Perspectives
on current developments

Hair Dyes, Cancer, and the FDA

The catalyst for the current controversy over regulating permanent hair dyes is a finding by the National Cancer Institute that a principal ingredient of these dyes causes cancer in animals. Subsequent to the release of this finding, the Food and Drug Administration announced (*Federal Register*, January 6, 1978) that it would require certain coal-tar hair dyes to bear a label warning consumers that the ingredients had caused cancer in laboratory animals. The resulting debate is a microcosm of the problems of legislation, laboratory testing, and conflicting views about appropriate government action that often complicate the regulation of substances posing chronic health hazards.

As for the legislation, the Food, Drug, and Cosmetic Act of 1938 authorizes the FDA to regulate cosmetics (including hair dyes) and, in most cases, to remove demonstrably dangerous cosmetics from the market. But in the case of coal-tar hair dyes, Congress limited the FDA's authority to requiring that package labels carry warning information. The merits of the limitation have been argued intermittently for forty years, but all attempts to modify it so far have failed.

As for the second problem, regulation of health hazards often depends on results from laboratory testing involving animals. In the case of coal-tar hair dyes, NCI researchers fed test groups of male and female rodents either high or low doses of a principal chemical (2,4-diaminoanisole sulfate) of these dyes, and post-mortem examinations of the test and control groups indicated higher incidences of some forms of cancers among all test groups. The matter at issue is the relevance of this finding for humans.

The Cosmetic, Toiletry and Fragrance Association, Inc., in recent testimony before the Congress, argued strongly that NCI's finding does not justify regulatory action since humans apply the substance to their hair; they do not eat it. The CTFA cited five industry-sponsored studies which concluded that rats whose skins were painted with hair dyes showed no increase in cancer. Stressing the significance of this result, the association said that even though the skin application method reduces drastically the amount of the chemical absorbed into the bloodstream, the test animals still absorbed far greater amounts, allowing for their size, than would humans using hair dye.

Laboratory testing on animals, of course, does not provide direct evidence that a suspect agent causes cancer in humans. But sometimes it is all the regulator has to go on. Ethical and legal restrictions prevent long-term testing on humans, and epidemiological studies on humans are extremely difficult to conduct, with years passing before very definitive findings are available. Thus, the extent, if any, to which a chemical in coal-tar hair dyes increases the incidence of cancer in humans is not really known.

As for the problem of conflicting views about the appropriate regulatory response, it is complicated in this case by the nature of the scientific data. The FDA's position is that any chemical yielding positive results in animal tests must be considered a potential hazard to humans and therefore be banned from the market. The CTFA's view is that informed consumers should weigh the risks and benefits of products they consider purchasing but that, in the case of hair dyes, the scientific evidence is so inconclusive that there is nothing about which consumers need to be informed.

Both approaches have their drawbacks. The FDA's alternative, pushed to its extreme, would deprive consumers of goods they may value highly and for which they would assume some risks. The saccharine controversy clearly demonstrated the willingness of some consumers to incur potential health risks for products they like. Yet, the association's alternative,

pushed to its extreme, might result in some consumers' using potentially dangerous products while assuming that the FDA is protecting them from excessive risks.

Millions of CBs That Can't Be Sold

Not too long ago, citizens' band radio was unknown to most of us. During the 1950s the Federal Communications Commission established a Class D Citizens' Radio Service having twenty-three channels and a range of from five to twenty-five miles. The service was open to almost everyone—that is, no specialized technical knowledge was required to obtain a license. Citizens' band activity grew slowly during the sixties but took off in the seventies: sales almost tripled each year between 1970 and 1974. If that growth rate had been sustained, the United States would have been covered by a layer of CB radios within fifty years.

Several factors combined to produce the explosive growth in CB radio sales. Advances in electronic technology reduced the cost of CB radios while improving their quality. Increased sales made them more valuable, since each additional CB user on the road meant another pair of eyes and ears reporting road hazards. Further, CBs attracted publicity during the 1974 truckers' strike, gaining glamor and becoming something of a consumer fad.

