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Top–up fees

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The Health Committee

The Health Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department of Health and its associated bodies.

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Footnotes

In the footnotes of this Report, references to oral evidence are indicated by ‘Q’ followed by the question number, and these can be found in HC 194–I. Written evidence is cited by reference in the form ‘Ev’ followed by the page number; Ev x for evidence published in HC 194–II, Session 2008–09, on 28 January 2009, and Ev x for evidence to be published in HC 194–I, Session 2008–9.
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Summary

In recent years the NHS has been criticised both for not funding certain drugs and for withdrawing treatment for patients who chose to purchase privately additional drugs which the NHS refused to fund.

In June 2008 the Secretary of State asked Professor Mike Richards, National Clinical Director for Cancer (the Government’s “Cancer Tsar”), to examine the availability of NHS medicines and to provide guidance on “if, when and in what circumstances patients should be able to purchase additional drugs that are not funded by the NHS”. Professor Richards’ report, published in November 2008, Improving access to medicines for NHS patients, concluded that there had been a loss of confidence in the system for making drugs available on the NHS and made fourteen recommendations to the Department of Health. Professor Richards made two particularly significant recommendations. First, the NHS should make more expensive drugs more widely available to NHS patients. Secondly, the NHS should allow the purchase of additional drugs privately as long as they were administered separately from NHS treatment—even though Professor Richards estimated that there were only 18 cases where NHS treatment had been withdrawn because the patient had purchased drugs privately.

The Department accepted all Professor Richards’ recommendations. In late 2008 and early 2009 the Department and NICE made three important decisions, designed to implement them. These were:

- NHS trusts were told to end immediately the practice of withdrawing NHS treatment from patients who purchased drugs privately;
- Where patients continued to purchase private drugs, the Department published draft guidance to NHS trusts about how to separate NHS and private treatment. Final guidance was implemented on 23 March 2009.
- Supplementary guidance was issued to NICE Appraisal Committees to make available a greater range of more expensive drugs to a greater number of NHS patients and thereby reduce the need for patients to buy drugs privately.

The Department’s instruction to NHS trusts that they should immediately cease the practice of withdrawing funding for NHS patients who had purchased additional treatment was generally welcomed. However some of our evidence expressed concerns about the risks, consequent on the Report, of potential disadvantages to NHS patients including the formation of a “two-tier” system.

While we welcome the Department’s proposals for separating NHS and private treatment we are concerned that separation will be hard to achieve in practice. We believe it would be wrong for very seriously ill patients to be moved from an NHS ward to a different location so as to administer a privately paid for drug separately. This undoubted disruption to a patient’s quality of life just to meet some bureaucratic requirement would not only endanger the patient’s care but would be unjust. There is also a danger under the proposed arrangements that two patients with the same condition on the same NHS ward might...
receive different treatments because one patient could afford it and the other could not. This must not be allowed to happen except in the circumstances described in the Department’s final guidance.

In addition, for the new arrangements to work it is essential that there is a good continuity of care between the NHS and the private sector in this area. This will not be easy and will only be achieved by the establishment of excellent working practices and the goodwill of clinicians.

More broadly we are concerned that the affirmation of the guidelines regarding the separation of NHS and purchased drugs will establish a precedent that would open up the possibility of a “core service” emerging in the NHS obliging patients to co-fund aspects of their treatment or to go without. We reinforce Professor Richards’ call on the Government to clarify its policy in respect of the arrangements which apply to the separation of NHS and private care in relation to non-drug interventions, including devices and procedures.

The Department and NICE have introduced two significant initiatives which are aimed at increasing the availability of expensive drugs so that patients will be less likely to purchase drugs privately, these are: the provision of supplementary guidance for end-of-life treatments to NICE Appraisal Committees and the introduction of a new Pharmaceutical Price Regulation Scheme.

While Professor Rawlins denied claims that NICE had raised its end-of-life cost per QALY threshold to £70,000, he accepted that the supplementary guidance to NICE Appraisal Committees would effectively raise the QALY threshold for end-of-life drugs. We believe that this decision is both inequitable and an inefficient use of NHS resources. By spending more on end-of-life treatments for limited health gain, the NHS will possibly spend less on other more cost-effective treatments.

In setting this new guidance, NICE said that it was important to place clear limits on the numbers of patients who would benefit from it because the NHS could not afford to apply the guidance for all conditions. Given that increasingly new drugs are ‘designer’ technologies for small subgroups of patients many new products can be viewed as treatment for ‘rare’ diseases. We consider the definition of subgroups of patients suffering from rarer cancers as “small populations” is too woolly and needs more clarity. We consider there is a clear danger that the new arrangements will lead to the system becoming unaffordable as pharmaceutical companies target new drugs on subgroups of diseases.

The Department has told PCTs to be more transparent in the way that they deal with exceptional funding requests. We welcome this and recommend that all decisions on exceptional funding should be consistent with this guidance and PCTs should provide a clear and easily intelligible explanation to patients explaining the reasons for any decision to approve or reject an exceptional funding request.

The Department has introduced a new Pharmaceutical Price Regulation Scheme which it claims will reduce the cost to the NHS of purchasing drugs. The new PPR Scheme will also place greater emphasis on risk sharing schemes which it has re-termed as patient access schemes. As we noted previously in our 2008 report into NICE, we have serious concerns
about the effectiveness of risk sharing schemes where they place the risk for proving the success of the scheme on the NHS and not on pharmaceutical companies. We repeat the recommendation we made in our previous report into NICE that risk-sharing schemes be used with caution and that the risks should be borne by the company concerned.

In conclusion, although we are not convinced by the arguments that dismiss the threats of establishing a two-tier system or that separation of patients is practicable for only a part of their treatment, we can see no transparent way of rapidly alleviating the problem other than Professor Richards’ proposals that NHS and privately purchased drug treatments are administered separately. We recommend that every effort is made to minimise the numbers of patients involved by:

- Speeding up the NICE process.
- Increasing the work on disinvestment on the least useful other treatments.
- Standardising PCTs’ Exceptional Funding Request procedures including the communication of decisions and the reasons for them to patients and families.
- Instructing NICE to issue brief, understandable, accessible and well publicised explanations for lay people to explain the reasons for refusing funding for drugs, to give patients and their relatives clearly spelt out information upon which they can base their decision about paying for some but not all medicines.

The Department should monitor the implementation of the Report’s recommendations by funding research to gather evidence about:

- The actual degree and modes of separation of care achieved by different trusts with and without existing private facilities.
- The support of consultants, especially those who do not normally undertake private practice, and other staff for the scheme.
- The effects on PCTs’ ability to fund other established, essential treatments for other conditions that do not have the benefit of NICE guidance.
- The numbers of patients applying to pay for extra drugs.

Finally, we recommend that the Department also actively addresses the problems of prioritisation by initiating open discussions about NHS treatments or services that should be reduced or not provided.
1 Introduction

1. The Health Committee has long had an interest in the way the NHS allocates its resources through the National Institute of Health and Clinical Excellence (NICE) and Primary Care Trusts (PCTs). We have published two reports into NICE since its establishment in 1999. In 2002 and 2008 we examined how NICE had performed as an independent organisation to help the NHS set priorities and make choices about how it allocated resources.1 We have also held a number of inquiries involving the way that PCTs have allocated resources since their inception in 2002.2

2. In recent years the mechanism by which NICE and Primary Care Trusts allocate NHS resources for drugs, particularly drugs administered to patients with a terminal illness, has become ever more contentious. Some patient organisations, drug companies and clinicians believe that NICE has made the wrong decisions about whether to make certain drugs available on the NHS. Where drugs have not been funded by the NHS, some patients had paid for drugs privately. This has led to concerns, on the one hand, that some parts of the NHS have effectively subsidised private treatment, and on the other, about incidents where NHS care has been withdrawn from patients who have privately purchased drugs.

3. In the light of this growing public and media concern, the Secretary of State commissioned Professor Mike Richards, National Clinical Director for Cancer, to conduct a review to examine the availability of medicines and in particular “if, when and in what circumstances patients should be able to purchase additional drugs that are not funded by the NHS”.3 Professor Richards’ report, Improving access to medicines for NHS patients, published on 4 November 2008, made fourteen recommendations which were on the same day accepted by the Department. Two were particularly significant. These were: the decision to allow the purchase of additional drugs as long as they were administered separately from NHS treatment and measures aimed at making expensive drugs more widely available to NHS patients. Subsequently NICE gave its Appraisal Committees new guidance aimed at improving access to expensive medicines licensed for terminal illnesses, affecting small numbers of patients.

4. On 21 November 2008, following the publication of Professor Richards’ report and the announcement of NICE’s consultation on appraising end-of-life medicines, we decided to undertake an inquiry into the purchase of additional drugs by NHS patients (“top-up fees”). Individuals and organisations were invited to submit evidence outlining their observations about these decisions. We received written evidence from 44 individuals and organisations.

