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THE POLITICS OF PRESCRIBING

Introduction

At present Britain is one of the seven most successful countries in the world in its record of pharmaceutical innovation.(1) The other six are the United States, West Germany, Switzerland, France, Italy and Japan. No other country has made anything approaching the same contribution to pharmaceutical progress as these seven nations. However, their continuing success could easily be thwarted if their governments were to follow the example of some other countries, such as Australia, Canada, Greece and Spain, which have pursued a 'cheap drug' policy at the expense of the prosperity of their local pharmaceutical industry. Pharmaceutical manufacturers in Britain and the other successful countries do not want special protection or encouragement. However, they do need proper recognition of the economic conditions which affect their survival. This paper sets out to describe the 'politics of prescribing' in this context. Its aim is to create a better understanding of the dangers of an overenthusiastic 'cheap drug' policy, and of the economic misconceptions which lie behind the arguments for such an ill-conceived approach.

Four basic premises

First, however, four basic premises need to be stated. None of these are now particularly controversial, and they are taken as given in this paper. They have been extensively substantiated in much of the literature on pharmaceutical innovation. (2,3,4,5).

First, it is now generally accepted that pharmaceutical treatments are particularly cost-effective forms of medical care. By contrast, surgery, radiotherapy and hospitalisation are vastly more expensive. Whereas pharmaceuticals represent about 10 per cent of health service costs, hospitals represent more than 60 per cent. In addition, although the risks associated with medicines receive much publicity, in reality their risk-benefit ratio is much more favourable than with surgery. Thus in general, where a pharmaceutical treatment can be developed for an illness, it represents a relatively cheap and a relatively safe solution to the problem. Pharmaceutical innovation is, therefore, highly desirable in both medical and economic terms.

Second, since the seminal work of the economist, David Schwartzman, it has been proved that the great majority of pharmaceutical developments come from the international research-based pharmaceutical manufacturers. (6) He showed that, between 1960 and 1969, 91 per cent of all new pharmaceutical chemical entities came from the industry. Of course academia is often responsible for the fundamental advances in knowledge on which these developments are based, but the development of the medicines themselves usually takes place within the international research-based pharmaceutical companies.

Third, the economic and scientific drive for this innovation stems from the free-enterprise competitive system. State bureaucracies have in general been remarkably unsuccessful in developing new medicines. Thus attempts to put the free-enterprise industry into a bureaucratic straight-jacket could be disastrous. This is not simply an arugment against nationalisation; it is an argument against all forms of excessive bureaucratic interference.

Finally, however, it is axiomatic that neither the public nor taxpayers (through the state health services) should pay higher prices than those which are necessary to provide a continuing incentive for optimum investment in pharmaceutical innovation. It is on the implications of this fourth and final axiom that the remainder of the discussion in this paper will focus.

Problems of profitability

The 'politics of prescribing' centres primarily on this economic issue, because there is a widespread suspicion that pharmaceutical manufacturers, and those who have invested in them, are deriving disproportionate benefits from their pharmaceutical achievements. That is, it is believed that pharmaceutical profits are excessive.

The suspicion that pharmaceutical manufacturers may be unduly profitable arises because of five factors relating to the pharmaceutical market.

First, pharmaceutical innovations are protected by effective patents in each of the seven successful countries.

Even though effective patent life is now only eight to ten years (because of the length of time it takes to develop and test a new medicine), the manufacturers nevertheless enjoy the exclusive rights to market their innovation during these years.[7]

Second, even when the patents have expired, the manufacturers still enjoy some degree of protection for the fruits of their industrial innovation through the brand name system. Although cheaper 'generic' competitors containing the same chemical may be available and can compete freely with the original innovations, many prescribers will still choose the original branded medicines for their patients.

Third, the market success of the original innovations will be reinforced by the use of sales promotion. This encourages prescribers to choose the original brand.

In fact each of these three factors in the pharmaceutical market have been accepted as necessary for all 'specialty' and 'innovative' goods since the writing of the two economists Chamberlin[8] and Robinson[9] in the 1930s, and, more particularly, the work of Schumpeter[10] in the 1940s. Although economists differ in their interpretation of the desirability of these forms of 'protection' for innovation, almost all of them recognise that innovative progress would be impossible in the conditions of classical price competition alone. Patents, brand names and sales promotion are essential concomitants of successful innovation.

The fourth reason for suspicions of excessive rewards for pharmaceutical innovation is, ironically, the high cost of innovation itself. It is now estimated that a successful new medicine costs on average between £50 million and £90 million to develop.[7] The Chairman of ICI's pharmaceutical division recently estimated that it could cost as much as £1.5 billion for a new company to enter the pharmaceutical market in the 1980s.[11] This creates a formidable 'barrier to entry', and economists have always been suspicious that if the barriers to entry are too high those already inside the barrier may be unduly prosperous.

