Perspectives
on current developments

Mount Laurel II: State Courts Rush in . . .

"Enlightenment comes also from the New Jersey Supreme Court." These mysterious words come not from some satirical Zen handbook but from the *Harvard Law Review*. Their author is Justice William Brennan, who himself came from the New Jersey bench to his present seat on the United States Supreme Court. His epigram refers to a controversial zoning case the New Jersey court decided in 1975, a case that has just spawned an even more controversial sequel. More broadly, it refers to a process by which assertions of judicial power too ambitious for the Warren or Burger courts can be picked up and adopted as their own by courts in the several states.

These courts assert this power in interpreting their various state constitutions. In each state's bill of rights are many provisions similar or identical in wording to those of the corresponding amendments to the U.S. Constitution. When construing these provisions in considering state laws, nothing compels a state court to interpret any word or phrase the same way that the U.S. Supreme Court interprets the identical word or phrase in the federal Constitution. Thus if a state court dislikes the Rehnquist or O'Connor majority definition of "infringe" in a given federal case, it can interpret its own constitution's use of the word in accord with one of the Brennan or Marshall dissents—or some third definition not espoused by any of the Court's justices.

This anomalous situation is a wholly unavoidable result of federalism, and the federal courts could never hope to correct it without trampling on the sovereignty of the state courts. Still, it is something more than a mere curiosity in practice. Note, for instance, that the process is usually a one-way street. A state court may give its legislature less but usually not more leeway than the Supreme Court gives it. Specifically, when the Supreme Court declares something to be an "individual right," the states (including state courts) are bound to respect it. But when the Supreme Court finds an asserted individual right to be outweighed by some competing "governmental interest," state courts are free to redraw the line to assign more weight to the right, and state legislatures are free to assert or not assert the interest as they choose within those limits.

At first blush, this might seem to introduce a strong substantive bias in favor of individual autonomy and against government action. But in practice the bias it introduces can be made by an inventive judge to go in either direction. Almost any policy objective can be couched in terms of an individual right, and, conversely, almost any individual right can be couched in terms of a governmental interest in protecting that right. Thus, in a busing suit, judges can and do treat generalized demands for system-wide busing as claims of individual rights, while relegating the claims of individual schoolchildren to be treated with racial neutrality to the realm of government interests. Similarly, the procedural prerogatives of recipients of government benefits are found to be "individual rights," but the competing claim of taxpayers to minimize fraudulent or erroneous payments is at best a subconstitutional "interest" that governments may or may not choose to assert on behalf of those affected. Perhaps the most dramatic illustration of the conceptual randomness with which courts generate "rights" and "interests" is the pending case of Walter Polovchak, the Ukrainian teenager whose parents wish to return him against his will to the Soviet Union. One Illinois state court ruled for Walter's parents after their American Civil Liberties Union lawyer argued that their "individual right" to power over their child outweighed any "governmental

interest" in respecting Walter's own wishes in the matter.

The point of Brennan's article was to remind prospective litigants of the leeway state courts enjoy in construing constitutional provisions and to praise state court decisions that have taken advantage of this leeway. Of the decisions he cited, perhaps the most ambitious is *Southern Burlington County N.A.A.C.P.* v. *Township of Mount Laurel* (1975). Mount Laurel maintained zoning ordinances that encouraged the building of single-family homes on large lots and discouraged any land use that would not "have sufficient taxable value to come close to paying its own governmental way. . . ." The court struck down the ordinances, saying that they promoted not the "general" welfare of citizens of New Jersey (of whose government the township was a subdivision) but the welfare of the people who actually lived in Mount Laurel. This violated "the basic state constitutional requirements of substantive due process and equal protection of the laws," which the court said required a subdivision of a state to treat all the state's residents alike. The court also ordered the township to take unspecified "additional action encouraging the fulfillment of its fair share of the regional need for low and moderate income housing."

