# "Civilized" Pharmaceutical Price Regulation: Can The U.S. Have It Too?

## Richard T. Rapp and Adam Lloyd

The U.S. pharmaceutical industry is currently buffeted by criticism of drug prices by President Clinton, antitrust suits by retail pharmacies attacking price differentials, and health reform legislation creating price review boards and other authorities to reduce drug costs. In the United Kingdom, by contrast, a pragmatic approach to drug prices has apparently led to control without chaos. A compromise agreement reached in August 1993 between the British government and the U.K. pharmaceutical industry under the Pharmaceutical Price Regulation Scheme (PPRS) set in place the following controls that will govern the purchase of medicines under the National Health Service (NHS) for the next five years:

- a government-imposed across-the-board 2.5 percent price cut and freeze for the next three years;
- profits limited to 17-21 percent of capital employed; and
- pricing freedom for new products.

Moreover, according to a recent U.S. General Accounting Office report, prices in the United States are higher than in Britain. American onlookers may wonder why the United States doesn't have a similar means of settling pharmaceutical pricing issues by regulation. If regulation by negotiation produces such harmonious compromises in the United Kingdom, isn't it an improvement over the frantic, hostile U.S. approach to pharmaceutical pricing, and thus worth importing?

To answer that question, one must first understand the operation of the PPRS in the United Kingdom, paying special attention to the incentives it creates for pharmaceutical industry investors, managers, and the government.

### How the PPRS Works

Although the PPRS is a voluntary scheme, all firms who sell to the NHS participate.

Despite its name, the PPRS does not rely on direct price restrictions. Rather, the scheme imposes an upper limit to the return on capital earned by individual firms. In addition, the

*Richard T. Rapp is president of National Economic Research Associates, Inc. Adam Lloyd is an economic analyst at NERA.*

PPRS restricts changes in the prices of products, deductions for research and development expenditure, and deductions for sales promotion expenditure. The specifics of the PPRS are periodically negotiated and agreed to by the Department of Health (DoH) and the Association of the British Pharmaceutical Industry (ABPI). The latest round of negotiations resulted in an agreement effective from October 1, 1993, through September 1998.

The stated purposes of the PPRS are to:

- secure the provision of safe and effective medicines for the NHS at reasonable prices;
- promote a strong and profitable pharmaceutical industry in the United Kingdom capable of such sustained R&D expenditures as should lead to the future availability of new and improved medicines; and
- encourage in the United Kingdom the efficient and competitive development and supply of medicines to pharmaceutical markets both home and abroad.

In principle, the PPRS regulates all firms supplying branded prescription medicines to the NHS. The PPRS, however, does not apply to sales of unbranded generic products, to sales of medicines over-the-counter, or to sales of medicines through private (non-NHS) prescriptions. Moreover, the PPRS does not directly affect products exported from the United Kingdom.

The PPRS isn't "regulation" per se—it is a framework for bargaining between a monopsony National Health Service and a competitive pharmaceutical industry. Though it includes profit regulation, with its well-known distortions, it has not debilitated the domestic industry.

One reason is that the United Kingdom represents only 3 percent of the world market for multinational pharmaceutical manufacturers, and even the U.K.-based firms make only a fraction (16 percent) of their worldwide sales inside their home market. However adverse the climate for funding research under the PPRS, the rate of pharmaceutical innovation is unlikely to be much affected.

Observers generally do not consider the PPRS in Britain an especially harsh regime for pharmaceutical pricing. One reason is that, considering the nearly absolute control the NHS has over national drugs purchasing, the PPRS's stated mandate to promote the industry may be a partial brake on monopsony exactions.

But even at its most benign, the PPRS distorts the incentives to invest, to market drugs, and to conduct research. Transplanted to the United States—the single largest pharmaceuticals market, representing 30 percent of world sales—PPRS-style regulation would pose unprecedented dangers. There is no economic justification for it.

### Profit Controls Under the PPRS

Under the PPRS, firms that have sales of medicines to the NHS worth more than 20 million pounds per year must submit Annual Financial Returns (AFRs) to the DoH. In 1993, approximately 35 companies were required to supply AFRs. These firms are responsible for around 80 percent of the sales, by value, of medicines regulated by the PPRS.

