Readings
of particular interest

Trade Secrets and Disclosure

"The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies" by Thomas O. McGarity and Sidney A. Shapiro, in *Harvard Law Review*, vol. 93 (March 1980), pp. 837-888.

The Food and Drug Administration and the Environmental Protection Agency require manufacturers of drugs, food additives, pesticides, and many other chemicals to submit health and safety studies as a basis for agency decisions on whether a product can be marketed. Because the studies play an important role in the agencies' risk/benefit decisions, they are of great interest to physicians, scientists, public interest groups, and the public in general. Nevertheless, public disclosure of the studies has constantly been opposed—primarily because it would facilitate the licensing of chemically identical products and thereby discourage new chemical innovation.

Thomas McGarity and Sidney Shapiro, professors of law at the University of Texas and the University of Kansas respectively, examine the arguments for and against allowing public access to these studies. They conclude that, in general, the manufacturers' incentive to develop and market new chemicals can be adequately protected short of nondisclosure of health and safety data.

The authors first assess the social benefits and costs of complete disclosure of health and safety testing information. As a benefit, disclosure can enhance agency effectiveness. If data submitted by manufacturers were subject to scrutiny by scientists other than those employed by the regulatory agencies, there would be a scientific "pluralism that is vital to the exercise of informed scientific judgment." Public disclosure would also allow consumers, through consumer-oriented publications, to become more aware of the potential risks of chemicals and to decide for themselves whether the very broad risk-benefit determinations made by the agencies for classes of consumers are personally appropriate. Disclosure would also eliminate the need for wasteful and, in the case of human tests, potentially dangerous duplicative testing. Finally, nondisclosure can "hamper innovation by preventing researchers from becoming fully apprised of scientific findings relevant to their work."

On the cost side of the balance, disclosing health and safety data to competitors can reduce research incentives. For chemical products that are not patented, the government's restrictions impose an entry barrier to competitors that may be the only way a company has for recouping its large investment in generating the studies. With disclosure, a competitor might simply use the data to secure approval for a chemically identical product here and in foreign countries without undertaking a similar capital expenditure. For chemical products that are patented, nondisclosure still can constitute an important form of market protection. Because the patents for most chemicals are filed some years before regulatory approval to market them is secured, the "effective" protection of a patent may often be less than seventeen years.

Weighing these pro and con arguments, the authors find that even if the choice were between the extremes of pure disclosure and pure nondisclosure, current economic information would compel disclosure. Patents and market imperfections provide significant market protection. Moreover, industry has not established that profit rates are so low that nondisclosure is essential to facilitate product innovation. It was argued that "[s]ince such information is uniquely within the control of industry and since the case for disclosure is substantial, the burden of establishing the need for secrecy belongs with the individual regulated industries."

But, as the authors noted, there are alternatives to a pure nondisclosure scheme that can adequately protect research incentives.

McGarity and Shapiro then examine the extent to which the FDA and EPA are currently at liberty to disclose health and safety testing information. Analyzing the recent Supreme Court decision of *Chrysler Corp.* v. *Brown* (1979), they conclude that studies submitted to EPA pursuant to the Toxic Substances Control Act and the amended Federal Insecticide, Fungicide, and Rodenticide Act are clearly disclosable under the Freedom of Information Act, because those statutes explicitly authorize such disclosure. Furthermore, those statutes will probably withstand constitutional attack as valid exercises of the commerce power.

Studies submitted pursuant to statutes that do not expressly provide for disclosure (the Food, Drug and Cosmetic Act, for instance) can be disclosed under the Freedom of Information Act only if they are not considered "proprietary" within the meaning of the Trade Secrets Act. Traditionally, agencies and the courts have employed the broad common law definition of trade secrets (embodied in the *Restatement of Torts*) to set the boundaries of proprietary information, including health and safety information testing results within its scope. The authors argue that the applicability of such a definition to the public law context is undermined by the very different considerations that led to a broad definition of "trade secrets" in the private law area. Instead, they propose a balancing approach to determine whether health and safety data are proprietary information to enable a direct comparison of the public's need to know the data versus the need to protect incentives for innovation.