One measure of how expansively the *Mount Laurel* court interpreted the due process and equal protection clauses of the New Jersey constitution is that there are no such clauses in the New Jersey constitution. The court could have declared that the law violated those clauses in the *federal* Constitution, but then the decision would have been reviewable by the U.S. Supreme Court, which would probably have taken a very different view. The closest thing the New Jersey court could find in the state constitution was a provision recognizing "certain natural and inalienable rights" including the rights of property. To the naked eye, this provision looks as if it might be invoked by the residents of Mount Laurel to protect them from having to pay a "fair share" of other people's housing costs. But the court held that it guaranteed equal protection and substantive due process, which meant that local laws had to promote the general welfare, which meant that New Jerseyans had an individual right to regional fair shares of low-income housing, and perhaps to other good things. The contours of the right were left for specification at some time in the future.

The future is now. On January 20, eight years after the original decision, the New Jersey supreme court handed down *Mount Laurel II*. This time it left no doubt that its purpose was not merely to eliminate barriers but to achieve concrete results. The court was vexed by the fact that ending legal prohibitions on low-cost housing will have no effect if it is more profitable to build something else instead. Indeed, the township of Mount Laurel had amended its zoning laws to permit some high-density building, but the result was a proposal for luxury housing, which was not what the court had in mind. The court's 200-page opinion accordingly decreed the following:

- Each town's obligation to provide a "realistic opportunity" for the construction of the town's "fair share" of housing "may require more than the elimination of unnecessary cost-producing requirements and restrictions." Towns should therefore offer special exemptions from density restrictions to builders who agree to put up low-income housing; if necessary, they should even *require* such commitments before allowing developers to build anything at all. Towns are also constitutionally obliged to help developers try to secure federal subsidies.
- From now on, in order to allege a constitutional zoning violation, a plaintiff will need to prove only that a town has less than its "fair share" of low- and moderate-cost housing. The town will lose the case unless it can prove that it has taken steps that will soon correct the shortfall. Good faith—having sought diligently but unsuccessfully to fulfill the obligation—will not be a defense.
- Meanwhile, environmentalists need not fear a building boom. The court says that every town's "fair share" obligation will take into account the need to discourage all growth in forests, coastal marshes, farmlands, and other "environmentally sensitive areas." Other communities (the suburbs) will have to take a somewhat *larger* share of low-income housing so that these areas may remain scenic. "The Constitution of New Jersey does not require bad planning," the court says. To ensure good planning, the court will rely on something called the State Development Guide Plan

(SDGP), "a statewide blueprint for future development" prepared earlier by a state-level agency. The SDGP, whose maps are included in the court's opinion, designates "growth areas" that will be the areas subject to the fair-share obligation. What if the state agency revises the SDGP in the future? The court is prepared for this: it announces that it will continue to "defer to the planners" (that is, by incorporating their plan into the state constitution) so long as they "continue to act on the basis of sound planning principles." Presumably the court knows sound planning principles when it sees them.

- Like Gaul, New Jersey will be divided into three parts. The chief justice of its supreme court shall appoint one judge for each region to decide all future cases involving *Mount Laurel* issues. The determination of regional needs by any of these proconsuls "shall be presumptively valid as to all municipalities included in the region," even those who are not parties to the litigation. The chief justice also gets to draw the boundaries between regions at his sole discretion.

- Much of the opinion is devoted to a detailed plan for the orderly transition of power, and there are few descriptions of what life will be like under the new order. Some hints, however, are provided: "Mobile homes may not be prohibited, unless there is solid proof that sound planning in a particular municipality requires such prohibition." And "the 'subjective sensibilities' of present residents are not a sufficient basis for the exclusion."