Each AFR shows the value of the firm's sales to the NHS and elsewhere, the costs incurred, such as R&D expenditures, manufacturing costs, general administrative costs and promotional expenditures, and the capital employed. Those returns must be reconcilable with firms' audited accounts. Firms that submit AFRs must also provide the DoH with forecast returns for each reporting year within the first three months of the year to which the forecast relates. AFRs must be submitted within six months of the end of the firm's accounting year.

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The smallest companies—those with sales to the NHS worth less than 1 million pounds a year—are not required to supply financial information, while firms with sales to the NHS worth between 1 million and 20 million pounds per year must supply only limited financial statistics based upon their audited accounts.

The DoH sets the range of allowable rates of return on capital earned by individual firms on sales of medicines to the NHS; currently, the range is 17 to 21 percent. The actual maximum

allowable return on capital for each firm is the result of private, independent negotiation between the firm and the DoH. In those negotiations, the DoH considers various individual firm characteristics, including "commitment" to the NHS, level of exports, manufacturing carried out in the United Kingdom, and R&D expenditure. Exceptions to this rule are companies, mainly the U.K. subsidiaries of overseas multinationals, which have very small U.K. capital bases relative to sales. These companies are allowed to earn profits as a percentage of sales revenue.

In practice, these determinations seem arbitrary—for example, it is unclear what exactly constitutes "commitment" to the NHS—and entirely subject to the discretion of the DoH. Nonetheless, a firm that maintains a strong U.K. research and manufacturing base, has a large volume of exports, and sells a number of significant products to the NHS could expect to be allowed a return on capital at the higher end of the 17-21 percent range.

**New products can be priced freely under the formal terms of the PPRS but, in reality, the profit ceiling can be used effectively to constrain new product prices. Firms with many new products arriving at the same time, for example, will have trouble earning an adequate return.**

Individual firm profit rates are allowed to deviate up to 25 percent in either direction from the negotiated target rate. This band is known as the "margin of tolerance." A firm will be allowed to increase prices if its profitability drops below 75 percent of its target rate. Profitability of more than 125 percent of the target rate exceeds the margin of tolerance and is judged to be unacceptable. Profitability above the target rate, but within the margin of tolerance, is generally allowable. If, however, the firm in question has been allowed to increase prices in that year, profitability above the target level, even within the margin of tolerance, is judged to be unacceptable.

If a firm's profits are judged unacceptable by either of the definitions, the DoH negotiates one or more of the following actions with the firm:

- price reductions in the following year to bring profits back down to an acceptable level; and/or
- delays in price increases; and/or
- repayment of the amount of profit that was considered by the DoH to be excessive.

The PPRS regulates return on capital, valued at historical cost levels. Incentives to invest, however, depend on the real returns to new capital. There are two reasons why historical costs will not be a good measure of the current cost of capital. First, changes in price inflation alter the real rate of return that corresponds to a given nominal rate of return. The nominal rate of return implicitly includes expected inflation, but unexpected inflation will alter the real rate of return. The U.K. inflation rate has been unstable over the last decade—varying between 2 and almost 10 percent during the period 1986-93—but the allowed rates of return on capital have remained unchanged. Second, relative price changes mean that historical costs can diverge markedly from replacement values.

Pharmaceutical investments, in particular R&D, are especially vulnerable to those changes. First, investments in new drugs take a long time to pay off, thus increasing the risk of being caught by surprise by inflation. Second, the cost of R&D has increased sharply over the 10-15 years since today's leading products were developed.

National Economic Research Associates in 1986 performed an economic analysis of the relationship between accounting rates of return and economic rates of return in the pharmaceutical industry in the United Kingdom. That analysis indicated that the best-estimate accounting rate of return needed for the typical pharmaceutical firm to earn its cost of capital was 32.6 percent—much higher than the target return on capital of 17-21 percent under the PPRS.

As mentioned previously, a firm is only allowed to increase the prices of its products if the DoH's forecast of its return on capital in any year is below 75 percent of its target rate. New products can be priced freely under the formal terms of the PPRS but, in reality, the profit ceiling can be used effectively to constrain new product prices. Firms with many new products arriving at the same time, for example, will have

trouble earning an adequate return. The PPRS does not (and could not) make provisions for carrying forward losses on individual projects to the dates of product launch when low returns in the projects' early years must be recovered by high returns. When several successful new drug projects bear fruit simultaneously, the PPRS profit ceiling will interfere with pricing and cost recovery after the new product introductions. Firms that are not innovators, however, have nothing to fear.

