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# Perspectives

## on current developments

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### How to Turn Grandfather Drugs into Orphans

Not too long ago Ralph Nader's Health Research Group brought out a book called *Pills That Don't Work*. The work listed "over 600 prescription drugs that have not been proved effective and yet are still on the market." It blamed this seeming health scandal on "governmental inefficiency, lethargy and timidity, orchestrated by heavy pressure from drug companies. . . ." *Pills That Don't Work* became a paperback bestseller, and the same Nader group went on to prepare a companion volume, scheduled for release this fall, on "ineffective" over-the-counter (as opposed to prescription) drugs. That book, too, indicts the Food and Drug Administration for allowing thousands of apparently worthless preparations to remain on the market.

Usually muckraking books precede, rather than follow, the reform efforts they advocate. Both of these literary efforts, however, arrived after years of litigation by "public interest" lawyers had secured court orders forcing the FDA to act on the issue, and indeed after the agency had completed much of the action required. As one might expect, therefore, the full story is rather more complicated than it may seem. A suitable question to ask might be whether the Nader campaign to review the efficacy of older drugs has succeeded in proving its own efficacy or even safety. If not, the book might better be called *Regulations That Don't Work*.

Before 1962 federal law required simply that drugs be "generally recognized as safe." The Kefauver amendments that Congress adopted in that year added a separate requirement that they be effective as well. Specifically, the amendments required that the FDA find "substantial evidence" of a drug's effectiveness before approving it. In the agency's actual practice, as the director of FDA's Bureau of Drugs

conceded in rather candid congressional testimony in 1980, "the amount of evidence needed to support the effectiveness of a drug is closer to the legal standard of 'beyond a reasonable doubt.'"

As readers of these pages well know, the Kefauver rules led the FDA to demand more and more elaborate testing of the effectiveness of a new drug before approving it for marketing. Proving efficacy "beyond a reasonable doubt" has turned out to be quite a challenge, since skeptics can usually find some basis or other for questioning the conclusiveness of clinical trials. (Proving inefficacy would be at least as difficult, for that matter, which must make the FDA glad that it need sustain no such burden of proof.) With large-scale clinical trials some patients will inevitably drop out in a mobile society, so that it is hard to ensure perfect control; on the other hand, small patient samples, which may be the only option in the case of drugs for rare conditions, have less statistical reliability. By the mid-1970s, the FDA's testing standards had become the most exacting in the world, and the average cost of testing a new drug had soared to \$50 million. After this preliminary testing, which goes on for many years, FDA officials can demand further clarification and substantiation of the studies included in the drug's marketing application, which means that approval is delayed by an average of three or four more years. These and other problems have contributed to the rise to prominence of the "orphan drugs," new drugs whose commercial value is not worth the cost of the required testing. (See Louis Lasagna, "Who Will Adopt the Orphan Drugs?" *Regulation*, November/December 1979.)

Much less publicized, until recently, was the problem of what to do with the many prescription and over-the-counter drugs that were already on the market before 1962. Drugs first sold before 1938 were clearly "grandfathered," but the FDA was able to persuade federal courts

that the efficacy requirement should apply to all drugs approved between 1938 and 1962. Would the effectiveness of these drugs also have to be documented using the same involved research methods as new drugs, or should they continue to enjoy some sort of intermediate grandfather status, subject to review in cases where there was evidence of inefficacy?

The FDA took its first major step toward applying the Kefauver standards to these older drugs in the mid-1960s, when it asked the National Academy of Sciences to organize panels of medical researchers to review the effectiveness of all prescription drugs approved before 1962. These reports, which were substantially completed by 1968, covered some 3,700 drug formulations with (since many products had multiple uses) a total of more than 16,000 separate claims of efficacy. The NAS panels judged that only 7 percent of these drugs were “ineffective” for all claims—meaning that, in the panel’s opinion, no amount of testing would ever substantiate the therapeutic claims made for the drug. Most claims were rated either “possibly” or “probably” effective, which meant basically that the claims had not yet been substantiated by the most rigorous testing standards, and 20 percent of the claims were considered unqualifiedly “effective.” Quite often, however, this rating reflected the panel members’ personal experiences or beliefs, rather than the availability of unusually well-controlled studies—on the implicit view that certain preparations, such as most antibiotics, were so manifestly effective that there would be no point in putting them through the paces. Although the NAS conceded that its reviewers had not applied consistent standards in assigning their ratings, the FDA was content to accept the unqualified “effective” ratings.