The *Mount Laurel* opinions are hedged about with the usual reassurances that the limits of judicial power must be observed, but they could as easily be taken as proof that such limits no longer exist. A court that asserts the right to strike down any law that is not in accord with the "general welfare" can do anything. Nor are the courts continuing to respect the traditional limits on the kinds of coercion they can bring to bear in support of their opinions. Judges in busing cases, for example, have up to now been reluctant to order the achievement of racial balance in residential housing patterns. *Mount Laurel II* suggests that the barriers in principle to such rulings have disappeared.

If New Jersey is really blazing the trail, the doings of state supreme courts may someday succeed in making the advocates of judicial restraint appreciate the federal bench.

Regulation and the 1984 Budget

Since 1980, the staff and real budgetary levels of federal regulatory agencies have dropped significantly, around 11 percent. Most of that drop, 8.6 percent, took place in fiscal year 1982. Since then, the trend has been much more modest—but it is still down.

The summary figures shown here are taken from the annual roundup of regulatory agency budgets and staffs prepared by the Center for the Study of American Business at Washington University. The figures do not take into account congressional action on the 1984 budget, which will come later this year.

One reason to treat this year's figures with caution is that budget officials have not been very accurate in their projections in recent years. In fiscal 1982, for example, they ex-

EXPENDITURES ON FIFTY-SEVEN REGULATORY AGENCIES
Selected Fiscal Years, 1970–84

Area	1970	1980	1981	1982	1983 (est.)	1984 (est.)
	EXPENDITURES ($ billions)					
Social Regulation						
Consumer Safety & Health	$ 0.3	2.3	2.5	2.4	2.5	2.5
Job Safety & Other Working Conditions	$ 0.1	0.7	0.8	0.8	0.8	0.8
Energy & the Environment	$ 0.1	1.9	2.1	2.0	2.0	2.0
	$ 0.5	4.9	5.4	5.2	5.3	5.3
Economic Regulation						
Finance & Banking	$ 0.1	0.3	0.4	0.4	0.4	0.4
Other Industry-Specific	$ 0.1	0.4	0.4	0.4	0.3	0.3
General Business	$ 0.1	0.3	0.3	0.3	0.4	0.4
	$ 0.3	1.0	1.1	1.1	1.1	1.2
TOTAL	$ 0.8	5.9	6.5	6.3	6.4	6.5
TOTAL IN 1970 DOLLARS*	$ 0.8	3.0	3.0	2.7	2.7	2.6
PERMANENT FULL-TIME POSITIONS (thousands)						
Social Regulation	9.7	66.4	63.6	57.6	55.5	54.8
Economic Regulation	18.0	24.1	23.0	22.2	21.9	21.6
TOTAL	27.7	90.5	86.7	79.7	77.4	76.4

*Adjusted by GNP deflator (actual and, for later years, estimated in budget).
Source: Center for the Study of American Business.

pected real regulatory spending to fall by 4 percent; the actual drop was 8.6 percent. The next year the error was in the opposite direction: the projected drop was 7 percent, the actual 2.3 percent. (Congressional revisions may have accounted for some of the difference.) This year the budget calls for a further 3.9 percent cut in real terms, which would bring the total reduction since 1980 to 14 percent.

Most of the big cuts are occurring in the same areas as in earlier years: petroleum regulation, down from $66 million in 1983 to $37 million in 1984 (the figure for 1981 was $131 million); the soon-to-be-sunsetted Civil Aeronautics Board, down from $79 to $72 million (1981: $147 million); the Interstate Commerce Commission, from $64 to $58 million; and the Federal Trade Commission, from $65 to $60 million. The Environmental Protection Agency gets a slight nominal increase, from $1,270 million to $1,275 million; since 1981 it has sustained a 20 percent decrease in real terms. Some social regulation agencies are getting real increases in 1984, including the Equal Employment Opportunity Commission, the National Labor Relations Board, and the Office of Surface Mining, Reclamation, and Enforcement.