In addition, the PPRS restricts the amount of spending on promotion and R&D that it allows as deductions in calculating profits, and limits increases in manufacturing, general administrative, and other costs.

### Contradictory Mandates and Unbalanced Information

Because DoH officials have considerable discretion in negotiations with firms and the framework of the PPRS is extremely flexible, in principle each firm benefits by being able to agree to terms appropriate to its cost structure, product mix, and organization.

The DoH, however, represents the NHS, which buys the huge majority of prescription medicines sold in the U.K. pharmaceutical market. Therefore, its discretionary power carries with it the potential for abuse. In theory, the DoH has the flexibility to depress prices of pharmaceuticals to the point where they only cover the manufacturing cost and make no contribution to R&D and other costs. Any firm that was unhappy with this outcome could withdraw from the negotiations but only at the cost of losing nearly all its sales in the United Kingdom. The DoH, on the other hand, would lose only one of many potential suppliers.

The DoH is prevented from fully exercising this monopsony power by a number of features of the PPRS. First, the DoH is hampered in negotiations by its conflicting objectives and loyalties. The stated aims of the PPRS are contradictory: the DoH has to achieve both low prices ("affordable medicines for the NHS") *and* high prices (to support "a strong U.K. pharmaceutical industry"). The second objective not only prevents the DoH from using its monopsony power fully, but injects some uncertainty into the final outcome, since it is never clear how the DoH will weight the two objectives.

Second, the DoH lacks access to information from either independent sources or the pharmaceutical firms. The negotiations are treated as commercially confidential by both sides, and the operation of the PPRS is not open to public scrutiny, which hinders analysis by outsiders of its impact. Moreover, while the negotiators for the firms have a detailed knowledge of the firms' cost structure, sales patterns, capital structure, and behavior, the DoH's only source of information is the AFRs submitted by the pharmaceutical firms themselves and the firms' published accounts. Those AFRs are not detailed documents and omit a great deal of information that might affect the strength of a firm's negotiating position. The firms have no incentive to give the DoH information that might weaken their positions; instead, they are inclined to present only that information that tends to show them in a favorable light.

This lack of information restricts the DoH's options. Given imperfect information, there is a risk of accidentally undermining the firms' finances and removing their incentives to supply by imposing too low a price. Similarly, imperfect understanding of the research funding requirements of individual manufacturers may cause the government to undervalue the risk of curtailing R&D by imposing low prices and the R&D ceiling.

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Third, there is an imbalance in the resources available to the two sides. The DoH team that carries out these negotiations is small and can devote only a limited amount of time to each firm. The firms, however, are able to use whatever resources they feel necessary. This imbalance reduces the ability of the DoH to develop a view of costs independent of information provided by the firms.

The DoH, therefore, enjoys overwhelming monopsony power but is limited in its exercise

of this power by the conflicting objectives of the PPRS, the U.K. tradition of secret negotiations, the sparse financial reporting requirements, and lean staffing. None of these constraints, however, need apply if the system were transferred to another country. Absent such constraints, a government negotiating body could retain and employ its full monopsony power.

PPRS negotiations are carried out by the DoH Pharmaceutical Industry Branch, which has only 14 staff members, supported when necessary by specialists such as the DoH's accountants. The PPRS, therefore, appears to be cheap to administer.

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Limiting the focus of cost evaluation to the DoH, however, ignores the costs borne by the industry. Although these industry costs are not published, recent experience provides some indication of the effort required. For example, the 1993 PPRS agreement states that AFRs should be submitted within six months of the end of the firm's financial year, and that negotiations should be completed within six months of the deadline for submission. In reality, both deadlines are regularly exceeded, suggesting that the actual time spent producing and processing returns may be much greater than anticipated in the agreement. The negotiation of the 1993 agreement itself lasted 9-10 months and required substantial time and effort on the part of the industry and the ABPI.

### Incentives Under Profit Regulation

By controlling the allowed rate of return on capital, the PPRS leads firms to inefficient investment decisions, distorts capital market activity, forces arbitrary cost allocations, and encourages firms to cross-subsidize low-profit products with high-profit products.

In competitive markets, firms increase their profits by cutting costs and by investing in capital only when the expected increase in revenue exceeds the expected increase in costs. The PPRS, however, distorts firms' incentives to make such efficient decisions in two important ways. First, the PPRS may lead to overinvestment in plant and equipment. Under such rate-of-return regulation, firms have a general incentive to increase their capital base, provided only that the allowed rate of return exceeds their cost of capital. Second, rate-of-return regulation like the PPRS reduces the incentive for efficient operations, since firms that cut costs are not allowed to keep the savings, if their profits exceed the margins of tolerance. The end result may be wasteful R&D projects (although the effect is diminished in the United Kingdom by the need for each firm to compete in foreign markets).

