare the FDA's standard for mayonnaise, 21 C.F.R. § 169.140 (mandating at least 65% oil), with its standard for salad dressing, 21 C.F.R. § 169.150 (requiring only 30% oil).

49. For example, when the FDA attempted to revise the standard of identity for ice cream to permit use of cassein as an ingredient, it met withering criticism from domestic suppliers of other milk-based constituents, whose market would be damaged by the liberalization. They were joined by members of Congress with close attachments to the dairy industry. Ultimately, the Agency backed down. *See* R. MERRILL & P. HUTT, *supra* note 31, at 192-94.

sold under the same name and has provided a guaranteed market for the suppliers of the fat ingredient. Many remaining "recipe" standards cover dairy products, and the FDA has been notably unsuccessful in relaxing those products' fat requirements. Moreover, for some standardized foods containing significant fat, there even may be plausible health reasons to resist changes in formulation.[50]

The current statutory procedures for amending or repealing standards of identity give defenders of the traditional formula an effective weapon against change. The FD&C Act prescribes on-the-record rulemaking for the adoption of regulations under section 401, permitting any party who objects to a proposed standard—including any change in an existing standard—to force the FDA to hold a formal evidentiary hearing.[51] As a practical matter, this procedural right means that controversial changes in existing standards of identity are rarely implemented. Nonetheless, among existing standards of identity, particularly those that mandate a minimum level of fat, there are surely some plausible candidates for an amendment allowing manufacturers to reduce fat without forfeiting use of the food name. There also may be some candidates for new or amended food standards that would impose *maximum* limits on fat for the purpose of reducing overall dietary fat. In addition, the FDA could broaden opportunities for marketing reduced fat competitors for standardized products by viewing them as outside the identity standards.

It should be noted, however, that the major source of dietary fat—meat and meat products—is not as malleable by government edict as most dairy products, whose composition is more often a matter of design than of nature. Animal husbandry practices can affect the levels of fat in meat, but not as dramatically as the FDA can alter the composition of cheese. The United States Department of Agriculture (USDA) has comparable authority over the composition of processed meat and poultry products, but these items comprise only part of the market for meat and poultry products. Major reductions in the amount of fat that Americans now

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50. Some dairy products, such as milk, may provide a major source of calories and other nutrients for some segments of the population. (Both the FDA and the EPA assume for purposes of estimating exposure to pesticide and other residues that milk represents 100% of the diet of infants. *E.g.*, 44 Fed. Reg. 17,094 (1979)). If it were shown that fat content does make product quality, the FDA could allow manufacturers to determine how much fat to include but require disclosure of the amount of fat on food labels. But this option would leave open the possibility that most versions of a food will remain high in fat, thus shifting the burden of risk reduction to the consumer.

51. *See* R. MERRILL & P. HUTT, *supra* note 31, at 189, 231, 889-901.

consume from meat will require significant changes in consumption patterns as well as modification of government compositional requirements.

Government agencies that provide foods or meals to individuals—through school lunches, food stamps, the feeding of institutionalized populations—might have greater opportunities to effect reductions in dietary fat. These agencies confront fewer procedural impediments to implementing change, and their effective control over the actual dispensing of foods provides greater assurance of compliance. Yet these agencies, too, surely would encounter resistance from clients, who may view the dispensing of reduced fat, "lower quality" foods as disparaging, and from food suppliers, who may have a major stake in the continued sale of high fat products or ingredients.[52]

B. Transmission of Dietary Information

For major changes in American eating habits to occur, consumers will require straightforward information—not merely reports of scientific studies—about individual foods, meal composites, and long-term eating habits. Although providing that information may not alone be sufficient to bring about significant changes in dietary patterns, it is an essential first step. Consumers obtain information about foods from several sources, both public and private. In theory, the federal government can dictate, or at least influence, the information provided by both sources—as author of official communications, such as USDA pamphlets for homemakers, and as regulator of commercial messages from food distributors, both in labeling and advertising.

1. Government-Authored Information

The numerous possibilities for official communication of health enhancing dietary advice offer diverse prospects for success and pose varied problems of implementation. The USDA has a long tradition of distributing useful information to homemakers and no doubt has exercised positive influence on the nation's eating habits. One may question, however, whether the Department's traditional routes of communication—through Government Printing Office publications, local outreach programs, public schools,

52. Because the Department of Agriculture, the agency responsihle for hoth the school lunch and food stamp programs, retains close ties to the meat and dairy industries, one might expect innovations in these programs to come quite slowly.

and colleges—retain major influence in a society in which meal preparation often is shared among family members and in which the percentage of meals commercially prepared continues to grow. Another obstacle to effective USDA intervention on the diet-and-cancer issue is the Department's historical allegiance to producers of grain, meat, and dairy products, whose interests conflict with effective implementation of the NRC Committee's advice. Similar pressures are likely to be felt by other public agencies that play roles in educating consumers, including local governmental bodies and educational institutions.

