

DISEASE MANAGEMENT, THE NHS AND THE PHARMACEUTICAL INDUSTRY

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Anne Mason, Adrian Towse and Michael Drummond



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A Report by Anne Mason, Adrian Towse
and Michael Drummond



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Introduction

Disease management is a term with multiple and ambiguous meanings. For some, it is purely a form of managing care. For others, it is ‘strategic planning’¹ by the pharmaceutical industry to market its products in a different way. In between these two ends of the semantic spectrum are a wide variety of interpretations and usage. Forms of health care management exist that embody all the principles of disease management, but which are given a different label. In this report, we explore different notions of disease management and consider their relevance to the NHS. In doing so, we draw on a review of the medical literature on disease management, which comes mainly from the US, and on a survey we have conducted among senior personnel in the NHS and the UK pharmaceutical industry (see Appendix 1 for details of our survey). The report is structured as follows.

- In section 1, a working definition for disease management is assembled and the role of the pharmaceutical industry considered.
- In section 2, the background to disease management and its origins in the US are described. Some practical examples of disease management in the US are outlined.
- In section 3, the relevance of disease management to the NHS is explored. Viewpoints on the potential for pharmaceutical industry involvement in disease management are presented. The potential barriers to the development of disease management in the NHS are then considered.
- In section 4, examples of ‘joint ventures’ in the NHS are set out, based largely on a ‘joint venture’ survey (see Appendix 2), that followed on from results of the ‘disease management’ survey.
- Finally, section 5 addresses the future for disease management in the NHS.

SECTION 1 TOWARDS A WORKING DEFINITION OF DISEASE MANAGEMENT FOR THE NHS

1.1 Disease management: a matter of common sense?

On one level, disease management is a matter of common sense. It is clearly something to do with the management of disease. However, this begs the question about what form that management might take: what sort of care would be given? Who would manage the care? Where would that ‘managed’ care take place? In reality, disease management means different things to different people. Therefore, it is important to go beyond the term and explore some of these notions in more detail. They are discussed below.

1.1.1 Disease management and devising of guidelines

Disease management is usually discussed in the context of management by the production and use of ‘clinical guidelines’. But what exactly are ‘clinical guidelines’? Are they synonymous with other words that also appear alongside disease management, namely ‘treatment guidelines’, ‘protocols’ and the generic ‘pathways of care’?² A recent ‘Effective Health Care Bulletin’ defines guidelines as

*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.*³

Guidelines should describe ‘what care should be provided, by whom and in what setting’⁴. The production of a guideline presupposes evidence on the *clinical effectiveness* of the relevant interventions. There are different sources for this evidence. Guidelines for twenty different disease areas are compiled in a ‘Guide to the Guidelines’⁵. These are based on professional opinion (‘expert’ or ‘consensus’ guidelines) and on published papers (‘evidence-based’ guidelines). While, historically, guidelines have been about the identification of effective treatments, the Department of Health intends that the new National Institute for Clinical Excellence will

*produce and disseminate clinical guidelines based on relevant evidence of clinical and cost-effectiveness.*⁶

Clinical guidelines may then incorporate evidence on both clinical effectiveness and *cost*. If the interdependencies between cost components, or ‘economic levers’⁷, can be identified, then it may be possible to understand whether increasing costs in one part (manipulating a ‘lever’) of the treatment process may result in savings elsewhere or in improved health outcomes or other benefits. Synthesising cost and outcomes data allows an efficient, or cost-effective, treatment to be identified and incorporated in the guideline.⁸

However, there are certain methodological and practical challenges in introducing economic concepts into the guideline process, notably, the difficulties in determining the extent to which different resource and cost estimates can be relied upon⁹ and in deciding the role that economic evidence will play in determining treatment choice. The validity of the resulting guideline should therefore be tested. Guidelines may be said to be valid 'if when followed, this leads to the health gains and costs predicted for them.'¹⁰

The term 'protocol' is broadly interchangeable with 'guideline'. However, while the term 'protocol' has connotations of legally 'defensible' care, guidelines are usually considered to be advisory and to require contextual interpretation.

'Pathways of care' appear to have a slightly different meaning, insofar as they 'integrate clinical guidelines into practice'.² Clinical pathways are the *practical application* of guidelines, describing the specific ways in which the guideline may be interpreted for a particular setting. In addition, a clinical pathway differs from a guideline in that it involves an *in-built* feedback facility:

*a pathway is a dynamic document that is regularly upgraded according to best practice.*²

Disease management lends itself to the adoption of guidelines for two reasons. Firstly, guidelines tend to focus on a particular *disease*, rather than on a 'component' of treatment, such as nursing hours or drug consumption. This perspective encourages an integrated approach to treatment, with the patient with the disease at the centre of the analysis. Secondly, a guideline is a form of *management*: it seeks to modify the health professional's behaviour, in relation to 'best clinical practice'.

1.1.2 Disease management as an integration of care

The word 'management' implies an attempt to control with the objective of creating order. To manage a disease might therefore mean to understand the nature of the disease, find out how it progresses and what care may be given to the patient. This management must involve not just an understanding of the disease, but also the structuring of care, entailing the co-ordination of providers.

*'Critical pathways' ... document the most efficient and appropriate way of moving a patient from a presenting condition to complete recovery or the best improvement medical science can currently offer... they require multi-disciplinary co-operation.*¹⁰

The *implementation* of clinical guidelines will necessitate the co-ordination, or integration, of providers of care. This may mean a change in the way in which health care providers relate to each other, the 'breaking down (of) traditional boundaries'⁷ and creation of a new structure to relationships. Integration will

require good communication channels^{7,2}, guidelines that clarify the benefits of change and a willingness to co-operate.

Integration of the delivery of care can involve different bodies. This may take place within the NHS, forging closer links between primary, secondary and tertiary sectors. Alternatively, integration may mean partnerships between the NHS and outside bodies, be those the local authority, the voluntary sector, or the commercial sector.

Drawing from the American experience, there appear to be three basic forms that disease management partnerships can take. These are presented in Box 1.1 below.

Instances of pharmaceutical industry involvement in disease management in the NHS have all been *enabling* in character; more details of some of these joint ventures may be found in section 4.1 of this report.

Box 1.1 Types of disease management

◆ **Carve-out management**, which involves taking responsibility for the purchase and provision of care for a single disease programme and is also referred to as 'service provision'. Service provision usually involves a form of risk sharing: a carve-out manager may agree to cover the total cost of care for individuals suffering from a given condition for a set fee. An example of 'carve-out management' is the SalickNet cancer services (see section 2.2).

◆ **Integrated management**, which is a multi-disciplinary co-operation, supportive of primary care.¹¹ Sandifer explains that 'integrated disease managers cover a broad range of diseases and offer total medical coverage for these conditions. They attempt to co-ordinate primary and specialist care across traditional boundaries between medical specialities and institutions'.¹²

This is disease management operating at a 'macro level'. Health Authorities, or, in time, the new Primary Care Groups, may be seen as Integrated Managers.

◆ **Enabling management**, which supports health care providers with funding or expertise such as information technology or management system provision, contract specification, outcomes assessment or the supply of consumer education tools. This support may be offered within *integrated* or *carve-out* approaches to disease management. Enabling management may, like carve-out management, involve risk sharing: the enabling manager may, for example, offer financial support that is linked to the clinical outcome of a treatment programme. An example of this would be that of Merck Frosst, manufacturers of finasteride, a drug for benign prostatic hyperplasia (BPH). Merck Frosst made an agreement with the province of Saskatchewan, Canada, that it would cover the costs of care for patients with BPH who still had symptoms requiring surgery after one year on the drug.¹³

1.1.3 Disease management as a learning process

As noted in section 1.1.1, guidelines are usually considered to be advisory and to require contextual interpretation:

*any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament and preferences and thus whether it should be applied ... evidence-based medicine builds on and reinforces, but never replaces, clinical skills, clinical judgement and clinical experience.*¹⁴

We would therefore expect that the care given will not always mirror the care described in the guideline: variations in clinical practice will occur. If practice, using the relevant outcomes, is monitored and the findings are fed back to the relevant health professionals, then they can assess the practical application of the guideline, investigate the grounds for any variances and make improvements in the quality of care.

Disease management, then, makes use of the latest guidelines, but also gathers local clinical and economic information. But how are these different knowledge bases to be combined? It is clear that some *costs* will vary from setting to setting, which may well have repercussions on the relative cost effectiveness of different interventions at local level. It is not so clear how local *clinical* information should modify valid, evidence-based guidelines. The 'clinical freedom' of the health professional probably remains the decisive factor in determining which clinical pathway is adopted, especially within the NHS. It remains uncertain how the advent of Primary Care Groups, national guidelines, National Service Frameworks and enhanced clinical audit will affect the balance between clinical freedom and evidence.

1.2 Disease management: views of the survey respondents

A postal survey was sent to senior personnel in the NHS and pharmaceutical industry (see Appendix 1). Recipients comprised of Directors of Public Health in every Health Authority in England (102) and members of the Pharmaceutical Industry Health Economics Group (PIHEG) (83) in the pharmaceutical industry. The survey included questions to find out what they thought 'disease management' meant. The response rates for the survey were 66 per cent for all respondents, 78 per cent for the NHS and 51 per cent for the industry. Approximately 40 per cent of both groups of respondents were not those to whom the survey had been originally sent. Of all NHS respondents, 80 per cent were doctors in Public Health Medicine, 7.5 per cent respondents were pharmaceutical advisers and 5 per cent medical advisers. The position of industry respondents was seldom reported.

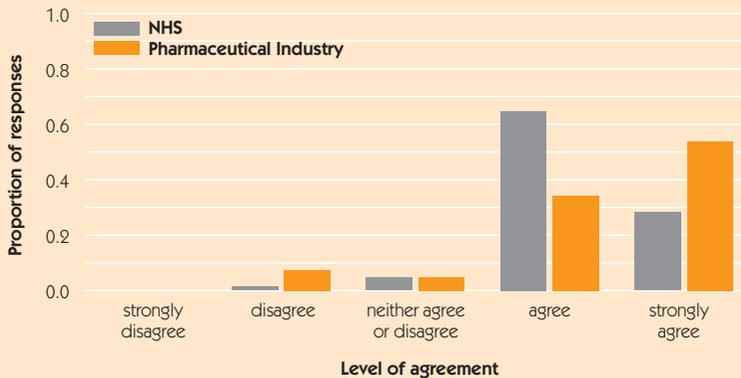
Data on the distribution of response for these two groups are shown visually (as bar charts of proportionate response) in this section (see Box 1.2, below), section 3.3.2 and section 3.3.4. On each chart is shown the median and mean scores for each group (assigning strongly disagree = 1 and strongly agree = 5).

The level of agreement between the pharmaceutical industry and the NHS, for each question, was assessed using the Mann-Whitney test.¹⁵ Since, in general, responses were not normally distributed, the Mann-Whitney test provided a non-parametric alternative avoiding any distributional assumption, by ranking and summing the responses. The null hypothesis was one of no difference between the response pattern of the NHS and that of the pharmaceutical industry. If $p < 0.05$, the null hypothesis was rejected indicating a statistically significant difference between the two patterns of response.

It should be noted that survey respondents' views may not be representative of others in the NHS and pharmaceutical industry. In particular, the

Box 1.2 Definitions of disease management... survey results

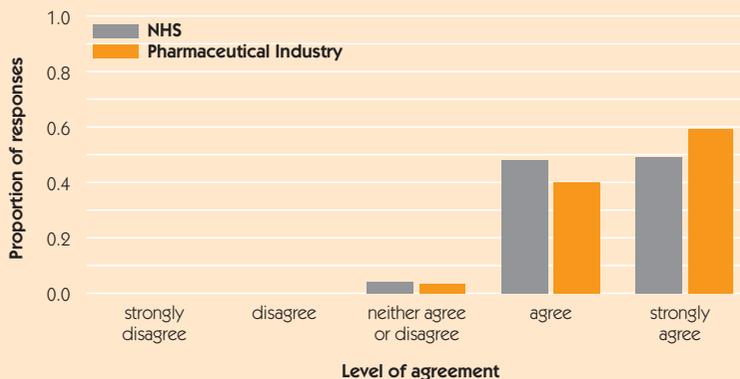
Figure 1.1 'Disease management' can include estimating the total costs of managing a disease



Note: Mean score, NHS: 4.2; PI: 4.3 Median score, NHS: 4; PI: 5 p (2-tailed) = 0.057

Figure 1.1 shows the response patterns to the question about disease management and the estimation of total cost. A large proportion of both the pharmaceutical industry (88 per cent) and of the NHS (94 per cent) agreed or strongly agreed that disease management can include estimating the total costs of managing a disease. Only 1 per cent of the NHS respondents and 7 per cent of the industry respondents disagreed with this notion. None strongly disagreed. The response patterns of the two groups were similar, but on the margin of showing a statistically significant difference, with $p = 0.057$. The difference that did occur between the two patterns of response was that a higher proportion of industry respondents agreed strongly with the notion.

Figure 1.2 'Disease management' can include the devising of clinical guidelines for managing a disease



Note: Mean score; NHS 4.5; PI: 4.6 Median score; NHS: 4; P: 5 p (2-tailed) = 0.302

There was no statistically significant difference in response patterns between the two groups shown in Figure 1.2. Both the NHS and the industry respondents overwhelmingly endorsed the notion that disease management can include the devising of clinical guidelines. Only 2 per cent respondents neither agreed nor disagreed with the notion and none disagreed or strongly disagreed.

response rate for the industry (51 per cent) limits the interpretability of the results.

Respondents were also asked to define disease management in their own words. Of all respondents, 83 per cent chose to do so. More than 72 per cent of these respondents referred to the use or gathering of information, evidence or data as being part of their definition. The integration of care, in terms of an approach that transcended traditional sectors, was part of the definition for over 70 per cent of respondents. However, only 8 per cent of respondents mentioned feedback or audit. The term 'quality' was used by under 7 per cent respondents. 'Cost' or 'cost effectiveness' was mentioned by almost one third.

1.3 Towards a working definition

From the survey results presented above, some conclusions about the concept of disease management may be drawn. The survey respondents indicated clearly that both the devising of clinical guidelines and the estimation of the total costs of a disease may safely be included in a definition of disease management. This supports views from the medical literature that a knowledge base, incorporating clinical and cost evidence, is a key feature of disease man-

agement. The survey question, in which respondents were asked to define disease management for themselves, also supported this concept. The emphasis found in some of the medical literature on the role of a feedback mechanism as an essential part of disease management was not mentioned by the majority of survey respondents. However, an emphasis on the application of comprehensive and reliable evidence could presuppose that audit procedures are part of this process.