Those distortions are well understood and lead to further intervention by the DoH as a corrective measure. Provisions in the PPRS to restrict allowances for manufacturing, administration, and other costs and to dictate R&D and sales promotion expenditure can be viewed as direct attempts to undo the damage to investment incentives created by the regulation of rates of return.

In addition to distorting decisions by each firm, rate-of-return regulation distorts the decisions of investors by confusing the signals given by capital markets. In competitive financial markets, investors choose to invest in different firms by examining their returns and the degree of risk. Firms that operate efficiently will attract capital by offering investors high returns on capital, and firms that are more risky will offer higher returns. Firms that perform poorly are unable to offer either high returns or low risk and are not attractive to investors. The return on capital, therefore, acts as a signal to investors, channeling capital towards its most productive uses.

Under rate-of-return regulation, however, assets no longer provide these signals. Firms cannot make themselves more attractive to investors by increasing their returns; similarly, returns do not reflect the risks of investing in a firm. As a result, the PPRS may support investment in less efficient pharmaceutical companies and prevent efficient pharmaceutical companies from growing. The scheme may also distort incentives to invest in the pharmaceutical industry, as opposed to other sectors, by masking the riskiness of the sector. The cumulative effect of

capital market distortions can wreck an industry.

Applying rate-of-return regulation to the pharmaceutical industry is further complicated by the difficulty of identifying the relevant asset base on which a return should be allowed. The incremental cost of producing an extra unit (ingredients, manufacturing, and packaging) is very low. Most of the costs of producing research-based medicines are fixed; R&D expenditure, manufacturing overheads, and some components of promotional expenditure do not depend on the number of units that are sold. Unregulated firms generally have no need to allocate such costs among projects, countries or customers. Indeed, allocations of this sort are more likely than not to lead to bad decisionmaking.

As a further complication, the ability of a government to control drug prices without fear of constricting the supply of new drugs depends on its ability to free ride on higher price regimes elsewhere. The small size of the U.K. pharmaceutical market (3 percent of the world market) and the remoteness in time of adverse consequences (fewer new drugs 10-20 years hence) lessen the apparent risk of regulatory harm under the PPRS. Therefore, decisions about the amount of fixed costs the U.K. market is willing to bear have only a marginal effect on the incentives of firms to carry out basic research. Even the U.K.-based companies do not depend on home market sales to fund research—they make 84 percent of their sales abroad. The PPRS, therefore, does not have a major impact on firms' incentives.

A similar scheme in the United States, however, would have a far more significant impact. Not only do U.S. pharmaceutical firms make a high percentage of their sales in the domestic market (about 64 percent), but the U.S. pharmaceutical market is the largest in the world (30 percent of worldwide sales).

### Other PPRS Measures

While the major effects of the PPRS relate to profit regulation, other aspects of the scheme affect incentives and tend to undermine the efficiency of the pharmaceutical industry.

Pharmaceutical companies are global firms and they typically carry out manufacturing and R&D in several countries. Firms are allowed higher returns on capital if they have a strong manufacturing or R&D presence in the United Kingdom. That advantage distorts the normal commercial process of siting facilities where costs are lowest and offers an incentive for firms to make decisions that do not minimize costs.

The restrictions on allowances for promotion expenses under the PPRS affect incentives in several ways. First, the formula is the same for all firms in the industry. The level of promotional expenses dictated by the formula is unlikely to be appropriate for all firms; arithmetically, the formula is weighted in favor of smaller firms. The spending levels may be both too low for firms launching New Chemical Entities (NCEs), thereby leading to a suboptimal rate of diffusion of new medicines, and in excess of what firms without innovations to promote would spend in an unregulated market. Second, the 1993 agreement deleted earlier provisions that allowed extra promotional spending in the first two years after the launch of an NCE. This change may further reduce the ability of firms to diffuse new medicines.

**Promotion quotas should be seen for what they are: cost control measures that restrict information about newer, more expensive medicines to the advantage of older, cheaper ones.**

It is worth emphasizing that the PPRS promotion caps are pure quotas which do not attempt to control or reform promotional abuses. The right way to do that is simply to ban practices that veer too far from the mere dissemination of information. Promotion quotas should be seen for what they are: cost control measures that restrict information about newer, more expensive medicines to the advantage of older, cheaper ones.

