Perspectives
on current developments

DNA Regulation: Can the Genie Be Rebottled?

Scientific breakthroughs that merit Nobel prizes often have unanticipated ramifications. The discovery of the molecular structure of deoxyribonucleic acid (DNA)—the fundamental building block of life—was heralded as a great advance in man's knowledge of genetics. An important step in the exploitation of this discovery has been the recent success of scientists in combining DNA molecules from different organisms. The problem is that such research presents risks.

The potential benefits of recombinant DNA research are clear. In addition to increasing our knowledge of genetics, this research might make contributions in such fields as pharmaceutical manufacturing and agriculture. It might be possible, for example, to develop bacterial strains that produce certain antibodies or hormones needed to treat illness or to develop plants that draw their nitrogen directly from the air rather than from costly fertilizers.

But the potential risks of recombinant DNA research have been the object of scientific controversy and have led to calls for governmental regulation. The risks are of two types. First, there is the danger of an accident, such as the escape into the environment of a new, disease-causing organism. Second, there is the danger that recombinant techniques could be used for sinister purposes—to manipulate human genes, for example. Opponents of regulation in this new field do not deny the existence of dangers. Instead, they argue that the greater risk is that overzealous regulators preoccupied with remote dangers would deny society significant benefits by unduly discouraging research.

Partial government regulation of recombinant DNA research began in December 1975, when the National Institutes of Health (NIH) promulgated standards that apply to federally funded research facilities. The standards specify four levels of physical containment of organisms whose DNA has been altered and three levels of biological containment. The strictest level of physical containment requires airlocks, protective clothing for laboratory workers, and decontamination of everything leaving the lab. The strictest level of biological containment requires that the host microorganism for recombinant DNA be genetically weakened so that only one in 100 million could survive outside the lab. The NIH controls also prohibit some experiments considered especially dangerous. A common criticism of these regulations is that they do not cover recombinant research in private facilities—for example, those of pharmaceutical manufacturers—and some scientists have urged that this be remedied by legislation.

Two major proposals to regulate recombinant DNA research are now before Congress —S. 1217, introduced by Senator Edward M. Kennedy (Democrat, Massachusetts), and H.R. 7897, sponsored by Representative Paul G. Rogers (Democrat, Florida). Both would require licensing of private and public facilities and both would apply stiff penalties (fines and/or forfeiture of license) for breaches of the standards.

The regulatory mechanisms spelled out in the two bills, however, are considerably different. S. 1217 would establish a National Recombinant DNA Safety Regulatory Commission, a majority of whose members would be laymen. This commission would license recombinant research and promulgate regulations prescribing physical and biological containment. These regulations would have to be at least as stringent as NIH's standards for federally funded research. H.R. 7897, on the other hand, would require the secretary of health, education, and welfare to promulgate standards governing laboratories where recombinant DNA research was performed. This bill con-

tains no requirement on the stringency of the secretary's standards, and he would be authorized to exempt from regulation any recombinant DNA activity found not to present "a significant risk to health or the environment." All recombinant DNA research facilities would have to be licensed by the secretary and/or local committees composed of local government officials, scientists, and community representatives.

Any DNA regulatory system is fraught with dangers. The most important is that the regulator, whether an independent commission or the secretary of HEW, would be under considerable pressure to err on the side of safety. Consequently, license approvals might be delayed and approved projects subjected to unnecessarily high (and expensive) containment requirements. The cumulative effect of persistently overcautious regulation could be severe, as experience with the Food and Drug Administration's regulation of pharmaceuticals attests. (Many studies have cited excessive FDA regulation as a reason why many therapeutically important drugs available in Western Europe are not available in the United States. See, for example, page 46, this issue.)