Disease management would therefore appear to be a matter of common sense: it is the management of a disease, taking evidence on costs and clinical effectiveness into account and co-ordinating care accordingly. But if this is the case, then why does the term seem to attract such controversy? Wehrwein may be able to shed some light:

*The goal of disease management is clear enough... namely, to co-ordinate and manage the care of patients throughout the course of their disease. But as is so often the case, the devil of high-minded aspirations is in the details of their execution.*¹⁶

The role played by the pharmaceutical industry in disease management may explain the controversy. In the US, this has taken the form of ‘vertical integration’:

*Vertical integration can be viewed as the opposite of specialisation... (it) refers to the action of a firm moving into another processing or distributing stage... By companies managing the disease process... they have moved from their traditional manufacturing role into distribution, prescribing and other health care provision. Manufacturers transform themselves from pharmaceutical firms into health care firms.*¹⁷

Vertical integration by the pharmaceutical industry is what some people mean when they use the term ‘disease management’. This one facet – a potential offshoot – of disease management has become, for some, the exclusive meaning of the term. Of those respondents who defined disease management for themselves, 3 per cent used the term in this way and a further 5 per cent referred to the pharmaceutical industry as being a potential player. However, 4 per cent of respondents specifically excluded the industry from their definition! Respondents were also asked a number of questions to determine the nature of any industry involvement that they might class as a case of disease management. Almost 57 per cent of respondents agreed, or strongly agreed, that ‘disease management’ can include a pharmaceutical company offering a new type of service to the NHS. Whilst a small minority would define disease management as the involvement of a pharmaceutical company in health care provision, most would accept that the definition can include this notion. Comprehensive coverage of these survey results can be found in section 3.3.2.

We now consider the origins of disease management and of the involvement of the pharmaceutical industry in it.

SECTION 2 ORIGINS OF DISEASE MANAGEMENT

2.1 The American roots

Credit for the term ‘disease management’ is attributed to the Boston Consulting Group¹⁶. Working with managed care providers and pharmaceutical clients in 1991 on a study for Pfizer Inc., the Group claims to have ‘pioneered the development and dissemination of the disease management concept.’⁴ They define ‘disease management’ as:

*an approach to patient care that co-ordinates resources across the health care delivery system and throughout the life cycle of the disease.*⁷

If this definition is correct, then Burns argues that ‘disease management’ has existed for much longer:

Looked at in its widest sense, it is what the NHS has been doing for 40 years.
Burns, cited in reference 18

Hunter corroborates this view:

*We do ourselves a disservice in thinking of disease management as something wholly innovative. The language may be, but not the substance. Many of the concerns surrounding disease management, such as achieving integrated care across professional and inter-agency boundaries, have been with us for decades. Moreover, notions like case or care management... are not dissimilar to the principles behind disease management.*¹⁹

This may be true of the NHS; it is less obvious that the same can be said of health care in the US. Given that disease management ‘is an American import’¹⁹, its evolution can only be appreciated in the light of the workings of the US health care system. This involves an understanding of both Managed Care Organisations (MCOs) and Pharmacy Benefit Managers (PBM).

2.1.1 Managed care organisations (MCOs)

Iglehart defines managed care as:

*a system that, in varying degrees, integrates the financing and delivery of medical care through contracts with selected physicians and hospitals that provide comprehensive health care services to enrolled members for a predetermined monthly premium. All forms of managed care represent attempts to control costs by modifying the behaviour of doctors, although they do so in different ways.*²⁰

There have been three main reasons for the rapid development of managed care in the US this decade. These are presented in Box 2.1

Box 2.1 Reasons for the development of managed care

(1) An uncoordinated delivery system

Healthcare in the US was provided by an uncoordinated delivery system¹⁹ and funded in a pluralistic fashion via competing private insurance companies. There was a bias to acute treatment, neglect of preventative, chronic and long-term care²¹ and extensive evidence of variations in clinical practice.²² Inequality in health care coverage was rife, with insurance companies having an incentive to cover only those with a favourable risk profile. Lack of comprehensive coverage for many citizens and lack of coordination between different institutions and professionals had a detrimental effect on the cost and quality of care.

(2) Health care cost inflation

Up to and including the 1980s, private insurance companies retrospectively reimbursed physicians on a fee-for-service basis.²³ Incentives to over treat and to rapidly adopt new procedures are implicit in this method of payment and it is likely that this, and not the affluence of US citizens, (and hence their desire to consume more health care services), was responsible for the higher rates of medical intervention evident in the US. Furthermore, most patients did not pay directly for their health care but indirectly via their employee benefit package, and, with a free choice of practitioners, there was little incentive for them to consider cost when consuming health care.²⁴ Indeed, tax incentives encouraged the provision of generous benefit packages. The situation led some to conclude:

*Pluralistic funding for medical care has permitted and even fuelled the explosive growth of the US health care industry.*²⁵

Explosive growth in the volume and value of health care services consumed left many employers faced with rapidly rising health care premiums, adversely affecting their ability to compete in international markets and left employees facing cutbacks in coverage, or demands for higher out-of-pocket co-payments and deductibles. Following the failure of the Clinton reform proposals, it was commerce that exerted pressure on insurance companies to act to redress the spiralling inflation of health care costs. Managed care, although not a new concept, attracted a new level of interest as a possible solution to this problem.

(3) The unproven nature of many health technologies

Lastly, there was an increasing awareness of the lack of evidence for the effectiveness of many health technologies.²² The rapid adoption of new and expensive technologies was one of the factors fuelling cost inflation. This led to questions about the implications of use of clinically unproven technologies for payers and patients.

Managed care evolved in response to these problems, seeking to integrate a fragmented system and to replace the financial incentives to over consume health care resources with new management techniques, including the use of protocols and prior authorisation to control treatment and referrals, capitation funding and restrictions on the choice of physicians. Managed care takes a multitude of forms and has been described as an 'unintelligible alphabet

soup of 3 letter health plans'²⁶. These plans vary in the extent to which they are managed and in the degree to which financial risk is shared between the insurer and the provider. The Health Maintenance Organisation (HMO) has the longest history, the first having been created by Kaiser Permanente in 1942.²⁷ HMOs seek to integrate insurance and provision, offering comprehensive care, via contracts or direct provision, for a set premium.

2.1.2 Pharmacy benefit managers (PBMs)

The development of managed care ushered in a new role for Pharmacy Benefit Managers. Historically, PBMs had acted as claims administrators for plan sponsors, negotiating discounts from pharmacies (in terms of dispensing fees) and rebates from pharmaceutical company managers. However, it became apparent that discounts alone did not control cost: only one third of the increases in pharmacy benefits could be attributed to price inflation. Increased drug utilisation, inappropriate use of medications, and the high cost of some new drugs were blamed for the remaining increases.²⁸

Health Maintenance Organisations began to subcontract PBMs in a new role, namely 'managed pharmacy'. Formerly, plan sponsors had focused on the control of drug costs; they now began to use their extensive information systems to control additional medical expenditures. By combining medical and pharmaceutical claims data, information on an individual's health could be derived. This information could be used in a number of ways, such as for patient education, drug utilisation reviews (DURs) and physician profiling and education. Contact with physicians proved to be a stumbling block for the PBMs. A number of solutions to this problem were explored, including supplying physicians with protocol information via a computer network, managing or owning physician group practices and forming 'strategic alliances' with the pharmaceutical industry. A series of vertical integrations took place, which are summarised in Table 2.1.

These 'strategic alliances' have benefited PBMs in the form of funding and of access to pharmaceutical industry expertise, particularly in regard to facilitating communication with physicians. The advantages for the pharmaceutical company include access to the databases of pharmacy claims and an increase in the control of product distribution. By providing PBMs with the lowest prices, drug companies can be reasonably confident that their products will be formulary-preferred drugs.²⁸ We should, however, note that the Federal Trade Commission imposed a number of constraints on three pharmaceutical companies who purchased PBMs, requiring them to operate the PBM on an 'arm's length' basis. This may have reduced some of the benefits for the pharmaceutical companies.

Table 2.1 Strategic alliances between PBMs and the pharmaceutical industry

| <i>Date</i> | <i>PBM</i> | <i>Pharmaceutical company</i> | <i>Nature of relationship</i> | <i>Cost in US \$</i> |
|-------------|--|--|---|----------------------|
| July 1993 | Medco | Merck & Co. Inc. | Merck bought Medco | \$6.6bn* |
| May 1994 | Caremark International | Pfizer, Bristol Myers Squibb, RPR, Eli Lilly | Caremark 'formed alliances' with these four companies | N/A |
| May 1994 | Diversified Pharmaceutical Services (DPS) | SmithKline Beecham (SB) | SB bought DPS | \$2.3bn* |
| May 1994 | Value Health Inc. (incorporating ValueRx, a PBM) | Pfizer | 50-50 joint venture, Disease Management Sciences | \$100m |
| July 1994 | PCS Health Systems Inc | Eli Lilly | Eli Lilly bought PCS | \$4bn* |

N/A = not available.

*US billion.

Medco offers pharmacists financial incentives to provide patient education. *Medco* also provides patient information directly to diabetes sufferers.

Caremark International worked with its partners to develop disease management programmes, guidelines and formularies. Physician group practices can purchase *Caremark's* administrative services.

Diversified Pharmaceutical Services has grown from managing prescription drug benefits for 11 million covered lives at the time of acquisition to 26 million covered lives at the end of 1995. The *Diversified National Network* includes approximately 45,000 licensed pharmacies. SB is now selling DPS.

Disease Management Sciences was created by *Value Health Inc.* in partnership with *Pfizer* to establish networks of physicians and facilities to offer speciality disease management services to MCOs. Each party committed resources to capitalise the joint venture under the guidance of its Management Committee. No significant investments were made and the organisation no longer operates.

PCS Health Systems Inc. describes itself as a health solutions company. It manages and monitors 300 million individual prescriptions each year, for 56 million people, representing \$10 bn in drug expenditures. Employers, insurance companies and HMOs are among its customers that pay for health care products and services, such as health care information technology and advice on setting up disease management programmes.²⁹ *Eli Lilly* has now disposed of PCS.

2.1.3 Why did disease management evolve?

Coupled with the growth of managed care organisations (MCOs), the development of PBMs and their integration with the pharmaceutical industry resulted in a less fragmented health care system for the US. The effect on the US health system was

*to move from the historic model of individualistic, physician-based interaction to a more composite framework of care.*²⁵

However, this greater integration was bought at the price of a loss of freedom for certain parties as employers sought to keep down the growth in the premiums they paid on behalf of their employees. There were more restrictions on patients' choice of insurance cover (in particular requirements to pay more of the costs of the more generous benefit plans), but competition for patients between MCOs was strong. It is possible that MCOs might consider disease management, with its emphasis on chronic disease and patient-centred care, as a means to attract patients, although we found no evidence for this. Indeed it could also be argued that MCOs may not have wanted to attract patients with chronic diseases. Box 2.2 discusses which groups might benefit from the adoption of disease management.

There are other factors responsible for the popularity enjoyed by disease management in the US. In keeping with other countries in the Western world, there is an increasing proportion of elderly people in the population. This means that there is likely to be more chronic disease and consequently an upward pressure on health care expenditure. Disease management concentrates on chronic, high cost disease.⁷

*Organising health care delivery and financing along disease management lines is simply the best fit for most of what modern medicine does, which is not so much to rid a person of a disease as to favourably alter its course and stave off death.*¹⁶

Finally, the evolution of disease management has been made possible by modern developments in information technology. In both the area of guideline production and dissemination and in the area of cost and outcome measurement, computer networks facilitate the implementation and monitoring of a disease management programme.

2.2 Examples of disease management practised in the US

This section contains some instances of disease management programmes in the US. The pharmaceutical industry is involved in all but one example. This case involves CVS (Consumer Value Stores) Pharmacy Inc., which has over 4000 branches in 26 US states. The examples presented in Box 2.3 are not intended to give a comprehensive coverage of disease management in the US, but are the result of searches of the medical literature.

Box 2.2 Who needed disease management and why?

(1) The pharmaceutical industry

The advent of managed care threatened to put pressure on the profit margins of the pharmaceutical industry. According to Wehrwein,

the initial impetus for disease management came from pharmaceutical companies worried about selling to managed care organisations¹⁶.

MCOs 'require adherence to guidelines and can refuse to pay and drop clinicians from their plans if guidelines are ignored.'¹⁷ These guidelines restrict clinical freedom concerning, among other factors, the choice of drug a physician may prescribe. The emergence of PBMs (see section 2.1.2) threatened to put a further squeeze on drug companies profits.³⁰ A form of health care management that embraces a wider perspective on costs is more compatible with the drug companies' profit-making position. Furthermore, disease management may offer the pharmaceutical industry a means to diversify, offering new types of service.

(2) Managed care organisations

Managed care, or component management, yielded only 'modest achievements in reducing costs'.¹² In the first year of the decade, total health expenditure in the US grew by 12.7 per cent. By the mid-1990s, the increased use of managed care *appeared* to have stemmed this tide: the rate of growth of health expenditure had fallen to 5.3 per cent for the years for the years 1994-95. However, these figures belie the fact that total US health expenditure had risen by 41.7 per cent during this period. In 1997, despite a further slow down in the rate of growth of health expenditure, the US still had the highest per capita health expenditure in the world, at \$4,090, and 14.0 per cent of US GDP was spent on health care.³¹

Svensk sees disease management as 'a logical protest'⁷ against health care delivery systems which are not organised to deliver on either quality or cost objectives.

in contrast to managed care, where the focus is on the components of care, and the unit cost of each component is driven down by aggressive contracting and tight control of providers, disease management attempts to co-ordinate resources across the entire health care delivery system and throughout the life cycle of the disease.¹²

Disease management changes the perspective on cost control. Instead of managing cost by creating incentives and penalties to reduce particular cost components, a full range of costs is considered¹⁷ in an attempt to understand the relationship between cost components. (see section 1.1.1) Thus, disease management offers an alternative method of cost control for MCOs. A disease management programme can also help to supply information on patient satisfaction and outcomes, required from MCOs by the US National Committee for Quality Assurance (NCQA).

(3) Physician groups

Most MCOs no longer pay physicians by the traditional fee-for-service method, but rather by capitation. Capitation is a per-member per-month fee paid to health care providers with the aim of reducing the incentive to over-treat. Under capitation, the physician assumes a financial risk: should the patient require a higher cost of care than can be met by the capitation fee, then the insurance company will not cover those extra costs. Disease management, with its focus on the development and application of cost-effective guidelines, offered physicians the information on costs they needed to efficiently assume financial responsibility. In addition, familiarity with risk-bearing may have made some physicians more inclined to participate in a form of disease management such as the 'carve out', where full responsibility for care, with the associated risks, for a particular disease group is assumed.

Box 2.3 Instances of disease management in the US

CVS Pharmacy, Virginia

MedOutcomes Inc., an affiliate of McKesson Corp., conducted a study aiming to evaluate, in clinical and economic terms, the effect of pharmacist intervention in the community retail setting. Pharmacists from three of the chain of CVS pharmacies were trained to follow standardised practice guidelines in four target disease states (see Table 2.3). Competency in therapeutic, communication, assessment and monitoring skills was taught. Collaboration between the pharmacists and patients was achieved by an appointment system, in which patients and their drug therapy were assessed. This was held at the intervention pharmacies and was separate from drug distribution. Patient and drug information was then documented. Collaboration with physicians took the form of regular communication of this documented information. MedOutcomes Inc. randomly reviewed selected charts to maintain quality assurance. Insurance claim data were used to monitor health care costs. The results from the intervention group were compared with those from a control group of patients who attended one of five pharmacies where no pharmacist intervention was carried out. After adjusting for differences in the characteristics of the two groups, it was found that, for the intervention group, mean monthly *prescription* costs were higher, but mean monthly *total* costs were lower.³²

Disease management science

In May 1994, Value Health joined in partnership with Pfizer to form a \$100m 50-50 joint venture, a PBM called Disease Management Science.^{33,34,28} The venture aimed to investigate 400 disease states. Value Health was to offer information services to providers and Pfizer formed a partnership that could improve the use of its products through clinical protocols, other physician decision support tools and formularies.³⁴ However as noted above, no significant investments were made and the organisation no longer operates.

