



A COOKBOOK FOR A CONSISTENT FOOD SAFETY STANDARD FOR CARCINOGENIC FOODS: LOOKING TO THE INGREDIENTS OF A FOOD RATHER THAN ITS RECIPE

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A COOKBOOK FOR A CONSISTENT FOOD SAFETY STANDARD FOR CARCINOGENIC FOODS: LOOKING TO THE INGREDIENTS OF A FOOD RATHER THAN ITS RECIPE

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INTRODUCTION

The current food safety standards are based on the implicit assumption that the food that people traditionally have eaten is fundamentally risk-free. This may be an accurate assumption in the context of risks from acute health effects of poisonous foods. However, this assumption cannot be maintained in the context of risks from chronic health problems, such as cancer. The current regulatory scheme reflects people's irrational bias against non-natural carcinogenic foods. This scheme has proven to be relatively unworkable, and has led to an examination of the wrong issues in attempting to eliminate the health risks from carcinogenic foods. Indeed, the focus on a food's recipe in the context of carcinogens has caused us to reduce the risks of cancer inefficiently. This paper will present proposals that will make the food safety standards for carcinogens consistent. This will allow for the reduction of the risk from carcinogens in a more cost-effective manner. This paper will also consider the implications of risk perception and risk communication research in formulating effective risk management policies.

I. THE BASIC PROBLEM

A. The Importance of Risk Perception in Our System of Government

In a democratic system such as ours, people's beliefs and preferences are often enacted into law. Implicit in our determination that such a democratic legal system is wise rests an assumption that people are capable of governing themselves. That is, we believe that citizens will not elect legislators who will consistently design laws that are not in the citizens' best interests. With regard to the regulation of substances which are harmful to humans, the assumption translates to a belief that our democratic processes will effect laws which will protect people from these harmful substances. Of great importance in determining whether a set of laws will in fact protect the public rather than exposing the public to risks is the public's perception of those risks.

In an ideal world, people would be able to perceive the risks that surround them accurately and take appropriate precautions through laws or otherwise. However, current literature regarding the public perception of risk reveals that we do not live in such a utopia.

B. The Basic Tenets of Risk Perception Research

During the past 15 years a great deal of research has been conducted to discover what risk means to people. Ostensibly, this research will enable health and safety regulators to better perform their task.¹ Studies have conclusively determined that people perceive risk as being more than merely a calculation of the expected number of fatalities from an activity.² Thus, the public's perception of risk appears to be more robust than the technical approxi-

¹See, e.g., Paul Slovic, *Perception of Risk*, 236 SCIENCE 280 (1987). However, actual attempts to utilize this risk perception research have not been easy. See William D. Ruckelshaus, *Risk in a Free Society*, 4 RISK ANALYSIS 157 (1984).

²See, e.g., Paul Slovic, *Perception of Risk*, 236 SCIENCE 280 (1987); Paul Slovic, *Informing and Educating the Public About Risk*, 6 RISK ANALYSIS 403(1986).

mations of risk given by experts.³ Although the public perceives risks differently than experts, the public's perceptions cannot be dismissed as being irrational. People do not ordinarily have complete information when assessing complex risks and therefore must resort to using mental shortcuts, called heuristics, to respond to various risks.⁴ These heuristics necessarily are not always effective; there are certainly limits to people's rationality.⁵ The public perception of food safety risk is an example of people's heuristics leading to severe and persistent biases.

C. The Biases in the Public's Perception of Food Safety Risks:

*The Fear of Anything Added to Natural Foods*⁶

The basic psychometric theory of risk perception predicts that people will generally perceive risks of an unknown technology to be greater than the risks of a known technology.⁷ This bias is not necessarily irrational. In the context of acute health risks, people are rational to recognize that traditional foods are safer than new foods, because the traditional foods have not displayed any poisonous effects in the past. Additionally, with incomplete information, people may be correct to view cautiously activities which may have a delayed,

³Nancy Kraus et al., *Intuitive Toxicology: Expert and Lay Judgments of Chemical Risks*, 12 RISK ANALYSIS 215 (1992).

⁴See generally, DANIEL KAHNEMAN ET AL. EDS., JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES (1982).

⁵See, e.g., Richard J. Zeckhauser & W. Kip Viscusi, *Risk Within Reason*, 248 SCIENCE 559 (1990); see generally Baruch Fischhoff et al., ACCEPTABLE RISK (1981).

⁶This paper discusses the bias against products which distort nature. This subsumes the bias against synthetic or artificial products. To illustrate (in the context of animal drugs), the bias that this paper discusses would be against giving any growth producing hormones to an animal. The bias would include feeding cows synthetic compounds (such as DES) and feeding cows naturally occurring compounds (such as estrogen) that they don't normally get in their diet. Henceforth, I shall refer to the bias against products which distort nature and the bias against artificial products interchangeably.

⁷Paul Slovic, *Perception of Risk*, 236 SCIENCE 280, 283 (1987).

unobservable, or unforeseen effect. This bias is especially evident in the context of cumulative and delayed food risks, most notably the risk of cancer.⁸ In the context of food safety, this bias is reflected in reasoning such as: Natural food must be safe... people have eaten it for hundreds of years. In effect, people perceive a world in which nature is safe and anything added to nature is unsafe.

The bias against additions to nature is enhanced by many factors. The regulatory system that we have established amplifies the bias by making the public aware of the risks of artificial additives rather than natural foods. Mar, DES, saccharin and similar non-natural compounds come to mind when people think of the risk from food. News media coverage of hazards of these artificial compounds signals people that these are the types of risks with which they should be concerned.⁹ Risks are communicated and amplified through a complex combination of social and cultural mechanisms.¹⁰ Once formed, strong beliefs are hard to modify.¹¹ Furthermore, people have difficulty comprehending low-probability events, and systematically overestimate the probability of low-

⁸See *id* Cancer is particularly feared because of its dreaded nature. Cancer is a risk that is perceived as being untreatable. potentially global, involuntary, and posing a risk to future generations. Dreaded is another type of risk that the psychometric model predicts people will be biased against. *Id*

⁹See, e.g., *How a PR Firm Executed the Alar Scare*, WALL Sr. J.. Oct. 3, 1989, at A22.

¹⁰Roger E. Kasperson et al., *The Social Amplification of Risk: A Conceptual Framework*, 8 RISK ANALYSIS 177(1988). In the food safety context, Lewis A. Segall has noted: The case of alar on apples seems a good example of how cultural meanings (in this instance the possibility of cancer in the school lunchbox) may play a significant role in shaping regulatory policy .. Food regulation. .. operates in a world of cultural meanings. The point is not that these cultural meanings are wrong or misguided, much less that they should determine regulatory decisions. Rather it is that accounting for culture may give a fuller account of the dynamics of regulatory policy. Letter from Lewis A. Segall to Peter B. Hutt (April 12, 1990) in PETER B. Hurr & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 36 (2d ed. 1991).

¹¹Paul Slovic, *Informing and Educating the Public About Risk*, 6 RISK ANALYSIS 403, 405 (1986). Generally, new evidence that confirms one's initial beliefs is accepted as reliable; conversely, new evidence that contradicts one's initial beliefs is dismissed as unreliable. *See id*

probability events.¹² The most heavily regulated food safety risks – those from carcinogens – usually represent extremely small probabilities. However, people cannot readily perceive the difference between probabilities of 10^{-7} and 10^{-8} , and thus cannot readily understand health standards which distinguish between the two. If people cannot differentiate between these probabilities, they are even more likely to rely on their bias against additions.

D. The Bias Against Additions to Nature is Irrational for Carcinogens

As discussed above, it is not necessarily irrational for people to be more skeptical of artificial products than natural products. The heuristic that people use is simple: people live for a long time today and therefore nature cannot be very harmful... what we really have to watch out for new foods that people haven't eaten for centuries. This heuristic may be useful, but only up to a point. The logical fallacies in this reasoning are apparent. First, people are not immortal. It may be the very foods that we have consumed for hundreds of years that cause us to live for only seventy years.¹³ Second, people's diets are not constant across time or cultures. Many of us are eating plants (such as coffee and potatoes) that are ancestors did not. In addition to the faulty logical reasoning of this heuristic, recent scientific evidence has called into question the basic assumption that nature is safe.

¹²See Zeckhauser & Viscusi. *supra* note 5. at 559; Fischhoff, *supra* note 5.

¹³This issue can be viewed in a more scientific framework. There is no reason to think that natural selection would eliminate the hazard of carcinogenicity of a toxin that causes cancer in old age past the reproductive age. Natural selection would, however, lead to a resistance to acute effects of carcinogens. See Bruce N. Ames et al.. *Ranking Possible Carcinogenic Hazards*, 236 SCIENCE 271, 277 (1987).

The concern about controlling the risks of non-natural food carcinogens is misplaced given the significant amount of new evidence showing that the risk of cancer from natural foods dwarfs the risk from non-natural foods. Scientific studies have examined a variety of natural foods and concluded that their carcinogenic potential is often greater than many additives that have been banned because of their carcinogenicity.¹⁴ This scientific evidence has led the director of the

FDA's Office of Toxicological Studies to conclude that the risk... from natural carcinogens in the diet... overwhelm the risk from food additives.¹⁵ Furthermore, although about half of all the artificial chemicals tested in labs have been found to be carcinogenic¹⁶, leading risk assessors have concluded that

¹⁴See, e.g., Bruce N. Ames et al., *Ranking Possible Carcinogenic Hazards*, 236 *SCIENCE* 271 (1987); Bruce N. Ames, *Dietary Carcinogens and Anticarcinogens*, 221 *SCIENCE* 1256 (1983); see also Prival, *Carcinogens and Nutrients Present as Natural Components of Food or Induced by Cooking*, 6 *Nutr. Cancer* 236 (1985); Doll & Peto, *The Causes of Cancer: Quantitative Estimates of A voidable Risks of Cancer in the United States Today*, 66 *J. NAT'L CANCER INST.* 1192, 1256 (1981) (estimating that approximately 35 percent of all cancer deaths are caused by diet, but only approximately 1 percent are caused by food additives); COMMITTEE ON DIET, NUTRITION, AND CANCER OF THE NATIONAL RESEARCH COUNCIL, *DIET, NUTRITION AND CANCER* (1982) (suggesting a highly significant correlation between traditional foods and cancer incidence).