5. We took oral evidence from: NHS Chief Executives, senior clinicians, patient organisations, academics, the Chairman of NICE and Professor Mike Richards. We are extremely grateful to our witnesses and to all those who submitted written evidence. We

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2 For example, Health Committee, Fifth Report of Session 2007–08, Dental Services, HC 289–I
3 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
are also indebted to Professor Alan Maynard and Dr Daphne Austin, our Specialist Advisers, for their advice.\footnote{Dr Austin declared her interest as Chair of the UK Commissioning Public Health Network and Professor Maynard declared his interest as Chair of York Hospitals NHS Foundation Trust.}
2 The nature and scale of the problem

6. Over the last decade the NHS has been increasingly challenged by patients, their relatives and patient groups to provide a growing number of new drugs to treat cancer and other life-threatening conditions. These drugs are often the product of years of expensive research and development undertaken by pharmaceutical companies and as a consequence many are expensive. The NHS uses two main methods to determine whether or not it will fund a drug: nationally through the National Institute of Health and Clinical Excellence (NICE) and locally through Primary Care Trusts (PCTs).

The role of NICE and PCTs in determining access to drugs

7. In 1999 the Government established the National Institute of Health and Clinical Excellence (NICE) as an independent organisation with a remit to help the NHS set priorities and make choices about how it allocates resources. Since 1999 NICE has produced a range of mandatory guidance to the NHS on health technology appraisals (covering medicines and medical or diagnostic interventions) and advisory guidance on clinical practice and public health interventions (since 2005). The organisation produces its guidance in the light of an analysis of the clinical and cost-effectiveness of interventions and treatments. The mandatory guidance NICE gives on whether health technologies should be funded by the NHS is a key aspect of its work because PCTs must fund drugs which are approved by the organisation. While many routine treatments in use today in the NHS were produced before the establishment of NICE and have not been subjected to clinical and economic evaluation, many new technologies since 1999 have been evaluated by NICE.

8. In most cases clinicians will treat patients using high cost drugs approved by NICE (or funded by their PCT through the exceptions panel) but there are occasions when a clinician wishes to prescribe a drug which is not funded by the NHS. This happens for:

- Drugs on which NICE has yet to issue final guidance;
- Drugs that NICE will not appraise or that a clinician wishes to use for a non-licensed indication;
- Drugs that NICE has declined to recommend for use in the NHS.

9. Where a particular drug is not routinely funded by the NHS but for clinical reasons a doctor determines that it would benefit a patient, a doctor may ask the patient’s PCT to fund the drug. Where a PCT refuses to fund a drug that does not have NICE approval, patients have a choice: to accept the decision of the PCT and receive NHS care only; or to

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5 For further information about the work of NICE see Health Committee, First Report Session of 2007–08, National Institute for Health and Clinical Excellence, HC 27–1
6 PCTs are able, if they choose, to fund drugs on which a NICE decision is pending
7 The use of drugs for outside of their licensed indication where there is a reasonable prospect that the drug will lead to clinical benefit is sometimes referred to as “off-label”
8 Department of Health, Improving access to medicines, “A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
pay for the drug and combine their NHS and private treatment. A number of different terms are used to describe the process of mixing NHS and private care (see Box 1 below).

**Box 1: Common terms for mixing elements of NHS and private treatment.**

During this inquiry we have heard a number of different terms that have been commonly used to describe the methods for mixing NHS and private treatment. These terms are often used interchangeably and inconsistently. In this report we use the following terms:

- **Top-up payments:** Payments made by patients who chose to pay privately for extra treatment in addition to the care provided to them free at the point of delivery by the NHS.
- **Co-payments / user charges:** Where the patient must make a financial contribution in order to access a standard NHS clinical service.

**Criticisms of the system**

10. A number of criticisms have been made of the way that NICE and PCTs decide which drugs should be funded:

- NICE makes its decisions too slowly;
- NICE is too ready to reject expensive new drugs on the grounds of cost-effectiveness;
- There are inconsistencies both within and between PCTs about the decisions they reach on whether to provide exceptional funding for the drugs which NICE has not approved or has not yet made a ruling on; and
- Some clinicians and trusts have decided to withdraw funding to patients for the NHS element of their care when they have chosen to purchase a drug which NICE had either rejected or not assessed. They believed wrongly that this was the correct interpretation of NHS rules.

**The role of NICE**

11. NICE has faced widespread criticism for taking too long to reach a judgment on technology appraisals. This Committee found in its 2008 inquiry into NICE that the process can take up to two years. This criticism was accepted by the Department which announced in the 2008 NHS Next Stage Review measures to ensure that the maximum time between a drug’s referral to NICE for assessment to being available, if approved, for prescription by doctors, would be a maximum of six months.

12. Other critics of NICE, including the Rarer Cancers Forum and Beating Bowel Cancer, argued that NICE placed too much emphasis on the cost per quality-adjusted life year (QALY) measurement when deciding whether or not to recommend funding for drugs for patients with a terminal illness. In 2008 the Health Committee Report on NICE identified the cost per QALY cut-off point to be £30,000, a figure subsequently accepted by NICE to
be broadly accurate. By broadly keeping to this cost per QALY value for end-of-life patients, patient groups argued that NICE had effectively set a “price on time” without sufficient weight being put on the value of a dying patient’s last few weeks and months of life. The charities argued, in effect, that NICE should approve more drugs.

13. NICE argued that the NHS funded a “large proportion” of the drugs it had evaluated. For cancer drugs, between January 2004 and November 2008 NICE reported that it had:

- fully approved 13 drugs for the licensed indications examined;
- approved 14 drugs for use with particular sub-groups within the examined licensed indications;
- recommended that one drug for a particular indication should be used only in the context of research (i.e. the company should fund further research and return to NICE with better evidence of clinical and cost effectiveness); and
- terminated four appraisals because either the manufacturer failed to provide evidence or provided inadequate evidence.
- In five instances recommended that the drugs should not be used for particular indications—in all cases because of the lack of demonstrable evidence of cost-effectiveness as shown in clinical trials.

Given the criticism that NICE has received, the last category seems to be a small number of cases. However, Professor Richards said that the number of drugs rejected by NICE would subsequently have increased:

In recent months there have been a few drugs that have not been recommended on the grounds of cost-effectiveness. Evidence suggests that, in the future, in certain circumstances it may become more challenging to demonstrate cost-effectiveness…it may well be that higher numbers of patients will be placed in a position where their clinician feels that they could benefit from a drug that will not be funded by the NHS.

14. Part of the problem is that confusion arises because while some unfunded drugs do give significant benefits (measured in cost per QALYs) to certain individual patients, they are only marginally, or not at all, beneficial to the great majority of patients.

**The role of Primary Care Trusts**

15. Funding those drug treatments approved by NICE is one of several responsibilities of the 152 Primary Care Trusts in England. In addition to their funding role, PCTs assess the

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11 HC (2007–08) 27–I
12 Ev 12 (HC 194–II)
13 Ev 27 (HC 194–II)
14 For treating cancer and wet age-related macular degeneration.
15 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
needs of their local population, develop strategic plans for individual service and patient groups, and commission services to reflect those needs. As part of this process, PCTs have to decide where they focus their resources and new drug treatments have to compete for funding against other health priorities. The needs of different patient groups also have to be prioritised against each other.\textsuperscript{16} For drugs which have not been approved by NICE, patients or their doctor can request their local PCT to provide funding. Where that request is turned down, patients can, as has been seen, apply to their PCT for “exceptional funding”.\textsuperscript{17}

**Exceptional Funding Requests**

16. While NICE has rejected funding for a relatively small number of drugs, criticisms were also made of the process by which individuals ask their PCT to provide funding for drugs which NICE had previously judged to be not cost-effective. Professor Richards estimated that there were about 15,000 patients per annum who asked for local funding from PCT Exceptional Case Panels.\textsuperscript{18} Figures from the NHS National Prescribing Centre report that during 2007–08 the number of requests for funding considered by each PCT ranged widely from 1 to 1,000.\textsuperscript{19} Of that figure, 22% of PCTs had considered 40 cases or fewer and 12% of PCTs had considered more than 200 cases. Of the total figure of funding requests, the Rarer Cancers Forum estimated that approximately 3,000 applications had been made by or on behalf of cancer patients.\textsuperscript{20}

17. According to Professor Richards, applications for exceptional funding in a typical year related to over 50 different drugs of which over 30 were cancer drugs.\textsuperscript{21} The largest category of requests appear to be for drugs on which NICE has yet to issue final guidance:

