Economic Aspects of the Development of New Medicines

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When your Senior Tutor did me the honour of inviting me to give this lecture, he asked if I would speak on the economics of developing new drugs, particularly in relation to whether this should be a national or private enterprise. If I had been naive, I suppose I should have interpreted that as a tactful way of posing the old chestnut "should the drug industry be nationalised?". It would, however, be an insult to your intelligence if I were simply to rehearse the arguments about why a private enterprise competitive pharmaceutical industry on the whole serves society better than a state owned industry. I shall mention this only in passing. Instead I have chosen to address myself to a more positive issue. This is the extraordinarily fruitful way in which the relationship between the privately owned pharmaceutical companies and the government and universities has evolved in Britain and a few other countries. This evolution has resulted in a partnership which has been remarkably effective in developing, assessing and introducing new methods of preventing and treating disease. My principal theme will be that each party in this tripartite relationship has made its own distinctive contribution to the success of pharmaceutical innovation. On the one hand there has been the spirit of enterprise in the pharmaceutical industry, characterised by competition, innovation, flexibility and a willingness to invest huge sums in risky projects. On the other hand, this has been backed by the academic expertise of the universities and at the same time has been set opposite the combined effects of the government regulatory controls and of the influence on prices from the Health Service. The balance of power between these interacting forces has in the main operated very much in the public interest. However the privately financed pharmaceutical industry, for its part, has had to be constantly vigilant that the forces opposing it do not stifle its creativity. But more of that subject later.

The form of this lecture in developing this theme will be as follows. I will look first at the history of the industry, and then at its present structure. Next I will examine the sources of pharmaceutical innovation, and the costs and methods employed in pharmaceutical research. This will lead on to a discussion of the economic concomitants of innovation—patents, brand names and information for the prescriber. Next I will look at the pattern and role of competition and at prices and profits in the industry. I will then come back specifically to the effects of the countervailing forces outside the industry on the success of its innovation. Finally, I will look to the future, so as to examine the prospects for pharmaceutical innovation over the next twenty years. This is a rich and varied menu, and inevitably it will allow some of the subjects to be covered only sketchily. Even more seriously, however, certain topics are excluded altogether. Notably, I am not touching upon the role of the industry in the Third World. This is an important and controversial topic, but it would need to be the subject of another lecture. I have also taken it for granted that society has enormously benefitted from pharmaceutical innovation, although even this concept is sometimes challenged by critics such as McKeown (1976); but again it would require another lecture to answer such criticisms. Finally, I have omitted the important role of medicines in animal health.

Starting first with the history of the industry, it is important to realise how young it is. Until the 1940s, materia medica consisted almost entirely of naturally occurring substances such as aloes, digitalis, ipecacuanha, nux vomica, opium and thyroid. In those days, there were only a very few synthetic pharmaceutical substances, such as aspirin. It was not until the 1950s that specific pharmaceutical chemicals started to be developed and synthesised in large quantities. Hence the modern research-based pharmaceutical industry as we know it today is less than 40 years old. Nevertheless by the 1940s it had

already experienced a long gestation period. The fundamental scientific discoveries from which the industry eventually emerged date back to Pasteur's germ theory of the 1860s and to Ehrlich's dream in the 1890s that it should be possible to develop a "magic bullet" to attack the invading germs without harming their human host. Other equally important preliminary developments are characterised by the work of Barger and Dale in the Wellcome Research Laboratories in the first decade of this century. These scientists discovered the chemical basis for the transmission of signals in the autonomic nervous system. It was developments such as this which paved the way for the broadly based biochemical approach to human pathology of the 1950s.

However it was not until 1935 that Ehrlich's dream of the "magic bullet" became a practical reality. This occurred with the development of the anti-bacterial Prontosil by Domagk in the German Bayer laboratories. This was shortly followed by the production by May and Baker of their compound M and B 693. It was the use of this sulphonamide in an attack of pneumonia which later prompted Churchill to write "This admirable M and B, from which I did not suffer any inconvenience, was used at the earliest moment, and after a week's fever, the intruders were repulsed".

