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Prologue: The Food and Drug Administration (FDA), like most government agencies, is greatly influenced by the milieu in which it operates. For example, the deregulatory thrust of the Reagan administration has influenced FDA policy by easing the restrictions on pharmaceutical manufacturers in an effort to bring new drugs to market more rapidly. The flip side of this equation, of course, is the potential risk involved, but as Donald Kennedy suggests, this pendulum swings back and forth. During Kennedy’s two-year stewardship as commissioner of FDA, from April 1977 to July 1979, regulation as a policy instrument had already begun to lose favor. He points out that, in an effort to counter this movement, he and his counterparts at other agencies sought to distinguish between economic regulation and regulation affecting the health and safety of the populace. The effort failed, but many of the same issues that Kennedy discusses in this article, which was adapted from the Messenger Lecture he delivered originally at Cornell University, remain. Kennedy departed government for Stanford University where, one year later, he assumed the presidency. Once in that post, ironically, Kennedy found himself dogged by economic regulation that sought to curb the growth of public health expenditures and thus make management of Stanford’s medical school and teaching hospital complex more difficult. Kennedy commands a wide following today as one of the nation’s most articulate and thoughtful university presidents. He has demonstrated leadership by convening a distinguished group to set guidelines that universities and private businesses might follow when negotiating research-based relationships. Most recently, Kennedy has been instrumental in drawing together with Harvard University President Derek Bok - a group to discuss how higher education institutions can work with secondary and elementary schools to upgrade the study of science in the United States.
When I first arrived at the Food and Drug Administration (FDA) in April of 1977, I found myself receiving a good deal of companionable commiseration; a typical greeting was “Welcome aboard the Titanic.” It did not take long to identify this as the kind of gallows humor to which able people resort in difficult situations, and I came to enjoy it—especially after I realized that the agency was of basically sound health and morale. One specimen of the genre, however, did stay with me because it struck me then—and strikes me now—as epitomizing the political dilemma of a modern regulatory agency. “The FDA,” a colleague told me after a particularly difficult oversight hearing, “is a slowly moving target that bleeds profusely when hit.”

In about forty more Congressional appearances over the next twenty-seven months, I had ample opportunity to reflect on the aptness of that statement as a description of the political crossfire which one finds not only at FDA, but at the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Environmental Protection Agency, and even parts of the Department of Agriculture and the Federal Trade Commission. All these agencies have been assigned by the Congress statutory responsibilities for health and safety regulations. FDA, for example, is charged with accomplishing the following remarkable range of things: assuring the safety and purity of all of the nation’s food supply (except for meat and dairy products, which are the responsibility of the Department of Agriculture); validating the safety and effectiveness of drugs and medical devices as well as vaccines and biologic products; inspecting and safety testing of such radiation-emitting products as X-ray machines and lasers; evaluating animal drugs and additives to livestock feed; and assessing the safety of cosmetics. These responsibilities add up to the regulation of nearly twenty-five cents out of every dollar of consumer expenditure in the United States; and to accomplish the work Congress now appropriates for FDA just little more than $1.25 for every U.S. citizen.

It would seem that the tasks FDA performs are in the interest of unarguably valid social objectives and that they are being taken care of at bargain rates. They are certainly taken care of well, at least in my experience. FDA had, and has, a first-rate cadre of professionals staffing its twenty-three district laboratories and working in over fifty inspection posts around the country. FDA's basic strategy of plant inspections, in which quality control of manufacturing practice is emphasized, has virtually eliminated such major incidents as botulism epidemics to which the food supply is potentially vulnerable. Public confidence in the quality of medical technology is high, and the representatives of organized medicine, whatever else they may be complaining about, are not calling for a return to the good old days of caveat emptor in the pharmaceutical business. Why, then, is FDA- and health regulation more generally-so controversial?