Risk-averse physicians will at the outset prefer older treatments which do no harm, to newer ones whose effects may benefit patients more, once adopted. The launch of a new drug may require heavy promotional spending in order to persuade doctors that clinical evidence indicates a favorable ratio of benefits to risk. A binding promotion quota that leaves just

enough money for a plodding manufacturer periodically to remind prescribing physicians about its old line of products, when applied to an innovator, will surely be insufficient to get the word out about a new product. Any saving comes at the expense of better treatment and pharmaceutical innovation.

Upper limits on R&D allowances are a surprising feature of a scheme that aims to encourage research and innovation. There are two reasons for their existence under the PPRS. First, as mentioned above, rate-of-return regulation reduces the incentives to control costs. Without R&D caps the possibility exists that manufacturers might overinvest in R&D without reducing allowed profits. Second, rates of return on capital are only weakly linked to the current costs of research. Pharmaceutical firms are not expected to finance R&D from historic returns on capital but instead must negotiate with the DoH over how much they will be allowed to charge against NHS profits.

**According to the available data, prices in the United Kingdom are fairly high by European standards: around 15 percent above the European Community average.**

Because the government is also the buyer of most branded medicines—meaning that it both negotiates and pays the R&D allowance—the allowed R&D deductions effectively constitute a direct payment by the government to support research. This has two effects on firms' incentives. First, firms have an incentive to behave specifically to affect the level of the R&D allowance. For example, firms may locate facilities in the United Kingdom that could be located elsewhere at lower cost. Second, firms have an incentive to overspend on U.K.-based R&D since expenditures up to the level of the allowance effectively cost the firm nothing. Firms without strong research agendas may not have enough potential projects to carry out productive R&D up to the limit. Under the PPRS, they may end up using part of the R&D allowance to carry out research that is essentially unproductive.

An implicit premise of the PPRS is that regulatory distortion of firm-level allocative decisions about R&D in the U.K. will have no adverse effect on the worldwide rate of pharmaceutical innovation. Indeed, the effect of these distortions on incentives in the U.K.-based pharmaceutical industry alone is small. The U.K. market accounts for only a small share of world sales of pharmaceuticals, and the industry does not rely on its home market to finance its R&D. The effects of applying this system to the United States, where domestic firms expect to make a large proportion of the return on their capital investment, might well be more substantial.

### Introductory Prices

Under the PPRS, firms are only allowed to increase prices when their profit margin falls below the margin of tolerance (75 percent of the firm's target rate of return on capital). Firms with strong product lines and effective marketing are likely to remain above this level of profitability and thus will not be allowed to increase the prices of their products. If an individual product price is initially set low, the firm cannot simply increase its price, even if the product is not covering costs. The resulting danger of setting the introductory price too low—and never being able to increase it—gives firms an incentive to introduce products at high prices. The following forces counteract this tendency:

- Competition. Firms *always* set the highest price they can; the main impediment is the availability of substitute products, including therapeutic substitutes and generics.
- The PPRS profit cap. DoH officials can go hard or soft on a firm concerning what goes into or out of the NHS "rate base," as well as other subjective choices that affect allowed profits.
- Measures outside the PPRS, including blacklisting.

The arbitrary nature of the real price path under the PPRS, which depends on general inflation rather than market conditions, also represents a considerable departure from the price path under competition. In a competitive market, one would instead expect the prices of individual medicines to gradually decline over time due to emerging competition, first from similar products and then, once patents expire, from generics.

### Outcomes of the PPRS

Two points are critical to the analysis of the U.K. pharmaceutical market. First, U.K.-based firms

derive most of their revenue from sales outside the United Kingdom. Therefore, the performance of the U.K.-based industry is only marginally dependent on conditions within its home market. Second, the observed outcomes in the U.K. market reflect the existence of both the PPRS and the NHS, which functions as a monopsony buyer.

Comparing pharmaceutical prices in different countries is difficult to do accurately. While several different indices have been derived, no measure has been accepted as the consensus index. Nonetheless, according to the available data, prices in the United Kingdom are fairly high by European standards: around 15 percent above the European Community average.