But growth also led to congestion on CB channels and interference with home television reception. In July 1976, the FCC took a major step to resolve these two problems: it expanded the number of CB channels from twenty-three to forty and tightened the restrictions on "extraneous radiations" for CB sets so as to reduce interference with television reception. To ease the effect on the industry, it ordered that the new forty-channel sets not be put on the market before January 1, 1977, that the manufacture of sets not meeting the new, tighter radiation limits cease by August 1, 1977, and that retail sales of such equipment cease five months later (January 1, 1978).

Despite the advance notice and general industry support for the FCC's initiative, confusion overwhelmed the CB market. Whether because the market was already saturated or because consumers were confused by the change from twenty-three to forty channels, the demand for sets weakened. Consequently, late in 1977, retail inventories included millions of units that could be legally sold for only a few more months. Retailers who had inaccurately estimated demand for the old sets—or who had become aware of the ban too late—were faced with the prospect of owning merchandise they could not sell. Prices tumbled, but sales still were not sufficient to deplete the inventory.

In August 1977, manufacturers and retailers petitioned the FCC to extend the sales deadline on old sets from January 1 to August 1 (1978). Consider the FCC's dilemma when asked for this extension. If the FCC granted the petition, manufacturers, distributors, and retailers who had dumped their inventories in anticipation of the January deadline would suffer significant losses because of a seemingly capricious regulatory action. If the FCC held fast, millions of dollars of perfectly good hardware would probably be scrapped. The chief engineer of the commission supported the request for an extension, but the commission itself, seeing no easy way out, chose consistency and voted it down, four to two. Retail interests appealed in court, but the court denied a stay, and the sale of the old twenty-three channel units became illegal at midnight New Year's Eve. According to some accounts, retailers who have millions of these units are engaged in enormous haggling with manufacturers over who is going to bear the loss.

New Federal Budget Calls for More Regulators

If the 1979 budget is any guide, the increase in regulation undertaken by the federal government will continue. Of course, larger budgets for regulatory agencies do not necessarily mean more regulation, since the additional resources could be consumed by efforts to reduce regulation or by reduced agency productivity. Nonetheless, the amount of activity an agency undertakes would appear, in most cases, to be positively related to its available resources. More specifically, the number of regulators and supporting staff is one measure of an agency's capacity to increase the detail and breadth of its regulation.

GROWTH IN EMPLOYMENT FOR THIRTY REGULATORY AGENCIES

Agency	Number of Employees [a] 1977	1978	1979	Percentage Increases (Decreases), 1977–79
GROUP I				
Equal Employment Opportunity Commission	2,298	2,312	3,114	35.5
National Labor Relations Board	2,751	2,886	2,984	8.5
Occupational Safety and Health Administration	2,591	2,655	2,650	2.3
Employment Standards Administration	3,114	3,209	3,509	12.7
Federal Trade Commission	1,648	1,650	1,716	4.1
Antitrust Division	907	920	977	7.7
Securities and Exchange Commission	1,930	2,025	2,065	7.0
Patent Office	2,673	2,640	2,597	(2.8)
Consumer Product Safety Commission	914	900	899	(1.6)
Food and Drug Administration	7,340	7,490	7,583	3.3
Environmental Protection Agency	9,779	10,216	10,840	10.8
International Trade Commission	348	386	386	10.9
TOTAL, GROUP I	*36,293*	*37,289*	*39,320*	*8.3*
Internal Revenue Service	70,609	71,467	73,607	4.2
GROUP II				
Civil Aeronautics Board	779	790	820	5.3
Interstate Commerce Commission	2,161	2,133	2,128	(1.5)
Federal Maritime Commission	304	345	351	15.5
TOTAL, GROUP II	*3,244*	*3,268*	*3,299*	*1.7*
GROUP III				
Federal Aviation Administration	55,760	56,495	56,640	1.6
Coast Guard	6,333	6,421	6,421	1.4
Customs Service	13,519	14,581	14,903	10.2
National Highway Traffic Safety Administration	818	878	878	7.3
Federal Railroad Administration	1,447	1,604	1,642	13.5
TOTAL, GROUP III	*77,877*	*79,979*	*80,484*	*3.3*
GROUP IV				
Federal Reserve Board	1,516	1,516	1,520	.3
Federal Deposit Insurance Corporation	4,162	4,362	4,500	8.1
Federal Home Loan Bank Board	1,363	1,475	1,503	10.3
Comptroller of the Currency	2,907	3,002	3,186	9.6
National Credit Union Administration	576	639	639	10.9
TOTAL, GROUP IV	*10,524*	*10,994*	*11,348*	*7.8*
GROUP V				
Energy Regulatory Administration [b]	2,893	1,999	1,999	17.6
Federal Energy Regulatory Commission [b]		1,403	1,403	
Energy Information Agency [b]	631	776	776	23.0
Nuclear Regulatory Commission	2,499	2,723	2,788	11.6
TOTAL, GROUP V	*6,023*	*6,901*	*6,966*	*15.7*
TOTAL, ALL GROUPS	*204,570*	*209,898*	*215,024*	*5.1*
TOTAL, FEDERAL EMPLOYMENT	*1,908,988*	*1,930,100*	*1,931,600*	*1.2*

