INNOVATIVE COMPETITION IN MEDICINE

A Schumpetarian analysis
of the pharmaceutical industry
and the NHS

Edited by George Teeling Smith

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The Rt Hon Enoch Powell, MBE, who ceased to be a Member of Parliament in 1987, was Minister of Health from July 1960 to October 1963 and was responsible for the Hospital Plan 1962 and the Welfare Plan 1963.

Lord Jenkin of Roding, perhaps better known as Patrick Jenkin, was Member of Parliament for Wanstead and Woodford from 1964 to 1987. In the Heath Government of 1970/74 he was a Junior Treasury Minister and Minister for Energy. In Opposition he was appointed Shadow Spokesman on Health and Social Services, a job which brought him into contact with all the problems surrounding Britain's National Health Service. When the Conservatives were returned in 1979, Mrs. Thatcher appointed him Secretary of State for Health and Social Services. It is not widely known that towards the end of his two-year stint in that office he set up an enquiry into the financing of the National Health Service.

After serving in the Departments of Industry and of the Environment he left the Government in 1985 and was appointed a Life Peer in 1987. He is currently Chairman of Friends' Provident Life Office and other companies, and in 1992 he was appointed Chairman of the Forest Healthcare NHS Trust.

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Foreword

Professor George Teeling Smith

It is almost twenty years since I realised the significance of Schumpeter's work to the pharmaceutical industry. But since the references to his conclusions in 'The Canberra hypothesis' in 1975, comparatively little attention has been drawn to the relevance of Schumpeter's theory of 'creative destruction' and the need for shelters against the 'perennial gale' of innovative competition in relation to pharmaceuticals.

Hence when I was encouraged to look again at industrial economic theory relevant to pharmaceutical pricing in 1991, it seemed opportune to draw attention to the 50th Anniversary of Schumpeter's publication of 'Capitalism, Socialism and Democracy' in 1942. Although Schumpeter's more general thesis that the bureaucratization of innovation would lead from classical entrepreneurial capitalism to a form of socialism has proved wrong, his chapters on the nature of innovative competition have largely stood the test of time. Indeed that is the very issue to which Professor Richard Nelson addresses himself to in the first chapter of the present book.

The book as a whole is based on a symposium in London in March 1992, entitled 'A Perspective on Pharmaceutical Economics: 1942–1992', held to mark the 50th Anniversary referred to above. The meeting, although it was excellently chaired by Lord Peston, did not altogether succeed in drawing together the threads of Schumpeterian theory and the current economic situation of the pharmaceutical industry. Indeed the papers by the Rt Hon Enoch Powell and Lord Jenkin strayed into the more general field of health care strategies as a whole. Nevertheless the seven papers taken together provide a wide and extremely interesting picture of the economics of innovation, the situation of the pharmaceutical industry, and the current issues facing the British National Health Service. They deserve a much wider audience than the hundred or so participants at the meeting itself. This is the logic behind the appearance of this book.

In fact the issues raised by the individual authors do have much more coherence than may at first be obvious. I have pointed out that the work of Schumpeter covered a much broader field than merely industrial innovation. He was concerned with the shift from the individual entrepreneur and inventor to a new type of industrial organisation and with the whole subject of change in social structure. These subjects, on which Schumpeter wrote so clearly in the early decades of this century, are just as relevant to Britain's National Health Service as they are to the transnational pharmaceutical industry. Hence the issues covered in these chapters do in a very real sense each come back to Schumpeterian principles. Each of the authors has been conscious of the shadow of Schumpeter's

theories which fall over so much of industrialised and post industrial society in the 1990s. That is what draws an apparently diverse set of essays into a cohesive whole and links each of them to the intended theme of the Symposium itself.

I hope that the readers of this book will derive as much interest from it as did, I believe, the audience in London in March 1992. It should certainly establish more formally the relevance of Schumpeter's work to the economic study of the pharmaceutical industry in particular.

Schumpeter and contemporary research on the economics of innovation

Professor Richard Nelson

Over the past thirty years a number of economists have dedicated themselves to studying technical change, or innovation more broadly, its sources, and its economic consequences. Their empirical findings and their theories have had a significant influence on how economists now understand economic growth, on analysis and argument in the field of industrial organization, and recently have been a significant factor behind the rise of what has come to be called 'the new trade theory.' In all these branches of economics, as well as among scholars directly concerned with technical advance, Schumpeter is widely cited as an inspiration. Some of the recent work even calls itself 'neo-Schumpeterian.'

This essay is about the influence Schumpeter has had on the research and thinking by contemporary economists about innovation. To anticipate my conclusions, by flagging attention to innovation in the way he did, Schumpeter clearly became a source of inspiration, even legitimacy, for economists turning to that subject. On the other hand, the specific areas of research in this field most closely identified as drawing from or testing specific Schumpeterian propositions have, I believe, been based on a misreading of Schumpeter, or at least a failure to think through what was basic in Schumpeter's arguments and what was not. More, it can be argued that, with few exceptions, economists studying innovation have ignored or repressed Schumpeter's most consistent and elaborated argument about innovation, that it fundamentally involves disequilibrium and that standard equilibrium theory in economics cannot cope with it and its economic consequences. Schumpeter himself clearly harboured the same hang-ups about abandoning equilibrium theories, but he was far clearer than most contemporary economists regarding what their problems are. My discussion will most draw from his *Theory of Economic Development* (first published 1911) and his *Capitalism, Socialism and Democracy*, (first published 1942) but in places I also will refer to *Business Cycles*, (first published 1939) and his posthumous *History of Economic Analysis* (1954).

Both the *Theory of Economic Development* and *Capitalism, Socialism and Democracy* clearly lay out the argument that innovation, and the economic development innovation drives, are the really important economic phenomena, and that economists should wake up to that fact. The wake up call is rather gentle in the *Theory*, perhaps reflecting the fact that, while formal theorizing then was fastening on equilibrium concepts, much of the less formal analysis of contemporary economists was

recognizing innovation. Indeed a good case can be made that Schumpeter's writings then were in the mainstream of the history of economic thought which from Smith through Marx through Marshall was very much concerned with economic development.

However a case also can be made that the way formal theory in economics was developing around the turn of the century was fore-ordained to drive interest in innovation and economic development outside the mainstream of economics. Thus in a well-known passage Marshall attempted to explain why, while his central interests were in change, his formal analytics would be static:

> The Mecca of economics lies in economic biology rather than economic mechanics. But biological conceptions are more complex than those in mechanics; a volume on foundations must therefore give a relatively large place to mechanical analogies, and frequent use is made of the term equilibrium which suggests something of a static analogy. (Marshall, 1948, p.xiv)

In *The Theory of Economic Development* (1911) Schumpeter both indicates his admiration for general equilibrium theory, and states clearly that in his view such theory could not cope with innovation.

> But static analysis is not only unable to predict the consequences of discretionary changes in the traditional ways of doing things; it can neither explain the occurrence of such productive revolutions nor the phenomena which accompany them. It can only investigate the new equilibrium position after the changes have occurred. (p.62, 63)

There is scarcely a hint then, however, that Schumpeter was aware that intellectual structures like those put forth by Walras, which clearly was an inspiration for his analysis of the circular flow of economic activity in equilibrium, might actually interfere with ability to theorize about innovation and, indeed, might drive concern for innovation to the outlands of the discipline.

By the time he was writing *Capitalism, Socialism and Democracy* (1942), Schumpeter had seen the thrust of main line economic analysis turn away from development and innovation and towards matters that could be treated with equilibrium concepts, and towards the treatment with equilibrium concepts of economic activity and phenomena for which, in Schumpeter's view, equilibrium theorizing was completely inappropriate. Thus the famous Chapter 7 must be understood as a clarion call, with a strong undertone of scorn, that the way economists were coming to look at competition, and large firms, and market power, and indeed what capitalism is all about, was rooted in a totally misleading statical equilibrium theory. Read again his famous statements on the competition that matters

> But in the capitalist reality as distinguished from its textbook picture, it is not that kind of competition (read competition through low price-

> cost margins) which counts, but the competition from the new commodity, the new technology ... This kind of competition is as much more effective than the other as a bombardment is in comparison with forcing a door. (p.84)

And

> It is hardly necessary to point out that competition of the kind we now have in mind acts not only when in being but also when it is merely an ever-present threat. It disciplines before it attacks. The businessman feels himself to be in a competitive situation even if he is alone in his field or if, although not alone, he holds a position such that investigating government experts fail to see any effective competition between him and any other firms in the same or neighbouring field, and in consequence conclude that his talk, under examination, about his competitive sorrows is all make believe. (p.85)

Note that Schumpeter here is, at once, railing at the then (and still largely now) tendency of economists to pose the economic problem in static equilibrium terms, and trying to get economists to focus on innovation and competition through innovation. Here he is again:

> In other words the problem that is usually being visualized is how capitalism administers existing structures, whereas the relevant problem is how it creates and destroys them. As long as this is not recognized, the investigator does a meaningless job. As soon as it is recognized his outlook on capitalist practice and its social results changes considerably. (p.84)

This message really is not much changed from the message he presented thirty years earlier in the *Theory of Economic Development*. What did change in a major way between the two books was his treatment of the sources of innovation.

In the *Theory of Economic Development* his orientation is towards entrepreneurship and new firms.

> In the first place, it is not essential to the matter — although it may happen — that new combinations (innovations) be carried out by the same people who control the productive or commercial process that is displaced by the new. On the contrary, new combinations are as a rule embodied, as it were, in new firms ... (p.66)

In his *Theory*, Schumpeter is curiously uninterested in where the basic ideas for innovations, be they technological or organizational, come from. The 'entrepreneur' is not viewed by Schumpeter as having anything to do with their generation:

> It is no part of his function to 'find' or 'create' new possibilities. They are always present, abundantly accumulated by all sorts of people. Often they are also generally known and being discussed by scientific or literary writers. In other cases there is nothing to discuss about them, because they are quite obvious. (p.88)

It would appear that it is this passage that lies at the root of the argument, often made, that Schumpeter considered invention and innovation very different acts.

By the time he was writing *Capitalism, Socialism and Democracy* that sharp separation is gone, as is the notion that the 'new possibilities' are lying around for anyone to take up. The venue of innovation is the large firm with attached R and D laboratory that creates the new products the firm introduces. He clearly had firms like General Electric and Dupont in mind when he wrote:

> The first thing a modern concern does as soon as it feels it can afford it is to establish a research department every member of which knows that his bread and butter depends on his success in devising improvements. (p.96)

The difference between the two books in viewpoints on the sources of innovation certainly is not surprising, given that the earlier was written in the Austro-Hungarian empire shortly after the turn of the century, and the latter in the United States in the late 1930s.

Schumpeter's argument in Chapter 7, and elsewhere in *Capitalism, Socialism and Democracy*, however, came to be interpreted by economists not simply as stating that large firms with affiliated laboratories had by mid-century become the principal source of technical innovation. Rather, it became the conventional wisdom in economics that Schumpeter had argued that for innovation 'the bigger the firm the better.' His argument that a firm may feel great competitive pressure even when it appears to be alone in a field came to be interpreted as 'monopoly power is conducive for innovation.' There are a few places in *Capitalism, Socialism and Democracy* that Schumpeter came close to saying that. Thus in Chapter 8 he writes:

> Actually however there are superior methods available to the monopolist which either are not available to a crowd of competitors or are not available to them so readily: for there are advantages which although not strictly unattainable at the competitive level of enterprise and as a matter of fact are secured only on the monopoly level, for example because monopolization may increase the sphere of influence of the better or decrease the sphere of influence of inferior, brains, or because the monopoly enjoys a disproportionately higher financial standing. (p.101)

However, a reading of quotes I earlier gave from Chapter 7 should suffice to persuade that Schumpeter never had in mind what came to be called the 'Schumpeterian hypothesis.' He certainly had in mind a different kind of competition than that modelled in the price theory texts, but the competition he had in mind was fierce. He warned against using numbers like four firm concentration ratios as indicators of the strength of competition in a field, but stressed how insecure the footings were of firms that, by the static statistics, looked as if they held great market power.

Nonetheless, casual reading of *Capitalism, Socialism and Democracy*, or, as time went by, more likely mostly reading of the statements of other economists about the 'Schumpeterian hypothesis' without reading Schumpeter, led to the rise of a little industry of economists exploring that hypothesis econometrically and theoretically. Throughout the endeavour there were some economists arguing that Schumpeter never said it, and also that the issues of the connections between firm size and market structure and innovation were far more complex than the relationships being tested. In any case, the evidence is now clear that the 'Schumpeterian hypothesis' doesn't square with much of the data, and that things are indeed much more complex than that. (For a good up-to-date statement, see Cohen and Levin, 1989).

Was it all a wild goose chase? In some ways yes, but the blame should not be on Schumpeter. And in other ways the pursuit has been fruitful in that, finally, it seems to have led economists (or at least some of them) to a much more sophisticated vision of the relationships between market structure and innovation than contained in the simple arguments of twenty years ago.

The 'Schumpeterian hypothesis' undoubtedly is the specific argument about innovation most often tagged to Schumpeter, if wrongly. The second most commonly tagged argument probably is about 'long waves' and here too I would argue that the economists following the trail basically missed or forgot what Schumpeter had foremost in his mind.

Business Cycles is a long complex book. The organizing theme of it is that patterns of economic activity display the interaction of several different kinds of cyclical movements, each associated with a different kind of economic force. It was Schumpeter's treatment of 'long waves' that has attracted the most subsequent attention. The presence of long waves in economic activity, of approximately fifty years cycle length, had been suggested by several economists prior to Schumpeter's treatment of them, and Schumpeter gives considerable credit to the Russian economist, Kondratieff, for mapping them out. A good portion of *Business Cycles* is dedicated to examining data bearing on the presence, duration, and regularity of long waves. Schumpeter came out strongly arguing their existence, and their regularity (about fifty-six years).

Much of the subsequent research stimulated by *Business Cycles* has been concerned with two issues. One is whether the 'fifty year' Schumpeterian long cycle clock (or calender) scheme can explain the rapid growth of many countries for the quarter century after World War II, and the slowdown that has occurred around 1970, and whether the scheme suggests that rapid growth will be renewed in the 1990s. The other is more general assessment of the argument that long cycles are 'regular.' Many sophisticated economists take the position that, while there certainly are eras of rapid growth, followed by periods of slower growth, the pattern is so irregular that the very term 'cycle' is inappropriate.

However, it is not clear how much stock Schumpeter himself put in the 'regularity' argument. He thought he saw it in the data, but nothing in his broad theoretical arguments would imply regularity, or explain it. Indeed his verbal discussion of the historical distinctiveness of each 'long wave' indicates he wouldn't have been shattered if the evidential case for 'regularity' fell apart.

In my view the genuinely interesting and provocative part of Schumpeter's discussion of 'long waves' was his explanation for them. His basic explanation was that different economic eras are marked by different clusters of technologies and associated industries. A long 'upswing' is stimulated when a new set of technologies and industries comes into existence stimulating investment and an expansion of economic activity. Thus the long 'upswing' of the early 19th century was associated with the rise of textiles, iron and coal, and steam engines. The upswing which began in the mid-19th century was associated with the rise of railroads and steel making. The boom of the early 20th century was driven by automobiles, electric power and associated systems and products, and the modern chemical industries. Schumpeter proposes that each of these long booms ultimately petered out as technical advance in the key sectors slowed, and investment opportunities got saturated. Thus each long upswing was followed by a long period of slower expansion and decline. Then a wave of new innovations would set the stage for the next long upswing.

The argument here is provocative, but not at all associated with any case for regularity. It hinges on whether or not there are forces at work so that basic new industry generating innovations tend to cluster, with on average some considerable time between the clusters, so that they can be considered the basic cause of a subsequent more general boom in economic activity. Contemporary economists are not yet in agreement as to whether this is right. To say that different eras are marked by different clusters of strategic technologies and industries is one thing, and many economists would agree on that, If that is accepted, one must accept as well that the key technologies had to be around, at least in embryonic form, before the surge of development employing them could begin.

But if one is to buy into Schumpeter's theory one must argue that the advent of these technologies, the key inventions or innovations that made them possible, were bunched together at a time shortly before the upswing. However, in some cases it can be argued that the key inventions occurred at different times, with many of them significantly before the upswing that exploited them, even though their development occurred together. They developed together, at the time they did, as a result of forces impinging on the economy that had little to do with the timing of the basic technological breakthroughs. The jury is still out on this one, but at least this is an interesting set of questions (for good discussion see Rosenberg and Frischtak 1984).

I want to concentrate now on Schumpeter's argument, articulated in both *The Theory of Economic Development* and in *Capitalism, Socialism and Democracy*, that one cannot understand, or model, innovation using equilibrium concepts. Earlier I gave Schumpeter's clear direct statement of this in the *Theory*. Here he is again on the problem:

> In the accustomed circular flow every individual can act promptly and rationally because he is sure of his ground and is supported by the conduct, as adjusted to the circular flow, of all other individuals, who in turn expect the accustomed activity from him ... (But) while in the accustomed channels his own ability and experience suffice for the normal individual, when confronted with innovations he needs guidance. While he swims with the stream in the circular flow which is familiar to him, he swims against the stream if he wishes to change its channel.' (p.80)

Now while Schumpeter's insistence that competition through innovation is the most important kind of competition has gradually taken hold in models in industrial organization and international trends, almost without exception these models assume that firms are able to 'see through' the competition generated by rivalry in innovation, and have as solutions equilibrium conditions. But Schumpeter's views on human cognitive capacity are far closer to those Herbert Simon later associated with the term 'bounded rationality' than with the exquisite rationality of modern game theory. One must

> bear in mind the impossibility of surveying exhaustively all the effects and counter-effects of the projected enterprise ... In economic life action must be taken without working out the details of what is to be done (p.85)

Twenty years later Baumol stated very clearly the reason why the by then standard models of the firm that assumed firms maximize profits could not deal with entrepreneurship, laying out an argument with which Schumpeter almost surely would have agreed.

> In all these (maximizing models) automaton maximizers the businessmen are and automaton maximizers they remain. And this shows why our body of theory, as it has developed, offers us no promise of being able to deal effectively with the description and analysis of the entrepreneurial function. (Baumol, 1968, p.68)

What is most catching about Baumol's remarks is that he recognizes, as did Schumpeter, that maximization models actually imply a sort of automaton quality to human decision making. They assume a context which is sufficiently simple so that it can be seen through, or so familiar that old habits don't just satisfice but maximize, which is exactly how Schumpeter characterized the circular flow. To model decision making that aims to break new ground, one must model with other stuff.

But what kind of a 'model' of innovation and economic development

driven by innovation would Schumpeter have advocated, had he been inclined to formal modelling? I believe some clues are provided by the following much quoted passage:

> The essential point to grasp is that in dealing with capitalism we are dealing with an evolutionary process. (*Capitalism, Socialism, and Democracy*, p.82)

But what did he mean by that? It is not sure, but it is clear that he would not have approved of the modelling of innovation in modern game theory. It also is clear that he did not have in mind a simple biological analogy. Thus he argues in the *Theory of Economic Development*:

> But the evolutionary idea (that drawing from Darwin) is now discredited in our field especially with historians and ethnologists for another reason. To the reproach of extra-scientific mysticism that now surrounds the 'evolutionary' ideas, is added that of dilettantism. With all the hasty generalization with which the word 'evolution' plays a part, many of us have lost patients. (p.58)

He did use the 'e' word, however, in *Capitalism, Socialism and Democracy*, and his language about 'creative destruction' give us some hints of what he meant. But he never got beyond the hints.

Geoffrey Hodgson, in his recent manuscript on evolutionary theorizing in economics, suggests that while, ultimately, Schumpeter used the word, he made no substantive contribution to the serious development of an evolutionary alternative to neo-classical theory. Partly Hodgson's argument is Schumpeter's failure to spell out the idea. Partly it is that, until the end, Schumpeter remained strongly attracted to Walras, and general equilibrium, as the basic formal conceptualization in economics.

However, Sidney Winter and I thought we saw more than simply a few hints and a metaphor in Schumpeter. As I have pointed out, in both *The Theory of Economic Development*, and in *Capitalism, Socialism and Democracy*, competitive innovation is always described as a highly uncertain business, one in which the innovator cannot clearly foresee the consequences. Schumpeter is clear in both *The Theory of Economic Development*, and *Capitalism, Socialism and Democracy*, that the economic context in which innovation is going on is one of disequilibrium, even turbulence. And *Capitalism, Socialism and Democracy* certainly stresses the competitive aspects of innovation. There are going to be winners, and there also are going to be losers. In our *An Evolutionary Theory of Economic Change* (1982) Winter and I tried to develop formal models, in the spirit of Schumpeter. While we cannot be sure that Schumpeter would have approved of them, we believe that they are much more consonant with how Schumpeter thought of competition through innovation than the innovation models using modern game theory.

While a few other economists have followed along the same road as we have, there scarcely is a crowd. Indeed, until recently at least there

has been strong resistance among economists to treating competition and economic change as 'an evolutionary process' in the sense that that process is described in Schumpeter's words, and our models.

Why should this be? I noted above the strong hold that the concept of a circular flow had on Schumpeter. In his *Theory of Economic Development* his innovation concept is defined in terms of a circular flow — innovation is a break from that flow. He defined his *Business Cycles* as deviations from an economic (general) equilibrium. More, in various passages where the matter comes up, it appears that Schumpeter thought that there always were natural economic forces pulling the economic system toward an equilibrium. To the extent that this so, and to the extent that innovation is not so powerful, or so frequent, as to keep kicking the economy far away from equilibrium, a theory that focuses on equilibrium configurations may be a powerful analytic and predictive tool. It is not clear whether Schumpeter was attracted to it because he believed this, or because of aesthetic considerations.

However, chapter 7 of *Capitalism, Socialism and Democracy* appears to depict innovation as being sufficiently common and powerful that 'equilibrium' is not a particularly relevant concept, even if it could be assumed that, if innovation stopped, the system would quickly get to equilibrium. Winter and I interpreted the message of that chapter, and our own reading of competition through innovation in industries like semi-conductors and pharmaceuticals, as indicating that economic modelling of competition through innovation could make little use of 'equilibrium analysis' but rather had to treat disequilibrium dynamics explicitly.

The point of view that one ought to model the dynamics explicitly, and treat equilibrium as a special case of 'rest,' represents a rather radical departure from the modes of economic modelling that have grown up as developments of the basic Walrasian idea of general equilibrium. The standard mode in economics has been to centre the analysis on equilibrium configurations, and then to worry about whether those configurations are 'stable' in the face of perturbations. Economists working within this orthodox theoretical framework long have recognized that there might be multiple equilibria, and that a particular equilibrium (or equilibria) might not be stable. But these possibilities have rightly been seen as fundamentally threatening to the basic intellectual enterprise, and as matters to be put aside unless there were compelling reasons to attend to them.

For a variety of reasons, mostly having nothing to do with the influence of Schumpeter, over the past few years economists have begun to pick up the analytic stick by the other end. Once one starts with express models of dynamic process, one discovers that the conditions under which there is a unique equilibrium (in the sense of rest) are rather stringent, that in any case the system may be close to an equilibrium only a small portion of time, and that disequilibrium dynamics are analyzable

and interesting. This is leading to a surge of new interest among economists in 'evolutionary models.' I do not know whether or not Schumpeter would have approved of all this. However, I believe he should have, while cautioning about the potential hype.

In my view Schumpeter's argument that one must understand economic development fuelled by innovation as an evolutionary process is exactly right. However, it would seem that Schumpeter viewed this as a matter of contemporary circumstance, rather than something fundamental. Thus Part III of his *Capitalism, Socialism and Democracy* is oriented around the proposition that, as science becomes stronger, innovation will become planable. The consequences for capitalism would be profound, in his view:

> This social function (entrepreneurship) is already losing importance and is bound to lose it at an accelerating rate in the future even if the economic process itself of which entrepreneurship was the prime mover went on unabated. For, on the one hand, it is much easier now than it has been in the past to do things which lie outside familiar routine — innovation itself is being reduced to routine. Technological progress is increasingly becoming the business of teams of trained specialists who turn out what is required and make it work in predictable ways. (p.132)

As a result the ideological support for capitalism was doomed to fall away, and socialism would emerge.

This leads directly into Schumpeter's forecast about viable socialism:

> Can socialism work? Of course it can. No doubt is possible about that once we assume, first, that the requisite stage of industrial development has been reached ... but if we accept these assumptions and discard these doubts the answer to the remaining questions is clearly yes.' (p.167)

Recall that *Capitalism, Socialism and Democracy* was written during a period of time when capitalism throughout the world was in deep trouble. It was written during a period of time that the Soviet planning system was still taking form, and well before it proved its economic bankruptcy.

Actually, some aspects of the Schumpeterian prediction about the socialization of capitalism look pretty good. He was writing before the widespread development of 'welfare states' but his analysis of the ideological resistance to capitalism clearly is consistent with the strength that socialists (and modern liberals) had after the war in putting in place fundamental reforms.

However a strong case can be made that he is just wrong in arguing that socialism can work, and that a central reason why socialism didn't was exactly that innovation wasn't reduced to a 'routine'. Peter Murrell (1990) has written a fascinating book arguing the inadequacy of the

socialist innovation system and he is not alone in arguing that what brought down the Soviet economy, and its Eastern European satellites, was the ineffectiveness of socialism as an engine of progress. The socialist economies set themselves up organizationally on the presumption that innovation could be reduced to a routine. It couldn't be.

Of course one must recognize the importance of Schumpeter's caveat that socialism would work if 'the requisite stage of industrial development has been reached.' Russia clearly was a very backward nation when socialism was put in place, and so also were a number of the countries of Eastern Europe. But socialism also failed in East Germany, and Czechoslovakia, which were pretty advanced industrial nations at the time of takeover. What is remarkable about the innovative performance (to use Schumpeter's broad concept) of the Soviet Union and the Eastern European countries from 1960 until their collapse is that they were in the innovative forefront of practically nothing. Almost all of their technical progress came about by copying developments that had been made earlier in capitalist countries.

A strong argument can be put forth that the socialist economies did not collapse because their economic performance was miserable on absolute terms. In virtually all of them the bulk of citizens experienced very major improvements during the post-war era in their standard of living, compared with what it had been before the war. However, by 1980 or so it had become evident that these economies were incapable of closing the gap in economic and technological performance with the advanced industrial nations. For a system whose legitimacy depended on claims that it was innately superior economically and technologically, this failure was fatal.

Schumpeter was right — the technical change he saw around him was proceeding through an evolutionary process. He was wrong in thinking that this was just a stage that would pass when science got stronger.

Let me conclude this essay by returning to the basic question I was asked to address. What has been Schumpeter's influence on economic research on innovation? I think his main influence has been to stimulate economists, and I believe that there have been more and more of us, to understand that innovation is a central aspect of economic activity, not a peripheral one, and that economic progress is what counts over the long run, rather than static economic efficiency. Schumpeter more than any other economist has been influential on this point. But he has yet to persuade the bulk of the economics profession.

Pick up any introductory economics text, and look to see what fraction of it is concerned with innovation. You will find that precious little is. Pick up a text in microeconomic theory and explore the same question. The way most of them are written, Schumpeter might never have lived. Or pick up a text on industrial organization. You will find that the

treatment of innovation tends to be quite limited, and confined largely to description of studies that have chased after the 'Schumpeterian hypothesis,' and to models that purport to be 'Schumpeterian' but which I have argued are not. Economists indeed have become very interested in economic growth, and in their models 'technical advance' usually is the driving force. However, virtually all of these models assume continuing economic equilibrium. Economists by and large continue to adhere to the equilibrium models that Schumpeter rightly argued could not deal with innovation, and the economic change caused by continuing rapid innovation, although as I have noted there are now some signs of new developments on this front.

Capitalism, Socialism and Democracy, which was Schumpeter's next to last great statement, not only about economics but about the state of economic thinking, was an impatient book about the latter. His posthumous *History of Economic Analysis* paints influential economic theorists in a kinder light, but perhaps that was because he was mainly looking backwards towards the great economists of an earlier era. I suspect if he were around today looking at contemporary economic analysis, he would be very impatient.

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Schumpeter, formal analysis of innovation and pharmaceuticals

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Technological progress is increasingly becoming the business of teams of trained specialists who turn out what is required and make it work in predictable ways. . . *so many more things can be strictly calculated* that had of old to be visualized in a flash of genius'. Joseph A. Schumpeter [1947, p132 (italics added)].

Introduction

Between 1911, when *The Theory of Economic Development* first made its appearance, and 1942, the year of publication of *Capitalism, Socialism and Democracy*, there was a major change in Joseph Schumpeter's view of the innovation process — a revision on which the analysis of this paper rests. In his initial discussion innovation was taken to be carried out primarily by entrepreneurs, those adventurers who guided the course of earlier capitalism, largely on the basis of intuition, daring and a finely honed instinct for strategy. Their unpredictability was not among the least of their strengths, but it did place their activities largely beyond the reach of refined mathematical analysis of the sort that today seeks to encompass virtually every other facet of business activity. In his later work Schumpeter believed that the day of the freebooter-entrepreneur was drawing to a close, and that innovative activity had been taken over and routinized by the corporate bureaucracy, because it was too important for the welfare of the firm to be left to happenstance. Decisions relating to innovation (for example, the size of the budget to be devoted to R&D by the company,) were now reached by processes little different from those dealing with advertising or inventory management. Innovation was then, and apparently continues to be, governed preponderantly by managers rather than entrepreneurs, and the logic of managers' activities is sufficiently repetitive and calculated to lend itself far more readily to formal analysis. As Schumpeter put it, '...so many more things can [now] be strictly calculated...'.