The prospects for passage of legislation to regulate recombinant DNA research are unclear. On September 29, Senator Kennedy withdrew his support for his own bill and called instead for a one-year extension of the present NIH guidelines to allow time for further study of the issue. In a speech announcing his decision, he cited as his reasons "high emotions" among scientists opposed to tight controls and "new evidence" that the research may not be nearly as dangerous as earlier supposed. The legislation sponsored by Congressman Rogers has been bottled up in the House Interstate and Foreign Commerce Committee for similar reasons.

A Soap Opera—To Be Continued

Would it help consumers to know the ingredients in the detergents they buy? On June 29, 1977, the Federal Trade Commission unanimously withdrew a proposed rule which would have required detergent producers to provide consumers with that information. The proposal, issued in early 1974 under the Fair Packaging and Labeling Act, would have compelled detergent manufacturers to list, by common name or accepted chemical term, all ingredients on detergent containers. (Percentages were not required, as the FTC does not have this authority under the act.)

In canceling its proposed rule, the FTC noted that the bulk of the 500 or so comments it had received during the consideration period were from consumers and consumer organizations. Mostly, their comments emphasized the general desirability of making ingredient information available to retail customers and tended not to give specific reasons why this would be a good idea in the case of detergents.

In fact, one specific argument usually made for mandatory labeling—that consumers can use ingredient information for comparative shopping purposes—was explicitly rejected on the basis of evidence collected during the proceedings. According to a survey by the FTC's Office of Policy, Planning, and Evaluation, consumers who were shown lists of detergent ingredients were seldom able to determine which combination would produce the more effective detergent. (This was the case whether the ingredients were described by their chemical names or by their "functional" properties —for example, "optical brightener" or "antisoil agent.") Two industry surveys reinforced the point. One showed that consumers tended to be confused by the technical language required by the proposal; the other concluded that, although "functional" names were more understandable, detailed ingredient information did not help consumers judge the performance of different detergents.

Other factors contributed to the FTC's decision. Proctor and Gamble estimated that it would cost industry $15 million initially and $7 million a year thereafter to meet the standard—costs that presumably would be passed on to consumers. The industry argued that this expenditure was unwarranted for a product so frequently purchased that consumers can easily make value comparisons on the basis of experience. In addition, the industry pointed out that, depending on the availability and price of ingredients, manufacturers often make slight changes in the production formula. Thus, the performance of the detergent might change although the ingredient list would not.

In concluding its notice of cancellation, the FTC stated that the comments and surveys largely supported the consumer's general "right to know" but failed to show that, in this instance, knowledge of ingredients would enable a consumer to make a better purchasing decision. The commission also mentioned that its Bureau of Consumer Protection is currently working on a proposal to require performance labeling for detergents instead of ingredient labeling. Under this system, which the FTC considers the more promising of the two alternatives, the effectiveness of each detergent would be rated on a numerical scale and the rating would be printed on the container. This proposal is expected some time next year. Stay tuned for the next installment.

Making Appliances More "Energy-Efficient"

Although their approaches differ, both the Congress and the new Department of Energy are contemplating rules to make new home appliances more "energy-efficient." The appliances in question—water heaters, freezers, room air conditioners, room heaters, refrigerators, dishwashers, television sets, cooking ranges, and clothes washers and dryers—now account for between 4 and 5 percent of the U.S. energy bill. Ways in which such appliances might be designed to be more energy-efficient include putting thicker insulation in stoves, water heaters, refrigerators and freezers, replacing tubes with transistors in TV sets, and installing heavier-duty, yet less energy-consuming, motors in washers, dryers, and room air conditioners.

The Department of Energy's effort proceeds from the Energy Policy and Conservation Act of 1975, which requires that the Federal Energy Administration (now a part of the department) establish targets for energy conservation in a variety of areas, including appliances. In its proposal of May 14, 1976, the FEA set preliminary targets for each group of appliances—ranging from a 3-percent reduction in energy consumption for cooking ranges to a 65-percent reduction for black-and-white television sets. The targets were *averages*: less efficient appliances could be sold as long as enough appliances exceeding the target were also sold so that the target for the group would be met. Under the act, FEA was instructed to establish individual targets that it thought were "feasible" but that would, in any case, yield overall energy savings for new appliances of at least 20 percent.