¹⁵*Healthy Food.ijania Rolls on, but How Healthy is Healthy? Frozen Foods in North America*, 32 *QUICK FROZEN FOODS INT'L* 201(1990) (quoting Dr. Robert J. Scheuplein). Dr. Scheuplein has concluded that over 98 percent of the cancer risk in the human diet comes from natural carcinogens or from cooking foods. *Experts Question Science Behind Health and Safety Regulations*, *PR NEWSWIRE (FINANCIAL NEWS)* (May 21, 1991); Daniel P. Puzo, *Pesticide Cancer Risk Downplayed*, *L.A. TIMES*, July 19, 1990, at H2. Although Scheuplein's assumptions have been challenged by some health advocates (see Lisa Y. Lefferts, *Carcinogens au naturel? Claims That Natural Carcinogens Outweigh the Risks from Pesticides*, 17 *NUTRITION ACTION NEWSLETTER* 1 (CENTER FOR SCIENCE IN THE PUBLIC INTEREST) (July 1990)), his conclusions are largely a result of the accurate assumption that people eat a great deal more natural food than chemical compounds. See Hemminki et al., 1 *J. ENVIRON. SCI. HEALTH* 55 (1983). Furthermore, Dr. Scheuplein's qualifications as the leading FDA risk assessment official have not been called into serious question.

¹⁶See, e.g., Haselman et al., *Results from 86 Two-Year Carcinogenicity Studies Conducted by the National Toxicology Program*, 14 *J. Tox. & ENVIRON. HEALTH* 621, 634 (1984). See also Richard A. Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 *YALE J. ON REQ.* 1, 17-18 (1988) (describing results of some NTP studies).

this same proportion may very well hold for natural foods.¹⁷ Thus, it appears that the public fear of artificial additives is misplaced given the high incidence of naturally occurring carcinogens. We certainly don't live in a world in which nature is benevolent.

II. THE STATUTORY SCHEME:

JIRRATIONALITY REFLECTED AND AMPLIFIED

The previous section discussed how people have a general bias against non-natural additives to food. This section will examine how the current food safety standards both reflect this bias and amplify it. The food safety provisions of the Food, Drug, and Cosmetic Act (FD&C Act) are based on an unstated assumption that a traditional diet of natural foods is risk free. This assumption may be proper in the context of acute health risks. However, in light of the current evidence, this assumption should not be maintained in the context of the risks from cancer.

Furthermore, the food safety standards magnify people's natural bias against artificial substances by maintaining a regulatory system that calls the safety of those substances into question without examining the same risks in natural substances. Finally, this section will examine the inconsistencies in the FD&C Act that the FDA and the courts have attempted to make workable.

*A. A Statutory Overview*¹⁸

¹⁷Robert E. Taylor, *Puttin the Money Where the Math Is*, GOVERNMENT EXEC. (Apr. 1990) (referring to the conclusions of various government officials).

¹⁸This discussion is only intended to highlight the differential treatment of natural and added ingredients under the FD&C Act. For a complete and insightful discussion of the finer nuances of the food safety provisions of the FD&C Act see Richard A. 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(1979).

The Food and Drugs Act of 1906 originally defined an adulterated food as one that contained any added poisonous or other deleterious ingredient which may render such article injurious to health.¹⁹ Since that time, the federal food safety provisions have drawn a distinction between harmful ingredients that are added to food and harmful ingredients naturally occurring in food. Congress enacted the present FD&C Act in 1938 to expand the regulation of toxic substances in food. Section 402(a)(1) states that a food is adulterated

[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.²⁰

The legislative history of the 1938 Act reveals that Congress was aware that some naturally occurring foods were hazardous, but inserted the second clause to avoid over-zealous FDA enforcement against those foods.²¹ In section 406, Congress also allowed for the establishment of tolerance levels for added constituents that were necessary or unavoidable in particular foods.²² The 1938 Act thus had three standards that applied depending on how a substance entered a food: (1) section 402(a)(1)'s ordinarily injurious standard applied to constituents that were not added; (2) section 402(a)(1)'s may render injurious standard applied to added constituents that were neither necessary

¹⁹Federal Food and Drugs Act of 1906, ch. 3915, § 7. 34 Stat. 768 (repealed 1938).

²⁰21 U.S.C. § 342(a)(1) (1994)

²¹See Merrill, *supra* note 18, at 186-87.

²²21 U.S.C. § 346 (1994)

or unavoidable; and (3) section 406 established tolerances for added constituents whose use was necessary or unavoidable.

Since 1938, Congress has amended the FD&C Act by carving out four categories of substances that are added to food for special treatment. Substances in each of these four categories must be approved by the FDA prior to their use in food. In 1954, Congress enacted the Pesticide Residues Amendment, now section 408 of the FD&C Act.²³ In 1958, Congress enacted the Food Additives Amendment, embodied in section 409 of the FD&C Act.²⁴ In 1960, Congress added the Color Additives Amendment, now section 706 of the FD&C Act.²⁵ Finally, in 1968, Congress enacted the Animal Drug Amendments, now section 512 of the FD&C Act.²⁶

One of the main problems of the current statutory scheme for the regulation of carcinogens is that food and drug regulation was initially designed to deal with acute causes of death.²⁷ As we have seen, the bias against non-natural substances may be rational in this context. However, the bias against non-natural substances is irrational in the context of carcinogens. Instead of establishing a different system for evaluating the carcinogenicity of foods, Congress has fit safety determinations for carcinogenic foods into the distinctions that were initially created to prevent the risk of death from acute effects. The result is an irrational policy for controlling the risks of carcinogens.²⁸

²³21 U.S.C. § 346a (1994)

²⁴21 U.S.C. § 348 (1994)

²⁵21 U.S.C. § 376 (1994)

²⁶21 U.S.C. § 360b (1994)

²⁷See Peter B. Hun, *Food and Drug Law: A Strong and Continuing Tradition*, 37 FOOD DRUG COSM. L.J. 123, 127 (1982).

²⁸The arguments established in this paper apply equally to other forms of chronic disease.

B. The Differential Treatment of Natural and Added Constituents

As discussed above, the FD&C Act generally categorizes and regulates food constituents based on their origin. For the purposes of our discussion, the constituents can be divided into three broad categories:

(1) Natural constituents of agricultural commodities (e.g., oxalic acid in spinach, ascorbic acid in oranges)

(2) Environmental contaminants of food, which are unavoidable in some foods (e.g., aflatoxins in peanuts, PCBs in fish)

(3) Substances used intentionally as food ingredients (e.g., sugar, sodium nitrite, food colorings) and substances that become constituents of food through their intentional use for other purposes (e.g., food packaging materials, animal drugs, and pesticides)

Thus, although the same constituent may fall into more than one category, it will be regulated differently depending on how it became a part of the final food product. The FDA regulation of chemicals is therefore highly dependent on the natural vs. non-natural distinction. Furthermore, this natural vs. non-natural distinction is crucial in determining a substance's treatment within the third category.

I. Natural Constituents

Under section 402(a)(1) of the FD&C Act, natural food constituents are regulated under the ordinarily injurious standard. In order for a substance to be considered ordinarily injurious, the substance must be injuri-

However, no other disease has seemed to catch the public's attention in quite the same way as cancer.

ous when eaten in ordinary quantities by ordinary consumers. The leading case interpreting this provision, *United States v. 1232 Cases of American Beauty Brand Oysters*,²⁹ determined that the clause did not apply in the context of oysters, some of which contained dangerous shell fragments. The ordinarily injurious standard is rarely utilized by the FDA and is enforced primarily through seizure or other court action.³⁰

2. Unavoidable and Added Food Constituents

Unavoidable and added food constituents, such as environmental contaminants, are currently regulated under two standards. First, the FDA may bring an enforcement action under 402(a)(1) against any food that bears or contains any poisonous or deleterious substance which may render it injurious to health. The leading case interpreting the may render injurious standard is *United States v. Lexington Mill & Elevator Co.*³¹ The Court in this case stated the particular individuals to whom the food might be fed could be taken into account. Thus the strong and the weak, the old and the young, the well and the sick need to be considered.³² Although this standard is easier to meet than the ordinarily injurious standard, it too must be enforced through court action.

The second avenue that the FDA has used to regulate unavoidable and added food constituents is through sections 402(a)(2)(A) and 406 of the FD&C Act. Section 402(a)(2)(A) states that a food is adulterated if it bears or contains any added poisonous or deleterious substance., which is unsafe within

²⁹43 F. Supp. 749 (W.D. Mo. 1942).

³⁰See Merrill. *supra* note 18, at 189.

³¹232 U.S. 239 (1914)

³²*Id* at 411.

the meaning of section 406....³³Section 406 allows the FDA to set tolerances for these substances based on their potential harm and their avoidability.³⁴ The FDA is not required to establish tolerances under section 406.³⁵ The FDA also cannot regulate an environmental contaminant under both section 406 and the may render injurious standard.³⁶ Section 406 affords the FDA the benefit of a premarket approval scheme. However, the FDA has not often established formal tolerances under section 406, and instead has often chosen to create informal action levels to guide enforcement of section 402(a)(1).³⁷

3. Food Additive ~ Color Additives, Animal Drugs, and Pesticides

These 4 categories of constituents have been singled out for special treatment by Congress based on their addition to foods. The regulation of these substances is complex, and this paper will not explore the intricacies of each provision. The regulation of these substances is stricter than the regulation of substances under 402(a)(1) in two important ways: first, each category is regulated through a premarket approval process; second, each category (with the exception of pesticides) gives special treatment to carcinogenic substances

³³21 U.S.C. § 342(a)(2)(A) (1994).

³⁴Section 406 provides: any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for the purposes of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a).. .. In determining the quantity of such added substances to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. 21 U.S.C. § 348 (1994).