Applications for off-label use are largely related to non-cancerous conditions and are numerous. True “exceptional case” requests for drugs that have been declined by NICE appear to be uncommon. It is uncertain whether this reflects demand or previous experience by clinicians or Trusts of rejections of such applications.\textsuperscript{22}

18. Patient groups argued, and Professor Richards acknowledged, that not only were there wide variations between PCTs in the number of requests for exceptional funding they received, but there were also differences in the way that they responded to the requests. The Rarer Cancers Forum argued that the way that PCTs dealt with the requests was inconsistent, with some PCTs accepting the vast majority of requests and others accepting none of them.\textsuperscript{23} According to the Forum this suggested that:

\textsuperscript{16} Q 11
\textsuperscript{17} Also known as an Individual Funding Request
\textsuperscript{18} Q 218
\textsuperscript{19} The Rarer Cancers Forum estimated that there was a 180-fold variation in the exceptional funding requests received by PCTs.
\textsuperscript{20} Ev 5 (HC 194–II)
\textsuperscript{21} Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
\textsuperscript{22} Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
\textsuperscript{23} Ev 5 (HC 194–II)
either some PCTs are particularly generous in their funding of cancer medicines which have not been approved by NICE, meaning that very few treatments ever get to the stage where exceptional requests for funding are made, or that some PCTs are discouraging clinicians from using the exceptional funding route.24

According to Beating Bowel Cancer, the exceptional funding route for cancer patients was often successful. According to the organisation, approximately 2,200 cases (76%) of exceptional funding applications to PCTs were approved.25 Moreover, the NHS National Prescribing Centre (NHS NPC) reported in February 2009 that an average of 47% of appeals by patients against PCT decisions were successful.26

19. In addition a number of witnesses were critical of what they argued was the lack of transparency about the decision-making process and of the lack of information made available by PCTs to patients about how their appeal was considered and the justification for the final decision. This view was reinforced by the NHS NPC which reported in February 2009 that a majority of PCTs which it had surveyed had estimated that only just over half (57%) of patients and the public were aware of the decisions they had taken about exceptional case appeals.27

**The withdrawal of NHS care for patients who chose to purchase additional treatment**

20. In cases where NICE has not approved a drug and PCTs have decided not to provide exceptional funding, a number of patients have sought to purchase the drug, in effect purchasing private care to add to their NHS care in the hope of extending their life for a few weeks or months. The Rarer Cancers Forum estimated that the average cost of purchasing cancer treatment was £20,821, an expense which patient organisations said had left some patients and their families facing the invidious position of using their life savings or selling their home to meet the costs.28 Many patients could not purchase additional treatment due to its expense; Professor Richards thought that most would have chosen to undergo further treatment if they could have afforded it in the hope that they would have extended their life even for a relatively short time.29

21. Those who had purchased additional cancer drugs privately, however, had to do so according to the guideline that “patients cannot be a private patient and an NHS patient for the treatment of one condition during a single visit to a health service hospital”.30 This guidance was based on the principle established in 1948 that “care should be provided to all on the basis of need and not according to ability to pay”, a principle that was reinforced in

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24 Ev 6 (HC 194–II)
25 Ev 5 (HC 194–II), Q 81
27 Ibid.
28 Ev 5 (HC 194–II)
29 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008 Improving access to medicines
30 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
the National Health Service Act 2006 and subsequently by a number of “codes of conduct” issued by the Department.31

22. Sir Len Fenwick, Chief Executive, Newcastle Hospitals Foundation Trust was one of a number of witnesses who argued that the existing guidance on the provision of NHS and private treatment had been clear.32 However, in practice the guidance has been interpreted differently across England.33 Some parts of the NHS had interpreted the rules to mean that care should be withdrawn from patients who purchased drugs, while other areas had permitted patients to do so:

In practice, some Trusts allow patients to buy additional private drugs while continuing their NHS care for the same condition as long as the patient is able to receive the private drug, as a private patient, in a private setting. However, another common interpretation has been that any mixing of NHS and private care for the same condition is not allowed. Some Trusts have maintained that if a patient wishes to purchase an additional private drug, they must then have the whole course of treatment for that condition as a private patient, including that treatment which the patient would usually have received free of charge on the NHS. Such patients therefore lost their entitlement to NHS care.34

23. A much publicised case of a patient who had their NHS treatment withdrawn as a consequence of purchasing drugs privately was that of Linda O’Boyle who, while receiving NHS treatment for bowel cancer chose to purchase privately a drug, cetuximab, which was not routinely funded by the NHS. As a consequence, it was reported that Southend University Hospital NHS Foundation Trust withdrew her free treatment, including the chemotherapy drug she was receiving.35 The extent of this practice was unclear. Dr Jacky Davies was one of a number of witnesses who judged that “One of the problems we all seem to be suffering with here is that we simply do not know the scale of this problem”.36

24. In contrast, The King’s Fund argued that some Trusts had effectively subsidised private care by hospitals choosing to “top-up NHS care on behalf of their patients”. However, Sir Len Fenwick, believed that some parts of the media had exaggerated the scale of the problem.37 Certainly the figures that are available suggest that the problem has been remarkably small: Professor Richards and other witnesses indicated that there had been around 18 cases of patients having had the NHS element of their care withdrawn.38

25. Despite there being only 18 cases, Professor Richards said that the problems with the NICE process and inconsistencies in the way that PCTs had interpreted rules on providing

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31 For example, management of private practice in health service hospitals in England and Wales, 1986 and The code of conduct for private practice 2004
32 Qq 6–8
33 Q 214
34 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008 Improving access to medicines
35 The Times, NHS scandal: dying cancer victim was forced to pay, 1 June 2008; and HC Deb 10 June 2008, Col 54WH
36 Q 98
37 Q 40
38 Q 213
care, had resulted in confusion among patients and a loss of confidence in the system. He added that this confusion arose for patients and their families at the same time they had to come to terms with a fatal illness.

Conclusions

26. The NHS faces growing pressure to make available an increasing number of expensive medicines to patients. The NHS uses two main methods to determine whether or not drugs are sufficiently cost-effective to be funded by the NHS: nationally through the National Institute of Health and Clinical Excellence (NICE) and locally through Primary Care Trusts (PCTs). A number of criticisms were made about the system for making drugs available on the NHS. These related to:

- The NICE process for appraising drugs for end-of-life conditions, both in respect of the speed of appraisals and the failure to approve drugs of some clinical effectiveness which were not demonstrably cost-effective.

- The inconsistencies in the decisions made by PCTs in assessing exceptional funding requests.

- The decision by some NHS trusts to withdraw care for patients who chose to purchase additional drugs.

27. The Department has accepted the Health Committee’s criticism made in 2008 that NICE had, in some cases, been too slow in appraising new drugs. We welcome the Department’s commitment that the maximum time between a drug’s referral to NICE for evaluation and its availability for prescription will be six months.

28. Of the twenty one cancer drugs that NICE considered between 2007–08, the organisation did not approve funding for five on the grounds that they were not cost-effective. Some witnesses argued that patients had been denied drugs that would have benefited them. While some of them do give significant benefits (measured in QALYs) to certain individual patients, they are only marginally, or not at all, beneficial to the great majority of patients.

29. However, owing to the increased number of drugs that it was due to consider over coming months, Professor Richards stated that without closer working between Government and industry, some will fail the cost-effectiveness tests that are currently used and that “it may well be that higher numbers of patients will be placed in a position where their clinician feels that they could benefit from a drug that will not be funded by the NHS”. 39

30. Currently there are around 15,000 applications per annum made to PCTs for exceptional funding for drugs. The number of cases considered by each PCT varied widely between 1 and 1,000. It is, however, unclear how many of these cases were subsequently approved. For cancer drugs, it is estimated that about three quarters of the 3,000 requests were approved although this figure varied greatly between PCTs.

39 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
31. There were a number of criticisms about the lack of information made available by PCTs to patients about the appeal process and the justification for the PCT’s final decision. PCTs themselves estimated that only just over half of patients and the public were aware of the decisions they had taken.

32. Some patients whose funding requests for drugs had been rejected by PCTs had decided to purchase the drug privately. Although we were told that NHS rules about purchasing treatment were clear, PCTs had applied them inconsistently. Some PCTs withdrew funding for patients who chose to purchase additional treatment, while other PCTs effectively subsidised the private treatment.

33. Professor Richards stated that the failure of the NHS to meet the demand for expensive drugs, and concerns that some PCTs had withdrawn NHS funding for patients who had purchased drugs, had combined to result in a loss of confidence in the system for making drugs available on the NHS. Despite much media coverage of the issue, Professor Richards estimated that there were only 18 cases where PCTs had withdrawn NHS funding for patients who had purchased additional drugs.
34. In 2008 and early 2009, faced by the problems identified in the previous chapter as well as the campaign by patient groups, the media and some others, the Department and NICE made a number of decisions which were designed to make it easier for NHS patients to receive drugs not currently provided by the NHS.

