

**THE NEEDS OF THE
PHARMACEUTICAL MANUFACTURERS
FROM THEIR MEDICAL DEPARTMENTS
IN THE 1990s**

by
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OFFICE OF HEALTH ECONOMICS

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FOREWORD

This paper was originally written for the benefit of a single pharmaceutical company. However the company agreed when it was commissioned that it should be made generally available once it had been studied within that company, and this publication is the outcome.

I am extremely grateful to the Directors of several individual Medical Departments in Britain, on whose expertise the study is based. The conclusions and predictions are, however, my own responsibility. I trust they may be of interest to those in the pharmaceutical industry who have responsibility for the forward planning and organisation of the Medical Departments. Their accuracy and relevance, however, will not be able finally to be judged until the end of this century.

GEORGE TEELING SMITH

I. INTRODUCTION

This paper suggests a number of ways in which the work of the Medical Departments may change over the next 20 years, and discusses some of the factors which are likely to affect these changes. It does not set out to prescribe the way in which a company's Medical Department should be organised in the 1990s. Nor does it spell out in detail the functions of such a Department. It is up to the individual company to plan its own organisation and pattern of work in the light of the probable developments discussed in this paper.

The paper is organised in five parts including this introduction. The next part sets out the background, discussing how Medical Departments are organised at present, how pharmaceutical innovation is likely to develop in the next 20 years, and how pharmaceutical markets are likely to be structured.

The third part of the paper spells out 'predictable changes' affecting existing activities of the Medical Department. Its seven sections cover basic clinical pharmacology, clinical trials, adverse reactions, computerisation and information, regulatory affairs, relations with the Marketing Departments, and medico-political activities. The final two parts discuss more speculative changes. The penultimate part discusses the way in which the Medical Department may become involved in more sophisticated economic evaluation of the effects of new medicines in the 1990s. The last part of all discusses the possible effect of 'demedicalisation' of health care, and the greater involvement of the consumer (or patient) in his own treatment.

II. BACKGROUND

(a) The Definition of a Medical Department

The scope of work and responsibility of a Medical Department in the pharmaceutical industry varies considerably between companies. For example, in some companies it covers the first administration of a new chemical entity to human volunteers, and all the work involved in the registration of the medicine prior to marketing throughout the world. In other companies this work is the responsibility of the Research Department. At the other extreme, the Medical Department may have substantial responsibilities for the preparation of 'sales promotion' material and the education and control of medical representatives. In most companies, however, this is the prime responsibility of the Marketing Department.

For the sake of completeness, this paper discusses all the activities which may come within the ambit of the Medical Department.

In almost all cases, however, the work of the Medical Department can be divided up in two different ways, forming a matrix of four relatively distinct areas of activity:

Pre-registration information function	Post-registration information function
Pre-registration evaluation function	Post-registration evaluation function

Pre-registration 'information' includes general literature searches, and a build-up of the portfolio of data required for registration. Pre-registration 'evaluation' covers the main clinical trials. Post-registration information refers to the provision of data to the Marketing Department and the answering of queries from doctors and others. Post-registration evaluation includes, for example, general practitioner clinical trials after marketing and the all-important function of monitoring for adverse reactions.

In many companies the pre-registration activities are performed centrally, at the headquarters located alongside the Research Departments. On the other hand, the post-registration activities may be performed in the local national 'marketing' subsidiaries. Even in a multi-national company's parent country the pre-registration and post-registration activities may be physically separated. There is, however, always likely to be some overlap between the functions, for example with central monitoring of reports of adverse reactions.

Further subdivision of the functions within the Medical Department can often be distinguished. For example, different sections of the Department may be responsible for a compound at different stages of its development. Alternatively, different sections may be responsible for different individual products or groups of products throughout all stages of their development. The geographical responsibilities world-wide may also be organised in different ways. As already indicated, however, this paper makes no attempt to suggest which of these different ways of organising the international responsibilities of a Medical Department is most desirable.