The authors next examine specific regulatory policies embodied in existing statutes for protecting research incentives, including complete nondisclosure (the FDA's current approach to drug data), complete disclosure (the FDA's approach to antibiotics and food additives data), and compensated disclosure (EPA's approach to pesticides and toxic substances). For reasons already mentioned, they reject nondisclosure and uncompensated disclosure as too protective and not sufficiently protective of research incentives. Compensated disclosure is considered an attractive alternative because it would make the studies available to the public while forcing competitors to pay for making use of them. However, an administrative scheme for implementing compensated disclosure poses practical problems, including defining the scope of "health and safety studies," measuring the total compensation due a data producer, and apportioning compensation among several "me-too" data users. Therefore, existing compensated disclosure schemes are found to impose substantial transaction costs upon the parties and the agency involved.

McGarity and Shapiro conclude that Congress should provide that all testing data be made public and that research incentives be protected by giving data producers a "generically determined" lead time during which the relevant agencies will refuse to rely upon their information for purposes of approving a competitor's product. The length of the lead time could be determined by Congress, the relevant agencies, or some quasi-independent body such as the Office of Technology Assessment. Under the proposal, since competition would be reduced, the burden of proving the lead time that is necessary to adequately protect research incentives is assigned to the manufacturers, who are thought to be uniquely in possession of such information.

The authors consider this proposal to be the fairest and most practical solution to the "continuing paradox in the American free enterprise system"—the need for informing consumers and, at the same time, protecting research incentives.

OSHA Policy Revisited

Regulating Safety: An Economic and Political Analysis of Occupational Safety and Health Policy by John Mendeloff (Cambridge, Massachusetts and London, England: The MIT Press, 1979), 219 pp.

In this study, John Mendeloff of the University of California at San Diego assesses actual agency performance in reducing work-place injuries and examines current safety policy and its origins. He suggests two plans for improving OSHA performance: (1) the targeting of safety inspections in a way that relates them to actual injury rates and that motivates employer ac-

tion, and (2) the reform of standard-setting procedures.

The author's assessment of OSHA's safety impact, based primarily on California experience, suggested that the agency had caused a reduction in injury rates of a few percent. This finding is credible because, despite OSHA's small initial penalties, compliance will usually be rational for firms that have been cited. And, although only a small percentage of all firms are inspected, the ones that are employ large numbers of workers in hazardous industries. Any useful cost-benefit judgment on OSHA's safety program is precluded by the uncertainty that besets attempts to estimate the incremental costs attributable to OSHA.

Yet the evaluation revealed that the potential impact of OSHA's current approach is quite limited and indicated that other strategies could be both more effective and more efficient. There are several reasons why this is true. First, most of these injuries are not caused by violations of standards and even fewer injuries are caused by violations that inspectors can detect. Consequently, the potential impact of a standards-enforcement approach is limited compared with an approach that offers general incentives to prevent injuries. Second, good standards require an enormous amount of information about the real value of specific safeguards employed under a very wide and diverse range of industrial circumstances. In fact, Mendeloff notes, employers often are better equipped than a government agency to understand the relationship between risk and safeguards in the real context of the work place. Third, even when accidents are standards-related and the standards are worthwhile, compliance with the standards may not be the cheapest means of preventing injuries.

As Mendeloff points out, legislative and union leaders are obviously unhappy with the strict enforcement of trivial violations, but have been unwilling to support change in the policies that are responsible for them. Moreover, unions and OSHA are against giving inspectors increased discretionary authority.

A tax on injuries might be the simplest and most efficient alternative, but Mendeloff argues that the substitution of a tax for standards is politically unfeasible. Instead, the author recommends redesigning the enforcement of standards to simulate some of the attractive features of a tax.