³⁵ See *Young v. Community Nutrition Inst.*, 476 U.S. 974 (1986).

³⁶See 21 U.S.C. § 348 (1994).

³⁷Poisonous or Deleterious Substances in Food: Notice of Proposed Rulemaking, 39 Fed. Reg. 42743 (1994); see also Merrill, *supra* note 18, at 201 (explaining that the FDA's policy is caused by the expense of the procedural requirements to set formal tolerances).

through their Delaney Clauses. *a.Premarket approval*

The premarket approval system allows the FDA to enforce statutory standards much more effectively than any court enforcement mechanism. The failure of the original act to provide for the premarket approval of substances added was seen as a loophole.³⁸ Many serious health effects could be observed before the FDA could enjoin the use of a particular substance. The premarket licensing scheme effectively shifts the burden of proof from the FDA to the regulated industry. With a premarket approval system, the user must prove a substance to be safe before it can sell the food; without a premarket approval system, the FDA must prove the food to be unsafe before it removes the food from the market. Under the premarket approval system, the FDA is also permitted to establish conditions under which it believes the substances can be safely used. *b.Delaney Clause*

The Delaney Clause was first introduced along with the Food Additive Amendments. Its proper interpretation has been a source of constant struggle for the FDA, the courts and commentators.³⁹ The Delaney Clause was designed to prevent the addition to food of any substance that has been shown to induce cancer in man or animals. The clause in the Food Additives Amendment, now part of section 409 of the FD&C Act, is illustrative:

[N]o such regulation [authorizing the use of a food additive] shall issue if a fair evaluation of the data before the Secretary - (A) fails to establish

³⁸See S. REP. No. 2422. 85th Cong., 2d Sess. (1958).

³⁹See generally Richard A. Merrill, *FDA 's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 YALE J. ON REQ. 1 (1988).

that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be found 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....⁴⁰

The Delaney Clause in the color additive and animal drug provisions is similar. Originally, the FDA did not have a difficult time applying the Delaney Clause. In 1958, there were only four substances that were known to induce cancer in humans.⁴¹ In the 1970s, the ability of science to detect substances added to foods which induce cancer (at some level) increased dramatically.⁴² Thus, the FDA was forced to adopt policies to make the implementation of the Delaney Clause reasonable. Through administrative policy, the FDA has adopted a quantitative risk assessment method to evaluate the carcinogenicity of substances. The FDA has determined that the level of risk to humans must be greater than one in one million over a lifetime in order for a substance to be declared unsafe under the Delaney Clause.⁴³ However, an important court decision has since stated that the FDA must declare a color additive unsafe if it causes any risk of cancer in animals.⁴⁴ Thus, color additives which pose a

⁴⁰21 U.S.C. § 348(c)(3)(A) (1994).

⁴¹Listing of D&C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28331(1986).

⁴²See Merrill, *supra* note 37, at 12-16.

⁴³In the context of animal drugs, see the FDA sensitivity of method approach. Chemical Compounds in Food-Producing Animals: Criteria and Procedures for Evaluating Assays for Carcinogenic Residues, 44 Fed. Reg. 17070 (1979). In the context of food and color additives, FDA has declined to enforce the Delaney Clause against *de minimis* additives. See *Monsanto Co. v. Keunedy*, 613 F.2d 947 (D.C. Cir. 1979) (allowing the *de minimis* exception to be applied in the context of indirect food additives); Listing of D&C Orange No. 17 For Use in Externally Applied Drugs and Cosmetics. 51 Fed. Reg. 28331(1986) (applying the *de minimis* exception in the context of color additives).

⁴⁴*Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987). This case distinguished

lifetime risk to humans of only one in nineteen billion must be banned by the FDA.⁴⁵

4. The statutory definition of a food additive excludes GRAS and prior sanctioned substances

Another fundamental bias against substances which are non-natural in a sense is embraced in the definition of a food additive under section 201(s) of the FD&C Act. A food additive is defined as: any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food... if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or *experience based on common use in food*) to be safe under the conditions of its intended use; except that such term does not include –

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act or the Meat Inspection Act....

The definition applies to substances regardless of whether they can be found in nature or are manmade. However, the GRAS and the prior sanctions

Monsanto by noting that *Monsanto* involved the definition of a food additive. Thus, although the FDA may apply the *de minimis* exception to determine whether a substance is an additive, it may not apply the *de minimis* exception to determine whether a color additive induces cancer within the meaning of the Delaney Clause. It is unclear if the food additive or animal drug Delaney Clauses will be interpreted similarly in the future. See also, the constituents policy, discussed *infra*.

⁴⁵ *See id*

exception leave many commonly used foods out of the premarket system of regulation.⁴⁶ Although a substance's GRAS status may be changed, once a substance has been shown to have a prior sanction, it cannot be regulated as a food additive. Thus, the definition of a food additive again reveals the underlying premise of the FD&C Act: substances that we have eaten in the past are safe and it is only new substances that we must regulate strictly.⁴⁷ The FD&C Act also affords special treatment for color additives that were in use prior to 1960, although in milder form.⁴⁸

C. Determining Which Standard to Apply: Walking a Fine Line

The FD&C Act is structured by making distinctions based on the origin of substances. Furthermore, these distinctions are critical in determining whether a substance will be available to consumers. Thus, the FDA and the courts have often considered the issue of how to classify a substance. This section highlights the inconsistencies in the food safety regulations caused by the wide divergence of standards discussed in the previous section. The interpretations of the FD&C Act further illustrate the basic assumption of the Act that nature is safe, and the FDA's and the courts' attempt to regulate sensibly given important

⁴⁶The FDA lists substances that it considers to be GRAS. Furthermore, food processors are free to determine for themselves which food substances they use are GRAS. *See* 50 Fed. Reg. 27294 (1985); 53 Fed. Reg. 16544 (1988). This loophole, however, is rarely abused by food processors. *See* PETER B. HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 332-33 (2ded. 1991).

⁴⁷*See Federal Food, Drug, and Cosmetic Act (Chemical Additives in Food), Hearings before a Subcomm. of the House Comm. on Interstate and Foreign Commerce, 84th Cong., 2d Sess. (1956).*

⁴⁸Section 203 of the Color Additives Amendments allowed for the provisional listing of color additives that were already in use in 1960 and were believed to be safe. Although the provisional listing approach was designed as a transitional mechanism, FDA maintained a list of provisionally approved color additives for almost 30 years, which led to litigation. *See, e.g.,* Certified Color Mfrs. Ass'n v. Mathews, 543 F.2d 284 (D.C. Cir. 1976); Mclwain v. Hayes, 690 F.2d 1041 (D.C. Cir. 1982).

restrictions.

I. What is a Food Additive? a. The de minimis exception and the constituents policy

The *de minimis* exception was discussed above in the contexts of the food additive definition and the Delaney Clause. The application of the *de minimis* exception represents a recognition by the FDA that a literal interpretation of the statute would lead to absurd results. The second law of thermodynamics teaches that any two substances that contact each other will inevitably mix to some degree. In *Monsanto v. Kennedy*, the court avoided the result of banning many food packaging materials by invoking the *de minimis* doctrine to the definition of a food additive. However, the court in *Public Citizen v. Young* refused to extend this reasoning to the Delaney context. The two decisions thus create a stark tension: indirect food additives are regulated less strictly than color additives, and possibly direct food additives.

The constituents policy is consistent with the *de minimis* exception recognized in *Monsanto*. FDA takes the approach that:

- .. [T]he detection of a trace amount of a known carcinogenic substance naturally present in a food, or unavoidably added to a food in the course of its manufacture or processing does not invoke the anticancer clauses. It has been pointed out, for example, that there are small amounts of estrogenic substances, which are regarded as carcinogenic, naturally present in many foods. The anticancer clauses would be applicable, however, only if the food itself (containing the naturally-occurring substance) were, upon feeding to test animals

or some other appropriate test, found to induce cancer. If this were to happen, the food itself would then be prohibited for use as a food additive—i.e., for any use other than as an unprocessed raw agricultural commodity...⁴⁹

The FDA adopted this policy out of necessity; otherwise it would have been forced to bring thousands of foods under the strict premarket Delaney regulations.⁵⁰ Once again, this FDA policy highlights the intricate distinctions that the FD&C Act draws between natural and non-natural constituents. The constituents policy was upheld by the Sixth Circuit Court of Appeals in *Scott v. Food and Drug Administration*.⁵¹ Although the court in *Public Citizens v. Young* distinguished the facts with those of *Scott v. Food and Drug Administration*, the application of the two cases leads to potentially absurd results. To illustrate, suppose color additive A is found to be slightly carcinogenic in rats (with a risk of 10⁻⁶). Color additive B contains 1 percent color additive A and 99 percent of another component. Under *Public Citizens v. Young*, color

⁴⁹ *Agriculture–Environmental and Consumer Protection Appropriations for 1975, Hearings before a Subcomm. of the House Comm. on Appropriations*, 93d Cong., 2d Sess. (1974). As a point of interest, the FDA has appeared to adopt something similar to the constituents policy in the context of irradiated food. The definition of a food additive includes any source of radiation, but the FDA has interpreted this definition to require only the labeling of irradiated food products, and not the labeling of foods containing irradiated ingredients. See 46 Fed. Reg. 18992 (1981); 49 Fed. Reg. 5713 (1984); 51 Fed. Reg. 13376 (1986); 53 Fed. Reg. 53176 (1988); 54 Fed. Reg. 32335 (1989).