Fifthly, since the Kefauver hearings in the United States in 1962 it has been argued that pharmaceutical companies can charge abnormally high prices because the doctor who chooses the medicine does not himself have to pay for it.[12] It has also been argued that in the European countries where even the patient rarely pays the full price for the medicine, the normal market discipline of price competition is further weakened. In fact, however, Reekie has shown that both in the United States and in Europe, effective price competition exists in the prescription market.[13,14,4] The fact that a third party is paying for the medicine does not prevent the prescriber from taking its price into consideration when he decides whether or not to prescribe it. This is particularly true in Britain where the National Health Service authorities have subjected doctors to considerable pressure to prescribe economically.

Nevertheless, although each of these five causes of suspicion can be answered in economic terms, they have been manipulated by politicians of both the left and the right to suggest that pharmaceutical expenditures have been too high. As a result, the 'conventional wisdom' – or 'the word from the herd' – is that the free-market conditions, which are essential for successful pharmaceutical innovation, have in the event resulted in 'unnecessary' profits. In particular, they have allowed pharmaceutical manufacturers to indulge in 'wasteful' commercial activities, especially in relation to sales promotion. This, in turn, it is alleged, has created an unnecessary and undesirable demand for medicines.

'Need' or 'Demand'?

This raises two separate issues. First, are profits in fact too high, bearing in mind the economic risks associated with pharmaceutical innovation? Second, are companies also able to spend too much in order to stimulate too widespread a use of medicines, thus in turn inflating profits even further?

Taking the second issue first, it raises the conflict between the concepts of 'need' and 'demand' in medical care. In classical economics, 'need' is meaningless. Does anyone, for example, 'need' a second pair of shoes if they already have a serviceable pair? Does anyone 'need' a television set? Even more, does anyone 'need' a Dior dress? Implicit in the negative answer to all these questions is the principle that people in general buy what they want rather than what they need. But again, 'the word from the herd' is that 'health is different'. Doctors and health service administrators are expected to ignore what doctors and patients 'demand' and instead to permit them to have only what they 'need'.

The whole literature of so-called 'welfare economics' is concerned with this paradox, not only in health but in education and social security as well. Can 'demand' meaningfully be replaced by the concept of 'need'? In relation to pharmaceutical innovation, however, a particular problem is that the economists' and the politicians' concept of 'need' tends to be a static one. It does not usually take into account the potential improvement which should be encouraged in existing therapy, and it cannot always take into account the potential therapeutic breakthroughs which may occur in the future. It is genuinely extremely difficult to relate the profits earned from allegedly 'unnecessary' current consumption to the provision of the finance needed for future innovations. This is the central economic issue in the 'brand name versus generic' debate – apart, of course, from questions of quality, consistency of treatment and patient acceptance.

The question which neither economists, nor administrators nor doctors nor manufacturers themselves can answer at present is the extent to which current levels of consumption of medicines, and particularly of more expensive medicines, affect innovation for effective treatments of cancer, heart disease, Parkinson's disease, multiple sclerosis and senile dementia in the future.

These issues, which arise in the context of attempts to restrict natural 'demand' to meeting proven 'needs', are echoed – a fortiori – when it comes to the question of 'acceptable' levels of profit. So far, the pharmaceutical manufacturers have had difficulty in demonstrating unequivocally that higher levels of pharmaceutical profits necessarily lead to quicker solutions to the outstanding medical problems. The problem is that the timescale over which such a plausible hypothesis can be verified runs into decades rather than years. For example, the relatively high prices permitted for medicines in Japan in the early 1980s may not lead directly to the marketing of major successful Japanese innovations until the end of this century.

The present economic climate

Three things are certain. First a relatively favourable economic climate in the seven pharmaceutically successful countries has in the past been associated with a remarkable record of successful pharmaceutical innovation. Other countries which have hampered their industries by excessive regulations and controls, on the other hand, have had a negligible record of success. Second, those countries which have provided a favourable economic environment for their pharmaceutical manufacturers have also benefitted in national economic terms.[1] Britain, France, West Germany, Switzerland and the United States all have very large positive balances of trade in pharmaceuticals. Italy, which has only recently had strong patent protection, has not yet gained a major share of world markets. Nor has Japan, whose pharmaceutical research investment has only started recently. But these two countries are likely to join the major exporters as their industries gain strength.

Third, however, even the major European, American and Japanese governments are no longer at present willing to permit unfettered demand for prescription medicines together with unregulated market prices. They simply do not accept the hypothesis that greater pharmaceutical profits are justified because they will automatically bring quicker solutions to the outstanding medical problems and consequent overall economic gains. The authorities in each of the seven countries have taken steps either to restrict

pharmaceutical demand or to control pharmaceutical prices, or both. This is the practical aspect of the 'politics of prescribing' in the mid 1980s.

Governments or the health services have adopted two broad approaches in holding down pharmaceutical expenditures. The first has been to increase the effects of competition, by reducing the degree of economic protection afforded to pharmaceutical innovation. The second has been directly to regulate the market by controlling or limiting expenditure.