One method for doing this is to rely much more heavily on accident investigations, especially at smaller work places, which are rarely inspected but relatively hazardous. Employers could be given information on which violations are known to cause serious injury and told that if serious injuries occur they will probably be investigated and, if the violation caused the accident, fined heavily. The information gained from these investigations would also improve OSHA's organizational intelligence. This strategy, however, still confines OSHA to those injuries caused by violations.

For larger work places, a more general incentive to prevent injuries can be provided by making the frequency of inspections depend upon how the firm's injury rates compared with the average rate in their industry. This policy of "targeting high injury rate establishments" (THIRE) can be designed to impose additional costs on employers for each injury. According to the author, it gives employers an incentive to prevent *all* types of injury, not just those that are related to standards, and to find the least costly methods for doing so.

THIRE would largely supplant the general inspection program, but complaint-and-accident inspections as well as follow-ups would be maintained. Unions would retain the right to request inspections and, accordingly, should not oppose the policy. And because THIRE would lighten the probability of inspection for many firms, employers should support it. The firms that would be adversely affected—that is, the bad performers within their industries—would have difficulty in mounting effective opposition. Indeed, a policy of relating inspections to injury rates would have great appeal, Mendeloff notes, because it focuses on the poorest performers—the few really "bad apples."

THIRE's use for small establishments is limited, the author admits, and the policy is susceptible to underreporting of injuries. Also, because injury data would be required for individual establishments (data not readily available in many states), administrative implementation might prove to be ponderous. Success would depend on the quality of state workers' compensation data systems and the willingness and ability of OSHA to use them.

Mendeloff's second reform proposal deals with OSHA standard-setting. In his view, OSHA does not utilize a balanced cost-benefit approach in writing standards. The agency's legislative mandate, the professional backgrounds of its top officials, and the institutional and political milieus in which it operates all draw attention away from costs, focusing it instead on anticipated benefits.

When formal cost-benefit analysis is considered, Mendeloff says, there is difficulty in finding an operational method for quantifying the value of job-risk reduction. For example, there is political and psychological aversion to putting a dollar value on a human life. What needs to be done, according to Mendeloff, is to encourage decision makers to acknowledge the trade-offs they are making in setting standards and give outsiders a way of intelligently appraising their decisions. This might have the advantage for OSHA of promoting consistency in standard-setting and enhancing the agency's reputation as a responsible regulator. But in order to overcome OSHA's reluctance to becoming more expert in estimating costs and effects, Mendeloff suggests White House enforcement of the executive order requiring cost-effectiveness statements. [Mendeloff's book was published in 1979. A variation of his THIRE proposal is incorporated in the pending OSHA reform bill, S.2153.]

Prescribing Antitrust for Doctors

"Antitrust Enforcement in the Medical Services Industry: What Does It All Mean?" by Clark C. Havighurst, in *Milbank Memorial Fund Quarterly: Health and Society*, vol. 58, no. 1 (Winter 1980), pp. 89-124.

Antitrust enforcement "makes a great deal more sense than is generally appreciated and has the potential to overhaul the entire medical and health services industry." Taking a pro-competitive view, Clark C. Havighurst, professor of law at Duke University, examines the role of antitrust enforcement in the financing and delivery of medical care.

In the current debate over how to control health-care costs, two distinct approaches have emerged. One group would regulate doctors' fees and hospital revenues, the other would encourage competition among various health plans and providers. A key component in this second, competitive strategy, according to Havighurst, is the use of antitrust laws to break up anticompetitive combinations in the medical services industry.