With the outbreak of the Second World War, the Oxford scientists Florey and Chain next started a massive programme of successful co-operation with the emerging American pharmaceutical firms in order to turn Fleming's earlier discovery of penicillin into another practical therapeutic reality. This led on to the search for other antibiotics such as the tetracyclines, from the American firms Cyanamid and Pfizer, and to Beecham's eventual development of a range of synthetic penicillins. By the late 1940s and early 1950s the new pharmaceutical industry was becoming well established, and with it all the commercial practices which led to so much economic misunderstanding in the next two decades.

However, before discussing the economics of the industry, it is important to understand its structure and its approach to pharmaceutical research. Predominantly, the industry is an international one. This has to be the case, both because medicine itself knows no frontiers, and more mundanely because the cost of pharmaceutical innovation is such that a company must have worldwide sales to recover its R and D investment. Broadly speaking, the industry consists of about a hundred large and medium sized firms and a huge "tail" of smaller laboratories, none of which has worldwide sales and few of which are likely to survive into the next century. The substantial number of major firms in the industry indicates that in pharmaceuticals—unlike for example the oil or aircraft industries—there is no great concentration of economic power in any one enterprise. A recent OECD Report (1981) indicated that the largest international company (Hoechst) had only 3.9 per cent of the world market. The top ten companies shared only 28 per cent. There is, of course, much greater concentration within a particular therapeutic group, but the larger companies—over a period of time—are competing effectively across the whole therapeutic spectrum, so that in many ways it is most relevant to assess the concentration of the industry by regarding its activities as a whole.

Nevertheless, even if there is a very low degree of concentration between firms, there is an increasing geographical concentration in the industry. Countries such as Austria, Belgium, Holland and Sweden, which have made a significant contribution in the past, are gradually finding it more difficult to compete in the international scene. Now only five countries are left in the big league of pharmaceutical innovators. These are Britain, Germany, Japan, Switzerland and the United States. With the exception of Japan, which is a much more recent entrant into the field of pharmaceutical innovation, these are also the countries with the largest positive balance of trade in pharmaceuticals. In 1980, Britain exported £756 million worth of pharmaceuticals, and had a positive balance of trade of over £500 million.

The reason for this geographical concentration of pharmaceutical innovation probably stems from the nature of the industry. Essentially it is based on the production of new knowledge rather than mere chemicals. It produces treatments rather than tablets. The chemical substances themselves have little intrinsic value and are cheap to produce. What is more important and more expensive is their evaluation and development into modern medicines. Hence a country such as France, which has also been important in the past and which still has a strong positive balance of trade is likely to find it increasingly hard to compete in the future because it has had generally poor standards of academic pharmacology. British clinical pharmacologists describe the French method of assessing new medicines as "the French Impressionist" method. The Anglo-Saxon emphasis on the importance of the controlled clinical trial for the evaluation of a new medicine is too often replaced in France by a mere clinical impression of a new compound's safety and effectiveness. The probability of a decline in the French pharmaceutical industry, based partly on an underlying weakness in the academic pharmacology in the country, is likely to be accentuated by Mitterand's decision to take its principal producers into public ownership. The experience of the nationalised pharmaceutical industries in Eastern Europe suggests that without the competitive drive of private enterprise pharmaceutical innovation stagnates. In addition, the French government regulatory agencies have based their approval of new medicines on the prevailing scientific precepts amongst their academic pharmacologists. It has been left in the main to Britain and the United States to develop regulatory machinery based on sound pharmacological principles.

Thus clinical pharmacology and the evaluation of new medicines are the first areas in which there has, on the whole, been fruitful co-operation between academia, the Regulatory Agencies and the free-enterprise competitive industry in the principal centres of pharmaceutical innovation. Between them, they have set high standards for the assessment of the safety and efficacy of new medicines. These high standards are increasingly recognised and demanded in the other international pharmaceutical markets. In the five major countries likely to contribute substantially in the future to pharmaceutical innovation, academia, government and industry have combined to generate a creative and soundly based scientific climate for pharmaceutical innovation. Academic pharmacologists have spoken out against excessive government regulation and have been listened to.