2. Government Regulation of Commercial Messages

Many regulatory opportunities are open to the FDA and, in its role as regulator of advertising,[53] to the FTC. For the FDA, the regulatory weapons include required disclosures in labeling and evaluation of claims volunteered by food marketers who seek to exploit the NRC Report.

a. Mandated Label Information

As noted previously, the FDA possesses adequate legal authority to require food labels to bear almost any pertinent and plausible information concerning the food. The more difficult issues involve the information that should be required, the form it should take to be understandable, and the constraints that the inherent limits of the label format impose. As early as 1979, the FDA had acknowledged the limitations of the labeling format in an analogous context:

> [A] requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant (in contrast to a deliberately added carcinogenic substance) would apply to many, perhaps most, foods in a supermarket. Such warnings would be so numerous they would confuse the public, would not promote informed consumer decisioumaking, and would not advance the public health.[54]

The NRC Committee's brief recommendations still are too prolix to incorporate in the labels of most foods—which already

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53. *See* R. MERRILL & P. HUTT, *supra* note 31, at 134.

54. 44 Fed. Reg. 59,513 (1979). The Agency was responding to comments on a proposal to require a label warning on hair dyes that contained trace amounts of a carcinogen. Critics had pointed to the anomaly in the Agency's failure to require warnings about food constituents that appeared to pose substantially greater risks. The Agency's response ignored the possibility of labeling based on levels of risk—an approach that might be feasible with individual toxicants, but one that would not easily accommodate the sorts of findings about general dietary practices prescribed by the NRC Committee.

contain much useful information required by statute, such as net weight and a list of ingredients, and by FDA regulation, such as nutrition information.[55] Furthermore, those recommendations, with the possible exception of the caution concerning alcoholic beverages, themselves do not seem suited for the labels of specific foods. The recommendations do suggest, however, other product specific information that might be useful, such as mandatory disclosure of fat content. But the bare disclosure of fat content, already a part of nutrition labeling, may be inadequate without additional information placing the disclosure in context—such as a statement that a high fat diet increases the risk of cancer. Even a bare statement of the percentage of fat would not reveal whether a food is an important source of dietary fat, or whether the food contains more or less fat than possible substitutes.[56]

These speculations do not demonstrate that the FDA should refrain from trying to influence dietary habits through mandated label information, but they do hint at the complexity of the undertaking. As with nutrition labeling, the FDA must consider the roles of particular foods in the diet, other useful information on food labels, the interchangeability of foods, and the other sources of information that attentive consumers can consult in evaluating the sparse text of food labels. The agency also must take into account consumer buying habits—to the extent they are known. Many consumers pay attention to food labels, particularly when they wish to avoid particular constitutents, but a vast number ignore labels.[57] Predictably, those who do consult labels tend to be well educated, conscientious about diet, and exposed to other information that enables them to evaluate food labels. Further investigation might suggest that the persons whose dietary habits now place them at the greatest risk are precisely those least likely to be reached by innovations in food labels.

The NRC Report suggests other food labeling initiatives. It cautions against excessive consumption of alcoholic beverages, particularly by people who smoke. One could visualize a requirement

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55. *See* R. MERRILL & P. HUTT, *supra* note 31, at 148-50, 265-73.

56. There may be some question about the FDA's authority to require the marketer of Food *A* to include in its label information about Food *B* (for example, "this food contains *X*% fat, by comparison with Food *B*, which contains only *Y*% fat"). But resolution of this issue is not the key to the FDA's ability, should it have the desire, to incorporate many of the NRC Report's findings in food labels.

