

Modernize our Food Safety Laws: Delete the Delaney Clause

Prepared for the American Council on Science and Health by **Tom Holt**, a writer and public affairs consultant in Beaverton, OR.

ACSH gratefully acknowledges the comments and contributions of the following individuals who reviewed this report.

Norman E. Borlaug, Ph.D.
Texas A&M University

Joseph F. Borzelleca, Ph.D.
Virginia Commonwealth University

Zerle L. Carpenter, Ph.D.
Texas A&M University

Ilene R. Danse, M.D.
Enviromed Health Services, Inc.

Kenneth D. Fisher, Ph.D.
Federation of American Societies of Experimental Biology

Ralph W. Fogleman, D.V.M.
Upper Black Eddy, PA

F.J. Francis, Ph.D.
University of Massachusetts

Richard A. Greenberg, Ph.D.
Hinsdale, IL

Rudolph J. Jaeger, Ph.D.
Environmental Medicine, Inc.

Thomas Jukes
University of California, Berkeley

John G. Keller, Ph.D.
Apex Environmental, Inc.

Herman F. Kraybill, Ph.D.
Olney, MD

Manfred Kroger, Ph.D.
Pennsylvania State University

Floy Lilley, J.D.
The University of Texas at Austin

Bernard J. Liska, Ph.D.
Purdue University

William London, Ed.D., M.P.H.
American Council on Science and Health

Steven J. Milloy
Regulatory Impact Analysis Project, Inc.

Gordon W. Newell, Ph.D.
Palo Alto, CA

Thomas W. Orme, Ph.D.
Purcellville, VA

Alice M. Ottoboni, Ph.D.
Berkeley, CA

A.J. Siedler, Ph.D.
University of Illinois

Fredrick J. Stare, M.D., Ph.D.
Harvard School of Public Health

Elizabeth M. Whelan, Sc.D., M.P.H.
American Council on Science and Health

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Executive Summary

The overriding goal of federal policies governing the use of chemicals in agriculture and food processing is—and should be—consumer safety. One would hope that food safety regulation would be driven by the best scientific and medical knowledge. But instead, much of the American food supply is held hostage to the misguided absolutism of what is known as the Delaney clause, a nearly 40-year-old, 55-word quirk in the law. It reads, in its entirety:

No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or laboratory animals 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 animals.¹

The Delaney clause was an inappropriate regulatory standard from the moment of its enactment. Its intolerance for even the most minuscule risks and its singular focus on cancer as determined in animal tests would, if interpreted literally, force off the market many substances utilized in agriculture and food processing that are widely regarded as safe when used as intended.

“The [Delaney] clause does not provide for rational, scientific evaluation of carcinogens,” the International Federation of Societies of Toxicological Pathologists (IFSTP) declared in a major policy statement this year. “It ignores the fact that the diverse mechanisms now known to underlie cancer increases in rodents exposed to high doses of chemicals are often inapplicable to man. Current evaluation of chemicals based on the tenets of the clause is irrational in many cases.” It is little wonder that no other country has implemented comparable legislation.²

In the decades following its enactment, regulators for the most part declined to enforce the Delaney clause to the letter. No more. As a result of a 1993 court decision and subsequent settlements of follow-up litigation, federal regulators have begun to enforce Delaney’s zero-tolerance standard to the letter. Make no mistake: Vast technological advances since 1958 allow the detection of disappearingly minute amounts of virtually any substance. Thus, Delaney’s zero-tolerance standard really means *zero*. A number of useful and safe food chemicals already are in the process of being withdrawn from the market.

The end results for consumers will be grim: Fewer choices of fresh produce, frozen foods and canned goods, and higher prices for what will remain on grocers’ shelves. Fruit and vegetable grow-

ers, as well as grain processors, will suffer major economic dislocations. Although there are no firm estimates of total economic cost, they undoubtedly amount to many billions of dollars.

What's more, reduced selection at the grocery store inevitably will lead to a less healthy diet for most Americans. And for all that, it is exceedingly unlikely that there will be any detectable increase in the safety of the remaining U.S. food supply.

These costly consequences easily can be avoided—if Congress repeals the Delaney clause. Otherwise, strict enforcement of the law will run its costly course.

An overwhelming body of scientific evidence argues in favor of repeal. Without the Delaney clause, regulators would be freed to follow a more reasonable standard that allows for continued evolution in scientific knowledge while at the same time providing a margin of safety. Indeed, this is the approach followed in regulation of food additives wherever the Delaney clause does not currently apply, and this is the approach favored by regulators. As the IFSTP declares, “legislative changes should allow for negligible risk levels of chemicals that with reasonable certainty pose no risk of harm.”³

The Delaney clause is and for some time has been a scientifically indefensible double standard. It fails even in its stated objective to prevent cancer because it focuses on essentially hypothetical risks instead of real ones that people can change. Quirks in the law keep known hazards on the market that could be replaced by lesser hazards.

The political case for repeal is more problematic, primarily because an array of interest groups and bureaucratic constituencies would lose power. They are likely to cast any attempt to repeal Delaney as an effort to expose Americans to almost certain death from cancer.

A vote for repeal of the Delaney clause emphatically is not, as the Delaney clause's supporters contend, a vote “for cancer.” To the contrary, a vote to repeal the Delaney clause and, if politically necessary, explicitly to replace it with a more flexible process, is a vote for good health, a vote for worrying about risks people can do something about, a vote for availability of a wide variety of inexpensive, safe foods.

Who is the extremist: the group that would ban a coloring because there is a one-in-19-billion elevated risk of cancer, less than one in the entire world, or the lawmaker who says that's going a bit too far? Who is the extremist: the organization that would push Americans back to an 18th-century food supply; i.e., one held hostage to local markets and weather conditions, or the lawmaker who

says it is better for Americans to have access to a wide variety of foods all year long? Who is the extremist: the group that would deny Americans access to foods that could help prevent cancer, or the lawmaker who wants Americans to have access?

The Delaney clause is an anachronism that is hazardous to Americans' health. Congress should repeal it, not because the Congress is in favor of cancer, but because it is in favor of science and common sense.

Introduction

The Delaney clause, first enacted in 1958, in effect sets a zero-tolerance cancer-risk standard for substances added either directly or indirectly to foods. It applies to all food additives as defined by the Food, Drug and Cosmetic Act, a category that broadly includes pesticides used on food crops. In 1960 and 1962, Delaney clauses were included in laws regulating color additives and animal drugs and feed, respectively. Substances “generally recognized as safe” (GRAS) for their intended uses, substances whose approvals predate the Delaney clause, substances subject to Section 406 of the Food, Drug and Cosmetic Act and substances that do not concentrate in food processing generally are exempt from the law’s provisions.