Intergroup of Arizona

Intergroup is one of the largest HMOs in Arizona with an enrolment of 310,000. In November 1993, Intergroup, together with Eli Lilly, made one of the earliest attempts at risk sharing between an MCO and a pharmaceutical company. After six months of intensive negotiations, targets for reducing per-member per-month costs were agreed. The risks or benefits associated with meeting or exceeding these targets were to be shared. By this means, it was hoped that a 'win-win' situation would emerge, enabling 'both sides' incentives to mesh as much as possible.³⁵

The infectious disease programme was in two stages. Protocols were drafted, with input from the MCO physicians and from the University of Arizona, for eight infectious disease states. The aim of the programme was physician education, in particular the promotion of appropriate drug use by changing prescribing behaviour from second-line to first-line antibiotics. To achieve this, the sales force and disease management specialists were then re-trained 'to talk about treatment guidelines and disease states rather than products.'³⁵

Treatment algorithms, focused on patient outcomes, were developed to determine the effects of the antibiotic changes. The university helped to merge medical and pharmacy claims databases to enable outcome assessment. Intergroup believe the results to be encouraging:

Strategies that had formerly been the domain of a pharmaceutical company or an MCO were now being planned jointly... a focus on disease state rather than pharmaceutical product has resulted in the win-win situation.³⁵

MedImpact pharmaceutical management

MedImpact is a PBM with almost 800,000 members, of which 28,000 are asthma patients. In partnership with a pharmaceutical company, its asthma programme aims to lower total expenditures, improve the quality of care and engage 'previously passive patients.'³⁶ DaSilva comments:

When a pharmaceutical company gets involved in a co-operative program for drug use, risk sharing can be very useful to ensure that both parties benefit, by promoting appropriate use as opposed to increase drug sales.³⁶

Following an analysis of their patient population, MedImpact sought to identify efficient managers of asthma, taking the premise that 'physicians learn from other physicians' and that rather than trying to impose guidelines from above, these efficient managers could become the educators and leaders. Representatives of the programme's 'pharmaceutical partner' communicated guideline information. The programme's progress was assessed through the monitoring of average cost of care per member, acute episodic rates, severity migration, appropriate drug use and member satisfaction.

SalickNet

In 1993, SalickNet signed America's first cancer carve-out contract. Through a contracted health care delivery system, cancer-related care was provided on a capitated basis. In April 1996, SalickNet formed a partnership with Saint Vincent's Hospital and Medical Center in New York. A comprehensive cancer centre was established under Saint Vincent's operating certificate, with a managed care affiliated network in greater New York. By September, Salick was operating 11 comprehensive cancer centres³⁷, 7 diagnostic and treatment breast centres and 10 outpatient dialysis centres around the US.¹⁸ The provider network also includes nursing homes and home care programmes. Salick Health Care centres are open all hours and offer a comprehensive array of outpatient diagnostic and treatment services. Psychosocial services, a 24-hour help line and the opportunity to participate in clinical trials are also available. Patients requiring inpatient services are referred to an affiliated hospital, whose physical assets of existing oncology services Salick will generally own.^{33,34} These services are provided to MCOs, insurers, primary care physician networks, business coalitions and self-funded employers.³⁷

SalickNet believes itself to be in 'the business of improving the quality of life of our patients and, hopefully, their survival.'³⁷ Salick itself collects clinical outcome data and attempts to measure quality of care and patient satisfaction. An independent survey, carried out on SalickNet Florida patients, found that 83 per cent reported their cancer care was very good to excellent compared to 58 per cent in similar groups. Since conventional managed care generally 'produces low patient satisfaction ratings'³⁸, SalickNet would appear to be using a more patient-friendly approach. SalickNet explain their success with reference to factors such as the creation of an Integrated Delivery System, the focus on 'value' (cost-effective care) and the 'continuous and ongoing efforts to improve the existing system'³⁷, which includes the provision of a computerised database to inform providers on the latest cost, outcome and guideline

evidence. Interestingly, to improve the integration of the delivery of care through a re-alignment of incentives, SalickNet has replaced the capitation system of payment with a modified fee-for-service payment structure.³⁷

Stuart Pharmaceuticals (Zeneca)

Stuart Pharmaceuticals (Zeneca) offered a range of 'free' additional services alongside its selective beta-blocker (atenolol) and its ACE-inhibitor (lisinopril) in the treatment of hypertension. The Wellspring package consisted of lifestyle and 'healthy' food information for patients and follow-up checks on repeat prescriptions.¹³ Stuart Disease Management Services (SDMS) is a disease management company set up by, but working independently from, Zeneca. SDMS's performance is assessed by the income it earns from disease management activities, not by its impact on drug sales.

In these examples, the role of the pharmaceutical industry is one of *enabling*: the industry has moved from its traditional role of supplying pharmaceuticals to offering provider support (see section 1.1.2). Companies have supported providers financially and with re-orientated communication skills, whereby messages given by company representatives have been about protocols and appropriate use, rather than about the promotion of a particular drug. Table 2.2 summarises this information.

This change in approach is particularly well demonstrated in the case of SalickNet. Zeneca has had a financial interest in Salick Health Care Inc., of which SalickNet is a managed care subsidiary, since 1994³³. However, Zeneca realised,

*that if the credibility of the cancer care service provided by Salick was to be preserved, it should not seek preferential use of its anticancer drugs and it should be extremely cautious before letting Zeneca staff run loose in the company.*³⁹

By acquiring Salick, Zeneca has gained access to the 94 per cent of the US cancer market that is not related to drugs. It may be unlikely that Zeneca will find this 'diversification' profitable in direct financial terms; the benefits that accrue are more likely to be synergistic in character:

*Through Salick, Zeneca is definitely getting closer to its customers and their interests and is looking for solutions which are of mutual advantage... unless a company has a long-term commitment to a therapeutic area, there is little point in it even putting its toe in the managed care pond.*³⁹

Even though SalickNet is a case of *carve-out* disease management, its pharmaceutical partner is acting in the *enabling* role of provider support. Likewise, CVS Pharmacy Inc. demonstrates a shift from 'a product-orientated to a more patient-focused approach'³² for the pharmacy profession. In this

Table 2.2 US examples of disease management: The role of the pharmaceutical industry

| <i>Name and type of organisation</i> | <i>Year begun</i> | <i>Disease area(s)</i> | <i>Pharmaceutical company involved</i> | <i>Form of disease management: role of pharmaceutical company</i> |
|--|-------------------|------------------------|--|---|
| Disease Management Science: PBM | 1994 | 400 disease states | Pfizer | enabling: financial support |
| Intergroup: HMO | 1993 | 8 infectious diseases | Eli Lilly | enabling: communication, financial support |
| MedImpact: PBM | n/s | asthma | n/s | enabling: communication, financial support |
| SalickNet: managed care subsidiary | 1993 | cancer | Zeneca | enabling: financial support |
| Stuart Pharmaceuticals: disease management company | n/s | hypertension | Zeneca | enabling: communication |
| n/s = not stated. | | | | |

case, the participating pharmacies took an enabling role, communicating patient education and liaising with physicians.

To what extent can these examples be described as cases of ‘disease management’, with reference to the conclusions reached in section 1.3 of this report? If disease management is defined as pharmaceutical industry involvement in health care, then all but one qualify. However, if we take a more general view, we might want to consider whether these examples integrate care, how they involve the gathering and application of evidence and the emphasis they place on audit. Table 2.3. summarises the extent to which these three aspects of disease management are present in the cases considered.

Only two cases appear to include all three criteria, namely SalickNet and CVS Pharmacy. The latter improved integration of care through feedback to physicians of documented drug and patient information. SalickNet has an ‘Integrated Delivery System’: integration of care was the motive of founder,

Table 2.3 US examples of disease management: The nature of the disease management programmes

| <i>Name and type of organisation</i> | <i>Year begun</i> | <i>Disease area(s)</i> | <i>Type of care</i> | <i>Integration of care</i> | <i>Knowledge base</i> | <i>Monitoring and audit</i> |
|--|-------------------|--|-------------------------------------|----------------------------|-----------------------|-----------------------------|
| CVS Pharmacy Inc.: National Pharmacy chain | 1993 | asthma, diabetes, hypercholesterolemia, hypertension | patient education | ✓ | ✓ | ✓ |
| Disease Management Science: PBM | 1994 | 400 disease states | physician education | n/s | ✓ | n/s |
| Intergroup: HMO | 1993 | 8 infectious diseases | physician education | × | ✓ | ✓ |
| MedImpact: PBM | n/s | asthma | physician education | × | ✓ | ✓ |
| SalickNet: managed care subsidiary | 1993 | cancer | outpatient: diagnosis and treatment | ✓ | ✓ | ✓ |
| Stuart Pharmaceuticals: disease management company | n/s | hypertension | patient education | × | ✓ | ✓ |
| n/s = not stated × = not part of disease management programme ✓ = part of disease management programme | | | | | | |

Dr Bernard Salick, in response to his young daughter's experience of highly fragmented cancer care. SalickNet also documents clinical outcome data and patient satisfaction and runs a computerised database to inform providers on the latest cost, outcome and guideline evidence. In all the other examples presented here, the integration of care does not appear to have featured. However, these programmes concerned themselves with *part* of the health care system, whereas SalickNet is an example of a comprehensive service. It is possible that by improving physician compliance with a certain protocol, the effects of one sector's care on another's is implicitly acknowledged.

With the possible exception of Salick, evaluation of these instances of disease management has been inadequate, although guidance on the evaluation of disease management programmes is readily available in the medical literature.^{40,41} The interpretation of the trials described for MedOutcomes, MedImpact and Intergroup is fraught with difficulties. Confounding is a particular problem in the design of study used. Without randomisation, it is uncertain whether the changes observed can unambiguously be attributed to the disease management initiatives as opposed to other factors. In the absence of blinding, which is impossible in studies of this nature, some improvements may be reported not because the disease management initiatives are really better, but because those involved *believe* they are better. Therefore, it is important to identify objective indicators of service improvement, if the true cost effectiveness of disease management is to be evaluated.

SECTION 3 THE RELEVANCE OF DISEASE MANAGEMENT TO THE NHS

3.1 How has disease management developed in the UK?

The fragmented health care system of the US is very different from the British NHS. Financing and delivering care in the NHS is the responsibility of the public sector and, in a sense, the *financing* of care has always been externally 'managed' by this third party³⁰: specialists are paid a salary and GPs are paid largely on a capitation basis. While 'patients have restricted choice of hospital specialists and, realistically, of GPs'²⁷, there is little evidence of third-party management of the *delivery* of care.

The magnitude of health care costs differs dramatically between the two countries. In 1997, the UK per capita health expenditure was only 35.6 per cent of that spent by the US; in the same year, the UK spent 6.7 per cent of its GDP on health care, less than half the rate in the US.⁴² Over the decade, however, the *rate of growth* of total health care expenditure, as a percentage of GDP, has been similar in the two countries. In addition, the NHS may be subject to many of the pressures facing the US health care system:

*The forces for change appear overwhelming. The pressures from demographic change, developments in medicine, consumerism, information technology and a general re-thinking of welfare will continue to create a very different health service in the future.*⁴³

Changes in both the supply and demand sides of health care 'are likely to result in an unprecedented pressure on finite resources'⁴³, although the present government believes that 'the pressures on the NHS are exaggerated.'⁶

Is it possible that disease management, with its emphasis on the cost-effective treatment of chronic conditions, with the use of evidence-based clinical guidelines and the integration of care could be a useful management tool, enabling the NHS to be both more efficient and able to assess priorities more effectively in order to adapt to this 'unprecedented pressure'? Could it offer a means to assist in cutting the health care coat to fit the NHS budget cloth? To attempt an answer to these questions, we need to consider the relevant political background of the NHS.

3.1.1 The political background

The reforms of 1991, with the creation of an 'internal market' embodying the purchaser/provider split³⁴, appeared to move the NHS away from a managed care model in which the finance and delivery of care are integrated.²⁷ However, in practice, this was not the case: the creation of GP fundholders in

part reunited the roles. Managing a budget for the costs of the practice staff, drugs, community nursing services and for certain hospital referrals, fundholders were similar to 'a mini HMO'.²⁷ Certain problems persisted within the NHS.¹⁹ Care between primary, secondary and community sectors remained unco-ordinated, particularly in the interface between health and social services. Incentives to practise 'cost-shifting' were the unfortunate consequence. A bias towards acute care was accompanied by poorly integrated chronic care, especially in the case of elderly people.

Intended to integrate the purchasing and provision of primary and secondary care, the Health Authority Act of 1995 saw the merger in England of the District Health Authorities (DHAs) with the Family Health Service Authorities (FHSAs), resulting in about 100 Health Authorities (HAs). The White Paper, Choice and Opportunity (1996) accelerated the move to a primary-care driven NHS. An increasing range of services and improving facilities were to be made available, with new opportunities for primary care teams to 'develop their practice to the benefit of their patients.'⁴⁴ Devolution of decision making to local level was further enhanced by the advent of 'total fundholders'. Total fundholders, or Total Purchasing Projects (TPPs), consisted of groups of GPs, who together *could* purchase all their patients' health care needs.²⁷ Introduced in April 1996, the TPPs bore an even closer resemblance to HMOs than ordinary fundholding, having similar incentive and risk-bearing structures. Sandifer observed that 'it is only a small step from total purchasing to an NHS HMO'.¹² In practice, however, TPPs rarely exercised their full purchasing powers.

The last Conservative White Paper, A Service with Ambitions, was published in November 1996.⁴² Of the five key objectives that were outlined, a 'seamless service' and 'knowledge-based decision making' appeared to echo the rhetoric of disease management:

A seamless service is one where services which individuals need are co-ordinated and integrated across the health and social care system, including primary care and social care. In a seamless service ... all staff are trained to work in multi-professional teams, and there is support in working across organisational boundaries. (p28)

The 'patient with the disease' was not explicitly stated to be the cornerstone for this integration; however, the aim of 'a responsive service... that is sensitive to the needs and wishes of patients' would suggest that this was the case. 'Co-operation in joint audits and guideline development' was also cited as a feature of a seamless service. Reinforcing this was 'knowledge-based decision making', which involved the NHS in 'evaluating and assessing both new technologies and existing practice' and ensuring 'that professionals in all disciplines routinely review their performance and are able to bring the most effective practice into general use.'