That still left a huge residuum of possibles and probables to be dealt with. In 1970, fatefully, the FDA issued regulations decreeing that all drug claims in these categories would eventually have to undergo the full testing requirement. It did not contemplate forcing the manufacturers to do so all at once, however, and for several good reasons. First, clinical research is a scarce resource, and if manufacturers had to commission a great many studies at the same time they would cut massively into the time and personnel available for other valuable work ranging from epidemiology to research on new

drugs. (Research efforts spread out over many years would also compete for these resources, but less disruptively.) Second, many of the products no longer generated enough sales for their makers to justify the costs of full-dress testing. These costs would be less than those for a new drug, since such factors as safety would not be at issue, but they would still be quite substantial. Thus, many drugs with distinct if limited uses would simply become unavailable to the patients who needed them, creating, at one stroke, a whole orphanage full of former grandfathers. Finally, the law stipulated that the FDA could not withdraw marketing approval from a previously marketed drug until it had provided producers with an opportunity for a hearing, and with only two full-time hearing examiners the agency could not possibly handle all the cases it would trigger by trying to proceed at once.

Not surprisingly, then, the FDA proceeded to implement its review at quite a leisurely pace. “Public interest” groups claimed to be scandalized by the delays, and sued the agency to spur matters on. As happens so often, however, taking the dispute to court turned out to be an ineffective way to speed up its resolution. A district court judge in Washington, D.C., did rebuke the agency sternly in 1972, by which time it had taken final action on less than half the drugs in the NAS survey. But the resulting court order tacitly acknowledged the real difficulties involved: it gave the agency up to four more years to deal with the remaining drugs and held out the possibility of further extensions for drugs that the agency regarded as meeting a “compelling medical need.” By 1979, seven years later, the FDA had still failed to take 482 drugs out of limbo. All that a new round of litigation accomplished was to secure a settlement pushing the deadlines out to as late as 1984.

The FDA took a somewhat more creative approach to the over-the-counter (OTC) side of the problem, but there too it ran into trouble from a Nader suit. In the over-the-counter case, testing each product individually would clearly have been impractical, since there were some 400,000 such products. Accordingly the agency commissioned expert panels in 1972 to review and report on the effectiveness of the active ingredients used in twenty-seven broad categories of products, such as pain relievers, cold reme-

dies, laxatives, and so on. Based on these reports and any additional evidence submitted by manufacturers, the agency would then proceed to issue official monographs listing the active ingredients that were acceptable for use in each type of medication.

The agency planned to classify the OTC ingredients quickly into three broad categories: (1) ingredients that had been firmly proved to be safe and effective, (2) ingredients that had been judged to be unsafe or clearly ineffective, which would automatically be banned, and (3) a residual category of ingredients not yet fully proved effective, but still authorized for sale. In 1979 Nader lawyers succeeded in getting a court order abolishing the third category; it would have to classify all ingredients as either effective or not, regardless of the added burden in doing so. In fact, the agency simply ceased to issue any orders at all for more than two years thereafter. Even now it has published only ten of a projected eighty-five final monographs on acceptable over-the-counter ingredients. (The Nader lawyers are back in court.)

There is some hope for an end to the ordeal. The review of OTC products is now proceeding fast enough that agency sources predict it may be largely finished in three or four years. Moreover, the review of prescription drugs is approaching completion: by 1980, the FDA had taken final action on 87 percent of the prescription drugs in the original NAS survey, and had classified 72 percent of that total as "effective." Even so, counting different formulations of the same substances, the review had forced the withdrawal of several thousand previously legal drugs from the market. Among them were many "combination" drugs, banned on the grounds that they were no *more* effective than their ingredients taken separately. This policy, according to critics of the FDA's effort, ignored the advantages of "double-barreled" treatments in cases where an exact diagnosis was impractical. Physicians could get around this problem by prescribing the ingredients separately, but only at additional cost, and at the risk of less certain patient compliance.

As for OTC products, the agency predicts that when its review is complete perhaps a third of the currently available product families will have to be substantially reformulated or withdrawn entirely. A large share of these are antiquated remedies now sold mostly by mail or

through special-order wholesalers to a dwindling band of loyal, often elderly customers. It is worth quoting the late Dr. Michael Halberstam in this context:

One of the interesting phenomena in clinical pharmacology is that idiosyncratic reactions to a drug are universally accepted as valid—if they are adverse. . . . We accept unquestioningly that some people can be harmed by a drug which in the overwhelming percentage of patients is helpful (or at least innocuous).

It is curious that the converse is not true—a patient who claims unique benefit from a drug that is not generally considered effective is not likely to be believed. . . . Thus, if aspirin relieves discomfort in 40 percent of a population study and Wonder-A does the same, the latter is said to show "no advantage" over aspirin, even though its 40 percent response rate might at least in theory come from a different segment of the population [than aspirin]. [*Too Many Drugs?* AEI Reprint # 102, January 1980]

In the meantime, as *Pills That Don't Work* says, it is quite true that consumers are still permitted to buy hundreds of prescription drugs and thousands of OTC products "that have not been proven effective"—beyond any reasonable doubt, at least. That is, people are still allowed to request and buy products with therapeutic benefits some of which are merely "probable" or "possible," and others of which are nonexistent. It is even possible to find governmental "lethargy" in this circumstance, since the FDA has admittedly given higher priority to its other responsibilities.