At the time of its enactment, the Delaney clause may have been, in effect, a reasonable risk standard, because the comparatively crude scientific detection technology of the time precluded discovery of tiny amounts of most substances. Therefore, thresholds of what was detectable roughly equaled concentrations worthy of regulatory concern.

Over the years, both the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), bowing to technological advancements, sought to interpret the law’s clear zero-tolerance language as a negligible risk standard. In 1988, the EPA formally adopted a standard for pesticide residues found in processed foods. The new risk limit: one additional case of cancer per million people caused by daily exposure to high concentrations of a chemical over a 70-year lifetime.

The Natural Resources Defense Council, the AFL-CIO and Public Citizen later sued to overturn this standard for four pesticides. Ultimately, the case known as *Les v Reilly* was decided in 1992 by the Ninth U.S. Circuit Court of Appeals, which ruled that the Delaney clause must be enforced as written. “The EPA in effect asks us to approve what it deems to be a more enlightened system than that which Congress established,” the court held. “Revising the existing statutory scheme, however, is neither our function nor the function of the EPA. If there is to be a change, it is for Congress to direct.”⁴ Industry groups appealed the decision, but the Supreme Court in February 1993 refused to hear the case.⁵

Although technically the *Les v Reilly* decision applies only in the Ninth Circuit, which has jurisdiction only in Western states, its practical regulatory impact clearly is national. For it would be almost impossible to somehow separate agricultural and food-processing practices on the West

Coast from the rest of the country.⁶

Absent swift congressional action to repeal the Delaney clause, numerous useful and generally safe substances used in the production of a broad array of food crops, cosmetics and processed foods must be removed from the market. The EPA already has taken the initial steps to remove three dozen such products used in hundreds of different foods. As many as 140 currently registered, approved “tolerances”—permits for the use of pesticides on particular crops—involving 77 pesticides are in jeopardy of being revoked.⁷ Thus, the stability of much of the U.S. food supply is at risk in a game of regulatory “chicken.”

A far more responsible and scientifically sound approach would be to repeal or replace the Delaney clause.

The purposes of this paper are threefold: (1) to analyze how the Delaney clause works in practice and what’s wrong with it as an operating regulatory standard; (2) to examine the consequences of leaving the law in place, as many supposed environmental and consumer advocates support; and, (3) to outline a political strategy to repeal Delaney and replace it with a more flexible regulatory regime.

The Delaney Clause in Practice

A Brief History of the Delaney Clause

The first Delaney clause was the handiwork of New York Rep. James Delaney, who attached it as an amendment to the Food, Drug and Cosmetic Act of 1958. It was the culmination of eight years’ work by Delaney, who from 1950 to 1952 chaired the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics. At the time, Delaney was deeply suspicious of chemicals used in agriculture and in food processing. He believed there was a connection between increased uses of food chemicals and the then-rapidly rising number of reported cancer cases. “[C]arcinogens are subtle, stealthy, sinister saboteurs of life,” he said. “They have no place in our food chain.”⁸

Hence, through the Delaney clause, his effort to prevent man-made carcinogens from entering the food supply.⁹ His vehicle of legislative convenience was Section 409 of the Food, Drug and Cosmetic Act, which empowered the FDA (and later the EPA) to regulate the purposeful addition of

substances to food after it leaves the farm.

Added as an 11th-hour amendment to a House committee report, the Delaney clause says:

No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or laboratory animals 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 animals.¹⁰

Its placement in Section 409 is crucial to understanding the Delaney clause's application to agricultural chemicals. Farm chemicals are regulated under Section 408, under which "tolerances" for their use are set. Section 408 explicitly allows benefits to be weighed against risks, noting that regulators must consider the need for "an adequate, wholesome and economical food supply."¹¹ As long as chemical residues in a food product neither exceed Section 408 tolerances nor are concentrated in processing there is no Delaney problem. But if the chemical is discovered to concentrate in processing, then it becomes subject to the Delaney clause's zero-tolerance standard.¹² This is a three-step process: First, the substance must be deemed a "food additive"; second, it must be found to induce cancer in animal tests; and, third, the test animal must be exposed to the substance via ingestion or some other appropriate method. As a practical matter, a chemical that falls under the Delaney clause's authority and fails Delaney's zero-tolerance test is banned for all uses.

Subsequent to passage of the 1958 Delaney clause, which covered only food additives, similar language was included in the 1960 Color Additive Amendment to the Food, Drug and Cosmetic (FDC) Act and to the 1962 Animal Drug Amendment to the FDC Act. The EPA regulates pesticides, while the FDA regulates food and cosmetic colorings, animal feeds and animal drugs.

There are important exceptions to the Delaney rule. All three Delaney clauses (hereafter referred to simply as the Delaney clause) apply only to new regulatory approvals. The Delaney clause does not apply to substances "generally recognized as safe" (GRAS) for their intended uses in foods. Generally speaking, these are additives in use so long (mostly predating the Delaney clause) that their safety simply is assumed, unless new information is discovered.

One specific exception to the Delaney clause was diethylstilbestrol (DES), an estrogen used in beef production until 1979. DES was used on cattle to increase the yield of lean beef and to lower feed consumption per unit of weight gain. DES was a known carcinogen under the meaning of the Delaney clause, but its use was allowed provided no residues could be found in edible meat tissues.

But in 1979, under pressure of a sustained anti-DES campaign, the FDA banned the use of DES under any conditions. In 1980, the FDA sued 2,116 boxes of boned beef and 541 boxes of offal produced from cattle treated with DES in 1979. The FDA claimed that beef containing one part per trillion of DES poses a carcinogenic hazard to humans. A federal court ruled that the government's position "makes no sense at all." The beef was released for consumption, but the FDA's ban on the use of DES remains in place.¹³

Somewhat paradoxically, Delaney does not necessarily apply to a whole additive just because it contains a carcinogen as a constituent. But if the entire additive is found to cause tumors in laboratory animals or humans, then it is forbidden no matter how small the risk.¹⁴

Thus, it matters a great deal how a substance is characterized by regulators. What is merely a constituent ingredient and what is an additive? At what point does something become a processed food? These questions do not necessarily have obvious answers, but the FDA and EPA have to pick a point at which to regulate.

