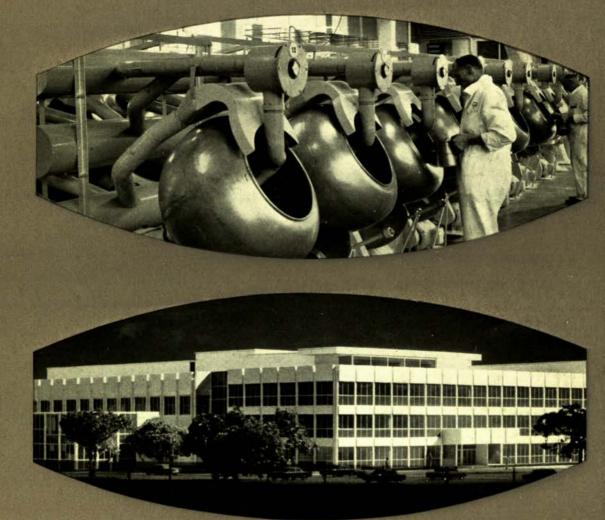
Economics and Innovation in the Pharmaceutical Industry



Edited by George Teeling-Smith

This book is the published version of the third series of Winter Lectures arranged by OHE. This series on Economics and Innovation in the Pharmaceutical Industry was planned largely to take account of the comments made by Mr Christopher Freeman, Director of the Unit for the Study of Science Policy at the University of Sussex, in his foreword to the published version of the second series of OHE Winter Lectures on Innovation and the Balance of Payments: the experience in the pharmaceutical industry. He drew particular attention to the value of case studies from industry and made a plea for more of these in the future. Thus the present series of lectures is returning to the theme of innovation in the pharmaceutical industry, looking on this occasion at the actual experience and practice of companies in various aspects of their activities. Two papers in the new series cover a range of experience with different companies, for example, on first entering the industry and on pricing policies. The papers on these two subjects are by University economists who have made special studies of them. Three other papers deal with the experience of individual companies, in the organisation of research, in marketing and in longrange planning. These are by senior executives of the companies concerned. The last paper reviews the relationship between government and the industry, again calling on actual experience both in Britain and overseas.

The foreword by Professor Kenneth Alexander reviews the six papers and discusses some of the still unanswered questions in respect of the economics of an innovating industry such as pharmaceuticals.

The previous series of OHE lectures, both of which have subsequently been published, have proved of value to those interested in the pharmaceutical industry, in other research-based industries, in government, in the relevant professions and in Universities. The third series in this volume covers an equally wide spectrum of interests.

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ECONOMICS AND INNOVATION IN THE PHARMACEUTICAL INDUSTRY

Economics and Innovation in the Pharmaceutical Industry

Symposium held at the Imperial College of Science and Technology by the Office of Health Economics in 1968-69

Edited by George Teeling-Smith

COHF

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Foreword

Kenneth J. W. Alexander

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THIS BOOK CONTAINS the third series of Winter Lectures organised by the Office of Health Economics, and the first to be given after the publication of the 'Sainsbury Report'.¹ Mr Freeman in his foreword to the volume containing the second series wrote: 'Not unnaturally some of the papers are concerned to justify the policies and practices of the principal firms in the industry.'2 However, in the earlier volumes there was evidence to suggest that the Office of Health Economics was concerned to have the pricing policies and other behaviour of the pharmaceutical industry critically explored. Readers who are properly sceptical about the motives and inhibitions of a body sponsored by the industry will find in the paper in this volume by the Director of the Office further evidence of such openmindedness, and in some of the other papers further evidence of a critical approach. The industry appears to be shifting away from a defensive posture to one based on recognition that there is a problem and that some means of meeting 'the public interest' must be found. At the same time the public and the Government have probably come to accept that the crude view of an industry exploiting the sick and pillaging the public purse misses many of the special features of pharmaceuticals and offers no firm basis for policy-making.

Mr Teeling-Smith's paper poses the problem clearly. Firms in pharmaceuticals earn above-average profits. This establishes a case for government surveillance, but economic theory provides no specific formula for price and profit determination in a research-based industry where most firms are multi-product. Therefore industry and government are left to 'horsetrading' about prices. This process must take account of the risk that surveillance and bargaining will inhibit the innovatory process in pharmaceuticals which has contributed so much to health and longevity in recent years.

The importance of economic theory could hardly be better illustrated than by an instance when its inadequacy could result in slowing down

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therapeutic progress. The modest and cautious economist must ask: 'Is this really where the difficulty lies?'

The supply of risk capital for research and development appears to be the crux of the problem. A surprising feature of the now considerable economic literature on the UK pharmaceutical industry is that although it abounds in references to the riskiness of research and development there are only a few examples quoted of major research efforts which came to little or nothing, and no detailed accounts of firms which because of this risk were themselves forced out of business. Nor are any of the quantative assessments of just how risky investment in pharmaceutical research and development actually is, either in absolute terms or relatively to similar investment in other industries, entirely satisfactory. This suggests a field for research deserving attention. Such research would only establish the ex post risk, on the objective basis of what actually happened: How many projects, costing how much, vielded zero or small returns? How many firms went out of business as a result of R and D failures? An alternative. and from the operational point of view more important, question concerns the estimate of risk made by the decision-takers who supply or withhold the capital necessary for specific R and D in pharmaceuticals. This estimate will always have a strong subjective element in it. The absence of industrywide studies of past experience plus the rapid growth of the industry involving many people with little past experience to draw upon in taking decisions makes it probable that the subjective element is very strong indeed. The problem would be to determine the going supply price of risk capital for R and D and to explore whether at this price the volume of capital available for research and development leaves promising avenues unexplored. In theory the demand price should reflect the value which society places upon having the R and D carried out. In practice this is obviously a very loose and indeterminate concept, even more so in an industry in which the wishes of individuals will be ill-informed, and to the extent these wishes are expressed they must operate through 26000 general practitioners and be strongly influenced by government policy on health expenditure and on particular pharmaceuticals. The problem of identifying the determinants of demand would be greatly simplified if it could be conceded that only at government level can an appropriate combination of medical expertise and economic calculus be brought together to reach an informed view of the volume and shape of R and D in pharmaceuticals. But can this be conceded without choking off some research and innovation which could attract commercial support but would not get through an official committee? This risk is obviously considerable and it would be a very bold government and an even bolder committee which would be prepared to decide against particular research projects which have scientific support and could get commercial support in a free market situation. The

inadequacy of any approach to the determination of the level of demand for the results of pharmaceutical R and D force one back to the supply side and to the question of whether the balance being struck between riskiness and return on R and D investment is too favourable to the suppliers of capital.

Mr Culver's interesting essay on 'Pricing Policies' raises hopes that a new approach to the theory of the firm might help us towards an answer to this question, but these hopes are not fulfilled. The notion that substituting 'wealth maximisation' for 'profit-maximisation' overcomes the need to distinguish between 'short' and 'long' run equalities between marginal cost and revenue falls down when one is dealing with products on whose lives some time-expectation must be placed, and has to choose given time periods over which to discount expected income flows. It is difficult to see why it should be easier to specify maximising conditions when what is being maximised is an open-ended list of utilities than when it is the reasonably clear-cut and quantifiable concept of profit. Unfortunately the example (p. 42) of the two firms, one wealth-maximising and the other including social service amongst its utilities, is not presented in any detail. If both firms are currently earning the same level of profits net of all R and D, their plough-back proportions will be identical. If the socially oriented firm has lower profits as a result of expenditure on 'pure' research, then the plough-back position of the wealth-maximising firm will be favourable-after the imposition of the profits-tax-as compared to the socially oriented firm. It is probably more realistic to regard the socially oriented firm as making a commercial judgement of the return to investment on its R and D over a longer period than is being made by the wealth maximising firm; that is both are wealth and profit maximising, but given the nature of their current research programme they are operating to different time-scales.

I am all for empirical attempts to refute theory, and even more for the formulation and testing of new hypotheses. The idea that the salient features of the economic environment surrounding firms should be isolated and the direction in which they push managements explored empirically must be the basis of any theory of economic decision-making in business. Mr Culyer's approach to a 'generalised utility theory' is disappointing, however, in that the economic environment surrounding firms is largely made up of the supply of factors of production to that firm, therefore bringing us back to a more traditional approach. In addition the distinction between wealth and profit maximisation breaks down in practice.

The essay by Mr Richard Bailey has thrown some light on the practicalities, but unfortunately does not clarify the central issue of the riskiness of R and D effort in pharmaceuticals. In fact it is surprising that R and D plays such a small part in the corporate planning approach which Mr Bailey

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outlines. In the first place the planning period, at five years, seems too short to encompass the time-span of pharmaceutical R and D. It was possible in 1964, with no product as an outcome of current research yet known, to plan on the assumption of a new product ready for introduction in 1967, which was to provide a large part of growth through to 1971. This suggests either that the risk-factor in such R and D is low or that this particular R and D was far advanced and its results fairly secure, and thus the five year time-span for corporate planning too short for general use in pharmaceuticals. I found particularly interesting, and surprising, the view that pharmaceuticals is not a capital-intensive industry. This puts less emphasis on R and D than I would have expected, or is based on a distinction between fixed assets and capital expenditure on R and D (the salaries of scientists etc. must surely be regarded as investment if rational decisions about the volume, spread and shape of R and D expenditure are to be made). Although Mr Bailey's essay contains many helpful insights on how a corporate planning approach can be applied with benefit in the industry it does not at all clarify how firms decide on R and D programmes, or on the supply of capital for such programmes. The role of R and D judged on the basis of this essay is much less than suggested for the whole industry.

In Dr Glaser's paper, too, there is an approach to the integration of R and D with production, marketing and over-all planning for the firm which does not quite fit into the picture of a very high rate of risk attaching to research effort: 'It would indeed be intolerable if production or marketing experts were idle because research dithered . . . although one cannot hurry research or take risks with quality, an efficient organisation must achieve the best in the shortest time.' This contrasts with the view sometimes presented of the great uncertainty involved in any attempt to obtain a new biologically active compound, with only one in three thousand of the compounds made actually becoming drugs. Thus the time required to discover an active compound can vary very widely. Once the active compound is found the years of development are reasonably predictable within three to five years. Perhaps some of the puzzling absence of evidence of concern with 'riskiness' in these papers springs from a concentration on this stage of development. Even so it remains surprising that these essays under-play the long, frustrating period of exploratory research on which the more certain development work must be based.

The paper by Messrs Kipling and Jones suggests a further reason for the lack of emphasis upon the riskiness of research effort. Commenting upon detergent technology they say 'It is the promise of product benefit which the consumer buys more than a real physical benefit—though it can be argued that this nonetheless represents a valid increase in utility for the consumer for all that it may be psychological in origin' and go on to suggest that a spectrum of technical change stretching from 'fractional tech-

nical improvements' to 'major therapeutic break-throughs' also exists in pharmaceuticals. As is to be expected in a paper on marketing strategies. the emphasis is upon how to promote what is known rather than on the problems and commercial implications of a search for the unknown. There is some evidence, too, that competitive pressures can slow down rather than accelerate the introduction of more effective drugs; 'while they knew it was beginning to be outdated by newer steroids they decided, as it was and still is the medical standard, to include it with gentamicin in the combination product rather than allow time to elapse in looking for and testing a newer one.' The marketing case studies in this paper are very well and frankly set out, and of great interest. It is also of interest that one of the lessons drawn is one also stressed by Dr Glaser in his paper, the importance of avoiding over-formalised structures within which the attempt to integrate successful production, finance and marketing strategies can be frustrated by bureaucratic rigidities. The central place given to marketing by Messrs Kipling and Jones leads on to the issue of competition and 'entry' to a market with which Mr Duncan Reekie's paper is concerned.

Mr Reekie's paper, too, gives us specific studies, in this case of four firms. He is concerned with the extent to which new firms can enter the pharmaceutical industry and, thereby, maintain competitive pressures on the industry as a whole. He produces convincing evidence of new entry, but this has to be qualified by the rapid growth in the industry's turnover. In such a situation new entry is not sufficient proof of the presence of strong competition, although the absence of new entry would certainly indicate that competitive forces were weak.

The importance of the high costs of promotion on a national scale as a barrier to entry for all but established firms (whether established inside or outside pharmaceuticals being largely irrelevant) is established in a very specific and convincing way. The argument runs as follows: A high volume of sales with high profit margin is necessary to sustain expensive and risky R and D effort. The character of the market requires a very expensive promotional approach if high volume sales at high prices are to be achieved. Therefore promotion costs are a barrier to entry. Given the emphasis Mr Reekie places on R and D riskiness as an (indirect) barrier to entry he has to go on to ask: Does the R and D effort have 'artificial elements', which may be bracketed with the 'fractional technical improvements' already referred to in the comments on the paper by Messrs Kipling and Jones. Three important benefits are suggested as flowing from imitative research and development. The first is that imitative products always embody some difference to which consumers may attach importance outweighing the costs involved. Some marginal advances are of undoubted benefit, but I would not hold out much hope of the suggested

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cost-benefit approach yielding much in the way of convincing evidence one way or the other in the majority of cases.

The second advantage of imitative research and fractional improvements in medicines is that such product competition weakens monopolistic distortions. Unfortunately there is an element of circularity in the situation which vitiates this conclusion. The high costs of R and D (including imitative R and D) have been advanced as a major cause of the monopolistic situation and then the results of that R and D (a number of very close substitutes in each major therapeutic market) is offered as weakening the monopoly distortion which their creation has helped bring about.

The third argument advanced for imitative research is that it can be used to hold research teams together, presumably where ideas for more fundamental research are not available to the firm. Without knowing a great deal more about the organisation and mechanics of research in pharmaceuticals it would be foolish to quarrel with this argument. It does suggest a shortage of fundamental ideas, and that at most moments of time within most firms most if not all of the fundamental ideas available to it are already being explored (this because most firms are regularly involved in imitative research). Whether this is the case should be relatively easy to establish, and would be of great interest. If it were so it might be that the conclusion to reach would be that most R and D teams as at present organised are too large given the restricted supply of fundamental ideas thought worth exploring. Perhaps they should be reduced in size, or possibly spend more time themselves on fundamental work, rather than pursuing a policy of 'feather-bedding' on imitative research. Alternatively there is the hypothesis that imitative research activity, with its quicker and more certain results and shorter lead-in time, is attractive on commercial grounds. Mr Reekie's footnote on the relationship between patents and profits suggests that he has not entirely dismissed that possibility. His estimate that only 9 per cent of a UK pharmaceutical R and D is imitative suggests that the problem is not a major one.

Mr Teeling-Smith's paper brings us back to the central problem of government-industry relations and, within that, of how to determine prices and profits in the pharmaceutical industry. Reference is made to the damage caused to these relations by the Minister of Health's action in 1961, authorising the importation of continental unlicensed copy products (thus removing from British manufacturers the protection they had had under the Patents Act) because he believed that UK prices were too high and that the companies were being deliberately obstructive in the discussion about 'reasonable' prices. I doubt whether the incident reveals the deviation by Mr Enoch Powell from his free-market philosophy which Mr Teeling-Smith sees in it.

Competition from without was a logical enough substitute for inter-

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vention, particularly given the absence of full information on costs, and given the complexities of the industry's cost and product structures. Invoking legislation to introduce previously absent market forces seems entirely consistent. The expectation that this would, by itself, exert pressures which would redress the mis-allocation of resources associated with high UK prices would also be consistent, but in this case with the naivety often associated with free-market philosophy. But the criticism that Mr Powell did not find a solution lacks force given that in the years since no satisfactory solution has yet been found, as is admitted by Mr Teeling-Smith. The point should also be made that Mr Powell's attack was primarily aimed at one firm whose prices and promotional efforts were thought to be particularly high. There is evidence that at the time the sales force of this firm was considerably more numerous than that of other firms of similar turnover size. Here again we are brought back to high promotion costs as a barrier to entry and possible cause of excessive prices, an objective factor capable of empirical examination which will presumably be one of the operating ratios on which government will be informed by the companies. This sharing of full information with government does seem a necessary first step between government and the pharmaceutical industry. As the exchange of information proceeds it will be necessary to work out guide-lines by which to judge price and profit policies. It is to be hoped that a more fundamental approach will also be encouraged so that in the longer run a comprehensive approach to the problem can be formulated; this would be the contribution of economic theory. In such a contribution it seems clear that the supply price of capital for R and D effort and the estimation of the risk attached to such effort will play a central part. This volume of papers-and the two in the same series which have preceded it are evidence that within and around the pharmaceutical industry there is thinking going on which can lay the basis for these necessary next steps.

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INTRODUCTION

ECONOMIC theorists frequently assert that ease of entry for potential industry members is as effective a means of ensuring the competitive behaviour of existing firms with regard to outputs and prices as is actual neoclassical perfect competition.¹ Mr Cooper has already performed sterling work to show the continuous existence of potential competition in the drug industry as implied by the rapid turnover of important participant firms in many of its essentially oligopolistic therapeutic sub-markets.² Cooper's evidence of the existence of competitive conditions in the industry, however, has not carried universal conviction. *The Economist* commenting on the Sainsbury Report³ gleefully remarked⁴ that 'bad guys' had been making 'profits of up to 50 per cent'. Had the continuous entry of new members into the sub-markets had the effect on existing sellers that received theory would lead one to expect and Mr Cooper would like one to infer then presumably there would be no room for 'bad guys'.

Is it not possible then, to look upon the various sub-markets as merely a large number of simultaneous games of musical chairs being played by one unchanging group of large drug firms? When the music stops the participants in each game have changed, but merely in order to effect a mutual exchange of one oligopoly situation for another. If this interpretation of Cooper's evidence is correct then the consumer of medicines in the long run is not, from a resource allocation viewpoint, faced with results similar to those of dynamic price competition but rather with a wasteful aggregation of oligopolistic short-runs.

This paper attempts by reference to theory and experience, to ascertain to what extent potential competition has been realised in the industry *as a whole*, and what and how great are the barriers to entry which potential member firms must overcome.

In order, first of all, to determine whether or not the community of firms comprising the industry was a static entity an analysis of its age

structure was performed; the results of which can be seen in Table A indicating a continuous and fairly even flow of firms into the industry since 1950. Over 30 per cent of industry sales in 1966 were made by post-1949 entrants, large and small. Further, except for the five or six most recent entrants there is no obvious relationship between age and company size. Unlike more traditional industries, both rapid relative and absolute growth can occur soon after entry. Table A consequently tends to refute the 'musical chairs' hypothesis.

Table B examines the origins of the entrant firms between 1950 and 1966 and indicates that nearly all have been established firms with the access to resources which that implies and not individual entrepreneurs. This fact *per se* need not influence the impact these entrants have on the competitive behaviour of existing firms but the fact that most industry entrants have been overseas drug houses certainly might. It may well be that a foreign entrant to the British market is seen as less of a threat to the existing cost/ price structure of the market than is a potential British entrant. This could be so since a foreign entrant, by definition, is a well established drug house whose competitive behaviour has already fallen within the group norms of the international industry. The world-wide concern at a political level over the price/output and promotional activities of the industry's members is too uniform and widespread to deny the existence of these norms. The desirability of these norms is, of course, still open to debate.

The 'musical chairs' hypothesis could, therefore, still be relevant in Britain. In the last sixteen years the number of players has certainly increased but most entrants have merely come from another league where the rules of the game are exactly the same. Further cause for concern is provided by the evidence that only one entrant was a completely newly established firm. *Ceteris paribus* this would suggest that large resources are needed to enter the industry thus deterring entry and by implication permitting some degree of non-competitive behaviour.

BARRIERS TO ENTRY IN THE DRUG INDUSTRY

Following Professor Bain's example⁵ we will examine entry barriers in three main categories. It will emerge that these overlap and are interrelated in practice but for analytic purposes they can be usefully treated individually.

I Absolute cost advantages of existing firms occur when a higher long run average cost curve faces an entrant than faces an existing firm. In drugs such a barrier can manifest itself through the ability of existing firms to patent a group of chemically related products thus precluding entry with these products unless royalties are paid to the patentee. Since some 72 per cent by value of all prescription sales are of patented products, and this a

Year of Entry	No. of Firms	<i>Total GP</i> <i>Sales</i> , 1966 (£'000)	Average GP Sales, 1966 (£'000)	% Total GP Sales	% Age Group Sales by Firm Size Grouping			
					Less than £1m.	£1 <i>m</i> .–£5 <i>m</i> .	Over £5m.	Total
Pre 1950	45	80 576	1701	69.2	15.5	55.1	29.4	100.0
1950		10 mm 10 mm	1 <u></u> 2	(<u>* 14</u>			100 miles	
1951	2	3548	1774	3.0	10.3	89.7		100.0
1952								
1953	4	10 488	2622	9.0		43.9	56-1	100.0
1954	1	4778	4778	4.1		100.0		100.0
1955	1	1222	1222	1.1		100.0		100.0
1956	1	2264	2264	1.9		100.0		100.0
1957						-	1 <u>2</u>	
1958	3	9501	3167	8.2	29.0		71.0	100.0
1959	2	408	204	0.4	100.0		-	100.0
1960	5	1160	232	1.0	100.0			100.0
1961	_							-
1962	1	1375	1375	1.2	5. <u></u>	100.0		100.0
1963	1	60	60	0.1	100.0		_	100.0
1964	1	441	441	0.4	100.0	1000	_	100.0
1965	2	329	165	0.3	100.0	3 		100.0
1966	2	50	25	0.1	100-0			100-0
	71	116,200	1637	100.0	19.6	49.5	30.9	100-0

 Table A

 Size and Age Distribution of Firms* in the UK Pharmaceutical Industry at 31st December 1966

* ABPI Division B members plus ICI Limited, and London Rubber Co. Limited. Affiliated companies have been treated as one 'firm'.

Table B*

Origins o	f Entrant	Firms.	1950-66
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		Market Share (%) 1966		
Origin	No. of Firms	Mean	Range	
Overseas Drug Houses	20	1.2	0.0-4.9	
Related Industries in Britain	5	1.3	0.0-5.7	
New Corporate Entity	1	0.3	0.3	

• I am grateful to Intercontinental Medical Statistics Ltd., for providing me with certain market research data used in this table and throughout the paper.

rising percentage,⁶ then 72 per cent of the market has this form of entry barrier. The performance of R and D to obtain a distinctive product for entry is, of course, rather an attempt to obtain a differentiated product advantage than an attempt to overcome absolute cost disadvantages and will be considered as such.

Absolute cost advantages from the economies of bulk buying do not appear to be such that entry will be seriously inhibited. Direct production costs of pharmaceuticals tend to be low in relation to price rendering savings on these direct costs, such as raw materials, of relatively minor value. In advertising there may be an advantage of reduced rates to the purchaser of 26000 glossy pamphlets for mailings vis a vis the purchaser of 1000. This is unlikely to be crippling, however, due to the fairly small absolute cost of such material.

II Economies of scale as an inhibitor of entry appear to be largely unimportant in the drug industry. In production, unless the firm is integrated backwards to fine chemical manufacture or fermentation then large and small firms can exist side by side at similar levels of efficiency.⁷ In promotion also there are no really evident economies of large-scale advertising except possibly as regards journal advertising, probably the industry's least effective medium.⁸ At a national level the small entrant firm might simply not have the funds to indulge in such an activity. At a local level, however, it is not *prima facie* evident that a small firm's representative force need have less impact on a doctor's prescribing habits than a large firm with a detail force covering the country. There may even be diseconomies of scale since the small firm can concentrate on urban areas, the large firm covering all prescribers may suffer from fewer visits per representative due to 'lost' travelling time in rural areas.

III Product differentiation advantages of existing firms are the most obvious entry barriers in the industry and probably also the most effective. With over 2400 drugs available in the UK and an average duplication of only 1·1 brands per formulation⁹ the extent of product differentiation is vast. Product differentiation in drugs is highlighted by the practice of branding and the entry deterrent provided by branding is measured by the extent of the 'financial sacrifice' an entrant firm must incur to sway prescribers away from loyalty to existing brands towards the entrant's products. The concept of brand loyalty in the industry is no chimera; in 1965, 88.8 per cent by value of all prescriptions were written out for products available only under a brand name.¹⁰ Existing firms will, of course, attempt to strengthen this loyalty and this they can do by emphasising product differences in advertising and/or by 'creating' new ones by conducting R and D to produce new, modified or improved therapies. Entrant firms can only revoke this loyalty, if, to paraphrase Bain, they incur some 'financial sacrifice' not currently incurred by existing firms.

This implies, for example, selling products at an attractively cheaper price; promoting products more effectively; producing products which are different again from those already on the market, for example by initiating a successful R and D effort; or some combination of those or other 'sacrifices'. If existing firms are continuously attempting to strengthen loyalty of prescribers to their own brands then a vicious circle commences. Entrants must cut prices still further; shout still louder through their promotional media; and make still bigger technical jumps through R and D, if their products are going to have the marginal attractiveness to shake existing loyalties.

SOME SPECIFIC CASES

In order to illustrate the above theory four cases are presented below. In two instances some of the information used was disclosed confidentially to me, pseudonyms are consequently employed. In the cases of Crookes and Syntex the information has already been published elsewhere and is freely available to those who care to seek it out.

I The Case of Syntex

Syntex has its origins in Professor Marker's discovery that progesterone, a steroid hormone, could be derived from a Mexican plant root. This was in 1943, a time when isolation of such hormones was difficult and costly, methods such as abstracting it from mares' urine being typical. Marker obtained financial backing from two Mexicans and in 1944 Syntex S.A. was incorporated and the first few pounds of progesterone manufactured commercially by Marker's method were put on the market. In 1945 Marker left commercial life and his financiers engaged Dr George Rosenkranz, an Hungarian in his late twenties, to organise Syntex' technical and scientific aspects. In the next five years Rosenkranz achieved the synthetic

production of the remaining three types of steroid hormones, androgens, estrogens and the corticoids. In this effort he was aided by a young Syntex chemist, Dr Carl Djerassi. Around this time Rosenkranz also engaged Dr Alejandro Zaffaroni. All three of these then young men now have worldwide reputations in the field of steroid chemistry and all three are directors, two executive directors, of Syntex Corporation.