Over the longer haul, however, economic regulation has been faring better in the battle for funds than social regulation. In part this reflects increasing concern about the stability of the banking and international trading systems. Since 1981, as savings and loans have become financially shaky, the Federal Home Loan Bank Board has increased its outlays 250 percent. In the same period the Farm Credit Administration has had a 75 percent budget increase in nominal terms, the National Credit Union Administration 35 percent, and the

CHANGE IN EMPLOYMENT FOR TWENTY-EIGHT REGULATORY AGENCIES

Agency	Permanent Full-Time Positions			Percent Increase (Decrease) 1982–84
	1982	1983 (est.)	1984 (est.)	
Consumer Product Safety Commission	631	577	542	(14.1)
Food and Drug Administration	7,377	7,185	7,188	(2.6)
Antitrust Division	829	742	704	(15.1)
Federal Railroad Administration	421	445	445	5.7
National Highway Traffic Safety Administration	686	617	617	(10.1)
Bureau of Alcohol, Tobacco, and Firearms	3,671	2,950	2,974	(19.0)
TOTAL, *Consumer Safety & Health*	13,615	12,516	12,470	(8.4)
Mine Safety & Health Administration	3,763	3,408	3,184	(15.4)
Occupational Safety & Health Administration	2,354	2,354	2,355	—
Equal Employment Opportunity Commission	3,137	3,000	3,100	(1.2)
National Labor Relations Board	3,213	3,213	3,213	—
TOTAL, *Job Safety & Other Working Conditions*	12,467	11,975	11,852	(4.9)
Economic Regulatory Administration	597	441	300	(49.7)
Office of Surface Mining	735	731	731	(0.5)
Environmental Protection Agency	9,364	9,125	8,669	(7.4)
Nuclear Regulatory Commission	3,315	3,280	3,235	(2.4)
TOTAL, *Energy & the Environment*	14,011	13,577	12,935	(7.7)
Comptroller of the Currency	3,071	2,925	2,905	(5.4)
Federal Deposit Insurance Corporation	3,435	3,554	3,554	3.5
Federal Home Loan Bank Board	1,447	1,451	1,437	(0.7)
National Credit Union Administration	613	614	614	0.2
TOTAL, *Finance & Banking*	8,566	8,544	8,510	(0.7)
Civil Aeronautics Board	498	434	366	(26.6)
Commodity Futures Trading Commission	550	550	550	—
Federal Communications Commission	1,862	1,896	1,896	1.8
Federal Energy Regulatory Commission	1,516	1,667	1,701	12.2
Federal Maritime Commission	306	290	252	(17.6)
Interstate Commerce Commission	1,662	1,378	1,200	(27.8)
TOTAL, *Industry-Specific Regulation*	6,394	6,215	5,965	(6.7)
Patent & Trademark Office	3,036	3,140	3,286	8.2
Federal Election Commission	219	234	234	6.8
Federal Trade Commission	1,322	1,168	1,131	(14.4)
Securities & Exchange Commission	1,925	1,900	1,700	(11.7)
TOTAL, *General Business*	6,502	6,442	6,351	(2.3)
TOTAL, TWENTY-EIGHT AGENCIES	61,555	59,269	58,083	(5.6)

Source: Center for the Study of American Business.

Comptroller of the Currency, which regulates banks, 38 percent. Similarly, the independent International Trade Commission and the Commerce Department's International Trade Administration, which regulates strategic trade, have both enjoyed 50 percent nominal budget rises since 1980.

Staffing figures in some cases diverge from those for budgets. The Antitrust Division of the Department of Justice has had a relatively stable budget since 1982, but is nonetheless decreasing its full-time positions from 829 to 704 in 1984. The Mine Safety and Health Administration's staff similarly dropped from 3,763 to 3,184 over the same two-year period, and the Federal Maritime Commission from 306 to 252. Of course, agencies sometimes operate below these staffing ceilings and frequently substitute outside contractors for civil servants, two factors that make it hard to draw more than tentative conclusions about the aggregates involved. Still, the general 1984 trend, down 1 percent from 1983 and 16 percent from 1980, more or less confirms the message of the budget figures. The Reagan administration has rolled back regulatory activity measurably, but its effort is now slowing down.