This leads on to the process of the discovery of new medicines. The first central point to make is that it has been the industry, rather than governments or academia, which has been responsible for the actual development of new medicines over the past 30 years. In a recent study the American economist Schwartzman (1976) calculated that 88 per cent of the new pharmaceutical chemical entities introduced between 1950 and 1969 came from the industry. The essential underlying role of the universities is to develop new fundamental knowledge leading to an understanding of disease processes, and of the biochemical and molecular behaviour of the healthy and diseased body. They generally have to leave it to industry to do the tedious development work on the new medicines themselves, because this involves the investment of huge sums of risk capital. Such funds cannot be raised or invested by the universities. This element of risk once again underlines the probable reason for the failure of nationalised enterprises in other countries to contribute to the stock of new pharmaceuticals over the past three decades.

These industrial developments come mainly from the four well established innovators out of the five countries already listed. A NEDO study (1973) indicated that between 1958 and 1970, the United States had been responsible for 204 new compounds, Switzerland for 54, the UK for 51 and Germany for 35. The traditional role of France

as a centre of pharmaceutical innovation was indicated by its contribution of 23 new compounds, and the still embryonic state of Japanese innovation by the fact that it contributed only four. It is, however, likely that the Japanese will soon be amongst the top five nations for pharmaceutical innovation. Already their substantial investment in research is beginning to pay off in a flow of important new medicines. The lack of success in pharmaceutical innovation from Eastern Europe has already been mentioned, and Schwartzman's figures seem to underline the fact that free enterprise is an essential prerequisite for the development of new modern pharmaceuticals.

The enormous cost of pharmaceutical innovation has also already been mentioned. Within Britain, the industry's pharmaceutical research expenditure escalated from about £30 million in 1970 to an estimated £280 million in 1980. The cost of developing a successful new pharmaceutical chemical entity has recently been estimated by the Pharmaceutical Sector Working Party of the Chemicals Economic Development Committee (1981) as £50 million or more.

With such large sums of money at stake, it is important to understand the process of pharmaceutical innovation in the industry today. There are broadly three approaches, which to some extent overlap. The first is to screen compounds from a wide variety of sources for potential pharmacological activity. For example, a company may take compounds occurring in nature (such as salicylic acid), modify them, and then see what pharmacological actions the new compounds have on animals; or a company manufacturing synthetic agricultural chemicals may randomly test these to see if they have any pharmacological activity. Second, more specifically, a company may take a new compound with a known pharmacological action and chemically modify it to see how its activity is affected.

This process is sometimes disparagingly dismissed as leading to unnecessary "me-too" medicaments. However, often the molecular variations are important therapeutic advances. Even if the new molecular modification does not represent a broadly based pharmacological advance, it may still be important for a minority of patients. For them it may be more effective than the original innovation, or it may have fewer side effects and be better tolerated. In addition, it is at this stage that an element of serendipity creeps into the process of pharmaceutical innovation. For example, in France a random evaluation of compounds known to be effective as antihistamines led to the discovery of their important psychotropic properties. The first major tranquillisers were developed in this way.

However, the third broad approach to pharmaceutical innovation appears on theoretical grounds to be the most scientific, although it is not always the most effective in practice. This is the specific synthesis of compounds which are expected from a scientific hypothesis to have a particular pharmacological action. The use of para-amino salicylic acid (PAS) in the treatment of tuberculosis was an example of this theoretical approach. It was known that the TB bacteria fed on para-amino-benzoic acid, and it was postulated that if they could be given sufficient PAS to feed on instead they would "starve to death" through lack of their essential para-amino-benzoic acid. This proved to be the case.

More recently the development of the beta-blockers in ICI by Sir James Black represents another example of a specific approach to pharmacology. It is interesting that in that case the medicinal chemists needed much persuasion to encourage them to synthesise such compounds, because they were sceptical of James Black's hunch that these chemicals would prove important in heart disease, and eventually in the treatment of blood pressure. It is this ability to back one man's hunch which perhaps explains the success

of competitive free-enterprise pharmaceutical innovation against that from state-controlled organisations.