Absolute-Zero Risk

The basic premise of Delaney clause regulation is that even one molecule of a cancer-causing substance can cause cancer. It is a "zero tolerance" standard—even one molecule of a substance deemed to be a carcinogen is assumed to entail an unacceptably high cancer risk. But that is an invalid standard. If it was scientifically valid, then coffee would have to be banned. The average American drinks three cups of coffee per day, and each cup contains at least 10 milligrams of known rodent carcinogens, both natural and man-made.¹⁵ Indeed, if human exposure to just one molecule of a cancer-causing substance actually caused cancer, then "everyone in the world is going to die of cancer caused by arsenic."¹⁶ Why? Because a normal, healthy human being has about 4.4 milligrams of arsenic in his or her body, and arsenic is a known human (though not animal) carcinogen.¹⁷

When the Delaney clause first was enacted, the technology of the time essentially did not allow the detection of insignificant amounts of substances that had been found to cause tumors in laboratory animals given very large doses. It was then possible to measure, roughly speaking, parts per million. Thus, as a practical matter Delaney's written zero-tolerance standard of law was in effect no more constrictive than a "negligible risk" standard in today's context.

But now it is possible to detect one part per quintillion. According to Ronald Hart of the National Center for Toxicological Research, “That’s almost the equivalent of filling the entire Great Lakes with gin and putting a single tablespoon of vermouth in it. That, I think you would agree, would be a pretty dry martini.”¹⁸

“The zero-tolerance standard for pesticides, as enacted in 1958, is no longer appropriate in light of modern science’s ability to detect minute traces of residues,” the American Medical Association has declared.¹⁹

The inevitable march of technology has brought—and will continue to bring—under Delaney clause regulation substances previously regarded as entirely safe. This is not a march toward more rational, knowledge-based regulation of risks, but, ironically, the use of newfound knowledge as a springboard into the realm of superstition.

One result of the Delaney clause is to preclude the replacement of GRAS pesticides or additives of some known risk with substances of lower risk, because the law forbids any risk whatsoever for substances given new regulatory approvals. Furthermore, research and development (R&D) costs for replacements that might pass any Delaney test have been driven upward. At the same time, greater uncertainty regarding product life spans has been introduced, because one cannot be sure if or when the forward march of detection and testing technology might bring a substance under the Delaney umbrella. Thus, even investment in replacement R&D is discouraged.²⁰

The ultimate force of the Delaney clause is not to enhance food safety, but “to prevent the evaluation for safety, at any level, of any additive that has been found to produce cancer in laboratory animals at any dosage rate.”²¹ Indeed, if rodent experiments show a substance is linked to an increase in tumors, then the fact that the same substance also may have anti-tumor properties is deemed irrelevant. This is not an uncommon phenomenon. One study examined the outcomes of rodent bioassays that were conducted under the auspices of the National Toxicology Program (NTP) between 1990 and 1993 (on a total of 37 chemicals used in 124 experiments); the study of NTP results found that 68 percent of the chemicals showed increases in tumors and 81 percent showed decreases. Thus, some showed both tumor-enhancing and tumor-inhibiting properties. Other studies have shown similar results.²²

The Delaney Clause’s Arbitrary Rule

Federal regulators have a great deal of discretion in determining at what stage to classify food as “processed,” and therefore subject to the Delaney clause’s zero-tolerance standard. This crucial decision may determine whether a product can be sold.

Hops, used in the production of beer, are grown on vines, and are dried before use. The fungicide fosetyl-AL and the insecticide bifenthrin both are commonly used by hops growers. Both chemicals are classified as carcinogens. The drying process, of course, greatly concentrates everything, ordinarily a Delaney clause trigger. Prior to the *Les v Reilly* decision, the EPA granted exemptions for the chemicals, but it subsequently decided it no longer could do so. Following the logic of the Delaney clause, the EPA chose to measure the two chemicals’ residues in dried hops, the final processed hops product—even though no one consumes dried hops. Brewers argued that the final processed food product really is beer, in which hops and anything used on hops are greatly dispersed. But this was to no avail within the regulatory process. The political process is another matter. Congress directed the EPA to reclassify dried hops as a raw agricultural commodity—and therefore not subject to Delaney.²³

Such arbitrary regulatory decisions are routine under the Delaney clause. But the law itself is arbitrary in several ways. First, as noted above, substances on the GRAS list simply are exempted from Delaney, unless dramatic new evidence is brought to light. Second, Delaney fails to scrutinize natural carcinogens, such as the safrole found in ordinary table pepper, that are present in Americans’ diets in far larger quantities than any man-made chemicals. Finally, it ignores non-cancer risks altogether.

Mouse Terrorism

Just as important as the arbitrary manner in which products are either subjected to or exempted from the Delaney clause is the law’s singular focus on animal testing as the determinant of cancer risk. The Delaney clause is an exception to the general rule that determinations of carcinogenicity should be based not on a single test, but on the weight of all evidence, including human epidemiology. Although the Delaney clause mentions only cancer, it has been interpreted to cover substances determined to cause tumors, whether cancerous (malignant) or not (benign). In addition, if a substance causes tumors in only one out of 100 different animal tests, the Delaney clause could be triggered.

An animal test alone is an inappropriate tripwire for regulation, for several reasons. First, there are major flaws in the way animal bioassays usually are conducted and interpreted. Animals specially bred to be prone to tumor production are given very large doses of the test substance; the high dose itself can cause ill effects. Second, to paraphrase a famous animal rights slogan, a mouse is *not* a rat is *not* a dog is *not* a pig is *not* a human. A substance that may cause tumors in laboratory mice may or may not do the same in humans. A single positive animal test is merely an indicator signaling a need for more intensive investigation.

Conventional animal-testing practices raise serious questions about using the results of animal tests alone as the determining factor for regulation, as required by the Delaney clause. Most often, tests involve mice or rats that are given an unlimited supply of food. The food is laced with a “maximum tolerated dose” (MTD) of the test substance, that is, the highest dose possible without the dose itself killing the animal.

The trouble here is twofold: First, the MTD itself is highly likely to set off physical reactions that would not be found at doses more closely resembling “real-world” exposures. In fact, in one-third or more of the cases in which the MTD caused tumors in laboratory rodents, one half of the dose—still many times the likely equivalent human exposure—did not result in more tumors than in control subjects (animals not given the substance).²⁴

It is as if one fed a gallon of ice cream to a five-year-old, and then, when the child felt woozy, concluded that ice cream in any amount would make him or her sick. It is now widely recognized that the magnitude of the dose of a substance and its resultant pathologies can obscure the actual physiological effects of that substance.

Second, rodents are very much like humans in one important respect: Fat rats are not nearly as long-lived nor free of cancers as those that are, in rodent terms, fit and trim. Not being particularly bright creatures, rats and mice allowed access to a constant food supply (called an *ad libitum* diet by scientists) can over-eat and get fat. These constantly munching creatures develop tumors at rates three or more times those of animals kept on calorie-restricted diets.