Box 2: Key decisions made by the Department aimed at improving access to NHS funded drugs

18 June 2008—The Secretary of State asked Professor Mike Richards, National Clinical Director for Cancer ("Cancer Tsar"), to lead a review of the current arrangements regarding the circumstances in which patients are able to purchase additional drugs that are not funded by the NHS.

4 November 2008—"Improving access to medicines for NHS patients A report for the Secretary of State for Health by Professor Mike Richards CBE" is published. The report makes a total of 14 recommendations, all of which are accepted by the Department on the same day.

4 November 2008—The Department issues for consultation draft guidance to all NHS Chief Executives about the principles which should be followed when separating NHS and private care. At the same time, the NHS Chief Executive directed NHS institutions not to withdraw NHS funding for patients who had chosen to purchase additional treatment privately.

17 December 2008—Following a short consultation NICE issues its Appraisal Committees with supplementary guidance aimed at improving access to expensive medicines licensed for end-of-life patients, affecting small numbers of patients.

27 January 2009—The consultation ends on the draft guidance for separating NHS and private care.

23 March 2009—Final guidance for separating NHS and private care issued to NHS Chief Executives

The Richards Review

35. The Department’s first decision in June 2008 was to appoint Professor Mike Richards, National Clinical Director for Cancer (the "Cancer Tsar") to lead a review of the Department’s policy on the provision of drugs. Professor Richards was asked to examine “if, when and in what circumstances patients should be able to purchase additional drugs that are not funded by the NHS”.

40 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
drugs, included an assessment of the experiences of comparable countries. It also addressed two areas of controversy identified in the previous chapter: whether PCTs (and individual clinicians) were justified under current legislation to withdraw NHS care for patients who had sought additional private treatment for life threatening illnesses; and the extent to which there were variations in the way in which PCTs were implementing existing guidance in this area.

**Box 3: The terms of reference for the Richards Review**

“To examine current policy relating to patients who choose to pay privately for drugs that are not funded on the NHS and who, as a result, are required to pay for the care that they would otherwise have received free on the NHS.

To make recommendations on whether and how policy or guidance could be clarified or improved.

In making recommendations, to take into account:

the importance of enabling patients to have choice and personal control over their healthcare; and

the need to uphold the founding principle of the NHS that treatment is based on clinical need not ability to pay, and to ensure that NHS services are fair to both patients and taxpayers.

The Review will take account of:

the Government’s wider strategy for improving the quality and effectiveness of NHS services; and developing policy and practice arising from the NHS Next Stage Review and Constitution.”

*Source: Department of Health, “Improving access to medicines for NHS patients”*

36. Over the summer of 2008 Professor Richards sought responses to his terms of reference from a range of individuals including patients, clinicians, and representatives of patient groups and pharmaceutical companies. On 4 November 2008, only four months after the Secretary of State had asked him to conduct the Review, and three weeks after the period of consultation had ended, Professor Richards published his findings in *Improving access to medicines for NHS patients.* Despite the limited time available to him, Professor Richards argued that he had reached his conclusions having conducted a “rigorous consultation”, involving “over 2,000 patients, members of the public, NHS staff and managers, and other stakeholders” as well as the involvement of a number of charities such as Macmillan Cancer Support, and the Long Term Conditions Alliance.”

37. A total of fourteen recommendations were made to the Secretary of State which if implemented, Professor Richards argued, would:

- minimise the number of patients who may want to purchase additional drugs by making more expensive drugs available from the NHS; and

- establish clear guidance for those patients who still wished to purchase additional drugs.

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41 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008.

42 Ibid.
Richards’ recommendations to minimise the need to purchase drugs

38. Professor Richards stated that the central aim of his Review was to make drugs more readily available, more quickly, to NHS patients. He also noted that the Department had previously announced measures which he argued would help achieve this aim, including the proposal to improve and quicken the NICE decision-making process for appraising new drugs and the establishment in the draft NHS Constitution of a patient’s right to NICE approved treatments.

39. However, Professor Richards acknowledged that these measures alone would not make more NHS drugs available in all circumstances or end the debate about access to drugs. To that end he recommended:

- closer collaboration between the Department and NICE to devise “affordable measures to make end-of-life drugs that do not meet the cost-effectiveness criteria”;
- negotiations with the pharmaceutical industry to promote more flexible approaches to the pricing and availability of new drugs; and
- more collaboration, carried out transparently, between PCTs when making decisions about whether to fund those drugs which had not yet been appraised by NICE.

We look closely at the potential impact of these recommendations in the following chapter.

Richards’ recommendations to ensure the separation of NHS and private care

40. Despite the implementation of the measures outlined above, there will remain instances where patients wish to purchase drugs not provided by the NHS. Although Professor Richards maintained that when this circumstance arose the existing rules governing the separation of NHS and private care had been clear, he also recognised that some clinicians and PCTs had interpreted them inconsistently. He also acknowledged that there was some confusion about how to separate private and NHS care in practice and looked at how this could be done.

41. Professor Richards considered five options for enabling patients to purchase additional drugs. He described the range of options as follows:

One extreme was that you say to patients, “Sorry, if you have any private care you cannot come to the NHS” and we got a very, very clear message from the public, from patients, from a whole lot of people that that was utterly unacceptable. At the other end of the spectrum we could have gone down a route—we looked at this and rejected it—of saying that effectively the NHS can have a set of basic care that you get free and then on a sort of top-up basis you can pay for extra things on top of that and

43 Q 237
44 Q 226
then there would be a lengthy menu of things you could pay for on the NHS. We rejected that as well because that is not the NHS that I certainly want to see.45

The diagram below illustrates the options considered by Professor Richards.

Option 1 – Either NHS care or private care: patients lose their entitlement to NHS care during the period they are purchasing additional treatment

Option 2 – Voucher scheme: the NHS provides patients who wish to receive specified unfunded drugs with a voucher to the value of NHS standard care

Option 3 – Separate care: patients can receive NHS and private care separately, but in a separate setting

Option 4 – Simultaneous care: patients can receive NHS and private care at the same time and in the same setting

Option 5 – NHS top-ups: patients can pay a charge to the NHS for providing additional drugs and associated care

Source: Department of Health, “Improving access to medicines for NHS patients”

42. Professor Richards concluded that separation of NHS and private care (option 3) was the best option because it enabled people to have that private care while at the same time preserving the fundamental principles of the NHS that the NHS should not subsidise private treatment.46 Of the options favoured by some witnesses vouchers (option 2) and co-payments (option 5) were rejected because:

We believed the voucher scheme was the worst of all options in fact largely because it would take money out of the NHS and also if people then went to a private hospital their NHS element would have transferred them into the private sector but they would be paying more for that same element in the private sector than they would in the NHS. So it would be bad for the individual and it would be bad for the NHS. We looked at that and we set out all the different reasons in the report why we rejected

45 Q 219
46 Ibid.
that. In terms of the option what might be called the full top-up scenario which is saying that the NHS has a schedule of things that you can get on the NHS but here are all the other things which you might want to pay for, I can tell you there was very little enthusiasm for that amongst the great number of people that I talked to.47

43. Having concluded that separation of NHS and private treatment was the best option for the NHS, Professor Richards set out the principles by which it should be implemented. These were:

- the NHS should make clear that no patient should lose their entitlement to NHS care they would have otherwise received, simply because they opt to purchase additional treatment for their condition.48
- the Government should make clear that when additional private drugs are purchased, the following criteria has been followed:
  - clinicians have first exhausted all reasonable avenues for securing NHS funding; and
  - patients should be able to receive additional private drugs as long as these drugs are delivered separately from the NHS elements of their care.49

44. Professor Richards argued that these principles (which following our evidence sessions were reaffirmed in the final guidance issues on 23 March 2009) would end any confusion about whether patients receiving NHS treatment were entitled to purchase additional private drugs, whilst ensuring that when drugs were purchased, the NHS would not subsidise private healthcare. Moreover, he argued that the Review had brought about greater clarity to how care should be separated, while at the same time avoiding the creation of a “two-tier” NHS that other options would have produced.50

**The response of the Department and NICE to the Richards Report**

45. On 4 November 2008, the same day that Professor Richards’ report was published, the Secretary of State accepted all fourteen of Professor Richards’ recommendations. In the weeks following the report’s publication, the Department and NICE made a number of key decisions which were aimed at implementing the recommendations. These were:

- draft guidance was issued for consultation on how to separate NHS and private drug treatments;
- revised “end-of-life” guidance to NICE appraisal committees was issued which encouraged “more flexibility” in the evaluation of higher-cost drugs which have been shown to extend the lives of terminally ill patients, and where “the less common nature

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47 Q 239
48 Recommendation 8
49 Recommendation 9
50 Q 222 and Q 240
of a particular condition may mean that the more flexible pricing arrangements the Department has negotiated with industry are not in themselves sufficient”. \(^{51}\)

- the introduction of “new, more flexible pricing arrangements” between the Government and the pharmaceutical industry through a revised Pharmaceutical Price Regulation Scheme (PPRS);

We now look at these decisions in turn.