57. *See* Good Housekeeping Institute, *Survey of Consumer Response to Food Labeling, FDLI Food Update* (March 1982); *see also* R. MERRILL & P. HUTT, *supra* note 31, at 269-70 (citing sources).

that alcoholic beverages bear a statement regarding the link between alcohol and cancer, but such speculation invites comparison with other proposed or implemented label warnings. One obvious parallel, the warning on cigarettes, has sparked two decades of controversy over its factual bases and its effectiveness in discouraging smoking.[58] The cigarette warning experience does not nullify the utility of a warning about alcoholic beverages, but it does forecast the sort of political obstacles that such an initiative would encounter and raises questions about a warning's ability to alter behavior. As a final obstacle, under a long-standing interagency agreement, the FDA in effect has surrendered its authority over the labeling of alcoholic beverages to the Treasury Department.[59]

Two other classes of foods effectively escape federal labeling requirements: fresh fruits and vegetables, which the NRC Committee found may protect against some cancers, and restaurant meals. The FDA never has acknowledged that either category falls outside its jurisdiction. The Agency toyed with a proposal to require nutrition labeling for fresh fruits and vegetables[60]—through the use of point-of-sale notices, and it has considered requiring fast-food operators to provide nutrition information as well.[61] But the difficulty of adapting labeling rules to foods that are sold without labels and the costs of effective enforcement—FDA inspectors would have to visit every grocery store and every restaurant—thus far have frustrated all initiatives to mandate point-of-sale information about these increasingly important classes of food.

There are other obstacles to effective communication of the NRC Committee's findings to consumers. The scientific bases for the Committee's recommendations are arcane and complex. Most members of the Committee no doubt would be reluctant to embrace statements simple enough to reach many audiences—for example, "eating carrots and cabbage will reduce your risk of stom-

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58. *See, e.g., Smoking Prevention Health and Education Act of 1983: Hearings on S. 98-232 Before the Senate Comm. on Labor and Human Resources,* 98th Cong., 1st Sess. (1983).

59. *See* R. MERRILL & P. HUTT, *supra* note 31, at 163-64.

60. *See* 40 Fed. Reg. 8214 (1975); *see also* 48 Fed. Reg. 27, 266 (1983) (withdrawing proposal to require nutrition labeling for fresh fruits and vegetables).

61. No official document chronicles the FDA's periodic entertainment and later rejections of suggestions for "point of sale" information about the composition of restaurant meals. The author here draws on personal experience as the FDA's Chief Counsel from 1975 to 1977. Note that in 1979 the FDA and the USDA announced that they would not take steps to require ingredient labeling of restaurant served foods. *See* 44 Fed. Reg. 75,990, 76,000 (1979).

ach cancer." Some of the associations between diet and cancer incidence are strong as epidemiological findings go, but they fall short of proof of causation. Therefore, even the strongest findings of diet/cancer association simply may not support the blunt conclusions that regulators and consumers will require.[62]

Furthermore, the risk in question—the increased likelihood of cancer—may seem extremely remote to many consumers. Other authoritative assessments of risk, as convincing as those of the NRC Committee, have not produced the changes in personal behavior necessary to effectuate their recommendations. As examples, consider the continued low level of seat belt usage and the equivocal evidence of whether cigarette label warnings have influenced individual smoking habits.[63] In each of these cases, the temporal remoteness of the risk described dilutes consumer response. Likewise, it is difficult to believe that the to dietary patterns the NRC Committee wishes to discourage will prove readily susceptible to modification. Dietary habits may be even *less* malleable to change than smoking habits. Smoking involves routine exposure to foreign substances whose character surely appears suspicious. By contrast consumers regard eating health enhancing and as involving ingestion of materials believed to be "good for you."

b. Limits on Product Claims

While the NRC Report and subsequent NCI dietary recommendations have disturbed producers of some foods whose sales would suffer from changes in dietary patterns, marketers of other products have discovered new commercial opportunities. Even a casual viewer of television is likely to have seen recent advertisements for Kellogg's "All Bran" cereal, which explicitly refer to the National Cancer Institute's (NCI's) endorsement of dietary fiber. Another firm is marketing a tablet under the name "Healthy Greens," promising that it incorporates nutrients believed protective against cancer. These commercial initiatives, which no doubt will be followed by other companies, have attracted the attention

62. *See* Motor-Vehicles Mfrs. Ass'n v. Stato Farm Mut. Ins. Co., 103 S.Ct. 2856 (1983) (overturning the Department of Transportation's decision to revoke the requirement for mandatory passive restraint systems).

63. Here we may detect a distinction between the type of evidence sufficient to justify voluntary claims in labeling or advertising—such as those made for Kellogg's "All Bran" cereal—and evidence sufficient to justify governmental intervention by mandating involuntary disclosure.

of the FDA and the FTC.[64] Both agencies have a history of impatience with claims that seek to exploit preposterous, speculative, or even merely preliminary reports of scientific investigations associating health benefits with specific products or practices.[65] Both agencies have authority to invoke legal sanctions against false or deceptive claims for foods. The very uncertainty of the NRC Committee's conclusions, however, makes vigorous prosecution of exaggerated "reduce your risk to cancer" claims difficult, and perhaps even undesirable in some cases.