(b) Pharmaceutical Innovation in the 1990s

Cassandras in the industry sometimes suggest that the Golden Age of innovation is over, and that in future the pharmaceutical companies will have to depend on an increasing proportion of 'generic' sales of patent-expired discoveries from the 1950s and 1960s. In reality, nothing could be further from the truth. The pharmaceutical industry is in fact on the verge of what has been described as "the second pharmacological revolution". This new wave of developments, starting in the 1980s and gaining momentum into the 1990s, will arise in three ways.

First, the elucidation of the structure of the DNA molecule by Watson and Crick in 1953, and all the associated discoveries in molecular biology at Cambridge and elsewhere, have laid the foundations for a whole new range of pharmacological products. These will attack many previously unconquered disease processes at the intracellular level. Obvious examples of diseases which are likely to be controlled in this way by the 1990s are the cancers, the virus diseases and the auto-immune diseases such as early onset diabetes, multiple sclerosis, and perhaps rheumatoid arthritis. The important points, in the context of this paper, are that these new medicines will greatly extend the range of pharmacology and will also increase its complexity. The control of the bacterial diseases which was achieved in the 1950s is an order of magnitude less complex than the control of the virus diseases which will be achieved in the 1990s.

Second, there are likely to be major developments in what have been described as 'targetted drug delivery systems'. These will get the active ingredient of the medicine exactly to the location of the disease, with as little as possible circulating to other organs of the body. This may be achieved by 'pharmacological engineering' or by such other methods as producing 'magnetic' medicines which can be directed to the target organ by physical means. Once again the important point is that such newly conceived medicines are much more complex to handle and evaluate than the simple tablets and injections of the 1960s.

Third, there is still much scope for further development of medicines stemming from 'the first therapeutic revolution' of the 1950s, 1960s and 1970s. These generally speaking act at the tissue chemistry level (as opposed to the intracellular level) and typical developments to be expected in the 1980s are much improved medicines acting on the chemistry of the brain, and on the causes of coronary heart disease.

(c) The Nature of the Market

It follows from a description of innovation in the 1990s, that the pharmaceutical market will continue to exist much as at present. The commercially most important products will be comparatively recent innovations, based either on original patented chemical entities or else on unique formulations. In addition, of course, older products will continue to come off patent and to be available from multiple sources as generics or 'branded generics'. It is probable that in some countries at least there will be increasing pressure to prescribe or dispense generics instead of the original brands and hence older patent-expired branded medicines may become commercially less important than at present. Ironically, however, the Medical Departments of the original innovating companies will still be called upon for medical information on these multi-source generics. Some companies have adopted a policy of refusing to provide a 'Medical Department Service' for the products of cheaper imitators. This tendency may spread if generic usage of older products becomes more widespread.

However, Medical Departments are likely to be faced with special problems in relation to the use of medicines in the Less Developed Countries. Many research-based companies are likely, for political reasons, to be encouraged to supply low-priced versions of their patent-expired innovations to the poorer countries. In order to maintain goodwill both with WHO and with the governments of Less Developed Countries, companies will probably want to provide a 'Medical Department Service' to support the sales and use of these older products in the Less Developed Countries.

III. PREDICTABLE CHANGES IN EXISTING FUNCTIONS

(a) Basic Clinical Pharmacology

The first change to be expected within Medical Departments over the next ten years, is a change in attitude towards basic clinical pharmacology. That is the testing of medicines in healthy human volunteers and in the first individual volunteers actually suffering from the disease. This change is expected to come about through developments in the recruitment and training of doctors in the Medical Departments. In the past, the tendency has been to recruit clinicians and to some extent to hope that they develop specific interests and skills in pharmacology. In the future, there will be more emphasis put on the basic pharmacological training which a doctor has received before joining the pharmaceutical industry, and there is likely to be specific 'apprenticeship' training in pharmacological methods and attitudes once the doctor has been recruited into the Medical Department. Some companies are already well advanced in this direction, but in general the scientific standards in clinical pharmacology are expected to become very much higher in the 1990s than they have been in the 1970s.