The proposal before Congress (H.R. 6831 and S. 1469) would amend the act by instructing the Department of Energy to achieve the same energy savings for home appliances (at least 20 percent) by establishing *minimum* efficiency standards for each appliance group. While the proposed amendment would not require that the improvement be the same for each appliance, it would prevent the manufacture and sale in the United States of any appliance that did not meet the standard applicable to its group.

In general, an appliance that is more energy-efficient has a larger initial price—a difference that the Department of Energy alleges is more than offset by lower operating costs. For example, FEA's economic impact assessment of its proposal estimates that consumers who in 1980 purchase appliances conforming to the proposed standard would realize savings in energy cost valued at $6.3 billion. This compares with an estimated initial cost increase to consumers of nearly $1.2 billion, yielding net savings of $5.1 billion.

One problem with FEA's average-efficiency approach is that the standards are "voluntary." While some manufacturers might exceed the targets—since energy efficiency can be a selling point—others might make no improvements, deciding to market their appliances to consumers who choose a lower initial price rather than lower energy costs (for example, to consumers who, having a high rate of discount, prefer the immediate cost advantage, or who expect their average use of the appliance to be low). If enough new appliances exceeded the target levels, the overall energy conservation targets could still be met. But if this were not the case, the secretary of energy would be forced under the act to impose mandatory standards on appliance manufacturers. The likelihood that this would happen is a major reason Congress is considering mandatory minimum standards.

The main advantage of the minimum efficiency standards being considered by Con-

gress would appear to be ease of enforcement. But there are at least two fruitful enforcement options under the average efficiency approach. First, the secretary of energy might be empowered to rule that, unless a specific manufacturer's weighted average production met the targets, that manufacturer could not sell its line of appliances. Alternatively (and better from the standpoint of economic efficiency), a program of "entitlements" could be developed whereby manufacturers that fell short of the targets would have to purchase "rights" to sell less efficient appliances from manufacturers that exceeded the targets. This would give financial incentives to manufacturers not merely to meet the targets but to exceed them. It would also allow for some specialization in product lines. For example, one manufacturer might specialize in appliances having a lower initial cost and another in those with long-term energy savings. The matter is as simple as giving consumers a choice. Moreover, under the minimum efficiency approach, the burden of the effort to reduce the energy consumption of appliances would fall disproportionately on low-income consumers, who would tend, given a choice, to buy models that would cost them less initially but more over the long term.

Citizens' Band—Citizens' Language

There it was in the July 20, 1977, *Federal Register*—a proposed Federal Communications Commission rule on the operation and registration of CB radios, written, believe it or not, in plain English. This is the first significant product of President Carter's effort to make government regulations intelligible to more people. And it is particularly appropriate that it should have come in this area, since CB radio users are growing at the rate of one-half million each month.

Part of the rationale for plain English regulations is the belief that much "bad" regulation goes on the books precisely because people do not realize its implications. Furthermore, even a good regulation might be improved if written more simply, since people cannot intelligently comment on something they do not understand. For example, a CB radio operator can easily respond to the new requirement:

> You must have all repairs or internal adjustments to your transmitter made by, or under the direct supervision of, a licensed first- or second-class radiotelephone commercial operator.

But imagine that operator's bewilderment when faced with this:

> . . . except as provided in paragraph (b) of this section (95.511), all transmitter adjustments or tests, while radiating energy during or coincident with the construction, installation, servicing or maintenance of a radio station in this service, which may affect the proper operation of such stations, shall be made by or under the immediate supervision and responsibility of a person holding a first- or second-class commercial radio operator license, either radiotelephone or radio telegraph as may be appropriate for the type of emission employed. . . .