In these early days Syntex' output was going to existing pharmaceutical houses in both Europe and America, who at last had a cheap and plentiful supply of steroids for processing into final dosage form. It was in the fifties that the explosion in knowledge about possible therapeutic uses for steroids really occurred. The necessary discoveries were made both in existing drug houses and in Syntex. The use of hormones as anti-inflammatories, as anabolic agents and as contraceptives became biologically possible and with this increase in knowledge therapeutic demand expanded apace.

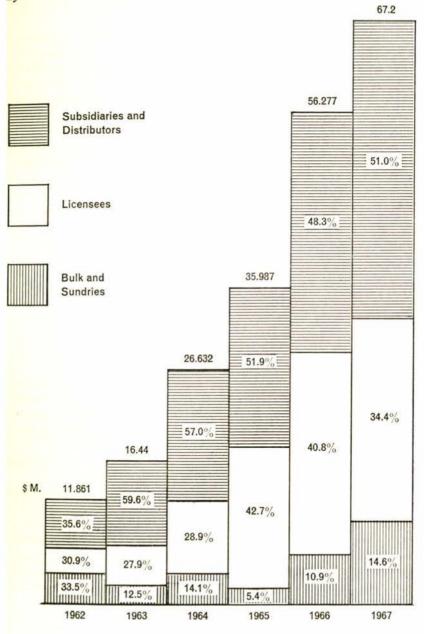
Syntex' scientific successes were not at this stage receiving the financial and commercial reward commensurate with their magnitude; principally because it was producing its discoveries as bulk chemicals, requiring in most cases pharmacological bioassays and dosage form development before they could be produced as finished medicines. The proportion of profit on final sales value accruing to Syntex was consequently small. A decision was consequently taken to expand the company into a fully integrated pharmaceutical house conducting dosage development, manufacture and distribution.

About this time in 1956 Syntex was acquired by an American holding company, the Ogden Corporation, which in 1958 launched its recently acquired subsidiary as a public company quoted on Wall Street. Liquidity problems were thus reduced to a minimum. Syntex' scientific reputation gained it still further access to funds when in 1958 it entered into an arrangement with the Eli Lilly Corporation to conduct a jointly financed R and D programme. This agreement has since been terminated amicably, both firms acquiring new products and know-how, Syntex having received a financial booster. Syntex is now performing R and D under a similar arrangement with E. I. Du Pont de Nemours.

1956 was also the year Syntex introduced its first 'speciality product', norethisterone, originally synthesised in 1951, which was marketed by licensees, Parke Davis in America and Schering in Europe. Clinical investigations soon revealed that norethisterone was a conception inhibitor as well as a gynaecological agent. From these findings a development effort was launched and in 1962 Ortho Pharmaceuticals marketed 'Ortho-Novum', licensed from Syntex, the world's second contraceptive pill. By 1968 over half of the oral contraceptives sold were Syntex products or had some link, such as licensing, with Syntex research.

Barriers to Entry and Competition

FIGURE 1 Syntex' Sales Mix; 1962-67



Abstracted from Syntex Corporation A/cs. 1967

Simultaneously Syntex was working on anabolic agents and in 1959 'Adroyd' was launched on the American market by Parke Davis as licensee. In 1960, this same product, in Mexico, was introduced by Syntex, the first time it had ever marketed direct to prescribers.

In 1958 the now famous anti-inflammatory 'Synalar' was synthesised and after a development period was introduced to the American market by Syntex' own newly formed sales force. In Britain 'Synalar' is marketed by ICI. Syntex now markets direct in all its three main therapeutic areas in the States and since entry into Britain in 1966 has entered the anti-oestrogen cum anabolic and contraceptive markets with 'Masteril' and 'Norinyl-1' respectively.

The result of Syntex' decision to become an ethical house proper and market direct to the prescriber can be seen from a study of Figure 1 showing the firm's sales mix. In 1955 all Syntex sales were of bulk chemicals, by 1962 this proportion had fallen to one-third of total sales value and by 1967 sales of Syntex' own finished products had risen to over 50 per cent of total sales value. This is even more astonishing when it is observed that total sales expanded between 1962 and 1967 by about 600 per cent.

II The Case of Crookes

In the early fifties Crookes was a proprietary medicine house whose fortunes were primarily linked to its famous Halibut Oil product. By the midfifties demand for this product began to fall away drastically and the owners of Crookes, alarmed at this turn of events, *inter alia*, sold the business in 1960 to Philips Duphar and Arthur Guinness jointly, with Guinness having the majority shareholding.

The reasons for the sale are apparent. The purchasers' motivations differed, however. Philips, a Dutch drughouse owned by the Eindhoven electrical firm, had previously marketed the products of its own R and D through a British agent. At the same time as Crookes was looking for a buyer, Philips' agent was taken over and Philips duly compelled to obtain a more satisfactory method of marketing in the UK. This Crookes was meant to provide.

Two years prior to this in 1958, Guinness,* probably from a mixture of philanthropic and commercial motives, had set up Twyfords, a pharmaceutical R and D team, as a corporate entity. However, the products of R and D are of little value unless they can be brought to the market place by means of commercial production and distribution. Guinness consequently required the means of full integration and Crookes with its manufacturing plant geographically close to Twyford Laboratories provided a possible solution.

* The Guinness family are well known for their charitable benefactions towards medicine.

After the dual take-over Crookes' business objectives were re-directed to the ethical industry proper. Its product-mix was determined by four differing parameters. Historically some of Crookes' proprietary medicines overlapped into the ethical field and were retained on reorganisation. Both Twyfords and Philips had R and D efforts whose output Crookes would market in Britain, and finally Crookes' own policy makers apparently decided on the need to market licensed products if they were to have a sufficiently large range to base future growth upon.

As late as 1962 Crookes was still going through the arduous and costly task of reshaping its predominantly retail pharmacy sales team into a trained force of medical representatives calling on practitioners. Success was achieved with this and by 1966 the sales team had been doubled in size. Simultaneously a high level of mailing and journal advertising was being engaged in, in an effort to make an impact on the market. The new chief executive installed in 1962 realised that to break into the ethical market quickly and on a substantial scale required high advertising outlays. The profit forecasts which must have been agreed with the parent companies consequently showed substantial losses for the first few years and were in turn duly fulfilled. 1964 promotional expenditure, for example, was almost equal in size to 1963 turnover. Guinness' accounts in turn, showed, in 1964, a loss of £612000 on its pharmaceutical operations. This would include its proportionate profit or loss on Crookes plus the whole of Twyford's operating budget.

By 1966 Crookes had achieved a not insignificant market share and its product range had been expanded to include sixteen products of moderate turnover. In 1967, nearly ten years after the formation of Twyfords, Crookes had still to launch a human ethical product received from its sister company. Such is the unpredictability of pharmaceutical R and D. Nevertheless by this time Crookes had considerably increased its share of the NHS market and the implication of the most recent Guinness accounts is that its total pharmaceutical operations are pulling round to profitability.

During this period, Crookes, with at least sixteen products to promote, each with its own journal advertisements and mailings, had concluded that promotion was too high for the return it provided. In 1966 mailing and journal advertising was consequently slashed by 90 per cent of its 1965 value to a nominal figure. Shortly afterwards the now well known house magazine *New Doctor* was introduced. This magazine serves the function of a multi-mailing, an impossible concept otherwise since doctors obviously will not receive favourably an envelope through the post with sixteen advertising pamphlets in it. It also acts as a substitute for journal advertising elsewhere. *New Doctor* contains articles of medical and general interest, it is circulated free of charge and has been well received by the profession;

the advertisements include ones for Philips electrical fittings and Guinness stout thus indicating its ultimate origin as well as providing Crookes with invaluable support for a promotional strategy which an independent company of its earlier turnover size could probably not contemplate.

III The Case of Pharma

Pharma in 1966 had a turnover in GP sales of less than half a million pounds. It was established before World War II by an entrepreneur who had obtained the rights to market a German ethical. The founder shortly after sold Pharma to a second entrepreneur who remained chief executive until the early sixties. A derivative of the original German product, 'Coffcure', was to be the rock on which Pharma was built; in 1962, almost all the firm's ethical sales were attributable to 'Coffcure'.

Over the years Pharma's profits were used to diversify its owner's interests, not to consolidate its ethical position and by 1960 Pharma had become a subsidiary company of one of these other interests. Unfortunately the holding company is in a line of business in which liquid funds are at a premium for stockholding purposes and Pharma consequently has now to finance any organisational or policy changes from within its own flow of funds resource strength. This it has been trying to do since 1962 when a new managing director was engaged, a pharmacist with sales and administrative experience at a high level with three large pharmaceutical firms in the British market.

His brief was to expand Pharma as an ethical house and his strategy was based on the dependence of growth in pharmaceuticals on the introduction of new products. Since Pharma has not the resources to conduct R and D these come on an *ad hoc* basis from licensors in Europe or America who have no selling organisation in Britain.* Pharma has also negotiated first refusal rights for the UK market with one large European firm on all new products which are produced by its R and D effort. Pharma aims to introduce one 'major' and one 'drop' product per year. A major product is an important therapeutic advance intended to capture a comfortable share of the market. A drop product, possibly only a slightly modified existing one, serves several ends. It cushions revenue if the major fails, it maintains the enthusiasm of the representatives in the field, it may prove fortuitously to be a market winner and finally it can act as a market probe, testing selling conditions in an unfamiliar area.

Although Pharma did double its turnover between 1962 and 1966 its chief executive considers that its lack of resources hinders more rapid growth. Pharma's sales force is only half the size of the forty men it con-

^{*} Thus Pharma is not confronted in the usual manner with entry barring royalty levels. It is in the interest of Pharma's licensors to assist Pharma in establishing the licensed products on the NHS market, not to deter this.

siders the absolute minimum to cover the market (forty men can visit each of the nation's 26000 GPs every five or six months). This means a limitation is placed on absolute sales and possibly also relative sales since even a five monthly visit may be insufficient in frequency to catch the doctor's ear if he is receiving, say, a six-weekly visit from the giant firm.

This difficulty is further increased by an earlier decision to select for visitation those GPs most likely to prescribe 'Coffcure'. This task was performed by the Pharma sales team and obviously could improve the productivity of each call, provided the call was made to promote 'Coffcure'. The whole, slow expensive process has to be repeated again for Pharma's next major product, a problem which a large firm with blanket coverage and frequent visitation just does not face.

Changing governmental requirements for new product introduction also hinder Pharma's ability to grow. The new products it acquires from Europe have frequently not had to undergo pre-marketing tests of the same stringency as Dunlop requires in Britain. Pharma must consequently perform, for example, a considerable amount of prolonged toxicity testing in Britain. This it does by sub-contracting to a Research Institute. Pharma with a turnover of several hundred thousand does not lack the funds to finance this nor even the expertise to collate the results and prepare the submission. It does not, however, possess these resources in sufficient quantity to concentrate them at any one time and so push the effort along at a decent pace. The result is a delayed innovation date. Pharma's most recent product, 'Dilation', introduced in 1967 could have been introduced in 1966 by a more plentifully endowed firm. A year's revenue was consequently lost and also the immeasurable loss of market position to other products entering the market in the interim.

IV The Case of Chemica

Chemica was incorporated in 1953 by a single entrepreneur who perceived profitable opportunities in the pharmaceutical industry. On incorporation his total assets were less than £300 and he commenced trading with a single salesman and an advertising budget in his first year of £1500. Chemica's products were manufactured by a sub-contractor and were well-established, non-patented ethicals already on the market.

Table C illustrates how Chemica was able to slowly build up its advertising budget on both journals and mailings from its small beginnings. Within ten years of commencement Chemica had expanded from a turnover of zero, one salesman and an advertising budget of £1500 to a firm with a turnover of approximately £250000, twenty representatives and a promotional budget of £50000 per annum. The total asset valuation of Chemica had risen in the same period from less than £300 to £75000.

Chemica's success lay in its ability to spot non-patented drugs selling at

Table C*

Year	Sum	Year	Sum
1953	£1500	1959	£20000
1954	£2000	1960	£25000
1955	£3000	1961	£30000
1956	£4000	1962	£40000
1957	£5000	1963	£50000
1958	£9000		

Chemica Limited, Promotional Budget, 1953-63

* I am grateful to the management of Chemica Ltd. for this information.

a very high profit margin, obtaining a supplier of these drugs and subsequently persuading doctor's to prescribe its, Chemica's, cheaper brand.

These four case studies, Syntex, Crookes, Pharma and Chemica have been chosen to show in varying ways the differing combinations of price, product and promotional competition which businessmen use to enter and/or grow in the pharmaceutical industry. The next three sections of this paper will examine in turn each of these three means of combating entry barriers.

PRICE COMPETITION

Price competition is unusual in the drug industry for a variety of reasons. Firstly firms adjust their strategy most according to the anticipated actions of those rivals whose output has a high cross-elasticity of demand with their own. In drugs this condition exists not in the total industry but in the oligopolistic therapeutic sub-market.¹¹ From the theory of oligopoly one would consequently expect that price inflexibility would characterise the behaviour of firms.

Price inflexibility is also to be expected from the inelastic nature of the industry demand curve. Medicines are a necessity and a rise or fall in price will do little to deter or attract purchasers. Demand is rather a function of disease incidence than of price level. In Britain this 'necessity' effect is reinforced by the provision of medicines either free or at a nominal price unrelated to cost. The necessity effect is then complemented by the 'isolation' effect unique to this market. Because of the highly technical nature of the product, selection is done not by the consumer but by the doctor. Unlike specialist 'buyers' in industry he is not employed to make a financial bestbuy or to justify his actions in terms of a balance-sheet. His isolation from financial responsibility extends until his prescribing costs are 'substantially above average'.

Finally, since 72 per cent of the market is accounted for by patented products price competition is effectively precluded there since licenses will usually only be granted at royalty rates ensuring almost equivalent pricing. Table D gives a non-random selection of the prices of some important patented drugs to illustrate this.

Price competition can and does successfully emerge in the non-patented section of the market, however. Chemica provided an outstanding example of this although its promotional tactics would have had the barrier of the isolation effect to overcome. Chemica, of course, is an exception and it is a debatable point whether or not a small firm could emerge in a similar manner in 1968. The revelations of the imperfections of some 'cheap drugs' by Frank Stock¹² led even the most price conscious of prescribers to be wary of the products of little known firms. It is difficult to decide whether to be perturbed or grateful at this turn of events but one can take heart at least from the introduction and success of ICI's 'Imperacin', a brand of oxytetracycline. The isolation effect was minimised in this instance by continuous Ministerial publicity about the high price of oxytetracycline and ICI, on introducing its cheaper brand, stressed its own house name and nationality in order to convey to doctors a feeling of confidence in 'Imperacin's' quality and consistency.

Since the introduction of 'Imperacin', other firms, such as Berk and Glaxo, have introduced similar non-patented antibiotics using aggressive pricing policies as a major means of establishing themselves in these areas. It would appear that the isolation effect can be minimised effectively and doctors persuaded to be price conscious and prescribe accordingly. This conclusion, however, is primarily relevant to the non-patented market. In the patented market where products differ either marginally or substantially then price is only one of many product characteristics which doctors may or may not take into consideration. Even in the antibiotics market where much of the current price competition is occurring it would appear that price consciousness has only become really prevalent since oxytetracycline's patent expired and other chemically equivalent brands were introduced.

Table E provides part of the Sainsbury evidence on GPs cost consciousness in 1966, the year 'Imperacin' was introduced. Even then, several years after continuous criticisms and publicity about the costliness of antibiotics substantial numbers of GPs could give no accurate assessment of the prescription costs of the one product they were 'most likely to prescribe' if presented with a case of acute bronchitis, a very common disease. This is very frequently treated with antibiotics which in turn are also frequently prescribed for many other respiratory infections.

The diagonal cells indicate the proportion of GPs who provided correct assessment of price. In broad terms doctors appeared to be aware of

Table D*

Comparative Pr	ices of Some	Chemical 1	Equivalents
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Market	Compound	Pack†		Marketing Company and Price				
Tranquilisers	Meprobamate	30 x 400 mg. Tabs	Wyeth 4s. 4 ¹ / ₄ d.	Wallace 4s. 41d.				
Psychotropics	Amitryptiline	100 x 10 mg. Tabs	Roche 10s. 4d.	Merck 10s. 4d.				
Diuretics	Hydrochlorthiazide	100 x 25 mg. Tabs	Merck 23s. 6d.	Ciba 23s. 6d.				
	Bendrofluozide	100 x 2.5 mg. Tabs	Boots 9s. 3d.	Glaxo 9s. 3d.	Leo 9s. 3d.			
Hormones	Cortisone Acetate	100 x 25 mg. Tabs	Glaxo 48s. 0d.	Merck 48s. 0d.	Boots 48s. 0d.	Roussell 48s. 0d.		
Antibiotics	Phenoxymethyl penicillin Potassium	100 x 125 mg. Tabs	Abbot 14s. 0d.	Glaxo 14s. 0d.	Dista 14s. 0d.	ICI 14s. 0d.	Boots 14s. 0d.	
	Tetracycline	100 x 250 mg. Tabs	Lederle 65s. 2d.	Nicholas 65s. 5d.	Squibb 65s. 3d.	Pfizer 65s. 2d.		
	Chloramphenicol	100 x 250 mg. Tabs	A & H 74s. 2d.	Parke Davis 74s. 2d.				
	Erythromycin	100 x 100 mg. Tabs	Lilly 38s. 10d.	Abbott 38s. 10d.				
	Lincomycin Hydrochloride	100 x 0.5 gm. Caps	Boots 256s. 0d.	Upjohn 256s. 0d.				
Anti-T.B.	D. Cycloserine	40 x 250 mg. Tabs	Lilly 54s. 8d.	Roche 54s. 8d.				
Agents	Viomycin Sulphate	1 gm. Vial.	Pfizer 13s. 6d.	Parke Davis 13s. 6d.				
Antidiabetics	Tolbutamide	100 x 0.5 gm. Tab.	Hoescht 19s. 0d.	Riker 19s. 0d.				

Data abstracted from Medindex, 1967.
 All the companies cited do not necessarily market their products in the pack size referred to here. Medindex prices, however, have been adjusted on a pro rata basis to ensure like pack is compared with like.

Table E*

	Calculated Price Range							
GPs Estimate of Cost	Up to 5s. 0d.	Over 5s. 0d. to 10s. 0d.	Over 10s. 0d. to 15s. 0d.	Over 15s. 0d. to 20s. 0d.	Over 20s. 0d			
	%	%	%	%	%			
Up to 5s. 0d.	62	7	2	1	1			
Over 5s. 0d. to 10s. 0d.	24	52	18	9	2			
Over 10s. 0d. to 15s. 0d.	4	22	32	26	15			
Over 15s. 0d. to 20s. 0d.	2	14	23	25	33			
Over 20s. 0d.		2	23	27	45			
No Answer	8	3	2	12	4			
	100	100	100	100	100			

Proportion of GPs Estimating the Cost within the Calculated Price Range for the Amount of the Preparation Prescribed

* Source: Sainsbury Report, Table 14, p. 191.

whether they had chosen a cheap or expensive preparation. However, 68 per cent of the GPs questioned could not tell, within a 5s. 0d. range, the cost of these prescriptions costing between 10s. 0d. and 15s. 0d. Sixty-three per cent gave incorrect answers on those costing between 15s. 0d. and £1 and 51 per cent gave incorrect estimates on those costing over £1. To some extent these high 'failure' rates may reflect the weakness of basing the test on arbitrary 5s. 0d. price brackets.

PROMOTIONAL COMPETITION

Promotional competition as a facet of product differentiation is a prominent practice in the industry. The case of Chemica showed that it is an insignificant obstacle to an entrant into the non-patented portion of the market. An entrant can gradually expand his promotional activities from a local to a national level as his resources grow apace. Physicians already know the attributes of the product in question and need be persuaded to switch brand alone.

In the remaining section of the market, 72 per cent by value, the need to spend highly on promotion is a very real barrier. The important question from an economist's view point is whether or not the barrier is a 'natural' one, or is 'artificially' heightened by the activities of existing members. Products for this section of the market can only be obtained by paying royalties or conducting R and D.

Pharma's sales force is the same size as Chemica's, yet what was ample for Chemica is inadequate for Pharma. The reason is obvious. Pharma is dependent for growth on technically new products, yet it will not receive licenses for such products unless it can provide a large market and the accompanying royalties to its licensors. By the same token Guinness is attempting to provide a net revenue through Crookes to cover its R and D expenditure at Twyfords. Only a large pharmaceutical turnover can support an R and D effort and only a nationwide and intensive promotional effort can provide that turnover quickly. Unlike Chemica, slow growth cannot content Crookes and Pharma who must conduct R and D and negotiate royalties respectively. Only Crookes, however, has the resources to ignore, at least for a period, the commercial losses entailed by heavy advertising prior to growth.

The barrier was no less real to Syntex who entered the drug industry proper only when it was large enough to market on a national scale. Prior to that it had licensed its products to already nationally operating firms in order to obtain sufficient royalty revenue to pay for its ever increasing R and D effort.

In so far as national promotion is required to provide funds for R and D, or a market for license bargaining, then high promotion is a real but unavoidable entry barrier and helps explain why all but one of the industry entrants since 1950 have been established firms. The suspicion remains, however, that this entry barrier has been artificially raised still further. Pharma maintained that forty representatives was the minimum it required. The marketing manager of a large and successful British firm recently remarked to me that it is an 'abuse of privilege' to visit a GP more than quarterly. This in turn necessitates a force of, say, over seventy-five representatives, each man visiting probably five GPs per day. The implication was that firms can and do visit more frequently than quarterly and that the message passed to the GP from the firm like Pharma will be drowned in the competitive din.

PRODUCT COMPETITION

The other main facet of product differentiation is competition between technically varying products themselves. Chemica and ICI's 'Imperacin' illustrate how firms need not participate in product competition to enter the industry. Most entrants must, however, and the difficulties of Pharma in obtaining unique licensed products, the costliness of Twyfords' R and D to Guinness and its riskiness epitomised by its lack of technical success have already been shown to be formidable inhibitors of entry to any but the deepest of pockets and stoutest of hearts. Size of R and D effort, however, is apparently unrelated to success in producing technological differentiation. Unlike promotion, in R and D manpower unit does not neces-

sarily need to be matched with manpower unit in order to provide equivalent competitive strides forward. This Syntex, in its early days, clearly illustrated. Even Syntex, however, did not commence the costlier, more routine, long-term pharmacological testing and dosage form development associated with later stages of the R and D spectrum until the mid-fifties when its liquid resources were increasing fast. Pharma has already been seen to have problems in pushing along this sort of development and minimising its lead times.

Product competition, like promotional competition, as performed in the drug industry is thus an important barrier to entry. Is R and D then a wholly natural barrier to entry, or may it, like promotion, have artificial elements? Mr Steele for one, claims that drug industry R and D has not been successful in producing new products, it has produced 'merely substitutes' not contributing to firm growth and hence should not be regarded as a natural entry barrier.¹³ While it is unpleasant to see a member of one's own profession putting forward sweeping beliefs of this nature so obviously at odds with the facts it is nonetheless true that many more balanced commentators do consider that some drug R and D is directed merely at producing technically illusory but highly marketable product differences. R and D could then be suggested to contain elements of artificial entry barriers in the same manner as promotion, as R and D departments vie with one another for the latest marketable advance.

Socially many such 'advances' are, of course, readily defensible both from the patient's and the prescriber's standpoint. They may be quicker acting, more pleasant-tasting, have fewer side-effects, present less complicated regimens, be synergistic in action and so on. There are many reasons why the 'more equally suitable medicine' be prescribed. Can the small proportion* of R and D which is directed at such real or apparent technical differences, and by implication the promotion of such differences, be justified from a purely economic standpoint?

It must be conceded that imitative R and D is a real cost to the community. Resources have been removed from other uses whose value discounted in perpetuity will measure the cost of imitation to society, namely the continuous loss of future production possibilities. Clearly this is wasteful but three important factors have been ignored.

Firstly, it is assumed that the R and D has merely resulted in a second source of production of the commodity, this source being precluded in the past by patents or some other imperfection. However, this will not be so, the 'me-too' R and D will have at the very least resulted in the discovery of some modification of the imitated product. Unfortunately purely theoretical analysis provides no tools to justify or condemn outright such

^{*} Of £16.6 million spent on pharmaceutical R and D, only £1.5 million (9.1 per cent) was spent on research of a 'me-too' nature.¹⁶

modifications. Each case would have to be evaluated on its merits. It is possible that this is an area where techniques such as cost-benefit analysis could be used to substantiate the economic and social values to be gained from the appearance of a 'not-quite-me-too' drug.

Secondly the ease of appearance of a production source of a 'me-too', or even a 'not-quite-me-too', will tend at least to keep the price and profit levels of the manufacturer of the original discovery to a point at least below the monopoly level. Product competition weakens monopolistic distortions. The community is better off with 'wasteful' imitative research than without it provided the discounted gains from decreased monopolistic imperfections exceed the discounted costs of the imitative R and D. This competitive result seems at least to be the case in the drug industry, since profits, at a modal 20–25 per cent, although possibly higher than normal under competitive conditions, indicate that any excess in price above a fair level 'seems', according to *The Times*, 'almost paltry'.¹⁴

The third factor ignored by those who assert that emulative R and D is wasteful is its effects on the firm in the long-run. Imitative R and D merely provides the company with something 'new' to sell. Should this be condemned in an industry where a company must innovate to stay in business? If *major* technological advances are to be achieved then R and D teams must be held together for a considerable length of time. However, no company, however big, however advanced, can remain technically in the lead all the time. Recognising this, Professor Levitt suggests that all companies must be aware of imitation as an essential to survival¹⁵ and hence, in the long run it is a social and corporate prerequisite.