Here I undertake to build upon this observation by offering two formal analyses of important issues relating to innovation in pharmaceuticals. The first deals with the optimal length of time that new drugs should be subjected to testing before they are made available for general prescription by doctors. Here, I am using the length of the testing period as

1 Princeton and New York Universities. The author is very grateful to the Price Institute for Entrepreneurial Studies, the Alfred P Sloan Foundation and the C V Starr Center for Applied Economics at New York University for their support of the research that underlies this paper.

a shorthand and directly measurable proxy for the rigorousness of the testing requirements. Obviously, testing periods that are extremely brief are apt to subject patients to unjustifiable risks, while excessive testing periods not only deprive them of access to useful drugs but also reduce the incentive for drug companies to invest in the creation of valuable new medications. I will provide a model that describes the formal calculation of the optimal testing period. More than that, the model will be shown to have the capacity to provide concrete and rather surprising answers to puzzling questions related to the choice of testing period.

In a second application of Schumpeter's observation that 'many more things can [now] be strictly calculated,' I will provide a new explanation of a most unSchumpeterian phenomenon — the apparently widespread and voluntary exchange of new technological information by firms, even competitor firms — an explanation which also appears to account for the relative rarity of such exchanges among pharmaceutical firms, in comparison, for example, with those in the computer industry.

On optimal length of testing period and improvements in testing techniques

In his classic 1973 article Sam Peltzman demonstrated the damage to the welfare of the public that can result from the adoption of excessively strict testing requirements for new drugs. For the uninformed observer it undoubtedly strained credulity that the severe testing requirements adopted in the U.S. in 1962 might not only fail to protect his interests, but that they could in fact prove unambiguously deleterious to the health of the general population, both by postponing the date at which valuable medications were released for general use, and by reducing the flow of new medicines. If we use average length of testing period as a simplifying index representing the severity of testing requirements, it is now clear to every thoughtful observer that this period of time can well be set so as to be excessive from the point of view of the public welfare. But it should be equally clear that too weak a testing requirement can also be detrimental, not only to the interests of consumers of health care, but also to the longer term well - being of the drug manufacturers. In the absence of governmental testing requirements it is more than conceivable that competitive pressures and, in particular, the entry of unscrupulous producers, could drag even the most conscientious of manufacturers into a race to cut costs by shaving of testing time and effort. This would surely harm those firms in the long run, not only by subjecting them to legitimate lawsuits, but it might very well reduce sales by undermining the confidence of doctors and their patients in the quality and safety of medical products. Thus, there must be some *optimal* intermediate length of testing period, a period that lies between levels that are clearly inadequate and those that are patently excessive.

In practice, such optimal testing periods can probably never be known with anything that can pretend to approximate exactitude. It must vary from product to product, its degree of similarity to or dissimilarity from other drugs whose risks have previously been thoroughly explored, the nature of any possible side effects suspected of the new product and a host of other considerations that, ultimately, probably cannot be combined and weighed without some substantial exercise of judgement and intuition. Still, as will be shown next, it is possible to construct a mathematical model that embodies at least some of the elements that must be taken into account in a calculation of the optimal length of testing period.

The reader can hardly be blamed for scepticism about the value of such a purely theoretical exercise. Who can ever hope to put such an abstract model to use if the pertinent considerations are hardly known, and little more information is available on the magnitudes, parameters and variables? It is my task to show that the exercise is in fact not pointless and that the model enables us to derive important relationships that without it might entirely elude us.

To show that this is so, let me begin by describing a problem that the model can be used to resolve. To bring the issue home let me first describe a completely analogous decision problem that is surely familiar to all of us. Who of us, when having to decide on a date for the purchase of a rapidly evolving item of technological equipment (such as a VCR or compact disk player or a laptop computer) has not struggled with that daunting dilemma — does one wait just a little bit longer until there appears on the market a better model, one that is likely not to be obsolete quite so soon? Or, does one rush out to buy now, and get rid of the ancient instrument now in one's possession, in order to begin at once to enjoy the superior performance such as is already available? Let me compound this all too familiar problem by introducing another complication. Suppose that you had made a tentative decision to wait until next October to purchase your VCR, and then you read in the newspaper that the pace of technical progress in VCR manufacture has suddenly sped up. My challenge to everyone in the audience is the following: Can you, without recourse to a formal model, decide whether the news of more rapid technical progress speeds up the optimal purchase date, advancing it, say, from October to July, because the July product will now be so much better than it was before? Or, is it now optimal to postpone the purchase date a bit longer, say to December, when even better VCRs can be expected to be available? I am rather confident that few will guess the correct answer, which I will describe and explain presently.

The choice of testing period for new drug products can face an issue that is perfectly analogous to the one just described. Suppose that there is an improvement in the techniques of statistical analysis, or the discovery of a species of animal previously unused as laboratory subject, that can provide information on the safety of new drug products faster and more

reliably or more fully than before. Should such a development be expected to increase the length of the optimal testing period for a representative new product, or should it reduce that period? Let us see.

The mathematical model I will employ is expressed in highly general and abstract terms in order to extend its range of applicability as far as one can. But to provide some sense of the nature of the construct one can illustrate it with the aid of a model that is slightly more concrete. Let T represent the length of time during which a product is tested, so that the testing begins at time t = O and ends at time t = T. Let L(T) represent the rate of social loss for a representative new product during its testing period, where L(T) is composed of two elements: first, the value of the inputs used in the testing process, including the earnings of the testing personnel and, second, the opportunity loss to the general public of delay in the availability of a valuable medication. L is expressed as a function of T to take account of the possibility that the cost per day (taking the day as our unit of time) incurred during the testing period may itself depend on the length of that period. Once that period comes to an end, the process can be expected to change from cost to benefit, thereafter yielding an expected social gain equal to B(hT) per day, where h is a technical parameter whole role will become clear presently. Thus, the choice of T affects the magnitude of the daily cost of testing, the daily benefit accruing from a new medicine, as well as the length of time over which those costs and benefits flow. But the choice of T also affects the magnitude of N(T), the number of new medicines launched in the testing process per unit of time, since a rise in T entails an increase in the cost of doing so, and can be expected to reduce N(T), the number of new pharmaceuticals in which the manufacturers are willing to invest per year. Then, the present value of the net social gain from the entire process can be written (letting r represent the discount rate)

$$(1)\quad G(T) = N(T)\left[\int_{t=O}^{T} L(T)e^{-rt}dt + \int_{t=T}^{\infty} B(hT)e^{-rt}dt\right].$$

Of course, this expression can be complicated and modified in various ways to take other pertinent considerations into account, but it is clear that the optimal value of T (that is, the length of the testing period that best serves the social interest), is the magnitude of T that makes G(T) as large as possible. Here, h, as already indicated, is a technical progress parameter, a rise in whose magnitude indicates that there has been an improvement in the technology of testing that raises the incremental benefit of an additional unit of time devoted to product testing. This is the parameter that will be needed to solve the puzzle with which the discussion began.

It is easy enough to carry out the analysis with the aid of expression (1). However, as already noted, the process can simultaneously be generalized and simplified by a change in notation. We let W(ht) be an index of the welfare gains or losses expected to be generated by the testing and subsequent sale of a new drug product. Thus, the expression in square brackets in (1) can be interpreted as a special case of the functional relationship W(hT). The optimal T, then, will be the magnitude that maximizes

(2) $G(T) = N(T)W(hT)$.

This, of course, requires (writing $G_T = \partial G/\partial T$, etc., and, for brevity, W' and W" for the first and second derivatives of W with respect to hT),

(3) $G_T = N_T W + hNW' = O$,

which is the standard first-order maximum condition. We have, by assumption, and by the second order conditions

(4) $N_T < O$, $W" < O$ and $G_{TT} < O$.

From (4) and (3) we obtain directly

(5) $W' = -N_T W/hN > O$.

Intuitively, this tells us that, since an increase in T always reduces the number of new medicines undergoing development, optimality requires that T never be set so high that $W' < 0$, i.e., that the opportunity cost of delay in availability of new medicines swamps the benefits of any associated reduction in risk.

First — order condition (3) can now be used in an ordinary comparative — statics calculation to determine the effect of a rise in the value of h on the optimal value of T, that is, to find the solution to our puzzle. For this purpose, we differentiate (3) totally, allowing both T and h to vary, and set the resulting total differential, dG_T, equal to zero. That is, we ask what change, dT, is necessary to offset an exogenous change, dh, in the technological progress parameter, in order to resume satisfaction after this change of the optimality requirement (3), $G_T = O$. This total differentiation process yields

(6) $dG_T = G_{TT}dT + G_{Th}\,dh = O$, or,

(7) $\partial T/\partial h = -G_{Th}/G_{TT}$, where, by (3),

$G_{Th} = TN_T W' + NW' + hTNW"$, or,

(8) $G_{Th} = T(N_T W' + hNW") + NW'$.

Our objective is to determine the sign of $\partial T/\partial h$, as given by (7). Now, by the second-order maximum condition (4), G_{TT}, the denominator of (7), must be negative. Hence, the sign of (7) must be identical with the sign of (8). But, by (4) and (5), the coefficient of T in (8) is clearly negative, while the last term in (8) is positive. Hence, for T less than $K = NW'/(N_T W' + hNW'')$ $\partial T/\partial h$ will be positive, while for $T>K$ that derivative must be negative. Gathering all this information together, we are now in a position to supply the solution to our puzzle.

> A technical improvement in the testing process, dh, will increase the optimal length of the testing period, T, if the optimal value of T had been relatively low ($T < K$) before the technical change. On the other hand, dh will lead to a reduction in the optimal length of testing period if the initial value of T had been relatively high.

This answer is clearly unambiguous, albeit convoluted. It is simply not true that the technical change in question should *always* lead to a rise in T or that it should always do the reverse. Yet, analysis tells us categorically under what circumstances which of these will hold, and the answer depends simply on the previous value of the optimal T.

A few words can be said by way of intuitive explanation of this surely surprising result. A key role is played by the realistic observation that the returns to more protracted testing of a given drug must (at least eventually) diminish, so that $W'' < O$, together with result(s) that *at the optimal value of T* the marginal benefit must be positive ($W' > O$) even though, for T sufficiently great, we can expect that marginal yield to become negative. Thus, as T grows larger within the relevant range, W' must approach zero. Now envision a graph of W_T, the marginal benefit curve as a function of T, where $W_T = hW'$ whose slope is $W_{TT} = h^2W''$. We see immediately that a rise in h increases the vertical intercept of that marginal benefit curve. That is, in the neighbourhood of $T = O$, when the testing period is initially very brief, an increase in h raises W_T (and, hence, G_T) and therefore increases the gains from an extension of the testing period. On the other hand, the rise in h also increases the downward slope, W_{TT}, of the marginal benefits curve, and leads it to approach zero sooner than it did before. In other words, a rise in h exhausts the marginal benefits of additions to T sooner than it did before, so that if T was previously rather large the rise in h makes it desirable to select a value of T lower than before. That, deliberately avoiding some complicating details, is the essence of the explanation of our result.

The point in all this is not to provide a ready-to-use formula for the selection of an optimal length of testing period for the pharmaceutical industry. Any such interpretation of the preceding materials must surely constitute an exercise in advanced naivitè. Rather, the objective of the exercise is to demonstrate what a strong foundation Schumpeter has provided for further analysis, and to suggest the way to others for further construction on this solid base.

On market incentives for sharing and trading of technology

Still, there are developments in the innovation process that seem to violate the predictions of Schumpeter's models. In both his early and late visions innovation is the prime instrument of direct rivalry — a weapon used to secure competitive advantage over others in the industry. In the Schumpeterian paradigm the successful innovator receives its reward in the form of acquisition of temporary monopoly power which permits the earning of profits exceeding the competitive level, because competitors' products are condemned by the innovation to be inferior to, or more costly than, those of the innovator. So long as the innovating firm can keep the source of its technological edge out of the grasp of its rivals, and as long as the latter do not succeed in producing counter-innovations of their own, the market power and the resulting profits will be immune from erosion. The implication is that every innovating firm will have an irresistible incentive to do everything in its power to keep its proprietary technology to itself. Patents, secrecy, lawsuits and any other conceivable means would appear to recommend themselves to the innovating enterprise for this purpose. Systematic sabotage of technology transfer becomes a major goal of such an enterprise. If so, that is surely unfortunate from the point of view of promotion of economic growth which is undoubtedly stimulated, indeed, probably to an extent not generally recognized, by rapid diffusion of more efficient production techniques and product improvements.

Yet, there is growing evidence that in many industries firms are not the determined hoarders of their technological advances that the preceding scenario would suggest. On the contrary, cross-licensing of patents, research joint ventures, and even totally informal arrangements for sharing of technology and know-how seem more the rule than the exception. There are a number of industries in which such a propensity of firms to engage in voluntary exchange of technology is well documented, as will be described presently. Pharmaceutical firms are probably less active participants than enterprises in some other fields, but even for them activities such as cross-licensing are substantial. The purpose of the discussion that follows is to explain why the Schumpeterian technology-hoarding scenario is far from universally applicable. In the course of that explanation there will also emerge a reason to expect that voluntary dissemination or exchange of technology will be less common in pharmaceuticals than in, say, consumer electronics.

The situation in the pharmaceutical industry is suggested by some pertinent observations in several of the available studies of the field. Thus, Pazderka [1985] writes,

> 'There seems to be a consensus in the literature that the pharmaceutical industry differs from many others in that licensing for cash considerations is infrequent. However, considerable cross-licensing exists, sometimes with cash transfers to compensate for differences in values of the patents being exchanged' (p. 47).

This picture is supplemented by the observation of Taylor and Silberston [1973] that,

> '...drug companies were frank about their unwillingness to licence important patents to competitors without a 'very substantial' *quid pro quo* in terms of patent rights or know-how (p. 247).'

Pazderka offers as an explanation the reports by industry executives that, 'to develop a specific drug, they may need licenses for one or more intermediates from other patent holders,' while, he reports, others attribute the frequency of cross-licensing in the industry simply to 'high costs of R&D' (*loc. cit*). However, George and Joll [1981] suggest another explanatory influence which is, essentially, the one that will be emphasized in the ensuing discussion:

> '...a group of firms in research-intensive industries may operate a patent-pooling and licensing arrangement by which all the firms agree to licence one another but no outside firms. Indeed...in the British pharmaceutical industry the most important advantage claimed for the patent system was that it gave the firms something to put into such a patent-pooling system so as to gain access to the other firms' patented drugs' (George and Joll [1981] pp 231-232).

The pharmaceutical industry is by no means the only one in which technology sharing occurs. Indeed, as the reports just quoted indicate, it appears to be a relatively reluctant player in the game of technology exchange. The justly noted studies of Von Hippel [1988] have documented the extensive exchange activity among the enormously successful steel minimills of the U.S. where, without the use of any procedures as formal as patent licensing, even direct competitors are prepared not only to reveal technological information to one another on request, but even to train one another's personnel in its use, and to carry out the training without charge. Apparently, the only compensation entailed in the process is the implied commitment to reciprocation as the occasion arises.

In the computer industry technology exchange arrangements are rather different, but are apparently all but universal (see Baumol [forthcoming, Chapter 10]). There, the major firms, often from different countries, meet in pairs and do so routinely, each firm bringing to the bargaining table a list of the patents it currently holds in a particular technological arena (e.g., input-output devices). In addition, each firm brings a list of the patents it expects to receive in the next five years, or some other preselected period. The object is to arrive at a contract that will permit each firm to make full use of the other's patents, current and in the future period specified. The bargaining is over the amount that the firm with the inferior list of patents and expected patents must pay to the other company in order to compensate the latter for the superiority of its offerings. The point here is not the particular character of the agreement not the nature of the bargaining process, but the fact that such patent exchange reportedly approaches ubiquity

in the industry and is carried out routinely.

Still other arrangements occur in other industries. Japanese and American automobile manufacturers have organized research joint ventures designed to provide new technological information simultaneously to the competitor partners in the enterprise. There are records of rival firms entering into contracts in which each undertakes to provide the other with a frequently updated menu of its patents and technological developments, with each firm entitled to use of the other's patents at the preset royalty rates specified in the contracts. Some of these arrangements specify terms on which each firms will provide training to the other's personnel, while some explicitly provide for no such training.

In sum, the variety of technology-exchange arrangements that are encountered in reality is enormous and the practice is clearly widespread, though certainly not universal. Most important, except where something like compulsory licensing is imposed by government authorities, a relatively rare occurrence, the exchange of information is entirely voluntary. Thus, rather than moving heaven and earth to prevent their technology from leaking to others, as the Schumpeterian paradigm suggests that their self-interest requires them to do, firms seem deliberately to seek out other enterprises, in many cases direct competitors, and actively undertake to provide proprietary technology to them, of course, for a suitable *quid pro quo*.

Many explanations have been offered. For example, it has been argued that research has characteristically grown so expensive that many firms now feel they can no longer finance it all by themselves. Others have suggested that exchange takes place because firms recognize that their secrets will eventually be discovered by rivals in any event, or that those rivals will learn to invent their way around patents, so that the holder of the technological information may as well undertake to market it, getting the best compensation it can obtain in the exchange process.

But none of these stories seems to survive the logic of the Schumpeterian argument. If, as Schumpeter claimed, in the absence of proprietary innovation the firm is condemned on the average to earn no more than the cost of capital on its investment, and if innovation is the only source of real economic profits, it would appear to be self-destructive for any enterprise to give up this unique source of profit. The fact that the secrets will eventually get out is beside the point. As Schumpeter emphasized, it is during the period *before* this happens (which can sometimes be of considerable duration) that the innovator reaps her reward, and if secrecy, patents, or other means can extend that period, even marginally, the resulting addition to the innovator's profit is surely better than none. Why, then, should so many firms volunteer to act in a manner directly in conflict with the Schumpeterian scenario?

Before turning to the answer that I will propose here one preliminary observation is needed about the comparative expected profitability of

routine and non-routine innovation. Schumpeter's profit analysis, as we know, appears in his work of 1911, where the subject is the non-routine innovation produced by the entrepreneur. And for that case, the analysis remains entirely convincing. However, in the managerial world of routinized innovation the story is different. In that state of affairs there is no longer any reason to expect innovation activity to be any more profitable, on the average, than any other activity of the firm. True, given the stochastic character of the process, it is to be expected that from time to time it will yield new products or new processes that are extraordinarily profitable. However, those abnormal profits will tend to be offset by the losses on the failures which are also confidently to be expected.

A profit-maximizing firm will be guided by precisely the same logic in deciding on its budget for R&D as in the choice of budget for advertising or the purchase of new equipment. In each case rationality requires the firm to extend the activity to the point at which its marginal net yield is zero — that is, to the point at which the firm has taken advantage of all opportunities for net profit. Moreover, in a highly competitive or contestable industry, not only will the *marginal* profits of each such activity be driven to zero. The total profit contributed by each activity will also be held down to a competitive level and, in particular, this will be true of the expected yield of investment in innovation, balancing off the likely successes and failures. The implication is that, in contrast to the case of entrepreneurial innovation, routine innovative activity can be expected to yield only routine profits, and so there will no longer be quite the incentive that is present in the Schumpeterian scenario for the innovating firm to fight determinedly to retain exclusive possession of its technological developments.

But that is merely a preliminary remark. It is certainly not incentive enough, by itself, to account for the profusion of prosperous firms that seem to be seeking out partners to whom they are prepared to reveal the secrets of their proprietary technology in return for suitable compensation, probably most commonly in the form of reciprocation. I shall argue now that far from giving away a competitive advantage, such an arrangement confers an unbeatable competitive advantage to all the members of such a technology exchange grouping over all those who refrain from participation or are excluded from it. Indeed, I will argue that in a broad range of circumstances the forces of the market offer firms little option. They *must* join the technology exchange grouping or suffer competitive disadvantages so serious that even long run survival may be in doubt.

To get at the logic of the argument we must first note that in some industries inventions tend preponderantly to be *complementary*, each innovation likely to supplement the competitive advantages offered by another. In other industries, innovations tend usually to be either *independent* or *competitive (substitutable)*. To see what is meant by complementarity of inventions,

consider three manufacturers of VCRs, firms A, B, and C. The labs of firm A come up with a better remote control device. Firm B's R&D division invents a method for elimination of electrical interference in the recorded picture, and firm C designs a better slow-motion display. While each of these can confidently be expected to prove attractive to buyers, no one of them is a substitute for either of the others, making those other inventions less useful. Moreover, the inventions can supplement one another and add to one another's attractiveness to consumers. Clearly, a VCR that is offered to the market will be more attractive, *ceteris paribus*, if it provides two of the new devices or all three of them, than if it provides only one. This case can readily be contrasted with the case of substitute inventions, for example, the inventions of two firms, D and E, both of which reduce the pain of earache. Clearly, if D's product is superior to E's, the latter becomes redundant or if D's product arrives first and acquires a loyal market E may also find itself heavily handicapped competitively.

Now, much of the literature on the economics of innovation is focussed on innovations of the latter variety — substitute or competitive products. The many articles on the subject of 'patent races' only make sense if applied to rivals seeking to produce similar products, each hoping to beat the other to the goal. The same observation applies to Schumpeter's discussion of the profit of the innovator — profit from an innovation that is destined to erosion as a result of imitative innovations by competitors. Clearly, that story makes sense, as it does, only on the interpretation that innovator and imitator are suppliers of innovations that are substitutes rather than complements.

In products such as computers, cameras, and VCRs, the typical history of innovation is a fundamental and initial breakthrough that accounts for the existence of the product itself, this then being followed by a series of innovative improvements that reduce the cost of the product and increase its reliability, convenience and attractiveness to consumers. A number of economic historians, perhaps most notably Nathan Rosenberg (see, e.g., [1976, pp. 64-74]), have concluded that the bulk of the benefits that the economy derives from the innovation process is accounted for by such incremental improvements, and others have observed that the bulk of the economy's outlay on innovation is devoted to them. Whether or not one agrees with this judgement, unsystematic observation certainly suggests that it accounts for a very substantial proportion of routine corporate innovation activity.

The crucial point to be noted is that where innovations predominantly take the form of incremental product or process improvements, they are more likely to be complementary than substitutes. Different R&D organizations are likely to present the market with different product improvements, which consequently supplement the values of the others rather than render them redundant. Where this is true, for reasons we

have already seen, there is a marked advantage to be gained over non-cooperating competitors by a set of firms that agree to permit one another to use each other's product and process improvements freely. The individualistic supplier that has access only to the improvement ideas that emerge from its own R&D division can expect its products to be judged by the market to be inferior to those that emerge from the combined research efforts of a large group of rivals. Moreover, any cost reduction innovations that are provided from that firm's isolated research efforts are likely to be swamped by the efficiencies made possible by the combined process innovation activities of the rival group that enters a technology-exchange arrangement, formal or informal.

In addition, the advantages to the members of the technology-sharing group can be expected to grow cumulatively, year after year, with the distance between the quality of their products and those of the non-participant firm growing successively larger and larger. The case of cost-reducing process innovation can be used to make the point more tangible. Suppose that in a 9-firm industry 8 of the firms agree to share technology, while the 9th holds out from doing so. If each firm's laboratories design process improvement that reduce costs on the average by 0.5 per cent per year, then the eight-firm group can expect to enjoy cost decreases close to 4 per cent per year, year after year (making some allowance for overlap in the innovations provided by the different members of the technology-sharing group). The individualistic firm, which can expect to attain cumulative cost reductions of only 0.5 per cent a year will surely not be able to compete for very long and is virtually certain ultimately to be driven out of the field altogether by the forces of the market.

Thus, where innovations are complementary rather than substitutes, the market mechanism, rather than encouraging firms to fight the spread of their proprietary technology with every means they can muster, will virtually force them to join into technology-exchange arrangements, and to work determinedly for membership in such a group, given the severity of the penalties for abstention or exclusion. This surely is a view of the matter very different from those that have been offered before. It is also possible to carry out a formal analysis of the behaviour of such technology exchange groups and their consequences for economic welfare. Elsewhere [forthcoming], I have undertaken such a study and have shown that these arrangements can be expected to be stable, that there are strong forces that work against cheating, and that the net result of such coordination of the activities of even horizontal competitors is likely to be an enhancement of welfare and productivity growth.

While this technology-sharing model is very different from Schumpeter's vision, it does not follow that if the new model possesses some validity, Schumpeter must be judged in this arena to have been mistaken. It seems clear, on the contrary, that there are different sectors of reality

some of which are better described by the one model, some by the other. Specifically, it seems quite clear that computers and pharmaceuticals lie near the opposite ends of this spectrum.

The computer is a complex piece of equipment with many features, and many models are available, all of them offering features different from the others. The more of these advanced features that a particular computer is able to offer, the larger the share of the market it can expect to be able to attract, other things being equal. Innovations that contribute to the set of available features clearly are likely to be complementary with many of the features that are already available as well as with others that are emerging from other innovative efforts at about the same time.

In medical research, in contrast, to a nonspecialist such as the present author, it appears that many drugs are designed to deal with a single and unique problem. A new medicine seems more likely to render another obsolete, that is, to serve as a substitute for the latter, than it is to increase the usefulness of some other pharmaceutical. It would seem much rarer than in computers that a joining of forces and simultaneous harnessing of knowledge derived from two independent research efforts will result in a better product than one that is derived from a single research effort. There are undoubtedly exceptions, but medical research, as already asserted, seems to be engaged in the production of innovations that are preponderantly substitutable (or independent, i.e., innovations that are neither substitutes nor complements).

The implication of these observations and the preceding analysis is that one should expect to find a far weaker propensity toward technology exchange in the pharmaceutical industry than in computer or camera production, for example. The reports that appear to confirm this prediction of the theory, then, are not to be interpreted as a peculiarity of those who manage the pharmaceutical firms or a manifestation of a special history or social setting of its operations. Rather, the behaviour pattern in question can be interpreted as the working of the forces of the market that guide the behaviour of this industry in a free enterprise economy, just as they do and should influence the behaviour of every other industry.

Concluding Comment

The central purpose of this paper has been to show how much there is to be gained by way of analytical insights by building upon Schumpeter's wisdom. Two examples have been offered here, both resting on the notion rightly emphasized in his later writings that much of innovation in the modern economy has been routinized and rendered managerial, thereby minimizing the entrepreneurial role of inspiration and genius whose unsystematic behaviour all but preclude rigorous formal analysis. Two applications to the pharmaceutical industry have been provided,

one in formal terms, and one only descriptively. In both cases the analysis offered some novel conclusions that appear to promise to contribute something of significance for practice. Whether or not this proves to be so, these analyses surely confirm that, as is true of the work of all great thinkers, Schumpeter's work is not the end of a line of investigation but, on the contrary, only the beginning.

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Schumpeter and UK pharmaceuticals

Professor Michael Beesley

Introduction

This paper considers how Schumpeter would have tacked the problem of giving policy advice to governments about the pharmaceutical industry, singling out the UK government in particular. It would be impertinent to claim that what follows is anything more than Schumpeterian in spirit. Had he now been given the problem directly, we may be sure that he would have surprised us with new insights. He would, however, have recognized what follows as closer to his teachings than most contemporary arguments about the industry.

Fifty years on from *Capitalism Socialism and Democracy*, (CSD) Schumpeter would have been pleased to acknowledge too pessimistic a view of the longevity of capitalism. He certainly did not visualise how its international competition with socialism might go. From the viewpoint of this paper, we can assume that he now would have set the problem in a context of continued capitalist economic organisation. Specifically, he would have started from the perception that the 'perennial gale of creative destruction' was operating. That is, all firms have to conduct their affairs in the knowledge that whatever their economic strengths now appear to be, all, sooner or later, will be threatened, and many depleted, by exogenous changes in technology, organisation, shift in consumer preferences and the rest. One can safely guess that Schumpeter, taking the broad sweep of post-war industrial development, would have regarded Japan in particular as the outstanding example of the inexorable pressures on established positions of the 'new men'. As we shall see, there are difficulties in making this idea of generalised competitive pressure operational, particularly in a given industry context. But Schumpeter would have stoutly resisted any temptation to throw out the baby with the bathwater in order to make a problem more tractable.

Profits were at the centre of Schumpeter's general view of how the capitalist system works. Innovation of all kinds, organisational as well as research for new products and services, provided the opportunity to make profits. Profits, however are subject to decay from the activities of forces over which the innovator has no influence — the 'perennial gale of creative destruction' (CD) as Schumpeter called it. The latter is basically a function of that freedom to engage in economic activity which is also characteristic of capitalist societies. Entrepreneurs search for (or are given by Governments) commercial shelter to stave off the tendency for profits to dissipate. Among these will be patents, and any device against direct competition that firms can muster, including the whole gamut of

devices usually thought of as anti-social, for example restrictive collusion and merger.[1] Thus, in dealing with 'cases', as he would have called them, of a particular industrial phenomenon, Schumpeter was working with two parallel ideas. The first was CD, always in the background, always strongly influencing firms' strategies. The second was the idea of prospective profit as a motive for action. Monopoly devices were to be seen essentially as alternative forms of shelter, necessary to yield a prospective profit. We can add that entry into an activity, where this was not itself innovative, had similarly to be profitable, or in other words itself anticipating some form of shelter, if only in the guise of first-mover advantages, as they would now be called, as for example in an industry which expands too fast for earlier incumbents to mop up all the demand. The famous, and for many devastating, critique of the neo-classical competitive paradigm in Chapters VI through VIII of CSD consists of *both* the assumption of CD and of 'monopolistic' practices as alternative forms of contemporary shelter. Indeed, with respect to the latter, Chapter VII stands up very well today as a first primer in investment strategy for individual firms — patents, secrecy, various forms of restraint of trade, long term contracts, and the rest, are all to be viewed as devices for keeping up the prospective cash-flow, otherwise likely to be dissipated.