To be sure, it is not always true that clarity means brevity. For example, if, in an attempt to avoid technical language, ordinary words are used to explain legal concepts, the result may be a longer, though much clearer, regulation. Also, initial regulations have often been so confusing that "clarifications" were later required to explain them. The new FCC approach used in the CB standard avoids this problem by comparing the proposed standard with the existing regulation, noting where changes have been made, and explaining the differences—all when the initial regulation is published. But a procedure of this sort does not necessarily require fewer pages in the *Federal Register.*

According to Fred Emery, head of the Office of the *Federal Register,* plain English should not be the sole guideline for writing clear regulations. Writers should ask themselves the simple question: "Who is my audience?" In the case of CB radios, it is 12 million CB radio users. The better the intended audience understands a regulation the better they are able to observe it. A hazardous materials or law enforcement regulation might have to be expressed in more technical language, but this should be a function of the regulation's audience, not of how "professional" the language sounds. In other words, it is a matter of assessing who is required to abide by, and therefore understand, any given regulation.

The press for clearly written regulations is part of a trend. Consumer groups are asking for contracts that can be deciphered without legal advice. Some insurance companies are providing policies that can be "understood by the consumer," and many banks are offering loans that spell out each monetary obligation in "laymen's" terms. But the optimists should be cautioned: the utopia of plain English is not just around the corner. Overcoming the inertia of government regulation-writers will be difficult and time-consuming. Moreover, clear regulations may still be bad regulations—in the sense that they may be senseless, unnecessarily burdensome, or inefficient in other ways. All we can hope for is substantial improvement. If the new CB radio standard is any indication, progress is being made.

Benzene and Worker Health

That benzene is toxic is well known. Prolonged exposure to low concentrations of the chemical has long been recognized to affect bone marrow (the major blood-forming organ), causing such blood abnormalities as altered red and white blood cell production, disturbed coagulation, and increased susceptibility to hemorrhaging. But, only recently have scientists concluded that the progressive effects of benzene on the blood-forming organs are sufficient for the substance to be considered leukemogenic—that is, carcinogenic.

On April 15, 1977, the National Institute of Occupational Safety and Health recommended that the Occupational Safety and Health Administration establish a new "emergency temporary standard" on occupational exposure to benzene. (The previous standard was based on benzene's general toxicity rather than on its carcinogenicity.) A temporary standard was published on May 3 and became effective on May 21. Subsequently, between July 19 and August 10, OSHA held hearings on the feasibility and applicability of its proposed permanent standard.

While benzene is primarily used as a raw material in the production of other industrial chemicals, the largest impact of the proposed standard would fall upon the petroleum industry. Over $1 billion of benzene was produced in the United States in 1976—94 percent of it derived in petroleum refining. Although only 48 of the 323 domestic refineries produce concentrated benzene for commercial sale, the others maintain petroleum processing streams with benzene concentrations that exceed the proposed standards. Benzene is also a constituent of automobile gasoline, where its presence contributes to the gasoline's overall octane rating. OSHA estimates that 65 percent of the workers protected by the benzene health standard would be in petroleum-related industries.

The proposed permanent standard would require that employees be protected from exposure to airborne concentrations of benzene in excess of one part per million (ppm) parts of air on an eight-hour time-weighted average, or in excess of 5 ppm as averaged over any fifteen-minute period. Employers would be required to monitor benzene-exposed work areas at least quarterly and to provide medical surveillance and testing for employees exposed to the chemical (but they would not be required to transfer employees showing blood abnormalities out of high-risk areas). Other proposed requirements include employee training programs, posting of signs and labels, and extensive record-keeping.

In setting standards for exposure to carcinogens, OSHA, for practical reasons of enforcement, usually chooses not what most scientists would consider the safest levels—zero exposure—but the lowest level that monitoring equipment can detect—a "technology-determined" standard of sorts. However, in a few cases OSHA has stopped short of comprehensive application of such a standard because of the infeasibility of industry's meeting it without creating a significant amount of unemployment.