In other words, the cost of imitative R and D is essential to provide the continuity which will indisputably result in new production possibility frontiers at a later date; it helps deter contrived scarcities and monopolistic pricing by facilitating market entry round patent barriers; and finally its 'imitative' content is itself open to debate since its output is so frequently of incremental social worth.

CONCLUSIONS

Product differentiation is the main barrier to entry in pharmaceuticals. Absolute cost barriers* and scale economies are of little consequence. In

* These are primarily the need to pay royalties, possibly at an excessive rate on existing patented drugs if the entrant wishes to market them. This, of course, begs the question as to why a recommendation that the artificial barrier of patents should be removed is not made. This is not discussed here, partly because of pressure of space, partly because of a conviction that some form of Schumpeterian protection from the Perennial Gale of Creative Destruction is necessary. In a technology such as pharmaceuticals where a new chemical can be quickly analysed and speedily copied by a clever chemist it is not automatically apparent that the innovator's 'head start' will be sufficient of itself to provide the funds and inducement for continuity of R and D. Such a 'head start' would [contd. on p.19]

nearly 30 per cent of the market even the former barrier is absent although fear by prescribers of sub-standard manufacture may render entry by newly established firms difficult.

In the remainder of the market promotion is needed on a national scale to provide the market size necessary to support the practice of obtaining technical product differences. It seems probable that this very real barrier has been raised still further artificially and that the ability to repeat the same message frequently has become necessary as firm vies with firm in a vicious spiral. Controls on advertising, however, must be imposed with care since any limitation on the *proportion* of turnover a firm can spend on promotion may, given the *absolute* threshold minimum of forty men, legislate against the small firm rendering entry barriers even more formidable than they already are.

Technical differences can usually only be obtained by large and continuing R and D efforts which require in turn either large resource reserves or a large market, in the long run a large market is essential to all. It is possible that this barrier, too, has been raised, like promotion, but straight comparisons of this nature cannot be made since R and D is intrinsically uncertain in outcome. Minor technical advances, however, need not be subjects for attack, but possibly for defence on social, medical and economic grounds. This is a subject which could well do with further analysis.

Product differentiation barriers, however, can be evaded as Syntex has clearly shown. This immediately begs the question as to why there is no British Syntex? Or at a wider level why no British Route 128? (There has, of course, been cross-entry by a few established firms, such as Crookes or Beecham, from other industries as Table B indicated.) Recent legislation has made successful and timeous innovation more difficult than ever for the smaller firm, however desirable at first sight that legislation is to the community. Is there then not a case for some form of easier credit provisions for R and D at the later, costlier and yet less risky end of the R and D spectrum? Say soon after discovery of pharmacological activity. This would encourage pharmaceutical innovation generally while simultaneously encouraging entry and growth of the smaller firm with a new, semideveloped discovery. In recent years exporters have been a favoured class in the industrial community. There are very many cogent reasons why innovators also should receive similar treatment. Certainly the open hos-

be exceedingly brief, at the end of which competitors with no R and D overheads to finance could quickly enter the market using the aggressive pricing tactics currently observable in the non-patented section. Having said this it is possible that the monopoly profits which are attainable behind patent barriers are so high that they encourage potential entrants to search for more minor (and patentable) product differentiations than can be justified by the arguments already put forward in support of 'me-too' R and D. This suggestion could provide material for a discussion in its own right, here a footnote must suffice.

tility to the pharmaceutical industry from many differing guarters in the past decade can have done little to encourage a truly entrepreneurial desire to enter the industry.

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Research Organisation

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RESEARCH is proliferating everywhere, and our lives are shaped to a large extent by research. To the pharmaceutical industry research is as fundamental as wheels to a motor car. But the organisation of research has received little attention, and the Office of Health Economics deserves thanks for having arranged this meeting, though it is doubtful whether they deserve any thanks for the choice of their speaker.

Since we shall be talking about research we should perhaps remind ourselves what it is. All research is of course an attempt to recognise facts by the application of logic to observation. An experiment is an arrangement which helps observation. These statements are true of all research, academic and industrial alike.

The kind of organisation which I shall discuss serves the medical profession. The medical profession exists for the prevention and treatment of disease. The pharmaceutical industry exists to serve both these aims, though at the moment the emphasis is more on treatment than on prevention. Good medical practice is a little art and much science, good pharmaceutical research is all science. Our work may be scientific, but our organisation is not. Science deals with facts, organisation is only a hope that certain arrangements will work. Inevitably a talk about organisation will lack the precision of a scientific report.

The views I shall give are not those of my company or of my group of companies, but obviously there is strong agreement on everything that matters. I have no doubt that my own idiosyncratic opinions can be easily recognised.

THE RIKER GROUP OF COMPANIES

Riker Laboratories were founded in Los Angeles in 1948 as an offshoot of Rexall Group, to develop new prescription medicines. Since then Rexall has grown into a very large corporation, diversified in many fields which include, in addition to the general pharmacy products for which Rexall

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have been long known, plastics, petro-chemicals, cosmetics, glassware, packaging, and several other kinds of manufacture and commerce. It has been headed for more than twenty years by a brilliant man who is one of the outstanding figures of American industry, and the Rexall board has several people on it who are world figures in their own right. Rexall is large by North American standards, very large by European standards. and it is growing fast. There is thorough financial control from the centre. coupled with much independence of subsidiary companies. So for the purpose of this talk we need only consider Riker Laboratories, a group of companies also based on Los Angeles. Riker Group deals almost exclusively with prescription medicines, in Britain only with prescription items and bulk pharmaceutical chemicals. The group chairman of Riker is a member of the Rexall Board, a former academic pharmacologist with a medical qualification, who has been research director and then president of the American Riker company. His predecessor who helped to build up Riker was also a former professor of pharmacology with a medical background; he retains his seat on the Rexall board and is still a consultant to the Riker group of companies. Thus Riker has had only two heads since it has achieved any sizeable activity, and both of them were able to exercise some of the functions of research and medical director for the group. There has never been a group medical director or a group research director as such.

The policy underlying Riker marketing is world-wide expansion and the formation of independent companies in any country where sales justify it. The first operation of Riker Laboratories outside the United States was in this country, and from the day when it began in 1951 Riker UK has been headed by its present managing director under whom the company quickly rose to be one of the top twenty suppliers of prescription medicines in Britain as well as a leading exporter. From what I have said it must be clear that Riker management has been characterised by independence, continuity, and success.

RIKER RESEARCH POLICY

Riker research, like everything else in Riker, began in Los Angeles as an offshoot of work going on in Rexall. It rapidly contributed to the growth of Riker in the United States and in all parts of the world. In particular it led to pioneering discoveries in anti-hypertensive treatment and in aerosols dispensing measured doses of micronised particles.

The policy underlying all Riker research has been that as soon as a research laboratory in one country was large enough to be viable, research should begin elsewhere. I have already said that marketing policy has been expansive, and there are now eleven Riker companies and three research laboratories. Exports to the many countries of the world where there is as yet no Riker company are almost entirely from the United Kingdom. The success of Riker Laboratories in Britain also led to it becoming the site of the second Riker research laboratory. This was started in Welwyn Garden City in 1964 and it is now close to what in present circumstances seems to be the right size of about 130 people. The third laboratory was started in Australia in 1966.

It would be unwise to predict what will be the future development of Riker research but I shall describe the work of the three laboratories as it is now. I might mention in passing that some research is planned or even in progress in France, partly because of French Government regulations which require that pharmacological and toxicological work for registration of a new medicine should be done under the supervision of experts appointed by the French government.

Riker Laboratories spend one-eighth of their gross receipts on research. There is no strict rule that the money should be spent where it was earned. The results of research are available to all Riker companies, the cost is shared in proportion by all. Until now Riker in Britain has been particularly successful in achieving a high volume of sales, much of it from exports, and the cost of research in this country is much lower than elsewhere, so that the British operation has helped to finance research elsewhere. But until now the success of Riker's British sales has been largely the result of research carried out in the United States, so that this country has benefited from American capital and brainpower, not the least by exports of Riker products from Britain.

THE ORGANISATION OF RIKER RESEARCH

Each of the Riker Laboratories is comparatively small, consisting of some 130 people. In Australia this figure is not yet achieved, and we are somewhat lagging behind it in England, partly because of difficulties in finding the right staff and because we lack suitable accommodation.

Until a little more than a year ago there was a single research director in each of the three laboratories, with a medical research department under him. Since I happen to have medical and scientific qualifications, it seems right that both these aspects of research should remain joined in the British research division. Conditions which are peculiar to the pharmaceutical industry in the United States have made it necessary two years ago to create a separate medical division in the American Riker company under a medical man equal in standing to the non-medical research director and working closely with him.

In Britain there has always been a special medical department responsible for carrying out trials of products already on the market, training medical representatives, and supervising promotional literature. This has historic and geographical as well as practical reasons, because this medical

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department existed before there was any research in the British Riker company. It continues because experience has shown that it provides marketing with the right kind of medical advice that it needs. It relieves the research division of some routine and it overcomes the fact that the research division is situated in Welwyn Garden City while the rest of the company is in Loughborough more than 100 miles away. Quite recently the American company has followed this lead and created a small medical department outside the research and medical divisions, to help train representatives, write literature, and service products already on the market. I think that this is a wise move because it gives the medical profession, who are our customers, a better service and it enables our medical research staff to deal with the difficult problems of products still under investigation.

In Australia clinical pharmacology and clinical trials of new substances originating in Australia are under the control of the research director. But there is also a separate medical director who carries out services to products in use and deals with trials of new medicines originating elsewhere in Riker Group than in Australia. This again is a logical arrangement because for the time being most of the new substances that are tested clinically in Australia have arisen from outside Australia and they would put an unnecessary burden on the growing and developing research division.

All this shows that details of organisation are flexible within any one research laboratory and vary between different laboratories. Adjustments are made all the time according to varying needs of the work and according to the training or skills of the people who are available. More will be said about this later, but adjustments are never made ruthlessly at the expense of the careers or of the scientific interests of those whom we employ.

AREAS OF RESPONSIBILITY

Clinical trials often have different requirements in different countries because social conditions, climate, race and medical customs differ. But laboratory research is more widely applicable. Each research division has areas of responsibility which go beyond the needs of the local company, though of course local needs are part of these responsibilities. The laboratory in Australia has some good chemical pharmacologists who are able to do metabolic studies, and it has good staff and equipment to deal with the pharmacology of the central nervous system and of sympathomimetic amines. Riker are of course predominant in the field of inhaled bronchodilators, so that pharmacological work on sympathomimetic amines is of great interest. But as far as the central nervous system is concerned the main interest is in the control of obesity, which is also a field in which Riker Laboratories are predominant, and the Australian laboratories are mainly concerned with this.

In the USA there are also good neuropharmacologists, and their inter-

est is again concentrated to some extent on the control of obesity. There is also much systematic screening of new chemical compounds available from all kinds of sources, synthetised for various purposes, which ought to be looked at from the point of view of other activities, such as the circulation or behaviour. One of the best abilities of the American laboratories is in the study of inflammation, and there is also good ability for radioactive absorption and excretion studies.

The main interest of the British laboratories is in broncho-pulmonary diseases. Thus in pharmacology we study mucolytics, bronchodilators and respiratory stimulants. The interest of the Australian laboratories in sympathomimetic amines is complementary to our work and fairly closely integrated with it. There is a microbiological laboratory in England, the only one in Riker. It has facilities for very wide work in microbiology but our studies in that field are also increasingly related to diseases of the lungs. We do not do much chemical pharmacology here. That is done in other Riker Laboratories. But we do study metabolites of chemical substances which we are investigating, often by advanced analytical techniques.

Toxicological tests can be carried out in all laboratories but teratological investigations are only done in England. Only the American laboratories use primates for pharmacology and toxicology.

In England there is a small special projects laboratory which is under my control, with two skilled technicians. It is available to deal with any unusual problem that may arise, but at present it is occupied almost entirely with the study of a special aspect of malignant tumours. It would be folly to spend much time or money on cancer research when thousands of people are engaged in it all over the world without any very brilliant success. But we have an approach which is to some extent our own. Although the chance of commercial success is small, this is a reasonable gamble of a little effort on important but remote aims. If nothing else, it gives me a chance to be directly involved in research. For a research director to do research at the bench and to publish papers about it is not an affectation. It is a safeguard against becoming obsessed by administration which is the servant not the master of research. It helps to understand the problems of those who do the exacting and often disappointing day-to-day work of the laboratory. It prevents the loss of scientific judgement engendered by desks-full of paper. There are few people in our laboratories who have been trained in research but never use their skills. In the case of heads of departments it is their own decision whether they do any laboratory work or not. Most of them do.

Pharmaceutical research depends largely on the chemicals available. We have medicinal chemistry sections of about eight graduates each in America and Britain and a smaller one in Australia, which synthetise substances for

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biological testing and work very closely with the biologists in modifying chemicals according to screening results. I have no doubts, and this is also clearly Riker policy, that it is the right way to do it. To synthetise large numbers of compounds and to screen them over a large number of tests seems wrong, especially for our kind of company. As we have seen, there is careful selection of what fields we enter, and there must be equally careful selection of the chemicals we test. Pharmaceutical research is like betting on horses or playing poker, where luck and judgement both count. It is not like roulette which is entirely a matter of luck. Firms that try to enter every field are like a man who backs every horse in a race and is bound to lose in the end (unless all the bookmakers are nodding).

It is clear from what I have said that although the three Riker research laboratories are at three corners of the world, they work as one, with a co-ordinated programme. The advantages of this are to my mind overwhelming. Because the approach to research differs in different countries, because each laboratory has its own academic contacts and consultants, because each laboratory has a certain amount of independence and ability to use its own initiative within a broadly defined research policy, the whole is undoubtedly bigger than the sum of its parts. A little overlap exists, yes, but if we all sat in one large laboratory there would still be some overlapping, though perhaps more surreptitiously. If people want to grip hands for support they cannot do it by merely touching fingers. There must be areas of contact and overlap, even areas of friction.

INTERNATIONAL LIAISON

Contact between the three laboratories is largely maintained by good personal relationships. It is a truism that if people are thrown together under any circumstances, they will mostly get on with each other and only rarely fight. If staff is carefully selected, then serious conflicts of personality can usually be avoided.

Research directors and medical directors have been meeting once or twice a year, occasionally even three times a year. When we meet we have some formal sessions presided by the group chairman and attended by the managing directors of the major companies in the group. The research and medical directors sometimes also spend a few days away from the laboratories, perhaps in a holiday resort or in somebody's country cottage, without deliberate emphasis on work, but in fact we seldom talk about anything else. Some of our best ideas, both in research and organisation, have originated on such occasions, although the ideas were usually developed later. We often disagree and sometimes argue, but all the research directors and medical directors in the different Riker laboratories are good personal friends who enjoy working together and who understand each others' minds. Heads of departments, such as senior pharmacologists, chemists, development pharmacists, and so forth, also meet from time to time, and as the years go by they get to know each other better and better. The time and money spent on air travel between laboratories is well spent. The extra cost of having separate laboratories is about 5 per cent and it is recovered many times over by the fact that research costs less in England or in Australia than in California and that the marketing of prescription medicines is more efficient if it is backed by locally established research.

Informal meetings between people working in different laboratories cannot be very frequent. This difficulty is partly overcome by personal letters and by the fact that many of us use the same kind of dictating machine, so that we can send tapes to each other and discuss things verbally before putting them officially to paper. By and large we have all the formal and informal contacts between laboratories that we need.

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Co-operation within this country is equally important. Departments of the research division must work as a team and all must fit as a single team into the company they serve. Departments are practical sections formed by people using similar techniques or dealing with similar aspects of the work. Teams for any particular task are often made up of people from different departments or even people outside the research division.

All the heads of departments in our research laboratories are present at monthly research meetings where work is planned and co-ordinated. It is important that they should all be there. They may get a bit bored when talk is remote from their field, but they are mostly interested in all aspects of our work. Although they might be fielding as it were near the boundary, they might suddenly see a high ball coming towards them and have a chance to contribute to the match. To take an example, it is invaluable that pharmaceutical development should be represented at all stages of planning. A medicament is something that has to be stored, transported, swallowed. Unless it is thought of in that way from the beginning, much work may have to be discarded, or time-wasting work may have to be done later when everything else is ready.

Team work at formal meetings and every day is the essence of our internal organisation. People drop into each other's rooms and speak to each other on the telephone at any time. The disturbance which such interruptions cause is of course a disadvantage, but it is better to have problems discussed when they arise than to wait for a prearranged meeting by when the idea might have evanesced. I see everybody in the research division at any time. Thus I get a better sense of what is going on and the staff get a better understanding of the main issues. Decisions are only made in conjunction with heads of departments, but problems are discussed by all concerned, regardless of standing. As a result, some problems are solved

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almost before they arise. But many of us find that work requiring continued concentration has to be done in the early morning, in the evening, or at the weekend. This kind of system is only possible if everybody is prepared to work hard and to get on with each other.

Our relationship with the rest of the British company is similar. The company of course exists to find, make, and sell, medicaments for prescription by doctors. The research division is that part which deals with the finding. Finding does not only mean the invention of new molecules. though this could be the most important function, but also new applications of old molecules, new formulations, and work on substances which are obtained under licence. Obviously the rest of the company cannot make or sell what we do not find. Equally obviously there is no point in our finding what others cannot make or sell. Therefore, we must work closely with production and marketing. This is again achieved by regular meetings and by good informal relations. Those who inform doctors or train representatives know about research projects at a very early stage, as soon as success seems at all possible. Consequently they must also share the many disappointments about hopes that fail. It is a matter of judgement when to bring in the production and marketing divisions so that they neither waste too much time on failures nor hold up development when the research division has done its work.

Co-ordination is the main task of a senior executive in the research division who has high academic and technological qualifications as well as wide academic and industrial experience. He is present at all meetings concerned with any aspect of new products or improved products. He heads a working party which contains, in addition to him, one key technical person from marketing, production, and research, and which meets every week to consider and co-ordinate the progress of all projects that have reached an advanced stage of development. This senior executive circulates progress sheets on every aspect of each product under development and issues a new sheet whenever there is any progress. The sheets are seen by all those concerned with the work, their superiors, and also by overseas laboratories. He also collates and edits submissions to the Committee on Safety of Drugs.

There remains much elasticity in the system. But our progress sheets always estimate the dates by which each aspect of a project will be completed, and we co-ordinate all these aspects on the basis of a flow chart. This means that we usually get answers quickly. If a new medicine fails for any reason it is important to know this soon, so that lessons can be learnt and efforts switched to something more promising. If the medicine succeeds it is important to get it produced quickly. It would indeed be intolerable if production or marketing experts were idle because research dithered, and worse still if therapeutic advances were withheld from patients because of administrative delays. Although one cannot hurry research or take risks with quality, an efficient organisation must achieve the best in the shortest time.

COMMUNICATION

An important feature of communication is that copies of letters and reports are widely circulated. Every day I find a number of copies of letters on my desk and I send many to various people all over the world in Riker companies. It is not up to me to judge whether they should see that letter or report; it is the recipient who decides whether he wants to know. By this system everybody is kept informed. This is one of the things American management does well and I am still learning something of their skills in that field. Of course there are lapses. Some of us are more sensitive than others if there is anything that we were not told. But sensitivities apart, there is hardly ever any serious breakdown of communications.

Reports are of course an essential part of all research. Results which have not been communicated are no results at all. The difference between academic and industrial research is that negative results and unsuccessful experiments are seldom reported in academic research but can be part of the general know-how of a company. There is still some selection, for some tests are not worth recording (failures when apparatus breaks down and such like), but by and large we report all our findings, especially syntheses, screening results and adverse effects. Reports go to top management and to technical staff in the same and other laboratories.

INTERNATIONAL REGISTRATION

Until recently any laboratory that began a project was responsible for it till it was ready for marketing. The research director of that laboratory co-ordinated all the work and asked for help from elsewhere if he needed it. If there was a separate medical director, he co-ordinated the work when laboratory research was complete. That is still true for projects which are not of interest to all or most Riker companies. But the complexity of registration in different countries and the difficulty of obtaining satisfactory clinical results makes it necessary that projects which may be of wide interest should be recognised at the earliest possible time. These projects are co-ordinated by the chairman of the group who, as mentioned above, is a medical man and a former pharmacologist. Information is still exchanged directly between the different laboratories, but the group office keeps a watchful eve on the need to get as much clinical pharmacology and as many clinical trials done as possible with the least delay, in order to make the right decisions about the product and to have all that is needed for registration wherever marketing is intended. Medical directors in Riker arrange their own trials in hospitals. Managing directors decide for

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themselves, in conjunction with their marketing directors and their own medical advisers, whether to market a product or nor. But the group chairman's co-ordination and his ability to judge the issue from a global point of view is a great advantage.

Requirements before anything can be marketed involve not only pharmacological, toxicological and clinical work. They involve chemical standards, quality control, formulations. In this the diversity and unity of Riker research is an advantage. All the three main laboratories and some other Riker companies, especially in Germany and France, have facilities for formulation and analytical control. Here again, close co-operation is kept up, and it often happens that a problem which arises in one country is solved by some experience or knowledge gained in another country in a previous similar situation. The advantage of recording and reporting all findings is evident in this context. Since many products are sold all over the world, a large body of knowledge has accumulated about them under all kinds of climatic and other conditions. This is as it should be, because patients and prescribing doctors must be served well. But there are the added demands of authority.

We should remind ourselves here that authorities impose much work on all industrial organisations. The amount of paper-work required by legislation is formidable and its cost in wasted manpower is terrifying. In the present context we need consider only work concerned with the registration of new medicines. All over the world registration authorities are becoming more and more difficult and new products are more and more scarce. As a result of this each Riker research laboratory must conform with the needs of every country where Riker has an interest. All work is so carried out that any laboratory test or human pharmacological result or clinical trial should meet the strictest registration requirements of other countries where Riker may wish to introduce the product. It is no use pretending that this is easy.

In this country and in some others, especially in Australia and New Zealand, the registration authorities have until now applied reasoned scientific jugdment rather than rigid rules. The advantages of this are of course overwhelming. The onus is on the company submitting a substance for clinical trial or for marketing to have thought of every risk and to produce adequate evidence of efficacy and safety in the knowledge that this evidence will be judged by experts who are not easily fooled. But in some countries the approach is bureaucratic. Assessment is made by officials according to rules from which they have no power to deviate. The rules may not be relevant to the situation, but they must be enforced. The assumption is that the public interest is better served by officials whose actions are laid down by law and against whom there can be few sanctions than by scientists whose reputation and livelihood depend on being right.

Scientists are trained to think of the unforeseen, legislation cannot allow for what is not yet known. Thus it is possible to combine inadequate protection of the public with unnecessary difficulties for those introducing a new medicine. These criticisms could not by any stretch of the imagination be levelled against the Committee on Safety of Drugs in Britain.

I have spoken about all this mainly because it shows that our research must be organised to cope with any legislative situation wherever it arises, whether it is reasonable or not, and that we must still be ready to notice what legislators cannot predict. Of course every treatment involves some risk, but treatment is the essence of medicine. It is the duty of doctors to balance the advantages and disadvantages of treatments, for they have the training and the responsibility to do this. It is the duty of manufacturers to provide evidence of advantages and disadvantages. It is the duty of Governments to help both. Authorities which assume that they know best are no less dangerous than a pharmaceutical manufacturer would be who thought he knew best and did not accept any control.

FREEDOM AND LIMITATIONS

The enforcement of ideas is a danger in all research, whether it comes from outside or from within. It is an occupational disease of research directors to draw complicated formulae, to ask chemists to make them, to tell pharmacologists or toxicologists how many animals should be tested and at what dose levels, to indulge in thinking up fancy clinical trials. We try to avoid it in Riker. This game is also commonly played with overseas subsidiaries. For example protocols are sent out to experienced clinical research men who are told to arrange a trial precisely as directed, although the clinical problems in that country may be widely different. We avoid that too. Indeed lack of rigidity could be one of the reasons why Riker has grown so fast in so many countries. Not only research directors and medical directors have freedom to plan their work within the general policy and within their budgets, but also heads of departments and people responsible for individual jobs.

I consider it important that all should know what freedom and what limitations they have, that they should be able to use their initiative and imagination and get credit for what they do. Useful knowledge can be gained from experiments carried out on the spur of a sudden idea. If the idea leads nowhere it will do no harm, at any rate no more than if it had originated from the research director or from a committee. But if a single good idea fails because the administrative structure has prevented it, then the structure has serious defects. If a good man gets bored and leaves a research laboratory it is not only that man who is lost, but several others who hear about it and do not apply for jobs in that laboratory. People with ability like to think for

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themselves and to act upon their thoughts, otherwise they deteriorate or go elsewhere.

STAFFING

Most of our staff have their first job in industry with us. This is not deliberate policy. We are trying to get people of ability, and we tend to get those who may not stay with us very long but who look upon Riker Laboratories as an opportunity to gain experience in the pharmaceutical industry. It is obviously better to have three good men doing one job successively for fifteen years than to have a mediocre one all that time. The loss of good people is sometimes avoided by giving them a standing and a salary that recognises their merits, but this is not always possible. It would be bad research management to create a new senior job only because somebody deserves promotion.

Our junior technicians mostly come straight from school, and we are generous in enabling them, even encouraging them, to obtain further training at technical colleges while they are working for us. Our young graduates mostly come straight from University with new degrees of various kinds. Our senior staff often comes from academic appointments.

During the last three years five people have joined Riker Laboratories in England at levels involving executive and managerial responsibility. Three of these were university lecturers without previous experience in industry, apart from short vacation jobs. One came from a senior academic job with previous experience in industry, and only one came from another industrial laboratory where he had worked for a number of years. One of the former lecturers has already moved on to a very senior job in another company. Three others of our senior research staff have obtained more responsible jobs in other companies during the last three years.