One or other of these three overlapping approaches to the search for pharmacologically active compounds will hopefully lead to a number of compounds which show a potentially useful action initially in animals. These compounds will then go into the development phase. First this will involve animal toxicity studies, and then the first tentative evaluation in man. If nothing untoward has occurred up to this stage, clinical trials may then start. This brings in the government, who under recent changes in regulations in Britain may now grant permission for trials to proceed, provided it is satisfied that proper preliminary tests have been carried out. Formerly, the company had to wait for the grant of a Clinical Trial Certificate, which involved a full evaluation by the government committees of all aspects of the chemical, pharmaceutical, pharmacological and toxicological data on the compound. The new abbreviated procedure was introduced because delays under the previous system were resulting in too many clinical trials being undertaken abroad instead of in Britain. This was undermining the academic basis on which the early evaluation of new medicines depended. One leg of the tripartite basis on which successful pharmaceutical innovation rests had been being eroded by excessive bureaucracy in another of the three legs. This has now largely been corrected.

In Britain, the full evaluation of the evidence on safety for the compounds which prove successful in clinical trials is now undertaken at the next stage, before a licence to market the compound is granted. Thus the stringent safety regulations introduced in this country in the wake of the thalidomide tragedy have recently been modified to achieve the joint objectives of successful pharmaceutical innovation in Britain coupled with a maximum assurance of safety of the compound in use. Increasingly in the future more emphasis is also likely to be placed on the surveillance of new medicines once they are on the market to some extent in place of preliminary animal toxicology. This is important because it has been shown that no amount of preliminary animal or clinical testing can guarantee the eventual safety of a medicine once it comes into widespread use. For example the compound practolol for the treatment of heart disease was discovered to have adverse effects on the stomach and eyes of patients. These did not occur until after the medicine had been given to patients for lengthy periods, and in retrospect it has never proved possible to reproduce the adverse human effects in any other species of animal. Hence animal toxicity studies could never have predicted this hazard, which could only be recognised once the medicine had been in extensive use in man.

This sort of episode is as much a commercial disaster for the company involved as it is a human disaster for the patients. Hence the company has a much more direct interest than a mere government agency in preventing such occurrences. The older idea that companies would choose to be reckless in this respect if there were inadequate government supervision is now recognised as a travesty of the truth. Companies welcome government advice in the assurance of safety, but are concerned to ensure that government regulation does not unwarrantably delay the processes of innovation. In this context, two economists from York University (Hartley and Maynard; in press) have suggested that the 1968 Medicines Act, which lays down the basis for present statutory controls for the approval of new medicines, could perhaps better be replaced by a return to a voluntary system, with less bureaucracy and more flexibility. Clearly government would still be involved, but less intrusively than at present.

Against that background, it is important next to understand the economic concomitants of innovation, which are as much a part of the process of developing new medicines as the research activities themselves. These are patents, brand names and information for the prescriber. It was the American economist Schumpeter (1942) who first described

clearly the role of innovation in modern economic competition. He referred to it as the "competition that counts" and as "creative destruction". The concept was later developed by Clark (1961) who used the phrase "workable competition" and emphasised the dynamic rather than the static nature of innovative markets. These and other economicst have all recognised the importance of patents, brand names and advertising in modern industrial society.