Any government has to consider its policy in what is in effect a cost-benefit framework, which considers what will be the impact of change in a given policy instrument open to it on an industry's performance, and thus upon the welfare of the (usually many) parties whom the government feels obliged to consider. In pharmaceuticals, governments have characteristically thought of the pharmaceutical industry as posing a trade-off which they have to evaluate, namely that between the production of new effective ethical drugs, requiring considerable investment in research and development over an extended period, and the price of existing drugs. The connection between these is recognized as profits, from which the bulk of research and development is funded. Lower prices for the set of drugs now available, *cet par*, will reduce the profits ploughed back into research and development. Policy instruments may be brought to bear through effects on prospective profits. The most important of these in the international arena is changing the effective length of the patent life which a successful drug may have, a change that is correlated with profit prospects. In the United Kingdom a second important policy instrument bears on the prices paid for the current portfolio of drugs, namely the price negotiated with the industry under the National Health drugs purchasing scheme, the PPRS.

1 'Collusion' might well include agreements between firms to cross-licence patents, where such collective shelter promises better profits than refusal to share. For reasons explored in W. Baumol's contribution to this book, and for reasons explained later here, pharmaceuticals is not characterised by such behaviour. However, I think such behaviour is quite consistent with Schumpeter's view of the sources and protection, of profits.

A common way to formulate the policy problem posed by Schumpeter's critique has been to speak of a 'Schumpeterian trade-off', namely the welfare losses to be anticipated from exploiting monopoly pricing versus the 'dynamic' gains to be anticipated from innovation.[2] In this it must be said that to anticipate any serious sacrifice from the 'exploitation' side of this is greatly to exaggerate Schumpeter's own position. His acknowledgement of such a trade-off seems at best grudging. He clearly did not weight the 'losses' at all heavily.[3] It would be truer to say that his attitude was that the burden of proof for policy intervention e.g. in an anti-trust mode, was firmly on the proposer. 'If it ain't bust, don't fix it', better characterises his position. Of course, he never denied that policy choices do face governments, and would, I believe, have been quite content to think of their task as essentially arguing a cost-benefit analysis directed to specific proposals for policy change.

Had he reviewed the literature since CSD, the problem for him would have been that neo-classical traditions have, on the whole, triumphed. In particular, the essential CD element of his thinking, and indeed a determination to see particular industrial situations as the creation and defence of profit, has not been a central concern for economists since. On the contrary, most explanations of 'Schumpeterian' hypothesis have picked up the 'monopolistic' sides of his argument and turned them into standard neo-classical enquiries.[4] Creative destruction, and thus the fundamental explanation of what makes capitalism work has simply been dropped from the main stream. The CD process has been, rather, the concern of studies in research policy. A prominent example, bearing on the pharmaceutical industry, is Kenney's description of the rise of the bio-technology industry from 1970 as an independent challenge to the traditional organic processes (Kenny 1986). Also, the notion of a probability of success in research activity drawing from an unchanging state of nature, and hence a profitable exploitation, and, by extension, of liability to attack from other successful firms similarly placed has been used, for example, to stimulate the effects of policy changes on firms' willingness in R and D (Grabowski and Vernon 1987) and as an element in determining outcomes from trade between countries (P Segerstrom *et al* 1990). But CD has not been incorporated explicitly in attempted judgements about whether intervention is needed in a particular industry. To do this some means must be found to (a) characterise it in concrete terms, and (b) to describe its past changes, so that some predictions, even if only simple extrapolations, can be made.

A 'Schumpeterian' policy analysis of the UK pharmaceutical industry

2 Examples are Tandon (1984), Grabowski and Vernon (1987), P A Geroski (1990).

3 See the discussion at pages 101-103, CSD.

4 For a review of this tradition, see P A Geroski, (1990) op cit.

would, then, have the following elements. First, one requires a description of recent changes in threats to incumbent firms' positions. The CD elements must incorporate all important factors incumbents will consider that their behaviour has to be adapted to, because basically beyond their influence in a manner which will be directly translatable to cash flow. These may be direct, as in displacement of sales; or indirect, as in increases of R and D expenditure directed to pharmaceuticals, but not under the control of incumbents; or latent, as in changes in prescribing habits of doctors (that is, change in what appropriate treatment is deemed to consist of); or substitute technology not in present R and D portfolios. Changes may be observed to go in either direction. CD can be more or less menacing at a particular time. On the other hand, we have a set of factors which relate to the incumbents' prospective and alternative shelters when proposing to invest in R and D and subsequently in marketing their products. Governments policies are relevant if they are capable of influencing these commitments.

In pharmaceuticals, the principal available shelter is patent protection. It is prominent because it is a particularly appropriate form of shelter where profits will depend on using research and development expenditure to discover, from a large number of possible products, the relatively few which will in the event succeed. Patents can be taken out on a large set at very low unit cost; but shelter will be available and potentially valuable when the 'winners' are defined. (Patent protection on the failures will then be revealed as worthless.) For the winners as for the failures patent life is limited, so the question of building substitute shelters will assume increasing importance with respect to given products, the winners, as time passes. These can in principle range from alliances of various forms up to and including merging of ownership interests to ad hoc agreements to limit price competition.

The second element in a Schumpeterian analysis will, then, be a description of how these alternatives may, at different times, be deployed and to explain why some are more likely to be adopted than others. The explanations are necessary when considering the likely effect of a governments' policy changes on firms' actions. In response to a given policy change, firms will adopt the course that will most likely be profitable, involving a review of the alternative shelters which may be available.

The policy model suggested by applying Schumpeterian thought is thus for a government, at the time of decision, to predict future changes in the CD elements, which will indicate favourable or unfavourable pressure on future profits. If it wishes to compensate for these pressures, say to affect the prospective rate of drug innovation, it will consider policy changes affecting the 'shelters' prospectively available, e.g. by changing patent lives, or by action (or forbearing to act) along conventional anti-trust lines. It will, at the same time presumably consider, and

weigh appropriately, the effects on the prices of the current set of available drugs. In all this, views on CD are essentially driving both firms' adaptive behaviour and the indicated direction of government action. The distinctively Schumpeterian elements in this form of policy analysis are expected shifts in the exogenous elements bearing on profits, and foreseeing what firms could do themselves to influence profit prospects.

This paper therefore sets out to explore the possibilities of setting up such a policy model for pharmaceuticals. The information requirements are likely to be formidable, so it is hardly worth making the attempt if pharmaceuticals do not already display convincing evidence that a Schumpeterian description of the industry is a plausible one. Accordingly, section II investigates whether the industry has indeed displayed symptoms which in particular show the outlines of creative destruction — challenge, decay of incumbent positions etc. Duly encouraged by the results, the third section considers the problem of predicting the likely direction of change in leading elements in 'creative destruction'. The fourth section describes how the search for profits is likely to work out in terms of the alternative available shelters. The final section considers the bearing of the analysis on policy issues important for the UK pharmaceutical industry, namely the change of patent lives proposed by the European Community, and the implications of the highly concentrated purchasing of drugs in the UK by the Department of Health and Social Security (DHSS).

I think there is also a highly practical reason, connected with the application of policy, for coming to terms with Schumpeter's thoroughly realistic view about the way in which profits are generated and protected, their source in innovation and their defence in shelter of many kinds, including anti-competitive devices like mergers and collusion. This involves an academic aside. The starting points for a Schumpeterian analysis — innovation and change — are of course very different from that adopted in neo-classical analysis, in which the method is to explore the consequences of deviation from an ideal, perfectly competitive industry. My own experience in the anti-trust field in particular is that while neo-classical procedures are useful, indeed possibly indispensable, in the posing of questions to put to participants in an enquiry process, the question of what to do to remedy the situation inevitably must address itself to the basic Schumpeterian question of how and why profit prospects for incumbents and potential challengers are changed by a given policy proposal. But I have to acknowledge that to adopt a wholly Schumpeterian stance involves accepting that analysis must be much more ad hoc and difficult. And using it implies forgoing the direct link with higher level principles of resource allocation which is the strength of neo-classical analysis. Thus before launching on it, one is, again, faced with a need to be convinced that a Schumpeterian policy model is really

apt for the industry in question. Looking at past behaviour, does it strongly display the symptoms one would expect from an industry in which Schumpeter's view of capitalist development fits well?

The pharmaceutical industry and the Schumpeterian view

This section considers the evidence for a Schumpeterian view of pharmaceuticals. Such a view might well run as follows: In ethical pharmaceuticals in particular, profits depend on generating winners from Research and Development expenditure. The means to establish rights to profits (patents) are available, but the pay-off is delayed and highly uncertain with respect to a particular tranche of R and D expenditure. Expenditures on R and D can be made by incumbents or new-comers; no substantial obstacles to entry in this sense exist. At any one time one expects to see many firms with R and D capability. Since the (remote) pay-off to a 'winner' is also difficult to impute in present value terms at that point, one expects there to be a reluctance among firms to merge to reduce R and D risks inherent in pursuing a line of research; the basis of a deal is too uncertain. For both these reasons, conventional measures of concentration will be low, whenever a cross section at one time is reviewed. At any one time there must be a high dependence on the particular product or products which happen to have achieved success. The firms should be rated by the markets as shouldering above average risks. Viewing the industry over time, one would expect to see no or little tendency for overall concentration to increase.[5] There should be marked shifts over time in the firms' ranking by size, and most important, shifts in the market pecking order for particular products, as challenges to previous market leaders succeed. To what extent are these expectations fulfilled? The evidence is far from satisfactory in many ways, as we shall see, but the cumulative picture is fairly convincing.

Concentration in R&D

First, on the overall concentration issue: Concentration among the leading owners of pharmaceutical research establishments is very low when measured in world terms. Thus, data for 1988 listing the top 22 companies in R and D expenditure terms, show these to have had 46 per

5 The caveat 'little' is entered because finding a zero concentration trend depends on continued free entry to pharmaceutical R and D. If incumbents can build superiority over outsiders, and thus the initial set of firms is given, the process might better be described by exposure to random growth on that set. This could lead to greater concentration over time. There is some evidence in UK experience that the concentration over time. There is some evidence in UK experience that the pharmaceutical firm population has changed considerably over a 30 year period. There were 98 manufacturing companies in 1962 and 90 in 1991, as judged by membership of the Association of the British Pharmaceutical Society. In between these years 64 ceased trading individually, 30 survived, and there were 56 new entrants. 'Ceasing trading' includes withdrawal and takeovers.

cent of the world pharmaceutical sales.[6] The largest reported share is about 4 per cent.[7] The Herfindahl index is so low as to be negligible (less than .01). Systematically tracing ownership on the world scale is extremely time-consuming; data based on ownership for earlier years are not available, but there can hardly have been any significant shift towards concentration. Also, all sales, including over-the-counter pharmaceuticals are included. The exact proportion of ethicals is unknown in such detail, but the increasing dependence on ethicals is widely accepted, and hence the importance of R and D in company strategy.

Dependence on assets not related to ethical pharmaceuticals also complicates attempts to test the perception that the firms are distinguished by acceptance of high risk, high return projects. The obvious source of this would be appropriately adjusted estimates of beta in pharmaceutical company stock-exchange prices. There is some, but not very persuasive evidence of this in raw UK figures. But the process of disentangling effects of company gearing and varying elements in risk among the company's total assets is a formidable task which I have not attempted.[8] However, R and D has been shown in general to be riskier than other assets, e.g. by G Wedig.[9]

There is some evidence to support the notion that the companies choose to accept fluctuations in net cash flow in order to gain a higher return in total. One of the most remarkable consistencies across leading pharmaceutical companies is the ratio of R and D expenditure to sales. In 1988 the top 28 world companies, domiciled in USA, Germany, Switzerland, UK, France, Japan and Sweden, averaged R and D expenditures of 16 per cent of their sales revenues. Sales among these ranged from £460 million to £2,200 million; R and D expenditures from £101 million to £341 million. The standard deviation of the respective percentages was 3.8 per cent; the coefficient of variation .238. Much of the observed variation was in fact due to the inclusion of the smallest company in revenue terms.[10] That companies have to adopt some rule of thumb, and not formal forward looking cash flow estimates, when deciding to invest from gross revenues for R and D is understandable when the principal pay-off is a hoped for success of a very few drugs some years hence. The only reference point may indeed be comparative — i.e. not

6 Source: Office of Health Economics, London.

7 Depending on source, this can vary.

8 The London Business School's Risk Measurement Service, July-September 1991, reports betas for the best-known UK specialist drug companies as follows: Glaxo 1:13; Wellcome 1:10; Smith Kline: 81. These are equity, not asset, betas.

9 G J Wedig, 'How Risky is R and D? A Financial Approach', Review of Economics Statistics, 1990 pp 296-303.

10 Omitting this outlier, the standard deviation was 2.74 and coefficient of variation .173. Data from Office of Health Economics, London.

to stray too far from what other companies are doing. Whatever the rationalisation, unless other costs are similarly strictly proportional to sales, acceptance of such a rule-of-thumb will increase the fluctuations in cash flow available to bond and shareholders when other costs are stickier in response to changes in sales, i.e. contain rather invariant outlays. This seems quite likely, on a year to year basis.[11]

Dependence on 'winners'

High dependence on particular successful, drugs in total ethical sales is well established. One indication of this is the systematic increase in observed concentration as the ethical market is divided in sub-groups. Drugs are grouped according to therapeutic area, of which some 17 are generally recognised. These refer principally to body systems or particular general conditions between which there is normally little possibility of drug substitution, but within which such substitution can and does occur. Within such areas, more or less closely competing prescriptions occur. Thus Wells describes pharmaceutical market shares in 6 therapeutic areas in UK, for 1984 as follows:

TABLE 1 **Therapeutic area, submarket 1**

	Sales of leading product in therapeutic areas as per cent of:		
	All ethical drugs	*Sub-market level 1*	*Sub-market level 2*
1 Alimentary tract and metabolism	2.32	15.0	49.1
2 Cardiovascular System	2.36	10.7	40.8
3 Systemic anti-invectives	2.30	27.1	70.1
4 Musculo skeletal system	1.7	14.3	16.5
5 Psycholeptics	0.7	5.5	15.4
6 Respiratory System	2.7	20.4	33.1

At level 2, the sub-markets are: 1 antiseptic ulcerants: 2 plain beta blocker agents; 3 broad spectrum penicillins; 4 non-steroidal anti-rheumatics; non-narcotic analgesics and antipyretics; 6 Bronchodilatory and other anti-asthmatics.

Source: Nicholas Wells 'Innovative Chemical Extensions: Office of Health Economics', December 1988.

The therapeutic area (sub-market 1) normally defines market scope at which the decision to invest in R and D is directed; the sub-market level 2 represents successful marketing of a product which may prove superior to other drugs, on average, in prescribers eyes, as remedies for a given condition. It represents the importance of the successful drug in the general portfolio of drugs being produced at any one time as a result of previous R and D expenditure. A well-publicised recent example is Glaxo's success in the first therapeutic area, where its Zantac outsells rivals at the

11 The effect would of course be dampened by tax reliefs.

sub-market 2 level (Zantac's world shares in 1988 and 1989 of this sub-market were estimated at 52 and 44 per cent respectively.[12]

Dependence upon a successful drug at one time by particular firms is clear. Thus Wells for 1980 quotes the 10 leading UK pharmaceutical companies' dependence on their first and second rating products as follows:

TABLE 2 **Dependence of companies on individual products**

	(Per cent of sales)		
Company	*Product 1*	*Product 2*	*Total, 2 leaders*
A	49	22	71
B	73	8	81
C	63	23	86
D	77	15	92
E	32	19	51
F	80	8	88
G	70	20	90
H	89	7	96
I	29	16	45
J	45	33	88

Some further estimates for 1990, concerning the worlds best selling single drugs are: for Glaxo 59.4 per cent of sales; B-M Squibb 33.8 per cent; Bayer 28.6 per cent; Smith-Kline-B 30 per cent[13].

A further implication of the reliance on 1 or 2 successful drugs from a search among a wider ranging set generated by R and D is of course a considerable tally of failures. Only those attempts which have been promising to a late stage in development, or are in fact marketed but withdrawn, are likely to be widely known and reported. A recent example of such listings of drugs is Barclays de Zoette's.[14] The ratio of discovery of new marketable ethical pharmaceuticals to new compounds found by research is very low.

Challenge over time

If companies, however large a size they may reach at any one time, are in fact challenged over the long term by the success of others, we would expect to see evidence of waxing and waning in their relative positions as time passes. Changes in companies' relative standing can be measured either at the level of the company, or with respect to their experience

12 Source: F Dell'Osso, 'When Leaders Become Followers: The Market for Anti-Ulcer Drugs', London Business School, Case Series No 12, Feb 1990.

13 Source: Tables 6 and 14, Paul West: Glaxo — a preliminary review, Mimeo Centre for Business Strategy, London Business School, August 1991.

14 Barclays de Zoette Wedd Research: 'Glaxo: Phenomenal Financial Flexibility', Autumn 1989, P 7.

within a given therapeutic area. Again, the evidence is limited, particularly on the company level. It is impracticable, without considerable resources, for example, to trace the destinations of assets of those companies which have given up the area. It appears however that the pecking order of the leading companies in the top ten companies world wide, and their presence amongst the top ten, is subject to marked change. Thus, if we take the 10 world leaders measured by revenue, in 1990, we can compare their position ten years earlier, in 1980, as follows:

TABLE 3

World Leaders, 1990	*Position in 1980*
1 Merck	4th
2 Bristol Myers/Squibb	8th
3 Glaxo	Not in 1st 10
4 Smith Kline/Beecham	10th
5 Hoescht	1st
6 Ciba-Geigy	3rd
7 Johnson & Johnson	Not in 1st 10
8 American Home Products	6th
9 Sandoz	7th
10 Eli Lilly	Not in 1st 10

Source: Paul West op cit p 6

There seems to be a considerable churn in leadership positions. This kind of material is available with respect to the experience of companies in a particular market, UK. For non-hospital sales it is possible to compare the positions of the top 20 corporations in 1990, tracing back their positions in 1980 and 1970.

Measures of instability in rank order are admittedly difficult to encapsulate formally and to compare, say, with other industries. One could conceive of a measure which incorporated a random change in the pecking order, with deviation from this for the observed change, but that would require a full ordering of positions, not easy to acquire. Nevertheless, the impression that much change is going on is reinforced. With the experience of two decades thus represented, a natural question is whether there is evidence of the propensity to challenge changing as between 1970-80, and 1980-90. The formal answer is that between 1970-80, the sum of the rank changes displayed was 149: in 1980-90, 96. This result, however, is almost entirely dependent on the meteor-like performance of 1990's second ranking firm in the earlier decade. Dropping the most extreme observation, in each case, the two decades displayed almost exactly the same degree of 'churn'.

TABLE 4 **Market position of top 20 corporations (excluding hospital sales), UK**

Corporation	*1990 Rank*	*1980 Rank*	*1970 Rank*
A	1	2	4
B	2	7	76
C	3	1	2
D	4	4	5
E	5	6	11
F	6	20	34
G	7	3	1
H	8	8	7
I	9	5	10
J	10	21	17
K	11	30	21
L	12	32	37
M	13	14	12
N	14	17	13
O	15	15	16
P	16	18	32
Q	17	9	6
R	18	12	8
S	19	16	14
T	20	19	18
Percentage of market accounted for:-	70.5%	67.1%	67.5%

Source: Office of Health Economics, London.

The same kind of approach may be applied to experience in particular therapeutic markets, this time working from the rankings of the top 10 companies at 1970 and 1980 respectively, taking their experience over the subsequent decade. We have data for 11 of the 17 therapeutic areas, covering sales in the UK, within which products may vie for acceptance. As will be seen from the details in Appendix 1, to hold one's leading market position over 2 decades was rare: it happened only in dermatologicals. A first position was held over a further five separate decades. In the rest of the 22 decades represented, first place shifted in 5 cases. In 92 cases out of a possible 220 companies appearing in the top 10 lost their position amongst the set over a decade. (Detailed figures show a much greater movement within the decade, year by year). By adopting the convention that a firm missing in a given year's list of 10 had a rank of 12, we can sum up the 10 year changes in rank, by therapeutic area, in the following table, 5.

For comparison, a complete reversal of ordering 1-10 over the decade would produce a score of 50. The average, following the tables conventions, for all eleven areas, is 35, 1970-1980; and 34, 1980-1990. Only sensory organs in 1980-1990 and respiratory in 1970-1980 have a score of less than 25. An apt conclusion seems to be that here, again, there was

considerable successful challenge in each market. There is little to suggest a trend in either direction as between the 2 decades. The small average difference is due to the exceptionally disturbed decade of 1970-1980 for the alimentary area.

TABLE 5 **Changes in rank position of drugs in therapeutic markets: UK 1970-1980, 1980-1990**

Therapeutic area	*Rank changes 1970-1980*	*Rank changes 1980-1990*
Alimentry	65	38
Blood and blood forming	34	40
Cardiovascular	28	39
Dermatological	33	36
Genito-urinary	44	28
Hormone preparations	27	32
Anti-infective	34	34
Muscular-skeletal	35	37
Central nervous system	36	44
Respiratory system	24	33
Sensory organs	36	22
	–	–
Total	386	373

Source: Appendix 1

Creative destruction and prediction

The previous section has demonstrated that pharmaceuticals displays many of the symptoms one would expect were a Schumpeterian interpretation appropriate. So it seems worthwhile to explore the appropriate policy model. This section considers the exogenous factors, those of creative destruction. There are three candidates for consideration: change in the aggregate demand for ethical pharmaceuticals, change in the structure of demand, and change in the quantity and distribution of research activity. They will be related in that realised demand will, at the time the current products of research and development come to market (perhaps 10 to 12 years hence, as shown later), largely determine net cash flow at that time (as also seen later, avoidable production costs at that time will usually be relatively small). The realised productiveness of present R and D effort is also an unknown quantity now. However its present distribution and structure will indicate how rivalrous with respect to the demand its product innovations are likely to be. We consider these factors, as far as the evidence takes us, in turn.

Demand for ethical pharmaceuticals

The overall demand for ethical pharmaceuticals, as it relates to innovation in ethical drugs, is both hard to define and to capture statistically.

We are essentially interested in that part of demand which relates to the prescribing habits of doctors who, in Western medicine at least, are the sole judges for consumption, and the terms of substitution between different drugs deemed to be capable of affecting illness. This is a subset of pharmaceuticals production and, for many of the world's markets, part only of the drugs commonly used, because of surviving traditional medical methods. So while world demand for ethical drugs is thought to be rising rapidly, we lack reliable figures for total world consumption for years earlier than 1989. We do have data, however, for the major western drug consumers, who also house most of the worlds expenditure on pharmaceutical R and D. Thus W Germany, France, Italy, Japan, Switzerland, UK and USA comprised 74 per cent of world ethical drug consumption in 1989.[15] Their consumption was £26.5 billion in 1980 and £70.1 billion in 1989 in nominal terms: real consumption rose by about 47 per cent.

The factors underpinning this growth are widely discussed. In these developed countries, for example, a principal driving force is a derivative of growth of income per head. The income elasticity of demand for health care for individual countries as measured by time series of expenditure, and real income, is probably greater than 1, even though countries at comparable income levels devote widely differing amounts of income to health care. Indirectly, income growth is associated with ageing in the population and ageing sharply increases the demand for drugs, as well as all other forms of health care. In this way, a growth of capacity to provide the means to prolong life as with innovations in drugs is a self-powered virtuous circle. There is no reason to suppose that widening ability to prolong the life, and to improve the quality, of the population will not continue apace. Indeed, the pressures cause never-ending embarrassment to public providers of health services, as in the UK. Success in developing particular new life enhancing drugs has a ratchet effect, creating further drug demands later not normally related to the original innovation. However, these conventional wisdoms about what drives demand have, so far as I am aware, been tested formally, still less incorporated into a formal predictive model. There is certainly a great need for this.

Changing demand structure

Of equal interest in judging how demand will develop is the prescribing behaviour of the final consumers' principal agents, the doctors. This has been changing over the long term in a way significantly affecting prospects for the output of R and D. The history of medical prescribing is one of a long term shift from naturally based to synthetically based drugs,

15 The respective figures were £70.1 billion and £95 billion.

i.e. towards typical R and D outputs. Fundamentally also, there is a long-term shift towards adopting practices, and thus prescribing, based on Western medical techniques. To the extent that prescribing habits converge, differentiation of drug markets based on prescribing divergence will diminish. Convergence is very probably reflected in the long term trend for imports of drugs to form a greater part of total drug consumption in each country. The 7 nation data certainly shows this over the period 1980-1989, as in Table 6.

TABLE 6 **Share of imports in drug consumption by country, 1980-1989 — percentages**

	1980	*1989*
West Germany	17.4	26.5
France	8.3	21.8
UK	12.2	28.2
Japan	6.9	7.0
Italy	15.2	26.0
Switzerland	36.5	85.3
USA	4.1	5.1

Source: Office of Health Economics, London, based on UN commodity Trade Statistics.

Most countries show a continuous shift towards imports over the twenty year period 1970-1989, as Table 7 shows.

It will be noted that Japan is an exception to the continuous trend of rises in imports. The check between 1985 and 1989 was probably the result of decisions taken there in the mid-80's in an attempt to reverse the heavy adverse balance of payments against Japan in drugs. This adverse balance had been sharply growing over the 1970-85 period. In 1970 it stood at £63 million, in 1985 £694 million. Indeed in yen, with 1970 as 100, the adverse balance increased fourfold to 1985. The reason for imports was again most probably a shift towards Western type prescribing, allied with a strong rise in domestic drug demand. Japan's intention to reverse what was for it a most exceptional industrial experience had long been known, together with its encouragement of local R&D spending from at least as far back as 1970. (Its expenditure on R and D, again indexed in local currency, grew faster than the other 6 countries. See table 9 below.) The intention, presumably, was to divert the shift into Western style medicine to more home sourcing of the products demanded.

TABLE 7 **Ethical pharmaceutical imports, 1970-1989**
Index based on local currencies 1970 = 100

	1970	*1975*	*1980*	*1985*	*1989*
West Germany	100	205	368	626	705
France	100	184	372	888	1440
Italy	100	247	624	3059	3044
Japan	100	169	315	398	393
Switzerland	100	131	205	361	382
UK	100	284	653	1722	3167
USA	100	272	923	1975	2433

Source: UN Commodity Trade Statistics.

This throws into relief the importance of trends in doctor's prescribing habits. We know that at one point in time, doctors do diverge considerably both in diagnoses of illness and, within a given diagnosis, tend to favour different prescriptions. We would like to know, in particular, whether these are tending to converge across the major markets, or the reverse. If the former, the international share of the total market will increase further, unless subjected to government intervention of the Japanese type. And, more important, there will be a further erosion of distinctions which create separate markets to supply idiosyncratic diagnoses. If doctors come to agree more about appropriate diagnoses, and reach greater agreement on the merits of alternative treatments, both risks and rewards to develop particular drugs will be increased. Competition will be based less on persuasion and more on consensus about therapeutic values. The importance of price as a competitive weapon will increase.

The most comprehensive evidence bearing on this issue seems to be Bernie O'Brien's 1984 study of the Patterns of European Diagnosis and Prescribing.[16] On diagnosis, widely varying rates of diagnosis of illnesses were observed. 'Essential benign hypertension' was the leading diagnosis in three out of the five countries, with a range of 433 per thousand population in Italy and 244 in Spain. 'Acute chronic and unqualified' bronchitis ranged from between 413 Spain and the UK's 214. Even the existence of particular conditions is moot; 355 per thousand population diagnosed in the UK with neuroses, but not listed as a leading diagnosis in France and Germany. Prescribing frequency varied widely, total annual prescriptions per capita at 6.5 UK, 11.3 Italy. Within agreed areas of illness, treatments also vary widely. In hypertension for example, German doctors favoured centrally acting hypertensive drugs, UK (this was 1982) thiazides and diuretics. In the treatment of bronchitis, 49 per cent of Italian scripts were for expectorants; 12 per cent in Spain and UK.

16 Office of Health Economics, London.

Recognising the difficulties in sampling efficiently and in interpreting across languages, we have to assume that real and significant different diagnoses exist, as indeed they do within a country to a lesser extent. We do not know how, if at all, they are changing; apparently no follow up study has been mounted. This is particularly unfortunate as the question of whether there is in fact a convergence has still to be shown. There probably is, because of the spread of common medical knowledge, but how fast it is progressing is critical.[17] Lacking direct comparisons over time we have to make do with a somewhat distant proxy involving the 7 country trade in pharmaceuticals.

The reasoning is that if there is a tendency towards uniformity in prescribing, this should be reflected not only in imports rising as a share of drug consumption in a given country, but also there should over time be a tendency towards countries' reducing their variance in the sources of their drugs. In a world in which all doctors in all countries took the same view, these sources be alike. Starting from a large discrepancy of views as now, there should be a change towards stability as attitudes across countries converge. We have already commented on the rise in the proportion of imports, with Japan as perhaps an emerging exception. We have matrices of imports between the 7 nations for 1980 and 1989. Are there signs of reduced variation of sourcing between these dates? Table 8 gives data measuring the coefficient of variance for imports from the 6 other countries at the 2 dates.