That is the central question I want to examine in the rest of this article.
Some general features of the social climate in which health regulation functions already begin to suggest an answer. These features include some very fundamental public attitudes: how many risks we are willing to take; how much we are willing to have government intervene in our lives; whom we hold responsible for our health; what social value we place on technological innovation; and what price we put on certain things we like to do. They also relate in a very important way to the history of technology and the expectations we have of it. The current controversy about health regulation owes much to mismatches in rates of development of different scientific capacities, and rates of social and political expectation.

Regulation And Disease Prevention

The early history of health technology is dominated by growth in understanding the role of the environment. In the seventeenth and eighteenth centuries, dramatic improvements in health were wrought through the recognition that some terrifying diseases had straightforward explanations, and sometimes even simple solutions. The discovery by John Snow that cholera was traceable to a disease organism in drinking water, or Sir Percivall Pott’s demonstration that scrotal cancer was an occupational disease of chimney sweeps, are examples to which beginning students in epidemiology and infectious disease are traditionally exposed. Large changes in human life expectancy followed as the new industrial societies developed the means to follow up such discoveries with the social actions necessary to turn them to human benefit.

Great gains had been achieved before the advances of modern curative medicine began in the 1930s, and still more followed. As a consequence, a new set of diseases came to replace the major infections as the primary medical scourges of humankind. Instead of being killed by smallpox, cholera, plague, or malaria, people in the industrial nations were surviving longer, and falling victim to other diseases. Modern biomedical research added some new achievements - the conquest of poliomyelitis and the management of various secondary infections, for example, and we soon found ourselves facing an array of stubborn, perplexing diseases that mostly affected older people. Cancer and cardiovascular disease moved to the top of the list of killers in the Western nations, and they have proved relatively resistant to the research and treatment strategies that were so successful against other health problems.

It is now becoming clear that cancer and heart disease are in some respects like the diseases Snow and Pott explicated centuries earlier: they are, in significant part, the result of the modern industrial environment, and can justifiably be called the “new social diseases.” Technology has relieved some scourges, but it has contributed to others. Life in a postindustrial society presents hazards; some are undertaken, like smok-
ing or an overly rich diet, while others are imposed, like the contaminated workplace, or job-related stress, or polluted air. The realization that these are avoidable risks has suddenly made disease prevention politically popular—a popularity helped by public exasperation with the growing per capita cost of health care, which in 1983 accounts for over 10 percent of the gross national product. It is believed that by pursuing sensible dietary goals, jogging, avoiding smoking, and staying out of unhealthy places, Americans can stay well—and save money by keeping out of those expensive, high-technology hospitals.

There is actually a good deal to this notion, but by itself it is inadequate because it does not take care of those health threats to which Americans are involuntarily subjected, and therefore cannot avoid. The Love Canals, the unclean air, the contaminated food, are things one cannot control by oneself; a social agreement is required. Over the past two decades, Congress has enacted at least a dozen new statutes or major amendments that attempt to control technologies associated with health risks. There can be no mistaking the positive political thrust behind such measures to bring governmental authority behind public health goals.

Yet there is equally unmistakable evidence of public ambivalence about the execution of regulatory power given government on behalf of disease prevention. When the FDA moved to remove saccharin from soft drinks and foods under an absolutely unambiguous provision of the law, an intense public reaction persuaded Congress to enact a moratorium against regulatory action. On at least three occasions in the 95th and 96th Congresses, language was added to appropriations measures that restricted regulatory agencies from carrying out actions under the law. And late in 1979 the “legislative veto” was formalized when the House of Representatives voted to require committee review of regulations proposed by the Federal Trade Commission. These things do not happen without constituent mail and other signals of public support. What is bothering people about health regulation?

