Institute of Medicine Report Recommends Complete Overhaul of Food Safety Laws

Panel proposes return to the philosophy of caveat emptor—reversing a trend of greater federal protection

Calling the present food laws inflexible, confusing, and cumbersome, a panel of the Institute of Medicine (IOM) and the National Academy of Sciences (NAS) has recommended that Congress rewrite the laws, permitting greater flexibility in the regulation of hazardous substances in the food supply. The panel recommendations, contained in a lengthy report ordered by Congress during the furor over saccharin, include a suggestion that the controversial Delaney clause of the food and drug act be dropped, enabling the Food and Drug Administration (FDA) to permit small amounts of carcinogenic additives in the food supply as it sees fit. This could include saccharin, the panel says. The panel also recommends that, for the first time, the health risks of a hazardous food be balanced against the economic benefits to food suppliers and others, and that risks of different foods be compared before they are regulated.

If the proposals were enacted into law, every hazardous substance in foods would be assigned to one of three broadly defined categories of risk: low, moderate, and high. Within each category, different regulatory options would be available, ranging from a ban for substances of high risk to a warning for those of lowest risk. In contrast to the present system, however, each substance would be judged on its own merits; a carcinogen or high risk substance would not have to be immediately banned. The proposals would make it easier for the FDA to remove nitrites from the food supply over an extended period of time, for example, while simultaneously educating the public about the need to refrigerate hot dogs (nitrites are added to hot dogs and other processed meats to prevent spoilage). Packaging materials that leach minute quantities of carcinogens into foods might also be permitted to remain on the market.

"This report recommends changes in current food law to make food safety policy simpler, more flexible, and more comprehensible," the panel wrote. "Statutory categorization of foods and food additives currently is confusing, cumbersome, and not always related to risks." Implicitly, the panel assumes that by more carefully considering risks, the FDA will more frequently take actions less drastic than an outright ban. Warning labels, logos, and educational campaigns are among the alternatives mentioned. Each would place greater reliance on consumer awareness and intelligence. The proposal would thus constitute a significant return to the philosophy of caveat emptor—reversing the trend of increasing federal protection begun with the enactment of the first food laws in 1906.

The proposals of the panel are sure to arouse controversy, and even the panel itself—composed of attorneys, scientists, and public policy experts—had difficulty arriving at a consensus. Seven of the members filed a minority report, expressing strong support for the Delaney clause as well as other parts of the current laws on food safety. The majority, led by Nobel laureate Frederick Robbins, dean of the Case Western Reserve medical school, felt that a major departure from current regulation is necessary. The immediate reaction on Capitol Hill has been mixed, in part because most of the key members of Congress have not yet waded through the report. Also, it has been characterized inaccurately by much of the press as a study of saccharin, and congressional members have played up that narrow focus.

It is likely that the report will have an enormous impact on the regulation of unsafe food in future years. All of its proposals are not likely to be enacted, but several are. Congress and the Carter Administration already are amenable to overhauling FDA's basic enabling legislation. The public is increasingly restive about real or imagined intrusions by the current regulatory scheme, just as industry is increasingly restive about regulatory costs. Even FDA Commissioner Donald Kennedy is willing to embrace a few of the recommendations. Kennedy predicts that when hearings on the topic are held late this spring, and perhaps when formal legislation is proposed, the IOM-NAS report will set the agenda for debate. The outcome will affect a matter of importance to nearly everyone: the safety of what is eaten.