But the slow pace of these proceedings is a scandal only if one starts from the assumption (as the Nader books quite explicitly do) that prescribing physicians and patients are incapable of making proper decisions on even repeated purchases of drugs. Under less paternalist assumptions—such as prevail in most other modern countries—the extravagant nature of the testing may appear in a different light. It may seem at best an example of the luxuries a rich country can indulge in, and at worst a woeful waste of medical and scientific resources. As for the other costs of the program—its reduction to "orphan" status of existing drugs that consumers use and value and its rejection of drugs that do have sponsors

but whose efficacy is merely “probable”—these may seem at best a stifling of harmless cultural diversity and at worst an assault on consumer well-being.

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## A Case of Labor Market Pains

Effective control of health costs is often thought to require restrictions on individual choice. Many reform plans would establish “gatekeepers” to prevent patients who do not pay their own medical bills from choosing overly expensive kinds of care. That sort of restriction might succeed in cutting costs, but at the price of taking away patients’ rights to decide who will care for them and how. Fortunately, for those who are troubled by this dilemma, there are a number of reforms that would combine cost-cutting and wider individual choice, by setting patients free to choose lower-cost alternatives that are now unavailable to them. Foremost among these reforms would be to let nurses, paramedics, medical technicians, and other members of so-called allied health professions handle more of the tasks now reserved for doctors. This particular reform effort has run into tremendous opposition from the doctors themselves, however, and perhaps nowhere more than in the case of nurse-midwives.

Up through the early twentieth century most babies were born with the assistance of midwives. The profession got a very bad press, however, in the reformist literature of the turn of the century. Such works as Upton Sinclair’s *The Jungle* portrayed venal or superstitious “lay” midwives (midwives without formal medical training) whose ignorance endangered both mother and child. Enlightened opinion was rallied to suppress the practice. Most states passed laws heavily regulating lay midwifery, and some outlawed it altogether, stipulating that only doctors and registered nurses could deliver babies. Furthermore, most states require a doctor’s collaboration in any event.

In the 1960s, however, midwifery began to make a comeback, for reasons that went well beyond the issue of affordability. The home-birth and natural-birth movements arose to argue that obstetricians have relied on superfluous and perhaps hazardous medications and technologies. The rise of feminism led many

expectant mothers to prefer to be attended by a (usually female) nurse rather than a (usually male) doctor. Moreover, midwives could offer a mother continuous care, while an obstetrician supervising several deliveries was likely to drop in and out of the room—another example of how “caring” as well as “curing” can be important to patients.

Some doctors still claim that midwifery is less healthful than physician care, but the midwives respond that their services are perfectly safe under modern conditions of practice, perhaps even superior in quality. They cite statistics from a New York City clinic and from rural California suggesting that nurse-midwife care brought about significant improvements in infant survival rates and other measures of well-being. Midwives can quickly call in a doctor’s help in the minority of cases in which complications arise. The American College of Obstetricians and Gynecologists joined with the American College of Nurse-Midwives in November 1982 to issue a joint statement emphasizing that “quality of care is enhanced by the interdependent practice of the obstetrician/gynecologist and certified nurse-midwife . . . [which] does not necessarily imply the physical presence of the physician.”

Despite these fine words, nurse-midwives have been subjected to no end of regulatory grief. In the District of Columbia, for example, local law does not explicitly refer to midwives—referring only to the practice of nursing generally—so that they are not reimbursed by Medicaid. (Nurse anesthetists have also run into trouble on federal reimbursement: see “Is HHS Trying to Deadend the Pain of Competition?” *Regulation*, January/February 1983.)

More often it is the exact relation between midwife and doctor that causes the regulatory controversy. Many physicians would prefer to reserve for themselves such functions as the prescribing of drugs. (“Good fences make good neighbors,” they say.) Some state licensing boards dominated by physicians are tightening restrictions on the scope of professional practice of both doctors and nurses. The Arkansas medical board, for example, has prohibited doctors from supervising any more than two nurse-midwives at a time. The New Jersey, Kentucky, and Maryland boards recently considered but did not adopt regulations to restrict the nurse-midwives’ scope of practice.

Meanwhile, hospitals in such cities as Richmond, Virginia, have come under pressure to grant hospital privileges to midwives and other health professionals, thus allowing them to admit, diagnose, treat, and discharge patients. In the regulation-charged atmosphere of modern hospital administration, this sort of decision has become a political rather than a private decision—all the more so because the allied professionals charge that the hospitals' credentials committees are dominated by physicians, who are thus in a ticklish antitrust situation. Again, the District of Columbia has been a major battleground. Doctors in the medical society there have fought against granting hospital privileges to nurse-midwives, nurse-practitioners, and podiatrists, and one major hospital revoked the nurse-midwives' privileges, accusing them of straying beyond their permitted scope of practice to perform general gynecological exams.