The Public Mistrust Of Regulation

Part of it is that they are bothered about regulation generally. Regulation in the interest of health and safety is a small part of government regulatory activity and, even though it has distinctive features, it often gets confused with the rest. Sometimes people even forget about it entirely. For example, Charles Schultze, a distinguished economist who served as Chairman of the Council of Economic Advisers in the Carter administration, wrote in a recent critique of federal over-regulation that in the 1950s, “There were but four areas in which the Federal government had regulatory responsibilities—anti-trust, financial institutions, transportation, and communications. In 1976 there were 77 Federal agencies engaged in regu-
lating some aspect of private activity." That account not only neglects the Food, Drug and Cosmetic Act, which antedated by nearly half a century the period Schultze takes for his dividing line, it also ignores other federal responsibilities in the area of communicable disease and other health matters. But Schultze's omission is significant chiefly because it reflects the tendency of health regulatory agencies to be the innocent victims of resentments that are aimed elsewhere.

The kind of regulation that concerns Schultze is more properly termed *economic* regulation. It grew out of dissatisfaction with the way in which the free enterprise system was working in an increasingly complex society. Usually the problem was too little competition, or a resource so limited that government had to intervene to parcel it out fairly. Allocating routes in transportation systems and setting rates for a basic utility are examples of this sort of regulation; so are the procompetitive requirements set out by the Federal Trade Commission. To carry out such economic regulation, Congress established the so-called independent regulatory commissions - multimember bodies that, although they are technically part of the executive branch of government, report directly to legislature. The Federal Trade Commission, the Federal Aviation Agency, and the Interstate Commerce Commission are all examples of this kind of regulatory body. In general, the health and safety regulatory agencies are, or belong to, conventional executive agencies with a single head. FDA is part of the Department of Health and Human Services; OSHA belongs to the Department of Labor; EPA is an independent agency whose administrator sits with (although he is not of) the Cabinet. There are exceptions to this rule: the Consumer Product Safety Commission and the Nuclear Regulatory Commission, both clearly health agencies, were created in the independent, collegial mode by Congress in the 1970s.

Confidence in the work of the economic regulatory agencies has been shaken by revelations about their closeness to the regulated industry and by the growing feeling that much regulation of the route-setting, rate-making type actually interferes with competition. That view was reinforced, early in the Carter administration, by the successful "deregulation" of air travel under the leadership of Alfred Kahn, then Chairman of the Civil Aeronautics Board. Although some local service routes were abandoned, prices on major transcontinental routes dropped due to the rise in competition, and load factors went up. The dramatic rise in fuel prices triggered by events in the Middle East made the later phases of this experiment a little hard to follow (especially for the rueful business traveler), but most observers were ready to credit deregulation with a major success. In Congress there have been subsequent efforts to extend the principle to the trucking industry and elsewhere.

It was not clear where "elsewhere" stopped. To the extent that economic regulation had developed a bad name, it was easy to lose the adjec-
tive and decide that all regulation was bad—even though health and safety regulation has an entirely different set of social purposes. As soon as it became clear, about the middle of 1977, that the antiregulatory mood in Congress was more than a passing fancy, I began to stress these differences. So did the heads of other health and safety agencies, especially the thoughtful and able administrator of EPA, Douglas Costle. So, to his great credit, did Alfred Kahn, after he had left his success at CAB to take charge of Carter’s voluntary wage and price control program. As far as I can tell, these efforts were to no avail. There is something quite generic about the appeal against regulation. And there are also some difficulties with health regulation that are special.

Accepting Technological Failure

Another part is related to the attachment all of us in contemporary America have to the quick technological fix. We have in this country a remarkable scientific establishment that has responded successfully to a series of social challenges. So accustomed have we become to these marvels that we expect them on demand—understanding, of course, that we will be charged for them. Indeed, the linkage between purchasing a result in advance and then getting it (illustrated most dramatically by President John Kennedy’s confident assertion that “we should go to the moon”) has led to the belief that scientific solution can regularly and easily be bought.

There is surely no disease to which Americans more ardently desire a scientific solution than cancer. Cancer is not so very significant outside the developed world; but there, longevity, industrialization, and altered life-styles have promoted it into a first-place medical worry. Nearly everyone in this country can recite personal tragedies of relatives or loved ones, tragedies that feature the properties that make cancer so fearsome: its unpredictability, its often disfiguring or painful character, its lingering nature. These attributes have given cancer an entirely unique leverage on health policy in the United States. A 1978 Harris poll showed that Americans fear cancer more than they fear war.