It will be seen that our staff movements are usually spontaneous and arise from people's ambition to get better jobs. We do not create or cancel jobs lightly. Internal reorganisation always considers the needs of projects and the interests of people who are already with us. This means careful planning because one cannot continue work on useless projects in order to keep staff busy and one cannot dismiss staff because their projects fail. But difficulties seldom arise because a good scientist is usually busy with a new and promising problem before others have noticed that his last one has died.

The brightness and unconventionality of some of our staff is an advantage. They themselves tend to select capable young people. They are young, fit, and ambitious. They accept with varying degrees of enthusiasm or reluctance that it is better to have too few people for the jobs in hand than too many.

This brings us back to our comparatively small total numbers. People

looking for something to do seldom find anything useful. People with too much to do will select (if they have the ability) those jobs that are the most important or the most promising. The history of research, whether academic or industrial, shows that success seldom comes to large leisurely teams, but that knowledge is often advanced by small overworked teams which must concentrate on what matters. This fits in with our policy of getting the best people we can find, giving them the best possible equipment, preferably of their own choosing, getting them to work on good problems, again preferably of their own choosing and within the limits of a policy which they have helped to formulate, and leaving them alone to do the job.

ACADEMIC CONTACTS

The transition from academic to industrial work is not as difficult as it may seem. I have done it myself. After having spent all my adult life except when I was in the army within the precincts of universities. I found myself plunged into industry as a research director with a large British group of companies when I was approaching the age of fifty. The biggest difference seemed to be in the greater efficiency and integrity of industry. The standards of British industry are those of the City of London where a man's word is his bond. The games played at academic committees (and before the committees meet) have little or no place in industry, at least not within my experience. A university lecturer who has recently joined us has commented with surprise that important decisions are being made at comparatively informal meetings. But if everybody knows his job and everybody's lovalty and decency is a foregone conclusion, there is no need for formality, only for good judgement. Indeed the main difficulty which I found (and occasionally still find) is that I sometimes relapse into arguing about trivialities, to me interesting trivialities, the way one does at academic committees or in scientific societies. This happens especially with colleagues who have also grown up in an academic environment. To us it seems clarification of a small point. To some of our colleagues who grew up in industry, it can sound like squabbling.

Yet it would be impertinent to claim any superiority for industrial research. We provide little fundamental knowledge, as a by-product of our research into applied therapy. When we need fundamental facts or advice on fundamental facts, we go to universities. Our co-operation with university departments, both in medical schools and outside them, is widespread and close. We have a number of academic consultants who visit us regularly and talk to those on the bench. We often take problems to university departments. In return we may contribute to the department by providing equipment or staff to do the work. Sometimes university departments or hospitals ask us to do certain tests for them, and joint publications between

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them and us are not infrequent. Moreover, in recent years there has been some government pressure on technical colleges and technological universities to co-operate with industry. We are often approached by these institutions and we have set up some useful collaboration with them. For example we are screening the actions of compounds synthetised in universities, and we accept research students who do part of their higher degrees with us, working on our problems. There is also close co-operation between Riker Laboratories and Indian Government research establishments whereby compounds synthetised in India are available for screening in any of the Riker Laboratories, and we have facilities to conduct clinical trials in India. This has been arranged through the initiative of the Riker research director in Los Angeles. It is of course a help to Indian research, and it widens our scope of activity without an excessive burden on our staff and resources.

CONCLUDING REMARKS

It will be seen that in many ways Riker Laboratories are far from typical among British or American pharmaceutical companies. Our loose administrative and close personal links, our wide geographical distribution and narrow specialisation in certain fields of therapeutics, make us unusual. Perhaps our obsession with quality rather than quantity is less unusual. In relation to the short life of the Riker Group of companies we have been successful. But the research laboratories in Welwyn Garden City have so far produced no major advance in terms of therapy or marketable products. We may have justified ourselves in small ways, especially improvements, new formulations, new evidence of the safety of existing medicines in the light of recent scientific advances. But if any project now in hand is successful, our method of working may help it to come to fruition more quickly and more effectively than might have happened otherwise.

As I have suggested earlier, organisation is a servant of quality, not a substitute for it. The distance between a promising project and a successful product approved for marketing, appreciated by patients, doctors, and shareholders alike, can only be shortened a little by good management. In the end success depends on the skills and the luck of the people inside the laboratory.

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ECONOMISTS have long considered it their prerogative to advise and criticise business management, to advise and criticise governments in their relations with the business world, and to construct theoretical models to teach their students that they may continue the tradition. My purpose in this paper is to re-examine the views that economists have traditionally taken of the business firm, which has always seemed to have many undesirable features, and to examine the underlying foundations upon which practical economic enquiries (whether surveys or case studies) have been built in order to evaluate their usefulness and to suggest alternative approaches which appear to me to be both intrinsically more interesting and practically more useful. Its full title should be 'The Economics of Managerial Behaviour and Pricing in the Pharmaceutical Industry'.

Unfortunately this paper will have a largely a priori flavour as there has been as yet no time to test any of the results here suggested, though at Exeter University we are beginning to formulate some ways in which this might be done.* In a sense, then, the title of this paper is a slightly fraudulent one, in that I am not going to tell you how it is that pharmaceutical managers make decisions about prices, nor how they ought to. Instead, I am going to examine the necessary initial stages before such important questions can be answered. Thus, we shall wind up with a set of propositions which remain to be tested properly in the case of the pharmaceutical industry, and only when that has been done will it be proper, in my view, to answer the questions which concern so many people-businessmen. health service administrators and lavmen alike-about whether profits. prices, advertising and so forth are excessive; whether patents have bad effects; whether innovation is too slow or too fast; whether the subsidiary structure of much of the industry makes it difficult to control, and so on and so forth.

^{*} This work is being done by Michael Cooper and myself.

The analysis here is therefore, for the reasons outlined, of general applicability rather than being specific to pharmaceuticals, but this makes it of none the less interest to those who are concerned, in whatever capacity, with the pharmaceutical industry itself, since the behaviour of this industry, once the basic principles are grasped, emerges as a special case of the more general theory. I make no apology for the use of the word 'theory', for it has been the absence of a really satisfactory theory of the firm which has led to the inability of professional economists to provide the kind of guidance to decision-makers of all types which they should have been able to provide. Instead we have had to make do with limited theories.* selective case studies, and liberal doses of dogma deriving not from a comparative advantage in technique but simply from political preferences-and economists' prejudices are worth little more than anyone else's. The absence of a satisfactory theory has led most practically-minded economists who are interested in industrial economics to adopt an eclectic approach to different problems, usually based upon a painfully acquired expertise with the ins and outs of individual industries and firms.

A valid theory, however, has enormous advantages, and we give up too easily if we reject the theoretical approach. First, and most important, theory gives us a short cut to the solving of some of the problems of industrial society, in that most of the predictions of theory are worked out in advance so that all one needs to do is to slot the specific problems into the appropriate part of a general theory for solution. Second, a theory gives one an understanding of how things work in practice-it gives one an analytical insight as compared with descriptive knowledge. Finally, only with a theoretical framework does it become possible to know what to look for as a result of changing one of the parameters that determine the behaviour of business firms. Without it, one has no alternative other than an exhaustive search of all aspects of a firm's behaviour before and after such a change, which is wasteful of time and expertise, and which is also aesthetically unsatisfying, and which also gives no basis for prediction. Usually, of course, students of business behaviour are less than fully exhaustive, and this is because, whether they admit it or not, they are working with some implicit theoretical apparatus. But it is far better to make the theory explicit and to search out as many of its implications in advance as one can. Then one has the usefulness of a proper theory and one also avoids the logical difficulties involved in using a whole collection of theories, perhaps one for each industry, and mostly mutually inconsistent.⁺

I do not hope to get very far towards providing such a theory in this paper, but I think we can travel some of the way. What we need is a more

^{*} For example, marginal cost pricing, normal cost pricing, full cost pricing, price minus pricing.

[†] For example, sales maximising is in general inconsistent with profit maximising.

general overall way of thinking about the operation of firms, into which idiosyncratic behaviour fits as a special case of the more general 'model', predicted under certain specifiable (and they must of course be specifiable) conditions. Furthermore, these conditions must be verifiable as well as specifiable. That is, it must be possible to go out into 'the real world' (as the empiricists like to put it) and actually be able to observe and ideally to measure these conditions.

Before progressing any further, it is as well to remind ourselves of the two major difficulties which have caused the traditional theory of the firm to stick in economists' gullets. These are first that businessmen maximise profits, and secondly that they set marginal costs of production equal to the marginal revenue derived from production. The theory is complicated to cope with monopoly, stockpiling, multiple products and so forth, but essentially the same analysis remains. Now in order to get our criticism of this classical analysis right we must beware of illegitimate objections. One of these, and it is a very famous objection, is in my view wholly erroneous and does no damage whatever to neoclassical theory. This is that since the vast majority of business firms have never even heard of marginal cost and revenue let alone understanding what they mean, they simply cannot equate them to discover the profit maximising rate and volume of production. The error in this criticism is to suppose that neoclassical theory was attempting to give a descriptive account of how pricing and output decisions are reached. It was not. It was an analytical framework not a descriptive one, which deduced perfectly correctly that if managers maximised profits (and the theory assumed that they did) then as a matter of logic, they must have been operating with marginal cost equal to marginal revenue. As a result, one may infer that the empirical discovery* that managers knew nothing of these concepts cannot have refuted the theory. Had the theory said that businessmen tried to maximise profits, and that to do so they tried to set cost and revenue equal at the margin of output. then the theory would have certainly been refuted, but it is my contention that the theory did not in fact postulate this at all, though the poorer sort of introductory text may well have given this impression of the theory to the unsophisticated reader. Thus a testable implication of neoclassical theory is not that mc=mr, which is in fact no more than a restatement of the assumption of profit maximisation, but the theory did provide a rich supply of other testable implications about what would happen to prices, profits, output, employment, investment, innovation, etc., if a parameter altered-for example if profits were taxed more heavily.

The first of the two objections to traditional theorising about the firm is,

^{*} The first of these was R. L. Hall and C. J. Hitch, Price Theory and Business Behaviour, Oxford Economic Papers, No. 2, 1939, reprinted in Oxford Studies in the Price Mechanism, ed. by Wilson and Andrews, Oxford, 1951.

on the other hand, far more damaging. This objection is to the assumption itself of profit maximising rather than the way it was implemented, and this objection I find overwhelming. There are several difficulties with it. First there is the difficulty concerning the period of time over which profits (whatever they may be) are to be maximised. Is it the short period or the long? In any case, is there any real meaning to be attached for operational purposes to 'short' versus 'long'. Given the assumptions of the analysis, there is, I believe, no solution to this problem. Rather, the difficulty derives from a more fundamental problem to which we shall return later.

The second difficulty derives from the definition of profits as a return to 'uninsurable risk'. If this is the correct definition of profit, and I believe that it is, then how can a businessman maximise something that an actuary cannot quantify? In other words, how is it possible to assume that anyone maximises what is uncertain? The answer, I think, must be that one cannot maximise what is not known, and that again the difficulty cannot be resolved.

The third difficulty arises from the curious schizophrenia in economics, which assumes that the ordinary consumer likes all good (as he sees them) things, whereas the entrepreneur, or business manager, seeks only profit: that is, that he is, in a way, the epitome of the economic man, getting as much money as he can and to the devil with a theory about human beings. Now it is, of course, an empirical assertion that all men have a diversity of tastes, but it is also one to which every human activity surely testifies. But if we now assume that businessmen are also human, we have clearly upset the foundation of the theory of the firm as it now stands, and we would not expect the traditional theory always to provide the right (in the sense of empirically valid) answers.

These points are, I think, enough to convince us that our starting point in theory, and therefore our starting point in practice, cannot be profit maximising, for not only are we unsure of what it means, but it is not easy to see how, even if we were sure of its meaning, it could be maximised, and it is decidedly odd to expect businessmen's behaviour to be so greatly at odds with the rest of humanity in seeking only money.

But if our starting point cannot be profit maximising, we have to have something else as the basic motivating force, for a behaviourist theory will have to have some maximand. What this something else is to be has long presented a puzzle, and the reason is probably that the answer was too simple to be noticed. It is that just as we assume that consumers maximise 'everything' so let us assume the same for businessmen. We will dispense with the old-fashioned concept of a single-purposed business motivation and then see how well the old wine will fit into the new bottles cast from this alternative approach. By maximising 'everything' I mean quite simply that anything that is desirable to businessmen will be an object of their

pursuit-they will want more of it than they have. By 'maximising' I mean not that they actually get everything that they want, but that they will, with the resources at their disposal, so arrange things that, at any moment of time, a businessman's decisions will be determined so that the things which he decides will bring him, so far as he can see, the best of attainable worlds. The jargon for this type of behaviour is well-known and being a convenient shorthand, we may as well use it: it is that businessmen maximise utility.* just as economists assume that consumers maximise utility. A little more precisely, what we mean is that businessmen behave as if they ranked preferences on a scale of better or worse, and that they choose, where possible, the better. With a little mathematics, and a few more assumptions to enable us to use it, we can define, in complete abstraction, the conditions for maximum utility, and then derive an extremely important implication which forms the foundation for the rest of the analysis.[†] This is the law of demand, which states that the more a person has to sacrifice of desirable things in order to attain a particular end, the less of the latter he will choose. t

Now it may, of course, be objected to this that though it appears perfectly reasonable to assume that managers have a utility function to maximise, it is also probable that one of the elements in that function may be profit. All that has been done is to reduce the status of profit from absolute to constitutional monarchy. In fact, the analogy is quite apposite, for just as constitutional monarchs are constrained by laws rather than God alone, so profit maximisation might be observed as an implication of environment rather than of the assumptions of a theorist-mystic. Some profits are, of course, desirable—or at least they are quite frequently, and so the terms of our new approach require us still to include them as an object of pursuit, but in general it is no longer expected on theoretical grounds to see people pursuing profits alone. Thus, if we have overcome one objection to the traditional approach, we have still to clear up the ambiguities surrounding the meaning and operationality of the profit motive.

The difficulty of asserting that managers maximise what is uncertain can be overcome by asserting that businessmen, when they seek greater profits, will be maximising the probability, given the information available to them, their hunches, and so forth, of achieving higher profits. The difficulty associated with the actual meaning of the word profit—whether it is long or short run, an economic or accounting concept, and so forth—can, I think, be resolved only by replacing the word by another which is less

* Not that they try to maximise utility.

[†] An explicit utility model of the firm is found in Oliver E. Williamson *The Economics* of Discretionary Behaviour, Englewood Cliffs, 1964.

[‡] In fact the theory is not quite as simple as this, and this prediction is only unambiguously true under certain conditions. As an empirical law, however, it has yet to be refuted.

ambiguous. It is, after all, rather naive to suppose, for example, that businessmen might want to maximise the net revenue for any particular year. He might in certain unimportant cases as, for example, if he knew that he would be dead next year and thus safe from shareholders after his blood for spoiling the market for years to come, but normally we may suppose that the businessman is after a flow of income through time. How else is it possible to make sense of the apparently responsible chairman who tells his shareholders that he anticipates 'losses' in the next few years but substantial 'profits' thereafter? When a businessman makes such a statement, and he is believed, the market value of his company rises, reflecting the increased expectation of future high income, but the effect of expectations occurs in the present—in the form of a change in the wealth of the owners of the company.* It is this increase in wealth which constitutes profit, and the appropriate variable in the utility function of managers to maximise is in fact the wealth of the company.

Now this interpretation of the concept of profit, while slightly different from the traditional interpretation, † has several advantages. First, it has the great virtue of being consistent with what businessment do, though they may not, of course, express it this way. As an example, the managing director of one pharmaceutical firm has said.¹ 'For years I have assessed every new project by the increase in the value of the business (as if it were taken over-not that I have thought that such an event were likely). It has been a way of translating all changes into a common denominator of capital that might be available under such circumstances so that the launching of a brand name product and the building up of goodwill in it. or the successful prosecution of research, can lead to assets of substantial worth, even though of course they do not show in the balance sheet. Paradoxically, they probably would in the balance sheet of any take-over company as goodwill'. Another leading executive in the industry has said,² 'Many companies in the pharmaceutical and other industries, including my own, often say that their pricing policy is dictated by "what the traffic will bear". This can be interpreted so far as my own company is concerned as meaning that price which will yield the maximum profit over the expected product life'. Not many businessmen would, perhaps, put the matter as succinctly as these two have, but here we have examples of

^{*} Wealth maximisation is explicitly considered and developed into a theory of costs and outputs by Armen Alchian, Costs and Outputs, in Abramovitz et al., The Allocation of Economic Resources, Stanford, 1959. A literature has since grown up around this theory, see: Jack Hirshleifer, The Firm's Cost Function—a Successful Reconstruction?, Journal of Business, Vol. 35, 1962; and W. Y. Oi, The Neoclassical Foundations of Progress Functions, Economic Journal, No. 307, 1967, for two out of several.

[†] The interpretation is, however, not new, and concepts of wealth, profit, income and interest consistent with those used here are in Irving Fisher, *The Theory of Interest*, New York, 1961 (reprint).

exceedingly able and rational management which illustrate perfectly the interpretation of profit, or wealth seeking, that I have suggested, which is in the first place a capital value concept relating, in the second place, to the period of time defined by an output programme.

A second advantage is that we thereby remove the inconsistency of statements like the anticipation of future 'losses' with a rise in the equity of a company. Now this approach also requires a modification of some other concepts at the analytical level-for example, it is no longer possible to identify costs with time rates of money flows. A capital value measure of costs must also be used. There are also several other modifications that are implied at the *a priori* level, which it need not concern us to go into.³ The interesting point which emerges, however, is that when marginal costs and revenues have been appropriately redefined, the conclusion of neoclassical theory remains that the wealth maximising firm will set marginal cost equal to marginal revenue for any output programme. Similarly, in this special case of pure wealth maximising, all the classical implications about changing prices and outputs as the parameters alter also hold. What does not hold, however, is that the businessman sets 'short' or 'long' run cash flow marginal cost equal to marginal revenue. Little wonder, therefore, that economists have had difficulty identifying this activity in practice, and in persuading businessmen of the meaning and relevance of the concepts.

The wealth of a firm is therefore its equity, and an increase in this value is termed profit, even if the businessman failed altogether to anticipate it and it arose, for example, from a sudden bullishness on the stock exchange. Not all companies are, of course, quoted on the exchange and we do not always have a ready measure of market-determined wealth, but it is there in principle—it is the maximum price for which an enterprise could be bought.

A difficulty in applying this theory, which is, incidentally, a difficulty common to the classical conception as well, lies in identifying wealth maximising companies, and I think we must face up to the fact that it is not possible ever to know whether a particular firm is maximising its wealth or not. This objection, however, is less damaging to the reinterpretation than it was to classical theory. In the latter, it was not possible to test the truth of the profit maximising assumption, and so the validity of the theory had to depend on whether the predictions of the theory held up in practice. Since they frequently did not, the advice and recommendations of economists were suspect, and furthermore, they had nothing else to fall back on. With the alternative approach, in which companies' wealth is merely one variable among many which enter managers' utility functions, we are not so helpless, for we can now attempt to specify the *conditions* under which we expect to observe wealth maximising, in other words, wealth maximising has now ceased to be an assumption and has become an impli-

cation (as we shall see) of the environment in which businessmen operate We still cannot identify the wealth maximiser, but we shall now be in a position to state the conditions under which we expect to see relatively more wealth maximising than other-maximising, and hence we can specify the conditions under which the traditional implications will hold true, and then test. This may be extremely important in some circumstances. In the case of the pharmaceutical industry, consider a very simple example. Suppose that there are two firms both spending substantial sums on innovatory R and D, but one firm is a wealth maximiser, while the other sees itself as doing a social service for society (by, for example, spending a fairly high proportion of money on 'pure' research). The effects of a tax on profits will be different in the two cases. For the wealth maximiser, forced by a reduced ploughback to go to the market (normally at a higher price) to finance research, the effect will be, among other things, to reduce research. For the other firm,* the cost of research will similarly rise, but since the firm's managers derive utility from the actual research itself rather than solely from the effects of research on profits, the effects of the tax on research are likely to be less than in the former case.

As has been asserted, wealth is only one of many things that a businessman may be seeking. Others, and these are only possibilities, might be: lavish offices, pretty secretaries, regular eating at the Café Royal, Rolls-Royces, no Negroes or Jews on the staff (or only Negroes or Jews on the staff), jobs for the family, old school chums and unemployed nobility, power and a vast Parkinsonian staff over which to wield it, prestige and charitable donations, lower than wealth maximising prices to ease the inconvenience of precise production scheduling and inventory control by investing in long order books and queues, plenty of 'pure' research, higher salaries at the expense of owners' wealth, and finally, but by no means least from this list, the ability not to have to bother too much about making the most efficient use of the company's resources.[†] Each of these objectives is as 'reasonable' to pursue as any other. Some may be more or less desirable according to one's prejudices, but to be methodologically proper we ought not to waste time bemoaning the fact that people are not as we would they were. Instead, this analysis takes them as they are. For those of us who are concerned, for example, about racially discriminatory employment policies, the emphasis shifts from the declaration of abhorrence to an examination of the conditions which permit such (inefficient at

† In the sense of producing products at least cost.

^{*} Note that both firms are utility maximisers. In the former the sole source of utility is assumed to be wealth. In the second, utility is derived also from prestige from pure research as well as wealth. Note that the provision of some sources of utility need not conflict with wealth if it increases people's productivity. In such cases, these sources are to be regarded as inputs in the production function rather than the utility function, but they may be in both.

wealth maximising) practices to exist. Should anyone doubt that these various practices listed here are in fact pursued by businessmen, there is abundant and well-documented evidence that all of these ends are actually sought, with various degrees of intensity.⁴

An implication of all this is that the type of industrial questionnaire traditionally administered to businessmen to test the veracity of marginalist theories was a waste of time since it sought to test what they neither did nor sensibly would do. More than this, it was harmful since it was based upon a naive misconception of the purpose of the theory, which was analytical not descriptive, and thus brought economic theory into disrepute. It also appears, however, that the alternative approach outlined here suggests two types of questionnaire or case study which could be both interesting to the theorist and useful to industry and to the government.

The first of these two types of investigation would be honestly descriptive. It would set out to discover exactly how actual decisions about prices are reached by industrialists. This is of intrinsic interest to anyone concerned with such problems, but it is of especial interest to other industrialists, and it is of importance for the efficient running of the economy as a whole. Its effect ought to be to disseminate information on techniques to businessmen, and with more technical information of this sort, the chances are improved that successful decisions will be made. In other words, more firms should survive longer. This is the first use of questionnaires, and it is not to be underrated. An important aspect of this is the method by which decisions, especially major ones are arrived at within the company, and it is not merely a question of the formal hierarchical organisation as shown by the typical organisation chart or job specifications.

The second use, which involves a different type of question for the most part, does not concern itself with its value in enabling firms to survive longer by reducing ignorance and the incidence of pure chance. This set of questions would be concerned with the environment in which a firm operates, for it is ultimately the environment which determines the behaviour of firms. A key example of what I mean is the conditions which imply wealth maximising versus utility maximising (more accurately, special case utility maximising versus general case utility maximising). If wealth maximising is a condition for a firm's survival, then a utility maximising staff which consumes any of the factors in the managerial utility function other than wealth will either have a shake-up from its owners, a shake-up from new owners, or, in the long run go out of business, by, for example, a sacking of the Board, by merger, takeover, bankruptcy, or any of the deaths that a firm can die. It now becomes rather important to examine these environmental conditions, because their implications can be various. If the environment induces wealth maximising,

then production tends to be more efficient. If it does not, then production tends to be at higher cost, and a whole variety of other behaviour may crop up, much of which will be regarded as socially undesirable. Furthermore, the implications of policy changes (for example, the imposition of higher taxes on profits) are different, so if one wants to know the effects of one's policy, the environment of a firm becomes an important variable, or set of variables, to be discovered.

Having completed these two sets of case studies, they can then be put alongside one another to discover whether there are any systematic patterns which emerge. Whether, to give an example, the wealth-maximising environment induces the use of any particular set of techniques of pricing and so forth.

The second type of investigation can constitute testing of the theory used by economists. Suppose we know which environment tends to imply wealth maximising behaviour. Under these circumstances, persistent utility maximisers, in the wider sense, would go out of business and there would be a continuing tendency for the population of firms to be wealth maximisers. Since economic theory has only ever concerned itself with the 'typical', 'representative', median or modal firm, we would thus have defined the circumstances under which traditional theory can apply, and we would then be justified in using the tools of traditional theory to investigate the industry concerned. But so far as I know, nobody has ever done this for the pharmaceutical industry, yet despite this, it has not deterred some people from recommending (e.g.) patent abolition, price controls, higher profit taxes, nationalisation, lower selling costs (especially advertising), and all the rest of the high-sounding paraphernalia of economic panaceas for the drug industry. The effects of these measures are, however, likely to vary (a) according to the current effects on the industry's performance of its environment, and (b) according to the way the environment shapes the industry's reaction to changes in these policy instruments. Another, not insignificant, effect of the absence of the second type of investigation is that it gives one no information on how the environment itself might be changed to produce the kind of behaviour that might be thought desirable.

The procedure to be adopted in the case of the first type of crosssectional investigation is fairly clear, and there are a variety of earlier studies on which one can draw, which though they have not dealt with the pharmaceutical industry, nevertheless they give one guidelines along which to work and illustrate pitfalls to be avoided.*

^{*} Unfortunately, many have fallen into the traps provided by the misconceptions, as I believe them to be, about what the classical theory of the firm was trying to do. For a survey, which is not as free itself of this fault as it should be, see R. H. Barback, *The Pricing of Manufactures*, London, 1964.