The FDA has two regulatory weapons it could enlist in any effort to curb overstated claims about foods offering qualities that the NRC Committee found might reduce the risk of cancer. First, the Agency could require manufacturers who make risk reducing label claims to incorporate appropriate qualifications, or face misbranding charges under sections 201(n) and 403(a) of the FD&C Act.[66] Section 201(n) permits consideration of omissions from labeling in assessing whether statements actually made are false or misleading. Thus, for example, the FDA might challenge Kellogg's "All Bran" claim—"the NCI reports that fiber reduces your risk of cancer"—for failing to state that the NRC Committee, on the other hand, found inadequate evidence for such an association. If Kellogg made no such claims in labeling, however, the matter falls to the FTC, whose authority to require affirmative disclosures, absent a prior finding of deception, is uncertain.

The second weapon available to the FDA is the use of a theory it has invoked successfully to combat more dubious promotions. The Agency could assert that Kellogg actually is making a "drug" claim for its cereal—that is, a claim of disease prevention—and, since the effectiveness of "All Bran" in reducing the risk of disease is not "generally recognized," the product is a "new drug" whose efficacy must be demonstrated affirmatively before it can be mar-

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64. *See, e.g.*, Mayer, *FDA Studies Advertising for Kellogg's All-Bran*, The Washington Post, Nov. 6, 1984, at E1, col. 4.

65. *See, e.g.*, V.E. Irons, Inc. v. United States, 244 F.2d 34 (1st Cir. 1957); United States v. "Vitasafe Formula M", 266 F. Supp. 266 (D.N.J. 1964); United States v. 119 Cases . . . "New Dextra Brand Fortified Cane Sugar . . .", 231 F. Supp. 551 (D. Fla. 1963). *See generally* R. MERRILL & P. HUTT, *supra* note 31, at 216-228 (providing edited versions of these cases). FDA regulations prohibit label statements that a food is adequate for the prevention or treatment of disease, 21 C.F.R. § 101.9(i)(1) (1977), and the Agency reaffirmed that policy in 1979, 44 Fed. Reg. 75,990, 77,006-77,007 (1979).

66. 21 U.S.C. §§ 321(m), (n), 343(a) (1982); *see, e.g.*, Research Laboratories, Inc. v. United States, 167 F.2d 410 (9th Cir. 1948).

keted.[67] In short, the FDA would point to the product's advertising to demonstrate the purpose for which it was being sold—that is, as a drug—and then shackle the product to obviously unachieveable standards of drug effectiveness. This would be an extreme response, but one that, if successful, would stifle the types of claims that now disconcert the Agency.

One may ask why the FDA might be concerned about the claims made for "All Bran." After all, these claims are relatively modest, they accurately describe the recommendation of the National Cancer Institute,[68] and they do not repudiate any of the conclusions of the NRC Committee. Furthermore, as the NRC Report intimates, the claims could be true. The FDA has a history of suspicion of health promotion claims whose scientific basis is dubious or uncertain. The concerns inspiring this suspicion are understandable: the Agency fears that consumers will be misled into purchasing products that not only fail to fulfill the health claims made for them, but also that have no other legitimate rationale. This indictment probably cannot be leveled against "All Bran" cereal or fresh vegetables, whose consumption the NRC Report explicitly endorses. Even if the theory that fiber or vitamin A protects against cancer is unsubstantiated, individuals who increase their consumption of these products will not have been harmed significantly.

A product like "Healthy Greens" presents a different problem. A product advertised as providing the disease prevention value of fresh vegetables, but that offers no other attribute of vegetables, is deceptive unless two things are true. First, the foods that the product simulates must possess the disease preventing qualities claimed. Second, the synthetic product must contain the constituents that make fresh vegetables protective against disease.[69] Uncer-

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67. *See* 21 U.S.C. § 355(a) (1982); *see also* Alberty Food Prods. Co. v. United States, 185 F.2d 321 (9th Cir. 1950) (finding vitamin and mineral supplements to be mislabeled because of advertising); R. MERRILL & P. HUTT, *supra* note 31, at 315-17 (discussing cases holding drugs to be mislabeled because the labels did not state the purpose or condition for which the drugs were intended).