Certainly no other disease ever had a war declared on it by an administration. In 1970, when President Nixon asked for and was given an extra $100 million appropriation for what he called the “War on Cancer,” biomedical research was clearly identified as the main weapon. To be sure, responsible scientists urged caution upon an expectant public, and some even rejected the effort as premature. The majority of citizens, however, have seen the war as they remembered the war on polio, and they can scarcely be blamed for expecting an equally dramatic result. It is hard to exaggerate the intensity of expectation. The largest-circulation newspapers in the seventies, the weekly tabloids like National Enquirer, sold at
checkout counters in supermarkets, know something about what is in the American mind, and nothing—not the private lives of starlets, not the sexual misadventures of rock stars—rates more lineage in them than prospective cancer cures.

Yet the cure, in the sense of the magic-bullet cure that ended the threat of polio, has not been forthcoming. It is difficult not to respond to the war metaphor by expanding it: if the war on polio was like World War II, then the war on cancer is surely a biomedical Vietnam. The more deeply we get in, the less clear-cut the solution appears; and the more resources we invest, the more we are asked to provide.

Now the American people are being told that cancer is quite probably a disease of multiple etiology, and that it is importantly related to environment and lifestyle. The message, to return briefly to the military metaphor, is: “We have met the enemy, and he is us!” The psychological impact of all this is complex, and not a little discouraging. Having engaged in their part of a peculiarly American bargain—the purchase of a solution through high technology—our citizens now discover that the deal didn’t stick. They are being asked, in effect, to pay again, this time by foregoing habits to which they have become attached. It is no great wonder that they respond with annoyance when told that, having already been taxed to cure cancer, they must now give up smoking, diet soft drinks, and possibly even grilled steak. What, they wonder, will be next—morning calisthenics?

Accepting Government Intervention

A second difficulty with health regulation is that it regularly presents questions about the appropriate degree to which the State can interfere in the private behavior of citizens, even in their best interests. The Boston Globe columnist Ellen Goodman described this social dilemma poignantly after reciting the history of a seventy-year-old woman named Mary Northern, who spent the final months of her life fighting off a well-intentioned government effort to require that she undertake medical treatment she did not wish to receive.

“Mary Northern...” Ms. Goodman said, “leaves us a legacy beyond the ramshackle old house she shared with her cats and family memories. She leaves a reminder of how often individuals, especially the weak, the sick, the elderly and the dependent, need protection from the powerful establishments—even the establishment of kindness.”

We have a vigorous tradition against such interventions, epitomized by John Stuart Mill’s assertion that “The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others.” The contemporary political controversies that swirled about the legalization of Laetrile and state re-
quirements for wearing motorcycle helmets have their antecedents in debates over the fluoridation of water supplies and the requirement for inoculation against communicable disease. These matters are difficult precisely because they raise basic questions of social justice. Such questions must be approached through the analysis of how particular actions affect the welfare of others in the society—or, in other words, by looking at the distribution of risks and benefits that resulted from whatever action we seek to regulate. 

We may start with a rather old example, one that entails the trade-off between a modest individual benefit and broadly diffused risk. The case is whether the government should be able to require immunization against a communicable disease. State-mandated programs of immunization are now common, but in the United States at the turn of the century there was strong resistance to such requirements. The situation for an epidemic disease such as smallpox or influenza can be described in this way: a large social benefit, shared equally by all members of society, can be obtained if the majority of members receive immunization. The relationship between the percentage of people immunized and the probability or severity of an epidemic is complex, but most authorities believe that group protection rises markedly between about 65 and 80 percent. If no one else is being immunized, an individual can purchase valuable protection at very small risk. The exact amount of risk is hard to measure, but as we learned in the swine flu inoculations for the 1976 epidemic that never came, a very small proportion of the persons inoculated developed a rare neurological disease called Guillain-Barre Syndrome. To this must be added the other unlikely hazards associated with any routine medical procedure-trauma to the elderly, with a few contingent heart attacks, accidents on the way to the dispensary, and so forth. The total is still quite negligible for a healthy person, but it is not zero. If our sample individual, instead of being the only person to be immunized in a population, is the last, that risk is highly significant because in a population in which an epidemic is impossible, a communicable disease presents no hazard to the uninoculated. Thus the last person to be inoculated can become a free rider and benefit fully from the risks taken by others. An incentive therefore exists to avoid immunization, at least if the program is going well.