Among the objections the doctors sometimes raise is one of cost. If allied professionals can admit patients, they assert, hospitals will have to add more personnel to their payrolls and costs will inevitably increase. They point out that hospital staff increased by 100 percent from 1960 to 1980, even after adjustment for the rise in population, and that this was a major factor in the general run-up in health costs.

The question is to what extent the allied professionals are adding to the total demand for services and to what extent they are simply substituting for the services of physicians. According to an article in the *American Journal of Obstetrics and Gynecology*, "The most significant decrease in health and medical costs that may result from collaborative practice [between a physician and nurse-midwife] is the substitution of the cost of physician resources. Clearly, more expensive physician time may be replaced by less costly nurse time." If this substitution effect outweighs the "demand creation" effect, expanding the use of midwives should help reduce health outlays. And although nurse-midwives may spend more time with their patients, they do not seem guilty of oversupplying services in general, since their cost per delivery is lower than that of doctors. Of course, the advance of midwifery could boost spending if it led to more deliveries, but the supply of new babies to deliver probably does not increase markedly when mothers are offered new ways of delivering them.

Whether because of increased activity by other professionals, incidentally, or because the population is growing more slowly than the number of doctors, the medical establishment is beginning to feel the spur of competitive pressure. The Minnesota state medical association found in a recent survey that nearly 40 percent of its members thought their communities were oversupplied with physicians, whereas only 10 percent of them had thought so five years ago. One result has been an upsurge of protectionist activity within the medical profession itself. The House of Delegates of the California state medical association, for example, asserted earlier this year that "physicians seeking to resettle in California are not a needed resource," and called for an end to automatic reciprocity between the states in physician licensing. As the pressure intensifies, professional groups will increasingly have to choose whether to devote their efforts to raising more barriers or whether to become midwives themselves, assisting at the birth of a more open and competitive health care system.

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## Clean Water: Apocalypse Later

Nineteen eighty-four is fast approaching, and commentators will soon churn out articles by the hundred on the significance of reaching the fateful Orwellian year. For regulatory buffs, however, the truly apocalyptic date is not 1984 but 1985. That is the year specified in the Clean Water Act for the goal of zero discharge of pollutants into the nation's lakes and streams. According to Martin Bailey (*Reducing Risks to Life*) this goal "may be technically impossible; the capital cost of closely approaching [it] would quickly exceed one year's national product, and the operating cost would consume a substantial fraction of every year's product." Just attaining the interim "fishable and swimmable" goal set for 1983 (and missed) would have cost \$468 billion, not counting whatever might have been required to limit agricultural runoff, according to a 1975 estimate by Allen V. Kneese and Charles L. Schultze for the Brookings Institution.

The amount actually spent on the clean water program so far is lower than this, but far from negligible. Counting both public and pri-

## In Brief-

### Scenic Resources Redistributed.

Under an agreement between a California motel and state regulators, some travelers get to stay in the rugged Big Sur area at a cut rate. When the Tickle Pink Motor Inn wanted permission to build a six-room addition in 1980, the California Coastal Commission made it agree to offer one of its rooms as a "lower cost visitor facility," according to the *Wall Street Journal*. So the motel charges only \$30 for the bargain room and \$82 to \$96 for the others. The provision was supposed to help poverty-stricken vacationers, but in fact the motel asks no questions about visitors' financial well-being before it rents them the room.

**The Sincerest Flattery.** Since the U.S. phone system works well, many foreign observers wonder at the Reagan administration's moves to break it up so as to encourage competition in long-distance telephone markets. The government of Japan, however, does not seem to

be among the skeptics. It is reportedly planning to follow the American example—first by dismembering its equivalent of AT&T, and then by partially deregulating it. Perhaps more remarkable, the Japanese telephone company seems to welcome its own breakup.

A bill will probably be filed in the national parliament next year to carve up Nippon Telegraph and Telephone, à la AT&T, into one nationwide long-distance-and-research company and two or more independent regional companies providing local service. The government may sell shares in the local companies to private investors and even foreigners; it will hold onto the stock of the nationwide company for somewhat longer, but will give it more freedom from political oversight in hopes of making it more competitive.

Kanichiro Aritomi, first secretary of the Japanese embassy, says that his country's officials, like their American counterparts, want to free up competitive market forces and believe that continued monopoly is holding up the convergence of computers and telecommunications. The *Economist* adds that be-

cause "everybody—with the exception of the telecommunications workers' union—agrees that NTT's monopoly is the biggest obstacle in the way of the wiring of Japan," the dismemberment "is proving fairly painless."

**Slowing Down the Charge.** Many state governments have been considering moving toward user charges instead of taxes, as a way to pay for their services. But according to a recent article, federal policy may be discouraging them from doing so.