The procedure of the second type of study is less sure. Not only are there fewer studies preceding, but none of them has investigated all of the aspects of environment which need to be studied. A little further thought on this part of the programme for research is therefore in order.

The conditions which determine whether or not a firm will be a wealth maximiser seem to me to be basically threefold. Where these conditions are weak, then there is a wider scope for managerial discretion first of all just simply not to bother too much and to enjoy the 'quiet life', alternatively to divert the owners' wealth into their own pockets either by engaging in cost raising activities of various kinds, or by raising their own salaries, or by giving the owners' wealth away to 'good causes'. The three conditions are all versions of different types of competition, or perhaps more accurately, the cheapness with which rights of various kinds can be acquired and exchanged. They concern first the state of the product market, second, the state of the capital market, and third, the state of technical and physical 'barriers to entry'. Competition has generally been smiled upon by consumers as working in their interests, where competition is usually thought of as price competition. Another important aspect, however, is in what competition implies for other aspects of a firm's behaviour, which is what we now turn to.

THE PRODUCT MARKET

Competition in the product market can have as many dimensions as the product. For example, there are price competition, quality competition, promotional competition, and 'substitute' competition. All of these are aspects in which inter-firm competition can be carried on, and there are no *prima facie* reasons for preferring one over another, since none is a costless activity. It is curious, in the light of this that opponents of the industry have used an alleged absence of price competition as a stick to belabour the industry with, while the industry has retorted with glamorous claims for substitute competition. Everybody's efforts would, it seems to me, have been spent better investigating the degree of each of these and the reasons for relative variations in degree.

In many oligopolistic industries, where for example, price competition is absent—or (better) *apparently* absent—list prices will not be the same as actual prices owing to the use of a variety of techniques for price cutting, such as trade-in allowances, quantity discounts, secret deals and so on, which are aimed at subverting the cartel-type structure of most of these industries, for it is in every oligopolist's interest first to form a cartel and then to break its rules. Generally, the number of sellers in an industry *is* important in the degree of competition since agreements not to compete tend to become more costly to enforce as numbers increase. Conversely, the number of buyers is also important since the more there are, the greater

the chances of discovery of cheating. Consequently, the fewer the firms and the fewer the customers the more likely one is to see some restraints of competition in the dimensions of the product that are less costly to control.

Competition can never be removed unless the whole industry is monopolised for the simple reason that conflict of interest remains, but even if the industry is monopolised, for example by centralisation of ownership by either horizontal or vertical integration, or both, there still remains the less direct competition from other industries. But so long as ownership remains decentralised there are strong motives for expanding one's share of the market. Similarly, a patent does not give a firm a permanent monopoly of a particular product so long as it is exchangeable and can, for example, be either bought outright or a licence purchased. Thus if one firm is not making the most efficient use of a patent, it is open for another to make a bid for the patent rights and use them more effectively.

A firm's behaviour must always be conditioned to some extent by the terms on which it can sell. It is always possible that it may be put out of business by a firm who sells cheaper, or a better product, or a better advertised product, etc. In other words, no firm can afford completely to ignore its profits, though it may be possible, if there are significant inroads on competition in some dimensions, to get away with lower profits than those possible. Thus, competition in the product market limits managerial discretion. The more competition in the more dimensions of the product implies higher costs to managers of their sources of utility and thus implies closer approximations to the wealth maximising position.

THE CAPITAL MARKET

Competition in the capital market also implies a limit to managerial discretion. This consists in the ownership of companies and the costliness of transferring ownership and implementing the owners' rights. Taking the latter first, we investigate the effects of the current ownership structure. Generally speaking it is usually held that the more the ownership of shares is dispersed, and the smaller the individual shareholders, the less effective is the control they exercise over management, and hence the greater the degree of discretion available to managers to maximise or not to maximise the owners' wealth. At the same time, however, some large and potentially powerful owners usually refrain from exercising control, especially the institutional shareholders such as trusts or insurance companies. For the most part, these investors would rather move out of suspect investments rather than attempt to influence the managers of the companies concerned, though of course the fact of their selling may draw attention to managerial inadequacies and may eventually result in the elimination of the inefficiency if the decline in wealth arose from this source.

A second aspect of the ownership structure which is also of importance

is the extent to which management is represented in the ownership. If management is represented, it is frequently asserted that it is in order to reap profits. It is also possible, however, that management has invested in its own company in order to buy off pressure and protect its non-pecuniary sources of utility. This latter case may be thought to be an example of irrational behaviour on the part of management, since although utility consumed inside the firm is desirable, profits can be converted into takehome money to be spent at home, or elsewhere—including inside the firm. so by adopting this policy, management would normally be reducing its options, not increasing them. However, since not all on-the-iob sources of utility can, in fact, be purchased out of take-home wealth, management ownership may work both ways. Thus, if management is strongly represented, one may or may not see relatively more pursuit of wealth. Nonrepresentation of management would, however, be pretty unambiguous pressure towards wealth pursuit, provided that ownership were not too dispersed.

The transferability of ownership is important because it represents the means by which shareholders who failed to exert pressure on managements can be supplanted by others. Since transferability is cheaper with joint stock companies, one expects to see a greater orientation towards wealth among companies quoted on the stock exchange. Thus, techniques such as buying and selling shares, or, more dramatically, takeover, merger or raid become possible. However, just as information is a scarce and costly good to shareholders who may not be aware that managers could do better, so it is costly for potential owners to acquire this information. One would generally expect that the more similar the products of different firms, the more firms, and the more of them that are quoted on the stock exchange, the greater the amount of information available, and the cheaper it would be to acquire it, and the more effective that this form of competition would be at promoting wealth maximisation.*

PHYSICAL AND TECHNICAL 'BARRIERS TO ENTRY'

In Bain's classic work⁵ on 'barriers to entry', these impediments are divided into three main types: economies of scale, product differentiation, and the absolute cost advantages of firms already in production. In addition, there may be monopoly ownership of factors or of rights to factors of

^{*} The evidence is that concentration in itself does not produce higher profit rates, see G. J. Stigler, *Capital and Rates of Return in Manufacturing Industries*, Princeton, National Bureau of Economic Research, 1963. A reason for this may be that the opportunity to earn monopoly rents is offset as far as profit rates are concerned by the opportunity to managers to raise costs in ways agreeable to them. That they do so in some cases, see G. Becker, *op. cit.* The evidence on relationships between management control and profit rates is not very conclusive, see David R. Kamerscham, The Influence of Ownership and Control on Profit Rates, *American Economic Review*, Vol. LVIII, 1968.

production, which would include patent rights over inputs. There may also be ownership of specialised equipment which may take a long time for another firm to copy or develop independently, or a long-term contract with specialised labour which would similarly take time for another firm to train up, and which would also be a costly process of investment in 'human' capital. These impediments all refer to the likelihood of new firms being able to enter the market and increase thereby the amount of competition in both product and capital markets. Each of these factors is. like many of the others, difficult to measure with accuracy, though there are methods for overcoming the chief difficulties. In the pharmaceutical industry there has been relatively little work on entry problems to date. But as one managing director has put it to me: 'It would seem that the scale is becoming such that one can only see the growth of the industry through the development of larger units rather than the entry of new organisations. The cost of research and the intensity of research, combining to make virtually the annual expenditure on research of less than £1 million almost a waste of time, unless the money is devoted almost entirely to pharmaceutical development work. Of course there may always be entries into a country market-place due to the large international organisation spreading its wings, but there will be no development of home pharmaceutical entities developing from their own "entrepreneurship"."

The reasonable interpretation of this is that there are substantial barriers to entry in terms of scale for the innovating pharmaceutical firm, though for production or marketing alone, Reekie's evidence in an earlier paper in this series indicates the absence of barriers.* One of the major difficulties of interpretation here is whether the existence of an innovational barrier and of patents has effects which are socially undesirable. Reekie views the results as a 'vicious circle' whereby entrants must cut prices, promote furiously and differentiate their products by innovation. The question of social concern is indeed whether this is 'vicious' and to whom.

A priori consideration of the innovation process does not yield an answer, for in the absence of patents the returns to innovatory development cannot be kept specific to the innovatory firm and hence the only period of time during which returns can be recouped would be the time it took for other firms to analyse his product and programme the production of an indentical private one. R and D then in the absence of private property rights in ideas will be socially sub-optimal if all firms are wealth maximisers. With patents, however, the argument is that there is excessive innovation to develop similar (but not identical) products, coupled with

^{*} Duncan Reekie, Barriers to Entry and Competition in the Pharmaceutical Industry, supra, pp. 1–20. It is, perhaps, worth noting that companies which are not wealth maximisers will tend to have higher unit costs, and that this might constitute a whole new realm of investigation for anti-monopoly agencies.

Anthony J. Culyer

'brand loyalties' of GPs and the public induced by implication by excessive advertising. Unfortunately, to my knowledge there is no analysis which can tell us what innovation is excessive, what brand-loyal GPs are dupes, nor what advertising is too much. The answer surely must be that if you want to limit any or all of these things for whatever reasons, then your objective must first be specified clearly in quantitative terms, and secondly, you must have a guide from theory as to how the objective can be implemented. One of my purposes here has been to provide the basis for just such an analysis, to discover, first, means of achieving these various ends, and second to assess their implications. Another has been to suggest that the abstractions of economics are not really so far divorced from the behaviour of rational businessmen. Finally, I hope I have laid some foundations upon which empirical academic enquiry may be built.*

IMPLICATIONS

Taking all the factors which have been discussed together, we have, I hope, a reasonably comprehensive, if not exhaustive, list of the factors which determine the degree of managerial freedom. The more effective that competition is in these various ways, the more the behaviour of firms will conform to my interpretation of the economists' traditional analysis, but the less effective they are, the more firms' behaviour will conform to the predictions of the generalised utility theory. It is therefore our task to attempt to measure these things in order to assess their relevance to the pricing and output decision.

The conclusions of this purely *a priori* prolegomenon to the search for factual information are briefly as follows:

(i) the economic theory of the firm does not attempt to describe the techniques used by managers to reach pricing and output decisions.

(ii) the economic environment surrounding firms determines their behaviour as regards pricing, output, input mix, etc.

(iii) salient features of the environment can be isolated and the direction in which they push the managements of firms can be postulated.

(iv) managements with a 'tough' environment will have strong incentives to use efficient techniques of production, etc.

(v) managements with tough environments are expected to have the most successful pricing and output techniques in terms of a profitability or wealth criterion.

The exciting task of testing these predictions remains to be done. It is my hope that the approach outlined here will at least assist those whose

^{*} My own intuition suggests that the pharmaceutical industry will contain companies compassing the whole range of motivation. I would expect subsidiaries to tend to be wealth maximisers, and some of the larger home-based companies which have diversified to be utility maximisers. This, however, is only my own conjecture.

speciality lies in refuting empirically the ideas of theorists, and if they still after all this have difficulty in so doing, I will be well satisfied.

- 1. Private correspondence.
- 2. Private correspondence.
- 3. A. A. ALCHIAN, Costs and Outputs, op cit. (footnote, page 40).
- A. A. ALCHIAN, Costs and Outputs, op ch. (Ioutiote, page 40).
 A. A. ALCHIAN and R. A. KESSEL, 'Competition, Monopoly, and the Pursuit of Pecuniary Gain', in *Aspects of Labor Economics*, Princeton, National Bureau of Economic Research, 1962; and G. BECKER, *The Economics of Discrimination*, Chicago, 1957.
- 5. JOE S. BAIN, Barriers to New Competition, Cambridge (Mass.), 1962.

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Stewart W. Kipling MANAGING DIRECTOR, NICHOLAS LABORATORIES

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INTRODUCTION

THE paper takes the form of the presentation of a case-history of the marketing of a range of pharmaceuticals by Nicholas Laboratories Limited, a member of the Aspro-Nicholas Group. We shall also outline the economic background to marketing decisions, and summarise the management thinking which lay behind the policies adopted. The paper will try not to get involved with the general apologia for prescription medicine marketing: the broad economic arguments will be assumed and the presentation will concentrate on discussing the real nature of pharmaceutical marketing in action. The paper is based upon a case-study written in 1968.*

It is well known that the prescription medicine market differs from that of other consumer goods, mainly in that the locations of product selection, product purchase or shopping, and final payment for the product are different. This is a phenomenon peculiar to the pharmaceutical market. Our theme is that, despite these differences, the marketing function in the prescription medicine firm is fundamentally and recognisably the same as in many others. Four instances of this may be given. Firstly, prescription medicines are sold as the outcome of a planned and controlled marketing strategy. Secondly, this is based on budgeting or cash-flow planning and a critical figure is, as usual, product contribution to overheads and profit. Thirdly, the strategy is implemented by means of advertising and promotion. Different media appropriations must be assessed and choice made. Fourthly, the prescription product is in a more or less well defined market, which depends upon its medical type, and at all times competitive action or reaction must be watched for and met.

THE ORIGIN OF GENTICIN

The products we are to discuss are antibiotics, i.e. they combat infective

^{* &#}x27;The Genticin Range' by Robert H. Jones in British Cases in Marketing, ed. J. S. Bingham, Business Books Ltd., 1969.

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illnesses. In 1961, the research department of Schering International, one of the leading American pharmaceutical houses, first fully identified and codified the bacteriological properties of a substance called gentamicin sulphate. It was found to represent a significant improvement in antiinfective therapy. It was effective against a wide range of disease-causing bacteria including some resistant to other antibiotics, while it had a low incidence of side-effects on patients.

At that time, Schering International did not have a suitable subsidiary company in the UK and had in the past generally issued licences to British companies to produce and market its new products here. The decision was taken to offer gentamicin in this way. Nicholas Laboratories Limited were already engaged in the marketing of antibiotics and so decided to submit a licence proposal to Schering International to market gentamicin sulphate in the UK. Schering International received several marketing proposals and after comparative study of these selected two, one from Nicholas and another from Roussel Laboratories Limited, the UK subsidiary of a French concern. Licences were granted to these two firms.

From the outset Nicholas were faced with the prospect of a complex competitive situation. In a position of immediate competition would be Roussel's gentamicin product, chemically very similar to their own, while both these companies would be introducing gentamicin on to the antiinfective market against already existing products, based on totally different antibiotic substances, marketed by such firms as Glaxo, Beecham, Pfizer, and ICI.

In the pharmaceutical industry product selection and initial objectivessetting is often different in an important way from that of the more usual consumer goods market. The breakfast cereal manufacturer, for instance, may decide that there is an area of the market in which he should obtain a stake. He then states more or less quantified market-share objectives and develops a product specifically to achieve these. The pharmaceutical decision is less straightforward. Before products can be marketed they must be scientifically developed and this is a slow and expensive business. Consequently, the firm will tend to market those products which become available to it over time, rather than 'tailor-make' particular products for a particular market. It can be said that its broad market decisions are made by the type of research it undertakes but even so occasionally products discovered turn out to have a different therapeutic action, and so may eventually be launched on an entirely different therapeutic market from that which had been expected.

What this means in this context is that the objectives of Nicholas Laboratories in wishing to market gentamicin could not primarily be stated in quantified form. As soon as the possibility was realised of a licence agreement with Schering on gentamicin, Nicholas began an assessment of its therapeutic and market possibilities. They came first to the conclusion that it did represent a worthwhile new development with tangible medical advantages over existing substances-in certain critical conditions it even offered life-saving possibilities more certainly than products then available. Secondly, the company concluded that gentamicin should prove a profitable product. While this is not the place for a discussion of pharmaceuticals and profits, it may be pointed out that a pharmaceutical company, like any other, must consider profitability as one of the factors determining its policy. Like any other firm, it must earn enough to provide a return to its share-holders, but more than this, it is from profit-earnings only that the pharmaceutical firm must maintain a continuing fund for research and product development. So in entering a proposal for gentamicin Nicholas' objective was to market a medical product which it was thought involved significant improvements and which would add usefully to the practitioner's armoury, and also was a product which would widen the company's profit-base and provide additional contribution to fund the overall pharmaceutical operation.

Even at this early stage, an intention was that gentamicin would be the base for a range of product preparations. To satisfy different medical requirements a pharmaceutical can often be produced and marketed in different forms or preparations—perhaps as a capsule or tablet for internal use, as an ointment for the skin, or as an injection, and so on. Nicholas recognised that gentamicin could be prepared in a variety of forms like this, and one of the first problems was to select the most useful preparations of the antibiotic from the medical and marketing points of view and to decide on the optimum order in which they should be launched.

THE FIRST LAUNCH-GENTICIN FOR INJECTION

It was decided to introduce the gentamicin range with the injectable product. From the scientific point of view this had already reached a marketable state of development while at this time, late 1965, further laboratory work remained to be done before other forms, such as topicals, or eye and ear products would be marketable. The general practitioner tends to use injection products only rarely since they require professional administration perhaps two or three times a day and most antibiotic sales through GPs are in tablet, capsule, or other oral form—preparations for which gentamicin is technically not suited. So the first experience with gentamicin would be in hospitals only; and this has one important implication.

There is a fundamental difference between the hospital and general practitioner markets and this concerns information available. In the GP market, the pharmaceutical firm can draw on market and promotional data

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prepared by Intercontinental Medical Statistics Limited.* In contrast, statistical information on hospital drug purchases does not exist in any comprehensive or organised form. Special surveys can be undertaken by a company with interests in this market but these are expensive and it is understandably often difficult to enlist the participation of the busy hospital pharmacist. Otherwise all that the firm can do in the way of market research is to make what it hopes are reasonable guesses or at best extrapolations of individual hospital contracts, and the reports of its representatives. Marketing a drug to hospitals, from the quantification point of view, is something of a 'seat-of-the-pants' operation. Statistical targets are often difficult to set and level of market share which they represent is little more than a guess.

At this time Nicholas knew that Roussel's first gentamicin product would also be an injectable preparation, and therefore a main concern was to obtain an initial foothold in the market for their own new product by being the first to launch. Also in mind Nicholas had the need to establish their chosen brand name 'Genticin' as the first gentamicin product available in the UK, to pave the way for future range developments. For, to establish historical connections, it was planned to call future preparations by the Genticin name with appropriate suffixes. Therefore, even though the injectable would only be used in hospitals, the company included in its promotional plan a requirement to inform the general practitioner that the injectable Genticin was available, to begin to develop his knowledge of the product in preparation for the intended marketing of future general practice Genticin products.

Bacteriological research had suggested that gentamicin's competitive strength would lie in its particular activity against a narrow group of bacteria which were frequently resistant to other antibiotics, the 'gramnegative' bacteria. This meant that Genticin would be especially useful in cases of kidney or urinary tract infections, peritonitis, pneumonia, bronchitis, and septic wounds. The product was also as effective as other drugs against the remainder of the spectrum of infective bacteria. However, there was a suspicion at this stage that high dosages might more frequently than with other products lead to toxic effects—dizziness and nausea. So, pending wider clinical experience with the product, Nicholas wished to present Genticin as the first choice against the resistant gram-negative bacteria and as second choice against the others, to be used when other antibiotics showed no effect.

To obtain full promotional coverage in advertising, space was booked in both general and appropriate specialist journals. Similarly, mailing was

^{*} We wish to thank Intercontinental Medical Statistics Ltd. for agreeing to our using certain of their market research information in this paper. All data concerning market sizes and product shares comes from them.

not restricted to hospitals doctors; a full introductory mailing was made on the launch date to all doctors though it was made clear that so far Genticin was available only in injectable form in hospitals.

But the main single promotional effort was, as is frequently the case with medicines, through the sales-force representatives. Previously the company had had relatively little experience of presenting antibiotics to the hospital doctor. For the representative the difference between the hospital doctor and the GP is that the former is a specialist. While the representative may present a whole variety of products to the same GP, in the hospital he will find himself talking to a different person about each drug, even about different aspects of the same drug. As routine in the case of new products the Nicholas sales-force received a thorough specific training programme, but the training received was based upon this new circumstance.

Sales management developed a programme of 'details'—as representatives' visits to doctors are called. A planned cycle of calls to be made in each hospital was drawn up, involving three distinct presentations. The first to be visited was the pharmacist, the person who controls pharmaceutical stocks and is responsible for the ordering and issuing of drugs. The second detail was made to the clinician, the doctor who is responsible for the patient in the ward and who takes decisions on therapy. Occasionally the clinician will send a specimen of the infecting organism to the bacteriologist for laboratory tests. The bacteriologist was therefore identified as the third member of hospital staff to be visited.

Nicholas considered the remaining 'front line' promotional medium, sampling. Points in favour of sampling are that the doctor can see and actually use the product if he wishes. Also, sampling effectively reduces the average cost for treatment. But the main consideration against sampling is the cost. It must be thorough to be effective which means it must be expensive, cornering perhaps a disproportionate share of promotional resources. Also, in some hospitals there is the possibility of reaction against samples as stock and distribution control can be confused by their independent appearance. So on balance the company decided not to undertake sampling. In addition to these promotional efforts, Nicholas instituted and promoted in advertising and mailings the Genticin Technical Service. Also, hospital clinicians were encouraged to undertake controlled trials in use of the product.

The broad trend for prices of pharmaceutical products is for them to be high at their introduction with the prime need to recoup immediate research and development costs and to obtain sufficient gross margin to finance the promotional break into the market. Once a degree of market success is gained, these requirements relax and prices are apt to fall. These factors can indicate a gross margin requirement for new products of 65 to

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80 per cent of ex-factory cost. Upper limits to reasonable prices are broadly a function of prices of immediately competitive products and the premium offered by the product's advantages. The company must hope to find an adequate gross margin in the consequently indicated price range. Genticin injectable was launched at an ex-factory price of 20s. per vial. Including wholesale margins, this meant a hospital purchase price of \pounds 7 1s. 0d. per six-vial pack. Hospitals were offered a discount price of 19s. 6d. per vial for direct high quantity purchase from the company. At the time of launch, daily costs in use (average adult dosage) of other products ranged from under \pounds 1 to \pounds 2 10s. 0d. On this scale Genticin was not expensive, the average treatment of one vial per day costing 23s. 6d.

What were the cash-flow implications of this price? First budgets for the product set sales of 100000 vials in the first full financial year of marketing, yielding revenue of £100000. From this had to be met: Schering International's 5 per cent royalty, direct production costs of £13000, and an attributed £36000 for advertising and costs of detailing, leaving a product contribution of £46000 or 46 per cent. Closer to launch date, first-year sales were revised downwards to £85000 and, with advertising budget remaining constant, the fall affected mainly product contribution.

Genticin injectable was launched on 1 July, 1966, and during its first full financial year of existence (April 1967 to March 1968) it easily achieved the target of £85000 with sales showing a rapidly rising trend. Estimates are that Genticin is now responsible for 2 to 4 per cent of total hospital antibiotic sales, and gentamicin as a whole for around 6 per cent. (There is still the difficulty of obtaining information on the hospital service markets.) From the marketing point of view Nicholas feel that Genticin injectable has obtained a satisfactory market foothold.

As expected, Roussel followed the company into the market with their own gentamicin injectable some six-months later. Their promotional response to Nicholas's lead was interesting. The aspect of Nicholas's marketing strategy which invited competitive response was the decision not to issue samples. Roussel adopted a complementary approach involving a strong sampling effort. Secondly, Nicholas had presented the wide spectrum activity of gentamicin with particular emphasis on its efficacy against gram-negative organisms. Roussel concentrated their platform solely on the product's effectiveness against gram-negative bacteria, suggesting that gentamicin should be restricted to usage in such cases.

The possibility that gentamicin might become cornered—regarded as a rather specialised sort of product—was feared in early 1968. This was contrary to the long-term aim of the Nicholas marketing programme. However, it was by now established that the toxicity problems were only significant in the presence of renal impairment and the main concern now was to demonstrate that Genticin had a broader usefulness than it had so far achieved. Clinical trial results were available of usage of the product in a wide range of illness and references to these have been presented in the Genticin Technical Service brochures.

A second event which affected Genticin was the introduction by Beecham of Pyopen. This is an antibiotic which has a specific action against some gram-negative bacteria and it is not intended for wider usage. It is a penicillin, a fact to which many doctors react favourably and, being a Beecham penicillin at that, carries a lot of prestige. The effect on Genticin of the launch of this product has been to emphasise the importance of the gram-negative diseases, and now probably the most effective treatment which has evolved is a combination therapy of both Pyopen and Genticin. This is widely used now in many of the London teaching hospitals.

Recent Genticin marketing developments have included a shift in advertisement style from a prosaic, if neat, presentation of journal references to an advertising design with more immediate visual impact. (Plate 7 illustrates the new styling, though in the context of the topical products.) Secondly, during 1968 the price of the product was reduced for all sales to 19s. 6d.

THE SECOND LAUNCH-THE GENTICIN TOPICALS

The long-term plan for Genticin was to produce a range of products based on the new antibiotic. At the time the injectable was launched the preferred order for successive preparations was eye and ear drops, an aerosol spray for sterile treatment of skin conditions and a topical preparation, i.e. applied to the skin. All these products would be presented to general practitioners as well as to hospitals. The Nicholas Research Institute, however, reported that technical problems were being encountered with the aerosol which removed it from immediate choice. The decision between topicals and eye and ear drops was based on competitive and product range considerations. Firstly, Nicholas already had on the market useful eve and ear preparations. Secondly, Schering International had granted an exclusive licence to Nicholas to market gentamicin sulphate in the eye and ear preparations: therefore, problems of direct competition in this field were not so applicable. In any case, some development work still remained to be done on the products and forward dates were not easily available. Finally, it was known that Roussel were planning to launch a topical product and this created a further factor for Nicholas to market topicals relatively soon.

However, the competitive situation was more complex than this, for the firm knew that Roussel had a brand leader in the topical market with Sofra-tulle and thus would be starting from a favourable position of experience and prestige. Nicholas felt that this potential position of strength could be counteracted, and the useful applications of gentamicin sulphate widened, by launching not one topical but two.