**Guidance on separating NHS and private care**

46. Immediately following Richards’ Report the Department announced that those patients who wished to buy additional private care would not have their NHS care withdrawn as long as the private care could be delivered separately. \(^{52}\) At the same time, the Department sought to address concerns that separation might not be possible to implement in all cases by issuing revised guidance about how the NHS should manage these situations.

<table>
<thead>
<tr>
<th>Box 4: Revised guidance on handling separation of NHS and private treatment</th>
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<tr>
<td>“It should always be clear whether an individual procedure or treatment is privately funded or NHS funded. Private and NHS care should be kept as clearly separate as possible. Private care should be carried out at a different time and place. A different place would include the facilities of a private healthcare provider, or part of an NHS organisation which has been designated for private care, including amenity beds. This guidance applies to additional private healthcare that patients receive over and above their NHS care. It does not permit a ‘pick and mix’ approach where patients can pay to upgrade any individual elements of their NHS care.” (^{53})</td>
</tr>
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</table>

*Source: Department of Health*

47. NHS Chief Executives were asked to comment on the guidance by 27 January 2009 and respond to the following questions:

- Is the principle of separateness clear?
- Are sufficient safeguards in place?
- Should there be more assurance mechanisms in place to ensure the guidance is followed and does not lead to any unintended consequences?

48. Although the guidance was issued to the Chief Executives for consultation, Mr David Nicholson, the NHS Chief Executive, asked them to apply the guidance immediately

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\(^{51}\) Ev 1 (HC 194–II)  
\(^{52}\) Ibid.  
\(^{53}\) Department of Health, Guidance on NHS patients who wish to pay for additional private care – A consultation, 4 November 2008
“owing to the need to end uncertainty for patients and the NHS as soon as possible and with immediate effect”. The Department proposed that in practice, the delivery of additional drugs in a private setting could mean their being administered in:

- a dedicated private facility within an NHS Trust;
- a specially designated area for those Trusts without private facilities;
- a private hospital; or
- at home by a private healthcare provider.

49. On 23 March 2009 the Department issued its final guidance on separating care. Although the final guidance contained a number of scenarios to exemplify situations where separation could be achieved, it was little changed from the draft version.55

**Review of guidance for NICE Appraisal Committees**

50. Central to the Department’s plans to minimise the number of patients who purchase additional drugs was the supplementary guidance issued by NICE to its Appraisal Committees which was aimed at improving access to expensive medicines licensed for terminal illnesses, affecting small numbers of patients. The guidance stated that in such circumstances the Appraisal Committees would be asked to consider recommending the use of medicines for use in the NHS even though the incremental cost effectiveness ratio was in excess of £30,000 per quality adjusted life year (QALY), the commonly accepted value given to QALYs for all treatments.57

51. The supplementary guidance was circulated to PCTs for comment on 10 December 2008. Following a brief consultation period, NICE published its final guidance on 2 January 2009. To be covered by the supplementary guidance, a medicine would need to:

- be licensed for treating “smaller populations” (not normally exceeding 7,000) of new patients each year;58
- be indicated for the treatment of patients with a diagnosis of a terminal illness and who are not, on average, expected to live for more than 24 months;
- have sufficient evidence to indicate that it offers a substantial average extension to life compared to current treatment; and
- have been assessed by NICE as having an incremental cost effectiveness ratio in excess of the upper end of the range normally considered by NICE’s Appraisal Committees to represent a cost-effective use of NHS resources.59

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54 Ev 1 (HC 194–II)
55 Department of Health, Guidance on NHS patients who wish to pay for additional private care, 23 March 2009
56 Sometimes referred to as “rarer cancers”
57 Ev 60
58 Professor Rawlins told us that his original guidance was for patient population not normally exceeding 7,000 (Q 244)
In addition, no alternative treatment with comparable benefits should be available through the NHS.

**The Pharmaceutical Price Regulation Scheme**

52. In January 2009 the Department announced a new Pharmaceutical Price Regulation Scheme (PPRS) which it hoped would result in “new, more flexible pricing arrangements” between the NHS and the pharmaceutical industry.\(^{60}\) As a result of this agreement the Department argued that patients would benefit from cheaper, cost-effective, and innovative drugs.

53. The PPRS agreement with industry includes the following measures:

- a reduction in the cost of drugs sold to the NHS: a 3.9% price cut was introduced in February 2009;
- a further price cut of 1.9% to be introduced in January 2010;
- a new non-contractual voluntary scheme providing stability and predictability in Pharmaceutical Pricing for the next five years;
- More risk-sharing arrangements between pharmaceutical companies and the NHS so that more flexible pricing arrangements will enable drug companies to supply drugs to the NHS at lower initial prices, with the option of higher prices if value is proven at a later date; and
- the more systematic use of patient access schemes by drug companies to allow access to medicines which have not initially been assessed as cost or clinically effective by NICE.\(^{61}\)

The Department expects the new scheme to “deliver savings of around £350m for the UK in 2009–10, and around £550m per year thereafter”.\(^{62}\)

**Conclusions**

54. Since 2008 the Department made a number of decisions to increase access to drugs. In November 2008, the Department accepted immediately all Professor Richards’ recommendations and made a number of decisions to implement the recommendations:

- Where patients continued to purchase private drugs, the Department published for consultation draft guidance in January 2009 about how to separate NHS and private treatment. Final guidance was implemented on 23 March 2009.

\(^{59}\) Ev 1 (HC 194–II)

\(^{60}\) The aim of the PPRS is to ensure that the NHS has access to good quality branded medicines at reasonable prices, and promotes a healthy, competitive pharmaceutical industry.

\(^{61}\) Ev 1 (HC 194–II)

\(^{62}\) Ibid.
- In December 2008 the Department introduced supplementary guidance to NICE Appraisal Committees to make available a greater range of more expensive drugs to a greater number of NHS patients and thereby reduce the need for patients to buy drugs privately.

- Other measures, including the new renegotiated PPRS aimed at reducing the price of drugs, have been introduced.

In the next chapters we discuss some concerns about the Department’s plans for implementing the Richards report.
The consequences of separating NHS and private treatment

55. Professor Richards was confident that his report had “resolved” the public’s concern about the availability of expensive drugs on the NHS. During our inquiry there was a generally positive reception for the Richards Report from a range of witnesses. Ms Sophia Christie, Chief Executive of Birmingham PCT considered the report to be a useful reminder of the “rules governing access to the NHS”. Sir Len Fenwick, Chief Executive, Newcastle Hospitals Foundation Trust, commended the report as “tremendously helpful”. The report was welcomed by patient groups including Beating Bowel Cancer’s Chief Executive, Hilary Whitaker who “liked very much the spirit of the report, which is to have a flexible and open approach to how we deal with these issues”.

56. However, some of the oral and written evidence we received did not share this degree of approval. In particular, the memorandum submitted by the UK Commissioning Public Health Network stated that:

The risks to the NHS are profound and continued by highlighting the four main risks they had put to Prof Richards in their response to the original consultation. These were loss of credibility for the NHS, worsening of inequalities through subsidies to private patients, risks from inadequate capacity and ‘the long term consequence of a two-tier system not being acceptable to the public’.

The Royal College of Physicians supported the UK CPHN’s concern about capacity: “In many cases, units are fully occupied and so would not be able to deliver top up care at a separate time without disadvantaging other NHS patients”.

57. In addition, a number of witnesses raised concerns particularly relating to how effectively the recommendations would be implemented by the NHS. Professor Christopher McCabe, Director of Health Economics, University of Leeds, argued that:

The thing about the Richards Review is that it was a set of recommendations and not actually a statement of a new policy. Those recommendations can be interpreted in a number of different ways and we are probably seeing PCTs interpret them in different ways in the absence of a clear specification of how the Department wants them to respond to the Richards Review.
In this chapter we consider the main difficulties facing the Department, PCTs and hospital trusts in implementing Professor Richards’ recommendations for separating NHS and private care.

**Potential problems in separating NHS and private treatment**

58. As we saw in the last chapter, the Department’s guidance states that the administration of purchased drugs should be carried out at “a different time and place” from NHS elements of care and gave four options for this to be done. Although the NHS already operates in a mixed healthcare economy, this is relatively simple to manage where the two elements of care can be kept separate easily for example, where patients receive an NHS hip replacement followed by privately provided physiotherapy. However, separating the administration of drugs, both orally and, particularly, intravenously, will not be straightforward.