Proponents argue that user fees are efficient, because they discourage wasteful overuse of government services, and fair, because they shift the cost of services to those who use them. State budgeters, meanwhile, are eager to explore any plausible way to raise revenues. The public has been supportive, too: a survey last year by the Advisory Commission on Intergovernmental Relations found that more than half the respondents considered user fees the best way to finance expanded local services, far more than favored reliance on any form of taxation.

vate spending, it added up to \$162 billion between 1972 and 1981, according to Department of Commerce data. Around \$40 billion of this money has taken the form of federal grants to help cities build sewage treatment plants that, according to a 1981 *Washington Post* investigation ("Costly Monuments to Idealism Now Lie Rusting in the Mud"), often don't work.

The achievement of the zero-discharge goal would be quite inconsistent with the continued allocation of large portions of the gross national product to purposes other than water pollution control. Assuming that citizens go on spending the GNP on the usual things instead, the entire country will thus lapse in 1985 into a sort of chronic state of noncompliance with the congressional will, as it has already done with respect to the 1983 interim goal.

You might think that this recidivism, along with the massive ongoing cost of the program, would have made for a big controversy now that the Clean Water Act has come up for reauthor-

ization. But you would be wrong. Congress and the Reagan administration are apparently going to leave the zero-discharge clause intact, but simply ignore it. At the same time they are planning to postpone, but not substantially revise, various of the law's other requirements. (The sewer grants, incidentally, were safely reauthorized in 1981, so they are in no danger this year.)

The legislative proposals offered by the Reagan administration have not, as of this writing, been embodied in an actual bill before the legislature. In any case, they are not much different on matters of principle from the leading bills offered by environment-minded members of Congress. These include H.R. 3282, filed by Rep. James Howard (Democrat, New Jersey), and S. 431, filed by Senators John Chafee (Republican, Rhode Island) and Jennings Randolph (Democrat, West Virginia) as modified by the Senate Committee on Environment and Public Works. Both these bills and the adminis-

The federal government, however, provides at least two disincentives for any move toward fees, according to an article by Steven Gold of the National Conference of State Legislatures, writing in the conference's magazine. First, user fee revenue is not treated the same way as tax revenue in federal revenue sharing allocation formulas. "If a state adopted policies that encouraged its local governments to employ user charges more, their [revenue sharing] aid would decrease." How much? The amount varies because the aid formula is complex, "but for each dollar of tax reduction, revenue sharing falls between 3 cents and 20 cents."

Furthermore, user fees are not deductible on federal income tax returns the way most state taxes are. "This implies that shifting from reliance on general taxation to user charges will increase the federal tax bills of state residents."

Whether for these or other reasons, the popularity of user charges at the town and city level has not been matched at the state level. From 1978 to 1981, in the aftermath of Proposition 13 and the tax revolt, "user charges as defined by

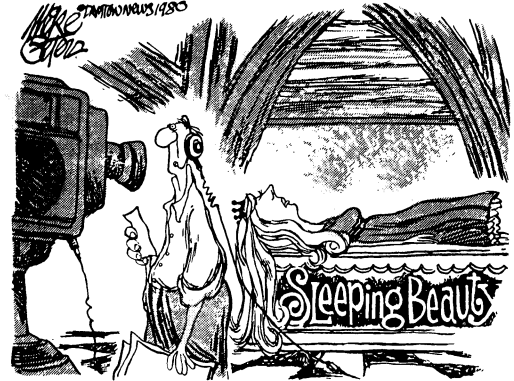
the Census Bureau rose from 12 cents to 12.5 cents per dollar of state tax revenue." Before 1978, according to the census figures, they had actually been falling compared with state taxes.

**Wipe That Smile off Your Face.** The *New York Times* best-seller list has lately been graced by volumes one and two of a work entitled "Truly Tasteless Jokes." To Representative Mario Biaggi (Democrat, New York) this is evidence that "the condoning of racial and ethnic jokes"—not just their commission, but their condoning—"has plunged to new depths," to quote the *Congressional Record*. So he has introduced H.R. 3105, a bill that would establish a complaint bureau in the Federal Communications Commission to "monitor such baseless attempts at ethnic humor." It would also authorize federal funds for educating the public on the issue.

Although his bill would reach only television and radio, not publishing

(which it turns out falls under the First Amendment), Biaggi says he believes "books such as these, which serve no positive role in building the moral fabric of our society," would become less popular as the government made it clear that they "are a dangerous influence on our young people." There is no word on what effect a campaign against humor would have on the *Congressional Record* itself.