Debate on the report will probably focus on three issues: whether the present regulatory system is indeed as complicated and inadequate as the panel claims; whether the panel's suggestions reasonably redress the inadequacies; and whether the food supply will become more or less safe as a result. The report is far stronger in answering the second of these questions than in answering either the first or third. Although long on prescriptions, it is short on predictions. At a press conference to present the conclusions, for example, panel representatives demurred when asked precisely how the FDA might act differently if their proposals were adopted. In the report itself, no specific recommendations were made for the four substances chosen as case studies: saccharin, nitrites, aflatoxin, and mercury. A majority of the panel did conclude that saccharin (i) should not be regulated by Congress, and (ii) should not be banned *or* freely permitted on the market. The panel, however, did not directly address what FDA had proposed: to restrict the use of saccharin by declaring it an over-the-counter drug. Instead, the report suggests that FDA declare saccharin either a moderate or high risk, and

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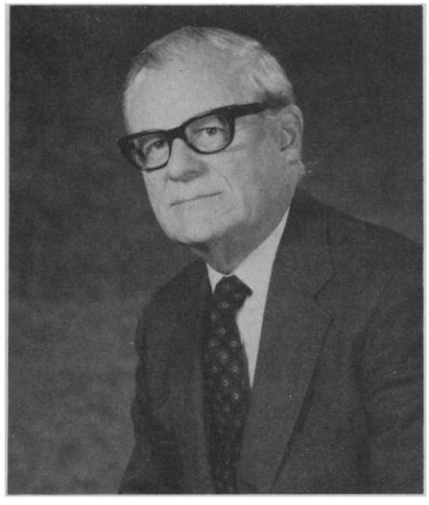
then determine the appropriate action according to newly available options. The choice would depend in part on the costs of replacing it or doing without it in the food supply.

The flexibility of the options and risk categories reflects a judgment by the panel that risks from food can be assessed qualitatively but not quantitatively. Robbins notes that "when we deal with issues where the science can only take you so far, whether you like it or not, you have to make judgments." (The panel's minority, on the other hand, deduced the opposite conclusion from the same premise. "The relative simplicities of our current food safety policy cannot be tampered with," the minority report reads, "because the structure of which it is a part can only support regulatory decisions no more complicated than a stop sign on a street corner.") The specific recommendation that risks be judged high, medium, or low was patterned on the different degrees of containment for recombinant DNA research, according to panel chairman Clifford Grobstein, a biology professor at the University of California, San Diego. "Foods that pose different risks would be contained in different degrees."



Frederick Robbins: Science goes only so far, and a subjective judgment must be made.

Though the panel took pains to avoid an undue emphasis on the saccharin issue, they found it a useful illustration. "Saccharin highlights the problems of a sharply defined and rigidly peremptory regulatory statute in a complex area such as food safety," the panel says. The statute mentioned is the Delaney clause, which was passed in 1957 and requires the banning of any additive shown to cause cancer in animals or humans.

To a minority of the panel as well as some outside consumer groups, the clause is worth retaining as a symbol because it strongly prohibits consideration of any benefits from a carcinogen. Moreover, the clause contains exact instructions for the FDA; it bars discretion that might be subjected to political pressure.

The panel's majority, however, concludes that the Delaney clause exemplifies the confusion that pervades the food laws. It exempts, for example, those substances sanctioned by the federal government prior to 1957, as well as those generally regarded as safe. Most of the recent controversy regarding the food laws stems from attempts by the FDA to ban or restrict the use of additives that come within these exemptions (for example, nitrites, cyclamates, saccharin). The Delaney clause also was enacted at a time when analytical chemists were able to detect carcinogens only in relatively large quantities in the food supply. Analytical abilities have been sufficiently refined to detect hazards of low magnitude that may not warrant a ban, the panel says. Although examples were mentioned only obliquely in the report, food packaging materials are said to be within this category. Richard Merrill, a former FDA general counsel, points out in an appendix that "many of these [packaging] materials are proving carcinogenic," in part because most are synthesized from hydrocarbons. Leaching of chemicals in minute amounts from packaging to food can now be detected, and many packaging materials may have to be banned under the Delaney clause, though the health risks may be slight. Merrill also claims that the Delaney amendment is redundant: serious carcinogenic hazards could be banned under a prohibition in the law against "unsafe" food additives.

Commissioner Kennedy is inclined to agree, and backs changes in the present clause. "I've never proposed the wholesale elimination of the Delaney clause because it isn't completely redundant; it does legislate something special about the dose-response curve for a carcinogen. But we need to get a definition in the law of unsafe additives that would permit trivial amounts to migrate into food. We could have a reasonably conservative and cautious approach by constructing a floor under the Delaney amendment; there is, however, no easy answer to where that floor would be set." Kennedy adds that the FDA will press its restriction of saccharin use, no matter what.