59. The final guidance on separating care, issued by the Department in March 2009, was not significantly different from the draft guidance and the Department remained confident that hospitals would be able to meet the challenges of separation. In contrast, some witnesses were concerned that the new arrangements might lead to:

- Patients with the same condition, on the same ward, receiving different treatment;
- Problems with ensuring both the separation and the quality of care;
- Additional costs to the NHS; and
- Whether the Department’s decisions opened the way for a “core service” in the NHS.

**Patients with the same condition, on the same ward, receiving different treatment**

60. We were concerned to determine whether under the proposed arrangements it would be possible for patients with the same condition on the same ward to receive different treatment according to whether or not they could afford to pay for it. Ms Una O’Brien, Director General of Policy and Strategy, Department of Health, stated that it would be the responsibility of individual hospitals, “guided” by Strategic Health Authorities, to choose which of the four options to provide additional treatment were followed. Professor Richards thought that the solution would vary across regions and between hospitals:

I know, for example, that in the north west they are opting to go for the home help care providers in some parts of the area because they believe the demand is going to be very small for this and they do not want to set up a separate facility; they believe it can be very safely done that way. In the north east they have taken a different approach; they have designated three hospitals—Carlisle, Newcastle and...
Middlesbrough—that will do this work. They all have a private wing already and they feel that is the safe way that they can manage this.

61. The Department confirmed that when NHS hospitals were not able to move patients to private facilities to receive additional drugs, they could, under certain conditions, make use of NHS facilities:

It would be possible to designate a chemotherapy unit out of hours at five o’clock on a Tuesday afternoon to be the place where you do the private chemotherapy. If that is kept separate then that is perfectly acceptable.72

62. Several organisations, including the Royal College of Nursing, argued that by temporarily designating part of the NHS hospital as a facility for providing privately-funded care, the NHS would blur the distinction between NHS and private facilities.73 A number of witnesses argued that the logical conclusion of assigning NHS facilities, even temporarily, for private treatment would be patients on the same ward with the same condition being treated differently—a situation seemingly against the founding principle of equal treatment in the NHS. We asked the Department whether this situation would be acceptable:

**Q 227 Chairman:** Could I ask you whether you could see a situation where you would have two patients presenting with the same problem in an NHS hospital and one of them goes for chemotherapy which is different to what the other one gets on the basis that they can afford it and that would be acceptable?

**Professor Richards:** I think that is an absolutely logical conclusion from this report, that there may be people who decide on the basis that they can pay that they will pay, but they will be paying for that element of care privately.

**Q 228 Chairman:** It could be on the same ward in the same hospital?

**Professor Richards:** With the arrangements we have said it will not be on the same ward, it will be, as I said, either in private facilities or through home help care or through specially designated areas. That is what we have set out, the principle of separation.

**Q229 Chairman:** Do you agree with that?

**Ms O’Brien:** I think it is theoretically possible but I would stress again that the thrust and intention of the policy overall is to reduce the circumstances in which that is ever likely to arise. The key thing would be that the circumstances in which someone was choosing to have additional medicine privately ought to be those circumstances where the choice of medicines is for something where it has been decided that it is not cost effective for the NHS to fund.
63. Sir Len Fenwick told us: “I think, in relation to cancer in particular, it is a little naive to believe that there would be complete separation. It is simply not possible”.

He also said:

As a Chief Executive, I do not apologise: patients first, bureaucracy second. In all my years, if the senior professionals in healthcare believe that we must do something for a patient and their supporters which will bring benefit, it is my responsibility to ensure the resource and the facility is there to deliver that…and that is when I am either working within or without the rules, and I believe that brings success.

**Problems with ensuring separation and the quality of care**

64. A number of witnesses argued that there were two linked aspects of treatment where separation might lead to difficulties: moving patients for the administration of privately purchased drugs; and information sharing.

**Moving patients for the administration of privately purchased drugs**

65. Not all hospital trusts have private facilities and, even in those that do, moving a patient to a separate facility (either a private wing / unit in the same NHS hospital, or a private hospital at another location), in order to separate NHS and privately-funded care, could cause discomfort or at the worst, harm the safety of patients. In these situations particularly where a patient needs, for clinical reasons, to receive privately a “cocktail” of drugs intravenously, the Royal College of Physicians argued that the introduction of additional “protocols” would be needed to “minimise the risks inherent in patients switching between units to receive different treatment regimens”. According to Dr Alison Jones of the Royal College of Physicians there would be fewer problems where additional treatment was administered in the same hospital or at home. However difficulties would be greatest where it was administered in separate institutions.

**The importance of information sharing**

66. To ensure that under the new arrangements a patient’s continuity of care is not compromised whether or not it is provided in the same institution, it will be vital that information is shared between the NHS and the private teams. However, in practice this might prove difficult:

Sandra Gidley: .. If somebody is going to a private hospital down the road for their episode of privately funded care, how does that information get back to the NHS?
Dr Alison Jones: If they are having one drug on the NHS and the other privately and the drugs have got to be linked in some way to a specific blood count and other supportive drugs, that would be extremely difficult. You have got two prescriptions for one patient; I think the issues in terms of data transfer are really difficult to maintain safely.  

67. Even for those hospitals that do have private facilities, at the very least, according to Sir Len Fenwick “there is a recipe for difficulty” in ensuring that good communication between teams takes place. Sir Len also argued that this might be made more difficult because “there are many senior clinical practitioners who simply do not get engaged or wish to contemplate any aspect of private practice.”

Additional costs to the NHS

68. Even where private care is delivered separately, the NHS will potentially accrue additional costs. The Royal College of GPs (RCGP) estimated that costs might occur in the following areas:

- the additional staff time needed to administer complex drugs and the monitoring involved in treatment;
- monitoring and prescription, including echocardiograms;
- training for staff who administer the new drugs; and
- an increase in demand for oncology inpatient and outpatient services as patients may live a few months longer.

In addition, witnesses questioned whether patients should be expected to be treated by the NHS for complications, as they currently are for private treatments, which might arise from new, unproven treatments. The RCGP argued that “the extra drugs would cause their share of side effects some of which will cause additional hospital stays. It is not unreasonable to ask who will pay for this treatment—whether this would be the taxpayer or the patient.”

69. Professor Richards was clear that where NHS resources were used, the private sector would be required to provide recompense. For example, Professor Richards maintained that monitoring of patients (following the administration of purchased additional drugs as part of a “cocktail” of drugs) would normally be undertaken within the NHS and that any additional tests related specifically to a privately funded drug will need to be charged for. He argued that:

80 Q 24
81 Q 17
82 Q 17
83 Echocardiogram is a test that uses sound waves to create a moving picture of the heart.
84 Ev 9 (HC 194–II)
The principle is there that the NHS should not subsidise the private element of care so yes, we would expect the NHS to charge for the drug, we would expect the NHS to charge for the time of the pharmacist preparing the drug, the time of nurse delivering the drug.\textsuperscript{85}

70. Professor Chris McCabe estimated that costs incurred by the NHS for administering and monitoring the separation of care might be larger than the organisation estimated. In his submission, Professor McCabe argued that

For Top-ups to be cost neutral to the NHS a new patient level resource use monitoring system would have to be created. Otherwise the NHS would not know who to bill for what.

71. When we pressed the Department to tell us how much they thought it would cost the NHS to monitor and administer additional private treatment, Ms Una O’Brien acknowledged that:

There are no detailed estimates of the administrative overheads…involved in charging, but a number of hospitals do this anyway because they have to, for example, charge for overseas patients; it is not at all uncommon in NHS hospitals. So there are methods for doing this; it is not something that has been brought to our attention as a major overhead or a significant cost that would be brought to bear on the NHS…I would not see it as a major problem.\textsuperscript{86}

72. Professor Karol Sikora, Professor of Oncology at Imperial College and Medical Director of Cancer Partners UK, argued that it would be relatively simple to develop a system for top up administration which evaluated not only the cost of the top–up drug or procedure but also the cost of administration dealing with side effects and a range of other factors.\textsuperscript{87} This he argued would enable the NHS to devise a fixed price for the provision of their private care in a relatively simple way.

\textit{Has the Department’s decisions opened the way for a “core service” in the NHS?}

73. As we stated earlier, patients have been able to buy certain treatments in addition to their NHS care for many years, for example in dental services, where the treatment was easily separated. Nevertheless, witnesses were concerned that the Department’s decision to allow the purchase of additional care for certain medicines would establish a precedent that would open up the possibility of a “core service” emerging in the NHS—a de facto exclusion of certain treatments from the NHS, forcing people to pay or go without treatment.