Havighurst first surveys the modest beginnings of antitrust efforts and then analyzes subsequent enforcement policies. Before *Goldfarb* v. *Virginia State Bar* (1975), in which the Supreme Court declared that the "learned professions" are not exempt from antitrust prosecution, antitrust enforcers neglected the health industry because the medical profession was assumed to be "special" and because the government lacked expertise about the industry and its competitive shortcomings. After *Goldfarb*, the Federal Trade Commission and the Department of Justice both initiated new enforcement efforts. But those early efforts "revealed some minor misconceptions" about the industry and how it functions, misconceptions that also prevailed among health economists and other experts.

First, the FTC and the Department of Justice overestimated the role that relatively unrestricted advertising could play in injecting competition into the industry. Havighurst maintains that, while agreements among health-care providers not to advertise do indeed violate antitrust principles, even the effective prohibition of those agreements may not contribute substantially to major structural reform. To be sure, advertising would benefit consumers and alternative health-care systems. But it would not contribute significantly to cost containment. Besides, peer pressure makes it unlikely that physicians will soon begin advertising, even in the absence of explicit agreements.

Second, in the author's opinion, the FTC overemphasized the importance of the American Medical Association's control of medical school accreditation. The commission challenged the AMA, believing it used this control to limit the supply of physicians and increase their income. Havighurst agrees that observations about the historical impact of AMA activities are probably accurate. He argues, however, that the major concern in this area is medical education itself, which emphasizes specialization, high-cost acute care, and fee-for-service

reimbursement rather than cost-effectiveness, efficiency, and primary and preventive care. It is the "sameness" of the medical education offered, more than the number of doctors being turned out, that restricts both the range of consumer choice and the growth of alternative delivery systems.

Havighurst perceives a more sophisticated focus in the recent efforts of the antitrust agencies. The new enforcement agenda includes strategies against doctors' boycotts of insurers, hospitals, and other doctors who participate in innovative plans such as health maintenance organizations (HMOs). For instance, the Department of Justice has been pursuing a case where a medical society and hospital were charged with anti-HMO activities, and the FTC has been active in a case against the Michigan State Medical Society which has vigorously attempted to discourage its members from providing services under an independent Blue Shield plan that has undertaken cost-containment measures. The FTC has also sought to enjoin collective negotiations between medical societies and third-party payers (insurance plans) to establish the conditions under which physicians will provide them services. Havighurst notes that third parties have dealt with these organizations for several reasons, "not the least of which is the fear of boycott or other unpleasantness should they refuse to do so." But even when negotiations are institutionalized and friendly, that does not change the fact that collective bargaining by competitors who are not entitled to form an exempt labor union is against the law and discourages initiatives by third parties to obtain providers' services on a competitively negotiated basis.

Havighurst recognizes that an enlightened antitrust policy cannot, by itself, overcome all the obstacles to competition contained in government programs and the health insurance industry. For example, while antitrusters are attempting to promote competition, government health planners often harm competition by preventing new providers from entering the market. Moreover, Medicare and Medicaid reimbursement methods do not encourage competition among alternative health plans but do generate sharp increases in health-care spending. Havighurst warns that the health insurance industry may not change appreciably, even if the present trade restraints are lifted, unless tax laws stop encouraging the purchase of insurance without adequate consideration of the costs and benefits of alternative plans. In spite of these limitations, Havighurst maintains that antitrust efforts can contribute significantly to more competition in the health-care industry.

The High Cost of Error

"Fuel Efficiency by Government Mandate: A Cost-Benefit Analysis" by Bruce Yandle in *Policy Analysis*, vol. 6, no. 3 (Summer 1980), pp. 291-304.

In 1977, the National Highway Traffic and Safety Administration of the Department of Transportation established industry-wide fuel economy standards for 1981–84 American cars. Bruce Yandle, professor of economics at Clemson University, using NHTSA's own 1977 background data, performs a cost-benefit analysis on the standards and then poses the question, "Were the regulations necessary?"