TABLE 8 **Coefficients of variance in imports from other countries, 1980 and 1989 (standard deviations in brackets)**

	1980	*1989*
Germany	1.21(67.2)	1.25(188.0)
France	1.26(46.4)	1.02(129.8)
Switzerland	1.54(185.4)	1.91(153.2)
UK	1.89(44.7)	1.25(113.6)
Japan	2.01(108,4)	2.06(405.6)
Italy	1.67(61.7)	1.41(219.5)
USA	1.09(27.2)	1.19(166.6)

Calculated from UN Commodity Trade Statistics. The standard deviations are of imports valued in £ millions.

Signs of convergence appear in only 3 of the 7, but those that do appear are quite marked, viz in France, UK and Italy. This suggests a contrast which could be formally tested by further direct enquiry. Meanwhile we are left with uncertainty about change in a key area.

17 Establishing the European Common market implies standardisation of medical school training, a development difficult to accomplish, but as in other community matters, subject to an increasingly urgent timetable.

Research and Development – growth and dispersion

On the third factor, the growth and distribution of R&D, we again are unable to bring data to bear at a sufficiently disaggregated level to form a fully satisfactory view. The problem is that knowledge of R&D expenditures involves reporting at company levels, tends to be confidential and is not necessarily disclosed in formal accounts. Moreover, for this critical element of the source of property rights, we would wish to be very careful about assigning R&D to a group of companies, at least where there is a majority shareholding link. Instead, information which can be used to measure change over time derives from pharmaceutical Associations in the several countries. It may not be complete; there is no reason to suppose bad misrepresentation but it has to be treated at country level. We must again do our best with the material at that level.

First however, we may note the state of concentration in R&D at one year, 1988, on which there are comparable data for the top 28 spenders on R&D worldwide. The total R&D expenditure was £5409 million valued across the exchange rates then ruling. The relevant measure of concentration for our purposes is again the Herfindahl. Since the largest single company expenditure (£341 million by Myers-Squibb) represented only 6.3 per cent of that total, the Herfindahl is very low, at about .028 (though confined to a R&D subset by omission of the 29th and subsequent smaller R&D company expenditure, the omission will affect the index only trivially). The assumption that firms must regard the total investment as outside their influence therefore seems safe.

Overall growth in R&D can be measured for 8 leading countries from 1970, and 12 from 1980. Measuring this over time presents obvious difficulties in dealing with inflation and exchange rates. An estimate for 8 countries over 1970-1990 and for 3 others, from 1980-1990 is in Table 9.

The 1990 expenditure for the 11 nations totals £10,895 million, a very high proportion, though unknown precisely, of the world's R&D effort. The growth overall is marked, far outstripping that of drug consumption. As noted above, drug consumption rose in real terms in the 7 countries by about 47 per cent between 1980 and 1989. Over those countries as a whole real expenditure on drug R and D rose by 151 per cent between 1980 and 1990. In no country was the increase less than 47 per cent. The range was from 64 per cent in Germany to 287 per cent in Switzerland. From the 5 year changes, any reasonable prediction must be for substantially greater R&D expenditure.

In deciding what this implies for the underlying threats from research in the therapeutic areas, in which research tends to be focused, it would be most useful to have an appropriate breakdown by ownership interest with respect to the therapeutic areas. This cannot be done. However, we have sub-sets of research activity by country. R&D measured at that level does indicate capacity by country to engage in relevant research. As

TABLE 9 **Real expenditures on R&D, 1970-1990[18]**
Local currencies, adjusted for respective consumer price indices
1970 = 100

	1975	*1980*	*1985*	*1990*	*% change 1980/90*
West Germany	136	173	214	283	+64
France	148	211	338	483	+123
Italy	131	159	252	440	+177
Japan	168	244	383	516	+112
Switzerland	86	85	253	329	+287
UK	147	240	371	573	+139
USA	135	155	217	360	+132
Denmark	132	160	223	467	+192
7 countries (excluding Denmark)	133	136	265	342	+152
Holland	223	467			
Sweden	111	173			
Finland	192	275			

Sources: Associations' Annual Reports and IMF.

TABLE 10 **Pharmaceutical – R&D**
Indices of concentration across countries 1970-1990

	1970	*1975*	*1980*	*1985*	*1990*
8 countries: West Germany, France, Italy, Japan, Switzerland, UK, USA, Denmark	.302	.226	.203	.235	.188
11 countries: West Germany, France, Italy, Japan, Switzerland, UK, USA, Denmark, Holland, Sweden, Denmark	–	–	.187	.215	.175

Sources: Calculated from Associations' annual reports and IMF.

this increases in real terms, it probably increases in potential scope. If so, one would expect an increasing internationalisation of research potential, and that such a convergence of international capacity would be reflected in more dispersion. This expected outcome can be tested. Is R&D becoming more dispersed as well as growing? Table 10 presents R&D based Herfindahls, measured across the R&D expenditures by country. Alternative accounts, based on 8 and latterly on 11 countries, also are shown.

Individual years are much affected by exchange rate fluctuations. In particular, the index is strongly affected by the largest constituent (in this case USA). 1985 happens to be a year which weighted the US heavily. As Table 9 shows, for example, US real expenditure on R and D from 1980-1985 failed to keep pace with the index for 7 countries as a whole.

18 Real Index in Sterling.

But the general trend seems clear — for a rise in the dispension of effort, as seen by the fall in the indices. Of particular interest is the latest period of great real increase in R and D expenditures, 1985-90. This was accompanied by a substantial increase in dispersion.

Summary

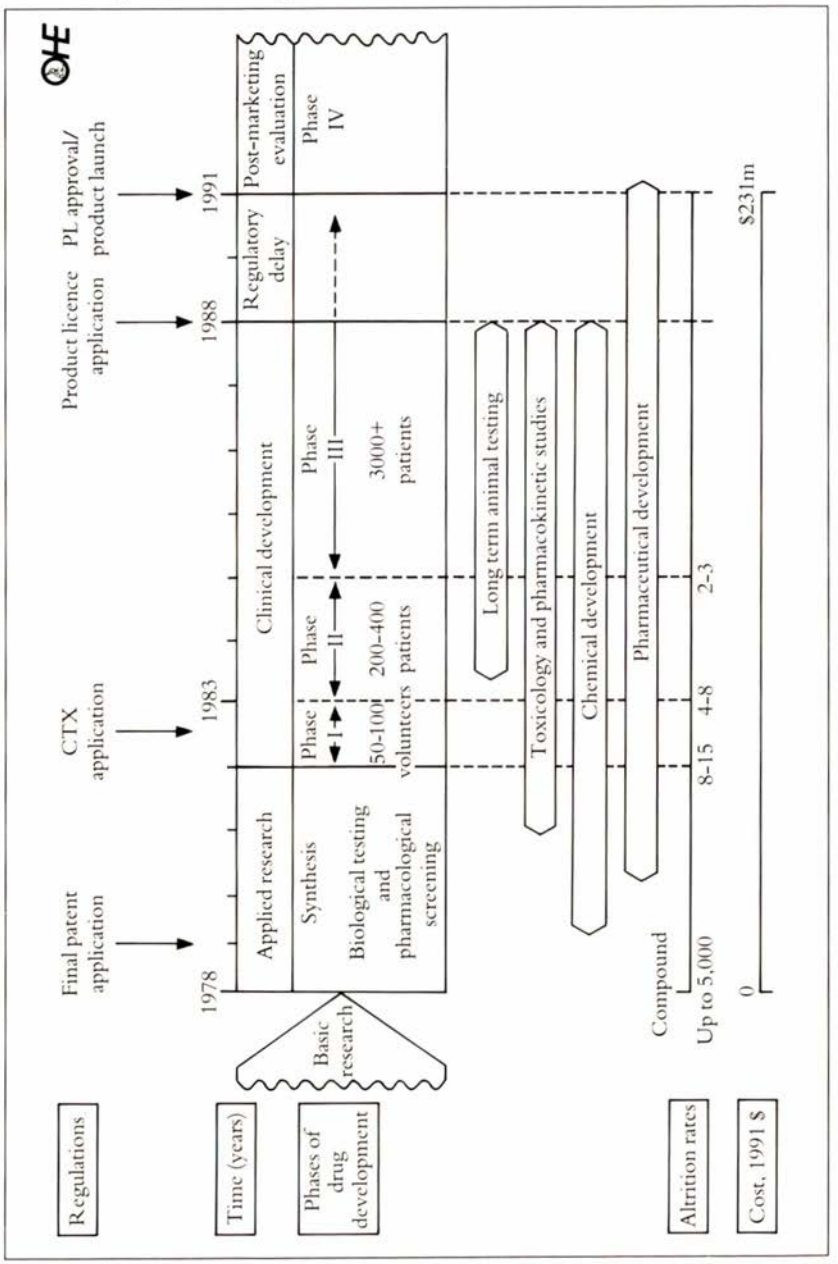
To summarise the findings of this section: Of the three elements in a prediction of the future impact of 'creative destruction', the clearest relationship is that between overall demand and total research and development expenditure. If the former continues to grow at its recent pace, when the very marked recent increase in R and D expenditure begins to yield its products, the drugs available to doctors will be substantially more in relation to that demand than they are now. But on the issue of how the structure of that demand will respond in prescribing habits, a critical matter in forecasting drug demand, no strong evidence for or against convergence emerges. On the likely impact R and D on the future supply of drugs, there seems little doubt of its strong growth and greater dispersion. On balance, therefore, it would be a reasonable position to approach policy formulation on the basis that there is no adverse trend in creative destruction. The more probable prospect is for an increase; profits will come under greater pressure.

Drug companies and Schumpeterian 'shelters'

For pharmaceutical firms, the question of specific action to increase the chances of a good pay-off to a potential 'winner' drug or drugs will arise at the time when research and biological testing has reduced the set of candidates to relatively few, compared to the initial set of entities found and patented. The following diagram is a useful stylisation of the 'discovery and development' of a new medicine, due to the Centre for Medical Research.

In terms of the diagram, patent protection on a relatively large number of chemical entities will have been taken out, earlier in the process. At about years 3 to 4 of patent life the winnowing process will have left the few serious candidates for the increasingly expensive later stages. The management of development is recognised as requiring, as West describes it, a 'different management style and indeed a different type of scientist'. In Glaxo, for example, 'two out of three new chemical entities', submitted by research laboratory heads, 'failed to pass the Central Exploratory Development committee's scrutiny'. At about this stage the options for involving marketing and detailed possible financial pay-offs begin to be considered, anticipating the later development stages which, as the diagram shows, involve increasing number of tests on patients, until the hoped for single 'winner' is defined and sent for product licence application. In the Centre's account, regulators' deliberation on licensing is set at two years, after which selling can begin.

Discovery and development of a new medicine



F: Update to Figure 1.13 Innovation and New Drug Development, S R Walker and J A Parrish in Trends and Changes in Drug Research and Development. Ed: B C Walker and S R Walker 1988.

Source: Centre for Medicines Research

Using shelters

Not noticed in the diagram, which rolls back, as it were, the history of the single product which eventually gets marketed, part of the strategy to create returns includes the possibility that additional patent shelter can be erected, by parallel research effort into 'improved chemical entities' (ICE's) which might substitute for the lines developed so far. At this stage, when the latter have become very few, the fact that patents are also a means of publishing information assumes great importance. The patent information is readily mapped to the knowledge that the developing company is indeed pressing ahead with the small subset of original possibilities. This is the signal for other companies too to attempt to develop ICE's of their own. (These will not necessarily be patentable as products, as they well might infringe the patents of the older rivals, but may well be patentable as processes). These imitative efforts (or 'me-too' products as they are unkindly called) will, if they survive the testing course, have a patent life extending a few years beyond that of the 'original'. Perhaps the most important recent example of a (very) successful ICE was Glaxo's Zantac, which followed the more original Tagamet (Smith Kline) to the market after 2 years delay in 1983. This was a case in which an independent ownership interest won the race to develop a successful ICE. An example of the reverse case, of common ownership of the 'original' and the ICE, was Valium following Librium.

The 'original' compound producer can thus also deploy a hedging strategy, in the light of judgements about the cost of such developments on the one hand, and the extra effective patent protection on the other. But patent strategy is not the only important dimension of profit seeking at this stage. By the time candidates have become few, it is possible to focus on actions which might advance the marketing date in a particular market and by expansion reduce the time taken to market in other countries. If this can be done, profits accrue earlier. A possibility here is putting more resources into speeding up the clinical trial phases. Companies can similarly shorten the regulatory delay, again with respect to a single country market and, at greater cost by attacking countries simultaneously. The choices in strategy are now richer, and there may well be trade-offs between them; for example, if extending effective patent protection has a present value of costs roughly th same as that of speeding up acceptance of a drug, the latter will be preferred simply because the revenues arrive sooner. With respect to regulatory delay, and to US conditions in the early 80s, such a trade-off has been noticed in the context of public policy to patent extensions. Grabowski's and Vernon's simulations calculated a company's break even between shortening of regulatory lag versus patent extension by a given amount of time as at 5 or 6 to 1 in the former's favour.[19]

19 H Grabowski and J M Vernon, (1987).

If the decision is to increase resources applied to testing, the problem will be to deploy a large extra capacity to do the testing at the appropriate time. In the later 80's there seems to have been a growing attention to this process. Pharmaceutical companies have realised better the advantages of a capacity to switch manpower from drug to drug as the potential of each comes clearer, so as to shorten the expected average testing period. The superior logistics have essentially stemmed from applying management skills more rigorously. Schumpeter might well have recognised this as an organisational innovation providing an extra shelter. Its effect is to improve profit prospects for the larger firms having a diversified portfolio of up-coming drugs.

The more remote event of marketing the product will arise at the time of concentration on a few front runners. Hence the question of marketing alliances arise, that is collaboration with firms willing to provide the required manpower for tackling the job of persuading doctors to prescribe a new drug. These are likely to be alliances confined to the need to speed action in particular markets. An alliance us unlikely to extend to sharing of the basic property rights in the drug or drugs, because at this point there must be lively hopes of very high pay off to the drugs while, at the same time viable options among established networks may well exist, so that there is no need to share in ownership of drugs involved. In 1991, for example. Scrip reported many such marketing oriented deals. Examples are the Sanofi-Sterling alliance giving Sanofi access to the US market. 'Both parties have insisted on retaining separate identities and headquarters (Feb 27, 1991). AHP set up a joint venture for the distribution of ethical and nutritional products in Japan with Eisai (20 September 1991). Astra bought Simes from Zambon to give 'access to its own marketing channel in Italy (25 September 1991).

Generic competition

Whatever marketing alliance has been formed at this stage (of a decision to major on a very few drugs) it will assume much greater importance at a later stage in the sequence, namely the time at which sufficient approvals have been acquired to begin active marketing. In terms of diagram 1 this might well arise at about years 10 to 12. At this stage, the disposition of own and competing ICE's will be known, and the time of effective patent shelter available determined. The principal further question affecting future profits will then be strategy with respect to prospective generic competition which may ensue when patent life expires. How acute this is at the time of marketing will of course depend on how successful a firm has been in shortening the previous stages. It will also strongly influence the price at which the product is brought to market and its desired future price path.

One would suppose that the most usual course would be to work back from the presumed date of generic entry and decide the pricing path for

the future in the light of that. Generic production has its own of costs of entry, principally of testing for licensing. At that point all the development costs put into the patented drug have been sunk. The current production costs will normally be very small. True, marketing costs will still be among the avoidables then to be taken into consideration. But there is no reason to suppose that possible generic manufacturers production or marketing costs will be much, if at all lower, at that point than those of the patented drug. The problem is largely one of maintaining exposure to drug prescribers to whom visits will have to be made at reasonably frequent intervals. Such visits are the more effective, of course, if the drug has an individual designation, not a simply generic one, so that the impact of the visit is not lost during the intervals of calling. (This is no doubt a reason why generic manufacturers have increasingly branded their products.) With a very large number to be called upon, in different geographical locations, the cost per call for generic or patented drug will not vary very much. So, relative to prospective generic competition, the patented drug will face lower avoidable costs at that point, because of the testing costs to be faced by the prospective generic rival.

In the case where the generic competitor is expected to have exactly the same therapeutic value as the patented drug, the implication for setting the most profitable course seems clear. One aims at an entry-forestalling price at the time when generics could enter and still make profit because the generic costs of seeking approvals is avoided. If the low price then anticipated stimulates so much demand that to serve it would seriously overweight a firms' commitment to manufacturing then the profitable course would be to licence the brand, which carries the tag of approval, to an independent manufacturer or manufacturers.

Until the point of a shift to generic production or licensing, one simply charges what the market will bear. This is basically a function of how superior the prescribers perceive the drug to be as compared to other treatments in treating illness. A doctor will, explicitly or implicitly, make the patient's trade-off between price as an efficacy of treatment. What the revenue-maximising price (or prices) are likely to be is no doubt judged by a combination of past experience and test results coming from early market experience. Because of the low avoidable costs at that point, at least in established sophisticated drug markets, the exercise is essentially one of revenue maximising. In this, one expects the principle of price differentiation to be uppermost — output and revenue are increased thereby. (Public sensitivity about drug prices in individual countries probably dictate that this differentiation is largely confined to separate countries).

However, an assumption of an exact therapeutic replication is extreme. More frequently, one would expect to encounter differences in perceived quality between the patented and generic drug. If, as one

would suppose, this difference lies in favour of the previously patented drug (or the relevant ICE's) then it is possible to sustain a price differential against the generic. Backing up the differential with persuasive advertising and promotional visits will often make this sustainable over a considerable time into the generic period. The important point of difference from the exact replica case is that the differing qualities/price mix which generics often have ensures that they too have a (differentiated) market opportunity, and will enter. Eventually the pressure of entry by many differently specified generics will erode the pay-off to support the original patent brand. Viewed ex post, the price patterns over time displayed by patented drugs will have in common a period of high price exploitation of what the market will bear, followed however by differing patterns of relative decline, depending on the factors just described. There are several descriptions of completed cycles of this sort.[20]

Alternative sources for shelter

At any time when Government policy decisions are made, drug firms will be managing the profit seeking process at each of these periods in market development. The parallel question to that of predicting the future of exogenous influences on profit is: will there be a further application of sources of shelter? In this period of what might be called 'managing the pay-off' to a bonanza and bonanzas, a natural Schumpeterian question is whether other possible sources for profitable shelter can be erected to increase it. The candidates of conventional importance in public policy are organising merger, and collusive activity. As argued earlier, proposals to merge are unlikely to be seen as useful (as distinct from buying, in one form or another, perhaps through 'alliances', extra capacity to sell one's product). They not only dilute the winner's prospective profit to new ownership interests but are also costly and time consuming to bring about, delaying changes in working practice. Mergers are more likely to be relevant for application at a much earlier stage in the process, and are most likely in order to hedge against the threat from a completely different R and D base. An outstanding example of such a merger appeared in 1991, relating to biotechnology, American Home Products acquisition of 60 per cent of the Genetics Institute for a reported $600 million (Scrip October 4th 1991).

At the point of confrontation with potential generic competition, there is little to be gained from merger with a revealed generic opponent, useful as this might have been had it happened at an earlier stage. The important potential for sustaining profits is that described earlier.

20 The discussion in the text underlines how difficult it is for drug interests to defend their position in neo-classical terms. At the point of anticipation of generic competition, prices for the patented drug will get little support from what are *then* avoidable costs, which will be very low. The actual mark-ups are justifiable only in the fuller, Schumpeterian, context.

With the winner in place, one is as likely to be discarding a generic as acquiring it — as is perhaps indicated by Glaxo's recent disposal of its antibiotic generic interest to Swedish interests. Similarly, probably nothing to be gained by formal or informal collusion on prices at this stage, when the large pay-offs are occurring. As seen earlier, the very success means that the vying products are few, and if there are generics, they will be occupying separate market positions dictated by price trade-offs determined exogenously. These market forces, and outcomes of the players' signalling, are sufficient to reach the most profitable outcomes. Collusion in an anti-trust sense is not required. As we shall see in the next section, in the UK, public drug purchasing policy has necessarily created the structure for cartel-like operation among drug manufacturers, by requiring joint negotiation between the DHSS and the industry. Despite this infrastructure, no suggestion of collusion on pricing has, to my knowledge, been raised, at least in recent years.

The further question arises of whether the responses to opportunities to increase profits by shortening delays to market entry can themselves be elevated to an independent source of Schumpeterian shelter. These were earlier identified as acquiring the means to test products in several markets simultaneously, and, applicable to the later stage, ability to speed up market acceptance after final approval. The former was argued to be an advantage of a diversified portfolio, and therefore an advantage to size. The latter was not so clearly prone to a size advantage, though there may well be some economics of scale in marketing across products, there may even so be some economies in combining the two functions. Acquiring the means of integrating to substantial operations of this kind, across the many cultures, is clearly an exacting task, as is its coordination to respond to fluctuating market needs. The critical question is whether the instances of those we have cited represent a one-for-all-shift in conditions to which the industry in general will quickly adapt, or whether some exclusive, long lasting, and therefore independently profitable rights can be attached to the developments. At the limit, one could conceive of these new found abilities to organise testing and marketing as potential substitutes for a strategy which is, as we have seen, based on R & D and patenting. A well known proposition in dealing with vertical chains is that most monopoly profit is likely to be exacted at the point in the chain where there are most obstacles to free supply. Is it conceivable that this could shift to the later stages of production and marketing in the drugs case?

Any judgement must be tentative, but there are two reasons for supposing the answer to be 'no'. First, no one has suggested that resources needed to establish the required positions in testing and marketing are in restricted supply. The skills involved are readily available; indeed the consumer industry itself — the hospitals and doctors' practices constitutes

a vast reservoir of such skills. A small differential pay-off offered in switching to drug companies' employment should find many takers. The second reason is that even large drug companies are each individually small in relation to the whole testing and marketing effort required. There then arises the possibility that independent organisations might well specialise in the functions required, acquire considerable size, and yet offer many alternatives to both large and small drug companies. The benefits would then be externalised, in so far as the R & D winner seeking mechanism is concerned. There is already at least one potential example of such specialisation. Innovex is a product of the mid-eighties, offering a marketing service particularly of regular visiting to doctors in which a large portfolio of drugs can be incorporated. It gained market entry through offering to represent manufacturers of 'non-winner' drugs — i.e. those drugs having small but useful potential niches in the market. It is moving to overseas representation on the same principle. Clearly the skills, once established, can be upgraded to appeal to more substantial lines.

Summary

This selection has shifted the focus from the exogenous forces comprising elements of creative destruction to elements manipulable by companies in their search for profits. The problem was seen as a conversion of a set of property rights (patents) of highly uncertain, and for the most part zero, value to eventual profit. Decisions at two points of time were seen as important, the first relating to alternatives to extend prospective patent life, or shortening time to market; and the second, around the point of marketing, when the best strategy vis a vis impending generic entry is faced. The purpose was to develop a plausible account of behaviour useful for judging issues of public policy, an assessment which has to be taken with the predictions of the previous sections in mind. A particular concern of this section has been that of whether the behaviour imputed to drug companies might be the basis of raising shelters from competition, which would add significantly to the protection given by patents. In the event, the picture is of a single-minded exploitation of these rights. Profiting from them tends to preclude the seeking of alternative shelters. There has emerged a relatively recent emphasis on shortening lead times to market. Here there is a pay-off scale in vertically managed operations. This was interpreted as realising a previously unexploited opportunity. The minimum required scale for most profitably exploitation may well have risen in the 1980's; however, this does not necessarily imply a commensurate rise in the scope of single ownership interests.

The conclusion of the previous section was that, if anything, the future prospects are for a strengthening of the forces of 'creative destruction'. The individual firms' strategy reviewed in this section are probably properly viewed as prospectively the best available adaptations to that

shift. In other words, it would be quite logical for a particular pharmaceutical firm to hold the view that the prospects are for more effective competition in the industry and that realised profitability from dug production will be protected so long as the down-stream market position is strengthened alongside continued generation of products from R & D. If that R & D base is itself threatened, e.g. by biotechnology, then a further defensive strategy may be to widen the R and D base, perhaps by merger, so concentrating more on ethical drugs, amongst other things by divesting irrelevant activities. This seems to characterise the recent actions, for example Glaxo and Borough Wellcome. (Both firms announced aims to concentrate on ethical drugs, widening the R & D base at the same time as strengthening the vertical relations through to markets.)

However, public policy concerns in this area are only, at best, indirectly expressed via the issues which concern anti-trust agencies, those which would be immediately concerned in any big shift in the exogenous and endogenous factors affecting an industry's competitive behaviour. Rather the policy issue is seen as a broader cost benefit one — will drug consumers benefit from a given proposed change in rules which apply to the industry? The next section takes this up in the UK context in particular. As pointed out earlier, governments have universally accepted the basic modus operandi here — the patent system. For the most part, a government, like the firms themselves, will be operating on matters which can be modified, accepting that basic framework. In the UK, drugs are not seen as an important anti-trust issue, though to be sure before MMC there is a question (of merging wholesalers of drugs) which could effect the terms on which distribution is conducted and there is the question of whether pharmaceuticals position as the only product (alongside books) for which resale price maintenance is legally approved should be challenged. As elsewhere in Europe, a major issue is the length of patent terms, and, peculiar to UK, is the impact of the National Health Services' purchasing policy, expressing the power of an exceptionally big buyer. This are instruments whose use will principally affect the outcomes for drug users. The next, concluding section addresses these issues briefly.

Conclusions

This paper has explored the application of Schumpeter's thinking to policy issues concerning industries, by concentrating on pharmaceuticals. It has not followed the convention of most industrial economic contributions in testing various 'hypotheses' culled from Schumpeter's views on monopoly. Instead it has attempted to apply directly the two complementary and essential strands of his thought, on the one hand the continuous action of 'creative destruction' and on the other firms' actions in

building various forms of shelter from it, usually monopolistic in character, and always involving innovation. The simple Schumpeterian policy model deduced from this is that judgements about a particular industry should be formed from characterising the elements of creative destruction, deciding upon their future direction, and interpreting firms actions with respect to shelters in the light of this. In all this firms are motivated to realise the (necessarily temporary) profits innovation can give them.

Policy must assume such motivation to continue. A particular policy maker, e.g. the UK government, can do far more to affect the terms on which firms can negotiate the profits from 'shelters' than it can the more fundamental forces of 'creative destruction'. In a nutshell, the indicated line for policy is to act in the light of assumptions about the latter. If the major issue for example, is the effect of intervention on the results expected of competition (e.g. lower prices, more innovation) one might well conclude that if the forces described in 'creative destruction' are predicated to rise, there will have to be compensating relaxation in the degree to which firms are permitted to profit from 'shelters'. Schumpeter never attempted, so far as I am aware, to apply his arguments specifically to a current industrial policy issue, but they would surely have run along these lines. The paper attempted to define the relevant elements of 'creative destruction' against which to interpret firms' actions to realise profits from innovation. As we have seen, the evidence which can be brought to bear is limited, so the ambition of these conclusion is likewise limited, namely, to establishing broadly whether the analysis gives reason to intervene currently and in what direction. The policies involved the European Commission's recent proposals for lengthening effective patent lives in pharmaceuticals; and the question of whether there is case for modifying the National Health Service's scheme for purchasing drugs.

It is worth pursuing such a Schumpeterian line for pharmaceuticals only if there is evidence that the scheme of thought reasonably well describes the outcomes in the industry. The second section reviewed this, coming to the conclusion that, indeed, characteristic symptoms were present — for example changing fortunes for individual firms over time and much displacement in pecking orders in therapeutic groups. The overall picture fits well with the vision of individual firms using the patent mechanism to innovate in competition with each other, continuously having to renew innovations to get shelter from the market power, which in the end, will inexorably drive the returns from particular innovations down. If ever there was a 'Schumpeterian' industry, this is surely it. The third section, however, took up the more difficult question of predicting the future course of 'creative destruction'.

This involved defining the factors involved to which firms essentially have to adapt. Four were identified:- shift in overall demands; change in

demand structure; and shifts in the amount and total distribution of research and development activity. Unsurprisingly, since the problem has not hitherto been posed in this form, evidence was far from satisfactory. Particular future needs for clarification were identified, particularly in the question of changing structure of demand, specifically in doctors' prescribing habits. We also had to develop measures of R and D dispersion, which, at the national level, were distant proxies for what was required, namely distributions at different points in time related unequivocally to ownership. However, a reasonable verdict seems to be that the prospects are that the 'creative destruction' elements on balance are now set to rise.

The following section traced the likely course of firms' strategy to seek the gains from innovation. It affirmed that, after the committal of R and D, used to set up many patented options for development, there were two chief periods at which decisions bearing on future profitability were made, at the point of narrowing options to a few and, later, in strategy vis a vis the ending of patent protection and (if successful) the onset of generics. Among the options to improve prospects which seemed most important for 'shelter' were extension of effective patent cover through ICE's; alliances designed to shorten effective time taken to get to market, and variations of limit pricing when facing the genetic threat. Forms of 'shelter' which have most excited anti-trust authorities — merger of ownership interests and collusive practices were argued to be of little importance because of little bearing on pay-offs, with the exception of merger to hedge against extreme threats to existing R and D expertise, as in biotechnology. It seemed unlikely that recent moves towards marketing alliances, useful for shortening market lead times, would themselves become an independent major source of shelter. They would not challenge R and D plus patents in this role.