As if all that were not enough to tip the scales, most laboratory animals are of special, inbred strains. The original theory was to ensure “pure” stocks of animals for testing. But inbreeding also makes rodents fatter and more subject to tumor growth. One strain, called Sprague-Dawley rats, has shown an increase in average body weight of nearly 50 percent over several years and many genera-

tions.²⁵ Again, fat rats get tumors more often. And even where inbreeding does not necessarily cause huge weight gain, it may leave the animals subject to spontaneous tumors—even if they haven't been given a test substance. For instance, a male mouse from a breed line known as the B₆C₃F₁, a commonly used laboratory animal, is abnormally susceptible to liver tumors.²⁶

Extrapolating test data from such animals to humans is problematic at best. The MTD “is likely to be anywhere from 10,000 to 100,000 times higher than the doses of interest in humans,” observes a Sandia National Laboratories report. “Extrapolations over such a large range would not even be attempted in most areas of science, where extrapolation beyond the range of observable data is generally discouraged.”²⁷

Several key assumptions—all of which are invalid, according to the Board of Scientific Counselors of the National Toxicology Program—undergird MTD testing:

- (1) The way a body absorbs, distributes and eventually disposes of a substance (called “pharmacokinetics”) does not depend on the amount of the dose.
- (2) The relationship between dose level and bodily response is linear at small doses. That is, if 10,000 grams of something is bad for you, one gram is one-10,000th as bad.
- (3) The body's ability to repair DNA does not depend on dose.
- (4) Response to a substance has nothing to do with age.
- (5) Test doses need not bear any relationship to human exposures.²⁸

To the contrary, all of these variables matter a great deal.

More than 50 percent of the 301 chemicals tested by the National Toxicology Program (as of 1991) for carcinogenic potential in lifelong rodent tests have caused cancer—in rodents. But only 35 chemicals or groups have been identified as carcinogenic in humans.²⁹ At the same time, some fairly common human cancers, such as those afflicting the prostate and colon, rarely show up in rodent tests.³⁰

Data derived from animal tests are not inherently invalid but should be kept in perspective. For substances that generate tumors in laboratory animals at doses well below MTD, there is still no guarantee the substance will cause cancer in humans. Animal tests at their very best merely are indicators. The Delaney clause, however, leaves no room for interpretation, forcing regulators to misuse

animal test results.³¹

Consequences of Leaving Delaney in Place

Past Applications

In 1986, the FDA approved for use Drug & Cosmetic Dye Orange No. 17. A review panel had determined D&C Orange No. 17 may cause at most one additional cancer case in 19 billion people over a 70-year lifetime of exposure—less than one case in the entire world. But the Delaney clause allowed no such exemption, and the FDA lost a court challenge. Orange No. 17 was ordered banned by a federal court in 1987. Food, Drug & Cosmetic Red Dye No. 3, which was used to impart a red color to certain drugs and cosmetics, similarly was ordered banned for some uses by the Bush administration in 1990. (Technically, an “interim” listing for such uses was revoked.) In use since the dawn of food processing and on the FDA’s “approved” list since 1907, Red Dye No. 3 had been found, in extremely large doses, to cause thyroid cancer in rats, although it did not do so in other animals tested. The risk to humans, according to the FDA, was between one in 100,000 and one in one million. The Delaney clause, Health and Human Services Secretary Louis Sullivan noted, mandated the partial ban. (Although previously classified as GRAS, the dye was subject to regulation under a regulatory provision that allows for new evidence.) At the time, the administration said Red Dye No. 3 would be banned for food, such as cocktail cherries, as well, but this hasn’t occurred.³²

Selenium, an essential nutrient, is given to farm livestock in areas where there is little or no selenium present in the soil and therefore in feed plants. Without selenium, animals may develop “white muscle disease,” deposits of calcium salts in skeletal and heart muscles. Affected animals may have difficulty walking, may be unable to rise to nurse or may die from sudden heart failure. Because tests conducted during the 1940s showed selenium to be carcinogenic, the FDA banned its use during the 1960s under the Delaney clause. It was reintroduced in 1974 under strict regulation. Selenium is no longer believed to be a carcinogen, and under certain conditions selenium is considered an *anti-cancer agent*.³³

Saccharin, first discovered in 1879, very nearly was driven from the American market during the late 1970s after two studies found that it causes bladder cancer in laboratory mice. Another experiment, on rats, also found a cancer link—at a dose equivalent to a human drinking 800 cans of

diet soda each day. The FDA in 1977 proposed a ban, as required by the Delaney clause. Under strong public pressure from consumers, who argued there was no substitute sweetener for saccharin, Congress specifically imposed a moratorium on any FDA ban, pending further research. Eventually, FDA withdrew its proposal. Nevertheless, the damage was done. One artifact of the controversy remains: a warning label on all products containing saccharin, part of the political compromise necessary in Congress to stave off a ban.³⁴

The most infamous example of mouse terrorism, of course, is the 1989 Alar scare. The Natural Resources Defense Council, with consumer advocacy groups such as Consumers Union playing important supporting roles, waged a high-powered publicity campaign against the apple growth regulating agent, or more specifically, its breakdown product, a chemical called UDMH [1,1-(unsymmetrical)dimethylhydrazine], which shows up as a consequence of processing apples into juice.³⁵ The campaign kicked off with a *60 Minutes* report on the chemical's supposed threat to children. A panic ensued. Apple farmers lost hundreds of millions of dollars, and Alar quickly was removed from the market by its manufacturer. The actual risk associated with Alar? Insignificant, unless one were to drink 19,000 quarts of apple juice per day for a lifetime or eat 28,000 pounds of apples daily for 10 years.³⁶

Subsequent investigations by the Congressional Office of Technology Assessment, the American Medical Association and the World Health Organization concluded that Alar posed no real threat to humans. As Richard Adamson of the National Cancer Institute put it, the risk was less than that from eating a well-done hamburger or a peanut-butter sandwich, both of which contain natural carcinogens.³⁷

These are just a few of many cases of mouse terrorism. Although the Delaney clause seldom was invoked by regulators prior to *Les v Reilly*, as a regulatory axe hanging over all agricultural and cosmetic chemicals it nonetheless imposed significant costs on industry and consumers. If the Delaney clause is left in place, there likely will be many more instances of mouse terrorism.

The EPA's Reform and Non-Reform Efforts

The EPA and FDA must enforce the letter of the Delaney clause as long as it remains on the books.