Because of the question of feasibility, the proposed standard provides two exemptions: The first covers operations where the only exposure to benzene is from liquids containing no more than 1 percent benzene by volume (0.1 percent after one year from the effective date of the standard). The reason for it is that benzene is an additive or constituent in a great number of hydrocarbon derivatives, though usually in small amounts. Given some evidence that employee exposure to substances with less than 1 percent benzene by volume can be below 1 ppm—though this point was strenuously

debated during the hearings—OSHA decided it would not be necessary to subject every substance containing benzene to the standard.

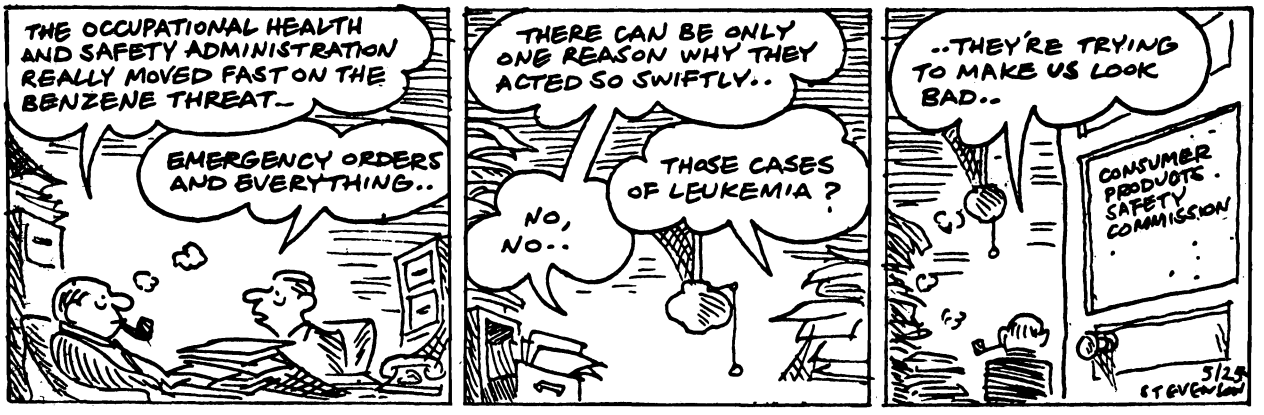
The second exemption covers the transportation, storage, distribution, dispensing, or sale of gasoline as a fuel subsequent to its discharge from bulk terminals. This exemption is proposed because the gasoline distribution network includes over 21,000 independent wholesalers (and 30,000 employees) who purchase and resell gasoline in relatively small quantities. OSHA concluded that the supply of safety equipment on the market would not be sufficient if this diversified group were to be included in the standard at the outset.

According to OSHA's economic impact statement on the proposed regulation, nearly 125,000 of the 191,000 benzene-related employees to be covered by the standard work in the petroleum industry. Protecting these employees, it is calculated, would increase the price of benzene by no more than 1 percent in the long run. (This calculation assumes an increase in direct capital investment and first-year operating costs of nearly $285 million in the petroleum industry alone.) Notably, because a price increase goes to the feasibility issue, the impact statement concludes that there would be no significant reductions in employment or in the production of benzene. For one thing, there are no direct substitutes for benzene in chemical products (which account for 98 percent of the benzene now used); this implies that the quantity demanded would not change much with changes in price. For another, even though the price increase would reduce the quantity demanded somewhat, this should be more than made up by normal growth in the use of benzene over time.

Other estimates of the proposal's costs differ. For example, the American Petroleum Institute concludes that the increase in direct operating costs would be twice what OSHA's impact statement predicts. The main reason for this difference is that API's analysis, unlike OSHA's, includes effects on crude oil production and transportation (because the benzene content of crude oils may exceed 1 percent by volume and frequently exceeds 0.1 percent). API argues that this and other factors would increase total compliance costs by 40 percent to 60 percent over the OSHA estimate. On the other hand, API also notes that some 50 percent to 90 percent more petroleum workers could be covered; this would imply an increase in the estimated benefits of the proposed standard.