With these indications, then, we may comment briefly on the two policy issues. The EC's decision was to issue complementary protection certificates, equal to the period between the start of the patent term and the date of the first authorisation to market the medicines, obtained anywhere in the EC, less four years, with a cap of 10 years total extension. This will imply for firms the second patent relief to apply in UK in recent years. (In 1988 the right of genetic companies compulsorily to acquire a licence after 16 years was withdrawn.) The straightforward implication of the analysis of this paper is that, since 'creative destruction' is set to increase, there will indeed be mounting pressure on realisation from innovations now in the pipe line at some future date. Governments might thus logically decide that compensation in the form of extra patent protection now will prevent some reduction in R and D investment in the future which would otherwise occur. But the analysis stresses the dissociation of realising returns from the commitment of previous investments, and the Schumpeterian-like emphasis on acting in hope for the

future bonanza. Particular incumbents have no monopoly of future R and D investment. In practice, no better explanation can be offered for the willingness to commit the original funds than a faith in the productivity of scientific thought. Moreover, the firms' have already moved to improve the effective patent life by measures to shorten the time taken to get to the market. It is difficult to see in these circumstances, why a refusal to extend patent lives would have very serious effects on R and D expenditure. Nevertheless, so far as it goes, there is some support here for the decision.

The second policy issue concerns the UK drug price regulation scheme, the PPRS, which covers 85 per cent of ethical drugs sold in the UK. Appendix 2 describes the operation of the scheme and how it might be argued to bear on drug companies opportunities and incentives. As the Appendix argues, the scheme has two probable effects. The PPRS may, or may not, succeed in what is in any case inherently an arbitrary decision, in keeping down drug prices below what they would otherwise have been, but it does offer drug firms more confidence in pursuing an internationally differentiated price policy, and it tends to stabilise income year to year, whilst giving companies useful degrees of freedom to improve home margins. UK drug companies can use the stability in income it generates either to accept greater risks in marketing efforts abroad or in increasing their R and D commitment. One would suppose that UK manufacturers would oppose any root and branch reform which might bring more independent purchasing, for example by breaking up the central price control mechanism. Their interest more certainly lies in pursuing opportunities to lever the price up through the bargaining mechanism, whilst leaving the structure essentially intact.

But if there were to be more effective measures on prices currently paid by creating say, more competition in purchasing, this has to be seen in the light of the policy model. What happens when one form of profit shelter is removed? The price control scheme is one such shelter: the central question is, if it is replaced, what moves are then open, if any, to UK firms to restore prospective profits necessary to generate the incentives for R and D? Clearly, much more work has to be done on options then facing firms before these questions can be answered satisfactorily. But an effective reduction in current drug price levels must, *ceteris paribus*, adversely affect willingness to take on R and D risks, given the earlier findings about the exogenous pressure tending to worsen profit prospects. Another such shelter which could be removed is resale price maintenance for drugs. In saying all this, one is very conscious also of the gaps in the analysis of the forces of 'creative destruction'. One can claim, however, that by using both strands of Schumpeter's thought, 'creative destruction' and the shelters from it, one at least puts the policy questions in the right form.

Appendix I

Market leaders by Therapeutic Group

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	Not in top 10	1	2
2	Not in top 10	2	4
3	Not in top 10	3	5
4	Not in top 10	4	6
5	Not in top 10	5	Not in top 10
6	2	6	10
7	Not in top 10	7	Not in top 10
8	Not in top 10	8	Not in top 10
9	Not in top 10	9	Not in top 10
10	6	10	3
	Ranks missing in 1980 – 1, 2, 3, 4, 5, 7, 8, 9	Ranks missing in 1990 – 1, 7, 8, 9	

Blood and blood forming Organs

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	3	1	6
2	1	2	Not in top 10
3	2	3	Not in top 10
4	Not in top 10	4	1
5	Not in top 10	5	4
6	5	6	7
7	Not in top 10	7	Not in top 10
8	Not in top 10	8	Not in top 10
9	Not in top 10	9	9
10	8	10	Not in top 10
	Ranks missing in 1980 – 4, 6, 7, 9	Ranks missing in 1990 – 2, 3, 5, 8, 10	

Cardiovascular system

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	2	1	8
2	5	2	4
3	1	3	2
4	4	4	7
5	Not in top 10	5	Not in top 10
6	Not in top 10	6	Not in top 10
7	8	7	1
8	Not in top 10	8	Not in top 10
9	6	9	Not in top 10
10	Not in top 10	10	Not in top 10
	Ranks missing in 1980 – 3, 7, 9, 10	Ranks missing in 1990 – 3, 5, 6, 9, 10	

Dermatological

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	1	1	1
2	8	2	3
3	2	3	Not in top 10
4	4	4	10
5	Not in top 10	5	2
6	Not in top 10	6	Not in top 10
7	3	7	Not in top 10
8	Not in top 10	8	Not in top 10
9	Not in top 10	9	9
10	Not in top 10	10	Not in top 10
	Ranks missing in 1980 – 5, 6, 7, 9	Ranks missing in 1990 – 4, 5, 6, 7, 8	

Genito-Urinary

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	1	1	2
2	10	2	4
3	Not in top 10	3	1
4	Not in top 10	4	6
5	6	5	Not in top 10
6	Not in top 10	6	Not in top 10
7	Not in top 10	7	Not in top 10
8	8	8	7
9	Not in top 10	9	10
10	5	10	Not in top 10
	Ranks missing in 1980 – 2, 3, 4, 7, 9	Ranks missing in 1990 – 3, 5, 8, 9	

Hormone

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	4	1	9
2	1	2	8
3	2	3	2
4	Not in top 10	4	5
5	3	5	3
6	8	6	7
7	Not in top 10	7	4
8	6	8	Not in top 10
9	9	9	Not in top 10
10	7	10	Not in top 10
	Ranks missing in 1980 – 5, 10	Ranks missing in 1990 – 1, 6, 10	

Anti-infection preparations

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	2	1	2
2	9	2	4
3	3	3	1
4	7	4	6
5	8	5	Not in top 10
6	Not in top 10	6	8
7	6	7	Not in top 10
8	5	8	7
9	Not in top 10	9	5
10	4	10	3
	Ranks missing in 1980 – 1, 10	Ranks missing in 1990 – 9, 10	

Muscular Skeletal

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	1	1	10
2	2	2	5
3	6	3	2
4	Not in top 10	4	8
5	Not in top 10	5	7
6	Not in top 10	6	1
7	4	7	Not in top 10
8	Not in top 10	8	Not in top 10
9	Not in top 10	9	Not in top 10
10	Not in top 10	10	9
	Ranks missing in 1980 – 3, 5, 7, 8, 9, 10	Ranks missing in 1990 – 3, 4, 6	

Carpal Nervous system

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	1	1	10
2	2	2	1
3	6	3	Not in top 10
4	Not in top 10	4	2
5	10	5	3
6	3	6	Not in top 10
7	Not in top 10	7	Not in top 10
8	4	8	Not in top 10
9	Not in top 10	9	Not in top 10
10	Not in top 10	10	Not in top 10
	Ranks missing in 1980 – 2, 7, 8, 9	Ranks missing in 1990 – 4, 6, 7, 8, 9	

Respiratory system

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	2	1	1
2	3	2	3
3	6	3	Not in top 10
4	1	4	Not in top 10
5	7	5	6
6	8	6	4
7	4	7	Not in top 10
8	Not in top 10	8	Not in top 10
9	Not in top 10	9	Not in top 10
10	Not in top 10	10	10
	Ranks missing in 1980 – 5, 9, 10	Ranks missing in 1990 – 2, 5, 7, 8, 9	

Sensory Organs

Market position in 1970	*Position in 1980*	*Position in 1980*	*Position in 1990*
1	Not in top 10	1	1
2	2	2	4
3	9	3	6
4	5	4	2
5	3	5	5
6	8	6	3
7	Not in top 10	7	10
8	Not in top 10	8	Not in top 10
9	Not in top 10	9	Not in top 10
10	Not in top 10	10	Not in top 10
	Ranks missing in 1980 – 1, 4, 6, 7, 10	Ranks missing in 1990 – 7, 8, 9	

Source: Office of Health Economics, London.

Appendix II

The UK Pharmaceutical Price Regulation Scheme

The British National Health Service accounts 85 per cent of ethical drug sales in the UK. Of NHS sales, hospital purchases account for15 per cent. The rest are prescribed by primary level doctors, local practitioners. Hence the principal instrument available to the Government is the bargains struck annually by DHSS with representatives of the industry, the ABPI, on which all suppliers of more than £4 million's worth of drugs have the right to be represented. The significance of the large proportion destined to be prescribed by the 25,000 local doctors lies in the mechanisms designed to control the quantity of drugs supplied, which must bear principally on their behaviour. The DHSS/ABPI confrontation is concerned solely with the price of branded, non generic drugs. For the balance — the 15 per cent of the drugs sold for hospital use — more widely spread bargaining exists, in the sense that purchasing is done by NHS regions, or sub-sets of the regions, who are free to negotiate the prices and quantities, including proportions of generics, that they wish. There is nowadays little central pressure to buy British, so sourcing for hospitals is quite free. There is little doubt that the price bargaining done through the 85 per cent under the PPRS — the Pharmaceutical Price Regulation Scheme, which is as old as the Health Service itself — sets the dominant, ruling prices which concerns ethical R and D firms.

In terms of recent history, the PPRS has become markedly more detailed in its control mechanism. Each pharmaceutical firm must submit each year its past results, referring to NHS sales, and its current year's forecast of results. These must be presented to sum to UK operations in 3 categories, Home NHS, Export NHS and other businesses (which will include over the counter sales). Export NHS are those drugs sold at home, but also exported, so if a drug is sold abroad exclusively, its 'results' will not be under scrutiny. An overall target profit varying recently between 17 per cent and 21 per cent on historical cost valuation of assets is set. If for any drug the firm's forecast is more than 50 per cent above target, an immediate reduction to apply in the current year is made. In between, the target and 50 per cent is a 'grey area' which becomes the subject of detailed bargaining. If the firm can persuade the other side that the superior profit is due to efficiency, not over pricing, the profit is allowed. Some compromise is of course normally reached. If, for example, the firm is on the contrary forecasting an overall current loss, and this is assented to by the other side as a reasonable view (perhaps there has been a substantial exogenous rise in costs), then the firm is allowed to compensate by raising prices in the current year on whatever drugs desired, subject of course to the 50 per cent profit rule's not being breached.

Not surprisingly, arguments over the years have become very detailed and sophisticated. There is no easy route for 'creative accounting' to pull the wool over the DHSS eyes. By now, it is probably not worth the candle to try, because every year's submissions divulge more comparative information; and there is a full cross-section of drug firms to which the DHSS can refer. Previous attempts have simply produced more breakdowns by ratio of types of cost to sales. Nowadays, each part of cost has its permitted margin — R and D capped at 17 per cent, Distribution at 3 per cent, Sales (e.g. the tally man) at 9 per cent and even as far as 'Information' at 1 per cent. The DHSS, in all this, take a view on what, in the circumstances, is reasonable. In effect, rule by exception, year on year, prevails. It is unlikely that a large shift in ratios would be allowed in one year.

Quantities taken are not directly affected by the bargaining. Doctors still determine these. This is not to say that there are not DHSS inspired attempts to influence doctors. On the contrary, the aim for some time has been a target that 60 per cent of prescriptions be generic as opposed to about 40 per cent now. A very elaborate system of persuasion is deployed to try to achieve this influence. This mainly consists of arranging for increases in the information reaching doctors, so that they may compare their own prescribing with that of some local average. Reasons for diverging from averages are legion of course. But there is a system of tracking high prescribers. Since April 1st 1991, Indicative Prescribing plans have been instituted. This involves justifying to a local District Medical Adviser large deviations from plans which a doctor has put forward. Disputes about alleged over prescribing can be raised to regional level and ultimately to the centre. However, action to respond to disapproved-of-behaviour by docking doctors remuneration is still very rare. Since some famous cases in the 1950's, when bizarre anomalies in prescribing quantities were discovered, there are no recent cases of actual financial penalties. Firms may still assume quantities to be unaffected by what is done centrally year by year.

The bearing of the operation of the PPRS on the concerns of this paper seem to be as follows. The price negotiation fixes UK prices of drugs. This is an important part, but by no means all, of the UK manufacturers market. Among the 7 nations which are referred to in the text, UK's exports of drugs amount to more than 50 per cent of home drug consumption, a figure only exceeded by Switzerland. At the point of the generation of profits on which the negotiation bears, vis, the production of drugs, the manufacturers problem is to determine mark-ups over very low avoidable costs. Differential mark-ups across main markets will increase the gross revenue, and therefore profits. The negotiation fixes one of these mark-ups in a way which in effect compensates companies for sunk R and D costs. There is no way of knowing whether this is

'generous' or not. Indeed the problem is in practice quite insoluble in terms of costs *now* relevant — i.e. forward looking cash flows. Working out a 'proper' remuneration would involve making central judgements on individual firms corporate plans and indeed double-guessing them. (It would also, I would argue, require adopting a Schumpeterian view of the industry.)

Nevertheless conventional mark-ups are adopted and back-up by scrutiny of accounting costs is now quite detailed. Quantities are left in effect as a free variable; the control system for prescribing can have little effect on the bulk of prescribing decisions. Companies are constrained in making use of this by the allowed limits on sales expenditure, but they can attempt to improve efficiency in their appeal to doctors, so are not entirely without influence on prescription. Basically the quantity supplied must be viewed as a variable neither side of the negotiation can influence much. Companies are, however, free to vary patterns of integration. The PPRS fixes retail prices from which wholesale mark-ups are given. Companies can acquire the margin for example by take over of wholesaling, or, as Glaxo recently did, decide to adopt direct selling. These moves are profitable if some new source of distribution efficiency accompanies them.

Drug companies, then, have part of their total pricing problem of mark-ups solved, even if arbitrarily, by the price negotiation. The context in which these decisions are taken makes it very likely that quantities will not be susceptible to changes in individual selling. There is every prospect of year to year stability of individual prices if the companies so desire. Net income from the UK portion of drug sales can be relied upon to be reasonably stable. There are two probable effects:- the drug manufacturers can (differently) price in other markets with confidence generated by relative certainty in a main one. Moreover, a significant part of net income is not subject to much perspective variation from year to year. Less risk is faced at home, or, to put it another way, greater marketing risk can be accepted abroad, or indeed more risky R and D than would otherwise be done can be undertaken. Companies are quite free to choose between these uses of the 'comfort' that the scheme brings. They are able to pursue some prospectively profitable actions within the scheme without possible adverse feedback.

In short, the PPRS may or may not succeed in pressing down on drug prices: the question is probably unanswerable. What it does do is to induce a useful element of stability in income, and simplifies the task of setting prices to all markets to which drugs may be sent. How firms use this is, no doubt, quite different across the set. Whether as a whole, UK manufacturers fare better or worse than other country's drug manufacturers faced with similar problems (e.g. the French) is another story. But one would guess that UK manufacturers would be loath to see a root and branch change in the scheme. It is far better to concentrate on small, favourable changes in applying price conventions.

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The British pharmaceutical industry: 1961-1991

Professor George Teeling Smith

The economic history of the modern research-based pharmaceutical industry dates from the 1950s, when the broad spectrum antibiotics were first discovered and marketed in the United States as branded and patented synthetic chemical entities. As new lifesaving compounds, they were an immediate commercial success. Within a few years, this conspicuous success led to the setting up of a US Senate Committee under Senator Kefauver, and this Committee reported in a very critical manner in 1961, under the title of 'Administered Prices'.[1]

Based on the picture shown in Figure One, the Kefauver Committee concluded that patenting, branding and advertising of the broad spectrum antibiotics had led to an absence of effective competition. They contrasted the constant and equal prices for the major antibiotics over the period shown in the picture against the steadily falling price for what would now be described as 'generic' penicillin and streptomycin, which had been unpatented, and hence subject to classical price competition. Kefauver's Committee concluded that patenting, branding and advertising of prescription medicines acted against the public interest.

The Committee failed to recognise that what they saw was a clear case of 'parallel pricing' for similar products, and they certainly failed to take into account the new form of innovative competition which had been described by Schumpeter twenty years earlier. Kefauver's conclusion had a worldwide impact and led directly in Britain to the events which occurred while Enoch Powell was Minister of Health. In Britain, the natural suspicion of apparent industrial collusion was enhanced by a Chauvinistic dislike of the American exploitation of the 'antibiotic era'. In a sense this had originated in England with Fleming's observations on penicillin and its development during the second world war by Florey and Chain; the British resented the American firms' profits from the subsequently developed antibiotics when Britain had gained so little from penicillin itself.

The resentment against the new 'big business' pharmaceutical innovators was reinforced by the thalidomide tragedy in the same year. Throughout 1961 and 1962 the thalidomide deformities coupled with American evidence of 'excessive' pharmaceutical prices led to universal hostility towards the pharmaceutical manufacturers. At that time the industry appeared to have no friends. It is typical, for example, that the two Members of Parliament who were Directors of pharmaceutical companies in Britain — Tufton Beamish at Smith Kline and French and Vere Harvey at CIBA — refused to speak for the industry in the House

of Commons because, reputedly, they felt it would be 'bad for their image' to have to declare their interest in the pharmaceutical industry.

To his immense credit, it was Sir Ernst Chain who was the first distinguished scientist at that time to speak up loudly and clearly in favour of the achievements of the industry. His Trueman Wood Lecture at the Royal Society of Arts in 1963 under the title of 'Academic and Industrial Contributions to Drug Research' catalogued the many major therapeutic advances for which the industry had been responsible.[2]

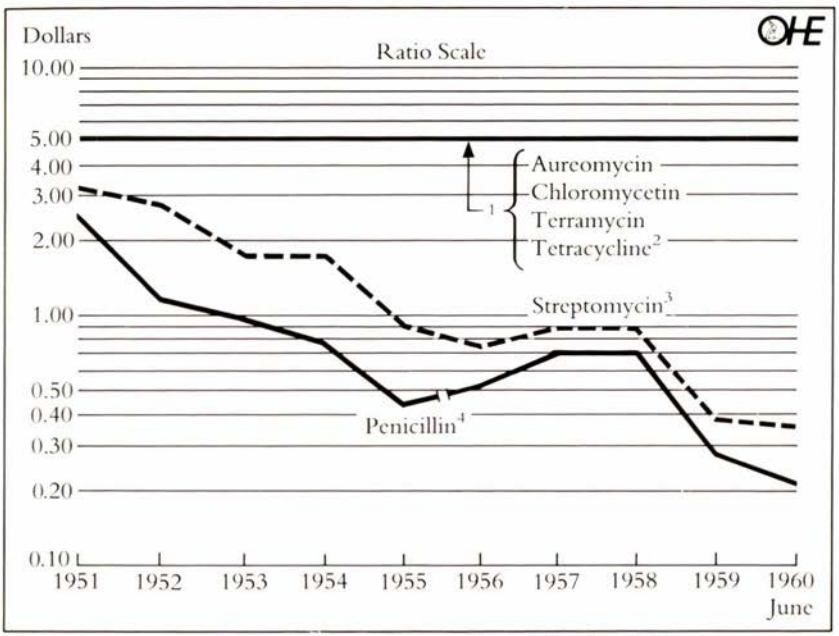
Nevertheless this valuable support did little to stem the economic and scientific criticism of the industry, and when the Labour Party came to power in 1964 they had a commitment to nationalise the industry in Britain. In fact, what they did instead was what all governments tried to do when faced with an embarrassing commitment. They set up a Committee of Enquiry, in this case to be Chaired by Lord Sainsbury, a Labour peer. The Committee as a whole, although made up of many distinguished members, had a left-wing bias and its findings when it published its Report in 1967 are therefore all the more interesting in the present context.[3]

Above all, they rejected nationalisation, on sound pragmatic grounds (paragraph 253). In general they stated that 'we see a general picture of reasonableness, but with some exceptions some of them important and serious' (paragraph 99). Specifically, they concluded that 'the evidence shows that profits and by inference prices, have sometimes been too high in this industry in spite of the fact that product competition has been intense' (paragraph 155). Thus they fully recognised the true competitive nature of the industry, based on innovative competition. Even more explicitly they stated 'We think, however, 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' (paragraph 134). This was a major step forward from the misunderstanding of the situation expressed in the Kefauver Report.

The repercussions of the Sainsbury Committee's Report will be discussed a little later. But the next major step in understanding the economics of pharmaceutical innovation can be said to be the publication by the Office of Health Economics of a booklet entitled 'The Canberra Hypothesis' in 1975.[4] It was based on a paper which I gave to the Australian and New Zealand Association for the Advancement of Sciences (ANZAAS) and which benefited particularly from the subsequent comments of Professor Tom Wilson and Professor Duncan Reekie. The former, not realising that I had written the draft which I sent to him, commented quite bluntly that the original paper read 'as if it had been written by someone who did not know the literature'! Duncan Reekie provided valuable help in overcoming this criticism.

In its final version, the paper did two things. First it argued in neoclassical terms that there was a significant element of price competition in the prescription medicine market. Second, and particularly relevant in

FIGURE 1 **Administered prices – drugs**



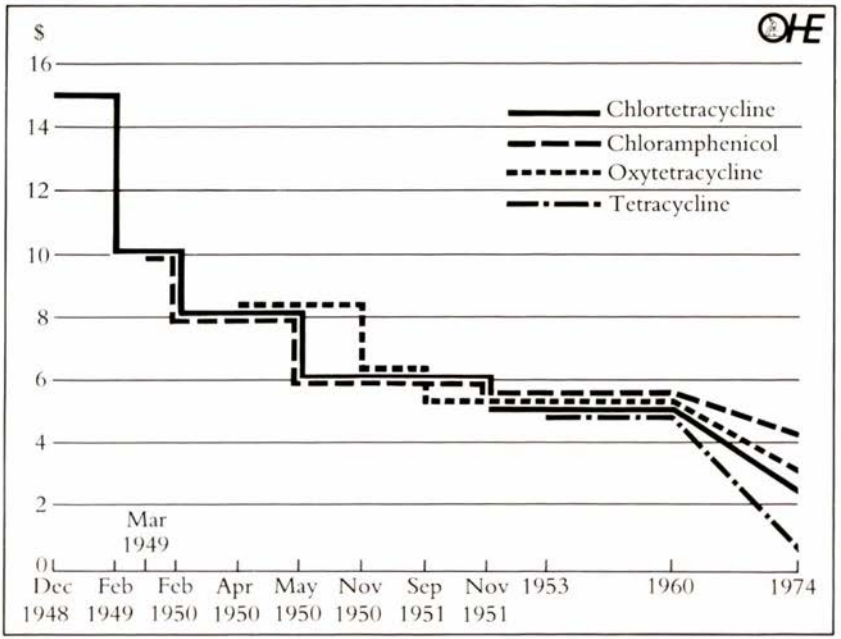
1 16 250 mgm capsules – price to druggists 2 Tetracycline introduced in 1953
3 10 grams, bulk prices 4 10 million units, bulk prices

Sources: Bulk prices of streptomycin: open market quotations, June figure, *Oil Paint and Drug Reporter*.
Bulk prices of penicillin: 1951-1955: Lilly prices compiled by FTC.
1956-1960: Open market quotations, June figure, *Oil Paint and Drug Reporter*.
Broad Spectrum: American Druggist *Blue Book*.

the context of this paper, it described the shift from classical price competition to the new situation based on innovative competition. It pointed out that Chamberlin[5] and Robinson[6] in the 1930s had argued that 'perfect' competition had been destroyed by patenting, branding and advertising, but the Canberra Hypothesis went on to argue that the true advance in economic understanding had come when Schumpeter added the element of innovative activity into the equation in 1942 calling it 'the competition which counts'. That is what we are discussing in this symposium.

However on the subject of price competition, the Canberra Hypothesis did challenge Kefauver's conclusions from Figure One, and showed what I described as 'a more complete picture' in Figure Two. It also showed that for the first four non-steroidal anti-inflammatories introduced into Britain, the highest priced one had the lowest market share (Figure Three). And as another example of price competition it showed that of the two British marketed topical steroids, the second one on the market at a lower price had captured the larger market share.

FIGURE 2 **USA broad spectrum antibiotic market, 1948-74. A more complete picture**



Source: Derived from Cooper table 71, updated by PMA.
Note: Time scale non-linear.

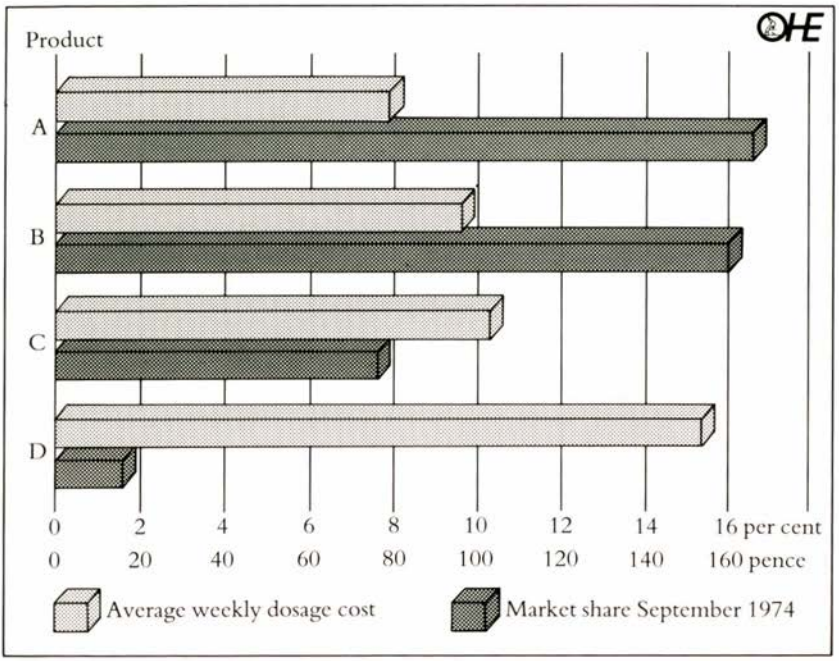
The competitive pricing behaviour of the pharmaceutical industry was subsequently tested by Reekie in three empirical studies in Britain, the United States and the Netherlands.[7,8,9] These demonstrated that in general companies marketed trivial innovations near or below the prices of existing competitors, and that companies only set a substantial premium price if they had a major innovation. Thus it appeared from these studies, at least, that the pharmaceutical companies were behaving as if they believed that they were selling in a price conscious market.

Nevertheless, while emphasising the existence of price consciousness amongst prescribers, the Canberra Hypothesis as a whole accepted that innovative competition was much more important than classical price competition for the research based pharmaceutical industry. Against this background, it is interesting to look at the historical developments relating to the industry under the headings of profitability, patents and brand names, promotion and research.

Profitability

The first point to make under the heading of profitability is that the

FIGURE 3 **Anti inflammatory agents**



major misunderstandings of the industry's position have tended to arise when outstanding peaks of profitability have occurred for particular groups of products. This has happened three times in the last thirty years. The first case was the broad spectrum antibiotics, which have already been mentioned, in the 1950s: the second case was the benzodiazepine tranquillisers in the late 1960s and early 1970s: and the third case has been the H2 antagonists for the treatment of ulcers in the 1980s. Each of these cases is worthy of further comment.

It has been pointed out that the antibiotics' success led to the Kefauver hearings in the United States, the use of Section 46 of the 1948 Patents Act in Britain, and indirectly to the setting up of the Sainsbury Committee. There is little doubt that one of the 'important and serious' exceptions to the general reasonableness seen by the Committee was the case of the broad spectrum antibiotics.

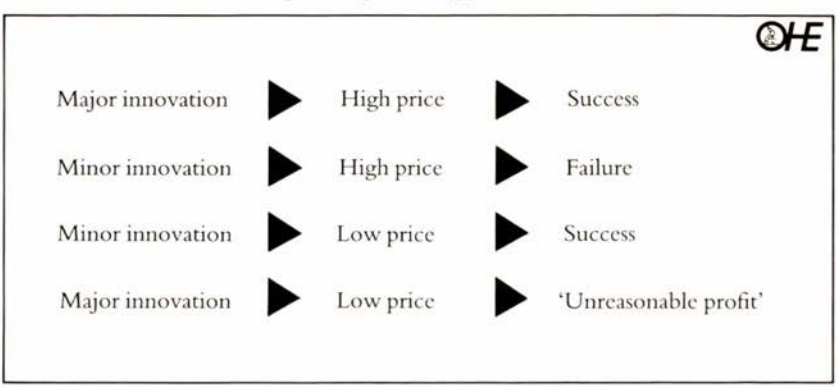
The second case of benzodiazepines led to the setting up of a Monopolies Commission investigation in 1971. This was the step taken by the government to deal with what they saw at that time to be intransigence by the Swiss manufacturer, Roche, who were reluctant to co-operate under the existing Voluntary Price Regulation Scheme (VPRS) because they said that their legitimate patents and their product monopolies had

been undermined by compulsory licences granted under Section 41 of the 1948 Patents Act. The Monopolies Commission did not accept this argument when they reported in 1973.[10] They recommended price reductions of 40 per cent for Librium and 75 per cent for Valium. These reductions were immediately implemented by government Orders.

The Monopolies Commission findings were the subject of much controversy. Within a relatively short time Roche's prices were restored to their original level, in return for a financial agreement between the company and the government. The Canberra Hypothesis specifically considered the benzodiazepine case, and Figure Four shows the Table which was included in that paper. The point it makes is that the benzodiazepines, in addition to being an invaluable replacement for the older barbiturates, had been cheaply priced — although even at their low prices they were still very profitable. Thus prescribers showed no price resistance to prescribing them (perhaps, with our present hindsight, at that time too freely) and consequently the benzodiazepines achieved very large sales volumes worldwide. This led to the appearance of the 'excessive profits' seen by the Monopolies Commission.