In the Western world, the role of patents for pharmaceuticals is fully recognised. Indeed the American economist Mansfield and others concluded in a recent study of innovation and imitation that "Practically none of the drug innovations would have been introduced without patent protection" (Mansfield et al 1981). There have recently been two developments in this respect which should improve the climate for pharmaceutical innovation in Britain. In the 1977 Patents Act the term of patents for all innovations was extended from 16 to 20 years. More importantly, Section 41 of the 1948 Act—which facilitated the grant of compulsory licences against pharmaceutical innovators—was repealed. Nevertheless the industry is still not satisfied that it has sufficient protection for its innovation. From what has already been said about the intrinsic cheapness of the pharmaceutical chemicals themselves, coupled with the fact that they are usually relatively easy to synthesise, it is obvious that pharmaceuticals need at least as strong patent protection as other classes of goods. Thus a present continuing bone of contention is the fact that so much of the duration of the pharmaceutical patent expires while the new medicine is still undergoing clinical evaluation prior to marketing. As much as half the patent life is usually lost this way. For this reason the Pharmaceutical Sector Working Party of the Chemicals EDC (1981) has recently argued that pharmaceutical patents should run from the date of marketing instead of the date of original discovery in order to put pharmaceuticals onto a more equal footing with other classes of goods. A similar argument in the United States has resulted in legislation currently in front of Congress and Senate.

Brand names are also primarily part of the economic infrastructure required to support pharmaceutical innovation. All international trade in pharmaceuticals—as with other classes of innovative goods—takes place using brand names, and they are generally used for prescribing (OHE 1976). This echoes the normal commercial practice for all modern economically differentiated and innovative goods, such as radios, cars, clothes and even processed foods.

Another argument in favour of brand names for prescription medicines is that they ensure that the patient invariably receives exactly the same medicine each time it is dispensed. In a few cases, the variation in biological availability between differently formulated medicines with the same active chemical ingredients from different manufacturers—which may be dispensed if the doctor prescribes under the generic name—can make an important therapeutic difference. Finally, brand names for all classes of goods stimulate improvements in quality and advances in methods of quality control.

Against this, some savings can be achieved if generic products are prescribed and dispensed for the older medicines whose patents have expired; but in Britain these savings amount to only two or three per cent of the National Health Service prescription bill. This surprisingly small figure results from the fact that most important branded medicines are also still patented, and hence only available at the original price from the original innovator even if they are prescribed by generic name. More importantly, however, it is argued that doctors can be more scientific in their prescribing if they use the generic name, which is usually more indicative of the pharmacological family of the compound than its brand name. My own inclination is to encourage doctors to write the brand name, but at the same time to ensure that they know the exact pharmacological

properties of the substance which they are prescribing. In this way, scientific prescribing is assured without the threat to pharmaceutical innovation which is implied by undermining the brand name system.

The last of the controversial concomitants of innovation is the information supplied by the pharmaceutical company to the prescriber—its "sales promotion". Emerson, of course, argued that if you built a better mousetrap the public would make a beaten path to your door even if it were "in the heart of the woods". No economist, I think, in the second half of the 20th century would still support that extraordinary proposition. Even the most important and useful innovations must be vigorously promoted if society is to benefit from them and if their innovator is to gather funds to continue his innovative activities. In this respect doctors are human beings, not scientific paragons, and they too have to be persuaded to adopt a new medicine into their practice. Indeed, there is probably more justifiable reluctance to prescribe new medicines than to purchase most other classes of new goods. Certainly there is evidence that since the thalidomide disaster doctors have been slower to start prescribing new medicines than they were before it (NEDO 1973).

Nevertheless, although sales promotion has always been essential to persuade doctors to prescribe new medicines, there were justifiable grounds for criticism 20 years ago or so when the pharmaceutical industry represented almost the sole source of information on pharmaceutical innovation. Since then, however, there have been major developments, which underline the interaction between academia, the government and the industry in promoting the rational use of new medicines. The pharmaceutical industry's sales promotion—representatives, literature and advertisements in journals—has both improved in quality of scientific content and also now accounts for only part of the information which doctors receive on new medicines. They also receive copies of Drug and Therapeutics Bulletin, prepared by academic pharmacologists and distributed at government expense. They receive the British National Formulary, similarly prepared independently and circulated by government. They can read regular review articles in the journals. They have also always received information on the cost of medicines direct from government, and if their prescribing has been too expensive they have been visited by a Regional Medical Officer from the Department of Health and Social Security. Thus although direct communication between the innovating firms and the prescribing doctors still provides an essential link for two-way communication between the developer and the "user", it is now by no means his only source of information.