The only other choice for the agencies would be to work actively for its repeal, and, indeed,

this is the course apparently favored by many of the agencies' scientists and front-line regulators. Alas, such decisions must be made by the politically appointed administrators of the agencies, and on Delaney there has been an abdication of leadership.

Until recently, FDA Commissioner David Kessler was virtually silent on the issue. However, in early July 1995 he declared his strong opposition to repeal of the Delaney clause: "These proposals [Delaney repeal and other proposed regulatory changes] are an assault on 40 years of consumer protection."³⁸

Although Kessler's demagogic language may indicate a more assertive position, up until then the policy lead on Delaney had fallen to the EPA.

Sparked by the *Les v Reilly* decision, current EPA Administrator Carol Browner in early 1993 briefly floated a proposal to eliminate or at least reform the Delaney clause, citing 35 farm chemicals that would have to be banned without a change in the law. (An internal EPA list circulated at the time suggested as many as 67 chemicals would be affected, or about 10 percent of pesticides then on the market.)³⁹ The trial balloon didn't even last 24 hours. It was shot down by a phalanx of consumer and environmental advocacy groups.

In June of that year, a few days prior to the long-awaited release of the National Academy of Sciences study, "Pesticides: Diets of Infants and Children," the Natural Resources Defense Council and the Environmental Working Group (a project of the Tides Foundation, which helped fund earlier NRDC publicity campaigns) almost simultaneously released headline-grabbing reports claiming that children are at risk from pesticides. The NRDC and EWG were joined by nearly a dozen other organizations in calling for the reduction and elimination of safe and effective pesticides: Public Voice for Food and Health Policy; Farm Workers Justice Fund; Physicians for Social Responsibility; Consumers Union; Friends of the Earth (another Tides grantee); the Audubon Society; the World Wildlife Fund; Citizen Action; the Government Accountability Project; the National Coalition Against the Misuse of Pesticides; Mothers and Others for a Livable Planet; and the AFL-CIO.

Although the NRDC and EWG reports grabbed headlines with alarmist allegations of a threat to children's health, the NAS study itself revealed no evidence of any special hazard to children posed by pesticides. The NAS simply called for further scientific study.

On the same day the EWG issued its report (the NAS study had not yet been released), the EPA, FDA and Department of Agriculture issued a joint policy statement committing the Clinton

administration to “reducing the use of pesticides and [promoting] sustainable [i.e., largely organic] agriculture.”⁴⁰

In September 1993, a dozen advocacy groups endorsed legislation that would have required the phaseout of many pesticides. Among the groups: Consumers Union, the Environmental Working Group, the Natural Resources Defense Council, Citizen Action and Friends of the Earth.⁴¹

Browner got the message. She, and thus the EPA, shifted focus to reducing overall pesticide use in order to reduce risks—ignoring whether or not the risks were significant in the first place.⁴²

Part of that policy is the systematic revocation of food crop tolerances for pesticides found to have caused tumors in laboratory animals. In addition, the EPA has stopped all regulatory review and processing work related to chemicals that would fail to gain approval under a strict interpretation of Delaney.⁴³ The implication of this misguided policy is that useful research on new products may be sidelined even though they may be highly beneficial and of little hazard to humans.

At the same time, the EPA has not formally asked Congress to revoke or revise the Delaney clause. Browner is thus engaging in a game of regulatory chicken; at stake is the ready availability to consumers of a wide variety of foods, and perilous economic consequences for agriculture may result.

For modern agriculture to continue to be successful in feeding the world, chemical crop protection absolutely is necessary. Without fertilizers and chemical crop protection, it would be nearly impossible to feed the roughly one billion people added to the world’s population every decade. To put the results of modern agricultural technology in perspective: in order to produce the equivalent of 1990s food crops using 1940s technology, it would be necessary to cultivate roughly two thirds of existing forest land and nearly three quarters of pasture and range lands, with clearly adverse environmental effects.

Implication of Delaney for the Near Future

“Virtually all perishable fruits and vegetables . . . depend heavily on pesticides,” the National Research Council noted in its report on the Delaney clause. “Some are treated a dozen or more times a year with six or more different active ingredients.”⁴⁴ For example, 80 percent of the potato acreage is treated with fungicides that cause cancer in laboratory animals. About half the acres of apples, tomatoes, plums, prunes and cherries are treated with fungicides that would fail a strict Delaney

test. Several common herbicides are presumed to cause cancer in animals (and therefore humans) by the EPA, including Atrazine; 2,4-D; glyphosate (Roundup); and Alachlor (Lasso). Many of these substances have been in use for 30 to 40 years without measurable adverse effects on human health.⁴⁵

Some other examples:

- Parathion is an insecticide used on lettuce. The EPA has determined that its use on lettuce involves a hypothetical elevated cancer risk of 4.3 in 10 million.⁴⁶ Parathion's removal from the marketplace might put at risk the ready availability of lettuce to consumers nationwide, at significant cost.⁴⁷ Recall, for instance, that retail lettuce prices roughly doubled in the wake of floods in California during the winter of 1994–95.
- Benomyl is a fungicide used to stop “rice blast,” a disease that prevents rice kernels from reaching maturity. It is the only known effective fungicide for this purpose. Benomyl is used on as much as one third of the rice acreage in the Mississippi Delta states of Arkansas, Louisiana and Mississippi, which together produce roughly 10 billion pounds of rice annually. Without benomyl, which the EPA has announced its intent to remove from the market under the Delaney clause, individual rice farmers could lose three quarters of their crops.⁴⁸
- Pendimethalin is a herbicide that was used by mint growers in 1991 and 1992 under an emergency EPA permit to prevent weeds that would inhibit growth—and therefore crop yields—of this perennial. But the EPA subsequently revoked permission to use pendimethalin, citing the Delaney clause. Mint production in one studied area dropped 13 percent, representing a loss of 625,000 pounds of mint oil. To put that in some perspective, a pint of mint oil will flavor 70,000 sticks of gum. Another mint herbicide, oxyfluorfen, is listed for cancellation under the Delaney clause; this has been projected to result in additional crop losses of 10 to 15 percent.⁴⁹
- Six fungicides used on apples—benomyl, captan, mancozeb, metiram, thiophanate-methyl and triadimefon—all could be banned under a strict interpretation of the Delaney clause. According to the EPA, none of these pose unreasonable risks to the population. They are used to control diseases such as apple scab, powdery mildew and bitter rot. This would leave seven remaining approved fungicides, which theoretically can be used to fight the same diseases, but they are not as effective and therefore would require increased applications. Some of them have undesirable side effects. They do not control rot nearly as well, and one chemical leaves a black residue. By some estimates, as much as half of the mid-Atlantic region's apple crop would rot if the above-

named fungicides were banned. All of these factors would increase consumer costs significantly.⁵⁰