The third 'peak' of profitability has occurred with Tagamet and Zantac. Possibly because the industry as a whole is now generally better understood, and certainly because of the developments with the Price Regulation Schemes in Britain to be discussed shortly, there has been a much better understanding of the substantial profits earned from these two products than there was in the two earlier cases. In so far as the earnings can be used to finance further research into untreated diseases, this is good news for patients. It is, also, it must be said good news for the shareholders, although in the case of Tagamet 'creative destruction' of its market prospects through competition from Zantac and through generic competition following the expiry of its patents may have contributed to

FIGURE 4 **Outcome of pricing strategy**



the decision of its manufacturers, Smith Kline Beecham (formerly Smith Kline French) to amalgamate with Beecham. It should also be pointed out that for Britain at least criticism of profits earned from the NHS was limited since almost all of the actual profits were earned on overseas sales.

Returning to the subject of the Sainsbury Committee and its effect on profitability and its control, the major result was a renegotiation of the VPRS. This led to a shift from an 'export criterion', which allowed prices to the NHS which were no higher than the average in export markets, to direct negotiation on profits based on the new 'Annual Financial Return'. This showed for each company the profits which they had earned from the NHS and the generally higher profits which they had earned on export sales. If the NHS profits were considered by the government to be too high, price reductions were required. Conversely, price increases would only be allowed if the profitability from the NHS seemed to be unreasonably low.

TABLE 1 **Profitability on home sales of NHS medicines 1967-70**

Year	*1967*	*1968*	*1969*	*1970*
Weighted average return (before tax) on capital per cent	25.5	22.5	20.5	18

Source: Department of Health, with the approval of ABPI.

Table One shows the reduction in returns on capital earned from sales to the NHS between 1967 and 1970. The strictures of the Sainsbury Committee and the resulting new VPRS had their effect in reducing profitability by about one third.

Since 1970, the operation of the VPRS (now renamed as the Pharmaceutical Price Regulation Scheme) has been successively tightened, putting limits on allowable expenses and adding back the disallowed costs onto profit. Particular attention has been paid to the disclosure of any 'hidden' profits contained in transfer prices or in charges levied from overseas affiliates. As a result of the concerns of the 1950s and 1960s about the possibility of earning 'unreasonable' profits from the NHS have largely ceased to exist. As I indicated, this has probably been largely responsible for the general acceptance of 'peaks' of profit in the 1980s. The British government is seen to have effective control over the industry's level of earnings from the NHS.

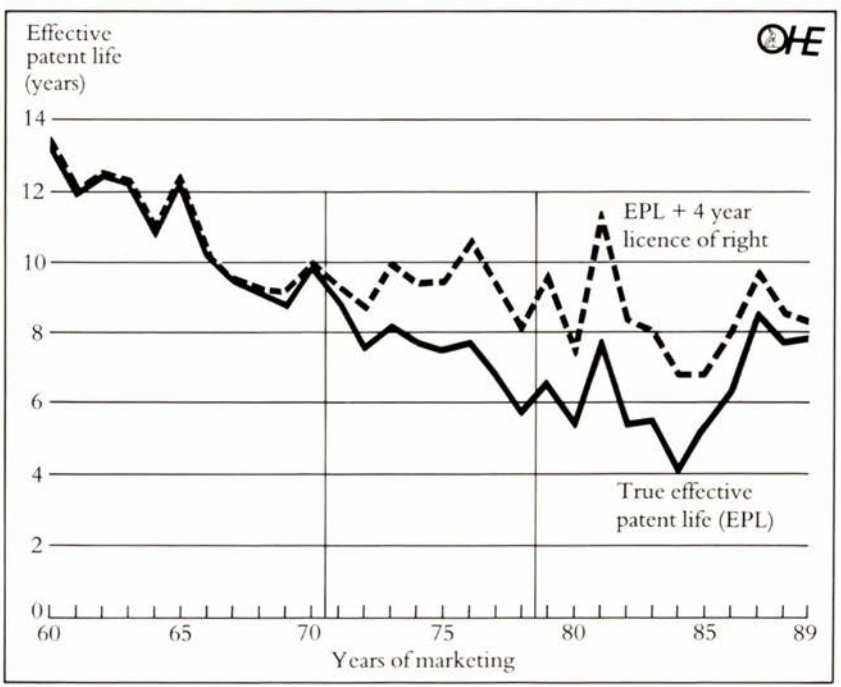
Patents and brand names

Turning to patents and brand names, there has been good news since 1960 in that the law requiring the grant of compulsory licences to copyists was repealed in the Patents Act 1977. However the outstanding feature of the past thirty years has been the erosion of effective patent life as a result of the lengthening time which it now takes to develop and test

a new pharmaceutical chemical entity. Figure Five shows the fall in effective patent life in Britain between 1960 and 1989. In the former year products could on average expect almost 14 years of effective patent protection. There was an all-time low in 1984 of four years (excluding the period in which 'licences of right' could be granted to competitors). Even with some recovery since then, by 1989 the effective patent life was still only eight years on average. But within the last four months, there has also been good news in this connection. The European Commission has approved regulations to give special protection to pharmaceutical innovations which will eventually add up to five years to the present effective patent life (with a maximum period of protection of 15 years).

Nevertheless the reduction in the protection of industrial property afforded by patents, has put greater emphasis on the economic importance of brand name protection. Ironically, brand names themselves, however, have also been under threat. In 1967, the Sainsbury Committee actually recommended the total elimination of brand names for new medicines (paragraph 279). This recommendation was rejected because the government accepted the arguments from the major British owned pharmaceutical companies that without brand names in Britain their very valuable export earnings would be seriously threatened.

FIGURE 5 **Effective patent life (years)**



However in 1983, a departmental committee of the Department of Health and Social Security (the 'Greenfield Committee') recommended that pharmacists should be allowed to substitute generic alternatives for the branded medicines prescribed by general practitioners.[11] This recommendation, also, was never implemented, although the general practitioners have been strongly persuaded to use generic names in place of the more familiar brand names.

Once again, the Office of Health Economics has advanced arguments to show that either patent life must be extended or brand name protection must be respected. Based on actual sales figures for medicines in Britain, it was shown in Figure Six that companies depended heavily on sales of their innovations after patent expiry in order to remain viable. The effect of eliminating the period of protection currently afforded by brand names was described in Figure Seven as 'the catastrophic alternative'. With only eight years of effective patent protection, and a statistical average of about 15 years between major new innovations, there would be about seven years of financial starvation between successive innovations. This argument, published in the Pharmaceutical Journal,[12] underlines the vital importance of effective patent protection because it seems inevitable that partly for ideological reasons brand names are likely to continue to come under attack.

FIGURE 6 **Existing market behaviour in Britain**

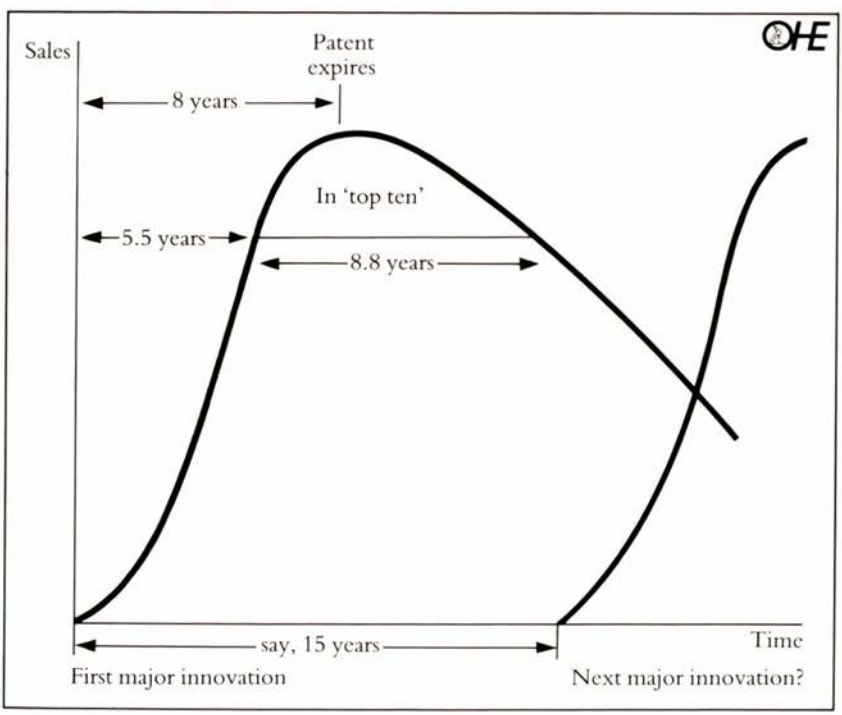


FIGURE 7 **Catastrophic alternative**

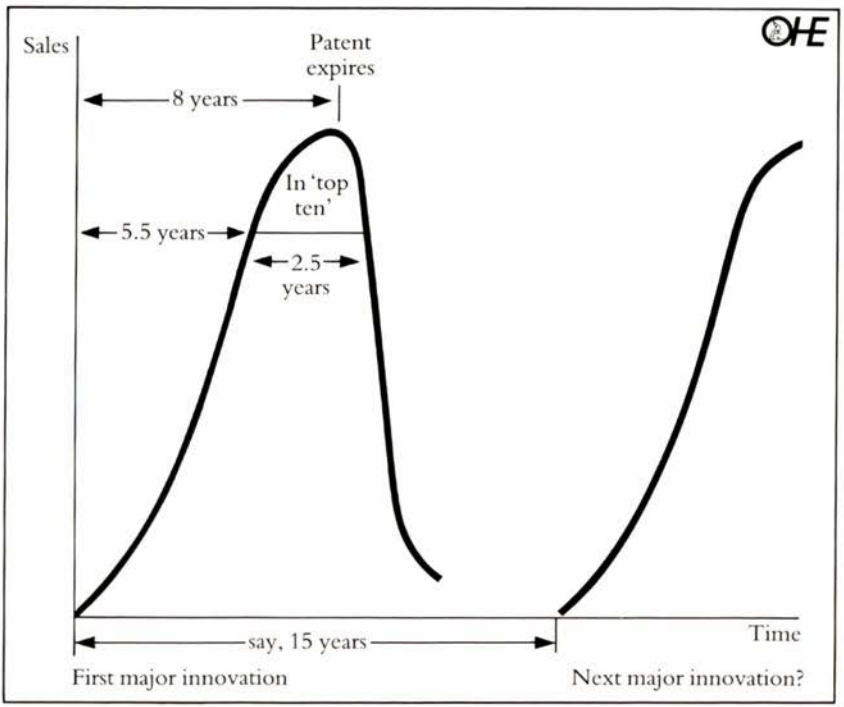


Figure Eight shows the current trend towards generic prescribing in Britain. In the 1950s and 1960s, the traditional generic preparations — the vegetable extracts and tinctures, for example — still dominated prescribing. By the late 1970s, however, generic prescriptions accounted for only about 15 per cent of the total, and these generic prescriptions were no longer for the traditional 'galenical' preparations, but instead for the generic copies of the patent expired new chemical entities. Since 1985, there has been a sharp upturn in the proportion of such scripts, so that generics accounted for almost 40 per cent of the total by 1989. It is often suggested that the British government would like to see this proportion increased still further, thus once again emphasising the importance of effective patents.

Promotion

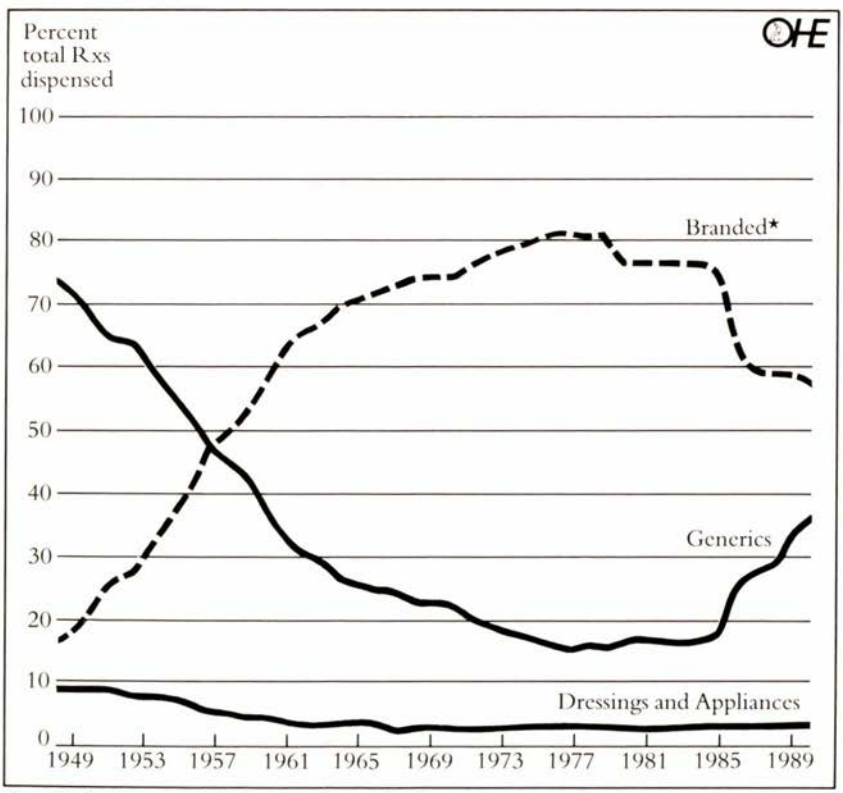
If the use of brand names is sometimes criticised, such criticisms pale into insignificance when compared to the hostility directed at the pharmaceutical industry's sales promotion. Thirty years ago, there was considerable antagonism towards advertising and salesmanship as a whole. To a large extent this has disappeared for industry at large. It is recognised that

Emerson's aphorism about beating a path through the woods to the inventor of the better mousetrap is nonsense. Innovations must be successfully 'sold' if they are ever to benefit the public, or even sophisticated specialist users. Marketing is just as much an essential part of innovation as research.

However although this truth may have come to be recognised in broad principle for medicines, there is still a suspicion that it is somehow wrong for the 'inventor' of a medicine to be too influential in persuading doctors to prescribe it. Certainly, if there is the slightest suspicion that legitimate persuasion starts to involve material blandishments, commentators on the pharmaceutical industry throw up their hands in horror.

In response, the industry, the medical profession and the government have all introduced controls to limit the extent of persuasion which

FIGURE 8 **Percentage distribution of chemists' prescriptions by type, UK**



Note: *Including prescriptions written in generic names.

Source: DoH.

companies are permitted to use. Taking the British government first, a limit on allowable sales promotion expenditure was introduced in 1976 to reduce the industry's average spend from 14 per cent of sales to 10 per cent. In 1984, new rules were introduced, so that any overspend was not only added back onto profit, but was also subject to a direct 100 per cent 'fine'. In 1985, the 10 per cent limit was further reduced to 9 per cent. In Schumpeterian terms, this can be seen as a brake on the extent of 'the competition that counts' particularly for smaller companies trying to break into the market. It acts as a 'shelter' for the large well-established companies.

This is particularly so since as early as 1967, it could be clearly demonstrated in Figure Nine that promotion was strongly linked to innovation, with a major part of companies' money being spent on new products.[13] Incidentally, harking back to the broad spectrum antibiotics in the 1960s, Figure Ten shows that not only their profit but also their promotional expenditure was exceptional. Against a generally strong correlation

FIGURE 9 **Promotional expenditure per product promoted by age of product**

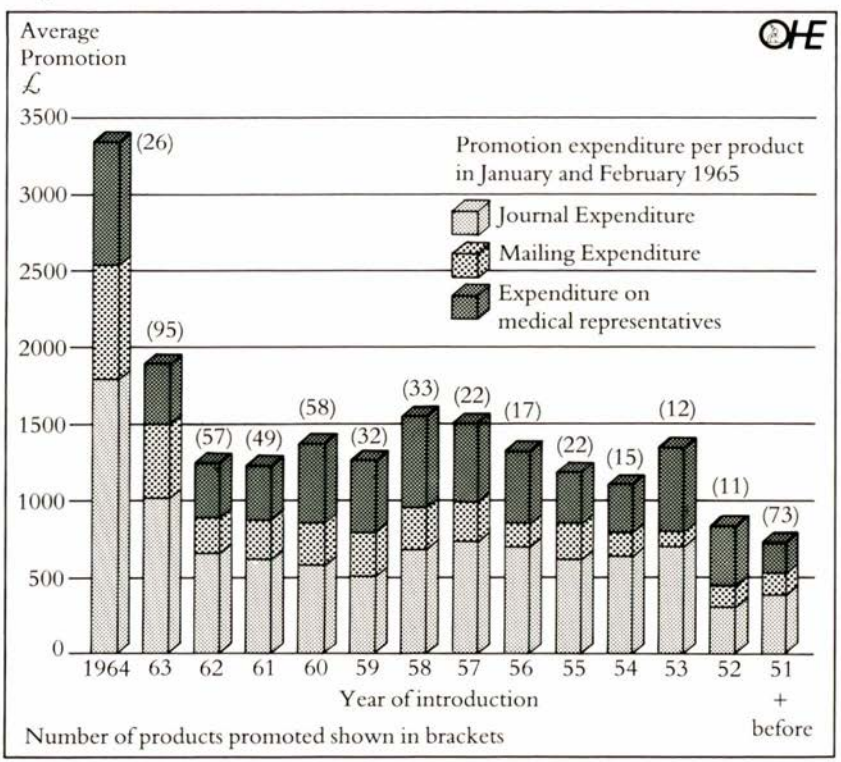
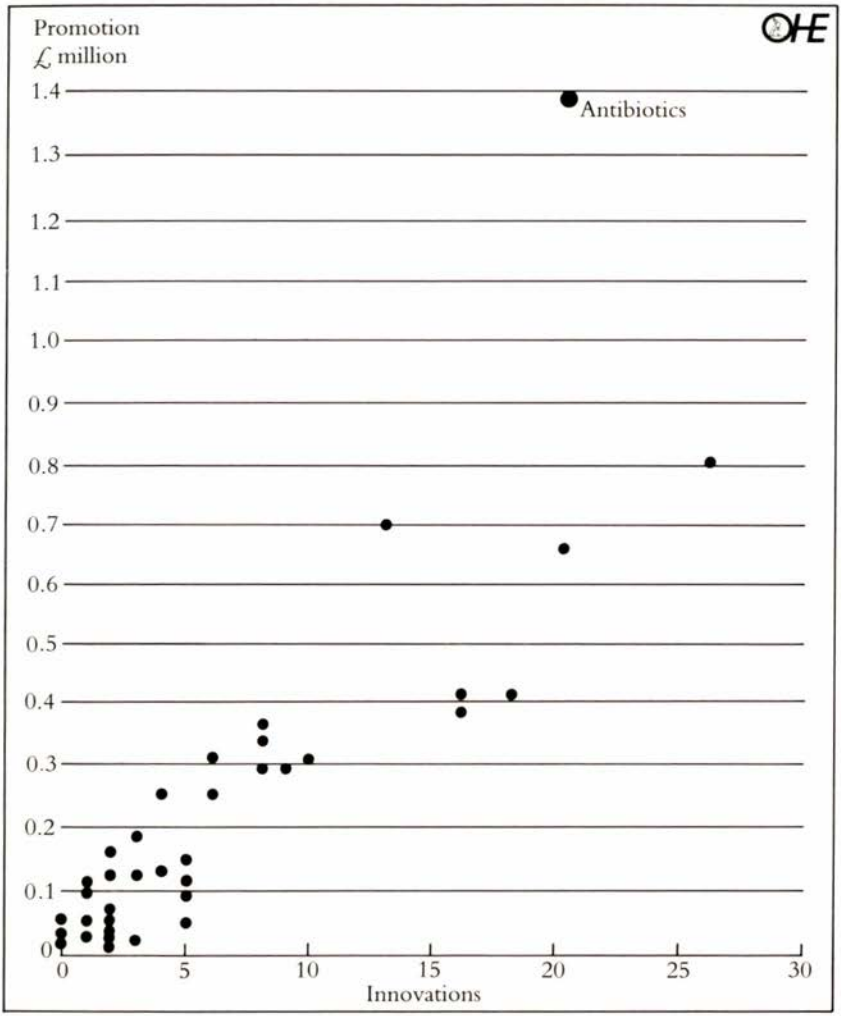


FIGURE 10 **Therapeutics classes, promotion 1966, innovations 1962-65**



Source: Reekie thesis, diagram XVI(1).

between the level of innovation in different therapeutic groups and the amount spent on their promotion (which is another piece of evidence for the importance of promotion and innovation) the broad spectrum antibiotics stand out as a striking exception.[14] They involved a much larger than expected spend on promotion. Possibly this was as much a reason as the profits themselves for the criticism directed against the companies concerned. The doctors' golf matches played with identifiably company golf balls, were legendary in their day — perhaps because there

was little incentive to recover balls played into the rough when a company representative was on hand to provide a replacement! The name of the company in question became well known not only to doctors but to golfers as a whole.

Since promotion has always been a source of critical attention, the industry, with the support of the medical profession, has consistently attempted to raise the professional and scientific standards in promotion, and to control 'excesses'. Since 1957, there has been an industry Code of Practice, policed by a Committee chaired by a barrister from outside the industry. The existence of this Code, and repeated steps to tighten it, does not of course totally prevent lapses by individual companies; but the increasing number of cases dealt with by this Code of Practice Committee indicates a steady trend towards stricter controls rather than deteriorating standards of promotion. In addition, unlike the situation in the 1960s, there are now many independent sources of information for doctors about pharmaceuticals. Promotion is still economically important, but it is now only one of many sources of information on new pharmaceuticals.

Research

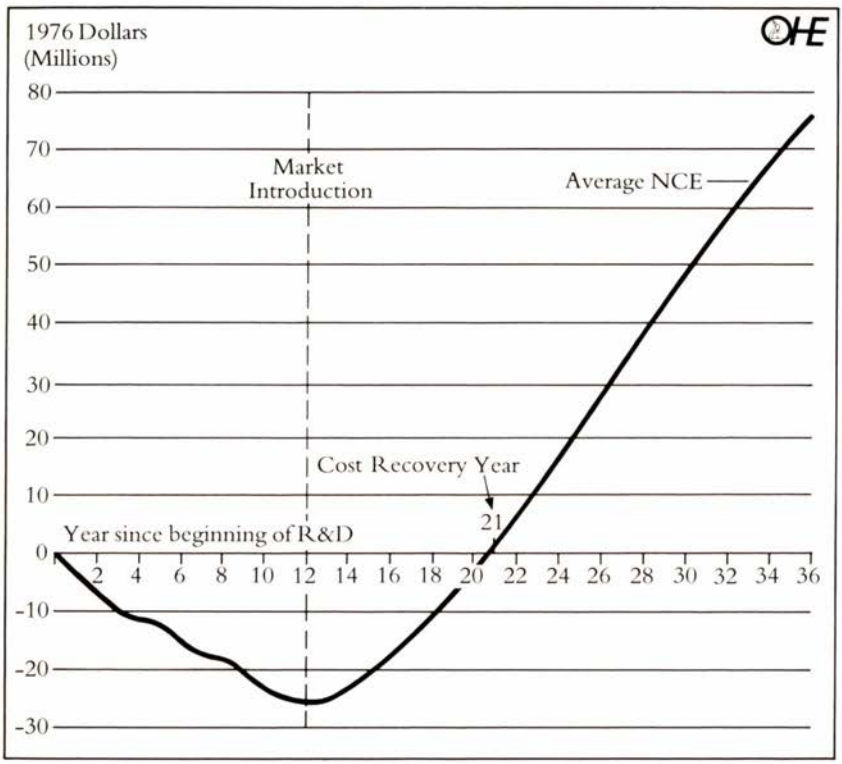
The final area in which better understanding of the industry has been achieved is with research and development. In the 1950s and early 1960s the general impression was that the Universities and even the National Health Service itself had largely been responsible for the obvious advances in therapy which were occurring. The industry was often conceived as only taking profits from others' inventions.

Sir Ernst Chain's Trueman Wood lecture in 1963 has already been mentioned as a landmark in recognition of the industry's major contribution to therapeutic innovation. This was followed in 1976 by a quantitative analysis by the American economist David Swartzman, who showed that 88 per cent of all new chemical entities introduced between 1950 and 1970 had originated in the industry. Furthermore, the percentage had increased from 86 in the 1960s to 91 per cent in the 1970s.[15]

There was also an increasing recognition of the huge cost of pharmaceutical innovation. Hansen in 1980 published an estimate that on average each new chemical entity cost 54 million dollars (at 1976 prices).[16] In 1991 this figure has been updated by Di Masi and others to 230 million dollars (1987 prices).[17] The magnitude of these figures is now widely recognised, and it is realised that the price of a medicine depends very much more on its development costs than on its cost of manufacture. This is a far cry from the days of the Kefauver Committee when the popular press had headlines screaming about thousands per cent of 'profits'.

It is also now well recognised that continuing pharmaceutical research is of great importance for the solution of still unconquered medical

FIGURE 11 **Cumulative worldwide after-tax earnings of average NCE**



problems. In a masterly review in 1990, Sir Christopher Booth catalogued what he called 'Holes in Therapy'.[18] This underlined the extent to which further progress in the control of diseases such as the cancers, Parkinson's Disease, multiple sclerosis and Alzheimer's Disease was still urgently needed. And it is now widely realised that such progress is most likely to come from the pharmaceutical industry's development of academic leads and from its own fundamental research.

The difficulty in financing this research was eloquently argued by Joglekar and Paterson in 1986.[19] Figure 11 shows that on average a new chemical entity could not be expected to pay off its investment until 21 years after its development had been started — that is nine years after first marketing. This in turn underscores the earlier argument about the importance of adequate protection for the industrial property arising from innovation — adequate 'shelters' against 'creative destruction' to use Schumpeter's terminology.

Conclusion

In the 1950s the economics of the pharmaceutical industry was almost completely misunderstood. Since then, it has encouraged sound economic studies to try to improve the understanding. One of the earliest empirical studies was that conducted by Michael Cooper of the University of Exeter in 1965.[20] At about the same time, the Sainsbury Committee recognised the importance of 'abnormal profits' to provide an incentive for research. Perhaps the next major step forward was the Canberra Hypothesis, which in its published form acknowledged the importance of both neo-classical price competition and Schumpeterian economics. As a result of these advances, and similar progress in many other countries, economic analysis of the pharmaceutical industry is now much more rational than in the dark days of the 1950s and early 1960s. Considering the scientific, medical and economic importance of the industry, however, it is still surprising how little economic evaluation there has been of its activities and of the government policies directed towards it. Today's symposium is an important step forward, involving outstanding economists who have not previously given detailed attention to the pharmaceutical industry. The whole principle of its analysis in Schumpeterian terms should help further to advance the understanding of the industry which has already been achieved over the past thirty years. A proper awareness of the economics of the industry in all its aspects is of vital importance to the health of the world, and to the economic strength of countries, such as Britain, which are centres of pharmaceutical research, production and exports. Without such understanding policies may be implemented — or fail to be implemented — to the detriment of all concerned.

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The economic implications of therapeutic conservatism

Dr John P Griffin and Timothy D Griffin

Introduction

This paper reviews the pattern of the prescription medicine market in the United Kingdom (UK) and makes a number of comparisons with the patterns of prescribing in other European markets. Its general theme will be to illustrate that the British market for prescription medicines has always been more conservative than other major European markets such as France, Italy, Germany and Spain and is becoming more so. The conservative nature of the British prescription medicine market is indicated by three international comparisons. Firstly, the British doctor prescribes fewer items per patient per year than his counterpart in other European countries. Secondly, the British doctor is much less likely to prescribe a product containing a new active chemical entity (NCE) than his counterparts in other countries. The resistance to the use of newer medicines has increased over the last decade. Thirdly, the British doctor is relying on a progressively small number of active substances for a greater proportion of his prescriptions.

As a result of these trends the industry — at least as far as the British sales are concerned — is becoming more independent on the sales of older products and on the occasional 'blockbuster' to finance its research. This is not a healthy situation especially as there is continual pressure for doctors to prescribe cheap generics instead of branded medicines. The paper concludes that this could be very much against the interests of both patients and the British economy.

Low level of prescribing by British doctors

Compared to his European counterpart the British doctor is a low prescriber of medicines (see Table 1). The British patient received 7.6

TABLE 1 **Prescription items per head in EC countries**

	Rxs per head 1989/90	*Rxs per head 1980*
France	38.0	27.6
Italy	20.1	19.9
Portugal	17.1	15.4
Spain	14.8	14.4
Germany	12.0	14.3
Belgium	9.3	10.3
UK	7.6	6.6
Denmark	6.1	6.5

prescriptions per head per annum in 1989 compared to the average French patient who received 38 prescriptions per head per year; and the average Italian patient who received 20 prescriptions per head per year. The average Spanish or Germany patient received 14.8 and 12.0 prescriptions each per head in 1988 and 1989 respectively.

In the UK patients under retirement age have consistently received 5.2-5.3 prescription items per head per year over the last decade but women over 60 years and men over 65 years have been receiving increasing numbers of prescriptions. In 1988 patients over retirement age but under 75 received 17 prescription items per head per year. Patients over 75 years received an average of 24 prescription items per year.

Resistance to use of new medicines by British doctors

The conservatism of the British pharmaceutical market was compared with the behaviour of other national markets.