Another area of contention is the amount of resources to be devoted to medical surveillance and exposure monitoring of the workers in the exposed workplaces. It is generally agreed that two-thirds of the compliance costs would be devoted to these endeavors. In many cases, API argues, the monitoring and surveillance would include workers who are rarely exposed to benzene concentrations in excess of 1 ppm. The industry argues that these resources could be devoted to more productive ends.

This obviously is an important regulatory proposal, and only the highlights of the cost and benefit impacts have been presented here. But we note that, in this case, as in many others involving worker health and safety, there is a reluctance to use as a policy guideline the economists' standard approach—cost/benefit analysis. Probably the main reason for this is the perception that cost/benefit analysis provides only a simple "yes or no" test for regulatory actions. Regulatory issues are complex,



of course, and few economists would argue against a health regulation solely on the basis of a mechanistic application of this tool. After all, some benefits and costs are not easily measured. What cost/benefit analysis does accomplish is to force policy-makers to think through their proposals, to identify more clearly who benefits from (and who bears the costs of) regulations, and to identify alternatives which might accomplish a given regulatory objective at lower cost or at least allocate the benefits and costs differently.

No-Fault Auto Insurance: A Federal Role?

President Carter's endorsement of federally mandated no-fault auto insurance marks the first time that the White House has supported such a plan and it increases the prospects that the comprehensive proposal now being considered on Capitol Hill (S. 1361 and H.R. 6601) will become law. Some type of no-fault insurance—under which an accident victim's insurance company pays at least part of the cost, no matter who was at fault—has been adopted in twenty-six states since 1971. Its objectives are (1) to curb litigation costs so as to increase payments to accident victims for a given level of insurance premiums; (2) to ensure that victims are paid at least something; and (3) to make payment more prompt. In order to restrain the total costs of compensation, sixteen of the twenty-six states having no-fault plans restrict the victim's right to sue for intangible damages ("pain and suffering").

State no-fault plans appear to be meeting two of these objectives, according to a Department of Transportation study summarizing the experience of the sixteen states that have adopted no-fault plans with provisions for restricting the filing of damage suits (*State No-Fault Automobile Insurance Experience 1971-1977*, June 1977). The results of the study support the contention that no-fault insurance compensates more accident victims than fault-based insurance, and does so more quickly. Under the Massachusetts no-fault law, for example, over 22 percent of single-car accident victims received compensation compared with the U.S. average of less than 3 percent. (Single-car accident victims typically receive very little compensation since there is no other party at fault to pay the damages.) For an example on the promptness of payment, in New Jersey, 80 percent of motorists injured during the first six months of 1973 were being compensated by the end of September 1973, compared to only 50 percent for the same period during 1972, the final year of the tort system.

Proponents of no-fault insurance rest their argument on additional grounds as well. They contend that much of the money now spent for lawyers' fees is wasted and should be redirected to pay benefits to accident victims. Also, a reduction of fault-based litigation, resulting in less court congestion and the freeing of resources for more "worthwhile" purposes (such as direct compensation of victims), is said to be a more efficient allocation of society's resources. Finally, proponents of no-fault argue that fault-based insurance systems overcompensate for minor injuries and undercompensate for major ones. No-fault seeks to rectify this by compensating all victims of accidents who sustain significant injuries, while (under most systems) restricting the right of accident victims to sue for intangible damages.