In spite of the high prices, the United Kingdom has one of the lowest per capita rates of expenditure on medicines in Europe. That implies either a low volume of consumption or that less expensive (and generally older) products constitute a relatively high share of the U.K. market. There is some direct evidence that NCEs diffuse more slowly in the United Kingdom than in other European countries. Whether this is due to the PPRS—particularly its restrictions on sales promotions—or to the NHS—with its monopsony power—or to conservative prescribing is unclear.

On the other hand, the total NHS drugs bill continues to increase—9.6 percent growth between 1991 and 1992, *after* correction for inflation—despite the PPRS. U.K. Health Minister Brian Mawhinney said recently that growth like this "cannot be sustained." As a result, demand-side measures have been tightened—reforms include the addition of new classes of drugs to the selected list and the 2.5 percent across-the-board price cut in 1993.

### The Pharmaceutical Industry as a Candidate for Regulation

The pharmaceutical industry bears little resemblance to other presently or formerly regulated industries in the United States. Nonetheless, industry critics sometimes argue that market failures interfere with the efficiency of the market for drugs. Therefore, the structure of the pharmaceutical industry and the nature of the competition therein are worthy of the same scrutiny that industrial economists give any industry when exploring the possibility of endemic competition problems.

The U.S. pharmaceutical industry, consisting of approximately 790 manufacturers, is structurally competitive. The industry is far from being dominated by a single firm or monopoly: the three largest pharmaceutical firms in 1990, ranked by share of world market sales, were Merck (4 percent), Bristol-Myers Squibb (3 percent) and Eli Lilly (3 percent). In most therapeutic categories, there are many sellers in the industry. To the best of our knowledge, profit regulation has never been applied to competitively structured industries in the United States.

Patents grant exclusivity, not market power. Occasionally, a patented "blockbuster" product appears that has no close substitutes. The rewards from being first to market a product with a major therapeutic gain create the incentive for researchers to develop improved products which will compete with established products. The history of the pharmaceutical industry is replete with examples of competitive entry; new firms and new products emerge regularly in various therapeutic categories. There were over 40 approved antihypertensive products in the United States by the end of 1989, for example, reflecting the dynamic competition characteristic of high-technology industries.

**The entire process from initial discovery of an NCE to FDA approval takes an average of approximately 12 years and costs an average of $259 million in 1990 dollars.**

Pharmaceutical firms face considerable risks in developing new medicines. In the United States, only five in 4,000 compounds screened in preclinical testing reach human testing. Only one of these five tested in humans is subsequently approved by the Food and Drug Administration (FDA). This process is lengthy as well as costly: the entire process from initial discovery of an NCE to FDA approval takes an average of approximately 12 years and costs an average of $259 million in 1990 dollars.

Manufacturing and distribution costs are only a small fraction of the total costs of bringing a drug to market. Instead, pharmaceutical manufacturers use the profits from sales of current products to fund the R&D of new products. In

fact, Grabowski and Vernon conclude on the basis of a recent survey of 100 new chemical entities introduced in the United States during the 1970s that a firm must have an occasional compound from the top deciles of the sales distribution if it is to cover the large fixed costs that are characteristic of the drug development process. Since manufacturers tend to depend upon a few blockbuster products to fund R&D for the next generation of products, regulation that forces the price of such products towards marginal costs in the United States will result in insufficient resources to maintain R&D funding levels, given the size of the U.S. market relative to the rest of the world.

F.M. Scherer has prepared an excellent summary of the lengthy and important debate on the implications of the high profits that have in the past characterized pharmaceutical company financial statements. Although the evidence clearly points to higher than average returns for the industry during the 1980s, several considerations militate against a finding of significant excess returns to pharmaceutical company investment.

**Transplanting the PPRS to the United States is hard to imagine because it is hard to imagine assigning one government agency the roles of price maximizing negotiator for pharmaceuticals and supporter of the domestic pharmaceutical industry.**

First, according to the latest research on this subject, the 1993 Office of Technology Assessment (OTA) study, the risk-adjusted return for a typical pharmaceutical investment project paid off more to its investors than was needed to recover the R&D investment by about $36 million, or 2-3 percent above returns earned on non-pharmaceutical businesses. Translated into prices, this figure equates to about 4.3 percent of the price of the typical drug over its product life. That rates of return on a risk-adjusted basis are 2 to 3 percent higher than returns earned on non-pharmaceutical investment is hardly a cause for concern, much less regulatory intervention. The U.S. Department of Justice-Federal Trade Commission Merger Guidelines use a 5 percent price impact as the minimum threshold for market power; the OTA result lies beneath this threshold.