This development will facilitate a much closer liaison between the Research Department, synthesising and testing the new compounds, and the Medical Department whose responsibility it is to carry out the first tests in man. This integration between the Research and Medical Departments will encourage much more precise early evaluation of the pharmacokinetics and pharmacodynamics of the compound, and better linkage between

animal and human testing. Animal species will be chosen more specifically to mimic the patterns of drug metabolism and drug response identified in man.

At the same time, there is a possibility that different patterns of drug metabolism and drug response may be more precisely identified in different groups of humans, for example the elderly, different racial groups, and even different genotypes. The problems involved in this subdivision of 'human reactors' is discussed in the next section on clinical trials.

In general, there have been enormous advances in clinical pharmacology in the industry over the past two decades: these advances are expected to develop very much further in the next two decades.

(b) Clinical Trials

The organisation and conduct of clinical trials of new medicines will also develop and change dramatically over the next two decades and will continue to become more extensive and more costly. By the 1990s the industry will look back on trials conducted in the 1970s as being crude and superficial.

There is, however, a difference of opinion as to the way in which clinical trials will actually develop in the next 20 years. Undoubtedly the more complex nature of pharmaceutical compounds and formulations will affect their pattern. But over and above this one school of thought argues that future changes will also become necessary because of the past failure to recognise the pharmacokinetic, pharmacodynamic and pharmacogenetic heterogeneity of populations included in present-day trials. Much publicity has been given in the 1970s to the variations in bioavailability of different formulations of the same active ingredient. Far too little attention has been paid to the individual variation in clinical and toxicological response to the *same* formulation by different individuals. Patients of different ages and different racial backgrounds, for example, have often been included in the same trial. However, it is recognised that the individual's pattern of drug metabolism and his response to a given dosage may vary markedly as a result of such factors. Average conclusions drawn from a group concealing such variations may fail to reveal significant benefits and also significant toxic responses for specific subgroups.

According to this line of argument, it follows that clinical trials would not only be attempting to define results for much more specific subgroups, but would also be attempting to identify 'markers' which would predict the individual response to a particular medicine in a particular individual. For example it is now known that individuals with a particular antigenic make-up may develop symptoms of systemic lupus erythematosus when given hydralazine. Many similar examples of identifiable drug 'idiosyncrasies' will probably be defined as a result of the more sophisticated methods of evaluation of new medicines which can be expected in the 1990s.

Particular attention would in the future be paid to the evaluation of the different action of medicines in the elderly. The sort of 'unexpected' adverse reactions which have occurred in some cases in the past would be preventable by estimating more accurately the way in which drug metabolism may change with age, and hence by calculating an appropriate adjustment of dosage for elderly patients at the clinical trial stage.

However the other school of thought within the industry argues that if clinical trials were to attempt to subdivide the population in this way and to identify different patterns of response for different subgroups the whole subject would become impossibly

complex. If regulatory authorities were to demand this sort of separate evaluation on a multiplicity of separate subgroups in the population no new medicines would, in their view, ever reach the market. Those who argue in this way feel that the differences in response for subgroups of the population can only be identified after marketing, using the methods of improved post-marketing surveillance discussed below. In their view, clinical trials will become more complex in the 1990s only because the compounds are more sophisticated and, more importantly, because their statistical evaluation will become much more precise. It is said that many clinical trials conducted in the 1970s contained statistical errors of interpretation.

Two other developments can be expected in clinical trials. The first is an extension of methods of measuring physiological changes in response to drug therapy. These will employ the latest methods of non-invasive investigation, such as Nuclear Magnetic Resonance and Computer Aided Tomography. The second, more mundanely, will be much closer supervision of patient compliance with the clinical trial drug regimen. It will no longer be assumed, without blood or urine analysis, that the patient has complied with the clinical trial dosage schedule.