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In treating a skin condition the doctor generally desires to achieve one or both of two effects—elimination of infection, and reduction of inflammation. Antibiotics perform the first, and another group of drugs, the corticosteroids, can assist in the reduction of inflammation. Thus, there are immediately two classes or markets of drugs for skin disease, the plain antibiotic and the plain steroid. There is also a third, which are a mixture of the two and achieve both effects at the same time. These are called combination products.

The first intended topical was the purely antibiotic preparation. Nicholas now proposed to introduce at the same time a combination product, made by combining gentamicin with a steroid drug. Examination of market research statistics showed that the combination market, at about £2.5 million per annum, was some four times bigger than the plain antibiotic market, and was growing more rapidly. Moreover, there was evidence from some other companies that the majority of sales, if both types were marketed, came from the combination drug.

Nicholas already had experience of a well known steroid called hydrocortisone in another product. While they knew it was beginning to be outdated by newer steroids they decided, as it was and still is the medical standard, to include it with gentamicin in the combination product rather than allow time to elapse in looking for and testing a newer one.

Following the policy of the product range the naming of the product was relatively simple. The name Genticin was kept and the plain antibiotic was referred to as Genticin Topical, or 'plain', and the combination, with hydrocortisone, was called Genticin HC.

The theme of the GP advertising platform was tested on a panel of doctors to assess likely response and check against the possibility of inconsistency—with much the same intention as the TV commercial may be tested on a sample audience. For the first time in the development of the Genticin medicine range, it was possible to link the new products with an existing one—the injectable—and representatives' details were designed to bring in the growing reputation of the injectable in hospitals.

As with the injectable, the main promotional effort was through representatives supported by direct mailing and journal advertising. But in contrast to the injectable, samples were used for the skin products. The GP views samples far more favourably than the hospital doctor, often using them as a reserve stock of medicines for urgent requirements, or when the local pharmacy is shut.

Though Nicholas expected the major proportion of sales of the two topical products to come from the large GP market, hospitals were not overlooked. Emphasis was placed on the plain topical's usefulness in major skin infections and especially treatment of burns which are always at risk of becoming infected. Again, promotional presentation was given a test run; each sales area organised a presentation to one selected hospital prior to full scale marketing.

It was planned that as the products reached their sales plateau and the initial major 'sell-in' was concluded the emphasis would shift from representatives to advertising within a declining total promotional budget. Thus, $\pounds 43000$ were budgeted as attributable cost of sales-force in the first year compared with less than half of this, $\pounds 20000$, for advertising. After five years the projected cost of sales-force was only $\pounds 5000$ with $\pounds 10000$ expenditure on advertising.

Returning for a moment to the market position, Nicholas were faced with a complex situation. For the plain topical they were sure that the greater efficacy of gentamicin provided a basis for a strong, straightforward presentation which could be summed up in a phrase such as: 'No other antibiotic offers as great a promise of therapeutic success'. But the situation was less simple for the combination product. In the last two or three years new and advanced products had made their appearance on the plain steroid market, notably ICI's Synalar and Glaxo's Betnovate. This had resulted in considerable concentration, with these two accounting for some two-thirds of all plain steroid prescriptions. They presented a strong claim, one to which the GP had responded, and Nicholas were aware that he would therefore be unlikely to register the appearance of a new combination product which included a steroid to some extent superseded by the newer ones unless the advantages of the accompanying antibiotic were clearly outstanding. This condition Nicholas felt they would satisfy with gentamicin sulphate.

The two topicals were priced differently, for the inclusion of the steroid in Genticin HC added significantly to its prime cost. The plain topical was given an ex-factory price of 7s. 3d. while the combination product was priced at 9s. 0d., in both cases per 15 gram tube. In contrast to the injectable these prices were high relative to the current leading products. The judgement was that the new and pharmacologically progressive properties of Genticin justified a price premium of about one-fifth.

The immediate pre-launch sales budget was: Genticin plain topical $\pounds 29000$, Genticin HC $\pounds 61000$. In other words, taking into account price difference HC was expected to move at a unit rate some 70 per cent faster than plain, a forecast based upon the market research evidence that doctors wrote about twice as many prescriptions for combination products as for plain antibiotics. Calculations had been done on the penetration—or the percentage of doctors who could be expected to use—as a result of promotional effort, coupled with the known average prescribing rate per GP of products in this field.

For these products, in contrast to the injectable, the high promotional outlay in the first year required by the size and competitive nature of the

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markets meant that little or no product contribution was expected in the early months of the product's life. But as promotional expenditure dropped sharply in year two and subsequently—as already mentioned—Nicholas forecast a subsequent contribution level of about 40 per cent of sales revenue.

The company managed to advance the date of the launch of the topicals by some months to February 1967, about two months after the Roussel topicals were launched. First sales reports were good as the products were sold into wholesalers. This was followed by the expected drop as wholesaler stocks moved through: but the magnitude of the fall was rather larger than expected and only slowly began to be made up. After seven months on the market (towards the end of 1967) combined sales of both products had reached only about one-third of their forecast first-year sales. The main cause of this was the low achievement of Genticin HC. Its sales were only about half that of the plain topical in contrast to an anticipated order of precisely the reverse. In other words it was running at only a quarter of projected sales. Its progress was distinctly sluggish. The plain topical's market share, in contrast, represented a useful market foothold after a relatively short period of availability.

At the end of 1967 it was decided to analyse in some depth what was happening and a detailed marketing profile was prepared. This analysis confirmed that the situation with Genticin plain was moderately satisfactory. Sales by then were running at around £30000 per annum, just about as forecast for the first year rate, though it had been slow in reaching that level. Genticin HC on the other hand was making a rate of only £15000 per annum. The study ascribed the early sluggishness which affected both products in part to low promotional spending relative to other products in this field. In big competitive markets, for pharmaceuticals as for other goods, there is no substitute for 'buying-in'. Promotional data showed that journal and mailing expenditure rates on the topicals were in the early months only between one-third and one-half of those of the brand leaders. Nicholas had known this would be the case; it was a situation that financial resources available to the range dictated. The study concluded that it was material in holding the products back.

A further contributory factor was identified as a somewhat overtechnical advertising platform to the G P. At the time of launching the topicals Nicholas were still involved in presenting the injectable product to hospital specialists and building sales there. As we have noted, emphasis in hospitals had to be on technical data. In retrospect it is clear that the handling of a product which is moving satisfactorily, such as the Genticin injectable, can tend to flavour the approach to immediately subsequent products of the range. In fact, it had already been suspected that the promotional approach to the general practitioner had become over-technical, and by the end of 1967 a major shift in advertising approach had occurred. Emphasis was now given to the product's unique breadth of effectiveness against disease, drawing attention to specific illnesses and symptoms, and secondarily presenting information of a more technical nature.

In examining the two products individually, the study confirmed that Genticin HC was suffering from fundamental troubles. And the main specific reason for its poor performance relative to budget was identified as an inadequate use at planning stage of market research data. This also may have resulted partly from the fact that the company was launching from a hospital base-line where there was little market information available. With the GP prescription market full market information is available: however, market research only featured in the topical product proposals in a relatively superficial form. Little more had been done than an identification of the leading brands and the main diseases for which topicals were being prescribed. This shortcoming had resulted in an underestimation of the importance of the steroid content of a product in the combination market. As mentioned, Nicholas had anticipated that the general practitioner would respond to the combination product not for the steroid it contained but because of its more important ingredient, gentamicin. This was over-optimistic and a more detailed study of market information would have revealed that beneath the attractive surface of the fragmented £2.5 million combination market a swing was developing away from products containing older steroids. Indeed, by the time Genticin HC had been on the market for a few months this had become obvious and sterling volume of the market had begun actually to decline. While an eventuality of this nature could perhaps not have been forseen the indications were already there that the attraction of the new specialist plain steroid drugs-Synalar and Betnovate-could well halt the growth of the combination market. At least their success meant that increasingly it was the steroid content of the combination product which interested the GP, rather than the antibiotic. With hindsight, the odds are clearly high against successfully launching a new product, whose main feature from the market point of view was being outdated by events, onto a market which, as it turned out, was beginning to decline.

As a result of this analysis it was decided to shift the emphasis from Genticin HC to the plain antibiotic preparation. Genticin HC became presented as an additional product to the plain, one that the doctor who knows Genticin plain can turn to in cases where he requires a combination product. The representative detail embodies this in this fashion: 'In addition, doctor, to complete the range of skin products there is Genticin HC which combines Genticin's unique antibiotic activity with the well accepted steroid, hydrocortisone.' The company is also drawing attention to specialised usage of Genticin HC in a limited range of conditions for

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which it is particularly appropriate, for children and for occlusive therapy.

Developments for the Genticin plain topical included a small 15-gram pack for the general practitioner, and a large 100-gram pack for hospital usage. A limited sampling promotion to hospitals has been run. A series of successful clinical trials has been carried out both in hospitals and in some general practitioner groups.

To support the shift in promotional approach from technical to practical a more strongly visual element was introduced into product advertisements (Plate 7). The advertisement draws attention to disease entities, and leaves no doubt as to the therapeutic possibilities of the product.

THE THIRD LAUNCH-EYE AND EAR DROPS

In parallel with the two distinct topical preparations, it was decided to launch next two products for eye and ear treatment, a plain antibiotic for the eyes and a combination product, again with hydrocortisone, for the ears. These were launched in November 1968. And what was of particular interest about their launch was the way in which the approach incorporated the experience of the previous Genticin products.

Basically what was needed was a far more detailed use of market research. Full market studies were carried out and these were built up in a stratified form to give, first, a broad study of the market, its size in prescription numbers and sterling terms, and the leading competitive companies and products. This was followed by an examination of the usage patterns of existing drugs on the market-conditions they were used for, in what quantities they were prescribed-with the prime objective of setting the advertising theme firmly on a usage basis and avoiding the semitechnical approach which characterised the early topical advertising. At this point it was discovered that the majority of liquid preparations in these markets were marketed in 5 mil. containers. But the average amount required for treatment was 7.5 mil. Therefore, to offer a complete treatment in one container Nicholas marketed a 10 mil. bottle. It was also decided at this stage that, for medical reasons, the problems of using hydrocortisone as against a more modern steroid would not have the same magnitude in the eye and ear markets. (In the light of the Genticin HC experience this was an important decision which made possible the actual marketing, for Nicholas had no other steroid available to them.) Full case studies were made of the leading products in the eve and ear subsections of the market to assess the kind of prescribing patterns typically adopted by doctors for each, and the interplay between the two subsections (some products are used for both ears and eyes). To establish the kind of progress which a new product could expect to make, and the order of advertising related to such progress, a special study was made of products launched in recent months and their market achievement to date.

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Plate 1: Market size, competitor products, sterling and prescription shares (Genticin-eye)

Plate 2: Market size, competitor products, sterling and prescription shares (Gentisone-ear)

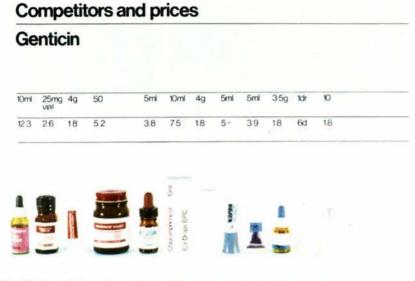


Plate 3: Pack design, size and price of competitor products (Genticin-eye)

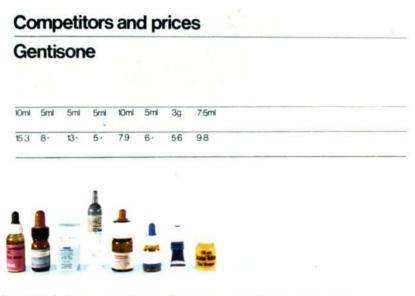


Plate 4: Pack design, size and price of competitor products (Gentisone-ear)



Plate 5: The original pack for Genticin and Gentisone



Plate 6: The new pack for Genticin and Gentisone HC

Nicholas Laboratories Limited

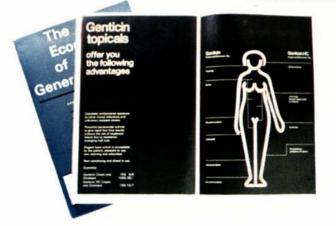


Plate 7: The revised style of Genticin range advertising

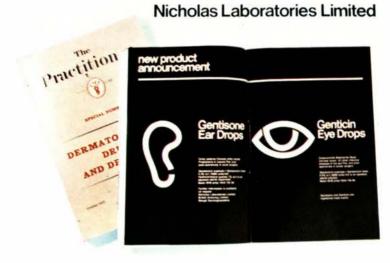


Plate 8: Advertisement presentation of the eye and ear drops

The Market						
Genticin's subsection Antibiotics for eyes and ears	Gentisone's Steroids wi infectives fo		Albucid's subsection Sulphonamides for eyes			
Total Market £1.5 n	nillion					
£227000 Branded 16% £63000 Unbranded 4%	£1030000 70%	£140000 10%				
Table B						
Product Forms						
Genticin's subsection		Gentisone's subsection				
Total Units 1 million (+8%)		1.4 million (+6%)				
topical eye 97% ointment 65% drops	topical ear 4% drops	topical eye/ear 64% ointment 18% (£-1%) drops	topical ear 37%			
32% (£+20%)	4% (£+6%)	46% (£+6%)	37% (£+8%)			
Table C Promotion						
Total Promotion £620 Genticin's subsection £16000 26%	000	Gentisone's sub £45000 74%	section			
Number of products promoted	3	Number of pro promoted	oducts 5			
Range of spending per product	£2-4000	Range of spend per product	£3-15000			
st year new product spending £11000		1st year new product spendi	ng £25000			

Table A

The Tables above and Plates 1–4 illustrate how the market analysis was built up. From the broad market outline (Table A), product forms or preparations were determined (Table B). For each of the two products, market size, and sterling and prescription shares of competitor products were assessed (Plates 1 and 2). Pack design, size and price of competitor products were examined (Plates 3 and 4), and promotional expenditures were compared (Table C).

In budgeting, too, the company was adopting a more sophisticated approach for the third launch. A sales forecast was constructed which hypothesised two levels of market penetration, one a 2-3-4 per cent share in the first three years, the other assuming a 3-4-5 per cent share as its basis. The comparative market studies which had been carried out were used to establish the order of advertising expenditure which was required to achieve a foothold of around 2 per cent in the first year—a figure in the region of £15000.

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A policy change was introduced after much discussion relating to the family name of the product range. As we have noted, there had previously been in product management an emphasis on the concept of the Genticin family or range of products and all the products bore the name plus specific suffix. After the problems of Genticin HC the advisability of continuing this was questioned. It was suggested that doctors had not responded to the name Genticin as a family name. It was also argued that in any case doctors preferred a drug name to give an indication of what the product did rather than what it was. On the other hand it was recognised that the drop the Genticin name would tend to halt any interplay between products and inhibit favourable spin-off from the Genticin drug in one market to that in another. But since it did not seem that this was proving of decisive importance a new departure was made. The name Genticin was not dropped altogether; it remains for one of the products. Genticin Eve-Drops. For the other the root of the name remains to establish an element of continuity and it is called Gentisone, the suffix '-isone' indicating to the doctor the hydrocortisone content of the product and hence that it has an anti-inflammatory action. Thus, there was a limited breakaway from the range-name continuity principle, based on the argument that adding further active ingredients to the medicine provides the scope, as well perhaps as increases the requirement, for a change of name.

It will be remembered that during the launch of the topical preparations, Nicholas had used a doctor-panel to assess G P reactions. It was decided for the new marketing operation that a way of arriving at the most acceptable presentation of the products as far as the medical profession was concerned would be to begin all production on a small scale—short productruns, small quantities of package and label printing—and then involve the sales-force in gathering reaction and opinion from doctors and pharmacists—in effect to enlist professional participation in final product design.

The products as they were first launched are shown in Plate 5. Nicholas were pleasantly surprised by the amount of interest and comment of the kind they were seeking which they were able to gather from the profession. This two-way communication soon revealed possible improvements. Both pharmacists and doctors pointed out that the often hurried writing of a prescription meant that it was sometimes difficult for the dispensary to be sure whether Genticin or Gentisone was required. Secondly, pharmacists reported that the two packs were difficult to distinguish on the chemist's shelf. To answer these the distinctive initials HC were re-introduced to the combination product and it was retitled Gentisone HC. Also visually striking logos were introduced, one for each product. The new packs, incorporating these changes are shown in Plate 6. Plate 8 shows how the new style was presented in advertisements in the medical press.

The company now felt sure that the product was close to its optimum as

far as acceptance by the medical profession was concerned. The complete change in pack—redesigning, printing, and packaging—took just twenty-eight days.

CONCLUSIONS

The Genticin products are in many ways representative of the pharmaceutical development and marketing process. Technical change is a muchvaunted ingredient in many new consumer products but the real nature of the change can vary widely. It can be suggested that there is a 'spectrum' of technological change. At one end of the spectrum for example, might be the marginal development in detergent technology. This is not to say that this is not real or genuinely progressive, but that often it is important less for itself than for the change in advertising theme, which gives a competitive edge, which it can support. It is the promise of product benefit which the consumer buys more than a real physical benefit-though it can be argued that this nonetheless represents a valid increase in utility for the consumer for all that it may be psychological in origin. At the other extreme are technological developments which are undoubtedly significant for themselves and which are exogenous to immediate marketing considerations-the stainless-steel razor-blade is an example. This spectrum is to be found in pharmaceuticals, too. Very occasionally pharmaceuticals are only fractional technical improvements. At the other end of the spectrum are the equally occasional major therapeutic breakthroughs. In the middle, and outnumbering them both by far, are those new products which represent a significant if limited development in current therapeutic knowledge within a specific medical area. Gentamicin sulphate was one of these, in certain applications doing a job no previous drug could do so well, and in others offering a useful alternative treatment. In time no doubt gentamicin will be superseded as future products achieve quicker or better results. This is the cyclical nature of research-based industry: the present state of knowledge is the spring-board for future development.

The Genticin range can also be seen as exemplifying the pre-eminent position of promotion in the marketing of a drug. Favourable technical journal comments are not a substitute for a planned and integrated promotional campaign. Genticin itself has an impressive collection of bluechip journal reports, but the marketing of the product range pivots round advertising and promotion. The journal reports—or at least references to them—do, however, provide an important constituent in advertising copy. And doctors, much though they may decry the suggestion, generally respond in the same way as other consumers to advertising; and they will at best only respond slowly to a good product if the advertising is bad or insufficient.

From the points of view of marketing management three main features

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of this history may be pinpointed. First: the approach to marketing—is it an art or a science? How far can the intuitive or 'creative' approach be trusted? How far should the market analysts or the psychologists dominate campaign planning by their findings? It is possible to use either approach to the total exclusion of the other, the process being in the one case very risky and in the other very dull. The problems of Genticin HC stemmed not simply from the fact that the wrong mixture of the two approaches was used but that it was not fully thought out beforehand.

Secondly: how much weight can be placed in marketing on the product range concept? To establish a product range or family can without doubt be a useful marketing tactic. But its danger is that it can be boosted in marketing planning beyond its real importance. The fact that product No. 2 bears the same main name as its predecessor should not be overemphasised as a marketing weapon in itself. It must be carefully decided whether there is yet adequate acceptance of the family name before a favourable spin-off from No. 1 to No. 2 is written into the product plan. The cautious might even say that in any event this should be accepted as a useful bonus if it appears to occur rather than be included as an explicit factor in the product development plan. Nicholas are now aware of the dangers of developing a family range, and future Genticin product proposals will be assessed purely on their own potential rather than as extentions of a family situation.

Thirdly: a final point which may be made is one which has not been mentioned before. This relates to the internal organisational control of marketing as determined by the company organisational structure. At the time of the launch of the injectable product, marketing control was based on a management committee system. The product committee made major decisions and delegated implementation and day-to-day control to individual managers. At least a system of committee responsibility will slow down decision taking and in certain circumstances it is possible that decisions resulting will be impersonal and unimaginative. In short, management by committee in this type of product context can, if not carefully handled, result in a remoteness from the market place. Because of this, the immediate responsibilities of the product marketing managers at Nicholas have been broadened and the necessity for referring back has correspondingly reduced. It is considered that this may have contributed to the more cohesive approach which was adopted for the launch of the eve and ear products. It is still too close to the event for certain judgements to be made on the full significance of this for the Genticin products. Moreover, the question of the organisation and devolution of management responsibilities is a subject of its own, and, who knows, it may well turn up as the subject for discussion at a future OHE Winter Lecture.

Long-Range Planning Richard A. Bailey

GENERAL MANAGER, ELI LILLY, FRANCE

THE pharmaceutical industry is not one which is notably advanced in the field of formalised long-range planning. It is necessary to make this statement at the outset because it would have been possible to have in my place, to talk about this subject, someone from one of the long-range planning units which exist in the car or oil industries, for example, where the capital intensive nature of the business calls for important decisions to be made today based on projected demand five, ten or even fifteen years ahead. However, the OHE felt that it might be of interest to have an account of how an international pharmaceutical group, with growing interests in the fields of agricultural chemicals and animal health, is attempting to apply the principles of formalised planning to its own situation.

My main experience in this field relates to the period up to the beginning of 1968, when I was a member of the staff group in London responsible for, among other things, co-ordinating and presenting the long-range plans for an area representing about half the sales of the international division of Eli Lilly. More recently, I have been responsible for the operation of the company's French subsidiary and have been able to experience at first hand the long-range plans translated into action in an extremely dynamic situation. (I will come back to this latter aspect after the general discussion.)

In view of this experience, and my lack of theoretical knowledge in this field, a more complete title for this paper would be: A discussion of the problems of introducing formalised long-range planning in an international pharmaceutical company. Anyone who was expecting a treatise on the general theory of planning will, I am afraid, be disappointed.

Having said this, I find it impossible to talk about the subject without discussing briefly some of its theoretical aspects, because it is doubtful whether any word in modern business usage is more misunderstood than the word 'planning'. This is partly because it is difficult to separate the

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popular sense of the word from the more specific usage which is intended here, but partly also because many top executives simply do not believe in the function of long-range planning as distinct from the day-to-day process of decision making. They feel that the future is so uncertain, particularly as one tries to look further ahead, that it is not usually possible to plan for more than a year or two at best.

However, the idea of planning for the future in business has been around for some time, as shown in the writings of the French industrialist Henry Fayol, who, in 1916, included planning as one of his five key functions of managing (the others were organising, command, co-ordination and control), and who understood planning to mean 'both to assess the future and to make provision for it'.

It is perhaps appropriate at this point to quote another source, this time a famous Englishman, who expressed in a single phrase the opposing point of view. Sir Winston Churchill, in a speech to the House of Commons in 1952 said: 'It is always wise to look ahead, but difficult to look farther than you can see.'

We regard planning not as a means of controlling the future, which is clearly impossible at the level of the individual enterprise, but as a process of assessing all the possibilities, however uncertain they appear to be, and making a choice between a number of alternatives.

Business planning is based on the belief that, even though the future is uncertain, we can do something to make ourselves better adapted to it than we otherwise would be.

Before embarking on the first exercise in long-range planning in 1962, a number of fundamental decisions had to be made by the international branch of the company concerning the logistics of the operation: the time-span to be adopted, the key factors of the business which were to be forecast, the people to be involved and so on.

In considering the time-span, it seemed that an important factor was the accelerating pace of technological advance in the pharmaceutical industry, matched by a similar pattern of change in the other areas of the company's activities, i.e. agricultural chemicals and animal health products. However, the pharmaceutical market, being the company's traditional business and still representing the major part of sales and income, weighed most heavily in the choice of a five-year period as being the maximum length of time for which the company could sensibly plan.

As everyone now knows, the life cycle of a successful medicine today is relatively short and is tending to become even shorter as the pace of technological change increases. This is not only the case in this field, of course; it is probably true that in all advanced industries the trend is towards a decreasing life-span of products and processes, together with increasing amounts of time and cost involved in research and development. Thus, new weapons for defence are today obsolete shortly after they enter service, whereas in the nineteenth century a military ship could look forward to a long and useful life. It is said that Nelson's flagship *Victory* was 40 years old at Trafalgar and was still a leading ship of the line. Today, a missile which is 4 years old is probably ready for replacement without even having been used!

It was also realised that ours was not a capital-intensive industry, requiring major investment decisions to be made many years before returns on them could be anticipated, as is the case in the chemical industry, for example, or the aircraft industry. Our heaviest commitments in fixed assets are probably those connected with antibiotic fermentation (for which we have capacity in this country as well as in the United States), and here the lead-time is generally of the order of two to three years.

Thus, five-year planning seemed to make sense and was adopted for the company as a whole.

The second of the factors which I have mentioned was the choice of the key elements of planning. As with most other major companies, the profitand-loss statement was the basic document on which short range (one year) plans had always been made and it provided a standardised, well understood tool for measuring the performance of the various operating groups which could be adapted to the needs of long-range planning. It was felt that its drawbacks, such as its lack of reference to manpower levels and fixed assets were offset by these great advantages and that it could in any case be supplemented by additional planning statements.

A Lilly profit-and-loss statement, which is very similar to the form used in nearly all large US companies, is shown in Table A. Thus the elements of planning, following naturally the use of an extended profit-and-loss statement are: sales growth (and therefore product availability), cost evolution, operating expense levels and income to sales ratios, to which are added other important factors such as rate of asset turnover, and manpower development of which I shall say more a little later.

Then came the major question—who should be responsible for establishing the five-year plans and to what extent should staff participate in the exercise? This is one of the most hotly contended questions in this field and there is a large measure of disagreement about it amongst the experts on planning and management, to say nothing of the confusion which exists within industry. The difficulty arises from the fact that planning of this kind presents two rather different aspects. These are, firstly, the gathering and analysing of data and their presentation in a coherent form, and secondly the taking of decisions between the alternative courses of action and the implementation of the plan. It is obvious that the first function, that of data collection and analysis, is best performed by a specialised group with the necessary skills and also with the time available to devote

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Table A.