- An estimated 50 percent of Florida tomato production would be lost if mancozeb, for which there are no alternative pesticides, was removed from the market.⁵¹
- Three pesticides listed by the EPA as subject to possible revocation under the Delaney clause—norflurazon, propargite and simazine—are considered by growers to be essential for production of apricots, cherries and almonds in California. There are no substitutes.⁵²
- Benomyl and dicofol are considered essential to production of melons, and there are no alternatives. Benomyl also is used to treat citrus for post-bloom fruit drop and sour rot. The U.S. Department of Agriculture estimates crop losses exceeding 10 percent without benomyl, representing an economic loss in Florida of half a billion dollars.⁵³
- Captan, as used on food crops, poses a lifetime elevated risk of cancer of 1.43 in 100 million—roughly four cancer cases in the entire country during the next 70 years. It is thus subject to the Delaney clause. Captan is used on the following food crops: blackberries, blueberries, lettuce, strawberries, celery, cherries, grapes, spinach, apricots, tomatoes, pears, plums/prunes, peaches, nectarines, peppers, green onions and apples.⁵⁴

Risks in Perspective

In virtually all of these cases, the chemicals or additives in question pose negligible risks, that is, less than one-in-one-million elevated lifetime risk of cancer.

What does one-in-one-million risk mean? For starters, for safety's sake regulators tend to take the worst-case scenario at every step of the risk-assessment process. By some estimates, this results in an over-estimation of risk by a factor of 100 or more. This may be a desirable margin of safety, but it also may mean the real probability of dying of cancer from consuming synthetic pesticides is as little as one in 100 million. To put that in some perspective, cancer deaths from all causes total roughly 237,000 per million population.⁵⁵

John Graham of the Harvard School of Public Health provided a useful illustration during testimony on Capitol Hill:

There is a small, tiny chance at the end of this hearing that several members and staff will walk out on the street, an airplane will miss National Airport and strike and kill several of the members and staff. . . . [T]he actuarial risk of that for a baby born today

is about not one chance but five chances in a million. Yet no one seriously argues we should hold this hearing underground.⁵⁶

In other words, the Delaney clause forces regulators and encourages the general public to worry about the wrong kinds of risks—exceedingly minuscule risks over which most people have little control. And in some respects, it encourages unhealthy behavior.

If, as a result of chemical scares rooted in the Delaney clause, consumers avoid eating a wide variety of fresh and processed foods—especially fruits and vegetables—they may be avoiding one of the best deterrents against cancer.

There are several basic actions people can take to reduce significantly their risks of cancer and other illnesses, debilitating injuries and even death. These involve truly threatening or fatal risks, not just hypothetical ones. They can, for example, refrain from use of tobacco products. Lung cancer is the leading cause of cancer death, and it is most commonly associated with smoking and certain occupational exposures.⁵⁷ They can avoid excessive drinking, and not drink and drive. They should always wear seat belts and motorcycle helmets. They should exercise regularly, eat a balanced diet and avoid excessive weight gain (as many as one-third of all cancer deaths in the United States are at least partly attributable to diet).⁵⁸ They should refrain from early, promiscuous or high-HIV-risk sexual activity. These are behaviors people generally can choose to adopt or modify to reduce risks that dwarf those associated with the consumption of food additives.

But until the Delaney clause is repealed, Americans will continue to be distracted from real risks.

A More Flexible Regulatory Alternative

Congressional Response

The latest congressional response to the threats to agriculture warned of by the EPA, farmers, food processors and others is a somewhat obscure amendment to Senate Bill 343, part of the Senate's version of the Contract with America's regulatory reform package. Originally added by Sen. Charles Grassley, R-Iowa, the amendment states, in full:

Notwithstanding any other provision of law, no covered agency shall prohibit or refuse

to approve a substance or product on the basis of safety, where the substance or product presents a negligible or insignificant foreseeable risk to human health resulting from its intended use.

(There is a corresponding bill in the House, HR 1627, which similarly would override the Delaney clause.) This Senate amendment is supported by an array of industry associations, who view it as an opportunity to take important steps toward reform.

Unfortunately, the Grassley amendment is at best a flawed solution to the problem. It leaves in place the Delaney clause and does not directly amend it, perhaps inviting litigation. Second, like the Delaney clause, the Grassley Amendment enshrines in law the principle that there is some magic “bright line”—a set standard that cannot be exceeded—at which it is appropriate to ban a product on account of risk, regardless of its benefits. “Negligible risk” generally has been interpreted to mean a one-in-one-million elevated risk of cancer.

A far superior solution would be explicitly to repeal all three Delaney clauses (1958, 1960 and 1962). Further, the one-in-a-million risk level under the adulteration provision of Section 402(a)(1) and the general safety provision of Section 409 also should be repealed. A strong argument can be made that this is the only action Congress need take, because absent the Delaney clause and these bright-line standards, the regulatory agencies would be freed to balance risks against benefits and use a more appropriate “weight of the evidence” test to regulate food additive risks.

But while that may well be the ideal policy, the politics of the Delaney clause probably require something to replace it, at least in regard to pesticide tolerances. (The combined effects of other laws governing food colorings place the burden of proving safety on the producer, thus imposing a very high safety standard.)

If so, then what should replace the Delaney clause?

A fundamental question is whether or not to replace the zero-tolerance of Delaney with some other bright-line standard, whether it is one-in-one million, one-in-100,000 or one-in-10-million elevated risk of tumors and other health risks.

The single advantage of a bright line essentially is economic. Although any standard that might be adopted clearly would be arbitrary, in the sense that a political decision would be made to adopt a set risk standard for all food, drug and cosmetic additives, a bright line has the significant economic advantage of clarity. Everyone involved in food production and processing would know,

with reasonable certainty, whether an additive could pass regulatory muster. It would be a yes/no answer, and one most likely insulated from legal challenges by chemophobic advocacy groups.

But while the advantage of a bright-line standard is not to be dismissed, a bright line also has a tremendous disadvantage. A substance that offered some specialized benefit but that also carried a risk exceeding a set standard would have to be kept off the market. Furthermore, who could say whether a bright-line standard that makes some degree of scientific sense today would not eventually be overrun by technology just as the Delaney clause has?