A Logjam for U.S. Exports

When members of Congress complain about Japan's and other countries' barriers to American exports, they do not come to court with clean hands: they are responsible for too many barriers of their own that block those same American exports. Most of those barriers specifically worsen our bilateral trade balance with countries like Japan. But except for the prohibition on export of Alaskan oil, they have aroused little controversy. One of the noteworthy examples is the federal ban on the export of softwood logs from federal lands in the Pacific Northwest. The major target of the ban is Japan, which imports two-thirds of the timber products it uses, although in the past few years China and Korea have been important buyers, too.

The ban originated in 1968, when Senator Wayne Morse (Democrat, Oregon) persuaded Congress to impose a quota holding log exports from federal lands to 350 million board feet per year. In 1973 Congress banned such exports entirely in an appropriations rider that it has renewed every year since. The rider also instructs federal agencies to take steps to prevent companies from sending more logs from their own lands abroad, and then harvesting more trees from public lands to make up the difference. Under Forest Service rules, therefore, companies may not let their exports rise above 110 percent of a 1971–73 base, on penalty of being excluded from future federal timber sales. Furthermore, as long as they continue to export any logs at all, they are barred from increasing their purchases of federal timber by more than 10 percent above base purchases. The Bureau of Land Management maintains somewhat looser substitution controls.

On their face, these restrictions have failed to halt the growth of log exports from the Pacific Northwest. Those exports rose during the 1970s from around 2 billion to 3 billion board feet, reaching 12 percent of the West Coast harvest. The reason is that a few timber firms rely mostly on their own forest holdings and are not dependent on federal timber. By far the most important of these firms is the Weyerhaeuser Corporation, which accounts for 40 percent or more of Northwest log exports. Another 15 to 20 percent comes from lands owned by the state of Washington, which unlike its neighboring states (including Alaska and the Canadian province of British Columbia) has thus far fended off pressures to adopt an export ban along the lines of the federal one. Firms can export Washington state logs, unlike private logs, without jeopardizing their access to federal timber.

The curbs may not have succeeded in preventing exports, but they have nonetheless had an important economic impact. They have made the market for northwestern logs a dual market, with the price of exportable logs higher in most years than that of similar logs for domestic use. (The estimated price premium ranges from 10 to 50 percent, depending on how quality is calculated.) The volume of log exports is ultimately lower, of course, because Japan buys fewer logs at inflated prices.

The added profits from the higher export prices are significant. In recent years Weyerhaeuser's exports to Japan have exceeded $500 million a year. The company probably derives as much as $100 million annually in profit from the export price differential.

In Brief–

Two More Court Reverses for Deregulation. The list of Reagan administration deregulatory moves struck down by the courts is getting longer all the time. Last year judges nullified the Department of Labor's amendments to its Davis-Bacon regulations, the Environmental Protection Agency's effort to expand the scope of emission "bubbles," and, of course, the National Highway Traffic Safety Administration's repeal of its passive restraint (air-bag) rule (see "Active Judges and Passive Restraints," *Regulation*, July/August 1982).

On January 28 the U.S. Circuit Court of Appeals for the District of Columbia added another notch to its belt when it prevented the Civil Aeronautics Board from relaxing three rules on smoking in airplanes. The agency may not, the court said, let the airlines decide whether to segregate cigar and pipe smokers in special sections, to ban smoking when ventilation systems are not fully functioning, and to institute measures to protect nonsmokers from drifting smoke. The court also ordered the CAB to reconsider some proposals it had rejected in 1981, such as banning smoking entirely in small aircraft and on short flights. Senior Judge David Bazelon wrote that a "general desire for a bare minimum of regulation cannot justify rejecting specific regulatory proposals"—leaving the board to wonder just what action such a desire could ever justify.