A further quite different development affecting clinical trials will be the extension of ethical committees, Codes of Practice and provisions to ensure the confidentiality of individual patient data. Already in some countries such Codes exist, and clinical trials cannot be undertaken until they have been approved by a large, influential and widely representative Ethical Committee. This is likely to extend to all countries, at least in the Western World, by the 1990s. The Medical Department will, therefore, need extra skills to ensure that planned trials comply with the appropriate national Codes of Practice, and that approval for them can be obtained from the appropriate local Ethical Committees.

At the same time, Medical Departments will face a dilemma internationally in respect of clinical trials. Clearly as trials become more complex and costly, it would be desirable to plan them so that their results would gain international acceptance. However, there remains the possibility that significant national racial variations may exist in the response to a particular new medicine. The Japanese are known to respond differently to the Europeans to certain medicines; it is at least theoretically possible that the Welsh might differ from the English, for example, in some pharmacological respects. How this dilemma will be resolved by the 1990s remains to be seen.

Another debating point is the extent to which clinical trials will in the future be conducted by companies' own clinical staff rather than by independent medical practitioners. Already some companies have medical staff either with part-time appointments in hospitals or on full-time attachment to Departments of Clinical Pharmacology. There have in the past been theoretical ethical objections to the use of company employees in this way, but such objections are generally regarded as irrational. More practically, some companies argue that it is more economical to have trials conducted by their own staff on attachment in clinical posts. Most others prefer the more traditional method of contracting for independent consultants to conduct their trials. It will no doubt continue to be a matter for individual company judgement as to which path to pursue.

However in all events there is likely to be much closer co-operation between company medical department doctors and University departments of clinical medicine by the 1990s.

One other thing is certain in respect of clinical trials. This is that by the 1990s all results will be analysed on computer, and all medical, scientific and technical staff involved in

clinical trials will need to be familiar with the use of computers.

Perhaps the biggest unknown in relation to clinical trials by the 1990s will be their conduct in the Less Developed Countries. Certainly the more sophisticated, and more tightly controlled, standards of the Western World are likely to influence trials in the Less Developed Countries. But their cultural differences are so great, that special consideration may have to be given to the planning and conducting of trials in the Third World.

(c) Adverse Reactions

Perhaps one of the most significant areas of extended responsibility for Medical Departments between the 1970s and the 1990s will concern developments in various methods of attempting to monitor for adverse reactions of new medicines. In 1982, this is a subject on which there is already a realisation that major developments are afoot, but which internationally is in a state of flux. A great many individual initiatives are taking place, but it is still too early to predict a clear pattern for the future.

On the one hand, there is the choice between so-called 'monitored release' and more general 'post marketing surveillance'. The former relates to a specific medicine, and normally restricts the use of the product to those willing to watch out for particular suspected adverse effects. The latter covers medicines as a whole, and is intended to give early warning of any totally unsuspected adverse reactions. Half-way between the two lies the British experiment in 'prescription event monitoring', which again relates to particular medicines, but is watching out for any sort of adverse effect which may be caused by them.

On the other hand, more philosophically, there is the question of whether programmes to attempt to identify adverse reactions should be conducted by the innovating company, by government or by some independent agency. In Britain, at present, all three alternatives apply. 'Monitored release' is the responsibility of the company, although in some cases it has been required by the government registration authority. 'Post marketing surveillance' is carried out jointly by the government, which asks doctors to report adverse reactions to the licencing authority, and by companies, who keep their own records of reports of adverse reactions. 'Prescription event monitoring' has been introduced by an independent individual, financed by industry and acting with the blessing of government but controlled by neither.