An obvious example of increasing the forces of competition has been to encourage generic prescribing or even to allow generic substitution. Either of these approaches cuts down the degree of protection afforded by pharmaceutical brand names. The extreme situation of allowing pharmacists to dispense a generic preparation even if a specific brand has been prescribed exists in North America, and has just been introduced in South Africa. In each of these cases, however, the patient normally pays for the medicine himself, and can, therefore, still choose at the point of sale whether to have what the doctor ordered or a cheap substitute. Normally, in the United States at least, the patient chooses the original brand at the higher price. They do not want a cheap substitute.

A very different situation would have arisen in Britain if the Greenfield Committee's recommendation for generic substitution[15] had been accepted. Under the British NHS the pharmacist would only have been reimbursed for the cheapest available generic, and hence the degree of patient choice which still exists in America (except under Medicare and Medicaid) would not have existed in Britain. Furthermore, if the British government had adopted generic substitution many other European countries might have followed their example. The economic effects – altogether apart from the effects on the patient – would have been disastrous. Instead Britain has merely remained in a position where generic prescribing is strongly encouraged, but substitution is not permitted.

Direct regulatory control of the pharmaceutical market is typified by the Pharmaceutical Price Regulation Scheme in Britain. This sets maximum profit levels which are permitted on sales to the NHS, with a certain degree of flexibility to take account of exceptional innovative performance, or extra profits earned on the home market as a result of export achievements. In 1983, the government announced that it was reducing the industry's overall level of profit on sales to the NHS from 25 per cent return on capital to 21 per cent.

More recently, the British government has announced that it intends to follow the example of other European health schemes in limiting the list of medicines which it will permit to be prescribed under the Health Service. The German health insurance schemes introduced similar restrictions about one year ago, but they confined the prohibited list of medicines to a few simple 'household remedies', such as analgesics and laxatives which could be purchased privately by patients. This has resulted in much smaller savings than were expected for the West German insurance schemes; but presumably there has been a corresponding increase in self-medication. Other countries also have restricted lists, although they do not always seem to have resulted in lower expenditures.[16]

The British proposals announced in November 1984 (and still being discussed) went further than the Germans, and also proposed excluding the minor tranquillisers, with the exception of three named generic preparations. The effect on some individual companies would be cataclysmic; one firm would lose 70 per cent of its NHS business overnight. One of the principal problems for the health services as a whole is that many of the medicines excluded in the preliminary British list are prescribed mainly for the elderly. It is to be hoped that the discussion at present taking place will at least protect the interests of this group of patients, by ensuring that effective and necessary medicines can still be prescribed for them under the NHS. They should also take account of the effects on research investment in Britain.

Striking a balance

This raises the much broader economic principles behind the current moves in European countries, including Britain, to restrict pharmaceutical costs. An important political and economic consideration is that measures either to increase competition or to control the market must have regard to the economic viability of the pharmaceutical industry. There is a very real danger that the governments of the so-far successful innovators could follow the example of the Australians and Canadians, for instance, and cripple the innovative performance of their pharmaceutical manufacturers. This would slow down the discovery of new cures, and would reduce the direct economic contribution which the industry makes in a country such as Britain, with over £1000 million pharmaceutical exports a year.

It should be clear from the discussion so far that the question is one of balance. The present British government, and its Prime Minister in particular, believes that the professions and 'protected' industries, such as pharmaceuticals have been too generously sheltered from the normal forces of competition. As far as pharmaceuticals are concerned, the government's attack on this 'protection' has concentrated on brand names and prices. And the present Conservative scepticism is reinforced by the hostility towards the pharmaceutical industry in the other political parties.

Interestingly, the Social Democrats have advanced their own rather different solution to the supposedly 'unsatisfactory' situation at present. Dr David Owen has advocated that the period of pharmaceutical patent protection should be lengthened in order to make up for the time lost during the testing of a new medicine. As a trade–off he proposes that brand name protection should be weakened.[17] This is, in fact, exactly what has happened with recent legislation in the United States, where a new Act gave up to five years extra patent life, in return for making generic competition a little quicker and easier once the patent had expired.

But in general the dilemma remains. Where does the balance lie between the successful stimulation of pharmaceutical research – with all its medical and economic benefits – and the risk of 'featherbedding' pharmaceutical employees and shareholders?

At least the issues are becoming a little clearer in the 1980s, than they were twenty years ago, when the US Kefauver hearings could give publicity to '1000 per cent profits'. However, the overwhelming necessity remains for better economic studies over long periods in order to establish exactly where the public interest lies. In the meantime, governments in the seven successful innovating countries would do well to hold back on excessive measures to reduce pharmaceutical consumption, and prices and profits. Such measures – aimed at short-term reductions in health service expenditures – could prove very costly in the long–term both in medical and in economic terms.

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