Less than two weeks later, on February 9, a D.C. district court judge ordered the Treasury Department to require liquor, wine, and beer makers either to list ingredients on their cans and bottles or to print an address where such information can be obtained by mail. The department had adopted such a requirement in 1980 and then rescinded it a year later, citing the Reagan administration's deregulatory drive and the burdens the rule would impose on the industry.

Pet Peeves. Progressive Washington circles are currently being torn by a controversy on an age-old question: the pet issue. On one side is Representative Mario Biaggi (Democrat, New York) who has reintroduced legislation to "establish the basic right of millions of elderly and handicapped persons to own pets in federally subsidized housing." He would prohibit such housing projects from exercising that "form of discrimination" on pain of loss of funds. One state already has such a law; it is, of course, California.

On the other side is *Washington Post* columnist Colman McCarthy, who says that pet ownership is bad for both pet and owner. For the pet, it is "animal slavery. . . . The pet cat may appear to be doing well in the human world. So did some of the 19th century field slaves plucked out of shacks and placed in the master's mansion as house servants." For the owner, it is a source of such health hazards as rabies and toxoplasmosis. McCarthy reports on the crusade of a national organization, Children Before Dogs, whose leader recently demanded (without success) that the Public Health Service curb the unhealthy practice of allowing cats and dogs in hotel and motel rooms.

The "there oughta be a law" syndrome has now transcended the merely human realm.

Keeping Up with the Jones Act. The federal Jones Act has long prohibited foreign-flag and foreign-built ships from carrying goods between points on the U.S. coast. Now a controversy has developed over whether the law forbids small foreign ships from hauling coal from a U.S. port to a larger parent ship waiting off the coast, whence the latter would proceed to a foreign port.

This procedure of "topping-off," as it is called, has been developed for practical reasons, since it allows large ships to patronize ports that are too shallow for them to enter or leave when fully loaded. U.S.-flag ship owners, however, would like a monopoly on the topping-off trade, and say they are considering legal action to sink the competitive flotilla. They may get help from the Reagan administration and Congress—both of which are reportedly considering proposals to extend the Jones Act's reach to 200 miles offshore.

Those who support the export ban have successfully practiced what can accurately (for once) be called interest-group logrolling. They include, among economic interests, sawmills and other timber processors, the housing industry, and the unions involved in both industries. For many years, while there were still large stands of virgin forests, these groups were accustomed to low timber prices and did not begrudge a certain amount of competition from foreign buyers. But in the 1960s, as supplies became tighter and prices began climbing sharply, they began to resent Japan's success in bidding away their supplies. The sawmills merely wanted to force Japan to buy U.S. timber in processed form; the housing interests, on the other hand, hoped to cut off exports entirely.

These economic interest groups were assured of success when the environmentalists joined their cause. For them, an export ban was first and foremost a convenient way to prevent the cutting of trees, especially on the public lands that they had most hope of influencing toward other uses. As in the case of Alaskan oil, a ban also appealed to the nationalist instinct to save American resources for Americans—that is, to meet "critical" U.S. in-

ternal needs, not merely to earn foreign exchange by satisfying the similar needs of people in other countries. On the opposite side were timber companies and loggers, as well as economists who warned of losses in foreign exchange earnings, federal timber revenues, logging jobs, and economic efficiency. Not surprisingly, Congress found the arguments of the processor-homebuilder-environmentalist coalition more compelling.

The economic situation has changed greatly since 1973; for one thing, there is a glut of timber now, and the industry is in considerable distress. In the late 1970s, predicting a continuing housing boom, timber firms had bid up the price of federal timber to unprecedented heights. When disinflation began to devastate the homebuilding market, however, demand for timber fell sharply, and by 1982 federal timber was often selling for half or less its former price. Since federal timber is usually sold several years before it is actually cut, and much of the payment is likewise deferred, the day of reckoning has been postponed until now. Companies will incur large losses if they harvest all the timber they bought earlier at the higher prices. So they are pressing Congress hard for relief.