In Figure 1 is shown the percentage of 11 national pharmaceutical markets captured by medicines launched in the previous five years for the year 1987. In Italy 29.3 per cent of the total national health service pharmaceutical market share went to products launched in the previous

FIGURE 1 **1987 sales of products introduced in the last 5 years as a share of total 1987 sales**

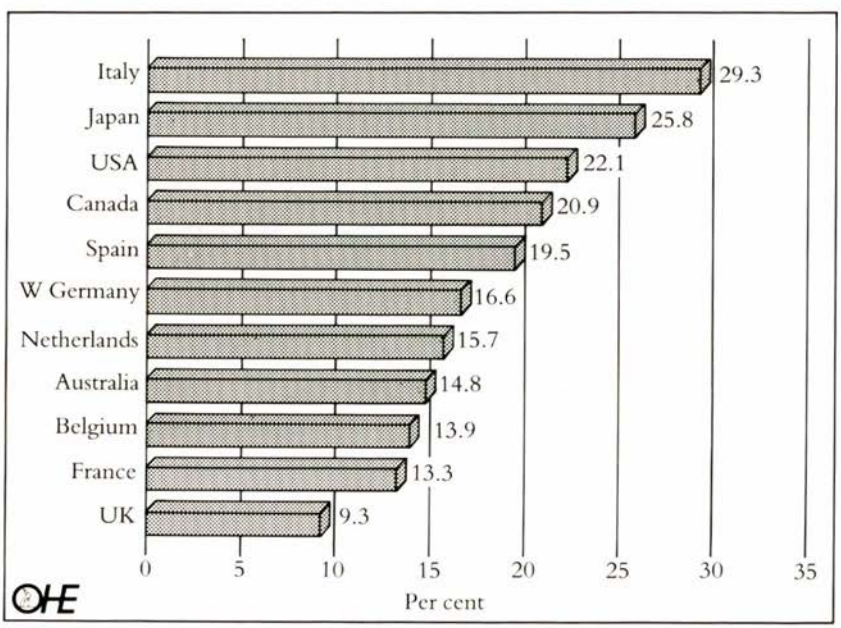
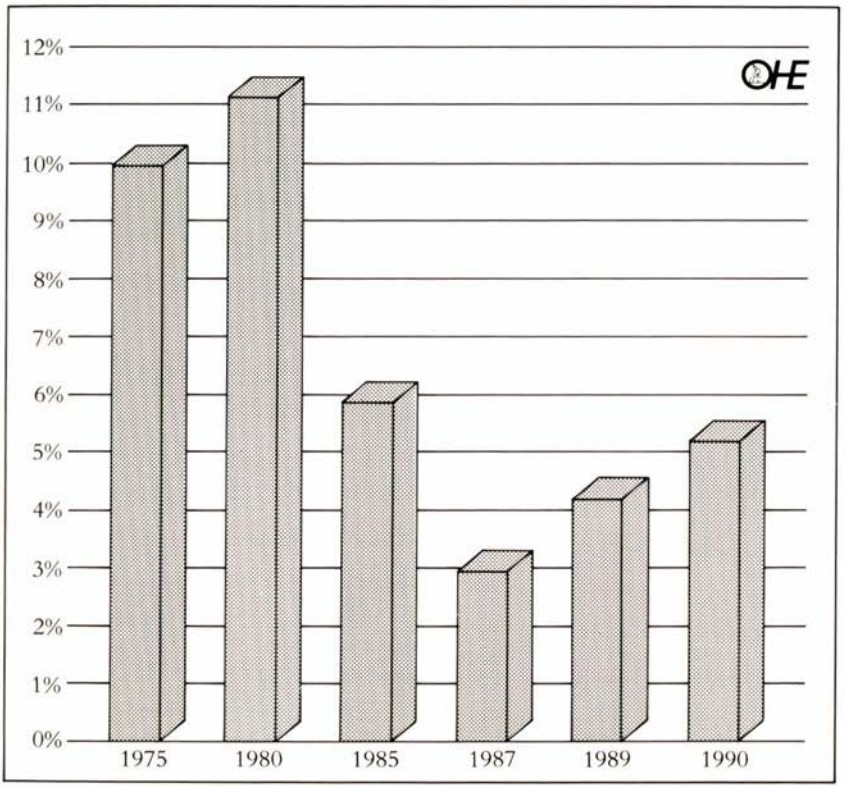


FIGURE 2 **Sales of new chemical entities introduced in previous five years as per cent of total NHS sales**

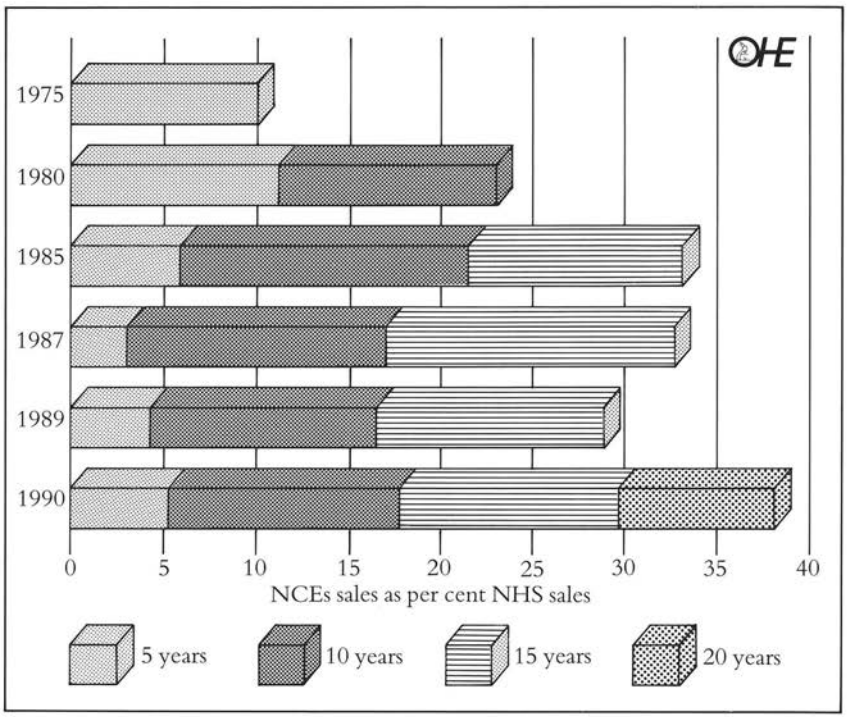


five years while in the UK only 9.3 per cent of pharmaceutical market share was taken by products launched in the previous five years.

A further analysis conducted by the ABPI based on prescribing by British general practitioners evaluated what proportion of prescriptions by value were for chemical entities introduced in the last five years in the years 1975, 1980, 1985, 1987, 1989 and 1990 (see Figure 2). In 1980 about 11 per cent of the National health Service (NHS) Medicines Bill was represented by products launched in the previous five years, but in 1987, 1989 and 1990 the market share of the NHS Medicines Bill for products launched in the last five years was less than half the proportion in 1980.

It was therefore decided to elaborate further on this analysis and determine what percentage of the NHS Medicines Bill was represented by medicines launched in the previous five, 10, 15 and 20 years in the years 1975, 1980, 1985 and 1990)see Figure 3). Data could only be obtained for new chemical entities (NCEs) launched in or subsequent to 1970.

FIGURE 3 **NCEs sales as per cent NHS sales, UK**

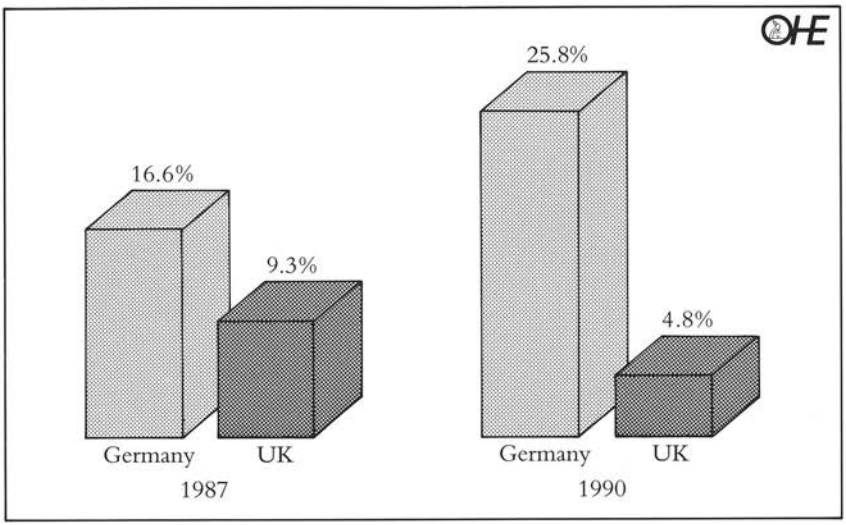


Thus in 1975 data could only be given for the previous five years, in 1980 for the previous five and 10 years and 1990 for the previous five, 10 15 and 20 years. In 1990 some 38 per cent of the Medicines Bill was for products launched in the previous 20 years and thus 62 per cent of the market was met by prescriptions for chemical entities 20 or more years on the UK market.

An international comparison of market penetration of new products at different points in time over the last two decades was attempted. Comparative data were obtainable from Germany and France.

In Germany in 1987, new chemical entities introduced in the previous five years captured about 17 per cent of the total market compared to 9.3 per cent in the UK, but in 1990 the top selling 20 new chemical entities introduced in the five year period 1986-1990 capture 25.8 per cent of the total prescription medicine market compared with 4.8 per cent in the UK (see Figure 4).

FIGURE 4 **Per cent of German and UK markets captured by the top selling 20 NCE launched in the previous 5 years in 1987 and 1990**

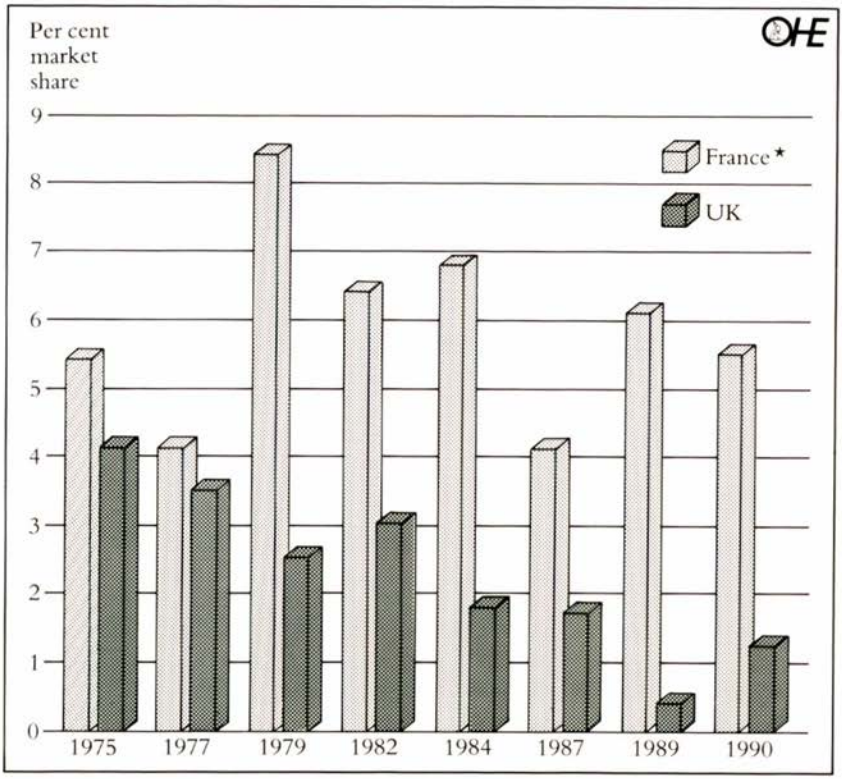


The data from France are shown in Figure 5 which shows the market penetration of one year's cohort of new products five years after launch, ie in 1975 the market share by value captured by products launched five years earlier and similarly for 1972's cohort of new products in 1977, 1974's cohort of new products in 1979, 1977's cohort of new products in 1982, 1982's cohort of new products in 1987, and 1984's cohorts of new products in 1989 and 1985's cohort of new products in 1990. Whereas in the UK there was a steady decline in the market share captured by each year's cohort of new products, in France no such trend was discernable.

In considering the real impact of these comparisons for research and development of new medicines it has to be appreciated the much greater values of the German and French national prescription medicine market compared to the UK. In 1990 the German pharmaceutical market size was 10,125 million ECU, the French 8,900 ECU compared with the UK market of only 4,742 million ECU.

The economics of the sales of a pharmaceutical product can be represented by Figure 6.[1] In this figure a patent is filed, after some 10 years the product reaches the market. The entry onto the market and subsequent sales do not follow the pattern of an unartificially regulated market. Firstly, market entry is delayed by regulatory requirements in most developed countries, prices are depressed by price or profit control systems, and then generic prescribing or generic substitution means that when the patent has expired the originator can no longer rely on brand loyalty to maintain his market share. Nevertheless, when a new medicine enters

FIGURE 5 **NCEs market share after 5 years of launch**



Note: *Figures relate to new introduction, including non-NCEs.

the market it follows the general sales pattern of rise, plateau and fall when the patent expires. The solid area of the graph represent what actually happens in the pharmaceutical market and the open line represents what would happen in a market with fewer controls.

In Figure 7 is shown the general pattern of the penetration of the year's cohort of NCEs for the years 1970, 1972, 1974, 1976, 1980 and 1984 etc, given as a percentage of the total NHS Medicines Bill up to 1990. It can be clearly seen that the aggregated sales of such cohorts of new medicines introduced after 1980 rise much more slowly than those introduced in the previous decade, reach a lower peak level and decline more rapidly.

In 1971 there were 39,000 products on the British market eligible for a Licence of Right under the provisions of the Medicines Act 1968. However, by 1991 there were 1,300 active chemical substances available in some 12,000 formulations each holding a UK product licence. Medicines available only on a doctor's prescription, i.e. prescription only formulations (POM), accounted for 7,600 of these; medicines available only

FIGURE 6 **Environmental influences**

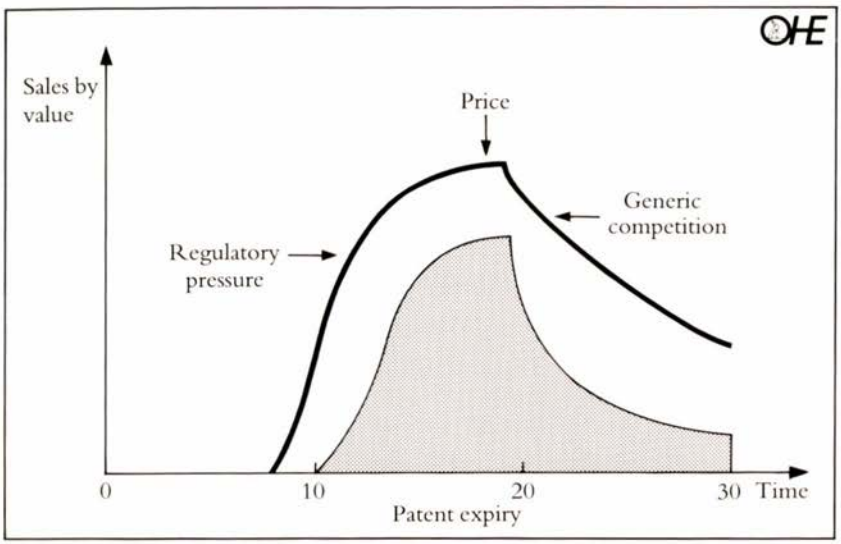
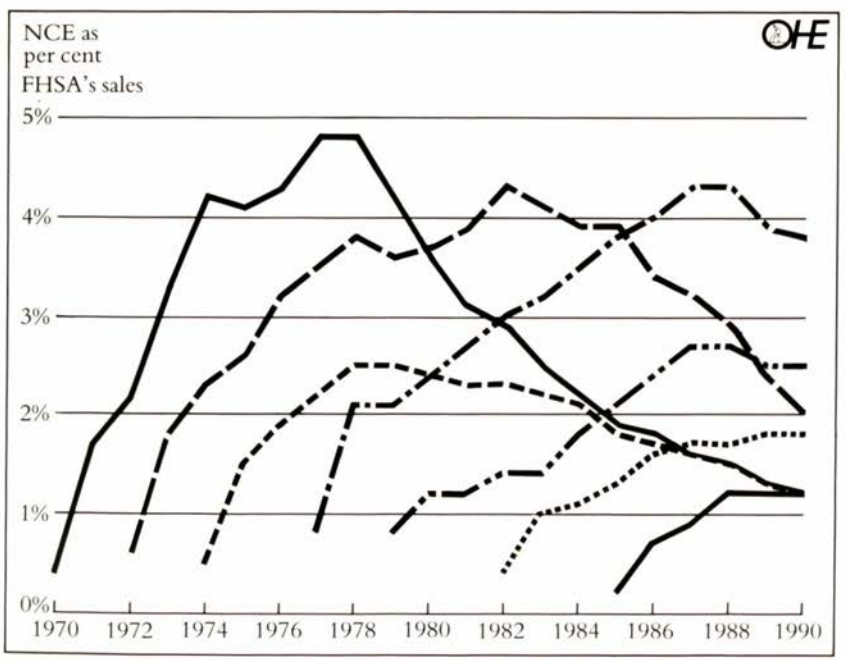
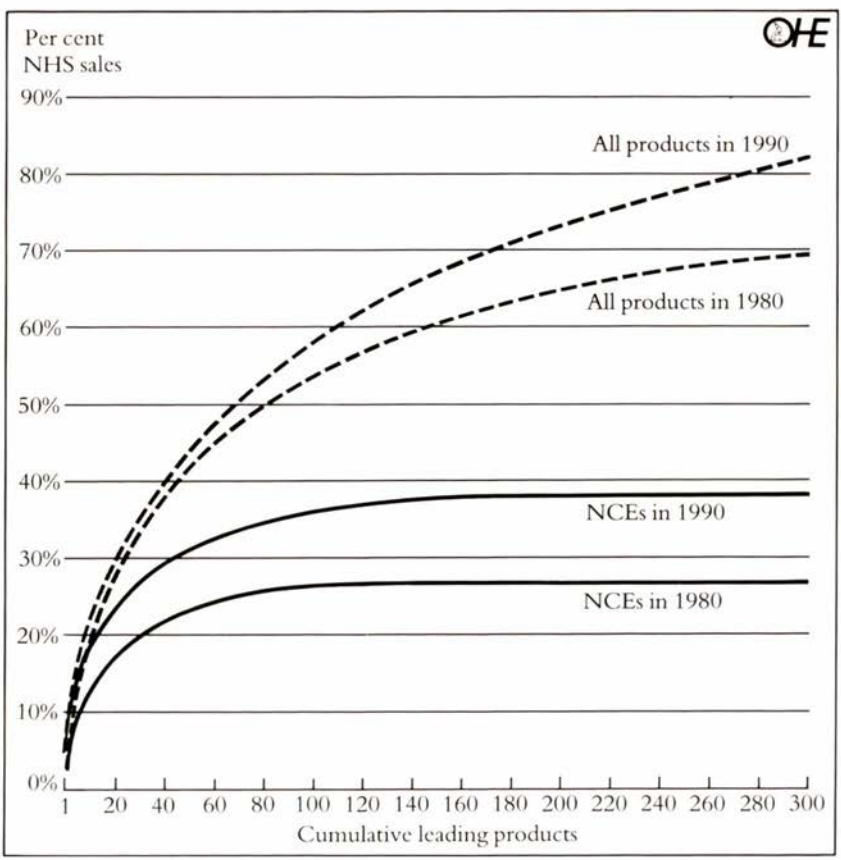


FIGURE 7 **NCE as per cent total FHSA's sales, UK**



from a registered pharmacy but without a doctor's prescription, **(P),** numbered 2,300; General Sales List products accounted for about another 2,000 products. In 1990 the 50 most prescribed active chemical substances, whether contained in branded or generic formulations, accounted for 44 per cent of prescription market by value, the most prescribed 300 active substances accounted for 80 per cent of market. Comparable figures for the year 1980 indicated that the 50 most prescribed chemical entities represented 42 per cent of the prescription market by value, and the top 300 achieved 70 per cent (see Figure 8). From these data it would therefore appear firstly, that the 1,000 or so less frequently used active chemical substances accounted for only 20 per cent of the prescription market in 1990 and secondly, that in 1990 British doctors were prescribing from a more restricted therapeutic armamentarium than in 1980.

FIGURE 8 **Top 300 products' sales as per cent NHS sales, UK**



New medicines are cost effective

Professor W J Louis of Melbourne, Australia wrote in the *British Medical Journal* in February 1989 'New drugs have the potential to reduce substantially the costs of medical treatment, reduce investigations and prevent illness'. This view lends further support to the case that initiatives to encourage doctors to prescribe cheaper medicines in the taxpayers' interests may not necessarily be the right way forward in terms of achieving overall cost effectiveness in prescribing.

This is revealed by an analysis of data supplied in the annual report for 1988-89 of the Prescription Pricing Authority.

It shows, for example, that in the Oxford region the average expenditure on medicines for each NHS patient in that year was lower than virtually anywhere else in the country although the average cost of each prescription written by doctors in the region was *higher* than in any other region in the country (see Figure 9).

FIGURE 9 **Relationship between annual medicines expenditure per person and average cost of prescription, 1988**

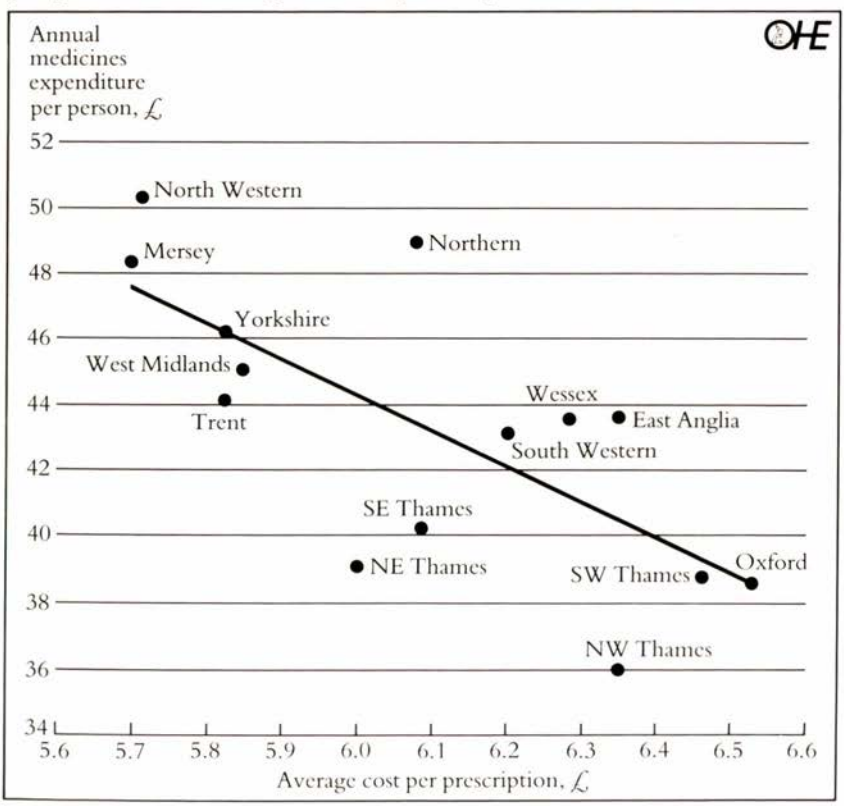
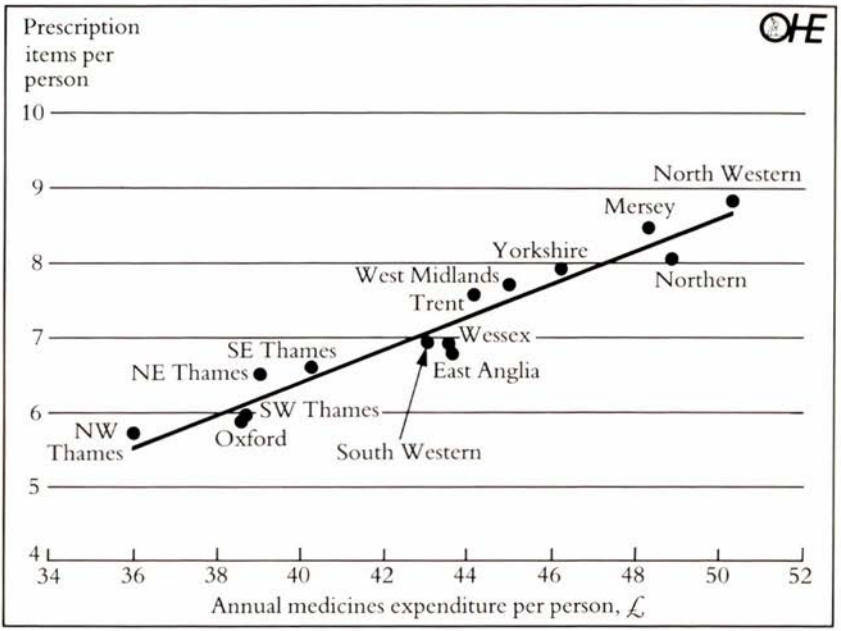


FIGURE 10 **Relationship between prescription items per person and annual medicines expenditure per person, 1988**



Figures for the other regions tend to confirm the Oxford pattern of prescribing, ie the use of more expensive modern medicines correlates with fewer medicines being prescribed on a per patient basis and lower overall expenditure per patient (see Figure 10).

Implications for the future

Sales of innovative products to the British NHS are declining as a proportion of overall volume. Annual cohorts of NCEs introduced in the 1980s are achieving an average, half the peak market share gained by annual cohorts of NCEs introduced in the 1970s.

The reasons for the British doctor's conservative prescribing can be attributed to a number of factors. The three most relevant would appear to be firstly, pressure to prescribe medicines by their approved INN name, ie generically. Secondly, the constraints placed on the level of pharmaceutical advertising, namely 9 per cent of total sales to the NHS in the UK compared with about 30 per cent total sales in Germany and France. Doctors freely admit that they obtain their greatest input of knowledge on new medicines from the pharmaceutical industry. Thirdly, there are definite financial constraints limiting doctors from prescribing costly new medicines, eg erythropoetin for patients in renal

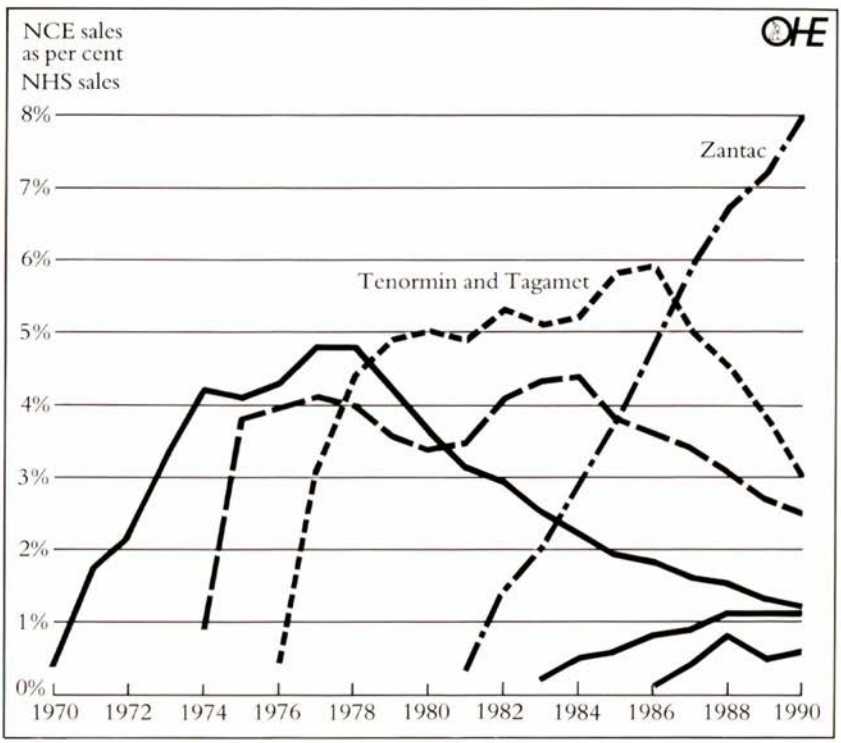
failure. This is one of the leading products in the German market, but many dialysis patients who could benefit from it in Britain are denied it 'because it is too expensive'. It would therefore seem reasonable to assume that cost reducing philosophies and constraints have resulted in comparative under use of therapeutic advances in the form of new medicines in the UK. The implications of such conservatism, if extended to other national pharmaceutical markets, would mean that the ability of the industry to fund research would be prejudiced. Current research is funded out of current sales.

The cost of developing a new chemical entity was estimated at 54 million dollars in 1976 and 230 million dollars in 1987, an increase of 425 per cent. The British NHS Medicines Bill in real terms is able to meet its current research expenditure from the total market but recently introduced products are not making a proportionate contribution.

The current downward pressure on medicines expenditure in Europe could see a general trend towards the prescription of older, cheaper, and in many cases less cost effective medicines. This will be to the detriment of the research based pharmaceutical industries' ability to conduct research. More importantly, these measures will deny patients currently available modern medicines and undermine research into treatments for disease where currently no adequate therapy exists. In the USA there are differences. Daniel Green writing in the *Financial Times* on 3 January 1992 pointed out that while cost containment pressures in the USA are increasing, 'if US doctors do not prescribe the most effective drug available even if it is only a little better than it rivals, they face the possibility of legal action from patients who do not return to complete health'. Such litigious pressures do accelerate market penetration of new products.

In conclusion, it is therefore vital that in addition to generating new and innovative medicines that the pharmaceutical industry convinces the prescribing doctor, the health economist and the politician of the cost/benefit advantages of new medicines. In the UK it would appear that this is an area in which a highly innovative industry is failing to achieve a vital objective. For the future, firstly, it is imperative that the cost/benefits of new medicines are established and become an integral part of the education of the doctor regarding new products. Secondly, industry must generate fundamentally new blockbuster products (see Figure 11), sales of which actually resource research into other less remunerative areas. It must be borne in mind that less than one in five NCEs marketed worldwide recoups its own research cost. Thirdly, patients and governments must realise that, for the future, products generated for small and specialised needs will have to be charged to health authorities or health insurance companies at a premium price or governments are going to have to generate the equivalent of orphan drug policies.