In 1905, in the midst of a threatening smallpox epidemic, the Supreme Court dealt eloquently and simply with this problem, without the benefit of recourse to modern risk-benefit terminology. The Court said: “In every well-ordered society charged with the duty of conserving the safety of its members, the rights of the individual in respect of his liberty may at times under the pressure of great dangers be subjected to such restraints, to be enforced by general regulations, as the safety of the general public
may demand... . ." So much for free riders.

Despite the complex relation between individual and group benefit in this example, it comes down to a fairly straightforward illustration of Locke’s social contract, in which individual risks are assumed in order to generate a large societal benefit. What, however, if the risk appears not to be undertaken reluctantly but gladly, and society’s stake in the matter is represented only by its obligations to the individual?

There is in the Appalachian highlands a fundamental religious sect that lays great stress upon the strength of its members’ faith. In their liturgy, this faith is put to test by deliberate exposure to harm. Possibly because many of the more familiar forms of risk cannot conveniently be taken inside a small church building, the communicants do an odd thing: they handle poisonous snakes. It is not surprising that faith occasionally proves inadequate, and backsliders have to be rushed to the county hospital. Even if they survive to sin again, their treatment—our health system being what it is—is likely to involve significant public expense.

A few years ago the state of Tennessee took the sect to court to enjoin it against the practice of snake handling. The defendants argued that the snakes were being handled as part of a religious observance, and that the practice should therefore enjoy constitutional protection. The State countered that the deliberate infliction of harm on others cannot be protected merely by assimilating it into a church service; other kinds of antisocial behavior (for example, sacrifices) are not permitted merely because it is alleged that they are essential to a religious observance. There is a substantial State interest in a healthy citizenry, supported by a system of welfare payments. These resources, Tennessee claimed, are unfairly consumed by the participants in this ritual. That claim apparently proved persuasive, because the Tennessee Supreme Court eventually ruled in favor of the State.

A similar argument can be made for government enforcement of measures designed to reduce the incidence of much less bizarre risks. Several states have passed legislation requiring that the riders of motorcycles wear helmets. A few years ago federal regulations mandated the installation of interlock devices on all new automobiles that make them impossible to start unless the seat belts were fastened. The former have aroused considerable controversy, and a number have been repealed. The latter promptly drew the ire of Congress, which put an end to the requirement.

Obviously these cases differ from the snake handling lawsuit in ways that go beyond their more prosaic character. It could not be argued, for example, that a special constitutional right like freedom of religious observance is raised by helmets or seat belts. But in two respects they are similar. First, the risks are well enough understood so that it can scarcely be held that the taker is being exposed to them unknowingly. Second, the risk is limited to the risk-taker; the helmetless rider of a motorcycle is
not, merely by virtue of his bareheadedness, more likely to run into somebody else.

But the Tennessee court was apparently very receptive to a different point that does find an analog in the case of motorcycle helmets. Although the risks may be fully internalized to the risk-taker, the costs may not be. Head injuries require treatment, and our society does not walk away from the injured merely because they have been foolish. Because there is public investment in the health care system, this means that others must pay to set right the consequences of individual risk taking. In the snake handling case this societal interest was held to be significant, at least more significant than the religious interest with which it was in collision.