The Delaney amendment is not the only portion of the law that would be changed, nor is it the only example of

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Research Guidelines That MIT Can Live With

The final draft of an arcane but—to university research administrators—very important document known as circular A-21 was published by the federal government on 5 March. It is the revised version of a circular put out originally by the Office of Management and Budget (OMB) in 1973, setting the ground rules for the financing of government research in educational institutions. The new circular will take effect on 1 October.

This 45-page, single-spaced memo is billed by its authors as containing "tight new rules" designed to "improve accountability" for the $4 billion in federal funds spent each year on this kind of research. The reform is being undertaken, OMB officials are quick to point out, at the behest of congressmen and department officials who feel that universities have not been held to account as firmly as they should be.

"We are prepared to live with it," said Thomas F. Jones, vice president for research at the Massachusetts Institute of Technology (MIT). "We understand that the final document is more restrictive on recovery of indirect costs" by the university than the rules now in force, he said, but it is an improvement over a draft that was proposed in March 1978. The March version was so bad, in MIT's view, that MIT president Jerome Wiesner singled it out for scathing criticism in a long speech last fall on the crisis in relations between the government and academia (*Science*, 1 December, p. 955). He told reporters that it would be best if circular A-21 were buried.

Since then, the OMB has modified the language of the circular to appease the universities. According to OMB official John Lordan, the memo now states explicitly what was implied before: that universities may count students both as researchers (chargeable to government contracts) and as recipients of instruction (not chargeable). In the earlier document, students seemed to fall only into the second category. The new memo also permits greater flexibility in negotiating individual reimbursement rates, is more generous in accepting some of the costs of running libraries and other

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regulatory inconsistencies and inflexibility cited by the panel. Under the present scheme, for example, additives are treated differently from adulterants. For regulatory purposes, nitrites in cured poultry and fish are considered to be additives, while nitrites in meat are adulterants. Two different statutes must be invoked to get them off the market and, according to a preliminary Justice Department opinion, neither may be adequate to support FDA's proposal of a nitrite

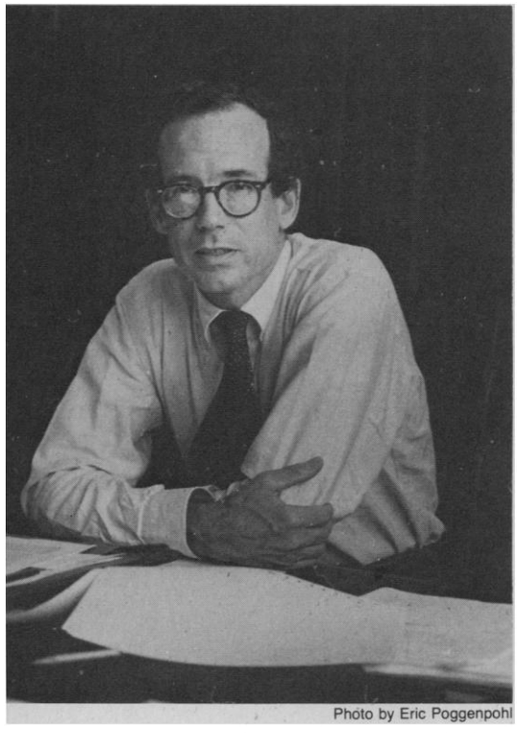

Photo by Eric Poggenpohl

Donald Kennedy: Discretion would invite a host of outside political influences.

phaseout over several years. As other examples, avoidable contaminants of food, such as pesticides and animal drugs, are treated differently from unavoidable contaminants, such as naturally occurring mercury. Instead of setting tolerance levels for avoidable contaminants, the FDA routinely sets quasi-legal action levels, which amount to a promise to set a tolerance level if the action level is exceeded. The panel suggests that all such substances be treated alike, and that comparative risks be determined prior to a decision to regulate.