Profit and Loss Statement

	Amount	% Sales
NET SALES		
Cost of Products Sold		
GROSS PROFIT		
Fees Earned		
GROSS INCOME		
Administration		
Administrative Services		
Selling		
Sales Promotion		
Shipping Research and Development		
Loss on Merchandise Destroyed		
Total Operating Expenses		
OPERATING PROFIT		
Interest on Loans		
Total Other Income—Net		
INCOME BEFORE TAXES ON INCOME Estimated Taxes on Income		
INCOME AFTER TAXES ON INCOME Loss on Net Asset Conversion		
NET INCOME		

to this complex task, whereas the second function, that of decision taking and implementation can only be carried out by top management and the operating line managers who are responsible for getting the job done.

Eli Lilly & Company has always taken the view that any plan, whether short-range or long-range, is of no value unless it involves the participation and commitment of line management. Experience has confirmed that, taken overall, our plans for sales and profits are usually realised with a high degree of accuracy. This is not because we are particularly good forecasters but because objectives seem to be to some extent self-accomplishing: a low goal will produce low results whilst a high target—provided management accepts it—will almost invariably produce higher results, even if they fall slightly short of the goal. This is probably true in many other fields, and probably explains why some companies have been known to have two sets of sales forecasts—one for the accountants and one for the salesforce!

Table B.

Year of planning f	or:	1962	<u>1963</u>	1964	1965	1966	1967	1968
1962		100	129	141	157	175	188	
1963			129	147	171	195	220	244
1964				144	164	198	232	270
1965					170	202	234	280
ACTUAL		99	128	143	169	197	229	266

Planned and actual sales growth—Eli Lilly International (Index with 1962 plan = 100)

Thus we began in 1962 by establishing a five-year plan for International, in addition to the plan for the coming year. This took the form of a detailed discussion between top management, general managers of affiliate companies and a staff group from head office, during which a number of goals were established for the total operation. These goals were based on the managers' assessment of the future, modified by some general objectives put forward by the president, who had been briefed in advance by the staff group.

This procedure was followed, with modifications, during subsequent years, but more recently managers have been asked to make their longrange plans in detail, based on guidelines given to them by a staff group working closely with top management. These plans have been consolidated at head office and used as a framework for the discussion at the annual managers' meeting during which new objectives are established for the coming five-year period.

What has been the result of six years of experience with five-year planning? It is interesting, first of all, to look at the growth projections which have been made in the past for the turnover of the international division as a whole. Although the area with which I am directly concerned, i.e. Europe, represents only about one-half of this business, it is the area responsible for the major part of the growth, and with which most of the important long-range decisions were concerned. The figures shown in Table B are in the form of an index, with the 1962 plan = 100.

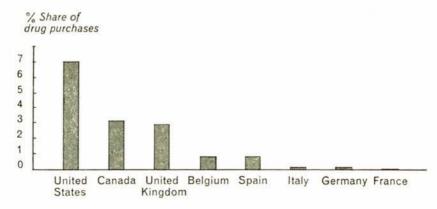
The most striking feature of these projections is the accuracy of the short-range forecasts; in each case the plan for the succeeding year is within 3 per cent of the actual attainment. This demonstrates the ability of our managers to forecast well in the short term and also probably the self-accomplishing factor which I have mentioned. It should not be overlooked, however, that some of these growth rates are relatively high for a

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Figure 1.

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company which did not make any major acquisitions during this period and which continued to devote a major part of its resources to its home market, which is not included in the figures.

Between 1962 and 1963, for example, the International division achieved a sales growth of 30 per cent, which was forecast in July of the previous year with an accuracy of better than 0.2 per cent! However, the five-year forecast of sales, made in the same year for 1967, turned out to be wildly wrong. The same managers who successfully forecast a growth of 30 per cent in one year failed by a wide margin to predict a growth of 79 per cent in the following four years—an average of only 16 per cent a year. Although this growth rate was certainly higher than the total rate of increase in pharmaceutical markets during the same period (which was probably between 8 per cent and 10 per cent), it was well below the capacity of the company if only for the following reason.

In turning our attention to the important European markets, we were faced with a situation in which our past performance was extremely limited, due to the earlier policy of non-investment in continental countries. This is illustrated by the 'market share' figures in Figure 1, which relate to the company share of retail pharmaceutical purchases in 1963.

This disparity between the company's market penetration in its traditional strongholds—notably of course its home market—and the important markets of continental Europe to which it was at that time beginning to turn its attention should have provided the essential clue to forecasting the average growth rates of around 23 per cent per year actually achieved in International between 1962 and 1967.

If it should be thought that I am expecting too much of forecasting in a high risk industry in which predicting the future is a notoriously difficult business, I should add that, with one important exception, the products were already available with which this growth was to be attained. The opening up of new markets in France, Germany and Italy was achieved with products which had already proved their value in the home market. In this way, one of the important 'unknowns' in the situation was less problematical than is usually the case.

Behind this forecasting failure of 1962 lies a fundamental lesson for long-range planning. This is that general managers working mainly with the knowledge relating to their own areas of responsibility cannot plan effectively for more than a year or two ahead, and particularly so when they do not receive some firm guidelines, based on the conclusions which can be drawn from considering the total company picture.

Managers working in these circumstances tend to make projections which are either (a) too conservative, because they are unwilling or unable to make assumptions about facts which are uncertain or which require decisions at high level about which they are not informed, or (b) too optimistic because they assume that the necessary decisions will be taken to ensure rapid growth or that the new products will come along, thanks to an effective research and development organisation.

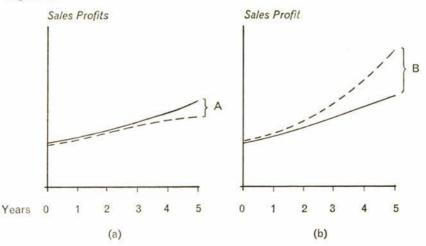
This produces one of the two situations shown in the graphs in Figure 2. These represent the consolidation of individual company plans and can refer either to sales or to profits, since other factors are assumed to be constant.

In each case the solid line represents the kind of growth which might be thought to be most likely, in an arbitrary kind of way, by the Board of Directors and corresponds approximately to the minimum achievement which it is prepared to contemplate. In example (a) however, line managers are not given any assumptions regarding new products, cost improvements or any other factors which would be likely to affect the business in a favourable way towards the end of the period and because they are accustomed to the 'life cycle' phenomenon in a research based industry, they forecast a declining rate of growth, resulting in the gap 'A' between the minimum goal and the forecast. This has been referred to as the 'product/ profit gap'.

In example (b), the same set of circumstances prevail, but in this case the managers have been working in an environment where goals are traditionally set high and where past performance has been good, due to a succession of new product introductions and technical improvements. They therefore assume that new products will come along to replace present ones and that improvements in productivity will take place without any specific action being taken. This produces a gap 'B' between minimum goal and forecast which I have called the 'credibility gap' because it is based on faith and hope rather than on definite assumptions.

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Our early experience has been, as I have shown, as in example (a). This is less dangerous than the reverse case because it leads to questions being asked and, finally, decisions being taken which are designed to fill the product/profit gap. Thus, the initial attempt at planning was extremely valuable and the experience was used to good effect in subsequent exercises.

In particular, a great deal of emphasis in planning is now placed on the preliminary staff work, during which top management is presented with a series of alternative assumptions regarding (a) the external environment in which the company expects to be operating in the future (markets, habit trends, legislation, etc.) and (b) the internal situation of the company (availability of capital, new product possibilities, acquisition policy, etc.). It is not until these basic assumptions have been agreed upon that the managers are asked to make their plans.

It is interesting to note that in the second year of planning, 1963, the forecast for 1967 was increased considerably, based on some firm assumptions about new products and investments and the figure was remarkably close to the actual achievement. Moreover, the 1968 forecast, made in 1964, was almost excatly right!

In addition to forecasting sales, long-term goals are set annually for other variables such as operating profits, total assets, net income, return on assets and total manpower levels. Although I cannot quote actual figures, it is interesting to note that the company set itself, in 1963, an extremely ambitious goal for return on assets in 1968. It appears now that this goal has been almost exactly achieved in International in the year just ended—a very gratifying result.

Table C.

Operating Profits in Eli Lilly International

	1962	1963	1964	1965	1966	1967
1962 long-range plan	100	111	138	148	171	198
ACTUAL	95	90	123	158	181	213

In the light of several years experience with this kind of planning, our approach now consists of a number of clearly defined steps, which can be summarised as follows:

- 1. The setting up of a number of general objectives for the operation as a whole.
- The collection and study of information about the past, present and future, both for the company and for the environment in which it is operating.
- 3. The definition of certain key assumptions to be made about the future.
- 4. The identification of a number of alternative courses of action which could be adopted.
- 5. The choice of a best course (or courses) and the establishment of a plan.

I would like to illustrate each of these steps with a number of examples relating to the period I have just referred to, although this will be by no means complete.

The general objectives established for Eli Lilly International from 1962 included: the steady development of profitable pharmaceutical business, with particular emphasis on the creation of new affiliates in Europe; the building up of a substantial business in animal and agricultural chemicals; and the realisation of these expansions together with improvements in operating profit levels, in net income, and in productivity per man.

This set the general 'tone' of the business for the years to come, with emphasis on profitability and the efficient use of assets, as opposed to maximum growth rates, the growth coming in fact mainly from the penetration of new markets. The achievement of the goals for operating profit is shown by the figures in Table C, which are in the form of indices with 1962 = 100.

The definition of assumptions, the third step in the procedure, included such considerations as new product availability, capital investment programmes, acquisition policy, and other internal factors of this kind. It also covered, however, some general assumptions about the external environment, to ensure that the plan was not built on conflicting ideas about the future. Thus it was assumed that, in spite of increasing political pressures

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on the pharmaceutical industry, the markets for the company's products would in general continue to grow, due to the anticipated rise in living standards and the extention of social security programmes in most countries, leading to the wider availability of advanced therapeutics. Assumptions were also made regarding population growth rates, per capita income levels, and trends in feeding and nutrition (important for the non-pharmaceutical branch of the business).

All these factors were of course derived from step two, the collection and study of data relative both to the company and to the environment in which it was operating.

The final steps, consisting of the identification of alternative courses of action and the choice of a 'best course', or perhaps rather a 'desired course', cannot be adequately covered here. However, if I had to list some of the most important decisions for the European area resulting from long-range planning in the period 1962 to 1967, I would quote the following:

- 1. The decision to promote intensively an existing product group to bridge the gap until the arrival of new products.
- The decision to give major priority to the development, registration and introduction of the cephalosporin antibiotics in all markets of the world where we are licensed to sell.
- 3. The decision to make a major investment in facilities in the EEC to supply the rapidly expanding business in Continental Europe.
- 4. The decision in 1966 to build up separate marketing organisations for the non-pharmaceutical products to take advantage of present and future developments in the animal and agricultural fields and for the sale of empty gelatine capsules to other manufacturers.
- 5. The decision to search for and hire well qualified young executives, particularly in the marketing areas, to support the rapid growth anticipated in Europe.

I will not comment in detail on all of these decisions, since each merits a separate study which is outside the scope of this paper.

It is perhaps interesting to mention, however, that the first decision, taken as a result of an examination of the 'product gap' perceived between the minimum sales goal for 1970 and the forecast based on assumptions about new products, was to promote intensively the erythromycin antibiotic range. Studies showed that Eli Lilly & Company had become, since the Second World War, increasingly successful in the field of antibiotics. It seemed logical to capitalise on know-how about the antibiotic market, together with a range of excellent products which was far from achieving its true potential. This was done, with extremely gratifying results in many countries of the world, our sales of erythromycin products in international market having doubled in three years between 1965 and 1968.

We are now benefiting from the rapid development and introduction of the cephalosporin antibiotics, a truly remarkable family of products which are fully justifying the enormous investment in research and planning which has enabled them to be made available to the medical profession in practically every country in the world.

I would like now to turn to the last and perhaps the most significant of these decisions—to build up rapidly in the European area a group of capable executives from which the future managers of the company can be drawn.

It has been observed that the pharmaceutical business is not capital intensive, in contrast to certain other international industries such as chemicals or oil. It is, however, a 'people intensive' business and will become increasingly so as the breadth and scope of research activities expands in relation to the life cycle of the products marketed. At the end of 1968, Eli Lilly & Company will employ worldwide a total of approximately 17 000 people, for a turnover of almost \$500 million. Each person will therefore represent about \$30 000 worth of sales revenue and whilst this is probably one of the highest ratios in the pharmaceutical industry, it clearly does not compare with the corresponding figures for such companies as Shell, ICI or General Motors.

We feel very strongly that our investment in people demands the same detailed planning that is normally given to major capital investment programmes. It is now regarded as one of the most important aspects of our forward planning and we have at the present time plans for the addition of personnel through to 1971.

This is, of course, one of the areas where the reality is most likely to differ from the plan by a large measure, but the existence of a forward programme ensures that managers are constantly thinking in terms of future requirements, as well as immediate needs. In due course, it will become accepted that future planning for people is as essential as future planning of sales and profits, since one cannot be realised without the other, and I feel that this is one aspect of long-range planning which is almost always neglected in the textbooks, which usually concentrate on the other important elements such as capital, products and fixed assets.

In case it should be thought from the examples given that forecasting five years ahead is easy, let me hasten to add that the law of large numbers has a significant effect on a total company plan of this kind, and that actual results for individual parts of the whole can show wide variations from the forecasts. In the case of the French affiliate with which I am concerned, the comparison provides some interesting material for discussion.

In order to make this comparison, which will have to be limited here to certain general observations, it is necessary to look at one of the first detailed long-range plans made for Lilly France in 1964. At this time both

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branches of the French company, that is pharmaceutical and Elanco, were in an embryonic state, although plans for the construction of local manufacturing facilities had already been made.

Assumptions were made about products which would be available for marketing, in addition to those already in the company's price list. For example, it was assumed that one major new pharmaceutical product would be ready for introduction in 1967, to provide a large part of the growth through to 1971. A similar assumption was made in the field of agricultural chemicals. In each of these cases, it should be realised that the product in question was not known at this stage, but a number of research projects were judged to be sufficiently promising to justify this hypothesis for planning.

Furthermore it was concluded, based on detailed market studies, that the empty capsule market in France would grow very rapidly, to provide the third major area of expansion for the company.

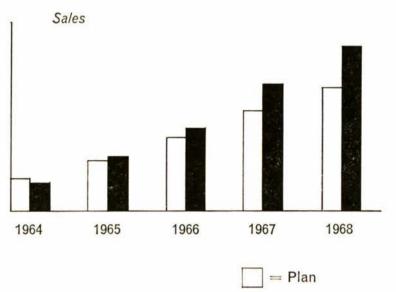
Fortunately, these major assumptions have been justified in general terms, and subject to normal variations, by the events in the years following. In each branch of the business sales have grown faster than planned. However, further assumptions were made about product and operating costs which led to a plan for profitable operation within four years. This was based on the belief that costs would fall from the high initial levels to provide an increasing level of operating profit and income. In the event, costs have remained at relatively unfavourable levels due to the continued high price of raw materials, and operating costs in the form of wages, salaries and purchase prices generally which have risen more rapidly than foreseen. To this has been added the problem of successive price decreases which have been forced upon us.

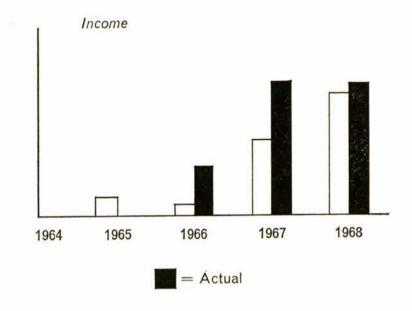
The relative progress of sales and income compared with plan is shown by Figure 3.

Clearly, profits would have been much higher than the plan in 1968, based on the rapid sales growth, but for the adverse cost factors I have mentioned. As a result of net income being about equal to plan, the overall size of the company has been developed approximately on the lines determined and agreed in 1964. Manpower, for example, is not far above the planned level, but assets are considerably higher than anticipated for the reasons connected with cost mentioned, and because the construction programme in France has been extended since the original plans were made. As a result, we find that return on assets, whilst very reasonable for a period of intense investment, is lower than was anticipated at this stage.

The important point to note here is that the long-range plan, once established, provides an excellent means of measuring progress in a rapidly changing situation. It helps to keep the company goals before the eyes of successive managers, and highlights deviations from the expected returns







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Long-Range Planning

on which past investment decisions were based. Perhaps one of the greatest advantages of long-range planning in an international company is that it provides the elements of continuity which are often lacking through changes of personnel due to promotions and transfers.

Returning to the main theme of this paper, I would like to conclude by outlining my own ideas on the direction in which, I hope, we will move in regard to the organisation of long-range planning activities.

The central problem, as I have tried to show, lies in the apparently opposing views of planning as a centralised or as a decentralised operation. Whilst it is certainly true that a centralised staff group, reporting directly to a senior operating executive, has an important role to play, it is also essential that the line managers who are responsible for implementing the plan should be fully aware of its implications and should feel involved in it to the extent that they are personally committed to achieving its goals.

French national planning, which is extremely well developed and often quoted as an example of the true scientific approach to this problem, probably suffers from the defect that, being largely carried out by a specialised government staff group, it does not achieve the involvement and commitment of industry groupings which are after all largely responsible for its implementation. It is widely felt to be 'the government's plan'. It must, however, be possible to adopt the good points from the French method to arrive at an effective procedure for industrial firms and, indeed, some companies have successfully done this. I would advocate the creation of a small planning unit, headed by a senior man having had good line management experience and reporting to the senior executive of the company. This group would work exclusively on future planning and would be in constant touch with top management, whose active participation is essential for defining company objectives.

It would also be able to co-ordinate the planning of the operating units, who would still be responsible for building up the component parts of the plan.

Participation is a key political word in France at the moment and I believe it is coming into vogue in this country as well. It could certainly be adopted by the company wishing to engage in constructive planning for the future.

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ALL industries, in all advanced countries, have to operate in a framework dictated to a greater or lesser extent by government. In the simplest terms, government taxation impinges, often heavily, on their finances. In this country companies also have to act as government tax collectors in respect of their employees' income tax and social security payments. Terms of employment and physical conditions are usually regulated. In some respects there are limits on the type of personnel who can be employed and there are laws concerning the training they should be given. The location and design of factories and offices must be approved. The raw materials which may be used and the wastes which can be discharged may be regulated. Companies must not only publish accounts, but are required to provide extensive operating statistics to government. The way in which a company describes its products is controlled by law. Prices are frequently either controlled or supervised. The size and scope of companies may be regulated.

In many individual cases there are further additional restraints. Publishers must avoid obscenities and libel. Food must be properly described, pure, and produced in hygienic surroundings. Vehicle manufacturers must comply with safety regulations. Clothing manufacturers are prohibited from selling certain types of flammable garments. Liquor manufacturers may only sell through licenced premises.

Apart perhaps from the tax laws, designed primarily to raise revenue from profits and earnings, all of these laws are to protect the interests of shareholders, employees or the public, although it is well to remember that these interests often cannot be determined on any particularly fundamental basis. Frequently, it is a matter of judgement by the government of the day, who may be concerned with protecting minority interests against those of the majority, or, of course, vice versa. The government, in deciding who needs protection against what, may be strongly influenced in many different directions by pressure groups. In some cases, the controls

have the effect of making manufacturers behave in a way *contrary* to that which the public as a whole—using the market place as a forum—would have chosen. Car safety is an example. However much the public may approve of road safety in principle, most people in practice rate the price or performance of their new car as more important than its likelihood of not injuring them in an accident. That is why legislation has been necessary, for example, to make seat belts compulsory.

It is not surprising, against this background, that the pharmaceutical industry has been one which has been subjected to extensive government regulation for many years. A multiplicity of Acts and regulations have controlled the distribution of its products, their labelling and in many cases their potency and purity. In Britain, the latest consolidation and extension of these government controls were embodied in the 1968 Medicines Act, which gives government powers which are intended to ensure the safety, efficacy and guality of all medicines and to determine their channels of distribution and labelling. Private industry is always naturally suspicious of very widespread government powers of this sort. On balance, however, responsible pharmaceutical manufacturers welcome the type of controls to be applied under the 1968 Medicines Act, because they will help to prevent irresponsible competition from shady operators. It is necessary to record, however, that laws, however stringent, cannot ensure perfect performance. Indeed, as legislation becomes so very much more extensive and so very much more complex than in the past its enforcement tends to become more difficult, and often more inequitable. The responsible company management painstakingly complies with the irksome details of regulations, while-as we have seen in the pharmaceutical field in the past few months-the irresponsible entrepreneur can run rings round law enforcement agencies at both the local and national level

In spite of this, however, there are few problems in the pharmaceutical industry's relationship with government as it concerns legislation controlling the safety and quality of its products. There is a common interest and purpose and the present legislation, provided it is sensibly applied, should do no more than back up the higher standards already set by the majority of companies. As far as industrial legislation generally is concerned, the pharmaceutical industry is probably neither better nor worse off than industry as a whole.

There is another aspect of industry's relationship with government, however, which presents very much greater problems of particular importance to the pharmaceutical industry. This is the behaviour of government as a customer of industry. Again, this relationship is more common than may be generally realised. Government now pays for very nearly half the total goods and services in this country—as it does in most industrialised nations. Over a wide range of industries the government is a major purchaser; civil engineering, electronics, aircraft, armaments and electrical generating plant of all types are examples where central or local government, directly or indirectly, has a commanding position as a purchaser. Furthermore, it is important to view this position against the background I have already described. That is, for many industries the government has extensive powers, both directly through legislative controls and indirectly as a customer. In this situation, many industries point to the extent to which they are at the mercy of the politicians and bureaucrats who wield this double power.

On the reverse side of the coin, however, is the view expounded by Galbraith and others; theirs is the philosophy of 'private affluence and public squalor'—the general belief that industry will always be rich and powerful, and that partly because of this power democratic governments will always more or less fail in their efforts to achieve social justice (whatever that may mean). In brief, they suspect that whatever measures government takes, industry will always be able to use its wealth, power and (most important) its ingenuity to thwart the 'public interest'. Theirs is the antithesis of the belief expressed in the aphorism that 'what's good for General Motors is good for the United States'.

This conflict of view is particularly important in reviewing any case history of government-industry relations. It is important because it means that much of the discussion on these matters is necessarily, if regrettably, polemic rather than rational. There is no generally accepted economic theory which can adjudicate between these two points of view—one that industry is shackled by excessive government intervention and the other that government is powerless to restrain industry in general from acting primarily in its own narrow self-interest. Perhaps the most rational attitude might be to assume that both points of view could be correct; however, I certainly do not wish today to discuss the wider political implications of that assumption.

Turning now to the specific case of the government as a customer of the pharmaceutical industry, I want to concentrate primarily on the question of prices and profits. Other issues have arisen, but I do not intend to mention these because they are peripheral to this one central issue. I would like first briefly to review the history. It has been accepted since the earliest days of the National Health Service that a special situation exists in respect of the pharmaceutical service. Namely, the doctors are free to prescribe as they think best and the government must pay for whatever medicines are dispensed as a result. Again from the earliest days, the Public Accounts Committee has expressed anxiety over this situation, and pressed the Ministry of Health to take measures to ensure that the prices they paid for the medicines were reasonable.

To this end, after some previous rather unsatisfactory efforts to scrutinise individual profits, the Ministry negotiated with the industry the first Voluntary Price Regulation Scheme which came into operation in January 1958. Basically, for the majority of products, this related the price of prescribed medicines in Britain to their prices in overseas markets. That is, the Ministry accepted the principle that prices to the NHS were reasonable provided they were no higher than prices being paid in other countries. It was assumed that since it was the patients or the private insurance schemes which were paying in these other countries the reasonableness of their prices was assured.

This assumption was almost immediately undermined, however, by the reports of the Kefauver hearings in the United States published in the same year. However irrational the underlying economics presented at those hearings may have been, it was clear that the 'free enterprise' market for pharmaceutical products in the United States was not achieving classical economic price competition particularly in the case of patented prescription medicines. Thus, in January 1961, under continued pressure from the Committee of Public Accounts, supported now by considerable public and political disquiet, the second Voluntary Price Regulation Scheme introduced the principle that the price of major products should be the subject of direct price negotiation on the basis of the overall profitability of the company supplying them. The application of this principle was further extended in the third VPRS in July 1964. By 1965 about half of the total purchases of the pharmaceutical service were covered by direct price negotiation on the basis of company profitability. That is, one had moved from the 1958 situation in which it was considered that NHS prices were reasonable if they were no higher than overseas prices, to a situation in which the prices were only regarded as reasonable if, in addition, scrutiny of the company's accounts indicated that its profitability was not excessive.

From the start, however, this second approach was bedevilled by two problems. First, the international structure of most companies made it extremely difficult to disentangle the profits relating solely to their United Kingdom pharmaceutical business. How much research carried out abroad should be charged to this country? What proportion of overseas capital was properly attributable to the UK business? How much profit was included in the price of raw materials and intermediates purchased from overseas associates? The second problem was even more intractable. What was a 'reasonable' profit for any particular company in the pharmaceutical industry?

It was on these issues that the first open dispute arose between government and the industry, exemplifying the conflict of view which I have already described. It arose against a crescendo of public disquiet about prices being paid for NHS medicines.