One way to evaluate this general proposition is to explore how far we might be willing to extend it. Heart disease is now the leading cause of medical problems in the United States and accounts for a large fraction of society’s health expenditures. It is generally agreed that the incidence of cardiovascular disease can be sharply reduced by a combination of proper diet, exercise, and the limitation of such risk-elevating behaviors as smoking and excessive alcohol consumption. If State action to wear motorcycle helmets is to be justified purely on the grounds that the State pays for the consequences of noncompliance, then surely State action not to smoke is justified on exactly the same logic. And if regulation to prevent risk-enhancing behavior is legitimate, then why not regulation to promote risk-reducing behavior?

It seems a long way from snake handling to compulsory morning calisthenics, but the individual steps are short, and the line difficult to draw. I argue, however, that there is a line, located somewhere between helmets and calisthenics. In some societies, including several peoples’ democracies and quite probably some summer camps right here in the United States, health-motivated intrusion into individual behavior enjoys tolerance if not broad support. But it is abhorrent to most of us most of the time. I cannot conclude that welfare investment by society purchases, by itself, any rights for the state to intervene in the private behavior of citizens.

The zone I have tried to sketch out in the last few paragraphs is the legitimate home for the contemporary debate called “freedom of choice.” During my term as Commissioner, however, that phrase was most used in connection with two issues that bear little relation to those we have been discussing here. These two involved the marketing of the cancer remedy called Laetrile as a drug, and the FDA’s proposal to withdraw the approval of saccharin as a food additive in diet soft drinks and foods. There is a surface plausibility to the assertion that the risks associated with a possibly unsafe, possibly curative drug or an artificial sweetener are, like the other risks we have been discussing, ones in the taking of which the
State has no right to intervene. In fact, however, I think the situations can be shown to be quite unparallel.

The case of Laetrile is made special by the participation of an important third party, the doctor. Such remedies are being offered to prospective patients not by people on street corners, but by physicians who are licensed by the State as professionally qualified to provide wise advice about medical treatment. The State, having placed certain qualified persons in a position of such power and responsibility, has undertaken the further obligation of certifying the tools of their trade. Accordingly, each new drug must be approved by the Food and Drug Administration for its safety and for its effectiveness. Were the State to relax this requirement, it would in effect be opening citizens to exploitation through a relationship in which the State itself has credentialed the potential exploiter. Thus the Laetrile situation fails the primary test of freedom of choice, that of the adequacy of information available to the chooser. Can society ask—indeed, require—that the ordinary citizen’s information on a medical matter stand against the confident representations of a licenced physician? Proponents of Laetrile treatment argued, in a class action suit appealed to the Supreme Court, that terminally ill cancer patients merit special exemption from the provisions of the Food, Drug and Cosmetic Act. In rejecting this claim unanimously, the Court said: “To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner’s authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including linaments of turpentine, mustard, oil, eggs; and ammonia; peatmoss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and ‘Fountain of Youth’ mixtures of spices, oil and suet.”

The Court’s rationale shows clearly how unwise it would be to decide such inherently generic matters by looking only at a single example. Even if one were to cast aside the argument about the special authority of doctors and accept the cancer patient’s choice of Laetrile as “free” choice, there would still be serious difficulties. As the Court’s decision points out, it would open the way to a host of other exceptions to the drug laws, and thus breach an entire system of protection. Resolving broad issues at the margin, however sensible it may seem when only the marginal case is in view, inevitably leads to other problems.

This same feature is also prominent in the case of saccharin. Amendments to the Food, Drug and Cosmetic Act passed in 1958 placed a heavy burden of proof on manufacturers to show that substances they add to food are safe.
At the same time these provisions were added, many hundreds of compounds were in general use as food additives. As is usual, Congress dealt with this circumstance with a “grandfather” clause, permitting the continued marketing of substances that were at the time “generally recognized as safe”. If safety questions are raised about substances on this list, FDA is required to remove them and subject them to further testing. This is what happened in the case of saccharin, with the now-familiar result that the additional tests clearly showed it to cause cancer in laboratory mammals.