The future pattern of development becomes even more difficult to predict when one takes an international view. At present, only the innovating company can collect worldwide reports on adverse reactions on its medicines. However, national governments can, and increasingly will, share information amongst themselves; and conceivably the World Health Organisation could set up an international monitoring scheme. As far as independent agencies are concerned, the present British scheme depends on the unique availability of national prescription records, from which samples of actual prescribers can be extracted and surveyed.

In the future it is conceivable that ordinary market research methods could be used by an independent agency on a national or international basis, in order to obtain a sample of prescribers from whom reports of adverse reactions could be collected. However such a scheme would be inordinately expensive, and there is the risk that by establishing the sample itself the agency could distort the pattern of prescribing. For example if doctors were paid to provide reports on a particular medicine they might be influenced to prescribe it more widely than their colleagues.

The most important point, looking to the future, is that companies must never be afraid of stimulating reports of adverse reactions by more positive measures to collect them. Companies have everything to gain by improved reporting of adverse reactions. In particular, if the national licencing authorities could be assured that any adverse reaction in man would be picked up at the earliest stage, they should be prepared to allow earlier marketing of new medicines and less extensive animal testing (which in any case is of doubtful predictive value). Hence additional costs in more efficient monitoring for adverse reactions could pay off in reduced costs for toxicity testing and in increased revenue from earlier marketing.

On a practical aspect, there has so far been very little rational basis for determining the number of patients who should be monitored in order to be reasonably certain of picking up any adverse reactions. Various figures have been clutched out of the air. For one product in the U.S., 10,000 patients were monitored; the 'British prescription event monitoring' programme relied on 7,000 reports out of a total of 16,000 requested covering the use of two medicines. It is likely that by the 1990s a statistically much sounder approach will have been agreed in this connection.

On an international basis, taking account of national idiosyncrasies, the numbers monitored must be large enough to distinguish significant adverse events from the background 'noise' or 'rumours' to be expected. In this connection, however, it will also be desirable to try to pick up significant reports of drug-interactions, and this may require even larger numbers. It is also clear from the earlier discussion that post marketing surveillance must try to identify adverse reactions for subgroups within any particular population.

There is also the question of whether specific doctors and scientists within the Medical Department should have an exclusive responsibility for processing adverse reaction reports from all sources. The alternative is that the responsibility is spread between different people for different products. Clearly the former approach produces more concentrated expertise, but it has been suggested that for one group of people to spend their time on nothing but adverse reactions would produce a very tedious pattern of work for the individuals concerned.

(d) Information and Computerisation

At one end, the informational activities of the Medical Department overlap with those of Research; at the other, they concern the companies' marketing activities which are discussed in a later section.

By the 1990s, the information services of the Medical Departments will be almost entirely computerised. As far as basic information is concerned, for example 'Chemical Abstracts' will never again be published in printed form: it will be on computer. The more highly technical journals are likely to follow this example. Already Medical Libraries depend heavily on the international index and abstract services such as Medline and Toxline. Companies' own product information is increasingly being put onto computer.

Against this background, the Medical Department will have to learn to use these new and extended sources of data more precisely than at present. 'Information Science' will develop so that better searches of the computerised data can be carried out. In particular, the new skills will include an ability to extract significant data, uncluttered by a mass of irrelevant material.

With the use of computers, there will be much more scope for the international transfer and standardisation of information throughout the company's subsidiaries. This will be particularly important as consumerist groups continue to pillory companies for discrepancies between claims made and warnings given for the same medicine in different markets. A company's Medical Department must lay down 'maximum claims' and 'minimum warnings' which every subsidiary must observe.

The traditional role of the Medical Department in providing information to prescribing doctors and pharmacists is also likely to involve the use of computers. The prescribers and dispensers will have terminals on their premises which will give them direct access to company information.