⁵⁰ The potential problems that the FDA would have encountered are illustrated by the FDA's regulation of sassafras tea. This tea is made from the bark of the sassafras tree. The bark contains safrole, from which it gets most of its flavor. In the 1950s, the FDA determined that safrole was carcinogenic. The agency therefore prohibited its addition to root beer and other soft drinks. 25 Fed. Reg. 12412 (1960). However, the FDA recognized a problem with banning sassafras bark. If the agency banned sassafras bark as a carcinogenic food additive under the Delaney Clause, it would be forced to ban other natural substances that contained carcinogens and were added to other foods. To avoid this result, the FDA distinguished sassafras bark by saying it was not independently consumed as a food. See 38 Fed. Reg. 20040 (1973); 39 Fed. Reg. 26748 (1974); 39 Fed. Reg. 34172 (1974); 41 Fed. Reg. 19207 (1976), codified in 21 C.F.R. § 189.180; *United States v. Articles of Food Select Natural Herb Tea, Sassafras, etc.*, 12 FDA consumer, No. 9, at 32 (C.D. Cal. 1978). The concurring opinion in *United States v. An Article of Food*, 678 F.2d 735 (7th Cir. 1982), provides an excellent summary of the sassafras tea case.

⁵¹ 728 F.2d 322 (1984).

additive A cannot be added directly to a food in any amount. However, under *Scott*, color additive B can be added to a food in almost any amount because color additive A is considered a constituent and not an additive in this alternate scenario. Furthermore, although in the *Scott* case the carcinogenic constituent was an impurity, it would be virtually impossible for the FDA under the current system to distinguish between impurities and intentionally added constituents. *Scott* thus appears fundamentally irreconcilable with *Public Citizens v. Young*.

b. The scope of the GRAS exception

The GRAS exception for substances commonly used in food applies upon a showing of a substantial history of consumption by a significant number of consumers in the United States.⁵² Important in the common use GRAS exception is the fact that the substance must be shown to be safe under the conditions of its intended use.⁵³ Thus, the court in *United States v. An Article of Food* held that potassium nitrate would not be considered GRAS for use in beverages despite the fact that nitrates are naturally present in vegetables and have long been used to cure meat. An obvious inconsistency results: the same substance is an additive for new uses but not for old uses. New uses will require premarket approval and be subject to the strict requirements of the Delaney Clause, while old uses can only be regulated under the may render injurious standard for added constituents under section 402(a)(1). A product's GRAS status is always subject to revocation based on evidence casting doubt on its safety. However, the revocation approach that the courts have taken again favors

⁵² See General Recognition of Safety and Prior Sanctions for Food Ingredients. 41 Fed. Reg. 53600 (1976).

⁵³ *United States v. An Article of Food*, 752 F.2d 11(1st Cir. 1985)

natural foods over non-natural foods.

The revocation of GRAS status for substances that are carcinogenic presents interesting issues regarding the interaction between the definition of a food additive and the Delaney Clause. Officially, the FDA will not recognize substances that are carcinogenic as GRAS.⁵⁴ Since the substances then fall under the definition of a food additive, they are then regulated under the Delaney Clause.⁵⁵ However, the FDA has adopted an important exception to the revocation of GRAS status because of its realization that most natural substances are carcinogenic to some degree. Thus, although a substance found to be carcinogenic in test animals cannot be regarded as GRAS, a substance that contains a carcinogenic constituent can be regarded as GRAS.⁵⁶ This GRAS constituents policy leads to the confusing result that substances (such as mustard seed) remain GRAS, while their primary flavoring ingredients (such as allyl isothiocyanate) cannot remain GRAS. The FDA was, in a sense, forced to make this policy choice because of the severe divergence in the regulation of natural and added substances. The FDA simply does not have the resources to consider natural products as food additives and require premarket approval and the application of the Delaney Clause. Thus, the FDA was consistent in adopting both the constituents policy and the GRAS constituents policy.

2. Added vs. not added

⁵⁴An example of this is the removal of cyclamate from the FDA's GRAS list because of evidence of carcinogenicity. See 34 Fed. Reg. 17063 (1969).

⁵⁵See Merrill, *supra* note 18, at 212.

⁵⁶See, e.g., 'Agriculture, Rural Development and Related Agencies Appropriations for 1984, Hearings Before a Subcomm. of the House Comm. on Appropriations, 98th Cong., 1st Sess., at 475 (1983).

The FD&C Act fails to define an added substance in section 402(a)(1). The FDA and the courts have developed two different standards to determine whether a substance is added. The FDA and some courts have adopted the inherency standard, which posits that all substances that are not inherent in the natural state of a food are added.⁵⁷ Other courts have adopted an agency theory, which posits that a substance can be considered added only if at least a small amount is present due to human intervention.⁵⁸ The choice of a definition is critical to determine the proper treatment of substances, such as aflatoxins in corn and peanuts, that are not inherent in a substance yet are not caused by man.⁵⁹ If a substance is not added, it can only be regulated under the difficult to enforce ordinarily injurious standard. However, if a substance is considered added, it may be regulated under the may render injurious standard. Additionally, formal tolerances may be established for some added constituents under section 406, and the burden of proof shifts to the manufacturer.⁶⁰ The FDA adopted the expansive definition of added substances because they saw a serious potential health threat from substances, such as aflatoxins, that were not added by man. The illogic behind the different standards for added and non-added substances can be illustrated by examining the FDA's inherency standard. If spinach naturally contains oxalic acid, and oxalic acid is harmful to man, the

⁵⁷See 21 C.F.R. § 109.3: *see also* United States v. Boston Farm Center, Inc., 590 F.2d 149 (5th Cir. 1979).

⁵⁸See United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980); *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38, 43 (D.C. Cir. 1982).

⁵⁹Aflatoxins present in corn, peanuts, and other natural foods are a product of molds which inevitably grow on these foods.

⁶⁰Although formal tolerances have rarely been set, informal action levels, which also aid the FDA's enforcement efforts, are more frequently set. *See* HurT & MERRILL, *supra* note 44, at 907.

FDA can ban spinach by proving spinach to be ordinarily injurious. However, if corn contains aflatoxins because of its symbiotic natural relationship with mold, the FDA can ban corn by proving corn may be injurious. Additionally (and more importantly), the FDA has the power to enact tolerances or action levels for aflatoxins in corn, but has no such power to regulate the level of oxalic acid in spinach.

3. Added substance vs. 'food additive

The definitions of an added substance to food and a food additive have led to some strange FDA policies. The FDA has established regulations that state that environmental contaminants, such as PCBs, are added substances within the meaning of sections 402(a)(1) and 406.⁶¹ Furthermore, the FDA has determined that aflatoxins in peanuts are added substances.⁶² However, the FDA's explanation for why PCBs are not food additives within the meaning of section 409 has been less than convincing.⁶³ Additionally, the FDA has never attempted to explain why the peanuts containing carcinogenic aflatoxins are not food additives when used to make peanut butter.⁶⁴ The FDA's approach in this area can again be seen as trying to find a middle ground between the widely divergent standards applicable to natural food constituents and non-natural food constituents.

D. Ad Hoc Fixes

⁶¹ See Department of Health, Educ., & Welfare, Food & Drug Admin.: Poisonous or Deleterious Substances in Food, 39 Fed. Reg. 42743 (1974).

⁶² See 39 Fed. Reg. 42748 (1974).

⁶³ See Merrill, *supra* note 37, at 23. The FDA reasoned that PCBs could not be food additives because they performed no functional purpose in food. See 39 Fed. Reg. 42746 (1974).

⁶⁴ See Merrill, *supra* note 37, at 23; Young v. Community Nutrition Inst., 476 U.S. 974 (1986).

Congress has had the chance to reexamine the inconsistencies and biases in the food safety provisions a number of times. However, Congress has chosen to fix such problems on an ad hoc rather than a comprehensive basis. Two of the more well-known incidents are in the context of DES and saccharin. Such incidents have led the public to distrust the FDA and further focus on the problems with artificial ingredients.

1. The DES proviso

Congress enacted the DES proviso to eliminate one of the inconsistencies caused by the prior sanctioned uses exception to the food additive definition. Thus, Congress decided to allow the continued approval of animal drugs as long as no residues could be found in humans.⁶⁵ However, as we have seen in the context of both the GRAS exception and the prior sanctioned uses exception, there is a bias against approving new food additives in general. Congress chose to fix only one aspect of the problem rather than fixing its source.

2. Saccharin

The FDA banned a series of non-nutritive sweeteners under the Delaney Clause in the 1960s. Following the removal of cyclamate from the market in 1970, saccharin was the only non-nutritive sweetener left on the market. In 1977, the FDA proposed to ban saccharin under the Delaney Clause after determining that it increased the risk of cancer by 4 out of 10,000 over a lifetime.⁶⁶ Following this proposal, Congress interceded and forbade the FDA from banning

⁶⁵21 U.S.C. § 348 (1994).

⁶⁶*See*, Saccharin and Its Salts: Proposed Rule Making, 42 Fed. Reg. 19996 (1977).

saccharin. Instead, Congress required that warnings about the risk of cancer be placed on all food containing saccharin.⁶⁷ A few troubling consequences of this saga should be noted. First, Congressional intervention caused saccharin to have a monopoly on the non-nutritive sweetener market until the introduction of aspartame in 1983. Not only did saccharin corner the market during this time, it was also more dangerous than some of the other non-nutritive sweeteners that had already been banned.⁶⁸ Furthermore, requiring a warning on saccharin, but not on carcinogens with similar risks, such as peanut butter, has led to increased public focus on the carcinogenic potential of artificial ingredients. The labeling of saccharin has exacerbated people's built-in bias against non-natural products.

LII. THE FOOD SAFETY STANDARDS ARE MISGUIDED TN THEIR

APPROACH TO REDUCE THE RISK OF HARM FROM FOOD

As discussed above, the food safety provisions of the FD&C Act implicitly assumes that we live in a world in which nature is benevolent. Relatively recent scientific evidence shows that this basic assumption is improper. Furthermore, because of its bias in favor of natural⁶⁹ ingredients, the FD&C

⁶⁷21 U.S.C. § 343 (1994).

⁶⁸AF-2 (furfuramide) was banned with a risk more than a 100 times smaller than the risk from saccharin. See Bruce N. Ames et al., *Ranking Possible Carcinogenic Hazards*, 236 *SCIENCE* 271, 273 (1987). Additionally, in 1985 FDA's Cancer Assessment Committee concluded that cyclamate is not a carcinogen, but other reports have stated that cyclamate may be a tumor promoter or co-carcinogen. See *Cyclamate Update*, FDA Talk paper T89-35 (May 16, 1989).