In prolonged discussions with the Ministry of Health during the early part of 1961, a number of manufacturers were continuing to produce facts and arguments to justify the prices of their patented products in what we now recognise to be an intensely complex economic situation. Meantime, however, some enterprising hospital pharmacists had started to obtain supplies of chemically identical products at much lower prices from unlicensed manufacturers in countries such as Italy, which did not grant pharmaceutical patents. The then Minister of Health, Enoch Powell, was faced with a dilemma. He could either instruct the hospital pharmacists to cease breaking the law, as they were doing by buying these imports from unlicensed sources. Alternatively, according to his legal advisers, he could use Section 46 of the 1948 Patents Act to authorise importation of these continental unlicensed copy products 'for the services of the crown'. He took the view, in the political climate of the day which was almost universally hostile to the pharmaceutical manufacturers, that he should follow the latter course. He announced his decision to do so in May of 1961 and imports of these unlicensed products started the following year. These imports were used only to supply the hospital service. Although the dispute with the original patent holders had been primarily over the price charged to the pharmaceutical service, for supplies outside hospital, the Patents Act did not, in the opinion of his legal advisers, authorise the Minister of Health to use Section 46 to obtain supplies for this larger part of the market even had he wished to do so.

Thus, in this encounter, Enoch Powell, arch-priest of the right-wing free marketeer philosophy, took the essentially Galbraithian view that the pharmaceutical companies concerned were adopting a narrow selfinterested pricing policy which was unacceptable in the context of the NHS. There is no doubt that this dispute did lasting damage on both sides to the government-industry relationship. The Ministry regarded the companies' protracted discussions on prices as deliberately obstructive behaviour, intended to postpone reaching a settlement on 'reasonable' prices; the industry regarded the Minister's use of Section 46 as an impatient and hostile gesture calculated to undermine the industry's confidence in government's policies towards it. The suspicions on both sides remain as a major obstacle to re-establishing mutual goodwill. The companies concerned did, however, continue negotiations on prices, and by 1965, the Ministry were able to announce that in the light of what they regarded as a satisfactory price settlement for supplies to the NHS as a whole, they would discontinue importations under Section 46.

It is interesting that even in retrospect Enoch Powell still took the view that he was relatively powerless against the industry. In *A New Look at Medicine and Politics* in 1966, he wrote: 'The government still possesses statutory power to control the prices of drugs. It is a power about as useful,

for practical purposes, as a hydrogen bomb in the Vietnam war'. He went on, however, to say that the existence of these powers might indirectly influence companies' attitudes to pricing. He also discussed the relative bargaining strengths of the two sides, which, as I shall quote later, he thought were determined primarily by the fear each have of public disapproval.

Since 1965, the powers under Section 46 of the 1948 Patents Act have no longer been used, but they remain as a threat to intransigents in price negotiation. Indeed in the 1968 Health Service and Public Health Act, the government powers were extended to apply Section 46 to the much larger market for the pharmaceutical service. This was regarded with grave misgivings by the industry, as a considerable strengthening of the government's hand in future price negotiations. There have also continued to be difficulties in reaching agreement on prices between the Ministry and individual companies, and the Public Accounts Committee has continued to express anxiety on these grounds. It was against this background that the government set up the Committee of Enquiry under Lord Sainsbury in May 1965 to investigate the relationship of the pharmaceutical industry with the National Health Service.

There is one other aspect of the government's activities which should be mentioned in reviewing the situation as it has developed so far. This is the pressure which government exerts on individual prescribers. They have recently been subject to regular and colourful propaganda from the Ministry of Health on comparative costs of different treatments. Those with above average prescribing costs have always been asked by their local NHS Executive Council to exercise greater economy. To back up such requests doctors may be visited by the Ministry's Regional Medical Officers, and there are financial sanctions for over-prescribing. These sanctions have very rarely been applied in practice; nevertheless they, too, remain as a threat against doctors who persistently select expensive remedies.

Before turning to the present situation in Britain, it would be useful to look even more briefly at government measures in relation to pharmaceutical prices in a few other arbitrarily selected countries. At one extreme, France has a rigid system of price control. Each price must be approved on the basis of a full calculation of costs, starting with the chemical ingredients, and with specified additions for production costs, packaging, research, advertising and finally a rather nominal profit. In practice, however, this is no more than a façade. Whatever quantum of real profit is desired is merely added on to the cost of the original chemicals. These are invariably supplied at a price including this profit by an associated chemical company, which is often distinct from the pharmaceutical company on paper only. French prices are generally a little higher than those in Britain under this arrangement. In Italy, where prices tend to be even higher, the government from time to time dictates an arbitrary percentage price reduction either across-theboard, for all pharmaceuticals, or for particular groups of products which are thought to be unduly profitable. This naturally tempts companies initially to price very high in anticipation of future statutory reductions. It also tends to encourage a proliferation of new products to supersede those whose prices have been unreasonably reduced. In Belgium, they rely on a direct comparison of the local price with that in the country of origin, insisting, despite the smallness of the market, that the Belgian price should be substantially below the original price. Clearly, not all countries can adopt this policy!

Germany has no price control, but there is a fixed per capita limitation on each doctor's prescribing costs. Those who prescribe in excess of this limit must meet the additional cost themselves. The stronger price consciousness which this instills into doctors is no doubt to some extent reflected in German pricing policies. It does, however, limit the doctors' prescribing freedom and it is doubtful if it would be acceptable in this country.

The Indians and the Canadians have both relied on erosion of patent protection, and the consequent threat of price competition, to bring pressure to bear on prices. It is only in the United States, despite repeated investigations and considerable adverse publicity on pharmaceutical prices and profits, that no restraints have yet been applied. They, however, have so far had no general health service providing pharmaceutical benefits. Now that Medicare and Medicaid are being extended into this field, the US government is looking extensively at what action other countries take in respect of pharmaceutical prices and expenditures.

Apart from attempts to control prices, there are also various forms of restrictions on prescribing in different countries which are presumably aimed at limiting costs. Thus in some, doctors practising under their social security schemes may select only from an approved list of medicines if the prescription is to be reimbursed by the scheme. In other countries, there are different rates of reimbursement for different types of products. and although this often depends on their therapeutic category, higher rates of reimbursement are sometimes restricted to relatively inexpensive products. In general, restricted prescribing lists do not appear to reduce the overall cost of prescribing in these countries although it may in some cases reduce the proportion of the cost met by the social security scheme. In the US for example, the government's 'Task force on prescription drugs' has estimated that the exclusion of certain duplicative drugs, combination products and 'non-critical' products such as obesity products, mild analgesics and antacids could reduce the pharmaceutical expenditure under 'Medicare' by about 10 per cent. In Britain medicines are classified accord-

ing to their relative efficacy by the Macgregor Committee and doctors can be called upon to justify prescribing adversely classified medicines. In this case, however, classification has nothing whatsoever to do with cost and it is only a matter of comparative clinical judgement between the Committee and the prescriber on the desirability of particular products.

Returning to the question of pharmaceutical prices and profits in Britain brings us to the Report of the Sainsbury Committee in September 1967. In parts, this was a very controversial document, and Professor David Walker, for example, has said that he did not 'consider that many of their economic recommendatoins were well founded'. However, there is no doubt that the better passages of the Report have helped to raise discussion on the subject of prices and profits on to a substantially higher plane.

It made three recommendations of direct relevance to the pricing question. The first was that companies should provde an annual financial return to the Ministry of Health, showing in prescribed form the financial results of its pharmaceutical business. Secondly, it recommended that the problems associated with financial transfers and transactions with associated companies should be resolved. Thirdly, it recommended that companies should submit 'standard cost returns' showing proposed prices and costs initially for new products and eventually for major products already on the market. This third recommendation was strongly opposed by the industry as being inappropriate. The Association of the British Pharmaceutical Industry contended that the operating ratios of a pharmaceutical company-with its heavy dependence on innovation-could only properly be reviewed as a whole rather than in terms of individual products. The Ministry of Health was also reluctant to implement this recommendation because of the large numbers of additional Civil Servants whom it was envisaged would be needed to scrutinise intelligently these individual product cost returns. This recommendation has, therefore, for the present been rejected while the government and industry continue to discuss the other two in the context of a further revision of the Voluntary Price Regulation Scheme.

The principal difficulty remaining in the wake of the Sainsbury Report is that it correctly identified the problem of measuring the reasonableness of pharmaceutical prices, but nevertheless offered little in the way of an answer to this problem. Although it felt able to conclude that the industry's profits had been 'excessive', it implicitly acknowledged that there is at present no accepted economic theory and very little empirical evidence to suggest what should be a reasonable average profit for the pharmaceutical industry. There is even less guidance available on how to judge the reasonableness of an individual company's prices and profits.

To understand the present position, it is necessary first to look at the

facts, which are not substantially in dispute, and secondly, to look at the alternative theories to explain these facts, which are the subject of intense controversy.

First, the facts. The pharmaceutical industry is an innovating industry. dependent primarily on research and new products rather than the production of established goods. It cannot, therefore, be judged on economic criteria developed from production-oriented firms which until recently characterised British industry as a whole. Furthermore, it has been shown that for any innovating industry the cost of innovation does not depend on the costs of research and development alone. These will be accompanied by substantially greater costs for other aspects of innovation-investment in new plant, market development and straightforward sales promotion. The pharmaceutical industry is no exception in this respect. Nor can the price of an innovation be related solely or even primarily to its production cost. In the United States Senate hearings, where they still naively refer to '1000 per cent profits', on the basis of differences between production costs and selling prices, they are simply ignoring the fundamental economics of innovation. So much is now common ground among economists in Britain

Further, on this subject of profitability, there is little doubt that the pharmaceutical sector is indeed more profitable than industry as a whole. In the United States, where it is important to remember that there is an entirely free market and no restraint whatsoever on prices, the leading pharmaceutical manufacturers are reported to earn about 21 per cent after tax on stockholders' investment compared with about 13 per cent for all leading manufacturers. For Britain the data are more difficult to interpret. This is because most pharmaceutical manufacturers in Britain are subsidiary companies, either of overseas parents or of larger diversified British groups such as Beecham or ICI. Thus, as I have mentioned already, it is difficult to isolate the true profitability of the pharmaceutical business by itself. The Board of Trade figures for profit, which inevitably suffer from this disadvantage, give figures of profits for 'pharmaceutical' companies of about 20 per cent return on net assets compared with about 14 per cent for all British industry.

The inclusion of the accounts of overseas subsidiaries in Britain (often undercapitalised and excluding many costs borne on their behalf by overseas parents) will certainly inflate the industry's published profits. On the other hand, if the profitability in the pharmaceutical divisions of integrated British companies were higher than in the rest of their business this fact would not be reflected in the Board of Trade figures which are based on the performance of the company as a whole. (The quoted British pharmaceutical companies show an overall return of only 15 per cent). These two considerations might, of course, tend to balance each other out. Figures

provided by companies to the Sainsbury Committee attempted to overcome these accounting problems and although they could not do so in all cases they probably give a better indication of the true position. The Sainsbury Report, rather strangely, did not quote an average return for the pharmaceutical industry as a whole. However, an independent analysis of the figures submitted to it did in fact suggest that, on balance, the Board of Trade figures probably give an approximation to the actual profitability of the pharmaceutical sector.

Thus, in Britain, it appears likely that pharmaceuticals earn a premium profit of perhaps five or six percentage points over industry as a whole. In addition, the Sainsbury Report concentrated on the fact that this average was arrived at by including some very high figures for individual profitabilities. Once again, it is common ground that exceptionally high profits of this sort are a necessary feature of the pharmaceutical industry. The Report itself said that 'there would be little inducement for firms to take on a specially high risk in searching for a particular medicine which may be eagerly desired in medical practice if there were to be no possibility of unusual profit, and a high probability of failure after considerable costs had been incurred. In such circumstances a "normal" return on the sum risked would provide little inducement for a firm with safer alternative uses for its money to undertake research with higher risks'. The Committee went on to comment 'that in the absence of the prospect of "abnormal" profits, private industry would have no special inducement to undertake research to which attached an abnormal risk of failure. There might even be some important disincentives to the acceptance of such risk'. The only question is one of degree.

On this analysis so far, the problem falls into two parts. First, to work out a basis on which the operating ratios and profits relating to sales of NHS products should be computed and the 'prescribed form' in which they should be presented. Second, to judge the reasonableness of the profits so revealed. On the first, there has been a great deal of common ground between the industry as a whole and government that every effort should be made to solve the very extensive and intricate accounting problems which arise. The very general and sometimes inappropriate recommendations of the Sainsbury Committee on these matters are now being worked into a detailed and practicable scheme which it is hoped will be acceptable to both sides. It is the second point which brings one out of the area of fact into one of interpretation and conflicting theory.

In economic terms, high profits are justified either by risk, by efficiency or by both. In the case of risk, extra returns for investors are necessary as an incentive to take the risk. If one is going to get no more than an average return in any case one might as well choose a secure investment rather than an insecure one. In the case of efficiency, a higher profit will attract invest-

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ment away from less efficient (and less profitable) enterprises. This is the essential process without which good managers and bad managers would prosper equally, and society would face economic disaster. Related to this point, high profits are used by the efficient managers to finance desirable economic growth in the more efficient sectors of the economy. On the other hand, high profits are economically unjustified if they are earned solely as a result of a monopoly situation by companies with an average or poor performance, facing no particular risks.

Economists and politicians seeking to criticise the industry's profits in both Britain and the US, favour the latter explanation for high profits in the pharmaceutical industry. They argue that patents, brand names and heavy sales promotion create very real barriers to entry and give manufacturers quasi-monopolistic powers. Economists supporting the industry. on the other hand, have pointed out that these are no barriers to entry for a company with large enough resources to undertake significant pharmaceutical research and to market its products effectively. They also point out that there is much evidence of vigorous competition in the industry. Furthermore, they argue that its riskiness justifies its exceptional profitability. The measure of risk normally used in this connection is the extent of the spread between the highest and lowest earners in different industries. It is argued that a high spread (such as that found between pharmaceutical companies) would mean that a new entrant to the industry would find it hard to predict the likely return on his investment. By contrast, for industries with only a small spread of profitability, a new entrant can reasonably expect to earn the same as others in the industry, and his level of profitability is, therefore, predictable. The pharmaceutical industry itself argues that its efficiency and record of innovation also justify an above average return. It asks why it should be expected to earn little or no more than the average figure, when the latter includes heavily capitalised, backward and sometimes inefficient industries, such as shipbuilding. The discussion of these issues, however, lies outside the scope of this paper. It is sufficient to record the point that there are strong differences of opinion between economists of considerable stature (though often of different political complexions) and that extensive arguments have been adduced on both sides. It can only be hoped that further economic analysis will resolve these differences, but in the meantime a genuine problem remains.

The implications of this situation for those attempting to construct machinery for price negotiation between the pharmaceutical industry and the Department of Health and Social Security are obvious.* In the absence of set guidelines the Department of Health foresee continuing interminable

^{*} The Ministry of Health became part of the new Department of Health and Social Security from 1 November, 1968.

arguments about the reasonableness of particular companies' profits. The industry, for its part, while it has always been prepared to disclose individual company profits, can see no basis for agreeing arbitrary ranges of acceptable profitability, a point of view with which the Department can sympathise. Upper limits which would be acceptable to the industry would be unacceptable to the Committee of Public Accounts, and those which would be acceptable to the Committee would be unacceptable to industry. Limits set at obviously 'reasonable' levels would run counter to the philosophy, spelled out in the Sainsbury Report, that 'abnormal' and even 'apparently unreasonable' profits are sometimes necessary to stimulate desirable forms of research. Nor, from either side, is there any logical basis on which to determine in advance what should be judged to be a reasonable average return for the pharmaceutcial industry as a whole compared with that for all manufacturing industry.

It is useful at this point to look back over the philosophy underlying the belief that the pharmaceutical industry should have to justify its prices and commercial policies to the government. Originally, this was thought to be necessary because the NHS provided a 'soft market' for prescription medicines, by making them available to the patient initially at zero price and then for a nominal charge unrelated to their cost. It was thought that this eliminated the normal economic mechanisms which in other circumstances would have regulated the prices charged. In the absence of these economic forces, special controls on price appeared to be necessary. Initially, as we have seen, these were based on prices in other markets. The British government was concerned to see that it did not pay more than other customers.

The developing situation over the first ten years of voluntary price regulation, however, has steadily reversed this original picture. It is now clear that classical price competition is absent in any situation where the doctor orders the medicament and the customer pays for it. There may be limited feed-back from patients who complain about the cost of medicines, but what evidence there is suggests that this may be less effective in restraining prices than the intervention of a third party who meets the cost of medicines on behalf of a large number of patients. Both the European social security schemes and the British government look critically at doctors' prescribing in a way that does not occur in the 'free market' situation, for example in North America. Furthermore, these European 'customers' have exercised various forms of restraint on pharmaceutical prices, and what evidence there is suggests that profit levels in Europe may also-perhaps consequentially-be lower than those in America. Thus it is not primarily the existence of the NHS which now provides the justification for a price regulation scheme for prescription medicines in Britain.

It is, of course, argued that the British government, as one of the indus-

try's major customers, should be entitled to preferential prices. This argument applies equally, however, to the continental social security agencies, and indeed is used by them in negotiations with the industry. Furthermore, in expecting these preferential prices, it is quite wrong to expect private customers (either here or abroad) to subsidise supplies to government. That is, the degree of preference should be a genuine reflection of the lower costs associated with bulk consumption, rather than a sale at more or less marginal prices, leaving other customers to keep the company profitably in business by paying higher 'open market' prices.

The extent to which the government is entitled to reduced prices as a bulk purchaser of NHS medicines needs further examination. Except in a limited sense in the case of hospital supplies, there is no contractual relationship between the Department of Health and the pharmaceutical manufacturers. The latter supply what doctors prescribe, and this cannot be predicted in advance. Thus the government cannot order any specified quantity of different medicines in anticipation of demand; to do so would be to court disaster in a market where products may sometimes be quickly and unexpectedly superseded. In this sense the Department of Health is unlike the armed services, for example, where the practice of medicine is more closely controlled. In both Britain and the US the Defence Department can, in fact, contract in advance for substantial quantities of medical supplies. There is also another difference. The Defence Department supplies are delivered in bulk, at more or less predictable intervals, to a small number of depots. Under the pharmaceutical services of the NHS, on the other hand, customers order as and when demand arises, in small quantities often for delivery direct to one of Britain's 14000 retail pharmacies. Thus the normal conventions for costing government contract purchases are not applicable to pharmaceutical supplies for the Health Service, and the arguments that the government are entitled to specially favourable prices under the NHS cannot be used to justify large price differentials between its prices and those which could reasonably be charged to private individuals.

In essence, therefore, the British government must now rest its case for a special relationship with the pharmaceutical industry primarily on the argument that without price controls there is no effective economic mechanism, in any circumstances, to ensure the reasonableness of the prices of prescription medicines. Furthermore, it must argue, as the witnesses before the Kefauver hearings and the Sainsbury Committee did, that in this situation prices have, in fact, been unreasonable. This is a charge which the industry does not accept. It brings us full-circle back to the original polemic argument about how industry can be expected to behave, and to the differences of economic opinion on the reasons for the industry's high profitability.

There are two further considerations. First, logic and economics apart, there is the question of politics. I do not think that I am being unduly sympathetic to the pharmaceutical industry in saving that, in the present state of knowledge, the charge that it has been making excessive profits is at least 'not proven'-bearing in mind the difficulty of defining 'excessive' in this context. When, however, there is a suspicion of excessive profits in the public sector, which has received support in an official report, it is difficult for any politician not to be seen to be taking actions which remove the suspicion. The pharmaceutical industry accepts this political reality, and it is for this reason that it has agreed to work out a procedure to share its financial information with government. What it does not accept-and in my view should not accept-is that this sharing of information should be expected automatically to lead to large reductions in prices and profits. Yet on the part of the politicians, acting against a background of allegations of excessive profits, there are strong temptations to ignore the economic differences of opinion and to demand satisfaction in the form of immediate and substantial price reductions.

To some extent, the industry has already faced this situation under the first version of the Voluntary Price Regulation Scheme. It was introduced on the assumption that British prices were excessive because the NHS provided a 'soft market'. Equating British prices with those overseas was, therefore, expected to lead to substantial savings for the NHS. In fact, a simple economic analysis would have proved in advance that British prices were generally lower than those overseas, and predictably, therefore, the VPRS did not produce the anticipated reductions in pharmaceutical expenditures. This caused political frustration. In that case the facts about the comparative prices were undeniable, and politicians were forced to look elsewhere for explanations of what they believed to be excessive pharmaceutical expenditures. In the present situation, however, there are greater dangers. Whereas comparative prices are exactly quantifiable, the 'reasonableness' of profits still defies quantification. Politicians could, therefore, avoid frustration in this case by arbitrarily determining 'reasonable' profits at a level which ensures them substantial price reductions.

This is a particularly sensitive issue in such an essentially international industry. Obviously, the subsidiaries of overseas parents, who account for some 75 per cent of sales to the NHS, must look at any agreement with the British government in the light of the effect which this may have on their very much larger businesses outside Britain. British companies also have world-wide markets of much greater potential than their home market. They are unwilling to accept restraints in this country, to satisfy local political considerations, which they believe would unreasonably handicap their businesses if they came to be copied—as they logically should on the basis of the argument so far—under social security schemes in many other parts

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of the world. The international companies, whether they are British-owned or not, are very much aware of this point and have brought it firmly to the notice of government. The ultimate sanction available to the companies is to refuse to sell in Britain and the ultimate sanction available to the government is to refuse to purchase. Both actions would force the government to obtain supplies of the nearest equivalent products which are available from alternative sources. Clearly both sides are extremely anxious to avoid this ultimate situation which would do immense damage to both parties in the dispute. In practical terms, a more subtle sanction on the part of the companies would be to shift their business more and more out of Britain into other parts of the world, leaving the British government to impose its unacceptable policies on small local companies or branches which would be increasingly dependent on associated companies operating in countries with a more congenial economic climate.

This brings us to the second consideration. Although the Department of Health's special relationship with the industry is usually considered only in the context of the NHS, there is another side to it. The Department is sponsor to the industry, responsible for its economic well-being and for the promotion of its export trade. This role is particularly significant in Britain at present, because of the growing realisation that our economic problems arise largely from our failure to innovate. Under these circumstances it can be argued that where the government is a purchaser of British-made innovative goods, it should sometimes be prepared to pay highly in order to stimulate innovation and the consequent growth of overseas trade. So far from representing a prodigal policy, this may, in fact, be in the taxpayers long-term interest, if the products have substantial sales potential in overseas markets. The overseas earnings and the tax on profits therefrom may represent benefits in excess of the short-term charge represented by the higher prices paid by the exchequer. This argument, also, falls outside the scope of this paper. It is, however, one of which the Department of Health is itself very much aware.

In summary, therefore, the position is as follows. In the light of the recommendations of the Sainsbury Report, the pharmaceutical industry has expressed willingness to work out a scheme for sharing with government full information about the profitability and operating ratios of individual companies. It does not appear, however, that limits of profitability can logically be set *a priori*; hence no specific formula to judge the reasonableness of a company's prices can be established.

It is argued on the one hand that no such formula is necessary, because over a sufficient time scale competition between products will control the average profitability of the industry. The fact that this average now lies above that for all manufacturing industry is merely a reflection of the special risks of the industry, its extraordinary achievements over the past

twenty years, and perhaps other as yet unidentified economic factors. With little or no more than 'average' profitability the industry could not have made its unquestioned contribution to the therapeutic revolution.

On the other extreme, it is argued that the profits of the pharmaceutical industry should be assessed little differently from those of any other, and that it is primarily its own economically undesirable practices which have created its high profits. Rigid restraints are, therefore, thought to be necessary to correct this self-imposed distortion to the perfect economic environment in which the industry should ideally operate.

Neither of these standpoints can at present be fully justified or refuted by economic theory or experience. However, from the broader viewpoint —taking a 'cost-benefit' approach to the industry's contribution to the national economy and to society—it can be argued strongly that one should avoid interference with the industry, the consequences of which could not, at present, be predicted. In this situation it seems inevitable that the patterns of price negotiation of the recent past must continue until the many economic unknowns are resolved. The determination of the reasonableness of prices and profits, must continue meantime on an essentially 'horse trading' basis.

On the one hand, the Department of Health will be anxious to have the satisfaction of achieving political trophies in the form of price reductions. On the other hand, companies will vigorously defend the interests of their employees, managers and shareholders. Both sides will argue persuasively that it is their point of view which is more clearly in the public interest. In a world in which few issues are pure black and white, however, it would be surprising if—with economic hindsight—the present, or any other, situation proved to be one which was universally agreed to represent the optimum.

Returning to Enoch Powell, he assessed the comparative balance of power between the government and industry as follows. 'The State dare not take any measures that would expose it to the accusation of having driven or held off the market drugs by which patients would have benefited, nor could it ignore the allegation, however hard to substantiate, that its actions had made the discovery of new "wonder drugs" less attractive or more difficult. On the other hand, the pharmaceutical firms cannot view with indifference the danger of being branded as profiteers; for in a country where making a profit is anyhow treated as prima facie calling for apology, to be represented as making large profits "out of the sick" would be highly dangerous: nationalisation or some other almost equally unpleasant form of interference could not be ruled out if that cry once took hold'. As we have seen, this philosophy applies on a world-wide basis, irrespective of the local considerations of the National Health Service. Furthermore, in Britain, the Department of Health and Social Security is the sponsoring Department for the industry, responsible for promoting its prosperity and its exports. Wearing that hat, the Department officials are aware that they must be especially cautious of imposing harmful controls on the industry.

I would point out, once again, that this paper has dealt primarily with the problems of profitability, ignoring other issues which could have taken at least as much time again to cover in the same detail. From this, it must be clear that the pharmaceutical industry's relationship with the government in Britain presents an immense and fascinating problem. These questions of government-industry relationships have never been adequately studied in the context of an economy dependent on innovation. The pharmaceutical industry epitomises one aspect of this situation, where the government is a major customer. May I make a final plea for more attention to be paid to this subject by sincere academic economists, not motivated by political doctrine or theory but genuinely anxious to throw light on the complex issues involved?

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