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WE'VE DECIDED AGAINST SHOWING THIS ILL-FATED LOVE STORY OF A POOR PRINCESS, FOR FEAR OF CREATING A GRATUITOUS SLUR UPON WITCHES, THEIR VALUES AND TRADITIONS...

tration's proposal would delay the compliance deadlines by a few years, generally three. Mostly the differences between Congress and the administration center on whether and how to make the law tougher. Among the topics of controversy, or lack thereof:

- All the major bills would increase criminal sanctions for violating the act. Both the administration bill and S. 431 would increase criminal penalties to a maximum of \$50,000 per day of violations and two years in prison. (H.R. 3282 would not.) Knowingly submitting a false material statement to the Environmental Protection Agency would be made a felony under all three bills. It would also be made illegal to introduce into a sewer system, either negligently or knowingly, pollutants that could not be removed by city treatment plants or were otherwise hazardous. Since there is no lower limit on the quantities involved, this could be interpreted to prohibit flushing a cupful of potentially harmful pollutants down a toilet. Incidentally,

the 1981 *Post* series reported that hundreds of city officials were already breaking the law and potentially subject to imprisonment because their federally financed sewage plants didn't work.

- Some companies discharge their wastes into municipal sewage treatment plants rather than directly into lakes and streams. Currently these companies have to pretreat the wastes, following EPA's technology-based standards, even if the effluent would have met water quality standards anyway after emerging from the city sewage plant. The administration initially wanted to let cities apply on behalf of such companies to waive EPA's pretreatment standards in such cases; now it is hedging.

- Companies that heat up the water (thermal polluters) currently have to use the best available technology to avoid harming local marine life. The administration would allow companies to use less exacting technologies so long as the resulting population of marine

life remained "balanced"; currently it has to be "indigenous."

- The original act required towns to build treatment plants even when their sewage output was small and was discharged directly into the ocean (see David M. Shell, "Skagway v. EPA: Cassandra's Prophecy Revisited," *Regulation*, November/December 1980). Public outcry, along with a General Accounting Office study entitled *Billions Could Be Saved through Waivers for Coastal Wastewater Treatment Plants*, prompted Congress in December 1981 to reopen a period during which coastal towns could apply for waivers from the rule. Three of the current bills—H.R. 3282, S. 431, and S. 1536, filed by Sen. Christopher Dodd (Democrat, Connecticut)—would restrict the granting of these waivers. The administration would prefer to leave the current waiver system intact.

- Currently states must achieve lower effluent levels in some streams and lakes for which they have designated special uses such as commercial fishing. Last October EPA proposed changing its regulations so as to let states delist these designated uses in cases where they could prove that costs far outweighed benefits. Later, however, it reversed itself, and endorsed the basic approach of the current regulatory standard, under which states have to prove substantial and widespread economic harm, among other things, before they can delist a use. Senator Chafee has responded by dropping a clause in his bill that would have frozen previously published designated uses so states could not downgrade them, with narrowly limited exceptions. Instead, his bill would turn the current regulation (along with several other tough EPA standards) into statutory law. Supporters of the status quo say they fear that states could easily perform the cost-benefit comparisons needed to justify the downgrading. To the extent that designated uses are effectively frozen, water once kept pristine for oystering will have to be kept pristine forevermore, even if the last oystering company goes out of business.

- The administration is seeking a number of other changes, none important in principle. It would like to exempt munitions from the category of pollutants; the Supreme Court recently held that the Navy must get an EPA permit before carrying out target practice that would result in the discharge of ammunition into water. The administration proposal would

also remove a requirement that businesses begin complying with new source performance standards as soon as the standards are proposed; instead, they would have to begin complying only when the regulations become final. The bill would also let EPA delegate part of its permit-issuing power to a state, rather than all or none as at present, and would allow the agency to charge fees to polluters for processing their applications for waivers and exemptions. Finally, the administration bill would extend the maximum length of plant discharge permits from five years to ten, in order to ease the oversight burden on EPA and the states. In the absence of any systematic reforms, this last provision would presumably entrench the regulatory principles now embodied in permits, for better or worse; it might also encourage the regulators to scrutinize applications more closely.

The attentive reader will search this list in vain for any mention of cost-benefit analysis of technology-based standards, for "bubbles" or offset trading or emissions fees, or indeed for any of the market-oriented reforms economists have been suggesting over the years. The forthcoming debate on clean water reauthorization will apparently include little controversy over such reforms, because neither camp is willing to endorse or fight for them. The consensus shared by both EPA and its environmentalist critics seems to be that any such reforms can wait until 1988, or such earlier date as the deadlines next have to be postponed.

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## **U.S.-Canadian Railroads: Bordering on Frustration**

Can a continent-wide railroad system endure half-slave and half-free—or, to put it less dramatically, half-regulated and half-deregulated? That is what Canadian railroads have been asking themselves ever since their American counterparts began to win their freedom from the U.S. Congress and the Interstate Commerce Commission some years ago.

The Canadians' chief worry is probably antitrust. Their law allows railroads to set rates collectively, which U.S. antitrust law does not. Given the "extraterritoriality" that U.S. courts have found in the Sherman Act, Canadian railroads can be prosecuted for setting rates in



their own country in ways that affect U.S. imports or exports—even if the Canadians' physical control of the goods stops at the border.