Some federal officials have suggested relaxing the export ban temporarily in order to increase the prices the timber firms receive. This might not be enough to solve their financial woes, they say, but nothing could be lost by trying. Key western members of Congress, however, have opposed any relaxation of the ban.

Any proposal for repeal would also inevitably raise the issue of reciprocity. The sawmills still complain that they are excluded from Japanese markets by both law and custom, citing, for example, the famous impenetrable Japanese distribution network. But we may never know whether comparative advantage would favor the U.S. mills even if Japan were the most open of markets, since those mills have for the most part not equipped themselves to produce the sort of lumber Japan wants, which differs radically from U.S. styles and specifications. The sawmills advise retaining the log export ban as suitable retaliation for alleged Japanese discrimination and, inevitably, as a negotiating tool to force further Japanese concessions in miscellaneous trade areas, presumably to be relinquished only when the business community expresses uniform satisfaction with Japan's conduct on these matters.

The intractable politics of federal forest management has cast increasing doubt on the sometime ideal of efficient public-spirited management in the national interest. Thomas Lenard described some of the inefficient supply (as opposed to demand) restrictions on federal timber in "Wasting the National Forests" (*Regulation*, July/August 1981). With 55 percent of the Pacific Coast inventory of softwood timber, the Forest Service supplies only 29 percent of the total harvest. A recent Washington State University study confirmed that the service's uneconomic harvesting policies were accelerating the projected rise in timber prices. Some critics have even charged that the Forest Service, by keeping its timber harvests artificially low, is deliberately generating monopoly prices and revenues for local governments (which get a share of the federal government's leasing income) as well as private timber owners.

The seeming impossibility of changing these policies under the current federal ownership has frustrated many in the forest management community. Some, like Marion Clawson of Resources for the Future, are going beyond their earlier recommendations for management reforms to ask publicly whether more radical changes in land tenure might not be necessary—including state management, management by private enterprise, or outright sale or disposal.

Tylenol: Regulate in Haste . . .

The regulatory response to last fall's Tylenol poisonings in Chicago was nearly instantaneous. By November 5, 1982, only five weeks after the Tylenol deaths, the Food and Drug Administration had skipped the normal *Federal Register* notice of proposed rulemaking, avoided normal Office of Management and Budget review, and proceeded to adopt a final rule requiring over-the-counter (OTC) drugs to come in tamper-resistant packages. The Proprietary Association, the industry trade group of over-the-counter manufacturers, had strongly urged

regulation and given the agency its cooperation and technical help.

This unusual haste was not motivated by manufacturers' sluggishness in mitigating the hazard. Johnson & Johnson, the maker of Tylenol, had immediately recalled some 30 million bottles of Tylenol nationwide, at an estimated cost of $100 million. Within a few days the other OTC drug firms had begun plans to improve the packaging security of their packages, and some tamper-resistant products were on the market within two weeks.

The FDA's alacrity was brought on mostly by the fear of chaos at the local government level. Chicago had banned the sale of Tylenol entirely, and other localities had begun to adopt vastly divergent laws on the subject. Only a preemptive strike by the FDA, it seemed, could prevent the United States from turning into the Holy Roman Empire of pill marketing, with manufacturers obliged to secure permission from hundreds of petty sovereigns before they could sell a pain reliever across the land.

The industry found other advantages in regulation, too, although mostly by comparison with the likely alternatives. The (more-or-less) known burdens of regulation might at least forestall agencies from ordering expensive recalls and help stave off product liability awards as well. On the more positive side, an FDA seal of approval might help maintain public confidence in the huge OTC drug market, which was of great concern since most such purchases are very much a matter of consumer discretion.