Whether political pressures will more easily influence FDA actions under the panel's proposals than under the current laws will be one of the hottest controversies during the congressional hearings. To several consumer groups, the portion of the recommendations that permits the FDA to consider economic costs certainly provides an opening for such pressures. Ralph Nader's Health Research Group, for example, says that "corporate health would once again take precedence over public health" if the proposal were enacted. Kennedy has called it a critical issue, adding that he opposes it absolutely. "I do not want the power to weigh economic benefits against health risks unless Congress explicitly tells me the value of a life," he says.

Judging the practical effect of the panel's proposal is difficult because members of the panel have interpreted it differently. At a press conference, panel member Don K. Price, former dean of the Kennedy School of Government at Harvard University, said the panel was recommending that "primarily health benefits be weighed against health risks, but that other benefits may be taken into account." The report itself, acknowledging the difficulty of accurately estimating economic and health benefits, says that economic benefits should be taken into account particularly "when no substitute for a food with a suspected or actual risk exists." Walter A. Rosenblith, one of the panel's chairmen and provost of the Massachusetts Institute of Technology, offered a slightly different view: "The risks should be the determinant, with benefits as a modifier." Alternatively, Robbins says "the benefits should be more modifying when the risks are low or moderate."

Although the FDA is not now authorized to consider economic and health benefits of hazardous substances in food, many observers would argue that the agency does it anyway, informally, by stretching the laws when necessary and applying another statute if the first will not do—indeed, by simply deciding to turn the other legal cheek and go after some hazards and not others. To the extent that this is true, the IOM-NAS report becomes merely an academic exercise in orderly thinking—orderly thinking that was absent from the Congresses that enacted and then amended the food safety laws in patchwork style. Price argues that there is a substantive difference between what the panel recommends and what the current practice is, however. "The FDA has smuggled a number of outside considerations into its decision-making process; it never seemed to me that political pressures were absent from the present system. But instead of the present highly confusing system, it would be better to have these things all out in the open." Political pressures in a system with great flexibility would be more obvious, he added; presently, they are concealed in the oblique and often arcane legal determinations of the agency's attorneys, enabled by the complicated statutes.

"This is like a proposal to expose the tunnels by cutting into the wall," says Kennedy, adding that he is concerned that political pressure might still be hidden: "the degree of tunneling is not proportional to the width of the room; there would still be an attempt to tunnel." Without specific guidance from Congress on which of the regulatory options to choose, Kennedy says, "discretion would invite a host of outside influences to try to push an action into this corner, or that one."

To help contain such efforts, the IOM-NAS panel recommends that a committee be established outside of FDA to render opinions on the risks and benefits of each hazardous substance in food. Presumably, in the eyes of the panel members, the National Research Council itself could fill the bill.

Ultimately, however, it is the consumer that would make the benefit-risk judgments under most of the options in the IOM-NAS report. A signficant drawback in the plan is that consumers may either disregard or fail to understand warning labels and public pronouncements on food hazards. Robbins acknowledged at the press conference, for example, that "there was a tendency among the public to ridicule some of the laboratory data on saccharin." Kennedy adds that "against all we know, the expensive Washington law firms and publicity mills regularly insist that there is no relationship between laboratory data and human risk, although the frequency of these assertions may be declining."

Even if health warnings are understood, a strong likelihood exists that many consumers will ignore them, particularly if, as at least one member of the panel fears, a large number of such labels and logos are used. Even with just a few, consumers may not be likely to heed them. Two of the panel members, Richard Hall, from McCormick & Company, a spice manufacturer, and Fred Abramson, a pharmacologist at George Washington University, wrote in an appendix to the report that "we speculate, based on the experience with the cigarette warning label, that consumption patterns of hazardous foods would be affected very little." What the IOM-NAS panel has apparently decided is that if the consumers of America—who so vocally expressed their demand to consume a nonnutritive carcinogenic sweetener—want to consume a host of hazardous foods, well then the federal government ought to let them.—R. JEFFREY SMITH