Sherman Act prosecution is not an idle threat to Canadian Pacific and Canadian National, the two major Canadian railways. Freight bound for the United States makes up about a quarter of their traffic. Although they usually transfer goods at the border to U.S. carriers, they also operate sizable subsidiaries in this country: Canadian Pacific owns the Soo Line Railroad and Canadian National owns the Grand Trunk, along with smaller lines. These extensive properties provide easy targets for the Sherman Act's criminal penalties (up to \$1 million per count for companies, and \$100,000 plus three years in jail for executives) and for the treble damages that can be awarded to private complainants. Canadian shippers' groups are also open to Sherman Act assault, since they often negotiate collective rates. So, conceivably, is a U.S. railway that cooperates with a Canadian railway to set a combined rate on a U.S.-Canada shipment knowing that its partner has set its rate collectively.

So far the Canadian railways and shippers have managed to fend off the extraterritorial menace, with the help of a formal diplomatic note from their government. The ICC gave them temporary immunity from antitrust in 1981 when it agreed to treat all Canadian railways as "one integrated enterprise." (It also granted immunity to the Canadian shippers and U.S. rail carriers for their involvement in Canadian rate-fixing.) This was hardly unprecedented: in 1978 the U.S. Civil Aeronautics Board gave foreign air carriers immunity to set fares collectively through the International Air Transport Association.

The granting of temporary immunity, of course, has simply changed the fight to one over whether the grant should be made permanent. The Canadian railways have tried to be helpful, even going to the lengths of outlining a process by which they would keep U.S. railroads that operate in Canada (Conrail, Norfolk Southern, Chessie, and Burlington Northern) from using meetings of the Canadian Freight Association to covertly discuss rates they charged in the United States. The Justice Department has gotten into the act, too, objecting that the ICC could not legally confer antitrust exemptions for types of traffic that it had com-

pletely deregulated, such as containerized flat cars and shipments of fresh fruits and vegetables. In the meantime, the Canadian railways say they have been complying with U.S. antitrust law (except in the case of shipments that are covered by U.S. rate bureaus of which the Canadians are members, since these bureaus still have some residual antitrust immunity).

Inconsistency between U.S. and Canadian law is also causing problems in the area of confidential rebates and contracts between railroads and shippers. In the United States, both are legal: contracts are filed with the ICC but are available to the public only in summary form, so that the exact amounts of the rebates and the nature of concessionary terms are kept secret from competing railways and shippers. These rebates have become a major mode of competition between U.S. carriers. In Canada, however, both contract secrecy and confidential rebates among railroads are prohibited: all rates and terms of contracts must be published. So although the U.S. railways can sign contracts with shippers on cross-border traffic, the Canadian railways cannot join in the contracts or give rebates of their own.

This has several competitive implications. Prices for most Canada-U.S. traffic are quoted in terms of a "through rate"—a single combined rate for the whole trip which the two or more railways involved have agreed to split among themselves in some manner. Historically, such through rates have been more common (and lower) than "combination rates" in which each railway charges the shipper a separate rate for its link of the movement. The reason is that the participating lines can adjust through rates more easily to keep them (and their customers) competitive with alternate routes.

Canada requires railroads to publish the full amount they charge for through rates from the United States to Canada, but the U.S. railways have (according to the Canadian lines) been ignoring this requirement, on the grounds that they carry the goods only within U.S. boundaries and are thus not subject to Canadian jurisdiction. To make matters especially confusing, northbound and southbound traffic may be subject to different rules. Canadian law explicitly requires every participating line to file through rates on southbound traffic ("the several companies shall file") but does not

*(Continues on page 52)*

### Why Local Rates Are Rising (Continued from page 36)

subscribers to drop out? The evidence suggests that even substantial price increases would have a rather small effect. To begin with, econometric studies of the demand for network access have shown that doubling the price would reduce the number of subscribers by about 10 percent (Lester Taylor, *Telecommunications Demand: A Survey and Critique*, 1980). Second, the forthcoming rise in local rates will be accompanied by lower long-distance rates, probably intrastate as well as interstate. These lower rates will provide a double incentive for subscribers to stay in the system: both because they could expect to get more incoming calls and because they would place more long-distance calls themselves. Overall, then, the reduction in subscribers should be even lower than the previous studies would suggest.

To be sure, the states with especially high subscriber access costs will be hit harder than the average. But it turns out that these same states will get a disproportionate advantage from the lowering of long-distance rates. In 1981, for example, the residents of Nevada and Wyoming spent about 19 percent and 17 percent (respectively) of their phone time on interstate calls, compared with a nationwide Bell System average of 8 percent. Thus, the residents of Nevada and Wyoming should be more willing to continue telephone service than residents elsewhere since they will enjoy large benefits from lower interstate rates.