74. Both Professor Richards and the Department were clear that the arrangements for separating NHS and private care only applied to purchasing additional drugs, although Professor Richards saw the potential for the principle being extended to other treatments

\textsuperscript{85} Q 23
\textsuperscript{86} Q 233
\textsuperscript{87} Ev 65 (HC 194–II)
and recommended that the Government should “clarify the situation regarding unfunded non-drug interventions including devices and procedures”. 88

75. However, Dr Jacky Davis, representing ‘Keep our NHS Public’ argued that:

Once you have people who are NHS patients but who can receive different treatments, you have a two-tier NHS and that it is almost impossible to introduce safeguards against that. 89

She also told us that:

but it has never been that we are facing a situation within the NHS where patients would be on the same ward or in the same hospital having two different treatments based on their ability to pay. There was talk this morning about: ‘Oh, well, we have amenity beds in hospitals.’ Those are hotel services. I have no problem with somebody being able to pay for SKY TV in their room, but there is a problem where people can buy different treatments which are going to affect their life. 90

76. The King’s Fund suggested that pressure to allow patients to pay privately for elements of care was likely to occur where financial separation could be easily defined, such as in the case of “upgraded implants, aids, and devices”. 91 Likewise, Professor Sikora saw the potential application of separation in costly and innovative forms of radiotherapy for cancer—Intensity Modulated Radiation Therapy and Image Guided Radiation Therapy—which are currently not available in the NHS, but available privately. 92

Conclusions

77. The Richards Report was generally well received by witnesses to our Inquiry. Particularly welcome was the statement that NHS care should not be withdrawn from the very small number of patients who purchased additional drugs as long as that care was delivered separately. However some of our evidence expressed concerns about the risks, consequent on the Report, of potential disadvantages to NHS patients including the formation of a two-tier system.

78. Although the Department was confident that its final guidance to NHS trusts would enable the separation of NHS and private care, one witness told us that in practice “it would be a little naive to believe that there would be complete separation. It is simply not possible”. We believe that separation will be harder to achieve in practice than the Department claims. We believe it would be wrong for very seriously ill patients to be moved from an NHS ward to a different location so as to administer a privately paid for drug separately. This undoubted disruption to a patient’s quality of life just to meet some bureaucratic requirement would not only endanger the patient’s care but would

88 Department of Health, “Improving access to medicines for NHS patients” A report for the Secretary of State for Health by Professor Mike Richards CBE, 4 November 2008
89 Q 70
90 Q 78
91 Ev 41 (HC 194–II)
92 Ev 65 (HC 194–II)
be unjust. We are very concerned that two patients with the same condition on the same NHS ward might receive different treatments because one patient could afford it and the other could not. This must not be allowed to happen except in the circumstances described in the Department’s final guidance.

79. Ensuring that treatment for patients is provided with good continuity of care between the NHS and the private sector will require close collaboration and sharing of information between NHS and private clinicians. This will not be easy and will only be achieved by the establishment of excellent working practices and the goodwill of clinicians.

80. We are surprised that the Department has not made any estimate of the costs associated with separating NHS and private care yet felt able to describe them as “not a major problem”. Other witnesses argue the costs may be significant. We were told by Professor Sikora that it might be possible to establish a tariff for treatments so that the true costs of separation can be identified and so ensure that the NHS does not subsidise private care. It will be important to establish costs without introducing an expensive bureaucratic system.

81. We are concerned that the affirmation of the guidelines regarding the separation of NHS and purchased drugs will establish a precedent that would open up the possibility of a “core service” emerging in the NHS obliging patients to co-fund aspects of their treatment or to go without. We reinforce Professor Richards’ call on the Government to clarify its policy in respect of the arrangements which apply to the separation of NHS and private care in relation to non-drug interventions, including devices and procedures.
5 The potential consequences of the proposals to make more drugs available

82. As we discussed earlier, the Richards Report made a number of recommendations aimed at increasing the number of drugs funded by the NHS. The challenge of making new, often expensive, treatments available quickly to patients within limited resources is faced by health systems around the world. In October 2008, the London School of Hygiene & Tropical Health published a report “Paying for expensive drugs in the statutory system: An overview of experience in 13 countries.” The report, which was commissioned and funded by the Department of Health, examined the process of decision-making by regulators / health authorities in 13 countries with regard to the funding of “expensive” licensed pharmaceuticals. The report noted wide variations in the way that countries go about licensing and funding drugs, but found that in each country “Tensions between authorities, whether governmental or non-governmental, responsible for reimbursement decisions and the pharmaceutical industry regarding reimbursement issues are seen in most countries.”

83. During our recent visit to New Zealand we met PHARMAC (the Pharmaceuticals Management Agency) and learned at first hand about some of these tensions. The organisation uses the same data as NICE in judging the effectiveness of drugs (based on QALYs) and has declined, on grounds of cost-effectiveness, to fund a number of drugs that NICE has also decided not to fund.

84. In the Next Stage Review Final Report, published in June 2008, the Department announced changes to the way that NICE assessed drugs so that the time from a drug’s appraisal by NICE to it being available for prescription by doctors, would be no more than six months. In addition the proposed NHS Constitution will reinforce the right of all patients to receive a drug approved by NICE. As we have seen, linked to these announcements, the Department and NICE made two significant announcements which were aimed at increasing the availability of expensive drugs to all patients:

• the supplementary guidance to NICE Appraisal committees on end-of-life drugs; and

• the new Pharmaceutical Price Regulation Scheme.

The review of guidance for NICE Appraisal Committees

85. The new NICE guidance was criticised by a range of witnesses. Concerns fell into four broad areas:

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93 London School of Hygiene & Tropical Health,” Paying for expensive drugs in the statutory system: An overview of experience in 13 countries.” October 2008

94 Ibid.

95 Department of Health, High Quality Care For All, Next Stage Review Final Report, Cm 7432, 30 June 2008
• The questionable basis for what amounts to raising the QALY for end-of-life drugs;
• Inconsistencies will remain between PCTs;
• Changes to the Exceptional Funding Request procedure; and
• Funding end-of-life treatments will not be affordable.

**The questionable basis for what amounts to raising the QALY for end-of-life drugs**

86. The issue of how to determine NICE thresholds has long been a concern to this Committee.96 As our 2008 Report into NICE noted, and the Department acknowledged, the QALY is not derived from empirical data and has been the subject of much debate amongst health economists; some economists suggest that it should be lowered, others that it should be raised.97

87. NICE’s instruction that Appraisal Committees should treat drugs designed to treat patients with rare terminal diseases with greater flexibility was not accompanied by any detail about what the new cost per QALY should be. Although when we pressed him for further information Professor Sir Michael Rawlins denied reports that the guidance had effectively raised the cost per QALY to £70,000 for patients at the end of their life, he acknowledged that “we have always given our advisory committees latitude to go above and below it [the threshold of £20,000–£30,000]” and that the guidance had made this flexible approach clearer.98 Two justifications for treating the end-of-life cost per QALY “more flexibly” (i.e. having a high threshold) were given. First, drug companies are not able to provide drugs cheaply to small patient populations and second, the public places a higher value on the treatment given to patients at the end of their life.

**Defining small populations**

88. NICE has defined the size of the population of patients suffering from terminal illnesses who would benefit from its new guidance as “small patient populations”. For cancer, this means that the four most common types of cancers in the UK (affecting the colon, breast, prostate, and lung) would not benefit from the guidance. Professor Rawlins argued that it was important to place clear limits on the numbers of patients who would benefit from the new guidance because: “we cannot do this for common lethal conditions. It would cost the health service hundreds of millions of pounds a year”.99

89. According to Professor Rawlins, the guidance on the cost per QALY threshold for less common cancers merited more flexibility because:

   All this recognises that the development costs for treatments for less common conditions are going to be pretty well the same as development costs for common

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96 See HC (2007–08) 27–I
97 Q 247
98 Q 241
99 Q 245
conditions but the market will be smaller and therefore the unit cost is likely to be higher. We recognise that manufacturers may well have to charge more for treatments for less common conditions.100

90. Less common cancers that would be covered by the guidance include: oral cancer, myeloma and cancer of the kidney.101 Hilary Whittaker, Chief Executive of Beating Bowel Cancer was one of a number of witness who argued for greater clarity about what constituted a "small patient population".102 Evidence submitted by the Centre for Health Economics, University of York, argued that:

Given that increasingly new drugs are ‘designer’ technologies for small subgroups of patients, often with particular genetic characteristics, many new products can be viewed as treatment for ‘rare’ diseases. For example, while breast cancer is not a particularly rare condition, treatments such as trastuzumab (Herceptin) are clinically effective only for a sub-group of patients—in this case those who have HER-2 breast cancer. Does this make it a rare condition? For the ‘rarer’ cancers, the argument is that there should be special consideration of patient sub-groups of 7,000 or less. Again, the central issue is demonstrable cost-effectiveness rather than special consideration.103