The author's analysis draws on documents produced by NHTSA when that agency established corporate average fuel economy standards for the 1981–84 domestic automobile fleet. Under Title V of the Motor Vehicle Information and Cost Saving Act, passed in December 1975, DOT was required to establish standards for 1981–84 to "obtain the maximum feasible average fuel economy level" that would also represent "steady progress toward meeting the average fuel economy standard for model year 1985." (As noted by the author, Congress had previously set standards for 1980 and 1985.)

Yandle suggests that "NHTSA's economists may have been in the position of those who tried to decipher the words of the Oracle of Delphi" when they set out to satisfy the congressional directive. Although benefits and costs were mentioned in the statute, NHTSA interpreted legislative history as precluding the use of cost-benefit analysis. As a result, industry impact was the main focus of NHTSA's economic analysis.

Using NHTSA's estimate of required capital costs, future demand for automobiles, and the agency's estimate of operating cost savings, the author calculates the associated social costs and benefits for six alternative standards considered by NHTSA, including the one adop-

ted. He finds that "the standard adopted is the only cost-beneficial rule, although barely so. Net benefits of $315.845 million are indicated" —which amount to ".000041 of the total expenditures on newly purchased domestic passenger cars and their attendant operating costs." Since these benefits are relatively small, Yandle questions the overall impact of the standard when administrative costs are taken into account.

Yandle raises other troublesome questions. For example, NHTSA's analysis (and Yandle's) is based on total capital costs of $3.3 billion. Later estimates of these costs by independent analysts indicated they would run $3.6 billion *for each mile per gallon gain in fuel efficiency.* (The standard called for 22 mpg in 1981 and 27 mpg in 1984, a cumulative improvement of 5 mpg.) Chrysler estimated its capital costs would be $430 million annually, 1978 through 1982, or a total of $2.1 billion. After the standard was imposed, DOT revised its capital cost estimate to $36 billion. Such increases, the author notes, "will swamp the net beneficial result" reported earlier.

Beyond this serious flaw, Yandle raises two other potential problems not addressed by NHTSA when formulating the final fuel efficiency standard. First, although the agency had acknowledged that smaller cars would predictably generate a larger number of accident victims, it assigned no cost to the pain and suffering or lost human life that might be induced by the standard. Second, if the estimate of 1981 automobile demand were too high by 170,000 cars a year (out of a total of 11 million), all the benefits indicated for the standard would be eliminated.

Who Caused the Wreck?

"The Wreck of the Auto Industry" by William C. Tucker, in *Harper's*, November 1980, pp. 45-60.

Ever since the gasoline lines of 1979, quarterly reports from the American auto industry have carried nothing but bad news—the companies seem to be vying with each other for the distinction of turning in the largest quarterly loss in history. According to William C. Tucker, a contributing editor of *Harper's*, the auto industry expects to lose about $3 billion this year—and, in the conventional view, the auto industry has brought this disaster upon itself. Tucker sketches the standard explanation for the wreck of the auto industry:

> Wedded to a 1950s technology and sure that it could go on selling the American people gas guzzlers despite a dozen oil embargoes or a hundred 'worlds of diminishing resources,' the auto companies went on churning out the same old monstrosities. . . . The motivation, of course, was obvious —profits. Detroit stubbornly refused to give up the Age of the Big Car because it made big profits on big cars and small profits on small cars.

The sole ray of light in this otherwise gloomy tale is provided by the U.S. government, which "had been *forcing* the industry since 1975 to build more fuel efficient cars"; without federal intervention, small foreign cars would have captured even more of the auto market by now than they already have. "The corollary to all this, of course, is that the auto industry is no longer really capable of making decisions for itself," and what is needed now is a "partnership between the industry and government. . . ."

Tucker says that the standard explanation is so different from what actually occurred in the recent five to ten years that "I am left with unhappy doubts about the nation's ability to understand its own experience." In the author's alternate account, constructed from daily auto industry reports in the *New York Times*, *Wall Street Journal*, *Time* and *Newsweek*, the roles of the major actors are reversed: Detroit—not Washington—had been struggling for a number of years prior to the oil shortages of 1979 to bring small, fuel-efficient cars to the public; Washington—not Detroit, had prolonged the age of the gas-guzzling behemoth, through the Energy Policy and Conservation Act of 1975—a statute that artificially held gasoline prices well below world levels, thereby preserving for the American people the illusion of a limitless supply of cheap gas.