⁶⁹Again, this bias subsumes the bias against artificial ingredients and also includes the bias against eating things that haven't been a part of the human diet in the past. Thus, estrogens that are naturally contained in a cow would be natural and any estrogens that wouldn't normally be fed to cows would be non-natural.

Act unwisely focuses on the origin of carcinogenic food constituents rather than on their health effects. This focus has caused the FDA to needlessly litigate the confusing boundaries of the different standards at a great expense.

A. The Bias in Favor of Natural Ingredients Results in Misplaced Resources in Attempting to

Eliminate Health Risks

I. The Air Pollution Analogy and the Goal of Effective Regulation

The regulatory system under the FD&C Act can be analogized to pollution emission limits under the Clean Air Act.⁷⁰ The Clean Air Act is premised on the assumption of a starting point of clean air. That is why it is rational to try to prevent emissions into that clean air. However, if it were discovered that the air emissions were only contributing about one percent of the total air pollutants, while the remaining 99 percent was naturally occurring, the rationale of the Clean Air Act would be called into question. People would suggest that it would be wise to divert resources from curbing emissions to reducing naturally occurring pollution. The goal would be to reduce the overall level of emission as much as possible with as few resources as possible. We would attempt to eliminate the risks in the most cost-effective manner. This is the fundamental flaw of the food safety provisions of the FD&C Act. Section 402(a)(1), combined with the GRAS and prior sanctioned uses exceptions to the food additive definition, basically make it impossible for the FDA to ban any natural substance with long-term chronic health effects. In contrast, the provisions that

⁷⁰This approach was suggested in Richard A. Merrill, *Reducing Diet-Induced Cancer Through Federal Regulation: Opportunities and Obstacles*, 38 VAND. L. REV. 513, 522 (1985).

govern food additives, color additives, animal drugs, and pesticides require the FDA to ban useful substances that pose virtually no risk to human health. This leads us to the inevitable conclusion that our current system makes us pay more dollars for our products and end up with greater risks to our lives.⁷¹

2. The Justifications for the Distinctions in the FD&C Act Merely Reflect the FD&C Act's Bias Against Non-Natural Foods.

Some have attempted to justify the differential treatment of additives based on the principle that Congress wished to permit no additional human cancer risk from food additives, color additives, or animal drugs.⁷² This reasoning was embraced by the leading case that applied the general safety standard to reject a new drug application for DES: The existence of natural estrogen in foodstuffs does not warrant the intake of DES by a deliberate means of exposure.⁷³ However, this justification for the structure of the FD&C Act is flawed in two respects. First, the GRAS and prior sanctioned uses exceptions to the food additives definition (combined with the constituents and GRAS constituents policies) don't lead to a regulation of additives over non-additives. Instead, they lead to a regulation of non-natural foods over natural foods. Second, this justification ignores the fact the goal of the FD&C Act should be to reduce health safety risks in the most cost-effective manner. The distinction between adding to the risk and lowering the risk is useless; the costs and benefits of regulations must be weighed. This justification is premised on the same faulty

⁷¹See Richard J. Zeckhauser & W. Kip Viscusi, *Risk Within Reason*, 248 SCIENCE 559, 560 (1990).

⁷²Chemical Compounds in Food-Producing Animals: Criteria and Procedures for Evaluating Assays for Carcinogenic Residues, 44 Fed. Reg. 17070 (1979).

⁷³Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).

assumption of the FD&C Act that natural foods are safe.

One commentator has attempted to justify the current system by arguing that the diverse safety standards represent an assessment of the benefits of the food categories rather than an assessment of the risks.⁷⁴ Although this justification makes some sense, it falls well short of completely defending the widely divergent standards. According to this formulation, the FD&C Act reflects differences in our capacity or willingness to limit human exposure to various substances. Thus, it is easy for regulators to make it a crime to add hazardous substances to food. It is more difficult for regulators to limit environmental contaminants such as PCBs in fish. Finally, it would be even more difficult to limit the exposure to unprocessed raw agricultural commodities. This argument thus validly shifts the focus from the benefits of avoiding various health risks to the *costs of avoiding various health risks*⁷⁵. The costs of avoiding various health risks would involve the actual costs of the regulatory system in addition to the costs of having to conform to the regulations. If we examine the food safety provisions closely, however, we can see that this justification for the different standards is not adequate. In fact, what are at first glance cost issues, upon reflection become other examples of the bias that people have against non-natural substances.

The costs of the regulatory system would appear to be higher for unprocessed raw agricultural commodities than for food additives. However, the costs of regulation would only be higher because of the large amount of natural

⁷⁴ See Merrill. *supra* note 67, at 526.

⁷⁵ Alternatively, the argument can be thought of as shifting the focus from the costs of having various health risks in foods to the benefits of having various health risks in foods.

substances in our diet. This is why a system that required premarket approval of natural substances would cost more than a system that required premarket approval of environmental contaminants or additives. However, this distinction does not address the cost-effectiveness issue. Our goal should be to eliminate health risks as cheaply as possible. It is not a proper response to assert that we should regulate the minimal risks because there are so many greater risks that would put a burden on our regulatory system.

Conforming to the food safety regulations leads to one of two costs: the cost of a food being banned or, alternatively, the cost of eliminating the health risk of that food.⁷⁶ Again, at first glance it might appear that the food safety standards can be justified because the cost of banning natural substances might be higher than the cost of banning food with environmental contaminants, which would be higher than the cost of banning food constituents. However, it is difficult to argue that the cost of banning a vegetable with many nutritional substitutes (such as broccoli) is greater than the cost of banning a valuable food additive with no nutritional substitutes (such as saccharin). It can be generally asserted that people value natural foods more highly than additives to nature. The wisdom⁷⁷ and accuracy⁷⁸ of this assertion can be doubted. However, assuming its truth, the FDA bans so-called additives to nature (such

⁷⁶It is also possible that the food will conform to the regulations without any cost.

⁷⁷If people do value natural foods more than non-natural foods, it would most likely be because of the perceived higher risks of natural foods. Again, this is the fundamental assumption of the FD&C Act that flies in the face of scientific evidence.

⁷⁸It is extremely hard to estimate how people value particular foods. Thus, although a great many people may consume broccoli, it is impossible to quantify how much more pleasure they get from consuming broccoli over consuming potential broccoli substitutes (such as asparagus, cauliflower, peas, etc.). Similarly, it is difficult to estimate the costs that manufacturers must expend because they can only use food additives that have been approved by the FDA.

as allyl isothiocyanate) that are the primary flavor enhancers of natural foods that it won't ban under the constituents policy or the GRAS exception (such as mustard seed). Furthermore, the FD&C Act does not allow for individualized determination of the benefits of a food additive in determining whether it should be banned. It implicitly assumes that natural substances are inherently more valuable than non-natural substances, which is dubious given the known utility of pesticides, animal drugs, and food and color additives.

The FD&C Act similarly cannot be justified on the grounds that it is cheaper to eliminate the health hazards in food additives than in natural foods. The FD&C is flawed precisely because it provides no incentives whatsoever for producers of agricultural commodities to eliminate the hazardous materials from their products. Certainly, no suits will be successful against natural products that have long-term health effects, such as broccoli. The constituents policy combined with the GRAS constituents policy has the effect of locking out natural products from the definition of food additives. Furthermore, any suits against natural products under section 402(a)(1) will undoubtedly be unsuccessful.

We cannot assess the potential ability to eliminate the risk of cancer from natural substances. Technology follows the legal incentives provided for it, and it is clear that the FD&C Act has not forced technology to develop any methods to eliminate carcinogenic substances in natural foods. Instead, the legal regime has provided incentives for manufacturers to develop a vast number of non-natural products in the hope that some cost-effective ones will pass the rigid requirements of the food safety standards. The FD&C Act does

have one limited provision, section 406, which allows the FDA to set tolerances for substances based on the ability of manufacturers to eliminate carcinogenic constituents.⁷⁹ However, this section is limited to unavoidable, added food constituents. However, whether a constituent is added is a semantic question, as evidenced by the various interpretations of added by the FDA and the courts. There is no reasonable explanation for having tolerances for PCBs in fish (the level of which fish producers have no control over) and not having tolerances for allyl isothiocyanate in broccoli (the level of which broccoli producers have no control over). The only real distinction is the bias that people have against non-natural products.

3. The FD&C Act Provides Perverse Incentives for Producers to Increase the Carcinogenicity of Common Food Products

Once we recognize that natural foods contain significant amounts of carcinogens, it becomes relevant to examine the incentives that the FD&C Act provides to increase the carcinogenicity of natural foods. For centuries, agricultural producers have attempted to breed plants that are resistant to insects. In effect, farmers have chosen to breed plants that have a high content of nature's pesticides.⁸⁰ The FD&C Act simply fails to regulate the carcinogens that are present in natural foods, thereby allowing natural food producers

⁷⁹See Aflatoxins in Shelled Peanuts and Peanut Products Used as Human Foods: Proposed Tolerance, 39 Fed. Reg. 42748 (1974). In determining what tolerance level to set, the Commissioner explicitly assessed the ability of peanut butter manufacturers to meet the tolerance. Thus, in setting tolerances, the FDA must weigh the health risk posed by a particular substance with the higher prices caused by limiting the production of that substance. *See id.* The agency, in deciding when to apply section 406, also implicitly weighs the benefits provided by particular foods. *See Merrill, supra* note 18, at 200.

⁸⁰The conclusion that many toxic substances found in plants are natural pesticides was originally made by Bruce N Ames, *Dietary Carcinogens and Anticarcinogens*, 221 SCIENCE 1256, 1258 (1983).

to increase the carcinogenicity of their foods. Thus, the FD&C Act prohibits the addition of pesticides that cause a very small risk of cancer and allows the creation of new plant varieties that are intended to have similar carcinogenic chemicals. The manual addition of pesticides is likely more cost-effective than the breeding of plant strains, but the FD&C Act provides incentives to engage in the less cost-effective activity. A similar problem can be seen with the FD&C Act's treatment of animal drugs.