In their December 1997 White Paper for the NHS⁶, the new Labour government resolved that:

the internal market will be replaced by a system we have called 'integrated care', based on partnership and driven by performance. It forms the basis for a ten year programme to renew and improve the NHS through evolutionary change.(p5)

The paper describes 'a new model for a new century'. Arguing that the internal market reforms of 1991 caused 'little strategic co-ordination' 'unfairness for patients' and 'a fragmented NHS', the government claims that fragmentation 'has lost the NHS the cost advantages that collaboration can bring. Co-operation and efficiency go hand in glove'. Co-operation, then, is to replace competition, brought about by a bewildering number of new bodies, armed with a glittering array of newly labelled concepts. There is mention not only of integrated, patient-centred care, but also of evidence-based guidelines (to be produced and disseminated by the National Institute of Clinical Excellence), National Service Frameworks and the establishing of 'quality improvement processes' in line with the new concept of 'clinical governance'. Disease management would appear to have very much survived the changes in political climate.

3.2 Can disease management be implemented in the NHS?

In the White Paper, *The New NHS: Modern, Dependable* (December 1997)⁶, disease management is described in all but name. There are a number of factors that will be crucial to successful implementation. What sort of knowledge base of clinical and cost data can the new organisations construct? Is the existing evidence of sufficient quality to meet the requirements of disease management? Some believe not:

*The majority of interventions are unproven in terms of effectiveness, and few interventions have an established evidence base in terms of cost effectiveness.*¹⁷

This is not *per se* an obstruction to producing guidelines. If there is insufficient evidence for the cost effectiveness of an intervention, the guideline may simply state this and allow the physician to exercise his clinical freedom in delivery of care. However, if disease management relies on an understanding of the 'economic structure' of the disease in order to achieve greater cost effectiveness in delivery, then an inadequate knowledge base could curtail disease management's delivery potential. The implementation of guidelines involves another set of difficulties. Guidelines have usually, in the NHS, been considered to be advisory (see section 1.1.3). Legislation will give NHS Trusts 'a new duty for the quality of care', overseen by the new 'Commission for Health Improvement'. This will be fashioned by the concept of 'clinical gov-

ernance', which aims 'to assure and improve clinical standards at local level throughout the NHS.'⁶ Productive efficiency is to be monitored through the new National Schedule of Reference Costs. Will 'clinical freedom' rise to resist the challenge? What are the incentives for health professionals to cooperate to produce integrated care or to comply with the administrative requirements of monitoring and audit? The government proposes that

*there will be a new statutory duty of partnership placed on local NHS bodies to work together for the common good.*⁵ (p26)

It remains to be seen exactly how this 'statutory' duty will work out in practice. A restructuring of care could itself create the fragmentation it was designed to resolve. For instance, National Service Frameworks (NSFs) are to be developed for major care areas and disease groups, beginning with mental health and ischaemic heart disease. Following the approach adopted in the Calman Hine Cancer report, which addressed the issue of the reorganisation of cancer services, NSFs aim to ensure a greater degree of national consistency in service provision. Care must be taken to ensure that such speciality services retain enough flexibility to manage the individual with multiple or complex diseases. The government believes that 'tailoring the NHS to meet the needs of individual patients'⁶ is an attainable goal. This will, in part, be facilitated by Primary Care Groups, which will be able commission care and

*have the opportunity to deploy resources and savings to strengthen local services and ensure that patterns of care best reflect their patients' needs.*⁶ (p37)

Time will tell how successfully disease management can be implemented; whether or not successful implementation yields cost-effective care remains to be seen. Whatever the difficulties and disadvantages of implementing disease management within the NHS, the potential for the pharmaceutical industry involvement raises a number of additional issues and concerns.

3.3 Viewpoints on the potential for pharmaceutical industry involvement in disease management

Joint disease management ventures between the NHS and the pharmaceutical industry are perceived in a variety of lights. In this section, we examine the views of the government, our NHS and pharmaceutical industry respondents and, lastly, the pharmacists. We conclude with viewpoints on the barriers to the growth of disease management within the NHS.

3.3.1 The views of the government

In December 1994, the UK government recognised that the 'joint venture' type of disease management, which 'stems from the concepts of Pharmaceutical Benefit Management (PBM)'⁴⁵, was beginning to develop in

the UK. These deals took the form of companies offering *to provide services to help support the effective delivery of health care locally... these are often coupled with financial discounts or other incentives. In return, the company usually seeks some form of exclusive supply agreements for its and other companies' products and access to local NHS data... It may also seek some form of preferential use for its own products (para 3).*⁴⁵

In the executive letter, EL(94)94 'Commercial approaches to the NHS regarding Disease Management packages'⁴⁵, the government clarified its position with respect to such deals. Although 'in principle, there is no opposition to collaboration between the companies and the NHS' (para 6), in practice, the green light was not given.

*While wishing to support innovation and encourage developments which improve cost-effective prescribing in the NHS, purchasers and NHS authorities must not make commitments to purchase drugs which exclusively link prescribing to a particular company's products (para 1).*⁴⁵

The government's reservations went further, ruling that

*Health Authorities and other NHS bodies who choose to do so may continue to work with the companies to explore the possibility of mutually beneficial partnerships. However, it should be made clear to the companies that at present NO deals are possible and there is no guarantee that they will become so (para 8).*⁴⁵

This executive letter had an expiry date of June 1996, but it remains in force and no revised guidance has been put in place. Early in 1996, the government had issued a working document for comment, which included the caveat that clinicians should not commit themselves to exclusive use of a company's products. A further draft of a working document, a Discussion Paper entitled 'Partnerships with Industry for Disease Management: General Approach', was issued in September 1996.⁴⁶ In this document, the government set out the criteria that would have to be met if 'joint ventures' were to be agreed. These included the identification and resolution of potential conflicts of interest, the protection of patients' interests, including confidentiality in the treatment of patient information, and the assurance that such deals were both legal and represented value for money. Furthermore, accountability for the services lay with the NHS and all deals were to be monitored and evaluated.

There have been no further documents issued on the subject of joint disease management ventures since this one. However, at the launch of the White Paper, *A Service with Ambitions*, in November 1996⁴⁴, Stephen Dorrell, the then Secretary of State for Health, made a statement on the subject. Plans for any joint disease management packages would have "to pass two tests: that they are clinically robust and that they would have cost benefits for the NHS. They would need to be independently audited on both those counts".⁴⁷

The present government has not revised policy in this area. Some ambi-

guity therefore remains between, on the one hand, the hurdles set out in EL(94)94 and in the later working documents, and, on the other hand, the blanket ban on deals also contained in EL(94)94. The hurdles can, in principle, be overcome with appropriate contractual arrangements. The ambiguity may perhaps be resolved by reference to the statement in EL(94)94 that the 'issues must be considered nationally before any local agreements are made between the NHS and the pharmaceutical companies (para 4)'. It could be argued that such consideration has taken place and hence the statement that 'at present NO deals are possible' (para 8) (our emphasis) is no longer applicable. In practice, EL(94)94 seems to be being interpreted by Health Authorities in a way that takes account of the clarification subsequently made in the working documents and ministerial statement. The key assumptions seem to be that no preferential treatment must be given to a company's products; that the NHS is accountable for any services provided; and that there must be benefits to the NHS that exceed any costs incurred.

The Labour Government's White Paper⁶ describes how 'practice nurses are taking on new disease management roles', but does not directly address the issue of joint ventures. However, the whole tenor of the document centres on the theme of the *integration* of care, both within the NHS and between the NHS and others. Does the pharmaceutical industry come into the bracket of 'others'? The Paper is silent on this issue: the pharmaceutical industry is not mentioned, either for the purposes inclusion or for exclusion. Local Authorities, the public and 'other partner organisations' are to assist health professionals in the production of Health Improvement Programmes (HIMPs). Health Action Zones (HAZs) were created 'to release local energy and innovation'⁴⁸ and will 'bring together organisations within and beyond the NHS to develop and implement a locally agreed strategy for improving the health of local people'.⁶ Primary Care Groups (PCGs) will have the resources 'to commission and provide services'. This 'devolved commissioning' will allow PCGs the freedom 'to make choices about cost-effective patterns of services and... to switch resources over time to support them'. However, there remains the legal constraint that doctors cannot be employed by non-NHS bodies if they are to work within primary care. They must be independent contractors or NHS employees. This means that subcontracting NHS services to private sector bodies employing doctors is not an option for the PCGs.

3.3.2 The views of the NHS and of the pharmaceutical industry

In our disease management survey (see Appendix 1), we asked respondents to give us their views on the role a pharmaceutical company might play in a joint venture, that could be classified as 'disease management'. For the purposes of comparison, the results are summarised in Table 3.1.

Table 3.1 Percentage of respondents agreeing or strongly agreeing that disease management can include different roles for a pharmaceutical company

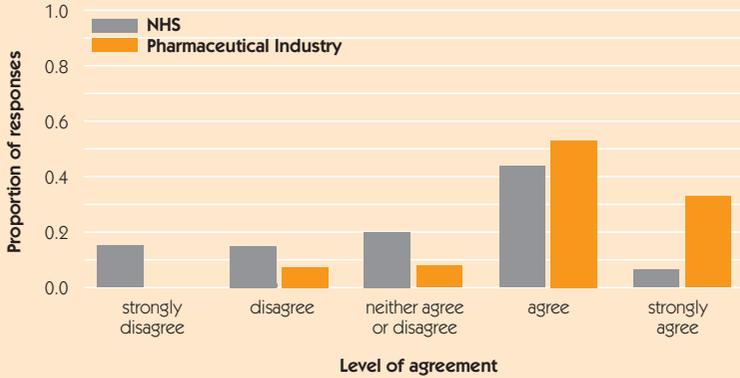
| <i>Respondents</i> | <i>Role of pharmaceutical company</i> | | | | | |
|--|---------------------------------------|---------------------|---------------------------|-------------------------------|---|---------------------------------------|
| | <i>Offering a 'package' of care</i> | <i>Risk sharing</i> | <i>Building relations</i> | <i>Encouraging innovation</i> | <i>Tailoring promotional activities</i> | <i>Offering a new type of service</i> |
| NHS | 50% | 40% | 42% | 42% | 33% | 47% |
| Pharmaceutical industry | 86% | 62% | 66% | 73% | 47% | 75% |
| All respondents | 62% | 48% | 50% | 53% | 38% | 57% |
| Statistical significance* | ✓ | ✓ | ✓ | ✓ | ✗ | ✓ |
| *Presence of a statistically significant difference in a comparison of the distribution of response patterns of the NHS and pharmaceutical industry (at $p < 0.05$ using Mann Whitney U test). | | | | | | |

The results of the survey are presented in detail below in Box 3.1, giving the respondents' range of opinion. A statistically significant difference was found between the views of the NHS and pharmaceutical industry response patterns to all the questions about a pharmaceutical company's role, with one exception. Details of the survey respondents and response rates can be found in section 1.2.

In general, it can be seen that the NHS was decidedly less enthusiastic in its endorsement of such activities, while the industry respondents indicated a higher level of agreement in each of these questions. However, despite the levels of agreement expressed in response to these particular questions, when asked to define disease management for themselves, 1 per cent of NHS respondents and almost 10 per cent of industry respondents referred to a 'partnership' between the NHS and the pharmaceutical industry in their definition. However, 4 per cent of respondents (all NHS) specifically *excluded* partnerships with the industry in their definition. These would suggest that, for the majority of both groups of respondents, 'joint ventures' are a possible, but by no means a necessary, expression of disease management.

Box 3.1 Potential for pharmaceutical industry involvement: survey results

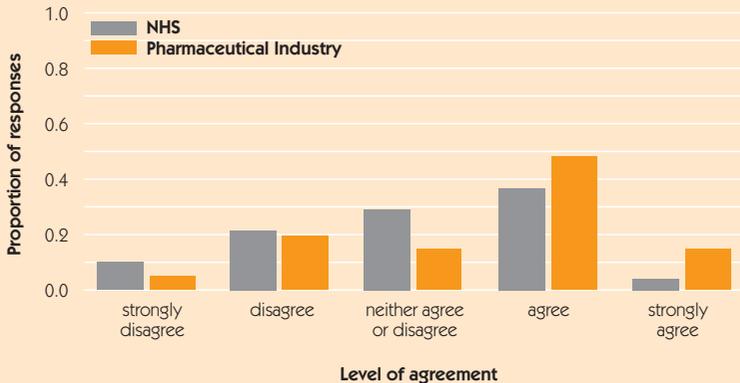
Figure 3.1 'Disease management' can include the supply of a 'package of care' by a pharmaceutical company



Note: Mean score, NHS: 3.1; PI: 4.1 Median score; NHS: 4; PI: 4 p (2-tailed) < 0.05

Half of the NHS respondents and 86 per cent of the industry respondents agreed or strongly agreed that 'disease management' can include the supply of a 'package of care' by a pharmaceutical company. Whilst none of the industry respondents strongly disagreed with this notion, 15 per cent of the NHS respondents took this view.

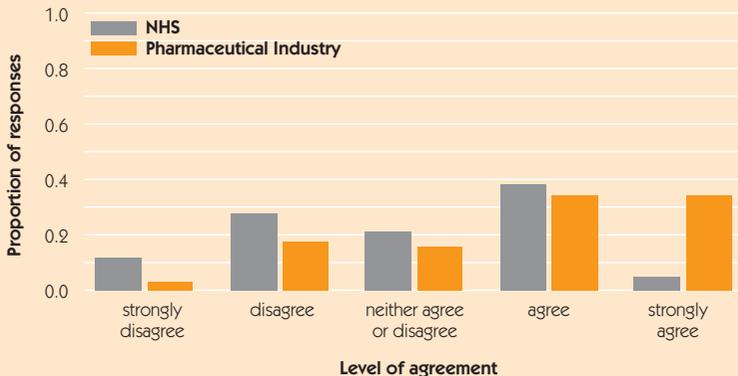
Figure 3.2 'Disease management' can include the determination of risk sharing agreements between a pharmaceutical company and the NHS



Note: Mean score, NHS: 3.0; PI: 3.5 Median score; NHS: 3; PI: 4 p (2-tailed) = 0.024

Just under half (48 per cent) of all respondents indicated that they would agree or strongly agree with this statement. A higher percentage of industry respondents (62 per cent) endorsed this view. Just under 30 per cent of all respondents disagreed or strongly disagreed with the statement, with NHS respondents forming a higher percentage in both categories.

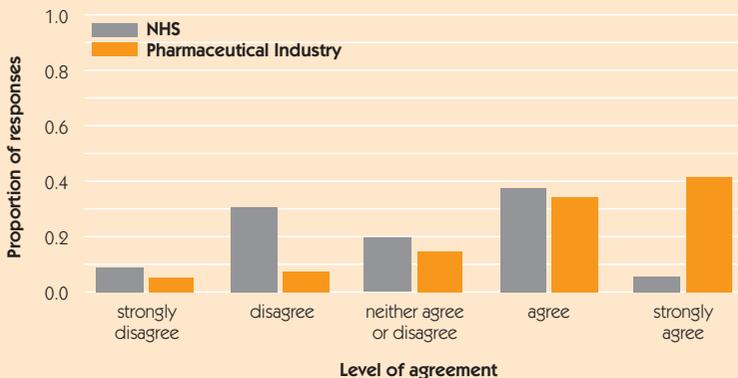
Figure 3.3 'Disease management' can include a pharmaceutical company building relationships with customers



Note: Mean score; NHS: 3.0; PI: 3.8 Median score; NHS: 3; PI: 4 p (2-tailed) < 0.05

Over half of all the respondents agreed or strongly agreed with this statement, with two-thirds of the industry respondents expressing agreement. Of all respondents, just under one-third disagreed or strongly disagreed with the statement, with almost 40 per cent of NHS respondents taking this view. The response patterns of the two groups showed a statistically significant difference.