Although it goes against the culture of the modern regulatory state, the optimal replacement for the Delaney clause would be a flexible regulatory process that does not specify in excessive detail a particular standard or standards of risk. *This would be a process, not a specific standard.*

The basic assumption of this approach is that with the advancement of technology and medical knowledge, general standards of acceptable risks also are likely to evolve. The Delaney clause's absolute-zero risk standard clearly is unreasonable. At the same time, however, it would be just as unreasonable to preclude regulation of any substance that poses a small but certain risk. A flexible process would allow such a product to be removed from the market, whereas a bright-line standard might not.

What should be involved in such a process?

First of all, tumors or cancer should not be the sole or even primary regulatory concern. Regulators should consider a broad range of possible health risks, including cancer.

There is a role for animal testing, including maximum tolerated dose tests, provided regulators interpret the results in the appropriate context. Animals are not little humans, as discussed above. Animal testing should take into account the physical mechanisms of response to invasion by a test substance, the actual route of exposure and how the animal responds. Some attempt should be made to convert the doses given in animal tests to equivalent human doses. For instance, if an animal test involves smearing a substance on the animal's bare skin, is that a likely means of exposure to a person? Does a substance cause physical problems in just one animal via a particular route of exposure, or in several animals via several routes of exposure? These types of questions should be considered when interpreting animal tests. But they are difficult, at best, to write into law.

Second, it may be necessary to set down a legal guideline that regulators cannot use worst-case assumptions in calculating risk except under extraordinary circumstances. By piling worst-case

assumption upon worst-case assumption, regulators easily can overestimate risks by multiples of millions. For instance, a Sandia National Laboratories report illustrates that by taking the worst-case assumption in calculating the risks of PCBs, one can calculate a risk estimate 150 million times greater than one using “reasonable, mean or median” values for exposure variables.⁵⁹

Third, regulators should take into account, in ways they currently are not allowed to do, negative and “no effect” test results as well as positive results. As noted above, many substances inhibit tumors in laboratory animals as well as cause them, while still others seem to have no effect on tumor formation at all. Yet current law only allows regulators to consider the positive development of tumors. Ninety-nine tests might show negative results or no effect, but if Number 100 shows a positive correlation to tumor growth, the Delaney clause may be invoked.

Fourth, although this is implied in the absence of a bright line, each substance should be evaluated on a case-by-case basis. Regulators should be able to weigh potential benefits (including a lack of suitable alternatives) against potential harm.

Last, at some point real-world human exposure and epidemiology must be taken into account. A substance that is toxic to some animals is not necessary toxic to humans, and vice versa.

Admittedly, a more flexible regulatory approach might make the regulatory process somewhat contentious, as interest groups, scientists and regulators argue through administrative and legal proceedings about what is safe and what isn't. Perhaps a general guideline in the law should specify that regulators must follow currently accepted scientific practice and judgment as evidenced, for example, in publications in independent, refereed, scientific literature. In addition, to bring proceedings to cloture, a provision should be made to guarantee continued approval for a reasonable period once a determination is made.

Such an approach would be far from perfect. But it would come much closer to scientific honesty and prioritization of risks than what we have now or would be likely to get from any bright-line approach. It would help regulators and, ultimately, consumers distinguish between those health risks worth worrying about and those that verge on superstition. And it would help to prevent advocacy groups from scaring people away from healthful foods.

This, of course, is a somewhat idealistic policy prescription for a less than ideal political world. Significant political barriers lie between the Delaney clause and a rational regulatory process.

The Politics of Delaney Repeal

Senate bill 343 and similar efforts, although well intentioned, are likely to generate just as much hostile media coverage and hostile interest-group activity as would a clear repeal and/or replacement of the Delaney clause. So, as there are no significant additional downside political risks to pursuing more comprehensive reform, why not at least try for the optimal solution?

Members of Congress must understand the nature of the pro-Delaney coalition and what its ideological goals really are. Composed of environmental organizations and so-called consumer-advocacy groups, as well as some labor unions primarily concerned about occupational exposures, the pro-Delaney coalition at the most basic level subscribes to the anti-chemical theology of Rachel Carson's *Silent Spring*. These groups do not merely want to regulate the use of food chemicals. In general terms, they want to eliminate them.

The ideal diet outlined by Michael Jacobson, executive director of the Center for Science in the Public Interest (CSPI), is typical of this mindset: "If we had our way, everyone would be dining on whole grains, beans, vegetables, and fruit, along with low-fat dairy foods and maybe a little lean meat or poultry. All of the food would be fresh and unprocessed, and grown organically on local farms."⁶⁰ What does this mean in practical terms? No canned or frozen foods. No out-of-season or non-native produce, such as Hawaiian pineapples or winter lettuce. Maybe, maybe a bit of meat. That is a highly restrictive diet most Americans neither want nor should eat.

Who are these groups? Numerous advocacy organizations are part of the coalition, but the most important in terms of their ability to generate hostile media are the following:

- Consumers Union, publisher of *Consumer Reports*. Its large mailing list and credibility with the general-interest media make it an especially potent pro-Delaney advocate. It has supported legislation that would keep or even strengthen the Delaney clause. It has been an important player in past scare campaigns, including the Alar scare.
- Public Citizen. Through litigation, lobbying and media campaigns carried out by Public Citizen and its subsidiaries (such as the Litigation Group and the Health Research Group), this organization has consistently supported the Delaney clause and opposed the use of pesticides and some forms of biotechnology. Led by former Carter administration official Joan Claybrook, Public Citizen is a very effective organization.
- Environmental Working Group. Formerly the Centre for Resource Economics, this somewhat

obscure advocacy group has emerged since 1993 as an important player in the Delaney debate, as noted above.

- Natural Resources Defense Council. This group orchestrated the Alar scare and other junk science.
- U.S. Public Interest Research Group (PIRG). This organization can tap into the network of state PIRG organizations to generate home-district media.

Although perhaps not as significant as these five, other organizations in the Delaney debate that are likely to oppose its repeal and that also have a history of being able to generate publicity include: Physicians for Social Responsibility; the Center for Science in the Public Interest (CSPI); the Sierra Club; and Public Voice for Food and Health Policy, whose former executive director, Ellen Haas, is now an assistant secretary of agriculture.⁶¹

These organizations will play hardball, as evidenced by the Alar scare, CSPI's campaigns against restaurant foods and Consumers Union's strange fear campaign against bovine growth hormone (used to help cows produce more milk—milk chemically indistinguishable from “ordinary” milk).

These are the true extremists in the Delaney debate. It is important to understand that they are primarily activists, not scientists. Therefore, when confronted by them, lawmakers should not hesitate to attack their use of junk science. Within the scientific community, the Delaney clause long has been the subject of criticism, as noted elsewhere in this report.