Of course, none of this provides much comfort to state regulators, state legislators, and members of Congress. They will have to listen to complaints about higher phone bills, even if not a single household drops out of the system. Those complaints will be especially persistent because, in contrast to the situation with electricity prices, the increases in phone rates will reflect not obvious increases in underlying costs, but only a change in how costs are covered.

#### Can Regulators Maintain Low Rates?

For better or worse, members of Congress, state regulators, and others are casting about for ways to relieve the pain of rising local rates. It is instructive to consider alternatives that

might do that while holding efficiency losses to a minimum.

*Taxing All Long-Distance Carriers.* There is, of course, the possibility of trying to preserve the current system with as few changes as possible. The obvious way to do this would be simply to enlarge the universal service fund in future years as particular states find it harder to subsidize residential access. But imposing substantial charges only on those long-distance carriers that connect their subscribers through local telephone lines would simply exacerbate the bypass problem that the FCC seeks to mitigate.

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**[The approach] embodied in the Packwood and Dingell-Wirth bills . . . would avoid the bypass threat. But it would discourage long-distance calling. . . . [while] penalizing the development of new and lower-cost technologies. . . .**

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So attention in Congress is turning in a different direction. Local rates could be kept down nationwide, or just in high-cost areas, by levying a charge on *all* long-distance carriers, whether or not they require access to the local telephone systems. This approach, which is embodied in the Packwood and the Dingell-Wirth bills, would avoid the bypass threat. But it would discourage long-distance calling to a greater degree than other alternatives. Moreover, such a clear-cut case of penalizing the development of new and lower-cost technologies raises major issues of national economic policy.

*Low-Cost Loans.* Another idea borrows from an old New Deal program. Today 95 percent of rural homes have telephones, compared with only 38 percent in 1950, thanks in large part to federal loans and loan guarantees made to rural telephone companies at low interest rates. Similar loans and loan guarantees could be used now to help reduce access rates in rural areas. However, any policy of subsidizing rural access per se is open to charges of inequity, one reason being that many rural people do not have particularly low incomes, especially in the West. Why—it would be asked—should working-class city dwellers pay taxes to bring telephones to

cattle ranches and oil fields? "Network externalities" are a poor justification, since middle-class ruralites will buy telephones whether they are subsidized or not.

Thus the question arises: why not subsidize just the poor?

*Telephone Stamps.* One straightforward way to reach the poor would be to establish "telephone stamps" as an add-on to the food stamp program. The recipient would cash in the stamps to cover some specified maximum dollar purchase of local telephone service. This approach would target many of those most likely to drop phone service as rates rise. It would also have the advantages of drawing on the food stamp administrative machinery already in place and putting the burden of subsidy on the general taxpayer, rather than on users of other telephone services priced above cost. Finally, the total outlay it would require (for any given level of subsidy) would be much lower than the one that would be needed to subsidize access across-the-board, since only about 8 percent of households are food stamp recipients.

Despite these advantages, this approach would be hard to sell. Economists are fond of saying that subsidies should be made explicit in order to subject them to public scrutiny. But politicians tend to prefer internal subsidy schemes whose costs do not appear as a line item in anyone's budget. Moreover, it is not clear why, if the food stamp program is to be expanded to include nonfood items, telephone service should be the top item on the list. A more compelling case might be made for fuel aid, or clothing, or shelter, or any other basic human need.

*"Lifeline" Pricing of Access.* "Lifeline" service, which is already used in some areas, employs a flat below-cost access fee, along with higher separate charges for local calls to meet the revenue shortfall. This approach has the attraction of not requiring explicit subsidies from taxpayers. On the other hand, it would be economically inefficient because some local calls would be priced above cost. And the higher the charges for local calls, the greater the incentive to bypass subscriber lines and compete with telephone companies for local service. Moreover, the task of metering local calls would be an additional burden to local exchanges that

do not now have metering equipment. Finally, unless some kind of means test is incorporated in the scheme, the subsidies are untargeted.

Despite these problems, lifeline service may prove to be a workable compromise. If it is targeted only to the poor (food stamp recipients, for example), the burden imposed on local calls might be small enough that uneconomic bypass would not be a serious problem.

BECAUSE THE ALTERNATIVES for keeping residential access rates low have serious drawbacks, it is likely these rates will rise toward the actual cost of service. This should stimulate more use of long-distance services and more cost-cutting efforts in local service—both of which should contribute to more efficient use of resources. Carefully targeted subsidies through a universal service fund—a political compromise—may suffice to keep rates within reasonable bounds in the highest-cost areas. Lifeline service with a means test might also help.

Moving beyond the current controversies, we should remember that our dilemma has been brought on by our good fortune. The new technologies responsible for the transformation of the industry are, overall, cutting the cost of transmitting information dramatically and stimulating a badly needed increase in the nation's productivity. Like the robot welders on GM's assembly lines, the new telecommunications technologies will benefit society as a whole. But not everyone will be better off—and that is why the problems arise. ■

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