68. Apparently Kellogg consulted with officials at the National Cancer Institute before launching its "All Bran" campaign; FDA officials, however, have voiced resentment that the company never discussed the issue with them. *See* Mayer, *supra* note 64, at E5, col. 3.

69. When the FDA has attempted to combat the marketing of fabricated products that incorporate nutrients found naturally in agricultural commodities on the grounds that they are nutritionally unsound or not the nutritionally preferred "vehicle" for those nutrients, the Agency has met resistance. *See, e.g.*, United States v. 119 Cases . . . "New Dextra Brand Fortified Cane Sugar . . .", 231 F. Supp. 551 (D. Fla. 1963). Thus, the NRC Committee's recommendation against supplements of vitamins A or C, by itself, probably would not be a basis for attacking a product such as "Healthy Greens."

tainty about the existence of a protective effect for the vegetables themselves and ignorance about the source of any such effect may impede a government charge that the product is deceptive. These impediments, however, should not bar an FDA claim that the product is a drug whose effectiveness must be demonstrated. The difficult determination will be whether the claims made for the product can be characterized as disease prevention—that is, as drug claims.

This Article does not intimate answers to these issues; its purpose is to depict another arena in which the recent speculations about diet's contribution to cancer incidence have implications for government regulators generally, and for the FDA specifically. The nature of these speculations arguably poses a novel dilemma for FDA officials. The dietary practices recommended by the NRC Committee and by the NCI have plausibility quite apart from their possible role in cancer prevention. For example, reduced dietary fat could lower the risk of heart attack, and a diet containing less fat and more fruits and vegetables than the "average" diet would reduce obesity. Thus, the government may desire people to follow the recommendations even if they prove futile in reducing cancer—and product claims calculated to effect such dietary patterns could be benign even if overstated or wrong. Furthermore, the various recommendations of the NRC Committee are linked together in one important sense: promotion of products fulfilling one of these recommendations may help popularize other recommendations. Therefore, Kellogg's claims for "All Bran," invoking the NCI endorsement of fiber, may raise the visibility of other suggestions as well—including the recommendation to reduce dietary fat. Accordingly, the FDA and the FTC perhaps should display tolerance in assessing the capacity for specific products to mislead.

V. Conclusion

The growing evidence that dietary patterns significantly affect human cancer incidence has profound implications for public health authorities. Bodies responsible for investigating the causes of cancer and for developing treatment—most notably the National Cancer Institute—no doubt will be grappling with these implications for decades to come. Primary responsibility for translating our improved understanding of the etiology of cancer into public policy lies with these bodies.

The NRC Report, and the scientific studies on which it relies, quite clearly have a message for the agencies responsible for regn-

lating the safety and quality of commercially marketed foods, primarily the FDA and the USDA. The NRC Report suggests opportunities for new regulatory initiatives that could make significant contributions to reduction in cancer incidence by altering the content of some foods and by providing consumers information that will assist them in modifying their own diets. The greatest opportunities for creative health promotion probably lie in increasing consumer understanding of the long-term health implications of different dietary practices, for it is at the level of individual choice of foods and meals that change must come if diet-associated cancer is to be reduced. We should not anticipate, however, that significant changes will occur quickly. The central recommendation of the NRC Committee calls for a one-third reduction in fat consumption by the general population—a massive change in dietary patterns that would have far reaching, and, in the short term damaging consequences for United States agriculture. A direct call for a thirty-three percent reduction in beef, pork, and dairy production would produce cries of anguish from the farm community, and from their representatives in Washington. The NRC Report endorses dietary changes destined, if accomplished, to have the equivalent effect. We should not be surprised, therefore, to find regulatory agencies proceeding cautiously and many food producers seriously questioning the scientific bases for this proposed dietary revolution.

Although focusing on the practical impediments to regulatory implementation of the NRC Committee's dietary recommendations (and similar future recommendations), this Article does not suggest that the effort is not worth pursuing. The discussion here acknowledges the significance of the Committee's findings for public health; the NRC Report reveals several ways in which Americans potentially could achieve dramatic reductions in cancer incidence. Additionally, existing statutes in principle provide the FDA (and the USDA and the FTC) with ample authority to effectuate almost any sensible regulatory requirements. The difficulty confronting regulators, therefore, is in determining just what policies make sense when the accumulating scientific evidence indicts dietary practices supported by long tradition, evident consumer preference, and powerful economic interests.[70]

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70. *See* Hutt, *supra* note 5, at 68-70.