Again, for centuries meat producers have been selecting the biggest animals to breed. Thus, animals that people eat today undoubtedly contain more natural growth hormones than animals people ate years ago. However, any attempt to add more natural growth hormones (such as estrogens) directly will be met with strict FDA regulations. Thus, the FD&C Act once again allows the indirect addition of carcinogenic substances and prohibits the direct addition of the same or similar substances. Meat producers will have distorted incentives to breed larger animals.

The perverse incentives given to plant and animal breeders once again reflects the bias that people have against non-natural foods⁸¹. People view breeding as natural because it has been done for centuries. In contrast, the advent of new technologies has made it possible to add chemicals to products only recently. Thus, the addition of pesticides and animal drugs is regulated while the natural selection of the same chemicals is not, despite the fact that the ultimate effect is the same in both cases.

⁸¹This example highlights that non-natural foods are foods with synthetic chemicals or foods made through processes that haven't historically been done in the past.

B. The FD&C Act's Focus on the Natural vs. Non-natural Distinction Leads to Excessive

Litigation over the Wrong Issues and Produces Inconsistencies

As discussed above, the central background assumption on which the food safety provisions are based is that nature is safe. Since the FD&C Act assumes that nature is safe, only products that distort nature are regulated. This is the true reason for the FDA's focus on the origin or purpose of food constituents rather than on the final composition of food sold to consumers. In effect, the FDA deems a food to be adulterated based more on how the food was created than on what harmful substances are in the food. This focus on a food's recipe has led to a great deal of litigation that examines exactly how a food was created. Furthermore, the recipe method of regulation has produced severe inconsistencies in the law that cannot be justified.

J. Excessive Litigation over the Wrong Issues

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The FDA and the courts have attempted to make the various provisions of the FD&C Act workable, but their attempts have led to a great deal of litigation over the application of various food standards. For example, the FDA determined that some environmental contaminants were not produced by man, but still caused significant health risks to humans (such as aflatoxins in corn and peanuts). The FDA thus developed the inherency doctrine, which led to litigation because the statutory standard was unclear. Furthermore, the GRAS and prior sanctioned uses exceptions to the food additives definition have

caused large expenses to determine exactly when particular substances are not food additives.⁸² The FDA's attempts to make the Delaney Clause workable have also led to a great deal of litigation.⁸³

2. Inconsistencies

The many inconsistencies created by the FD&C Act have been examined in the context of individual provisions. If we examine these inconsistencies, we can see that they are all caused by the focus on the recipe of a food. FDA and court attempts to minimize the divergent treatment between natural and non-natural substances illustrate these inconsistencies. The major inconsistencies include:

(1) the differential treatment afforded to added and non-added ingredients is inconsistent given the scope of the FDA's interpretation of added. The inherency doctrine draws a false distinction between substances that are naturally contained within a product, and substances that enter a product through unavoidable natural processes.

(2) the bias against natural substances led to the GRAS and prior sanctioned uses exception. This bias is highlighted by the fact that the GRAS prior use exception and the prior sanctioned use exception apply to only the

⁸²The FDA expends considerable resources compiling lists of GRAS substances. *Cf* HUTT AND MERRILL, *supra* note 44, at 33241. Additionally, cases are often litigated regarding the scope of the GRAS exception for various substances. *See, e.g.*, *United States v. An Article of Food*, 752 F.2d 11 (1st Cir. 1985); *United States v. Articles of Food... Buffalo Jerky*, 456 F. Supp. 207 (D. Neb. 1978), *aff'd per curiam*, 594 F.2d 869 (8th Cir. 1979); *United States v. An Article of Food*, 678 F.2d 735 (7th Cir. 1982). One commentator has noted that the prior sanctioned uses exception has become a great source of business for archivists. *See* Merrill, *supra* note 18, at 215.

⁸³*See, e.g.*, *Monsanto Co. v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979); *Public Citizen v. Young*, 831 F.2d 1108 (DC. Cir 1987), *Scott v. Food and Drug Admin.*, 728 F.2d 322 (6th Cir. 1984).

actual uses before 1958. Thus, potassium nitrate can be added to meat because it was added to meat before 1958, but it cannot be added to beverages.

(3) The FDA's attempts to limit the effects of the Delaney clause have been partially successful and have led to additional inconsistencies. Courts have upheld the FDA's constituents policy yet rejected the FDA's *de minimis* policy in the context of color additives. This leads to the bizarre result that a manufacturer can use a color additive known to contain a small amount of a carcinogenic color additive, but cannot use minute quantities of the carcinogenic color additive directly.

Although these examples do not exhaust the inconsistencies in the FD&C Act, they are illustrative of the bizarre results caused by an inquiry into a food's recipe. Such bizarre results, if publicly known, would certainly lead the public to question the wisdom of the FD&C Act and the FDA.

C. Public Reaction and Distrust in the FDA

The risk from natural carcinogens has not been adequately brought to the public's attention. Most people are aware of the carcinogenic potential of saccharin; few are aware of the carcinogenic potential of peanuts. This is partially a result of the statutory scheme of the FD&C Act. It is difficult to judge the public's reaction if they were made aware of the carcinogenic potential of natural foods. It is possible that they would call for stricter regulation of natural foods, and it is also possible that they would call for less regulation of non-natural foods. However, the public has not been given the chance to examine the proper issues in regulating health risks: how much are we willing

to pay to eliminate health risks, and how can we eliminate the health risks effectively?⁸⁴ The FD&C Act ensures that the media will receive a steady feed of information about the carcinogenicity of various substances added to food. In contrast, because the FD&C Act does not provide for the testing of natural substances, the media will have relatively little information to report regarding the carcinogenicity of natural substances. As a result of this dichotomy, people improperly presume that the risk from carcinogenic food additives is large and can be easily eliminated through a strict regulatory system.

The current regulatory system involves a potential indirect cost. Although the public is not currently aware of the extent to which natural foods cause cancer, they may be made aware in the future. If this happens, the effectiveness of the FDA in protecting the public from health risks will undoubtedly be questioned. This will lead people to distrust the FDA and lead people to question other FDA policies. Trust destroying events carry much greater weight in people's minds than trust-building events.⁸⁵ Thus, one negative event can effectively destroy much of the public trust that the FDA has managed to accumulate over the years.

IV. PROPOSALS FOR THE FUTURE

A. A Return to the Air Pollution Analogy

The air pollution analogy described above provides a good example

⁸⁴Congress has not attempted to address these important public policy questions in a comprehensive manner. Thus, although these issues appeared when Congress overrode the FDA's proposed ban of saccharin, these issues have not appeared when other useful substances have been banned by the FDA. Additionally, the issue of how much people are willing to give up to forego dangerous natural substances (such as peanuts) has not been properly addressed in a public forum.

⁸⁵See Paul Slovic, *Perceived Risk, Trust, and Democracy*, 13 RISK ANALYSIS 675, 677 (1993).

of the proper regulatory approach to control the health risks of cancer. The case of global warming caused by CO₂ is illustrative. As the consequences of global warming have become more predictable, many have suggested formulating policies to eliminate the future effects of global warming. The analogy between the risk of global warming and the risk of cancer is close: both situations involve cumulative, long-term risks; uncertain science and significant background levels. The most recent proposals for eliminating the potential effects of global warring have concluded that two stages should be distinguished: first, a target should be set for the total atmospheric CO₂ level; second, the total level of atmospheric CO₂ should be achieved as cheaply as possible. Thus, the most workable proposals for the elimination of carbon dioxide allow countries to meet their reduction requirements by lowering background levels of carbon dioxide (by planting trees, for example). Countries will thus be able to meet the requirements cost-effectively. A similar two stage system needs to be enacted to effectively reduce the health risk of cancer. This system will also likely call for a reduction of risk by lowering the background levels of cancer.

B. Statutory Amendments

1. The First Step. Setting an Acceptable Safety Level for Cancer Risks

The safety standards in the food safety provisions of the FD&C Act were not designed to deal with the cumulative long-term health risks posed by cancer. It is relatively simple to determine if poisons or pathogenic substances are safe. If people get sick or die then a substance is unsafe; if there

is no observed effect than a substance is safe. The FDA thus has the technical expertise to establish a definition of safety for poisons.⁸⁶ In effect, Congress mandated the FDA to approve food additives only after they had been shown to not cause significant harm. However, the FDA is incapable of defining safe levels of exposure to cancer because of its long-term, cumulative effects. There is not a definite no observed effect level for carcinogenic substances. Thus, Congress' safety mandate in this context is insufficient. A specific safety level for carcinogens should be determined by Congress.

The first stage in the two-stage system for the efficient reduction of the risks from carcinogens calls for a determination of the target level of risk. The basic inquiry in the determination of the target level of risk involves deciding how much we are willing to spend to eliminate the risks of cancer. This is essentially a political question: it is a matter of public policy to decide how to divide society's resources among a variety of laudable goals. It will not be simple for Congress to set this acceptable safety level for cancer. The total risk of cancer caused by substances in our diet has been convincingly estimated by various scientists.⁸⁷ However, FDA scientists should develop more conclusive studies that show the extent to which natural or traditional foods contribute to cancer risk.⁸⁸ Additionally, the FDA should compile a list of traditional foods

⁸⁶The safety level for poisons is equal to the no observed effect level (NOEL) divided by one hundred.

⁸⁷See, e.g., 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, 1256 (1981) (estimating that approximately 35 percent of all cancer deaths are caused by diet).

⁸⁸Dr. Robert J. Scheuplein has estimated that the total risk of cancer from traditional foods over a lifetime is 7.6 percent. See Charles E. Morris, *Realities and Risks*, FOOD ENGINEERING 63 (Aug. 1990). In contrast, Dr. Scheuplein estimates the risk created by non-traditional foods to be approximately 1 percent. However, his methodology has encountered some criticism from non-scientific sources. See *supra* note 15.

and their carcinogenic potential. Congress can have hearings on the

EDt:70403870 reliability of the quantitative risk assessment model and consider the uncertainty associated with assessing the health risks of cancer.