The auto industry, according to Tucker, had experimented from time to time with small, utilitarian cars. Therefore, when auto executives sensed a cooling of America's love affair with the large auto in 1971, they quickly responded with four-cylinder subcompacts like the Vega and Pinto. Detroit's small cars sold well in the early 1970s, especially after devalua-

tion of the dollar made them competitive with the imports; the rush to small cars after the oil embargo and gasoline lines of 1973 seemed to confirm the wisdom of Detroit's decision to "think small." However, once Arab oil began flowing again and "people were assured that gas supplies would be available, the interest in small cars diminished."

At this point, Tucker suggests, wise political action could have sustained the trend toward small cars. In early 1975, President Ford proposed that "the hopelessly outdated price controls on oil be phased out over a short period" so that Americans would start paying the world price for oil. This would have stimulated domestic oil production and moved Americans toward the kind of car the Europeans and Japanese had been driving for decades. Detroit, faced with huge backlogs of subcompacts, was giving full support to the Ford administration's proposals.

Congress would not hear of higher oil prices, however, because 1975 was the year when Americans were being told that the 1973 gas shortage had nothing to do with the OPEC cartel, but was actually an oil-company hoax designed to push up profits. Congressional Democrats, "partly riding this rebellion and partly creating it," passed the Energy Policy and Conservation Act of 1975, intending not only to keep oil under price controls at least through 1979, but also to "punish" the oil companies by actually reducing the price of oil. The American public, assured that whatever might happen in Saudi Arabia or Indonesia, "an evangelic Congress would always wrestle the oil companies to the ground and give American consumers eternal access to cheap energy," plunged into an "orgy" of gasoline consumption. Suddenly small cars had become "very passé," and Detroit had to scramble to meet a resurgence in demand for large cars that lasted to the very moment of the cut-off of Iranian oil in 1979. According to Tucker, a true world market price for oil in 1976—decontrol then would have increased the price of gas by only ten cents at the most—would have eased America into greater energy efficiency, and would have nurtured the small car market for which Detroit had been attempting to prepare. Instead, Congress chose to prolong the Era of Cheap Gas, thereby sustaining the Era of the Big Car and confounding Detroit's market predictions.

The author suggests that it is unfair to blame Detroit for the failure to have on hand the small cars that suddenly were in demand again after the Iranian oil cut-off and gasoline lines of 1979. The widespread impression that only the American companies were not prepared when the rush to small cars began again is "entirely false." The foreign manufacturers were caught just as "short-handed." Furthermore, Tucker maintains, it is wrong to claim that Ford and GM have not done well in the U.S. market because they do not know how to make small cars. Both companies have been immensely successful abroad. The problem for Ford, General Motors, and Chrysler is that they have operated mainly in the United States, "where consumers and politicians have been able to conspire among themselves to preserve the illusion of cheap gas."

The "greatest irony" of the story of the auto industry's wreck, Tucker concludes, is that government sustained the case of cheap gas as "a gesture 'to help the poor.' " Now that middle-class America has abandoned its big cars for smaller, fuel-efficient models, the gas-guzzlers crowding used car lots will have to be purchased and fueled by—the poor.

Antibiotic Patents and Market Structure

"Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry" by Peter Temin, *Bell Journal of Economics*, vol. 10, no. 2 (Autumn 1979), pp. 429-446.

The effects of regulation on industrial concentration and market power are often hard to gauge. In this review of the postwar American drug industry, MIT economist Peter Temin examines the way firm structure has been affected by patent protection of new drugs, Food and Drug Administration (FDA) regulation, and rapid technological change. He concludes that the effect of government policy has been to increase vertical integration and hence firm size, but not necessarily to increase horizontal concentration or profitability.