At the same time independent sources of product information and comparative assessment will develop outside the company. The concept of the 'information pharmacist' in the health services and particularly in hospital will be extended. External sources of reference such as the Physician's Desk Reference in the United States and the British National Formulary will become more common, and they too eventually may become available on computer. The industry as a whole must co-operate with these publications in order to ensure that they do not inhibit pharmaceutical innovation (by reluctance to include new products) and do not express unreasonable prejudices (such as opposition to 'combination' products). Given these conditions, companies must ensure that such publications get all the information which they require to make them comprehensive.

Doctors may also by the 1990s have developed their own personalised computer data-banks for the medicines which they most commonly prescribe. One of the most important developments in this connection will be the building in data about *significant* drug interactions. Present systems to warn doctors of interactions often include too many theoretical effects which have no significance in practice. This is another aspect of the need to separate important information from the mass of irrelevant material which will be in circulation to an even greater extent in the 1990s than at present.

(e) Regulatory Affairs

In many companies the responsibility for preparing submissions to the Regulatory Authorities lies in the Research Department. However, as an increasing proportion of the data may in the future relate to clinical experience with the medicine, companies may be right to regard this as a Medical rather than a Research responsibility.

The 1960s and 1970s have been called the 'Decades of Regulation' for the pharmaceutical industry. The Registration Departments within companies have experienced some of the fastest rates of growth anywhere within the industry. By the early 1980s there is some indication that this explosive growth is over, and that a more balanced attitude may in the future come to exist in relation to the need to provide registration data for new medicines. Individual countries may start to follow the example of Britain and the United States in relaxing the amount of data required before a new medicine can be released for clinical trials or marketing. However, it is clear that for political reasons there could never be complete deregulation in the marketing of new medicines.

There is also likely to be a much more scientific approach towards the sort of data which is actually meaningful in a clinical trial or marketing submission. Both governments and industry are starting to carry out retrospective evaluation of the data which has been collected, in order to try to discover which of it had a significant predictive value.

In the opinion of the regulatory authorities, companies as a whole also still need to be much more skilful in presenting the evidence for their new medicines. To some extent the improvements in clinical trials which have already been discussed will yield better data for regulatory submissions. Overall, the emphasis by the 1990s is likely to be on much *better* evidence for new medicines rather than merely *more* evidence.

Internationally, it seems inevitable that some sort of collaborative scheme under the aegis of the World Health Organisation will have come into existence by the 1990s particularly to help the Less Developed Countries in their evaluation of new medicines. This may run counter to the national trend of requiring less regulatory information. However the industry world-wide is at present hopeful that it can avoid a second tier of bureaucracy such as is implied by the WHO European Region's proposal for Scientific Evaluation Documents to be available internationally.

Ideally, reciprocal acceptance of individual national regulations, for example within the European Community, will be in force by the 1990s, and this too will tend to cut back on the present workload of Registration Departments. If this international acceptance of a single country's approval for a new medicine could be extended further it would significantly speed the international availability of new medicines. However it seems unlikely that by the 1990s countries such as the United States would have relinquished their sovereignty over drug approval. There is also the problem of national idiosyncrasies to individual medicines which is likely to prevent general internationalisation of drug registration.

(f) Relations with the Marketing Departments

There is at present a considerable variation in the extent and nature of the relationships between the Medical and Marketing Departments within companies. However, it seems clear that by the 1990s there will in all cases be a closer association than at present, with a strengthening of the Medical Department's position. For example, at present, not all companies have a system by which minimum warnings and maximum claims for a product are laid down by the Medical Department in the parent company. This has led to considerable criticism and undoubtedly by the 1990s companies will all be conforming to this pattern on a world-wide basis.

The standard of medical information will also continue to be improved for medicines. Both company publications and independent reference books (such as Martindale's Extra Pharmacopoeia in Britain) are subject to current criticism because of their unimaginative and indigestible presentation. In this case, the symbiosis between the Marketing and Medical Departments may gain more from the input of the former than from that of the latter.

The Medical Department will also play a much larger part in the continuing training and education of Medical Representatives ('Detailmen') in the 1990s.