Based on all of this information, Congress would be able to determine an acceptable safety level for carcinogens grounded on a thorough assessment of the costs and benefits associated with such regulation. Congress should also assign another agency to assess the technical feasibility of reducing carcinogenic chemicals in traditional foods. Congress would be free to carve out special exceptions for certain products, but would be able assess the costs and benefits of doing so.⁸⁹ Additionally, this approach would allow Congress to explicitly take public fear of cancer into account.⁹⁰ Central to the effective implementation of the acceptable safety level for cancer is an effective risk communication strategy. The public must be made aware of the risks of cancer and the ability to eliminate these risks in different contexts.

2. The second step: making the food safety standards consistent to allow cost-effective reduction in cancer risks

The adoption of an acceptable safety level for carcinogens would immediately eliminate many of the inconsistencies of the FD&C Act. The Delaney

⁸⁹We can contrast this situation with the saccharin saga, in which Congress determined that the benefits of saccharin outweighed the health costs of saccharin. After the saccharin saga, many legal commentators stated that a reform in the law was necessary to allow the FDA to assess the benefits of a food additive before banning it. See HLTr A.ND MERRILL. *supra* note 44. at 927-28. However, it may be unwise to allow the FDA to make such a broad cost-benefit analysis. The FDA is certainly not qualified to calculate the non-health costs and benefits of banning a particular additive. The acceptable safety level approach would thus allow this cost-benefit analysis to be considered by Congress with information regarding a variety of costs and benefits.

⁹⁰*supra* text accompanying note 8. There is an increased psychological fear of cancer. However, it is unclear as to whether the increased fear is at least partially due to a rational assessment that cancer deaths should be avoided more than other deaths because of the debilitating effect of cancer.

clause would no longer be necessary; Congress would replace the absolutism of the Delaney clause with a the acceptable safety level after explicitly considering the costs and benefits of reducing the risk of cancer. Once the Delaney clause is removed, the constituents policy, GRAS constituents policy and the *de minimis* exception are no longer necessary. Section 402(a)(1) should be amended to apply the acceptable safety level in the context of all suspected carcinogenic foods, thus eliminating the vexatious

added versus non-added distinction.⁹¹ Section 406 would also have to be substantially amended. Instead of allowing the FDA to set tolerances for unavoidable and added constituents, Congress could give the FDA the discretion to set tolerances above the acceptable safety level if the FDA concludes that banning such a substance would have serious detrimental health or nutritional effects.⁹² As under the present section 406, the FDA would be able to assess the technical feasibility of eliminating the carcinogen when establishing tolerances. Additionally, the FDA would retain the ability to set informal action levels under section 402(a)(1).

Perhaps the biggest change in the current system would be the removal of the GRAS prior common use and the prior sanctioned uses exception

⁹¹Although this paper has addressed section 402(a)(1) in the context of carcinogens, the added versus nonadded distinction can be criticized in the context of other health effects. The distinction could be eliminated entirely. Congress was originally concerned about over-zealous FDA enforcement against natural foods when it enacted this distinction. However, the FDA should be granted the discretion to bring suits against the most dangerous products, whether the products are natural or added. If anything, the FDA would more likely be biased against added foods given people's (including FDA official's) prejudice against additives.

⁹²This is the proper context for the FDA to utilize its expertise in determining whether to ban a product. Thus, although the FDA's discretion might increase, the same concerns raised about the FDA broadly weighing the costs and benefits of banning a substance would not apply here.

to the food additive definition. Section 409 would be reformulated to allow prior common use to be an exception for requiring premarket approval, but not in the unique context of carcinogens. Additionally, the prior common use exception would be formulated to allow new uses of a substance formerly and commonly used in other ways. The amendment of the food additives scheme would have the effect of shifting the burden of proof to the regulated industry to demonstrate that their products meet the acceptable safety level for cancer.⁹³ This burden-shifting would occur for many substances that were formerly GRAS or prior sanctioned.⁹⁴ The FDA would also have the ability to set tolerances under section 409 that reflect the same criteria as are proposed for section 406.

C. A Brief Assessment of the Proposed Statutory Scheme

The proposed statutory scheme eliminates many of the disadvantages of the current food safety provisions:

(1)most importantly, it would eliminate the statutory bias against non-natural substances in the context of carcinogens⁹⁵.

(2)because the bias against non-natural substances would be eliminated, the food safety provisions would not needlessly focus on the recipe of foods. Instead, the proposed scheme would lead to the elimination of the greatest risks to cancer.

⁹³Additionally, the color additives, animal drugs, and pesticide provisions would all be amended to adopt the acceptable safety level standard for cancer.

⁹⁴The burden shift would not take effect for GRAS substances whose safety had been shown *through scientific procedures*.

⁹⁵The scheme would, however, retain the bias against non-natural substances for short term health effects. Thus, newly created foods would still be forced to prove that they are safe (they are not poisonous, for example) in the non-carcinogen context. This bias is most likely not irrational, but merely a proper assumption that foods that we have eaten in the past are not poisonous if consumed in normal amounts.

(3)the scheme would allow Congress and the public to address the important issue of how much we are willing to pay to reduce the risk of cancer.

(4)it eliminates the perverse incentives of meat and crop producers to increase the carcinogenicity of their products.

(5)the scheme will inevitably lead producers of products that have been banned to seek cost-effective means of eliminating carcinogens from their products.

(6) the new amendments will eliminate the inconsistencies of the prior standards, which led to excessive litigation and possible distrust of the FDA.

(7) the new food safety standards will no longer exacerbate the public's irrational bias against non-natural carcinogens. Instead, the public will be made aware of the largest risks of cancer, whether they are from natural or non-natural sources.

(8) the scheme will ensure the saccharin incident will not happen in the future. If a product is necessary for nutritional reasons, then tolerances will be set under section 406 or section 409. Products that can meet these tolerances will be approved, while products that cannot meet these tolerances will be banned. Thus, a situation similar to saccharin cornering the market while cyclamate posed less risks would never occur.

The main criticisms of the proposed statutory scheme will likely stem from the fact that premarket approval will be required for many substances that had formerly been GRAS or prior sanctioned. First, it can be argued that

the proposed scheme will increase the costs of regulating substances dramatically.⁹⁶ However, the costs of regulating these foods need to be weighed against the benefits of regulating these foods, which is exactly what Congress will do when determining the acceptable safety level for cancer. Undoubtedly, Congress will choose to save resources by raising the level of risk required in order to deem a substance unsafe. Thus, although the cost of regulating natural foods will increase, the cost of regulating non-natural foods will decrease. In effect, resources will be shifted to eliminate the risks of cancer in a cost-effective manner. This is exactly the goal of effective regulation. Second, it will be argued that people have the right to choose to eat peanut butter if they want, despite the fact that it causes cancer. However, this argument is not consistent with the fact that we currently don't allow people to eat food additives or pesticides that cause cancer, despite the fact that people may really want to eat those substances. We have made a societal judgment that certain foods should not be eaten, despite the fact that the occasional consumer might want to eat the food after being fully informed of the risk. Third, it may be argued that the use of food additives will flourish after Congress increases the standard needed to show a carcinogenic

⁹⁶Alternatively, instead of making the food safety standards consistent by requiring premarket approval for all substances in the unique context of cancer, we could have a system that abandons premarket approval for all substances in the unique context of cancer. Thus, the FDA would be limited to enforcing the acceptable safety level through an application of section 402(a)(1). This option would have the advantage of conserving the extensive resources that currently are devoted to testing substances for their carcinogenicity. However, this scheme is flawed because the FDA would not be able to determine the carcinogenicity of certain foods. In order to effectively enforce section 402(a)(1), either the health effects of a food must be observed or the FDA must be made aware of the food's carcinogenic constituents. The nature of cancer precludes the first alternative. The second alternative is problematic because the FDA would only know the carcinogenicity of constituents that it had examined under the previous system. Additionally, the FDA would not know the all of the chemicals contained within agricultural commodities. Thus, section 402(a)(1) would likely be enforced against only processed foods.

substance to be unsafe. Thus, color and food additives could barely pass the safety test and then be added to foods in large amounts. This argument has two flaws: first, it ignores the fact that additives are rarely used in such large amounts; second, the food that the additives would be added to could be seized under section 402(a)(1) if the government could prove that the food did not meet the acceptable safety level for cancer.

D. An Effective Risk Communication Strategy

Effective risk communication to the public is necessary to effectively implement the proposed statutory scheme. Recent literature has developed concerning exactly how risks should be communicated to the public.⁹⁷ The proper goal of risk communication should be to raise[] the level of understanding of relevant issues or actions and satisfy] those involved that they are adequately informed within the limits of available knowledge.⁹⁸ Risk communication thus has the worthy goal of allowing the public and the government to make informed decisions. Effective communication is a function of both the process of creating risk messages and the content of those messages. Two important themes result from risk communication research⁹⁹ First, both the process and the content of risk messages should be oriented towards the intended audience. Second, the most effective risk messages are created in an open forum with dialogue between the public and the risk communicators. Communication should be a two-way

⁹⁷See, e.g., National Academy of Sciences, IMPROVING RISK COMMUNICATION (1989); Paul Slovic, *Informing and Educating the Public About Risk*, 6 RISK ANALYSIS 403 (1986); Lester B. Lave, *Health and Safety Risk Analyses: Information for Better Decisions*, 236 SCIENCE 291(1987);

⁹⁸National Academy of Sciences. IMPROVING RISK COMMUNICATION 26(1989).

⁹⁹See *id* at 9.

process. Communicating with citizens about risks can not only increase their understanding of risks, but also increase their desire to participate in reducing risks. To be informative, communications should contain facts relevant to the public's broad conception of risk and recognize that the public perceives risk as more than merely the expected number of fatalities from an activity. The messages should be formulated by public relations experts together with scientists. Additionally, risk communications must come from a credible source to be effective. Finally, risk communicators should use the media more effectively in helping inform the public about risks.¹⁰⁰

The results in risk communication research can be helpful in formulating policies for the effective communication of the risks from cancer. Central to the communication should be a comparison between the risks of cancer from natural foods, non-natural foods, cooking and food preparation, and non-dietary sources. Comparing the risks from cancer caused by these different sources will give the public the proper perspective from which to base its decisions.¹⁰¹ The FDA should create a task force to formulate risk communication policies. This task force should be composed of both public relations experts and scientists.