As far as the quality of the industry's information is concerned, companies are now strictly controlled in the material which they can provide to doctors. The fundamental basis of this control is the so-called "Data Sheet", which each company must prepare and circulate to doctors before it communicates any other information about the medicine concerned. For convenience, the companies' collected Data Sheets are published from time to time in a Compendium by the Association of the British Pharmaceutical Industry. For new medicines, the content of the Data Sheet is controlled by government at the same time that the medicine is licensed for marketing. Nothing which the company says elsewhere, either in the written or spoken word, must go beyond the claims approved for inclusion in the Data Sheet.

Going back as far as 1958, there has also been a system of voluntary self discipline within the pharmaceutical industry on the style and content of the information which companies may provide to doctors. Incidentally the fact that doctors are normal human beings is underlined by the fact that the industry's Code of Practice has through experience been forced to ban the use of representations of the naked female body in pharmaceutical sales promotion! Lavish hospitality and gifts are also prohibited.

Finally, apart from the controls on the content of the information which companies provide to doctors, there are also now restraints on the total volume of sales promotion, whose cost has worried successive governments. For many years this ran at about 14 per cent of sales value. Then in April 1975 the Minister of Health, Dr David Owen, arbitrarily imposed a ceiling of 10 per cent, to be achieved by progressive reductions over a period of three years. To achieve this reduction, a formula was applied to companies according to their size, giving smaller companies a larger percentage to spend and larger companies a smaller percentage. This formula, which is applied during the price negotiations which I shall be discussing shortly, is deeply unpopular especially with the smaller companies who claim that even their larger percentage puts them at a disadvantage in trying to grow in size. Nevertheless, the whole system which I have described emphasises the way in which industry, academia and government are all concerned to see that doctors are never misinformed about new medicines, or unduly persuaded to start to prescribe them.

In passing, it is worth mentioning here that the NEDO study which has already been quoted (1973) provided evidence to show that commercially successful new medicines correlated well with the medicines which pharmacologists judged to be scientifically important. Hence the traditional criticism that powerful sales promotion could sell even ineffective medicines has been shown to be statistically incorrect. In part, no doubt, this is because since the 1960s there have been powerful corrective influences from academia and government to ensure that information on new medicines acts for the wellbeing of patients as well as for the essential economic interests of the innovating companies.

This leads on to a discussion of the last aspect of economic competition in the pharmaceutical industry: pricing and profits. According to the Kefauver Committee in the United States in 1961, the pharmaceutical industry was able to "administer" its prices uncompetitively, because doctors were alleged to be indifferent to the cost of the medicines which they prescribed. This misconception was endorsed in Britain by the Sainsbury Committee in 1967. It continued to gain general acceptance until it was strongly challenged by the Office of Health Economics in 1975 in a paper which we entitled "The Canberra Hypothesis"—because it was based on a lecture which I had delivered in Canberra earlier that year. This argued that economists had previously been looking for "perfect" price competition in the pharmaceutical market, which was indeed absent. Instead there was "price and performance" competition of a type which was appropriate to an innovative industry. The truth of this hypothesis was subsequently established by the Scots economist Duncan Reekie in a series of studies in Britain, in the United States and in the Netherlands (Reekie 1977 and 1980; Reekie and Weber 1979). He showed that, in general, only major innovations were highly priced and that less important innovations tended to be priced lower in relation to existing competitive therapies in order to give them a price advantage. Furthermore, high priced innovations were less likely to be commercially successful than those priced more competitively; but minor innovations did not attract more than a small share of the market even when they were priced noticeably below competing products.