The final rule covers all OTC drugs intended for oral, rectal, vaginal, otic (ear), nasal, and ophthalmic use. The three exceptions are skin products, toothpaste, and insulin; the first two of these are thought inherently more difficult to adulterate in a harmful way, and the latter is already marketed in effectively tamper-resistant packages. Also covered are mouthwashes, gargles, and vaginal hygiene products. Contact lens cleaning solutions, which are sold in both liquid and tablet form, are regulated as medical devices and not drugs, but are covered by a closely similar regulation.

Vitamins and minerals sold over the counter are regulated as foods, not drugs, and are not covered by the new regulation. Since they too come in capsule form, however, the FDA is considering regulating them as well (although it cannot have fond memories of its earlier attempts to regulate vitamins, which provoked a major outcry from users). Presumably it also hesitates to open a Pandora's icebox of tamperable foodstuffs, including grapes, ketchup, Worcestershire sauce, and so forth.

The new requirements will be introduced in three stages, the first of which has already gone into effect:

First, by February 7, 1983, all of the covered products except for tablets and suppositories were to be manufactured in tamper-resistant packages. This means "having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred." Such barriers might include, but are not limited to, wraps or foils that must be torn to open the package, blister or bubble packs, shrink seals, breakable caps, sealed cartons, and the like. The barriers should not, the preamble suggests, be so difficult to open as to stymie arthritic or other manually impaired buyers.

Second, by May 5, 1983, tablets and suppositories (which are thought to be more difficult to tamper with than capsules and liquids) must be tamper-resistant. By this date, too, all products must comply with two further requirements. The first is that the barriers be distinctively designed so that they cannot readily be counterfeited by a tamperer. The second is that the packages carry a label identifying the tamper-resistant barrier and warning the consumer that the product may have been illicitly tampered with if the barrier is not intact.

By the final effective date, February 6, 1984, retailers must remove all products on their shelves that do not comply with the basic tamper-resistance requirement. All imported products must likewise comply by then. No "pull date" is set for the other two requirements, so that products with undistinctive barriers or without label warnings may stay on the shelves indefinitely (until further notice). The FDA plans to review the February 1984 deadline after it considers the effects of the earlier stages, including the possibility that enforcing the deadline could impair the market availability of some products.

Several features of the regulation seem to respond to the criticisms that regulatory scholars have been raising over the last decade. First, the FDA is explicitly not aiming at *absolute* safety; it requires not that packages be tamper-proof, which it regards as a practical impossibility, but simply tamper-resistant. Thus it is avoiding the "zero-risk" basis for which other regulatory programs are often chided.

Second, the FDA chose a performance rather than engineering standard. It did not mandate specific packaging methods, but simply specified the goal of tamper-resistance and then allowed manufacturers to come up with their own ways of reaching it.

Third, the agency presented the regulation as an informational one, stressing that the decision whether or not to use the product is up to the consumer: "Consumers must act to protect themselves from injury by inspecting the condition of the packages they buy. . . ." Thus it did not embrace the paternalistic notion of trying to protect consumers from the consequences of their own actions—which presumably would have taken the form of a ban on buying any item with a broken seal.

Fourth, the regulation tries to balance consumers' desire for safer packaging with their desire for uninterrupted access to over-the-counter products: the timetable phases in compliance for the most susceptible products and vital features first.

Despite FDA's best intentions, it is far from certain that the rule would have passed the OMB cost-benefit test that it was spared (not that the alternatives of recalls and product liability litigation would fare any better). The agency estimates the costs of the regulation to the consumer at a few cents per package, while industry estimates range up to ten cents. Multiplied by the 2 billion OTC drug packages sold each year, the resulting cost would be in the tens to low hundreds of millions of dollars. Yale economist Paul MacAvoy points out that "almost all the attempts at valuation of lives saved indicate that both consumers and voters act as if they value risk reduction at rates equivalent to $500,000 or less." At that rate, the regulation will be worth its overall cost if it averts from several dozen to several hundred poisonings a year.

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