¹⁰⁰See Slovic, *supra* note 94, at 410.

¹⁰¹Risk communication research has warned against the hazards of using risk comparisons haphazardly. Any attempt to compare risks that differ widely in nature is dangerous because people define risk more robustly than merely the expected number of fatalities. Thus, making risk comparisons between the risk from skiing and the risk from cancer are generally useless to the public. Furthermore, such comparisons may foster public distrust of regulatory agencies, leading the public to believe that such agencies are not doing their job of protecting the public. However, comparing the risks from different causes of cancer can be useful to the public because it accurately informs the public about different methods of preventing one disease, and the limitations of those methods. See generally, Emilie Roth et al., *What Do We Know About A'faking Risk Comparisons?*, 10 RISK ANALYSIS 375 (1990); Paul Slovic et al., *What Should We Know About Making Risk Comparisons?*, 10 RISK ANALYSIS 389 (1990); Richard Wilson and E.A.C. Crouch, *Risk Assessment and Comparisons: An Introduction*, 236 SCIENCE 267 (1987); JOHN URQUHART & KLAUS HEILMANN, *RISK WATCH: THE ODDS OF LIFE* (1984).

The task force should consider both the technical data given by FDA scientists and the likely public response to various risk communications. The task force should adopt an open policy with the public and share its interim results with all interested participants. Importantly, the task force should not conceal the uncertainty in the science surrounding the estimation of the health risks from cancer. Awareness of the uncertainty in the science is necessary to make informed decisions. Before disseminating official risk messages, the task force should conduct limited trial runs to gauge the public reaction. By having an open policy, the task force will be able to properly address the concerns that its audience has. The public confidence in the FDA is higher than in other governmental bodies; thus, the risk communications from the FDA will be trusted to at least some degree by the public. The task force should also try to effectively communicate to the media and properly utilize this free source of risk communication. Ultimately, the task force should publish a report which could be disseminated to the public. Congress may wish to establish an oversight committee on this task force to ensure that the public's concerns are being met.

E. Alternative Regulations

In response to the inability of the current regulatory system to protect the public from the chronic risks of cancer, it has been suggested that the regulatory tool of labeling should be considered.¹⁰² Certainly, if the proposed statutory scheme is enacted, the public will demand information concerning how they can avoid cancer risks by changing their diet. However, labeling in the

¹⁰²See Peter B. Hutt, *Food and Drug Law: A Strong and Continuing Tradition*, 37 FOOD DRUG COSM. L.J. 123, 130 (1982).

context of cancer risks has some serious drawbacks. Perhaps the ideal solution is a broader public education system concerning cancer. The public should be made aware of the inability of the government's regulation of cancer risks to increase our life expectancy significantly.

I. Labeling

The principle behind labeling the risks from cancer is that society can conserve resources wasted by intrusive regulation and increase individual autonomy. Thus, the FDA would be shifting to a strategy of indirectly promoting, rather than directly protecting, the public health.¹⁰³ The State of California has at least partially shifted to such a regulatory strategy in the context of carcinogens.¹⁰⁴ Such a labeling approach, however, may be unwise for three main reasons. First, it would be extremely difficult to require agricultural commodities to be labeled.¹⁰⁵ Any requirement of labeling for processed foods but not for raw agricultural commodities would exacerbate the public's bias against non-natural foods.¹⁰⁶ Second, the communication of relatively minor risks from carcinogens may dilute the effect of existing warnings.¹⁰⁷ If trivial

¹⁰³Id.

¹⁰⁴On November 4, 1986, California enacted Proposition 65 by public initiative. Proposition 65 requires the governor to publish a list of natural and synthetic compounds known to cause cancer. Food producers are responsible for providing warning statements on products containing these chemicals. See generally Peter B. Hut?, *Application of Proposition 65 to Food, Drugs, Medical Devices, and Cosmetics*, in National Legal Center for the Public Interest, CLEAN WATER AND TOXIC WASTE: AT WHAT COST FOR WHAT GAIN? 23; Matthew L. Kuryla, *California's Proposition 65 and the Chemical Hazard Warning: Risk Management Under the New Code of Popular Outrage*, 8 VA. J. NAT. RES. L. 103 (1988).

¹⁰⁵The FDA has encountered this problem in other food labeling contexts. See Hurr & MERRILL, *supra* note 44.

¹⁰⁶This is a major flaw in Proposition 65, which exempts carcinogenic substances that naturally occur in food from labeling requirements. Thus, peanuts (and peanut butter) need not be labeled because their carcinogens naturally occur, as defined by the law.

¹⁰⁷See Lam Noah, *The Imperative to Warn: Disentangling the Right to Know from the Need to Know About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 381 (1994).

risks are labeled along with significant risks, the public will be overloaded with information, which they will not be able to process effectively. People will not be able to distinguish between the trivial risks and the significant risks. Third, because people tend to overestimate low-probability risks, they will undoubtedly overreact to warning statements about carcinogens. Such overreactions will involve social costs because useful products will no longer be purchased because of an irrational fear. Similarly, such warnings may cause consumers to focus on the risks of carcinogenic substances and ignore their benefits.¹⁰⁸ The deficiencies in labeling derive from the fact that consumers need a great deal of information (such as risk comparisons) to perceive risks accurately.¹⁰⁹ There is likely not enough room on a label to provide this information, and any labeling that results in incomplete information will likely be harmful.¹¹⁰ Warning labels are ideally used in situations where useful products pose acute risks that are easily avoided.¹¹¹ This is simply not the situation for carcinogenic foods.

2. Public education

Public education, as with labeling, provides the advantages of conserving resources from intrusive regulation and increasing individual autonomy.

Effective public education campaigns would entail effective risk communication.

¹⁰⁸*See id.* at 387. For instance, requiring a warning on nitrites would not allow the consumer to weigh the fact that nitrites protect against lethal food poisoning.

¹⁰⁹Some commentators have suggested ways around these deficiencies by examining alternatives to providing warnings about cancer on labels. *See id.* at 391. The alternatives seek to provide information to consumers while avoiding the problems of information overload and overreaction. Some suggestions involve having labels contain a chronic risk code, perhaps differentiating among five levels of risk. *See id.* Other commentators have suggested using a logarithmic scale to convey risk information, although this approach may mislead consumers because of their unfamiliarity with logarithmic scales. *See id.*

¹¹⁰The goal of labeling, as one form of risk communication, should be to encourage the public to make informed choices.

¹¹¹*See id.* at 399.

In the public education context, effective risk communication would involve helping the consumer to make informed purchasing decisions. Thus, people should be informed of the limits on their ability to increase their life span through dietary choices.¹¹² The public should also be informed of the uncertainty in the science surrounding estimating the risk of cancer. Public education can take place through many media.

The FDA could use talk papers, press releases and articles to disseminate its messages. Additionally, the FDA may wish to compile booklets regarding cancer risks from various foods in our diet and make them available for consumers at supermarkets. Public education, in contrast to labeling, provides another advantage of being able to inform the public of the risk of cancer from cooking and preparing foods, which seems to represent a significant percentage of the dietary cancer risk. Additionally, it allows the FDA to use the media, which is a free source of risk communication. However, the FDA must be able to effectively interact with the media.

It is important to note that the goal of public education is not necessarily to help consumers avoid the risks of cancer. Consumers, after being informed of the carcinogenic risks of traditional foods, may wish to continue eating those foods. They will very likely decide that they value the pleasure they derive from food much more than the possibility of living an additional 10 days. Furthermore, consumers would be made to understand that the FDA would not be abdicating its responsibility to protect the public health. Rather,

¹¹²See Hut?, *supra* note 99, at 130.

the consumers would recognize that the minor health risk from carcinogens in foods cannot be easily avoided. Ultimately, increased public awareness may lead us to transfer society's resources to the elimination of more serious health risks than cancer.¹¹³ Certainly, increased public awareness can only help our democratic system of government function more effectively.

CONCLUSION

A careful examination of the current regulation of carcinogens leads us to the inevitable conclusion that a change is needed. Furthermore, the problems of the regulation of carcinogens cannot be simply attributed to the infamous Delaney clause. The problems stem from the fact that the food safety provisions in general carry an implicit assumption that natural food is risk-free. The Delaney clause, along with the premarket approval system and other factors, merely exacerbates the costly effects of maintaining this assumption in the context of carcinogens. The reforms that are necessary involve creating special safety standards that apply for all carcinogens, regardless of whether the carcinogen is natural or somehow added to a food. The reforms thus shift the focus to the constituents of a food rather than how the constituents became a part of the food. This focus on the food itself, rather than its recipe, will lead to greater efficiency in the elimination of carcinogenic health risks. Crucial to the implementation of these new proposals is a system that effectively communicates the

¹¹³Many have observed that the current costs associated with microbiological contamination are extremely high and have been relatively ignored. See Sanford A. Miller, *The Saga of Chicken Little and Rambo*, 51 J. ASS'N OF FOOD & DRUG OFFICIALS 196 (1987). Leading officials in the FDA have consistently stated that the primary hazard in the food supply stems from food-borne disease. Virgil Wodicka, *FDA's Objectives in Food Today*, 27 FOOD DRUG COSM. L.J. 59 (1972); Frank Young, *Weighing Food Safety Risks*, 23 FDA Consumer, No. 7, at 8 (1989).

risk of cancer to the public. People have an irrational bias against non-natural carcinogenic foods. If people were made aware of the true risks of cancer from various sources in our diet, they would make decisions more effectively. In our democratic system of government, it is crucial that the public is able to make effective decisions. Thomas Jefferson once said If we think (the people) not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion. Whatever decisions the public will ultimately make, the time has certainly arrived for those decisions to be informed ones.