Second, there is a fundamental problem with market power analysis in a technologically active industry with declining costs. In theory, static economic efficiency requires that price equal marginal cost. Once a new drug has been discovered, tested, and approved, economic efficiency dictates that it should be priced to exclude the already-sunk costs of these activities. If these costs are not recovered, however, there is no incentive to seek and find the next new drug: "What economists call 'dynamic' or `Schumpeterian' competition requires 'excess returns' to stimulate innovation."

Regulation along the lines of the British PPRS would pose serious problems if transplanted to the United States. The main problems are the incompatibility of secret negotiations as an approach to price regulation given the history of U.S. regulatory policy and, more important, the adverse effect that drug price regulation would have on the U.S. and worldwide pharmaceutical industries. When an adverse regulatory climate in a minor market like the United Kingdom—which leaves the global industry unscathed—is transplanted to a market representing 30 percent of world sales, the potential for real damage is high.

The secrecy and discrimination that characterize the PPRS negotiations are generally incompatible with the regulatory approach in the United States. There may be a precedent in the complex set of regulations, referred to as "profit policy," that governs federal negotiations with defense contractors in non-competitive procurements. Pricing is intended to be cost based, but in practice the departures from costs are extreme. In fact, the regulatory design takes on the aspect of a contest for a price, an unacceptable alternative to the imitation of competitive outcomes that typical public utility regulation intends. Given the fact that pharmaceutical markets are, with rare exceptions, quite competitive—with a sizable number of branded and generic competitors both within and among therapeutic substitutes—the analogy to sole source defense contracts is too remote to be considered seriously.

Apart from the secrecy that governs the negotiation of allowable profits in the United




Kingdom, there is the added problem of discrimination and the distortion of investment decisions. Because credit is given in the profit allowances for siting research and manufacturing facilities in the home country, the PPRS enables the government to bias firms' decision-making. Even if these aspects were left out of the formal arrangement of PPRS-style regulation in the United States, unless the scheme relied on formal, transparent, open-hearing regulatory proceedings—with all of their cumbersomeness and expense—regulation could lead to discrimination by the government among drug companies according to their willingness to accept distortions of the sort we observed in the United Kingdom. In essence, the choice is between the expense of a formal regulatory approach—such as we observe at the Interstate Commerce Commission, the Federal Energy Regulatory Commission, etc.—or the private, secret negotiations typical of the PPRS.

In the United Kingdom, the government's ambiguous and self-contradictory role as both the seeker of the lowest prices for NHS medicines and the supporter of the industry complicates and to some degree mitigates its unrestrained bargaining strength. Nonetheless, PPRS-style regulation implies that the government is both the regulator and the monopsony buyer in the relevant transaction. This differs markedly from U.S.-style regulation. Transplanting the PPRS to the United States is hard to imagine because it is hard to imagine assigning one government agency the roles of price-minimizing negotiator for pharmaceuticals and supporter of the domestic pharmaceutical industry. That self-contradiction leads to ad hoc haggling, not efficient regulation.

## Conclusions

There are two remaining questions to be considered before making a final judgment about the usefulness of PPRS-style regulation in the United States. First, does the PPRS do the job in the United Kingdom? While analysts are divided about whether the United Kingdom is a high-cost or low-cost pharmaceutical regime, it is notable that when the DoH wishes to crack down on the industry it does so outside the realm of PPRS with separate price controls—for example, the 2.5 percent price cut and subsequent three-year freeze that is part of the last round of negotiations. The DoH also uses a blacklist and other devices designed to keep the

drugs bill down by artificial means. The use of those measures suggests that the PPRS does not offer enough control to suit the government.

Second, is PPRS-style regulation needed in the United States? We think not. The pace with which managed care has spread in the United States in the past few of years, along with the reduction of the inflation rate for pharmaceuticals, are important indications that competition, particularly managed competition, is working to contain pharmaceutical prices in the U.S.

The recent decline in the share prices of major multinational pharmaceutical companies primarily reflects the belief of investors that the industry's pricing in the United States and other countries will be sharply constrained in the future. Profit regulation, one of the most intrusive forms of government controls, makes no sense in this setting. The competitive nature of the industry, combined with the increasing market power of buyers in the health insurance and provider marketplace, leave no room for PPRS-style regulation in the United States.

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