As far as information for doctors and pharmacists is concerned, there will be much more dependence on computer systems by the 1990s. By the latter part of that decade there should be routine two-way access on View-Data systems, so that doctors can report back experience with medicines, as well as obtaining information about them by computer. Company representatives also will be linked directly with their Medical and Marketing Departments by computer.

Medical Departments will continue to be responsible for world-wide 'demonstration' trials after a new medicine has been marketed. These both underline the benefits of the medicines in general practice, and can point to new and wider indications for its use.

Within the Medical Department, there will continue to be a variation in organisation, with some companies having 'product doctors' responsible for all aspects of the same medicine, while other companies will have 'information doctors' responsible for all aspects of information about many products. The extent to which doctors—as opposed to scientists—are involved in this work will vary between countries, depending on the availability of doctors and on the cost of employing them. In general doctors will be more involved in generating information than in processing it.

As has been implied above, the 'controlling' role of Medical Departments in marketing will be relatively more important by the 1990s in Less Developed Countries, where it tends to be less sophisticated than in the Western World at present.

(g) Medico-political Activities

Although Medical Departments have always been involved to some extent in medico-political activities, these have tended to develop and to become more formalised over the past few years. An important reason for this is that personal contact with individuals in the Regulatory bodies has become increasingly necessary. It is also because the Medical Department has inevitably been drawn into political controversies over questions such as generic prescribing, 'limited lists', National Formularies and Product Liability. There is now often at least one doctor whose prime responsibility it is to deal with issues such as these. His responsibilities are far removed from the principal traditional duties of a medical adviser in the pharmaceutical industry.

It is important that the Medical Department should not encroach on the activities of the Public Relations or Public Affairs Department in the company. However bearing this caveat in mind it seems likely that the Medical Department's own legitimate interests in this field will continue to expand. In particular it is likely to make more use of outside medical consultants in the medico-political field during the 1990s.

IV. ECONOMIC EVALUATION OF NEW MEDICINES

Up to the present, it has normally been thought sufficient to demonstrate the *clinical* value of new medicines, initially by trials and then by experience in practice. Such trials and experience indicate the therapeutic efficacy of the medicine and the extent of its risk of adverse effects. Increasingly, however, a new attitude is emerging in which the *economic* value of the new medicine is being considered. Instead of relying on general examples, such as the conquest of tuberculosis and the control of much mental illness, in order to indicate the economic benefits from pharmaceuticals, people both inside and outside the industry are starting to look at medicines as a whole to see whether they bring benefits which can be measured in economic terms.

This attitude has tended to develop partly in response to criticisms of the cost of medicines and partly in response to 'consumerist' emphasis on the harm done by medicines, which has ignored or underplayed their benefits. It is becoming increasingly obvious that manufacturers will in the future be expected not only to demonstrate that their medicines work, but also that they actually bring benefits in social and economic as well as in purely medical terms. Although this new development may not be the primary responsibility of the Medical Department, it must certainly have an important influence on the emerging pattern for the evaluation of medicines in the 1990s. Hence the Medical Department is likely to be centrally involved.

The economic evaluation envisaged in this part of the paper will take two forms. The first is in relation to direct financial savings, such as a reduction in hospitalisation and in less absence from work. Calculations along these lines have been carried out in the past, but they are likely to have more emphasis put on them in the future. The second form of evaluation is much less commonly understood. This is measurement of the effects on the quality of life from the use of new medicines. However, at least one American pharmaceutical company is already currently including this sort of evaluation in its initial clinical assessment of an anti-rheumatic preparation.

There is a good deal of basic academic work available on the measurement of the quality of life in relation to what is described as the 'health status' of a population. The measurements are made by interviews or questionnaires based on predetermined factors which are claimed to indicate the degree of 'wellbeing' of the individuals surveyed. This work is advancing fairly fast, and is likely to be applied more generally within the pharmaceutical industry by the 1990s. Clearly it affects the planning of clinical trials and the populations to be covered by those trials.