Overall, the existence of effective price competition in the prescription medicine market is still not fully accepted by government in the context of the National Health Service in Britain. Hence companies are still subject to negotiation over prices under what is now called the Pharmaceutical Price Regulation Scheme. This was first introduced as a Voluntary Price Regulation Scheme in 1957. Originally this depended largely on a comparison with international prices as a criterion of the reasonableness of the prices charged to the NHS. However because of the Kefauver and Sainsbury Committees' misguided argument that price competition was absent internationally, the British

Government felt in the late 1960s that an international comparison could not assure reasonable prices. The argument was that all countries were paying "uncompetitive" prices for their medicines. As a result the present Scheme depends instead on direct negotiations on profitability. Each year all the larger companies have to submit a detailed financial analysis of their activities to the National Health Service, and may be asked to reduce their prices if their profitability appeared excessive. Under this Scheme the profitability on sales to the NHS have, with fluctuations, fallen from about 27 per cent return on capital in 1967 to about 15 per cent in 1979. The exact interpretation of these figures on profitability are the subject of occasional discussions between government and the industry. However it is another aspect of the generally fruitful co-operation between these two parties that both are concerned to see that the industry's profits are sufficient to support continued pharmaceutical innovation in Britain. From the NHS point of view, it is in many ways surprising that despite the continued development of an ever widening range of pharmaceutical treatments, pharmaceutical costs have remained a more or less constant 10 per cent of total NHS expenditure ever since 1949. By contrast, both hospital and manpower costs represent some 70 per cent of Health Service expenditure, and it is in these areas that more obvious economies could be sought.

Finally, before turning to look quickly at the future, I promised that I would also look briefly at the countervailing forces outside the industry which could endanger or inhibit pharmaceutical innovation. The general picture which I have painted is one of co-operation between academia, government and industry. However I said at the outset that industry has had to be vigilant to protect its ability to continue successfully to innovate in this country. Government, for its part, has a natural desire to want pharmaceuticals "on the cheap". As taxpayers we must all sympathise with this objective, but as I have said the British Government also recognises its responsibility to stimulate pharmaceutical development and to protect the economic strength of the British pharmaceutical industry in world markets.

It is not always so in other countries. In Belgium, France and Italy, for example, a "cheap drug" policy has contributed substantially to the local problems of the research based pharmaceutical manufacturers. Such policies are implemented by direct price control, by limiting doctors' freedom to prescribe and by imposing proportional co-payments on the patients. There have been murmurings in this country of further developments along these lines under the NHS, and they are vigorously opposed by the industry.

However, across Europe as a whole it is the consumerist groups who have seemed most antagonistic to pharmaceutical innovation, probably because they do not understand the harm that could be done by their demands for generic prescribing and other restrictions on the industry. In particular, their attacks on the safety of pharmaceutical innovation often seem unbalanced and almost hysterical. Lectures such as this provide an important opportunity to put the industry into perspective, which hopefully can help to influence those who attack the scientific and economic patterns of pharmaceutical innovation.

The importance of a balanced perspective in relation to the economics of pharmaceutical innovation is thrown into sharp relief when one turns to the future. I indicated that the therapeutic revolution of the 1950s and 1960s was largely based on fundamental theories and discoveries from the previous century and from early decades of the 1900s. This first "pharmacological revolution" was based on an understanding of the tissue—or intercellular—chemistry in the human body.

More recently, stemming largely from the elucidation of the DNA molecule by Watson and Crick, there have been major developments in understanding human intracellular chemistry. In my view this will lead, in the next three decades, to what can be called "The Second Pharmacological Revolution". This will involve the control of the virus diseases, most of the cancers and the autoimmune diseases such as multiple sclerosis, early onset diabetes and perhaps rheumatoid arthritis. The medical importance of the second pharmacological revolution will probably be at least as great as that of the advances which we have already seen over the past 30 years. But as some of the figures I have quoted have already implied, these future advances will be enormously expensive.

I am optimistic, both from a scientific and an economic standpoint, that the pharmaceutical industries in Britain, Germany, Japan, Switzerland and the United States will continue to flourish during this future development phase. However it is essential that the economics of the industry should be properly understood if this is to happen. In particular, it is essential that the co-operation which has already developed between the free enterprise industry and academia and government should continue in the years ahead. A mutual understanding and discussion of the economic problems and the position of the industry is an essential element if this is to be the case. I am indeed privileged, in this lecture, to have been allowed to put forward some of the factors which I think need to be understood and accepted if society is in fact to enjoy the fruits of the second pharmacological revolution between now and the early part of the 21st century.

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