FIGURE 11 **NCE sales as per cent NHS sales by year of launch, UK**



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Challenges for the National Health Service

The Rt Hon Enoch Powell

The Acts of Parliament of 1946 which instituted the National Health Service in the United Kingdom opened up a new and hitherto unexplored dimension in the relationship between government and governed, between Parliament and people. They placed upon government a duty to provide health care to all within the jurisdiction at nil price at the point of delivery. In consequence government became responsible, in the person of the relevant Minister of Health, for each individual supply or failure of supply of health care in the United Kingdom and empowered to raise by taxation and to expend the relevant economic resources.

The bleakness of this consequence was limited in two ways, one legal and one conventional. The legal limitation was that specific performance of the statutory duty could not be claimed through proceedings in a court of law. The conventional limitation was that political responsibility was not held to extend to any acts of judgement made by members of the health professions in the exercise of their profession. Those qualifications apart, the politicisation of health care in the United Kingdom was complete and total, and has so continued to this day, unaffected by subsequent amendments of the principal Acts.

The novelty of all this did not lie in the immense range and extent of the matters for which government became politically responsible. The responsibility of ministers for matters within their departmental sphere of which they cannot possibly be cognisant personally is a commonplace of parliamentary theory. It is not different in kind when applied to the availability of a bedpan or to the sum for which a payment order is made out by a social security office or to the command issued by a sergeant on parade to a private soldier. The novelty lay not in the comprehensiveness of the new political responsibility but in the nature of the subject matter; and it is at this point that the National Health Service comes within range of the concerns of the economist Joseph Schumpeter enshrined in the programme of this Conference. The subject matter of the responsibility, and consequently of the measures adopted to fulfil it, was of a nature not capable of measurement or objective assessment. Destitution for the purpose of social security can be defined in monetary terms; there was no disputing in 1942 that British forces had been driven back within the frontiers of Egypt; but the health of an individual, let alone of a population, is unlimited both in its demands and in its potential interpretation. Yet the discharge of responsibility and the exercise of responsible management demand commensurability — a means of objective measurement — and that measurement was here to be applied in a service financed out of taxation in monetary terms. In the

absence of commensurability, the idea of competition and comparison takes wing and flies away.

This is perhaps the point at which I can most conveniently refer to the event which evidently earned for me a place in the demonology of pharmaceutical history; for that event illustrates admirably those consequences of political responsibility for health care which I have just been endeavouring to define in the abstract.

In 1962 certain medicines used in the National Health Service were being offered by importers at prices well below those at which they were being currently purchased from the patent holders. As Minister, I was advised, by those professionally qualified and in specific terms and in writing, that the importable medicines did not differ in efficacy or quality from those currently being purchased; nor have I heard that advice disputed since. I was further advised, by those professionally qualified to give the advice, that the medicines in question could be lawfully obtained for the National Health Service under the terms of the statute governing patent law, which provides, where patent rights are overridden in such circumstances, for arbitrated compensation for the patent holders.

I have yet to meet, or even to imagine, a minister responsible to Parliament for the National Health Service who would insist in those circumstances upon the medicines being purchased for the Service at the higher price. He might think it probable or even certain that by securing the higher price the patentees were enabled indirectly to promote the treatment of the relevant medical conditions or the progress of pharmacology in general. That, however, is not a matter on which he is responsible for forming a judgement. What he has been presented with is a straight comparison in monetary terms; and his duty, as politically responsible for the National Health Service, is not open to question. He would get short shrift from his colleagues in government if he asked them to support him in paying more than necessary for an item on the grounds of some unquantifiable and contingent benefit.

I have chosen, or rather this Conference has provided for me, a particularly uncomplicated case of the discharge of political responsibility in the National Health Service. In practice, a massive total of choices is being made continuously, from one end of the Service to another, upon data which are by their very nature unquantifiable. That being so, it is understandable that methods of reducing or avoiding political responsibility for those decisions have been eagerly explored by politicians; and there are reasons why that exploration has become noticeably more eager in recent years. They have been years of an exponential increase in the speed of change, not least in directions connected with the pharmaceutical industry. Change and innovation have a remarkable effect in a national health service in intensifying the difficulties attendant upon political responsibility.

That responsibility, remember, is equally for what is not done and not made available as for what is being done and is being made available. Every change seen as improvement which is pioneered anywhere creates an instantaneous replication of unrealised demand everywhere else. The political responsibility for non-provision is multiplied with the speed of lightning as health care, its methods. its fashions and its potentialities continue to develop at an increasing pace: what is achieved in Gateshead on Monday is an obligation unfulfilled in Exeter on Tuesday. The demand which is expanding and altering is unquantifiable — Schumpeter again! — while the political responsibility remains essentially quantifiable for a specific reason inherent in a service publicly financed. The political decisions — those to which the most embarrassing political responsibility attaches — take the form of financial allocation. Allocation, amongst a large number of potential recipients, of capital and current resources runs downward from the ministerial to the lowest administrative level.

There now: with the word 'administrative' I have touched a spring. We are at present witnessing within the National Health Service a comprehensive and unprecedented attempt to achieve a limitation and 'cut off' of political responsibility. 'Devolution' it would be wrong to call it; for devolution implies retention of ultimate responsibility by the devolver. The preferred euphemism is 'reform'; but the attempted reality is 'transfer'. 'Let us', the politicians have said, 'divide the Service into convenient units. Let us then throw into the lap of each of them a financial allocation. Then we will tell them to get along as best they can. Let them, in a word, 'compete'.' Hey presto! The problem of comparing the incommensurable is solved: competition — competition for patients, competition for efficiency, competition for balancing the financial books — that will do the trick and keep the political responsibility at a level sufficiently high to be remote: tell that to Schumpeter.

On the surface, the solution is very neat. It appears to allow for the incommensurables; for the incommensurables, too, are automatically taken care of in the course of competition, even though the competitors are provided with their 'counters' in financial terms. What is more, the old embarrassing dichotomy, between political responsibility and professional responsibility, appears to be done away with; for is it not the professionals who have been set to do the competing. At least it will be up to the professionals at each level to get their way with the bodies which are in competition. For the moment at least, until the General Election is over and the post-Election thaw comes, the world is watching and holding its breath. Is it really possible? Has Houdini really escaped? Have the politicians really discovered that philosopher's stone which earlier generations had sought in vain? In short, have we learnt how to finance health care out of taxation without there being political responsibility for how the money is spent? Those are the questions which all who have

business with the National Health Service ought to be asking themselves. 'Attitudes to health care expenditure', the Background Paper of this Conference tells us, 'have changed in recent years'. So have perhaps the built-in implications of a publicly financed health service free at the point of delivery evaporated and disappeared?

I have set a tempting trap for my own feet, and will proceed to infringe one of the politician's elementary rules: 'Never use the future tense'. I will endeavour to answer my own question.

So long as the National Health Service is preponderantly financed out of central government revenue — and I see no movement of popular or political opinion in favour of altering that — so long will the allocation of finance from the highest to the lowest administrative level remain a political responsibility. Those who are exploring with delight the novelties of internal competition in a publicly financed service will, when they encounter the inevitable limitations upon their freedom of action, begin to ask: 'This pile of counters which was dealt to us, where did they come from?' To that the answer will be: 'They came from the Secretary of State'. 'Then', will be the reply, 'the consequences are of his making not ours: the responsibility for them must be political'.

Meanwhile, a similar train of thought will be passing through the minds of the customers, the patients or the potential patients: 'Who took this decision, by which I am aggrieved, and to whom am I to complain of it? I was, so the professional explained to me, in competition with others similarily situated for a place in his budget, and I lost out'. The customer who thus ruminates will presently observe that not only the professional concerned but the administrator are non-elected persons. No point therefore in going on to the streets and shouting, 'Out, out, out!' The customer will then say to himself: 'Here am I, deprived of that to which I consider I have a statutory right, but there is nobody who takes responsibility for it. My Member of Parliament disclaims all interest; the Minister in Whitehall says he made an adequate allocation to my local providers; my local providers wash their hands and say they are doing their best. But it is *my* money, mark you, that keeps them in their jobs and pays their salaries'.

I do not believe that arrangements which have this result can prove inherently stable. As shifts take place in the content and pattern of medical demand, the pressure will mount to bring responsibility for allocation home to rest in a political quarter. Only the illusion of professional management and professional autonomy will be seen to have been created, with consequent disappointment and acrimony when it is discovered to be just that — illusion. The politician will find himself facing again the built-in contradications of the National Health Service. The pretence of his having escaped will gradually be shed.

Landed once more with the baby, the politician will behave as he is programmed to behave: he will endeavour to accommodate himself to

the conflicting pressures exerted by claimants and by colleagues in the manner best calculated to secure public popularity or at worst public passivity. This reality he will endeavour to conceal by presenting the results as the reflection of objective standards of judgement. Let us not be too hasty in despising him. His search for the crock of gold, for genuine competition in the National Health Service, will not have been wholly fruitless. He *has* discovered, or re-discovered, competition and thereby a kind of objectivity, though not in the form in which he had been seeking it. The competition to which he is yielding is that of conflicting pressures, sectional or general, public or political, from inside or from outside the area of health care. Nor need he be ashamed of this avowal; for such was the inner meaning, and must be presumed to have been the intention, of the politicisation of health care in the first place. If not to produce this form of decision-taking, what was the object of the exercise?

It is, or it used to be, an agreeable convention in the National Health Service that the members of the professions treat the individual who is Minister or Secretary of State for Health for the time being as a member of their own professions. One of the compensations for occupying that curious political office is in consequence to find oneself in the relationship of a colleague with men of zeal, ability and humanity, whose motivation in life is nevertheless so remote from that which has dictated one's own career. Indeed, I once entitled an address to the British Medical Association 'The Whale and the Elephant', as exemplifying the separation of the respective spheres which the professions and the politicians inhabit.

This privilege of the minister is accompanied by a corresponding duty; and perhaps it is in the fulfilment of that duty, if anywhere, that the resolution of the internal contradications of a national health service lies. He has been privileged to share, if briefly and at a distance, the enthusiasms, the excitements and the philosophy of another world. In return he owes a duty to communicate and explain the contraints, the peculiarities and the inner motivations of the world to which his own profession belongs.

To gain the understanding and carry with him the comprehension of the medical profession is the highest achievement to which a politician responsible for the National Health Service can aspire. A common understanding between the healing professions and the responsible politicians upon the lines on which the Service is developing within the limits of unavoidable constraints affords the best propect for its stable and consistent management.

The health care dilemmas

The Rt Hon the Lord Jenkin of Roding

I am extremely pleased to take part in this meeting and to contribute to the published proceedings. I am Chairman of the Forest Healthcare NHS Trust. This is one of the new NHS Trusts set up under the National Health Service and Community Care Act. It is of interest, I think, that we have been looking at our senior management contracts and finalising them, which we now have complete discretion as to how we draw them up. We have instituted, in principle, a system of performance-related pay with as much as a fifteen per cent add-on, though fifteen per cent is going to be bloody hard to achieve; many of the targets are based on the Patient's Charter and the standards which are set there. We have also been looking at the terms and conditions that we are going to offer to all our new staff (all the existing staff will transfer under their existing terms).

We have been looking, too, at our proposed capital expenditure. It took my predecessors eight years from the moment of approval to getting a contractor on to site to build Phase I of the redevelopment of Whipps Cross Hospital. We got approval for Phase II in December last and we are going to have the contractors on site before the end of this year. Because we are a self-governing Trust we can appoint our own professional advisers, our own architects, our own engineers, our own quantity surveyors. We can conduct our own consultations and we don't need to bother ourselves with any of the NHS hierarchy at all. All we had to have was a loan sanction from the Secretary of State.

We are what is called a 'whole district provider unit'; we are not just an acute hospital. We are embarking on what I can only describe as a very radical culture change for the National Health Service. We are seeking to change from being a producer-driven organisation to being a consumer-driven organisation, with the consumers being the patients and clients whom we seek to serve. An immediate step to achieve the change is to change our management structure. Hitherto, traditionally in the NHS, this has been based on institutions (hospitals) or on professional groups, shall we say, community nurses, or on geographical units where you can have managers for a particular part of your area. In place of all that we are introducing a management structure which is based on what we call 'client care groups'. We will have a single manager and his or her staff and the clinical director for general surgery all the way from the acute in-patient treatment to treatment in the community, convalescence and eventually the domiciliary care of that patient. Similarly, for the general medicine. That's surgical and the medical departments. Other care groups include the elderly, and women and children, so that

all your gynaecological obstetric and paediatric services come under one group all the way from acute in-patient to out-patient right back to domiciliary. Then there is mental illness and what I still call mental handicap, (though we're having to learn to call it 'people with learning difficulties'! In passing, may I add that a new member in the House of Lords is Brian Rix — Lord Rix, champion of the mentally handicapped. He ran MENCAP for many years. He was telling me with some asperity earlier this week that his daughter has not got learning difficulties; she is seriously mentally handicapped, and he has no sympathy with that particular new euphemism!)

For each of our client care groups there is a single management responsibility right the way through the whole spectrum of care. It has been warmly welcomed by GPs who can see that there will be continuity of care with none of this business of handing the patient over from one management team to another. One lot of managers will have clear responsibility at all stages of the patient's care and with, therefore, a much stronger focus on the patient as being the centre of our attentions and our activities. I have to say all this is being made possible because of the freedom which an NHS Trust has under the reforms which are in the 1990 Act which split the health service into purchasers and providers — I shall have a little more to say about that in a moment. That also established the principle that 'the money follows the patient', and has given management a much greater freedom to manage, freedom to determine their staff, pay and conditions. We can be entirely free from the whole of the cumbersome National Whitley superstructure; also we have some financial flexibility to cover short-term borrowing though we also have some fairly stringent financial objectives set by the Secretary of State.

We have to rely for our revenue on winning contracts from purchasers, from health authorities, not just our own immediate one but I saw this morning that we were dealing with a list of about twelve health authorities all round us, from our GP fundholders and no doubt some, what are called, ECRs — extra-contractual referrals — from a wider field.

It's already clear that this tension, as it were, which is set up between the purchaser and the provider (we are the provider, of course) is having a remarkable impact on the way that people see their jobs. It is the way that people are now focusing on the purpose of the whole exercise, namely the care and cure of patients. Waiting times are already falling rapidly because the purchasing authorities will not make contracts with providers who keep hundreds of patients waiting two years or even more for their care. They will go to where the waiting times are shorter. On the quality of care, the new contracts that are being spelt out now by the purchasers are setting very high quality standards in all sorts of ways, for instance, the quality of the information which is made available to the patient or to the patient's family, or perhaps almost important of all, back to the patient's GP. These are requirements which every good provider

ought to have done but are now to be found in the contracts and are actually being built into our management objectives.

Another issue concerns access by disadvantaged groups. We've all been trying to do that. Purchasing authorities are now requiring ways in which we are going to be able to reach our ethnic minority population which is quite substantial in our part of north-east London.

My Lord Chairman, I suppose an economist would seek to define what is happening now in the National Health Service (and this brings me a little closer to the purposes of this seminar) as 'supply side competition' among providers of health care to help to increase efficiency in the provision of services. One could go on to say that patients, and again in economist's language, 'purchasers' of all kinds now have more choice and they can make their choice effective by taking their custom elsewhere. The providers have new incentives to increase their workload, to earn more revenue and to improve their services, and that's the carrot. There is, of course, also the stick. That if they fail in quality, fail to reduce waiting times, fail to achieve standard quality objectives — I'm trying, for our nursing staff, to write in bed sores, cross infection, the sort of things that bad management produces and that that is written into objectives — if we fail to achieve that, the chances are we will lose revenue and in the end people will lose jobs.

I think that Schumpeter, if he were commenting on all this today, would say 'Well, if once you establish some of the pressures of the market, what did you expect? What's new'? He would say we're merely demonstrating the truth of the propositions with which his name is connected. And he might go on to say 'Why have you waited so long before doing this'? To which there is a variety of answers. But I have to say, that if he were then told that at this election the principal opposition party has gone very clearly on record to say that it is going to unwind the whole reform; that the Trust of which I am a chairman will disappear and I will be out of a job; that the purchaser/provider split is going to be abolished and the flexibility which we have been given, I suspect that Schumpeter's puzzlement would be great indeed until perhaps he was reminded that Labour's political power base still lies substantially with the organised providers, too many of whose leaders still see their role in trying to protect their members from the consequences of economic change.

If Schumpeter and other market economists were to ask the question — why not go further? Why not try to introduce a real market for health? 'Surely', he might say, 'that is the way really to match resources to demand'. And in the rest of my remarks I want to examine some of the problems and expose some of the dilemmas inherent in these questions.

They are problems and dilemmas which are present in every industrialised country which has substantial health services and it is not to be confined solely to the United Kingdom, as some people here might sus-

pect if they were to read the prints. The central problem in the provision of health care has always seemed to me to be able to be described like this:

(1) Health care markets are characterised by a multiplicity of actual and potential consumers, i.e., patients, and a large number of providers, for instance, hospitals, GPs, community pharmacists and so on.

(2) Economic theory states that the most efficient way of allocating resources in such a system is a free market in which market-determined prices influence the level of services provided to individual consumers and resources are drawn in as the consumers express their wish through the market; resources are drawn in to satisfy that market. However, —

(3) in most, and indeed I would suspect all, developed countries it is not considered acceptable to use the free market to allocate health care resources, primarily for distributive reasons. It would mean that those who cannot afford to buy services or cannot afford to buy enough services would go without or would go short. And therefore, —

(4) this has led governments to intervene in the supply and financing of health care to achieve their social and political priorities. These priorities inevitably interfere with and take precedence over any theoretically more efficient allocation of resources; this has given rise, in turn, either to large fiscal burdens or to large private financial burdens, or indeed, in many countries, to both.

Now, these raise fundamental issues about the working of imperfect markets and, after all, our market economists are well-schooled in seeking to analyse imperfect markets and find solutions. But no market is as imperfect as the health market. Unlike a normal market, in the health market the decision to consume health care and the decision to pay for that consumption are made by entirely different people. Indeed, it goes further, and can be summarised — the patient presents, the doctor prescribes and either the state or the insurer pays. And it is this inevitable trichotomy which creates the dilemmas for the economist who is seeking to provide an economic solution for health.

I think one can identify three dilemmas. There is first the dilemma of inefficient utilisation. If the price to the consumer is near to zero, then why not consume to the point of near zero marginal benefit? And if doctors, as in some countries, are paid on a fee-for-service basis then doctors will have an incentive to supply services even if the marginal benefit is near to zero. The resulting waste of resources if that were to be carried to its logical conclusion will, of course, be vast. I say 'would be', because of course, that isn't allowed to happen. Given financial constraints then other pressures inevitably are brought to bear. Ideally, all concerned — patients, doctors, hospitals, anyone who is involved in the

trichotomy should have incentives to take account of the costs of their decisions. And even in the imperfect market created by the NHS reforms here in Britain there is some evidence that this is beginning to happen; some evidence that with some pressure on costs doctors are beginning to question whether certain treatments are, in fact, marginally worthwhile. One can cite actual examples of that happening because they are now beginning to look at the costs and benefits of the various decisions that they have to make.

Now the second dilemma, which I call the insurance dilemma. If a purchaser or a provider faces increasing competitive pressures then there is a temptation to select preferred risk, in other words, to choose patients who are not very ill. And that is why insurers agree to cover healthy people but seem to be much more reluctant to cover people who have various forms of inherited or chronic ill health. In practice, of course, governments are increasingly the underwriter of last resort and where that is so, it should be feasible, in theory, for all risks to be covered on an actuarial basis so that you charge premiums or pay capitation grants on the actuarially determined estimate of risk. But one has to say that few, if any, countries have sought to go down that route.

So that brings me to the third dilemma — the dilemma of appropriate government intervention. Preferred risk selection in practice is avoided by governments setting up either compulsory insurance funds or by governments underwriting insurance pools or, as in the UK and some other countries, by governments simply allocating public resources to health services. And one simply has to say in all those areas classical economic theory is left behind. Health has become a political question whether it's in the policies to be followed, the levels of provision, the levels of reimbursement, and so on; all these are primarily political and not economic issues.

It is these dilemmas which currently lie at the heart of the problems confronting all countries. We complain in the United Kingdom of chronic underfunding and people point to the proportion of GNP which is devoted to health, which they say is lower in this country than it is in some other comparable countries. One's response is to point out that the *public* provision for health actually in all these countries, including the United States, is really very comparable, round about six per cent. What is different is the level of private provision which is made, which of course in the United States and some other countries is very much higher than it is here. And if I may be allowed my last commercial break, it therefore does seem strange that if you are in one breath complaining about the low proportion of national resources which are devoted to health, you at the same time promise to withdraw the only incentive to private provision which is the incentive of a tax allowance for those over 65 to take out private health insurance. But if you study the Labour Party manifesto when it comes out you will find that's precisely what they're doing, so that perhaps one doesn't necessarily look for logic in these things.

Of course Britain is not alone in having a chronic financing problem. I read the other day that the 1991 deficit of the German Krankenkassen is estimated at 7 billion Deutschmarks, as if Chancellor Kohl hasn't got enough problems already with East Germany. Different countries adopt different piecemeal measures to try to constrain the costs of their policy — queuing is one obvious way, or even in some cases, explicit rationing. Some countries exclude all together some medical or surgical procedures from financing by the state, the so-called 'Oregon solution'. And I find here, when I'm in medical company, and I mention the word 'Oregon' I pick myself up off the pavement outside. This is not one that is likely to find favour with doctors here.

Countries are increasingly looking at co-payments as being one of the ways of reconciling demand with resources. But even in the UK, where there are now quite stiff prescription charges, such are the reliefs and the exemptions necessary to make the charges politically acceptable that in 1990, which I think is the latest year for which we've got figures, only sixteen per cent of prescription items were prescribed to people who have to pay the full charge. The other eighty-four per cent went to those who are either wholly or partially exempt. And if you look over a range of years, that figure of sixteen per cent has been falling steadily year by year, and so co-payments at least for drugs doesn't look to me to be a way out. And also there is evidence that it can give rise to abuse. In Spain the consumption of drugs by pensioners who are exempt from co-payments is five times the consumption of drugs by non-pensioners who pay, and nobody has ever sought to argue that that differential reflects a difference of health care — or not fully, a difference of health needs.

So if queuing and rationing and excluding and co-payments are only partially effective or unacceptable, governments find themselves turning to cruder pressures to try to contain costs. They restrict pharmaceutical companies' profits as in the PPRS and, as we were hearing from John Griffin, every other country has some form of squeezing pharmaceutical companies' profits. In Italy, they are forcing companies to charge lower prices, and Japan is threatening now to do the same. But I mean, take Japan as an example, where is the sense of squeezing the companies' profits when actually every doctor makes a substantial extra profit for himself for every prescription that he writes? They are paid absolutely on an item of service basis in Japan. You could scarcely get more illogical than that.

Or governments set limits or budgets on pharmaceutical spending by doctors and then because immediately there's a medical explosion, they add the word 'indicative budgets' and have to give everybody a clear guarantee that doctors will not be allowed to run out of money for their prescriptions. Or they adopt national formularies, all the things that John was talking about. Germany and Holland are doing that, some with sophistication — coming from a surprising source because one doesn't

normally actually think of the Australians as being particularly sophisticated operators, but they are the ones who now have required new medicines to be evaluated for cost effectiveness, which may be a more promising way.

But one has to ask the question — why pick on the pharmaceutical bill? In no country does it exceed ten per cent of the total, and as we have heard very effectively stated earlier today, most medicines are very cost-effective; you need to look at the whole course of a treatment, and if a medicine can reduce from ten to two the number of days spent as an in-patient what does it matter if it costs twice as much as the one which will require ten days in hospital? And if the effect is to limit the resources to finance the research into new and improved medicines, then the process could lead, and may well be leading now, to increased costs in the future elsewhere in the service.

So quite rightly, governments are now turning to more radical solutions aimed not just at looking at the pharmaceutical bill but actually looking at the way health services are financed, and are facing now the problems and dilemmas which I described a few minutes ago. But what they are trying to do, recognising that you cannot have anything approaching a perfect market, and indeed it's, as I've said, a very imperfect market indeed, what you can do is to stimulate some economic pressures. And that is exactly what the United Kingdom reforms, which I described at the beginning of my remarks, is really seeking to do — establishing what some might say is an artificial distinction between a publicly-financed provider and a publicly-financed purchaser and setting up a tension between the two with some measure of competition.

In Spain the Abril report recommends a system based on internal markets and this may have much the same effect. In Sweden and in New Zealand governments are doing the same with the New Zealanders expressly separating out the purchaser and provider roles. In Holland, the Dekka proposals are for a much more market-orientated insurance system but a measure of the difficulty of introducing that is that Dekka Report was around ten years ago and it's taken a very long time to be implemented. And one had hoped perhaps, when it was known that President Bush was going to make health care reform the centrepiece of his State of the Union message in January, that something was going to come out of that; I think it was a matter of great disappointment that his advisers, having told him that he mustn't make a speech about international affairs, and must turn to domestic affairs because of the domestic political situation, hadn't given him anything very much to say about it.

But all over the world governments are now having to face up, not just to the problem of the pharmaceutical industry, that in a sense has been an Aunt Sally, but actually looking at the whole way in which their health services are financed. And I think there are a number of things which we should all be looking at which we might well do. We need to

get much better at measuring outcomes. In many other fields, not only the private industry but of public service, the attention has been turning increasingly to outcomes rather than to inputs. And when you can really measure outcomes effectively, and a lot of individual work has been done, you are in a much better position to make rational decisions about the allocation of resources and making rational choices based on some form of cost benefit analyses, and I hope we shall have a lot more of that.

My grandfather was a lecturer in medicine, he was a doctor, and his favourite outcome story was about the mythical town where there were several medical practices and a new resident wanted to choose which doctor he would go to. And he was given all the addresses and told 'If you go round on midnight on Hallowe'en, you will find standing outside the gates of each doctor the ghosts of the patients he killed'. And he went round and there they were — twenty, thirty, fifty; one doctor, a hundred. And he came around the corner to the last doctor and there was only one patient. 'Ha ha!' he said, 'That's the one'. So the next morning he went along and said 'I would like to join your practice as a patient'. 'Hah!' said the doctor. 'How splendid! You're my second patient'.

So outcomes must be sophisticated and need a lot more work.

Alan Maynard's work on developing the concept of what he calls 'qualies' — quality adjusted life years is a bold step in that direction though I can well understand that it's seen by many as a fairly crude attempt. But we do need to get more doctors recognising that they have a crucial role in deciding on a rational allocation of scarce resources and I would like to suggest to them that to devote more attention to that is perhaps a better solution so far as their patients are concerned than rushing out into the street waving the shroud and complaining that they have not been given enough money. We're getting rather tired of that in the world of politics and I think that something more constructive is required.

And I think we also need, and some work has been done on this by the Institute of Medical Ethics, work done to develop an ethical approach that recognises that the language of priorities applies as much to medicine as to any other discipline.

But above all what we really need to do is to recognise the problem for what it is. It is not just the stinginess of governments; it's not the greed of the drugs industry; it's not the extravagance of the health providers that is the problem; rather is it the product of a system whose political imperatives have decreed in one way or another that those who need health care, those who provide health care and those who pay for health care cannot be effectively conjoined into a simple classical market relationship where demand, supply and price can together operate as the hidden hand balancing the one against the others. That is a pipe dream in

health and economists would be doing a great service to us all if we could get that message across to more people and recognise the real world that we're in. I suspect that in this country and in an election atmosphere that might be a very difficult task indeed but it's got to start sometime.

So, for me, at the end of this session, it's back to the Forest Health Care Trust and trying to make my simulated market work in a way which I hope will help the patients for which I and my colleagues are responsible. Thank you.

INNOVATIVE COMPETITION IN MEDICINE

The theories of the economist Joseph Schumpeter on the importance of innovation to 20th Century competition are highly relevant both to the pharmaceutical industry and to the organisation of health care as a whole. Therefore the papers in this book, which were presented at what became known as the 'Schumpeter Symposium' in London in March 1992, are of great importance to all those concerned with the industry and the Health Service.

The contributions from two of the world's leading economists, William Baumol and Richard Nelson, set the scene for the more detailed discussion by Michael Beesley, who has produced a distinguished and masterly analysis of the pharmaceutical industry in Schumpeterian terms. As he says, if ever there was a Schumpeterian industry it is indeed pharmaceuticals.

However the book is not just an academic textbook based on modern economic theory. It has very practical messages for those working in the industry and more especially for those whose job it is to regulate prices and competitive practices in relation to pharmaceuticals. Too often the regulators still work on classical economic principles under which price dominates the discussion, whereas these papers show that the true competition is in innovation. The innovators face what Schumpeter described as the 'perennial gale' of competition, and need what Professor Beesley here describes as the 'shelters' from its chill winds. Thus patents, brand names and advertising are as essential to the process of innovation as the research department itself. At the same time, John Griffin's paper about the dangers of therapeutic conservatism underlines the economic hazards for the pharmaceutical industry.

These are the main messages from this book, and the reason why it should be so widely read. Its papers mark a major step forward in understanding the economics of the pharmaceutical industry and the Health Service. The tail pieces by Enoch Powell, the former Minister of Health, and Patrick Jenkin, the former Secretary of State, bring the discussion directly into the context of the Health Service as a whole.