[a] Full-time permanent employment as of September 30. [b] Department of Energy.

Source: Based on the *Budget of the United States, 1979,* and the Department of Energy.

Turning to the President's budget to get the numbers on regulators and supporting staff, we find there no conveniently assembled list of planned appropriations for all regulatory activity. So the data in the accompanying table reflect our selection of regulatory agencies, based on normal usage of that term.

Agencies are grouped according to their jurisdiction. Group I agencies have broad jurisdiction under specific regulatory statutes; Group II agencies engage in economic regulation of transportation services; Group III agencies regulate transportation goods and services for safety and other objectives; Group IV agencies regulate financial institutions, and Group V agencies engage in economic regulation of energy. The table gives proposed end-of-year employment estimates of thirty agencies for September 30, 1978 and 1979, as well as actual employment levels on September 30, 1977. (Budget estimates for 1978 are, to a large extent, influenced by already completed congressional action on the 1978 budget.)

As shown in the table, total federal employment is projected to increase by 1.2 percent during this two-year period, compared with 5.1 percent for our thirty regulatory agencies. For the same period, employment increases are expected to average 8.4 percent for the agencies in Group I, 4.2 percent for the Internal Revenue Service, 1.7 percent for the agencies in Group II, 2.2 percent for Group III, 7.8 percent for Group IV, and 15.7 percent for Group V.

While the future level and direction of regulation cannot be derived from budgetary estimates alone, the President's 1979 budget clearly calls for continued growth in regulatory capacity.

CPSC Redesigns Its Injury Information System

Whether explicit or implicit, all federal regulatory agencies have some basis for deciding which issues to address. The Consumer Product Safety Commission not only does this explicitly, but gives the appearance of an unusual degree of sophistication by setting its priorities on the basis of a computer printout.

The CPSC is required by law to assure consumers that products are not unnecessarily hazardous. In order to obtain information on a systematic basis about which products cause the most injuries, the commission established a National Electronic Injury Surveillance System (NEISS) in 1972. This system is based on a sample of 119 hospitals, each of which supplies emergency room data on product-related injuries. Information on the patient's age and sex, the type and severity of injury, and the product involved is coded and transmitted daily to the CPSC computer. (NEISS notes only whether the product was involved in the accident, not whether it *caused* the accident.) The data are compiled monthly to determine the frequency and average severity of injuries associated with specific products. Products ranking highest on a combined frequency-of-injury/severity-of-injury scale are given priority attention for possible regulatory action.

Injuries of particular interest to the CPSC (those resulting in death or associated with flammable fabrics) may be subjected to follow-up investigations designed to obtain, when possible, the victim's account of the accident and to determine the extent to which the product caused the injury in question. To make the most of the person's memory and to reduce the likelihood that the product involved would have been discarded, investigations are conducted within seventy-two hours of the report.