There are a few enthusiasts who feel that universal scales of 'disability' or 'quality of life' could be constructed and used to assess social and economic benefits across a range of diseases and therapies. However it is probably much more realistic to envisage individual scales for assessment being constructed in relation to individual diseases and therapies. The measurement of benefit on these scales will therefore be specific to the medicine involved, and will not be directly comparable against other benefits measured for other therapies. Nevertheless this sort of economic evaluation will throw much light on the benefits which are being achieved by new medicines, and will be valuable both in justifying their cost and in putting their risks into perspective. Clearly, of course, these risks will need to be taken into account in the assessments which are made.

It is even possible that by the 1990s Registration Authorities and certainly bodies responsible for drug reimbursement might start to expect an economic as well as a clinical evaluation of a new medicine before it was accepted for sale or reimbursement. In anticipation of these possible developments, the Office of Health Economics in England is running a Summer School on the Economic Evaluation of New Medicines at Brunel University in May 1983.

V. THE 'DEMEDICALISATION' OF HEALTH CARE

Over the past few years there have been a number of challenges to what can be described as 'the medical monopoly' in health care. Some of this is positive, in encouraging individuals to take more responsibility for their own health. In addition, from both inside and outside the medical profession itself, there have been criticisms of the effectiveness and efficiency of doctors in contributing to wellbeing.

This questioning of the dominance of the medical profession is clearly also taking place within the Medical Departments of pharmaceutical companies. It is recognised that doctors are often required more for the 'status' they bring than because of their specific training or skills. Doctors are obviously also required for 'ethical' and legal reasons when medicines are being administered to humans. However in general it seems likely that over the next two decades doctors are either going to have to become more 'scientific' in their attitudes or else are going to have to at least share their dominant position in Medical Departments with other scientists.

More generally, the movement towards 'demedicalisation' of health care is likely to affect the relationship between the public and the pharmaceutical industry. At present the manufacturers of prescription medicines can shelter behind the 'medical monopoly' to fend off requests for information from the public. Clearly companies welcome their ability to do this. However by the 1990s the increasing medical sophistication of the public, and their desire for 'more authoritative' advice than their own doctor can give, may make the pressures for a direct relationship between the medicine manufacturers and the public irresistible.

One possible channel for this breakdown in the 'doctor only' barrier to information will come with 'View-Data' systems on television. At present closed-user groups of doctors have exclusive access to company information being disseminated on television sets. It seems likely that the closed-user group codes will become available to the public, thus giving them access to information at present intended only for doctors.

Medical Departments will need to think carefully about the implications of information intended only for doctors becoming more generally available to the public. There are certainly those who would argue that the individual patient—who is actually experiencing the disease and the effects of medication—should at least share with the doctor the decision as to which medicines he is best to take.

On an even wider horizon, it is possible that by the 1990s pharmaceutical companies will be thinking of themselves more as purveyors of health than merely as purveyors of medicines. This overlaps with the discussion in the previous part of the paper, in relation to the measurement of 'wellbeing' rather than simple 'clinical improvement'. This may apply particularly to the elderly, who are so often taking large numbers of different medicines, and who tend to respond differently to therapy from younger people. In the extreme case, companies could possibly start to provide general health counselling to accompany the use of their medicines. The wellbeing of the patient would then depend on a tripartite decision-making process, made up of the doctor, the pharmaceutical company as a source of information, and the patient himself. These are speculative thoughts, but if society were to move in this direction (probably initially in the United States) the companies whose Medical Departments were alert to such developments would be in a strong position to take advantage of the new situation. Already there are movements towards this position, in which companies have co-operated in setting up 'self help' groups for patients with diseases for which they market medicines. This is a positive way in which consumerism, working together with rather than against doctors and the industry, could contribute to the wellbeing of society by the 1990s.