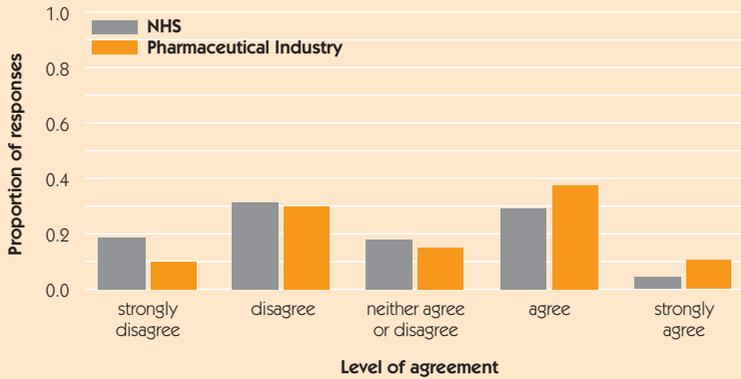
Figure 3.4 'Disease management' can include a pharmaceutical company encouraging innovation in health care



Note: Mean score; NHS: 3.0; PI: 3.8 Median score; NHS: 3; PI: 4 p (2-tailed) < 0.05

Whereas 40 per cent of industry respondents strongly agreed that disease management can include a pharmaceutical company encouraging innovation in health care, only 5 per cent of NHS respondents did so. However, 37 per cent of NHS respondents agreed with the statement as did a further 33 per cent of industry respondents. Of those disagreeing with the statement, NHS respondents formed a substantially higher proportion.

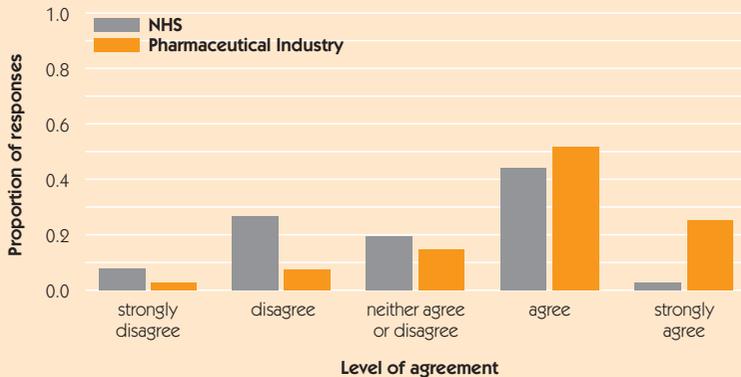
Figure 3.5 'Disease management' can include pharmaceutical company tailoring promotional activities



Note: Mean score; NHS: 2.7; PI: 3.1 Median score; NHS: 3; PI: 3 p (2-tailed) = 0.090

The presence of a statistically significant difference in the distribution of response patterns was not detected in this case. Just under half (46 per cent) of all respondents disagreed or strongly disagreed with the notion that disease management can include the tailoring of promotional activities; almost 40 per cent of all respondents agreed or strongly agreed and 17 per cent neither agreed nor disagreed.

Figure 3.6 'Disease management' can include pharmaceutical company offering a new type of service to the NHS



Note: Mean score; NHS: 3.1; PI: 3.9 Median score; NHS: 3; PI: 4 p (2-tailed) < 0.05

This question was designed to poll opinion on the issue of vertical integration on the part of the pharmaceutical industry. A majority of industry respondents (75 per cent) agreed or strongly agreed that disease management could include this activity and just under half (47 per cent) NHS respondents did so. A greater proportion (34 per cent) of NHS respondents disagreed or strongly disagreed with the statement compared with only 9 per cent of the industry respondents.

3.3.3 Barriers to the growth of disease management in the UK

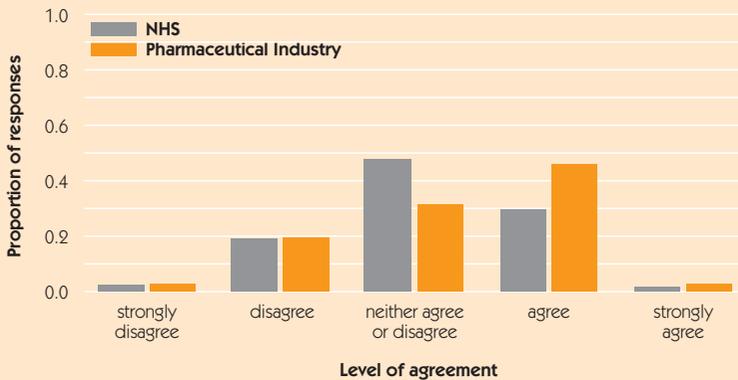
Our disease management survey attempted to identify which barriers are seen to be significant to the growth of disease management in the NHS by the NHS and the pharmaceutical industry. The results of the survey are presented in Box 3.2.

The two groups of respondents were very similar in their response patterns in their views on most of these barriers, with a statistically significant difference in the response patterns apparent in only two cases. This can be seen in Table 3.2 below.

Although 'NHS suspicion of pharmaceutical companies' was the most frequently cited barrier to the growth of disease management in the NHS, the difficulty in drawing up contracts between the NHS and the pharmaceutical industry came a close second and is a related issue. A number of papers on disease management contracts have been published in the US literature.^{49,40} The contract must identify and resolve potential conflicts of interests between the two partners, which will include taking due account of the issues of

Box 3.2 Barriers to the growth of disease management in the NHS: survey results

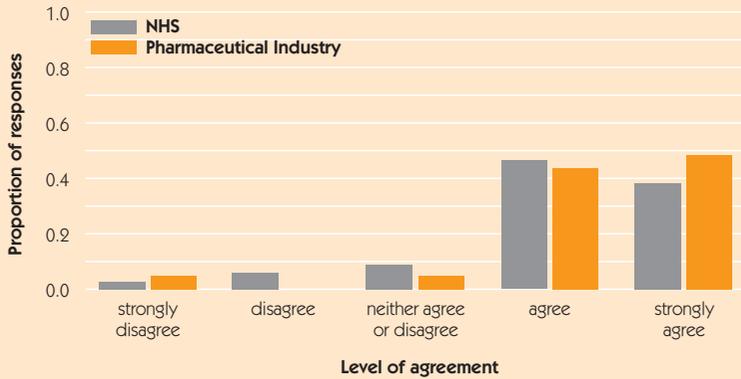
Figure 3.7 Disease management is not increasing in the NHS because there is government reluctance



Note: Mean score; NHS: 3.1; PI: 3.3 Median score; NHS: 3; PI: 3 p (2-tailed) = 0.191

Almost one half (47 per cent) of the industry respondents agreed or strongly agreed that government reluctance was a barrier to the increase of disease management within the NHS. The comparable figure for NHS respondents was 30 per cent. Under 3 per cent of all respondents strongly disagreed with this notion and a further 19 per cent of both respondent groups disagreed.

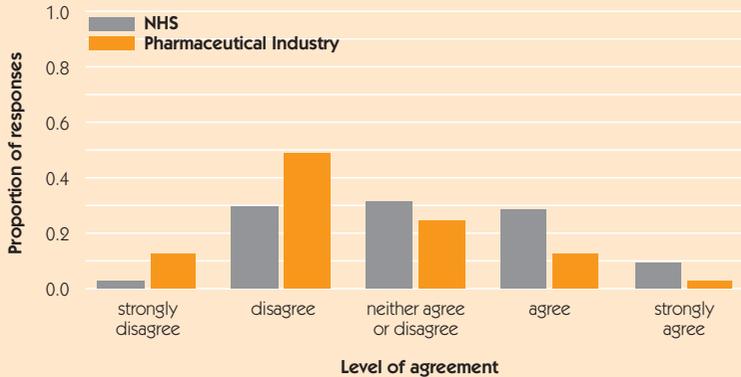
Figure 3.8 Disease management is not increasing in the NHS because there is NHS suspicion of pharmaceutical companies



Note: Mean score; NHS: 4.1; PI: 4.3 Median score; NHS: 4; PI: 4 p (2-tailed) = 0.935

The NHS and industry respondents were in agreement on their views on this statement, the results showing no statistically significant difference in the response patterns of the two groups. 'NHS suspicion of pharmaceutical companies' was cited as being a barrier to the growth of disease management by 86 per cent of respondents. Only 7 per cent of respondents disagreed or strongly disagreed with this statement.

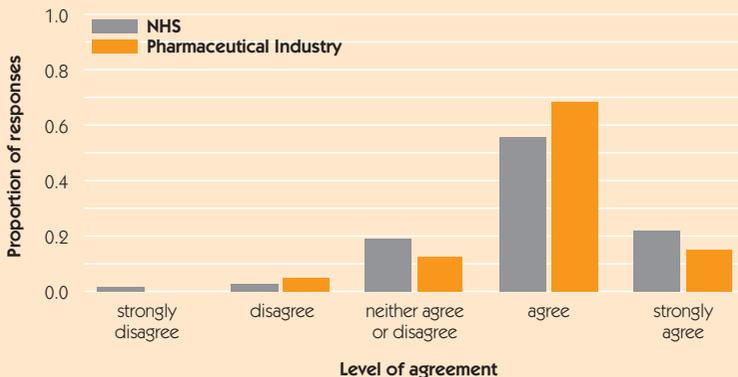
Figure 3.9 Disease management is not increasing in the NHS because the pharmaceutical industry lacks the skills to help the NHS in disease management



Note: Mean score; NHS: 3.1; PI: 2.4 Median score; NHS: 3; PI: 2 p (2-tailed) = 0.001

When asked if the pharmaceutical industry's lack of skill to help the NHS presented a barrier, only 14 per cent of the industry respondents agreed, compared with 37 per cent of the NHS respondents. One-third of NHS respondents disagreed or strongly disagreed with the statement, whilst the comparable figure for industry respondents was 61 per cent.

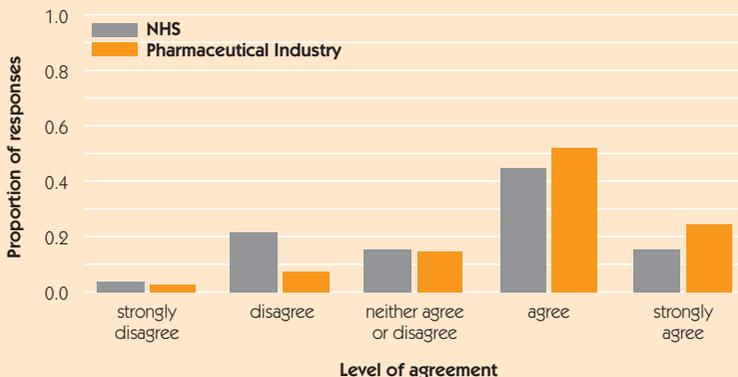
Figure 3.10 Disease management is not increasing in the NHS because it is difficult to draw up contracts between the pharmaceutical industry and the NHS for risk sharing deals



Note: Mean score; NHS: 3.9; PI: 3.9 Median score; NHS: 4; PI: 4 p (2-tailed) = 0.900

Second only to the barrier of NHS suspicion of the industry came the difficulty in drawing up contracts between the NHS and pharmaceutical industry. Almost 80 per cent of respondents felt this to be a problem, with the two groups of respondents showing a similar pattern in their views.

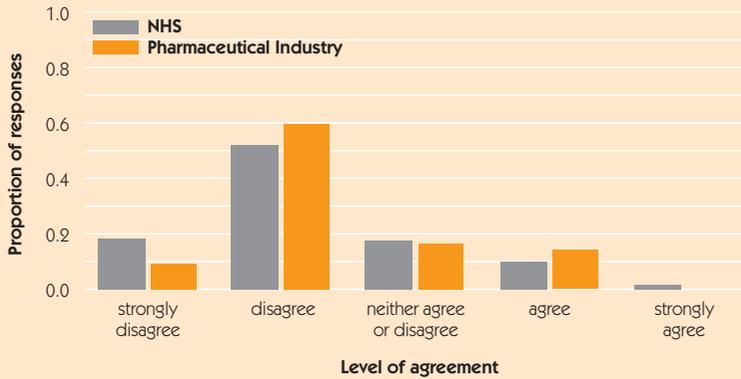
Figure 3.11 Disease management is not increasing in the NHS because the division between primary and secondary care inhibits disease management activities



Note: Mean score; NHS: 3.5; PI: 3.9 Median score; NHS: 4; PI: 4 p (2-tailed) = 0.044

Well over half (59 per cent) of the NHS respondents believed the division between primary and secondary care to be a barrier; but significantly more (75 per cent) of the pharmaceutical industry respondents agreed or strongly agreed with the statement. A larger percentage of NHS respondents (26 per cent) disagreed or strongly disagreed, compared with respondents from the industry (9 per cent).

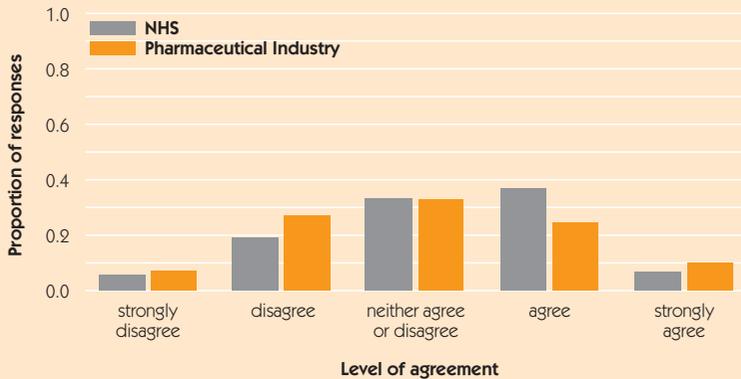
Figure 3.12 Disease management is not increasing in the NHS because disease management is only relevant for chronic diseases



Note: Mean score; NHS: 2.2; PI: 2.4 Median score; NHS: 2; PI: 2 p (2-tailed) = 0.390

Only 12 per cent of the respondents agreed that a focus on chronic diseases would present a barrier to the increased use of disease management in the NHS and there was no statistically significant difference between the response patterns of the two groups surveyed. Over 70 per cent of respondents disagreed or strongly disagreed that this constituted a barrier.

Figure 3.13 Disease management is not increasing in the NHS because the NHS is already practising disease management



Note: Mean score; NHS: 3.2; PI: 3.0 Median score; NHS: 3; PI: 2 p (2-tailed) = 0.314

Both groups of respondents showed a tendency to the centre ground on this question, with one-third of each neither agreeing or disagreeing with the statement. Under 6 per cent of all respondents strongly disagreed with the statement and just over 7 per cent strongly agreed.