The CPSC views NEISS as the best single source of statistics on product-related injuries. This is because the data are collected at a reasonable cost and are estimated to cover some 40 percent of the country's product-related injuries. But the difficulties involved in relying on such a system are apparent. First, there is the problem of how much confidence can be placed in projections based on the sample. Since data generated from the sample must be "inflated" to estimate total injuries treated in all emergency room hospitals, and then be further inflated to represent the entire injury picture (emergency room and non-emergency room), the statistical accuracy of the sampling base is very important. But the current sample is derived from dated hospital and population figures, represents just the forty-eight contiguous states, and includes only 119 of the 4,906 hospitals that had emergency treatment units in 1968. In addition, its statistical accuracy has been diminished by the fact that some hospitals originally included on the basis of random selection have left the program and have had to be replaced.

To correct these deficiencies, the CPSC is now redesigning NEISS. The sample for the new system will be larger (130 hospitals instead of 119), will be selected on the basis of current data, and will include hospitals in all fifty states. An attempt will be made to use only the initial—randomly selected—hospitals. Hospitals from which the sample will be drawn are grouped into five categories based on facilities and numbers of emergency room visits, and each category's weight in the sample depends on how many hospitals fall in that category. Finally, since accurate and uniform information collection and coding are crucial, full-time CPSC employees will be placed in the new hospitals to perform these functions. (Most of the data are currently supplied to the CPSC by trained hospital personnel.)

The second problem relates to the utilization of NEISS data. Many have argued that the frequency/severity ratings would be more useful to the commission if the system included additional information about the products involved—such as their age and frequency of use. Information on product age might be used to analyze the effectiveness of "voluntary" safety standards self-imposed by industry and the relative safety of products of differing ages (product-age information is now collected only during follow-up investigations). Frequency-of-use information might be used to distinguish low-accident-rate products that are frequently used from high-accident-rate products that are infrequently used, thus giving the CPSC more information on the innate riskiness of different products.

One thing to bear in mind about NEISS is that it can, at best, suggest only the *benefits* of

eliminating product risks. As the commission itself has noted, other factors, such as the cost and likely effectiveness of regulating a product, are considered before action is taken. But some have suggested—the Council on Wage and Price Stability, for instance—that since NEISS directs attention to products solely on the basis of benefits, a misallocation of commission resources might result. The alternative is a priority ranking scheme based on *net* benefits—that is, the difference between the benefits of removing (or reducing) a product risk and the cost of doing so. This would enable the CPSC to allocate its own internal resources so that, on balance, society would gain the most from the commission's actions.

Tighter Standards for Drinking Water

The Environmental Protection Agency is proposing new regulations for sharply reducing cancer-causing agents in municipal water supplies. This action, announced in the *Federal Register* on February 9, would amend EPA's 1975 interim drinking water regulations, which controlled harmful organic compounds only to a very limited extent.

EPA's proposal has two parts. (1) For trihalomethanes (THMs, that is, carcinogenic chemicals such as chloroform that are created when chlorine is added to drinking water), EPA would set a containment level of 100 parts per billion. (2) For water supplies susceptible to contamination by synthetic organic chemicals other than those resulting from chlorination, EPA would mandate a specific water-treatment technique.

Both parts of the regulation would initially apply only to communities of more than 75,000 people. One reason for the limitation is that the danger from exposure to THMs is less for small communities than for large—since the latter usually rely on surface water supplies that tend to have high bacteria counts and thus require more chlorine for purification. Another reason for limiting the standard to large communities is to minimize administrative problems and capital costs while still covering nearly 50 percent of the population.

The proposal outlines three ways of satisfying the THM requirement, their cost increasing with the seriousness of the problem. First, a community whose water slightly exceeds the allowable THM level could improve its filtration process through better coagulation and sedimentation practices (assuming it has a conventional filtration plant). Second, in more serious cases, a community could resort to disinfectants that do not produce THMs (such as chloramines, ozone, or chlorine dioxide). Third, in the most serious cases, a community could use a granular activated charcoal (GAC) filtering system. This last option appears to be the most practicable way for municipalities of over 75,000 to meet the allowable THM level since many large water supplies greatly exceed that level, and since other disinfectants are either relatively weak or potentially toxic.

As for the second part of the proposal, EPA decided to prescribe the GAC filtering system in this case because it would be difficult to monitor each synthetic organic chemical that might have an adverse health effect, and because synthetic organic chemicals other than THMs are best controlled by using the GAC filtering system. The proposal would affect water supplies that are near industrial discharges, pesticide run-offs, or other sources of possible contamination.