The twenty-five-year span from 1947 to 1972 saw a transformation of the drug business. Before World War II, it was a rather static manufacturing industry, one which concen-

trated on producing known substances using fixed technology. With the mass production of penicillin in World War II and the introduction of sulfa drugs and antibiotics, the introduction and promotion of new drugs became the leading form of competition among drug firms. Research expenditures as a percentage of sales went from 4 percent to 8 percent during the 1950s, and advertising went from 10 percent to 15 percent.

A major spur to this research binge was the decision of the Patent Office that many of the new drugs were patentable. In granting a patent for streptomycin in 1948, the Patent Office ruled that even though the substance occurred in nature, the steps taken to isolate and purify it made it in effect a new invention.

While firms could patent the new drugs, they could not patent the basic research method used to discover them: the analysis of soil samples to isolate germ-killing organic materials. The result was that various firms introduced, in quick succession, a series of chemically related antibiotics such as Aureomycin and Terramycin. Since these were highly substitutable for each other and for streptomycin, much of the monopoly power conferred by the patents was vitiated: the price of Aureomycin and other antibiotics had fallen by two-thirds by the end of 1951. Still, Temin says, the new drugs remained highly profitable. In 1955, Lederle Laboratories was earning a return on capital of 35 percent on its antibiotics and only 3 percent on all other drugs.

Product differentiation among antibiotics, and the eventual limit to the number of antibiotics which could be discovered by the soil sampling method, were among the factors that helped keep profits high. Moreover, Temin says, demand for the new antibiotics may have been rather inelastic, owning not only to their lifesaving capabilities but to the recently introduced prescription system. Until the Federal Food, Drug and Cosmetic Act of 1938 was passed, anyone could buy any nonnarcotic drug without a prescription. Only doctors could prescribe the new antibiotics, though, and doctors were thought to be less sensitive to price because they did not pay for the drug themselves.

The monopoly power of the drug patents led to new industry structures. When several firms independently discovered tetracycline, for example, they pooled their rights to the drug in a number of licensing and marketing agreements, thus forestalling potentially hazardous patent challenges. When one firm held clear title to a patented drug, however, it typically refused to license it and instead integrated forward into production and marketing. An industry which in the mid-1940s consisted mostly of unintegrated firms was transformed, generally through internal growth by firms holding patents, into one in which most major firms were integrated.

Temin advances several possible reasons for the rise of vertical integration among producers of the new drugs. Under a licensing system, Temin says, "the profit-maximizing royalty could have been (above) 80 percent of sales." That is to say, most of the revenue from antibiotic sales represented returns to successful investment in research rather than other variable costs of production. Royalties of such a magnitude might have encouraged cheating by licensees. Moreover, Temin says, "the political pressure against them could have been devastating. . . . Finally, exclusive production was more compatible with the forms of advertising made possible by the FDA's 1938 regulation than licensed production, even at high rates. In particular, detail men could represent a single supplier more easily than a group of licensees."

Exclusive production and vertical integration did not increase horizontal concentration in the industry as a whole. Four-firm and eight-firm concentration ratios actually declined from 1947 to 1972, and the share of value added held by firms of over 2500 employees, after rising from 23 percent in 1947 to 33 percent in 1958, fell back to 27 percent by 1972. There was a pronounced shift, however, from small to medium-sized firms over this period.

Not surprisingly, Temin finds that profitability was very high throughout the postwar years, well above the average for all industries. Earlier analysts have found drug industry profits well above average even when returns on intangible assets are taken into account. What is perhaps more surprising is that Temin finds no evidence of an increase in profitability during the period; profits were just as high in 1948, before the lucrative patents. One possible explanation, says Temin, is that product differentiation in the older industry had served much the same function as patent ownership.