Table 3.2 Percentage of respondents agreeing or strongly agreeing on types of barriers to the increase of disease management

| <i>Respondents</i> | <i>Type of barrier</i> | | | | | | |
|---------------------------|---|-----------------------------------|-----------------------------------|--|--|---|--|
| | <i>Government reluctance of companies</i> | <i>NHS suspicion of companies</i> | <i>Lack of skills in industry</i> | <i>Difficulty drawing up contracts</i> | <i>Division between primary and secondary care</i> | <i>Disease management relevant only for chronic disease</i> | <i>NHS already practising disease management</i> |
| NHS | 30% | 84% | 37% | 78% | 59% | 11% | 43% |
| Pharmaceutical industry | 47% | 91% | 14% | 83% | 75% | 14% | 34% |
| All respondents | 36% | 86% | 29% | 79% | 65% | 12% | 40% |
| Statistical significance* | × | × | √ | × | √ | × | × |

*Presence of a statistically significant difference in a comparison of the distribution of response patterns of the NHS and pharmaceutical industry (at $p < 0.05$ using Mann Whitney U test).

patient confidentiality, clinical freedom and patient interests. The desired ‘win-win’ situation can only be achieved if the incentives for both parties can be aligned, allowing companies to satisfy their shareholders and the NHS to ensure it has a deal that represents good value for money. Legal issues must also be addressed, as must arrangements for monitoring and evaluating any deals. As can be seen in section 4.1, such deals are taking place: contracts have been drawn up and implemented. Depending on the results of the evaluation process, NHS confidence in pharmaceutical companies may then either be diminished or reinforced.

The key barrier to more disease management activity *per se* (irrespective of industry involvement) was the division between primary and secondary care. The Primary Care Act Pilot Sites’ (PCAPS) initiative, which began in 1996, was designed to give NHS planners and professionals the opportunity to experiment with the delivery of primary health care services, especially in inner city areas. From April 1999, a PCAPS site may apply to hold and manage an integrated Hospital and Community Health Service budget. Alongside the new PCG-based commissioning arrangements in England, the

introduction of National Service Frameworks and national clinical guidelines, the PCAPS initiative may help to overcome this particular barrier.

Another key to opening the NHS door to disease management could be held by another primary care player, the community pharmacist. With the advent of managed care techniques into the NHS, the role of the community pharmacist would have either to be marginalised or reinvented, according to a report commissioned by the Royal Pharmaceutical Society.⁵⁰ This 'reinvention' could be modelled on the experience of PBMs in US, where pharmacists have moved away from their traditional dispensing role and into patient management services. Through vertical integration of care, the pharmacists aim to become a 'key accessible part of the care process'⁵⁰. Disease management could offer the community pharmacist a means to this end. In 1996, the chairman of the UK pharmaceutical wholesalers' association, the BAPW, advocated a joint venture between wholesalers, manufacturers and pharmacists.⁵¹ However, joint ventures could themselves pose a threat to community pharmacy:

*Local deals which by-pass the national system will distort (the community pharmacy's) operation.*⁴⁵

Like managed care, joint venture disease management could prove to be either a blessing or a curse to community pharmacy. Should local pharmacists perceive this to be the case, they would have an incentive to 'grasp the nettle', to avoid being stung. The 'development of professional pharmaceutical advice'⁵⁰ is another way in which the pharmacy profession could 'reinvent' its role. Although pharmaco-epidemiological data are available to prescribers via a range of databases, there is evidence to suggest that such information is rarely utilised. 'Academic detailing', in which independent pharmaceutical advice is provided to prescribers, is currently being explored in the IMPACT project, run by Keele University. The project began in June 1994 and continues in four Health Authorities. Over 100 community pharmacists have received specialist training, combining therapeutic knowledge and community skills, to target prescribers with evidence-based prescribing messages. These messages, which support the health authority agenda, are conveyed to 90 per cent of prescribers, who are also supplied with patient leaflets and cost comparison charts. Pharmacists are reimbursed on a fee-per-visit basis and the visits generally replace approximately one day per week of the pharmacists usual work. The results of the project are expected to be in the public domain in the near future.

Whether or not community pharmacy will play a role in the development of disease management within the NHS remains to be seen. An evaluation of the role played by the pharmaceutical industry has yet to be conducted. In the following section, we report on some examples of joint disease management ventures currently under way in the NHS, which involve the pharmaceutical industry.

SECTION 4 'JOINT DISEASE MANAGEMENT VENTURES' BETWEEN THE PHARMACEUTICAL INDUSTRY AND THE NHS

4.1 Examples of disease management practised in the UK

In 1994, encouraged by the spate of vertical integrations in the US between PBMs and the pharmaceutical industry and by the introduction in 1991 of the 'internal market' reforms in the UK, pharmaceutical companies in Britain began to approach Health Authorities, suggesting co-operative ventures.⁵² It was this activity that triggered the response of the Executive Letter EL(94)94⁴⁵. Following the subsequent working documents, issued in 1996, moves have been made. Details of some of these joint ventures came to light through the literature search, but most examples were uncovered as a result of our disease management survey of senior personnel from the NHS and pharmaceutical industry (see section 1.2). The response rate for NHS personnel was 78 per cent. Of these, 23 Health Authorities (29 per cent of NHS respondents) indicated that they were involved in disease management activities. The response rate for the industry was 51 per cent, of which 23 companies (55 per cent) reported an involvement in collaborative ventures. Details of half these activities (65 per cent of NHS reported activity and 35 per cent of the industry's) were available in the public domain. A follow-up survey (see Appendix 2) was sent out to these respondents and to two individuals whose involvement in joint ventures was documented in the medical literature. Of the 25 surveys sent, we had 14 responses, covering a range of different collaborative projects. *Thus, the research findings given below cover between one quarter and one half of all the joint ventures cited by survey respondents; the exact proportion depends on the extent to which the two groups of respondents referred to the same project.* Furthermore, these results do not include joint ventures in the fields of stoma care and renal dialysis, for which there is some evidence*, but which was not mentioned by our respondents. The results of the joint venture survey are presented in Box 4 below.

* The authors are grateful to two members of the OHE's Editorial Board for bringing instances of this activity to their attention.

Box 4 Joint ventures in the UK: survey results

Asthma Health Gain Group

Lincolnshire Health Authority is using British Thoracic Society guidelines in the diagnosis and treatment of asthma. Initiated by all the respiratory consultants and later joined by the Health Authority, the 18-month joint venture with Glaxo Wellcome began in June 1996. Routine information was supplied by the Health Authority; the company has provided an input to the asthma directory and training. The company has also provided funding for Group meetings and subsidies for the directory and for nurse training. The Health Authority has recently decided, however, that, as a general policy, joint ventures with the pharmaceutical industry are undesirable and permission for future ventures will not normally be granted.

Common goals initiative

In the spring of 1996, members of Calderdale and Kirklees Health Authority approached the pharmaceutical industry with a view to creating a more productive and positive relationship. The first phase of the Initiative led to a formal agreement between the Health Authority and 26 companies, aiming 'to more effectively achieve shared goals through more efficient use of the resources of the respective organisations.'

Five common goals were then identified:

- (1) To develop the capacities of primary, secondary and tertiary care.
- (2) To improve outcomes, effectiveness and compliance.
- (3) To develop clinical decision making.
- (4) To improve new product information.
- (5) To improve decision support information.

Companies each contributed £2,500 to facilitate the development of the initiative. Eight specific project areas were decided on; a separate project group was created to evaluate both these projects and the initiative in general. In the second phase of the initiative, there was a separation into a Strategy Forum and a Project Steering Group. Two levels of involvement were offered to pharmaceutical companies. The 18 companies involved in the Strategy Forum are described as having 'full membership' and contribute £2,500 each year. Three times a year, representatives from these companies meet the Health Authority, Trusts and 'key opinion leaders', such as doctors, pharmacists, members of the Local Medical Committee (LMC) and the NHS Executive. Strategic issues of common interest to the NHS and the industry are then explored. The findings of the Strategy Forum are fed back to the Project Steering Group (among others). This group includes representatives from the Health Authority, pharmaceutical companies, LMC and Community Health Councils. In addition to companies with full membership, 5 companies with 'project membership', who contribute £1,000 annually to facilitate the initiative, take part in the agreed project areas. The raison d'être of the Project Steering Group is to set up, manage and evaluate specific collaborative projects involving the NHS and industry. Issues and actions agreed are fed back to the Strategy Forum.

Calderdale and Kirklees Health Authority have designed the scope of the initiative to operate within national guidelines, including EL(94)94, the Pharmaceutical Price

Regulation Scheme, the Association of the British Pharmaceutical Industry code of promotional practice and Health Authority probity and accountability responsibilities. In addition, data is to be handled in accordance with NHS policy outlined in HSG 96(18). Therefore, while membership of a company at either level 'will confer enhanced status', the Health Authority explicitly states that it cannot support one company's products above another.

Following the proposed changes in the December 1997 White Paper⁶, Calderdale and Kirklees Health Authority plan to change their role in joint ventures. Although the Strategy Forum and existing projects will continue to receive health authority support, it is envisaged that support for new projects would be best provided at primary care level, by the new Primary Care Groups.

Leeds Health Authority

A joint venture with several companies was initiated by the Health Authority in 1996. Guidelines have been produced by GPs, hospital clinicians, Health Authority Public Health physicians, nurses and physiotherapists, to cover the areas of diagnosis, treatment and rehabilitation for several common diseases. The pharmaceutical companies are providing funding, while the Health Authority takes responsibility for preparation of the guidelines.

3M Health Care

3M Health Care is involved in a range of joint NHS projects, focusing on respiratory health, sexual health and cardiovascular health. In 3M's new Public Health Bulletin for NHS Policy Makers, the thinking behind these collaborative projects is explained:

The fundamental principle behind all the collaborative projects is that they help improve the diagnosis and management of disease areas. The company has products in the areas of interest, but the projects are not directly linked with these. The aspiration of 3M Health Care is simply that if good diagnosis and management is implemented through evidence-based care, then, as a result, its products will succeed.

Some of the projects have involved the company funding a team of 'NHS Alliance Managers'. Seconded from the NHS for six months, these senior personnel work two or three days a week with the company's pharmaceutical sales and marketing division. Initially, the secondees were recruited to help identify suitable collaborative projects, to which the company could contribute funding or expertise. It was hoped that this would prove to be of mutual benefit, the secondees sharing their knowledge of the new structure of the NHS, but themselves learning more about the pharmaceutical industry and developing their own marketing skills. However, some of the secondees are staying on for an extended period, providing support to established projects and feedback of research findings to interested parties in the NHS. All have been liaising with Health Authorities in their respective regions. One collaborative project underway involves the production and implementation of clinical management guidelines for the treatment of external anogenital warts. GPs and hospital clinicians are developing the guidelines in conjunction with an NHS secondee, a Public Health doctor. In addition to reimbursement of the Health Authority for the secondee's time, the company has identified potential areas of 'common ground' for collaborative

projects. In this example, the area of common ground is the desire to promote good diagnosis and management of genital warts. The company initiated and is facilitating the joint venture, with the NHS leading the initiative to develop and implement the guidelines.

In the autumn of 1997, the company set up National and Regional Advisory Boards, to provide a forum for members of 3M Health Care to meet senior NHS policy makers. The Boards discuss how the company's future developments can best complement the NHS agenda. NHS personnel may also learn more about the pharmaceutical business. As a result of 3M's awareness activity, various areas of research of interest to both the company and to the NHS have come to light. 3M Health Care is currently funding a number of research projects as a result. These include collaboration with the University of Liverpool on the introduction of CFC free inhalers in primary care; sexual health promotion, involving the production of an educational package for use in primary care and the community, with West Dumbarton Health Promotion; and collaboration with Hull University in the area of cardiac arrhythmia.

Managing asthma in primary care

East Kent Health Authority is involved in a number of joint ventures with the pharmaceutical industry. The Health Authority describes these as 'packages of care' rather than instances of 'disease management'. The packages of care include H Pylori eradication, the use of ACE inhibitors in heart failure and secondary prevention in coronary heart disease. The joint venture with Optimal Healthcare Solutions Limited, managing asthma in primary care, was begun in October 1997 and will run until January 1999. The Health Authority identified practice populations where patients did not appear to be benefiting from British Thoracic Society standards of care and persuaded 20 practices (comprising of 30 GPs) to co-operate with the programme to bring their patient management up to British Thoracic Society standards. The practices are offered a package of support covering the areas of prevention, which includes physician and patient education and training, diagnosis, treatment and rehabilitation and is expected to result in higher prescribing costs. 'Optimal', an independent disease management company, was contracted to assist the practices in delivering the necessary changes. As a result of the project, the issues of concordance and compliance in deprived populations has arisen and further projects are planned, in ventures with other companies, to target these populations by managed care, 'HMO style' interventions. East Kent Health Authority is also exploring full diabetes management with Optimal.

NHS pharmaceutical industry partnership project

Warwickshire Health Authority began planning for the Partnership Project in January 1997. Following an exploratory meeting with the companies in March, the plan was put into action the following October. Medical Audit Advisory Group (MAAG) guidelines for general practice are updated with the help of GPs, hospital clinicians and postgraduate tutors and key messages were identified. Overall responsibility for the content of the messages for GPs lies with the Health Authority. These messages are then delivered and reinforced by company representatives, using the usual marketing techniques. The five pharmaceutical companies involved are Rhône-Poulenc Rorer, Bayer, Wyeth, Glaxo Wellcome and Hoechst Marion Roussel.⁵³ At present the

guidelines focus on gastrointestinal and cardiovascular diseases, but after evaluating the first phase of the project in the summer of 1998, the Health Authority is to decide whether to extend the project to cover additional therapeutic areas such as asthma, diabetes and hormone replacement therapy. Identification of further 'win-win' situations may also result in partnerships with additional companies.

Northumberland Heart Health programme

Northumberland Health Authority initiated this project, which began in October 1997. A guideline covering the areas of prevention, screening, diagnosis, treatment and rehabilitation for heart disease is produced, updated and amended by GPs, hospital clinicians and Health Authority staff. The pharmaceutical companies involved in the project offer financial support in producing the document, but would like to have more influence.

Nottingham Health Authority

Merck Sharp & Dohme approached Nottingham Health Authority to initiate a joint venture for the production of a cholesterol guideline. The on-going project began in November 1996, with the pharmaceutical company sponsoring the printing and dissemination of the guideline. The Health Authority is responsible for the development, audit, implementation and monitoring of the guideline. MAAG, GPs, hospital clinicians and various Health Authority staff are involved in the production of the guideline.

Nottingham Health Authority is also involved in a one-year patient information project, which began in April 1998. A consultant surgeon from Nottingham City Hospital NHS Trust approached Zeneca with a view to gaining sponsorship for a colorectal nurse. The nurse acts as a counsellor to the patients, helping them with their informational needs at their first clinic appointment and throughout the treatment process. She is also responsible for co-ordinating their care and liaising with the stoma nurse. The patients' informational needs were assessed by way of a three month audit and patient information leaflets, based on the findings, were then drawn up by the nurse. These are given to patients at the appropriate stage of treatment. Zeneca has provided funding for the leaflets and a fax machine to facilitate contact with GPs. Having seen the benefit of the colorectal nurse, the NHS aims to fund the post when the joint venture ends.

Oxford Radcliffe Hospitals NHS Trust

The Oxford Radcliffe Hospital's Trust (ORH) is involved in two separate projects with pharmaceutical companies Merck Sharp & Dohme (MSD) and Boehringer Ingelheim.