The cost of implementing both parts of the proposal would depend on how many municipalities have to adopt the GAC filtering system to meet the THM containment level. According to information supplied by EPA, total capital expenditures required by the combined proposal would appear to range from $291 million under low-cost assumptions to $685 million under high-cost assumptions. Operations and maintenance expenses would be between $34 million and $92 million per year under the same assumptions. The cost would also depend upon how long the water had to be purified (contact time) and how often the carbon in the GAC system had to be replaced (regeneration). Actual increases in residential water bills would depend on what portion of the costs was borne by nonresidential water users.

EPA's analysis of the proposed regulation makes no attempt to estimate benefits in terms of either dollar savings or reduced risk of cancer. Without such information, the agency has no way of determining whether, given alternative demands for public and private re-

sources to eliminate health hazards, the proposed regulation is the most cost-effective means of achieving this goal.

Funding Public Participation in Regulatory Proceedings

In 1975, Congress authorized the Federal Trade Commission to compensate "interested persons" for their expenses in participating in agency rulemaking proceedings, if three conditions are met. The FTC must find (1) that the applicant represents an interest "which would not otherwise be adequately represented," (2) that the representation of that interest is "necessary for a fair determination of the rulemaking proceeding," and (3) that the applicant is financially unable to participate effectively without compensation.

In 1976, the General Accounting Office ruled that other regulatory agencies had general authority to pay the expenses of persons who would contribute substantially to a full and fair determination of a proceeding. Fortified by the GAO's position, additional federal agencies have proposed or adopted regulations to provide compensation funds. For instance, the National Highway Traffic Safety Administration budgeted a total of $250,000 for this purpose in 1977. But the recent case of *Greene County Planning Bd.* v. *FPC* (2d Circuit 1977, certiorari denied 1978), in which the court held that the FPC did not have authority to make public participation grants, raises doubts about the correctness of the GAO rulings.

A bill sponsored by Senator Edward Kennedy (S. 270) would create a government-wide program of compensating interested persons who participated in all types of regulatory proceedings (rulemaking, ratemaking, licensing, adjudication, and judicial review of agency decisions). Two conditions are specified. First, the applicant would have to be expected to contribute substantially to a fair determination of the proceeding. In deciding this question, the agency would have to take into account the possibility that other participants (except the agency itself) would adequately represent the interest, the number and complexity of the issues, the importance of encouraging public participation, and the need to hear from a balance of diverse interests. Second, the agency would have to consider the applicant's financial position. Compensation would be paid if the applicant could not participate without it or if the applicant's financial stake in the outcome were small compared with the costs of effective participation. A similar bill, H.R. 8798, is pending in the House.

Proponents of compensation for public participation point out that their proposals would not expand the existing legal rights of "interested persons" to participate in agency proceedings but are designed, instead, to overcome the high costs of exercising these rights. They argue that for some groups who stand to gain or lose from agency action, effective participation costs more than the members are willing to contribute.

Opponents of the idea maintain that additional participation would make agency proceedings more costly and time consuming, without demonstrably improving the quality of agency decisions. They also assert that a better way to guarantee representation of all interests would be to charge agency staffs with that responsibility. Furthermore, some critics worry that, in disbursing compensation funds, agencies would display favoritism or would reward and ultimately "capture" the representatives of interested persons or groups. They point out that the Kennedy bill would vest more discretion in the disburser than the FTC now has and that there is some controversy about how well the FTC program has worked.

Proponents respond that the problems of additional cost and delay could be offset by improved management of both the compensation program and the particular proceeding. They reject, on the basis of their experience, the argument that agency personnel can adequately represent disparate interests. And some of them contend that the risks of an agency's showing favoritism or "capturing" subsidized representatives can be reduced by having an outside agency make the compensation awards. Others, however, resist the notion of a central compensating organization.

Many other issues of organization, funding, and eligibility are also in dispute. Undoubtedly, the issue will receive much attention in view of the recent defeat of the proposed Consumer Protection Agency.