Two things about saccharin made it special at the time FDA proposed regulations that would have suspended its food additive uses. First, people had gotten used to having it around (the law more usually deals with newly-marketed additives); and second, it was the only artificial sweetener available (alternatives are available in most food additive categories). To these circumstances was added a third. Diet soft drinks, which held about 17 percent of the enormous soft drink market, also represented its most profitable segment because saccharin is much cheaper than sugar per unit of sweetening power. As a result, the Calorie Control Council, representing the diet soft drink and food industry, launched a massive advertising and public relations campaign to promote their side of the controversy. Even without that help, however, the wide acceptance of diet soft drinks and their use by those concerned about weight control and medical problems would have made the proposal to ban saccharin a media event.

Thus saccharin was familiar, unique, and famous. At the peak of the debate it could reasonably be argued that most adults had read of the animal tests, knew of the risks, and were theoretically in a position to make an informed choice. (For the moment, we ignore the large fraction of diet soft drink consumption attributable to small children.) Is there a way of singling out for special treatment in the law those food additives that are unique, or about which public knowledge is especially complete? No one has suggested one. In the debate over saccharin, the only uniqueness argument made by proponents was that saccharin provides a health benefit for diabetics and those for whom weight control is essential. But a legal requirement exempting such food additives from the other requirements of the law would not even solve the saccharin problem because the National Academy of Sciences committee, charged by the Congress to examine this question, could not reach a scientific conclusion that saccharin confers a health benefit. Perhaps, instead, the law could contain provisions for making available adequate public information about the hazards of each food additive. Such an approach has been suggested. It would require that logos indicating risks at three different levels (low, medium, and high) be affixed to food product labels. Since some processed foods contain a dozen or more additives, their labels would presumably require considerable study. It may be questioned whether the information
load generated by the proposed system could be absorbed. And even if it
could, it is not clear that the public would welcome a new knowledge
obligation that would bring safety into the supermarket to join price and
quality as a determinant of consumer choice. There are those who feel
that shopping already takes quite enough time.

In summary, Congress designed the food additive provisions of the
law - as it designs all laws - to apply generally to a class of circumstances.
The primary consideration was to prevent the attractions of a benefit to
food processors from resulting in risks to consumers. An unanticipated
result was the removal, on safety grounds, of an already-marketed sub-
stance to which people were attached; and as the matter became a cause
celebre, it seemed as though saccharin could be thought of as a risk taken
knowingly. But there is no way of treating food additives generally in the
way the “freedom of choice”! argument would say we ought to treat saccharin;
indeed, in five or ten years we could not even treat saccharin in that way.
The law has to treat categories; there can be no law for special cases,
especially when the cases won’t stay put.

To what degree, then, may the State intervene in the private behavior
of citizens in their own interest? The answer is not a simple formula, but
our society probably would want to include these principles. First, risk-
taking should be permitted as long as the risks are not spread to others,
and as long as knowledge of the risk and of its relation to the benefits to
be gained is available to the risk-taker. Second, the State has special obli-
gations to those exposed to risk wherever there is incentive to exploit
(that is, wherever benefits accrue to the persons who generate the risk),
and where there is a purposive or commercial element in the addition of
the risk. Third, that obligation is increased where the State has placed
the risk-taker in a vulnerable position by the use of its other authorities.

NOTES
2. There is good reason to believe that collegial commissions are not well suited to the work of
health regulation. The CPSC has been unable to make a decent start on its standard-
setting responsibilities, and has been periodically lambasted by the Congressional leaders
who insisted that it be designed that way. As for the NRC, its performance in the aftermath
of Three-Mile Island led the Presidential Commission that investigated that incident to
recommend that Congress reconstitute it as an executive agency with a single head.
4. For a review of the philosophical problems in public health regulation, see D. Beauchamp,
5. Congressman Thomas Foley (D-Wash.), the very capable Chairman of the House Agricul-
ture Committee, has a compelling theory about why Congress acted so quickly in the seat
belt matter, instead of reacting, in its more usual fashion to constituent pressure. “Congress-
men,” Foley told me once, “saw the problem before anyone else because they’re always
renting cars in airports.”