(1) ORH and Merck Sharp & Dohme (MSD)

The HEART project (Health and Education through Active Rehabilitation Therapy) began in January 1998 and will run for two years. The aim of the project is to establish and formally evaluate a new service lead by nurse practitioners in Cardiac Rehabilitation. The Rehabilitation team will deliver a new approach to cardiac rehabilitation that offers evidence-based, flexible and cost-effective care. The aim is to move away from the standard hospital-based programme to a more flexible approach, involving individually planned aftercare, bridging primary, secondary and tertiary care and integrating services available in the community. The project is led by

the ORH with the acute and community Trusts participating in the Steering Group. In addition to supplying information technology equipment, MSD is sponsoring two nurses and one exercise physiologist for the duration of the project.

(2) ORH and Boehringer Ingelheim

The NATALIE Project (Nurse Assessment and Treatment of Accelerated Lysis in Infarct Events) began in January 1998 and will run for two years. The aim of the project is to establish and evaluate a new role of nurse practitioner (NP) for the assessment and treatment of emergency patients presenting with chest pain. The nurse will work alongside the medical 'on take' team and, within limits established by agreed protocols, will be able to complete a full clinical evaluation, identify those patients presenting with an acute myocardial infarction and initiate the appropriate treatment. The aim of the guidelines/protocols is to improve the treatment and diagnosis of patients presenting with chest pain. Boehringer Ingelheim is sponsoring the salary of the nurse for the duration of the project.

PACE project

The PACE (Promoting Action on Clinical Effectiveness) project involves improving the diagnosis and treatment of patients with congestive heart failure, through open access provision of echocardiographic resources and the promotion of effective prescribing. Following its acceptance into the national PACE programme, North Derbyshire Health invited all companies producing relevant products to participate in a joint venture. The 2½-year project began in May 1996 and participating companies were required to sign an annual written agreement with the Health Authority. Defining the exact nature of the support provided, the agreement specifies that companies may not use this involvement to gain access to clinicians or to imply any preferential treatment. The companies offer financial support for the district wide audit, GP educational meetings and patient information production. One company provided an echo machine for use in the project as a pilot. North Derbyshire Health has local overall responsibility for developing, managing and running the project. The benefit to the companies is in increased prescribing of ACE inhibitor drugs overall.

PCAPS pilots in Hertfordshire

This Primary Care Act Pilot Site project is nicknamed TOPIC, which stands for Transfer of Patients from Inappropriate Care and involves a small GP practice in Hertfordshire. The GP behind the project believes that the current political climate, with its emphasis on holistic (patient-centred) medicine, means that it is a good opportunity to stop treating the pharmaceutical industry as a 'pariah'. The GP practice is involved in two projects in conjunction with pharmaceutical companies; in both cases, the pharmaceutical company approached the GP after hearing him speak about disease management. In one project that looks at the treatment of Chronic Obstructive Pulmonary Disorder in primary care, Boehringer Ingelheim is contributing information from the medical literature and suggesting research contacts to the practice. Using this information in conjunction with pulmonary disorder guidelines, this project aims to implement evidence-based medicine and prescribing in the primary care setting. Leo Pharmaceuticals are working on a project on Deep Vein Thrombosis at home, with the company again offering provider support in the form of information and research contacts. In collaboration with the local Trust, the GP practice is using this information

to produce guidelines. The goal of the Deep Vein Thrombosis project is to reduce the number of hospital admissions. In neither project does the pharmaceutical company offer any financial support.

Personalised care management in Dorset

Dorset Health Authority is involved in a joint venture to supply total patient packages of care for asthma, mental health and cancer. The project began in September 1997 and is expected to run for 18-24 months. GPs, hospital clinicians, the pharmaceutical company and patients are producing guidelines for the personalised packages of care. Funding and support for the project comes from the Health Authority and the participating pharmaceutical companies, including Lilly, Zeneca and Glaxo Wellcome. The Health Services Management Unit of the University of Manchester is evaluating the project and linking with other national research on managed and integrated approaches.

Psoriasis disease management project

This is a joint venture between Leo Pharmaceuticals and a primary care team in Staffordshire. In the one-year project, which began in 1998, guidelines are to be produced by GPs, hospital clinicians and the pharmaceutical company. These will cover the areas of screening, diagnosis and treatment for patients in the locality with psoriasis. Some of the nursing, patient information and audit resources required by the project are to be provided by the company, which will also contribute its expertise and experience of similar initiatives. The primary care team is responsible for delivering care and for developing a partnership with the company to allow improvements in quality of life for psoriasis patients.

Searle (UK) Ltd

Searle (UK) is also one of the companies working with Calderdale and Kirklees Health Authority in the Common Goals Initiative. One project undertaken as part of the Initiative is the 'Menopause Services' project. This project, which centres on the supply of a screening and diagnostic clinic, began in May 1998. Searle (UK) has taken responsibility for marketing the service, managing some of the logistics of the project and liaising with the media and the local population. The company has provided 'limited funding' for the project, but the Health Authority has been the chief source. As well as providing the service, the Health Authority has responsibility for overall management and control of the project.

Searle (UK) has also undertaken a joint venture in collaboration with North West Anglia Health Authority. 'Sexsense' is a sexual education programme that began in September 1996, with the aims of preventing of unplanned teenage pregnancy and of encouraging better use of Family Planning Services by young people. Searle produced educational materials, such as posters, leaflets and plastic information cards. The company was also responsible for distributing the materials to primary care, including individual visits to each GP practice and pharmacy and for liaising with the national media. This joint venture project won a Health Alliance award.

4.1.1 Types of support offered by the pharmaceutical industry

Joint disease management ventures currently operating in the UK appear to be taking the form of *‘Enabling Management’* (see section 1.1.2); companies are providing one or more of several types of support to the NHS.

Interestingly, our findings were much in line with West’s anticipation:

*In the short term, the contribution of the private sector is most likely to be in providing ideas, pump-priming funds and the kind of catalytic energy and initiative that the NHS, ground down by concerns with cash and contracts, often lacks.*²⁴

The majority of companies involved in joint ventures are offering financial support. This financial support may be as a ‘lump sum’ towards the cost of the project. This is the case in the ‘Common Goals Initiative’, instigated by

Table 4.1 Type of support offered by pharmaceutical companies

| <i>Project</i> | <i>Type of support</i> | | | |
|---|------------------------|-----------------|-----------------------------|------------------|
| | <i>Financial</i> | <i>Research</i> | <i>Communication Skills</i> | <i>IT Skills</i> |
| Asthma Health Gain Group | ✓ | ✓ | ✗ | ✗ |
| Common Goals Initiative | ✓ | ✗ | ✗ | ✗ |
| Leeds HA | ✓ | ✗ | ✗ | ✗ |
| 3M Health Care | ✓ | ✓ | ✗ | ✗ |
| Managing asthma in primary care | ✗ | ✗ | ✓ | ✗ |
| NHS pharmaceutical industry partnership project | ✗ | ✗ | ✓ | ✗ |
| Northumberland Heart Health programme | ✓ | ✗ | ✗ | ✗ |
| Nottingham HA | ✓ | ✗ | ✗ | ✗ |
| Oxford Radcliffe Hospital | ✓ | ✗ | ✗ | ✓ |
| PACE project | ✓ | ✗ | ✗ | ✗ |
| PCAPS pilots | ✗ | ✓ | ✗ | ✗ |
| Personalised care management in Dorset | ✗ | ✓ | ✓ | ✓ |
| Psoriasis DM project | ✓ | ✓ | ✓ | ✗ |
| Searle (UK) | ✓ | ✗ | ✓ | ✗ |

Calderdale and Kirklees Health Authority. Eighteen companies with 'full membership' of the Initiative, and another five companies with 'project membership', pay an annual membership fee which is used to fund a part-time Project Co-ordinator, administrative support and to 'pump-prime' the projects themselves. The companies' level of involvement in strategic debates and in the projects themselves depends on their level of membership. The pharmaceutical company 3M Health Care Limited is involved in a range of projects. Some of these involve funding into research areas identified as being of interest to both the NHS and the company. Other projects involve the help of an 'NHS Alliance Manager', seconded for short period from the NHS, which is reimbursed for their time. Three joint ventures currently underway in the UK involved sponsorship of guidelines and another three involved nurse sponsorship. Financial support for auditⁱ and training has been given by companies in separate ventures.

Research and development skills are a second form of support offered by pharmaceutical companies. Four instances of this type of support were found, only one of which (the Psoriasis project with Leo Pharmaceuticals) involved the company in the production of guidelines. Support in the form of communication and marketing skills was evident in six projects. In the Partnership Project initiated by Warwickshire Health Authority, Medical Audit Advisory Group (MAAG) guidelines are updated by health professionals and 'key messages' identified.⁵³ Company representatives then deliver these messages to the GPs. The industry's communication and marketing skills are also employed in the Personalised Care Management project, run by Dorset Health Authority. Lastly, IT support in the form of equipment and of assistance with systems development was offered by a small number of companies. No case of '*carve out management*' was found.

i We should note in this context that the Code of Practice governing companies' promotional activities does not permit financial assistance where it amounts to an inducement to prescribe. Companies are, however, permitted to provide financial assistance for the provision of a service that enhances patient care or benefits the NHS. In a recent case the Prescription Medicines Code of Practice Authority found that a company's financial support for an audit was in breach of the Code as the real purpose of the financial support was to boost the prescribing of one of its products. Companies have to ensure that their disease management activities do not breach the Code.

4.1.2 Disease areas covered by the joint ventures

Almost half of those involved in joint ventures were either working on, or planning to work on, the area of respiratory diseases. Work ranged from research funding for managing the transition to CFC free inhalers for asthma to the provision of total patient packages, covering all aspects of asthma. Two projects, one involving East Kent Health Authority and one with Lincolnshire Health, used British Thoracic Society guidelines to improve asthma health outcomes. Heart disease is another popular area for joint ventures. East Kent Health Authority is involved in two ‘packages of care’ in this area, as is the Oxford Radcliffe Hospital’s Trust. Some of the heart disease projects involve the production of guidelines. Sexual health promotion has been undertaken by 3M Health Care, who are involved in a number of projects in this disease area, and by Calderdale and Kirklees Health Authority, as part of their ‘Common Goals Initiative’. A range of other disease areas is covered by the joint ventures currently operating, including mental health, cancer, gastrointestinal diseases and psoriasis. No instances of ventures focusing on diabetes came to light; however, two Health Authorities were planning to undertake projects in this area, at the time of our survey. Table 4.2 summarises the disease areas covered by the joint ventures.

Table 4.2 Disease areas covered by joint venture projects

| <i>Project</i> | <i>Disease area</i> | | | |
|--------------------------|---|--|---------------------------------------|---------------------------------------|
| | <i>Respiratory</i> | <i>Cardio vascular</i> | <i>Sexual health</i> | <i>Other</i> |
| 3M Health Care | Research into transition to CFC-free inhalers | Cardiac arrhythmia | Genital warts. Bacterial vaginosis | |
| Asthma Health Gain Group | Asthma | | | |
| Common Goals Initiative | n/s | n/s | n/s | n/s |
| East Kent HA | Asthma | ACE inhibitors in heart failure. Secondary prevention in coronary heart disease | | H Pylori. Plan to look at diabetes |

| <i>Project</i> | <i>Disease area</i> | | | |
|---|--|--------------------------------------|----------------------|--|
| | <i>Respiratory</i> | <i>Cardiovascular</i> | <i>Sexual health</i> | <i>Other</i> |
| Leeds HA | n/s | n/s | n/s | n/s |
| NHS Pharmaceutical Industry Partnership Project | Plan to do work on asthma | Guidelines on cardiovascular disease | | Gastro-intestinal. Plan to do work on diabetes and hormone replacement therapy |
| Northumberland Heart Health Programme | | Guideline for heart disease | | |
| Nottingham HA | | Cholesterol guideline | | Colorectal disease |
| Oxford Radcliffe Hospital | | HEART project | | |
| PACE Project | | Congestive heart failure | | |
| PCAPS Pilots | Chronic Obstructive Pulmonary Disorder | | | Deep Vein Thrombosis |
| Personalised Care Management in Dorset | Asthma | | | Mental Health. Cancer |
| Psoriasis disease management project | | | | Psoriasis |
| Searle | | | Sexsense | Menopausal problems |
| n/s = not stated. | | | | |

4.1.3 A comparison of theory with practice

Our survey on disease management sought to find the types of pharmaceutical industry involvement that could be described as being instances of disease management. The results were discussed in section 4.1. It is interesting to compare the UK practice with the types of disease management discussed in the US context, and with the elements of disease management identified by our questionnaire.

No instance of disease management as a *package of care*, offered by a pharmaceutical company, was found. East Kent Health Authority uses the term 'packages of care' rather than 'disease management' to describe its joint ventures, but these packages are jointly produced and executed, rather than being a pharmaceutical company's product. Instances of *risk sharing* were evident in all instances of companies offering financial support, but no *capitation deals* were found. The strategy of *building relationships* appears to be central to 3M Health Care's secondment scheme and creation of Advisory Boards, although these are to facilitate joint ventures, rather than being instances of them. The Common Goals Initiative, run by Calderdale and Kirklees Health Authority, is aimed at developing more productive and positive relations between the Health Authority and the pharmaceutical industry, but the initiative for this project came from the Health Authority rather than from the industry. The *tailoring of promotional activities* was evident in both the Partnership Project initiated by Warwickshire Health Authority and in the sexual health projects run by Searle and by 3M Health Care. A case of a company *encouraging innovation* might be the sponsoring by Zeneca of a colorectal nurse in Nottingham Health Authority, although the nurse is involved in patient education, producing patient information booklets, rather than in using a new pharmaceutical product. 3M Health Care is funding research and projects in a number of areas where the company has new products it wishes to promote, such as a CFC free aerosol. However, the company stresses that the projects 'are not directly linked' with these new products.

As for the industry offering *a new type of service* to the NHS, all the joint ventures described in section 4 involve partnerships and deals that would fit this description. The new type of service, in the form of a more collaborative and diversified role, offered by the pharmaceutical industry in these joint ventures is perhaps the clearest form yet to be seen of disease management in the NHS.

SECTION 5 CONCLUSIONS

5.1 Definition of disease management

Our literature review and survey suggest that ‘disease management’ involves, in relation to a particular disease:

- identifying the numbers of patients and the associated total health care and non health care costs;
- using the evidence base to devise clinical guidelines for managing the disease;
- using the cost and treatment information to contract for and, if appropriate, to reshape, health care delivery in an integrated and cost-effective way;
- auditing the use of the guidelines and monitoring the outcomes, treatments provided and the costs of treatment;
- feedback to change the guidelines and/or the contract/delivery/compliance mechanisms.

In one sense it is cost-effective purchasing; alternatively, it is a framework for radical thinking about how care is provided, particularly across traditional primary/secondary care boundaries, and about the potential use of guidelines to reduce variations in treatment. In both cases, the potential role for the use of health economics to evaluate the cost effectiveness of alternative treatment and delivery options is considerable. ‘Managed care’ is a term often used to capture most of the elements of disease management that we have set out above. However, managed care is more appropriately used to mean a system-wide integration of financial incentives and delivery mechanisms, which will often result in component management of costs. The NHS already has this, but its efforts at disease management have hitherto been hampered by the financial and professional boundaries between primary and secondary care and by the lack of agreed clinical guidelines. The model of ‘integrated care’ set out in the December 1997 White Paper⁶ is much closer to disease management.