Many continue to oppose no-fault, either in principle or as a federally mandated program. There are seven major arguments: (1) The provisions limiting the recovery of damages penalize good drivers and lead to inequities when accident victims are unable to obtain full compensation. (2) The experience with state no-fault plans is too limited to enable us to predict how a federal no-fault law would work. On this point, opponents cite warnings in the Department of Transportation study that significant data shortcomings raise questions about the effects of no-fault systems that cannot be answered conclusively at this time. (3) A nationwide no-fault standard is inappropriate; instead, plans should be tailored to the needs of local populations. Proponents of this view note that a number of states have experimented with no-fault programs before arriving at the one that suited them best. (4) The liberal benefit levels specified in the proposals before the Congress are likely to result in overuse of medical benefits, thereby increasing costs. (5) Victims might well pad claims in order to exceed the threshold levels required to permit litigation. (6) State experience seems to indi-

cate that, if cost savings do occur under no-fault, they are absorbed in providing benefits to more people or more benefits to some people, so that insurance premiums are not likely to be reduced under federal no-fault (as some proponents have claimed). (7) The Department of Transportation report may be questioned because it failed to analyze data from the ten states that have a no-fault program that does not in any way restrict the victim from suing for damages (as long as any benefits gained through litigation are reduced by the amount received from the victim's no-fault insurance). The Association of Trial Lawyers of America (which opposes limiting the possibilities for trial litigation) points to the apparent success of such plans in compensating more victims more quickly than do fault systems.

Despite the criticisms, one must acknowledge that no-fault insurance plans have been effective for some purposes—at least when implemented at the state level. This very success, however, may have come as a result of continual experimentation and tailoring to state needs. Under the proposed legislation, federal guidelines would prevail, and such experimentation would be limited. This is a potential cost that should be carefully weighed against the potential advantages of federal legislation.

Lawn Mowers, Matchbooks, and Architectural Glass

Congress established the Consumer Product Safety Commission to protect consumers by prohibiting the manufacture of hazardous products and setting standards for the manufacture of products that, if used improperly, could cause injury or even death. Protecting consumers from unreasonable product hazards is only half the story. The CPSC must also, by law, take the economic effects of its regulations into account when setting its standards. Recent proceedings concerning lawn mowers, matchbooks, and architectural safety glass demonstrate the relevance of analyzing these effects.

(1) Back in mid-1974, the CPSC solicited proposals for a lawn-mower safety standard. This action was taken in response to the estimated 150,000 to 170,000 injuries and the thirty deaths that occurred in 1973 as a result of lawn-mower accidents. On May 5, 1977, the commission proposed a revised version of a draft standard submitted by Consumers Union. This proposal includes mower-handle specifications, shield requirements to keep the operator's foot away from the blade and to reduce the number of objects thrown from under the mower, and "deadman" controls (for both riding and walk-behind mowers) to stop the blade within three seconds after the operator leaves the normal operating position.

The CPSC estimates annual benefits from the proposed standard at between $285 million and $327 million in medical expenses and pain and suffering prevented. The Council on Wage and Price Stability predicts that the price of lawn mowers would rise between 4 and 27 percent (depending on mower type) as a result of the proposed regulations, suggesting a total cost increase on the order of $240 million to $330 million annually. Moreover, the council argues that, to compare costs and benefits, one must express the benefit figures in present value terms. (Reason: the benefits are strung out over time whereas the costs are incurred when the mower is purchased.) Since a dollar in the future is worth less than a dollar today, this lowers the CPSC annual benefit estimate to between $163 million and $213 million. Since the estimated costs exceed the appropriately adjusted estimates of benefits, the desirability of the overall standard is brought into question.

As for particular provisions in the proposed lawn-mower standard, the council and others have suggested that the elimination of the deadman control would significantly reduce costs (by one half to one third) without substantially reducing benefits. Moreover, the ultimate benefits of the deadman control are in doubt inasmuch as some consumers might disable it for convenience reasons.

(2) In its final matchbook standard (which became effective on May 4, 1977), the CPSC appears to have given more thought to the cost-effectiveness issue. The commission's original standard, proposed last year in an effort to reduce the 10,000 burns resulting annually from matchbook accidents, had four major parts: a quality control standard to prevent match fragments from endangering the user when the match is struck; a "reverse friction" requirement specifying that the striking surface be

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