Some of the nation's—indeed, the world's—most prestigious scientific organizations have either called for the Delaney clause's repeal or published devastating critiques of it (some scientific groups are reluctant to make policy recommendations). For example, the International Federation of Societies of Toxicologic Pathologist and its U.S. affiliate, the Society of Toxicologic Pathologists, have called for Delaney's repeal on scientific grounds. The National Research Council, in a 1987 report prepared at the EPA's request, emphasized the contradictions in regulation caused by the Delaney clause and its unworkability in the modern world. The NRC was not charged with making specific policy recommendations, but the clear implication of its report is that the Delaney clause should be repealed and replaced with a more flexible risk standard. The American Medical Association, as noted above, has called for Delaney's repeal.

The American Association for the Advancement of Science, perhaps the nation's foremost scientific organization, has criticized the Delaney clause on numerous occasions through editorials in

its journal, *Science*. The AAAS is not a lobbying organization, however, and its pronouncements generally have escaped media attention.

In the academic and scientific community, the debate over the Delaney clause has long since been settled: Delaney must be repealed.

Conclusion

The Delaney clause is indefensible as either a scientific or a regulatory standard. The United States stands alone in the world in such regulatory pursuit of a risk-free utopia. The Delaney clause should be repealed, and officials should instead seek to shift Americans' attention away from hypothetical risks and toward the real health risks that they can change.

- ¹ Food Additive Amendment of 1958, Section 409(c)(3)(A).
- ² “Risk Assessment of Carcinogens in Food with Special Consideration of Nongenotoxic Carcinogens,” International Federation of Societies of Toxicological Pathologists, Society of Toxicological Pathologists (USA), July 1995.
- ³ *Ibid.*
- ⁴ 968 F.2d 985 (9th Cir. 1992).
- ⁵ 968 F.2d 985 (9th Cir. 1992), *cert. denied*, 113 S. Ct. 1361 (1993).
- ⁶ *Les v Reilly* was the culmination of the regulatory petition brought by the State of California, the AFL-CIO, Public Citizen and the Natural Resources Defense Council on May 25, 1989, challenging the EPA’s minimal risk standard and demanding a “zero risk” interpretation of the Delaney Clause. The Ninth Circuit rendered its decision on July 8, 1992, and the Supreme Court denied cert. the following year. On July 14, 1993, the EPA revoked the food additive regulations (permits) named in the petition (60 FR 3607).
- ⁷ Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, “Fact Sheet on Feb. 8, 1995, Court-Approved Settlement Agreement on Pesticides Affected by the Delaney Clause,” Feb. 10, 1995.
- ⁸ Quoted in Whelan, Elizabeth M., and Fredrick J. Stare. *Panic in the Pantry: Facts & Fallacies about the Food You Buy* (New York: Prometheus Books, 1992), p. 131.
- ⁹ Despite the common usage of the title “Delaney Clause,” there is no such title in the law.
- ¹⁰ Food Additive Amendment of 1958, Section 409(c)(3)(A).
- ¹¹ 21 USC § 346(b)
- ¹² National Research Council, Committee on Scientific and Regulatory Issues Underlying Pesticide Use Patterns and Agricultural Innovation, *Regulating Pesticides in Food* (Washington: National Academy Press, 1987), pp. 25–27.
- ¹³ For detailed discussion of the DES exception and the FDA lawsuit, see: Jukes, Thomas H. “Carcinogenicity of Female Sex Hormones, Especially as Related to Use in Pregnancy and in Meat Production,” in *CRC Handbook of Endocrinology*, Vol. 2, Part B; G.H. Gass, H.M. Kaplan, eds. (Boca Raton, Fla.: CRC Press, 1987, pp. 143–158.
- ¹⁴ Flamm, W. Gary. “Regulatory Aspects of Carcinogenicity Studies and the Delaney Clause,” *Regulatory Toxicology and Pharmacology* 21, pp. 71–74 (1995).
- ¹⁵ Gold, Lois Swirsky, et al., “Rodent Carcinogens: Setting Priorities,” *Science*, October 9, 1992, pp. 261-265.
- ¹⁶ Jukes, Thomas H. “Molecular Carcinogenic Nonsense,” *Clinical Toxicology*, 17(3), pp. 475–476, 1980.
- ¹⁷ *Ibid.*

- 18 Quoted in Brookes, Warren T. "The Wasteful Pursuit of Zero Risk," *Forbes*, April 30, 1990, p. 160 (8).
- 19 Testimony submitted to House Energy and Commerce Committee and Senate Labor and Human Resources Committee (Joint Hearing), "Safety of Pesticides in Food," September 21, 1993, CIS No. 94-H361-14, p. 185.
- 20 For a more complete discussion of Delaney Clause enforcement's effects on innovation, see National Research Council, *op. cit.*, pp. 136–158.
- 21 Jukes, Thomas H. "The Delaney 'Anti-Cancer' Clause," *Preventive Medicine* 2, p. 138 (1972).
- 22 Davies, Thomas S., and Alastair Munro, "The Rodent Carcinogenicity Bioassay Produces a Similar Frequency of Tumor Increases and Decreases: Implications for Risk Assessment," *Regulatory Toxicology and Pharmacology* 20, pp. 281–301 (1994). Data drawn from NTP Technical Reports, Nos. 380–419 (March 1990–May 1993), with the exceptions of Nos. 383, 384, 400 and 404, which were not yet available at the time of Davies and Munro's analysis.
- 23 Gianessi, Leonard P. "The Economics of Delaney," paper presented at the 208th American Chemical Society National Meeting, Aug. 25, 1994, pp. 7–8.
- 24 Abelson, Philip H. "Risk Assessments of Low-Level Exposures," *Science*, September 9, 1994, p. 1507.
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- 26 *Ibid.*
- 27 Regulatory Impact Analysis Project, *Choices in Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process* (Washington: Sandia National Laboratories, 1994), p. 37.
- 28 *Ibid.*, pp. 38–39.
- 29 Ashby, J., and R.W. Tennant. *Mut. Res.* 257 (1991), pp. 229–306; Gold, L.S., et al., *Environmental Health Perspect.* (1989) 81, pp. 211-219.
- 30 Munro, Alastair. "The Paradoxical Lack of Interspecies Correlation between Plasma Concentrations and Chemical Carcinogenicity," *Regulatory Toxicology and Pharmacology* 18, pp. 115–135 (1993).
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- 41 Holt, *The Rise of the Nanny State*, p. 24. It also may be significant that Browner’s husband, Michael Podhorzer, worked for Citizen Action at the time.
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