5.2 Pharmaceutical industry involvement in disease management

The issues raised by a radical approach to disease management within the NHS include:

- the extent to which guidelines support or supplant clinical judgement;

- how cost-effectiveness criteria could be incorporated in guidelines;
- the wisdom of capitated agreements (i.e. set budgets for the management of particular diseases) within the NHS.

These issues would attract controversy in any context. However, disease management arouses particular controversy in the UK because of the possible links with the pharmaceutical industry. This arises because, potentially, it involves the private sector in contracting for or providing clinical services to NHS patients, but also in part because of the question as to the motivation of the pharmaceutical industry and its ability to contribute.

Private sector provision of clinical services has been resisted by many in the NHS, and the government has been careful to limit private sector involvement in the Private Finance Initiative to the provision of infrastructure, with the NHS providing the clinical services. In the US, where disease management originated, private provision is the norm – although many hospitals are run as not-for-profit bodies – and innovation in delivery through new entry is also common. In the UK, reluctance to contemplate private sector involvement can lead to the view that disease management is something for the NHS to do for itself. Indeed it can be argued that the NHS is heading in this direction under the banner of ‘integrated care’ with new contracting arrangements and a new emphasis on national frameworks of care for each disease, with guidelines and outcome measures. Our view is a pragmatic one: if the private sector can contribute skills and resources for the cost-effective provision of integrated care to NHS patients then it should be considered alongside ‘in house’ options and judged on its merits.

But can the pharmaceutical industry usefully contribute? Companies see their involvement in disease management as a way of increasing profit, either by increasing sales or by diversifying into a new business venture. However, institutional arrangements that promote the use of a product over and above that which the evidence of the literature and the experience of the doctor would suggest was appropriate are not acceptable. Industry involvement in a ‘carve-out’ model may, moreover, lead to arrangements that involve key judgments about the availability of treatment being made by private sector organisations that are not publicly accountable. Yet both of these issues can in principle be readily addressed by suitable contracting arrangements involving the use of NHS approved clinical and procedural guidelines.

Can suitable contracts be written? EL(94)94⁴⁵ was motivated by concern that the NHS was in danger of entering unsuitable contracts. The revised September 1996 draft Discussion Paper⁴⁶ suggested that if contracts were to be acceptable, key requirements would have to be met. These included the guarantee of patient confidentiality, clarification on the resolution of conflicts of interest and assurance that the agreement provided value for money for the

NHS. The evidence from the US is that contracts can be written, although our literature survey revealed little evidence of ‘carve-out’ contracts. Most arrangements were partial or ‘enabling’, involving provision of some elements of disease management services. We conclude from this that the pharmaceutical industry in the US has tackled the challenges of lack of relevant skill by concentrating on areas relating to the use of prescription medicines, using patient databases with event and outcome information to offer services to help improve the cost-effective treatment of particular diseases. We have to leave open the question as to whether contracts can be written which would overcome all of the potential issues involved in a ‘carve-out’ contract (including, for example, clear definitions of which patients were to be included and at what cost to the NHS). However, various types of ‘enabling’ arrangements have now been entered by the NHS and pharmaceutical companies.

5.3 Views of the NHS and industry personnel

Our survey shows significant NHS and industry agreement that disease management can include the two key elements of our definition above – the use of guidelines to manage disease, and costing the management of the disease. They also agreed that disease management could involve pharmaceutical companies offering ‘packages of care’ (although there was a statistically significant difference in the distribution of responses) and that it was not about companies tailoring promotional activities. However, there were significant differences of opinion between industry and NHS about whether it could involve the industry in risk sharing, building relationships, offering new services, or encouraging innovation. The NHS respondents were, on average, opposed to including these options within a view of disease management, whereas the industry was in favour.

Explanations for these differences can be found in the responses to the questions on the barriers to the greater use of disease management within the NHS. There was strong agreement that the NHS was suspicious of pharmaceutical companies. By implication, the NHS respondents were therefore more reluctant to see the pharmaceutical industry as a partner in disease management. More positively, neither side saw lack of industry skills as a barrier to co-operation, although the NHS was less convinced of the existence of distinctive skills. Nor did either group view disease management as only relevant for chronic diseases, or regard the NHS as already practising disease management. The key barrier to more disease management activity *per se* (irrespective of industry involvement) was the division between primary and secondary care. Not surprisingly, in an environment of concern about the practicability of disease management in the NHS and the ability of the industry to offer valuable benefits in this area, our survey found that joint ventures between the NHS and companies are of the ‘enabling’ kind, with companies

typically providing a financial contribution plus one of research, communications, or IT skills.

5.4 The way forward

Our view is that the move to ‘integrated care’ with National Service Frameworks and national clinical guidelines, together with moves to end the financial separation of primary and secondary care with one set of ‘cross-boundary’ commissioners, in the form of Primary Care Groups, provides new opportunities for the NHS to use disease management approaches to the commissioning and delivery of patient care. How radical changes in delivery should be will depend on the cost effectiveness of different treatment options and different service configurations. Economic analysis will be crucial in assessing the costs and benefits of alternative treatments and services. A role for the pharmaceutical industry should not be ruled out in principle, but considered on a case by case basis. Experience to date suggests that the health authorities and GP commissioners will want to ‘feel their way’ in developing links with the industry – looking for relationships that they are comfortable with, and for subsequent evidence that industry involvement is producing improved outcomes. In the future, the contracting flexibility introduced by the Primary Care Act may, if matched by changes in the pharmaceutical market (for example if Primary Care Trusts can negotiate pharmaceutical prices directly with pharmaceutical companies), open up wider opportunities for industry involvement in risk sharing and related disease management initiatives. In the short term, however, the challenge for the NHS is to put cost-effective integrated care into practice, and the challenge for the industry is to show that it can make an effective contribution to this over and above that of supplying innovative, cost-effective medicines.

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APPENDIX 1 DISEASE MANAGEMENT SURVEY

Disease management in the NHS

Actions or approaches by the pharmaceutical industry, going under the general label ‘disease management’, have become very popular in the USA. However, there appears to be uncertainty about what exactly ‘disease management’ is and about the extent to which it can be applied in the UK. With the changing structure of the NHS and development of Primary Care Groups, ‘disease management’ in the UK may become increasingly topical: indeed, the White Paper refers to the new roles for practice nurses in ‘disease management’ and places the emphasis on ‘integrated care’.

This survey has the following objectives:

- (i) to explore what is meant by the term ‘disease management’ and its relevance to the NHS.
- (ii) to assess the extent to which perspectives on disease management and the role of the pharmaceutical industry differ between senior personnel in the NHS and the UK pharmaceutical industry.
- (iii) to identify useful examples of disease management.

This survey has been sent to a number of senior personnel in the NHS and the UK pharmaceutical industry, chosen for their knowledge in this area.

The survey should take 10-15 minutes to complete. Responses to the survey will be treated in confidence and all respondents will receive a copy of the final report. All respondents will receive an advance copy of the report, a copy of Disease Management: Who Needs It and Why? (Discussion Paper 152, University of York) and a booklet containing information about useful data sources in health economics (including relevant databases).

Name:

Place of employment:

Job title:

Section A: Exploring what is meant by the term 'disease management'

In this section you are given a number of statements that reflect different notions of what the term 'disease management' might mean. In each case, please indicate *your* level of agreement with the **statement in bold** by placing a tick in the appropriate box.

1. Estimating the total costs of managing a disease

A holistic view is taken of the cost of a disease whereby the cost of drugs is considered alongside other costs such as investigations and hospitalisations. The cost of drugs is therefore put into a broader context. This comprehensive costing is similar to that undertaken in cost-effectiveness studies.

'Disease management' can include estimating the total costs of managing a disease.

| | | | | |
|-------------------|----------|---------------------------|-------|----------------|
| Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
| | | | | |

2. Devising clinical guidelines for managing a disease

Clinical guidelines or protocols may be devised for the management of particular diseases and the different health care and social services sectors co-ordinated around the patient's needs.

'Disease management' can include the devising of clinical guidelines for managing a disease.

| | | | | |
|-------------------|----------|---------------------------|-------|----------------|
| Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
| | | | | |

3. The supply of a 'package of care' by a pharmaceutical company

A pharmaceutical company may offer a discount if a hospital or health care provider buys a range or 'bundle' of the company's products. The company may also supply other services, such as lifestyle advice or monitoring of compliance, alongside its products.

'Disease management' can include the supply of a 'package of care' by a pharmaceutical company.

| | | | | |
|-------------------|----------|---------------------------|-------|----------------|
| Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
| | | | | |

4. The determination of capitated arrangements, or risk sharing agreements between a pharmaceutical company and the NHS

A pharmaceutical company may agree to cover the total cost of care for individuals suffering from a given condition for a set fee, or agree to cover the cost of a new drug for individuals whom conventional treatment has failed. Sometimes this may be linked to the development of protocols that encourage appropriate use of the drug concerned.

‘Disease management’ can include the determination of risk sharing agreements between a pharmaceutical company and the NHS.

| | | | | |
|-------------------|----------|---------------------------|-------|----------------|
| Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
| | | | | |

5. A pharmaceutical company building relationships with customers

Under ‘disease management’, attempts are made by a pharmaceutical company to improve customer relations by undertaking joint research studies or by supporting the development of treatment guidelines.

‘Disease management’ can include a pharmaceutical company building relationships with customers.

| | | | | |
|-------------------|----------|---------------------------|-------|----------------|
| Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
| | | | | |

6. A pharmaceutical company encouraging innovation in health care

The adoption of a new drug may be hindered by a lack of other resources (e.g., community nurses). A pharmaceutical company may provide these resources along with the drug. This may help overcome the constraints imposed by NHS organisational or budgetary arrangements.

‘Disease management’ can include a pharmaceutical company encouraging innovation in health care.

| | | | | |
|-------------------|----------|---------------------------|-------|----------------|
| Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
| | | | | |

7. A pharmaceutical company tailoring promotional activities

A pharmaceutical company may increasingly deal with a few influential customers, rather than targeting a large number of individual prescribers. It may also negotiate a price reduction in return for increased market share.

‘Disease management’ can include a pharmaceutical company tailoring promotional activities.

| | | | | |
|-------------------|----------|---------------------------|-------|----------------|
| Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
| | | | | |

8. A pharmaceutical company offering a new type of service to the NHS

New drug discovery is becoming more difficult and resource intensive. A pharmaceutical company can diversify by selling health care management expertise to the NHS, along with their traditional products.

‘Disease management’ can include a pharmaceutical company offering a new type of service to the NHS.

| | | | | |
|-------------------|----------|---------------------------|-------|----------------|
| Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
| | | | | |

9. How would you define ‘disease management’ in your own words?

.....

.....

.....

.....

.....

Section B: Barriers to disease management in the NHS

In this section you are asked to give your views on potential barriers to the increase of disease management in the NHS. Please place a tick in the appropriate box.

Disease management is not increasing in the NHS because:

| | Strongly disagree | Disagree | Neither agree or disagree | Agree | Strongly agree |
|--|--------------------------|--------------------------|---------------------------|--------------------------|--------------------------|
| 1. There is government reluctance (as reflected in EL94(94)) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. There is NHS suspicion of pharmaceutical companies | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. The pharmaceutical industry lacks the skills to help the NHS in disease management | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. It is difficult to draw up contracts between the pharmaceutical industry and the NHS for risk sharing deals | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. The division between primary and secondary care inhibits disease management activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Disease management is only relevant for chronic diseases | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. The NHS is already practising disease management | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Section C: Disease management in your company

In this section you are asked a number of questions concerning your own company's experience with disease management. Please place a tick in the appropriate box.

1. Does your company have an identified person or group dealing with disease management activities in the UK?

| Yes | No | Don't know |
|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

If your answer was No or Don't Know please go to question 2.

If your answer was Yes, please tick one or more of the boxes in (a) and (b):

(a) Is the person or group:

| | |
|-----------------------------------|--------------------------|
| In a separate company/subsidiary? | <input type="checkbox"/> |
| In a separate department? | <input type="checkbox"/> |
| In a section of a department? | <input type="checkbox"/> |

(b) What is the relationship between the disease management group and any group dealing with health economics, pharmacoeconomics, or outcomes research?

| | |
|--|--------------------------|
| The same group or person | <input type="checkbox"/> |
| In the same department | <input type="checkbox"/> |
| Totally separate | <input type="checkbox"/> |
| No health economics or outcomes research group | <input type="checkbox"/> |

2. Has your company engaged in any disease management activities with the NHS?

| Yes | No | Don't know |
|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

3. If yes, are any details in the public domain?

| Yes | No | Don't know |
|-----|----|------------|
| | | |

If relevant, indicate how details can be obtained?

.....

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Thank you for your co-operation.

Section D: Disease management in your authority or local NHS trusts

In this section you are asked a number of questions concerning your own Authority or local Trusts' experience with disease management. Please place a tick in the appropriate box.

1. Has your Authority or Trust engaged in any disease management activities with pharmaceutical companies?

| Yes | No | Don't know |
|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. If yes, are any details in the public domain?

| Yes | No | Don't know |
|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

If relevant, please indicate how details can be obtained.*

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*Please include your knowledge of any experience from Total Purchasing Projects or other primary care initiatives in your area.

Thank you for your co-operation.

APPENDIX 2 JOINT VENTURE SURVEY

Disease management in the NHS: Joint ventures with the pharmaceutical industry

As part of a report on *'Disease Management in the NHS'*, we would like to include some practical examples of *joint ventures between the NHS and the pharmaceutical industry*. We would appreciate your time and experience to help us to get our facts straight!

Please answer the questions below.

1. What title would you give the disease management project?

.....

2. When did it start and when will/did it finish?

| Start | | Finish | |
|-------|------|--------|------|
| Month | Year | Month | Year |
| | | | |

3. How was the project initiated?

| HA approached by industry | GP(s) approached by industry | TPP approached by industry | Industry approached by HA | Industry approached by GP(s) | Industry approached by TPP | Other (please specify) |
|---------------------------|------------------------------|----------------------------|---------------------------|------------------------------|----------------------------|------------------------|
| | | | | | | |

4. What type of health care intervention(s) is/are covered by the project?

| Prevention | Screening | Diagnosis | Treatment | Rehabilitation | Palliative care | Other (please specify) |
|------------|-----------|-----------|-----------|----------------|-----------------|------------------------|
| | | | | | | |

5(a). Is the production of guidelines part of the project?

| YES | NO |
|-----|----|
| | |

5(b). If YES, please specify who is involved in the production of the guidelines

| MAAG | GPs | Hospital clinicians | Postgraduate tutors | Health science researchers | Pharmaceutical industry | Other (please specify) |
|------|-----|---------------------|---------------------|----------------------------|-------------------------|------------------------|
| | | | | | | |

6. What is the role of the pharmaceutical industry in this project?

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.....

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7. What is the role of the NHS in this project?

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8. Is there anything else you would like to add?

.....

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9. We would like to have our summary of your project checked for accuracy before it goes into print.

If not yourself, would you please indicate the name and contact address of someone who could do this for us?

| Name | Position | Address |
|-------|----------|---------|
| | | |
| | | |
| | | |
| | | |

Thank you very much for your time and co-operation.

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