Willingness-to-pay exercises

91. NICE also partly based its decision to promote greater flexibility for end-of-life treatments on measures of society’s “willingness to pay for treatment of people at the end of life”.104 It does this through the citizens’ juries and surveys of the public which are designed to determine the level of funding the NHS should devote to treating patients at the end of their life. Professor Rawlins argued that these exercises were beneficial in a number of different ways:

First of all, would people want to be allowed to pay and all the evidence there is that four-fifths of the population are saying they would want to be allowed to pay on top of NHS care. Cambridge University Hospitals did some work where they asked people how much they would be prepared to pay. Only 120 people responded to this but over 50% of them said they would pay up to £10,000 and 30% of them said they would pay £30,000.105

Professor Cam Donaldson argued that public consultations were justified on the grounds that:

100 Q 245
101 Q 246
102 Q 105
103 Ev 80
104 Ev 27 (HC 194-II)
105 Q 250
what can be more legitimate than asking those who pay for services and who stand to gain or lose from different allocations of NHS resources—i.e. the public—what are their views about what should count?106

92. Other witnesses, however, questioned whether NICE’s assessment of public opinion was the best means of determining the value which should be put on treatment for patients nearing the end of their life. Professor McCabe argued that:

patient preferences…may not be relevant to the type of resource allocation…In reality, the evidence base to support a claim that society attaches a special value to interventions which extend life at the end of life is notable by its absence.107

93. PCT managers also questioned the validity of the exercises noting that they failed to inform the public beforehand of the treatments and services they would have to forego if additional funds were given to end-of-life treatments.108 The UK CPHN maintained that healthcare professionals were best placed to make these decisions in the context of the overall healthcare budget. The organisation argued that if the public was made aware of the opportunity cost of providing additional resources to treating the terminally ill, then the results of the exercise would be very different. The UK CPHN stated:

It is right that Society’s values need to be embedded into NHS decision making but this cannot be done in a piecemeal way. If politicians and the public wish resource allocators to give preferential treatment to certain patients then they will also need to say which services and treatments should be reduced or not provided at all.109

94. While witnesses disagreed about the weight that should be given to these studies, there was agreement that more work should be done to explore the public’s attitudes to funding treatments for rare cancers. The King’s Fund argued that:

If media coverage and political interest is anything to go by, there does appear to be public support for the idea that a patient who has been given just a few months to live may well regard the time left to them as particularly precious and that it is reasonable for the state to place additional value on that time compared to say someone who can expect to have say 20 years left. However, more work does need to be done to explore public attitudes and to have a wider and more considered debate than hitherto. There does not seem to have been much research in this area, the Review identified just two studies on patients’ notional willingness to pay for an extended, or improved, quality of life.110

Inconsistencies will remain between PCTs

95. As we discussed in Chapter 1 a recurring criticism has been the inconsistencies in the way that PCTs implement NICE guidance. The Department hopes that the commitment in

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106 Ev 52
107 Ev 72
108 Ev 17
109 Ev 20 (HC 194–II)
110 Ev 41 (HC 194–II)
the NHS Constitution, that patients will be entitled to NICE approved drugs, will address much of this concern. However, a number of witnesses noted that the supplementary guidance is mandatory only for NICE approved drugs. Whilst there might now be greater consistency in funding of drugs that NICE has approved, there remains significant scope for inconsistency, and consequently for controversy, in the cases of drugs that:

- NICE has not decided to appraise (a Department of Health survey for the Richards review found that 43% of PCTs which responded had funded drugs of this kind);
- NICE is still appraising (the review found there were “numerous requests” for such drugs);
- NICE has rejected on grounds of effectiveness / cost-effectiveness (13% of PCTs responding to the survey had funded drugs in this category);
- are being used for an un-licensed indication (i.e. for an indication other than that for which they are licensed).

96. In each of these cases, some PCT commissioners may be prepared to pay for the drug concerned, whereas others may not. There are no nationally set criteria or procedures to which PCTs must adhere in making determinations about exceptionality. As stated earlier, where funding of drugs is turned down by PCTs, patients can appeal against the decision through a process known as Exceptional Funding Requests.111

Changes to the Exceptional Funding Request procedure

97. Many patient groups complained that the individual funding request process was carried out inconsistently by PCTs. In 2008, Macmillan surveyed PCTs about their exceptional funding processes. According to Macmillan, the survey revealed:

- A lack of consistency across the country around the rules;
- A lack of doctors on the panel judging the requests; and
- Little patient awareness: only 38% of PCTs that responded said they actively promoted the process to patients.

98. The Department has accepted some of this criticism and through the implementation of measures in 2008/09 claimed to have addressed them. The most significant of these appears to be the commitment in the NHS Constitution and Professor Richards’ proposals that Exceptional Funding Requests should be subject to more openness and transparency. The Department’s final guidance on NHS patients who wish to pay for additional care, instructs PCTs to ensure that they have “robust, transparent processes in place to make sure such decisions, including decisions on exceptional funding”.112

99. The King’s Fund argued that Richards’ proposals for a more transparent process regarding appeals for exceptional funding would help to promote a degree of consistency

111 Also referred to as Individual Funding Requests

112 Department of Health, Guidance on NHS patients who wish to pay for additional private care, 23 March 2009.
because it would allow “both patients and clinicians to see and compare what information and arguments have been used in similar cases”. A number of witnesses argued that patients should receive information about how their application for exceptional funding was assessed and who had made the decision. A survey by the National Prescribing Centre (NPC) in October 2008 revealed that only 57% of PCTs “believed that there was some patient and public awareness of the decisions made by the panels which made them”. In addition, the NPC noted that even where there was awareness, the level of understanding was relatively low.

100. However, some PCT commissioners were concerned that the changes to the rules governing exceptional funding requests would put pressure on PCTs to fund drugs that they could not afford. The UK Commissioners of Public Health Network (UK CPHN) argued that PCT funding decisions were more likely than ever to be based on the phenomenon of “he who shouts loudest” and would be biased in favour of services for which there is private sector provision. According to the group, this would eventually lead to a “breakdown in any notion of a [cost per QALY] threshold and that there would be less consistency among PCTs about the funding decisions they reached, thereby making the application of value for money potentially redundant within the NHS”.

**Funding end-of-life treatments will not be affordable**

101. Several witnesses argued that within a finite, albeit large, NHS budget, devoting more resources to funding end-of-life drug treatments would divert funding from other areas. According to the UK CPHN:

> The effect of this will be that the NHS will spend an increasingly greater proportion of its funding on treatments which have the least effect, and proportionately less on other patient groups.

The Network added that:

> treatments for patients with metastatic or particularly aggressive disease are unlikely to improve five year survival rates but might compromise the NHS’s ability to deliver other aspects of care.

102. Ms Sophia Christie, Chief Executive of Birmingham PCT, questioned whether resources were best spent on giving patients a few extra weeks of life. In effect, she argued that money used to keep terminally ill people alive for a small additional period of time, could be better spent on caring for patients whose lives can be actually saved:

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113 Ev 41 (HC 194–II)
114 NHS National Prescribing Centre, A Comprehensive Survey of PCTs to Evaluate local decision making processes for funding new medicines, February 2009
115 Ev 19 (HC 194–II)
116 Ibid.
117 Ibid.
118 Ibid.
If NICE are not able to prioritise what they put forward for funding, then PCTs will not be able to prioritise our investment to local health need. We will not be able to deliver wise investment of taxpayers’ money, we will not be able to achieve the stated policy aims of tackling health inequalities and improving mortality and adding years to life as well as life to years, because all of our money will have gone in the last six weeks of people’s lives and potentially—and this is the bit that really worries me—without them getting any better service.119

103. Several witnesses argued that it might be more cost-effective for the NHS to focus resources on non-pharmaceutical treatments including surgery and radiotherapy, which it was argued would represent better value for money than drug treatment.120 Other witnesses including Professor Sikora argued that the Department was right to focus on making pharmaceutical treatments available because future breakthroughs in treatments for life threatening conditions was likely to come from developments in pharmaceutical research.121

104. The Department maintained that the proposals were affordable if the NHS carried out more disinvestments in technologies, which might be effective but had been superseded by other more cost effective medicines.122 Professor Richards argued that the Department had introduced a number of changes to clinical guidelines for certain treatments and thought that there would be scope in the NHS to eliminate waste and to use its resources more efficiently:123

It is not usually so much a question of stopping doing things altogether, it is refocusing and making sure that children with sore throats only get antibiotics under some special circumstances and not as a routine. These are the rather more subtle things. In 2007 we counted there were over 150 disinvestment opportunities from the guidelines and we keep on recycling these to remind people.124

The need for NICE to disinvest from old technologies was highlighted in this Committee’s two reports into NICE. Most recently, in 2008, we concluded “Many treatments currently used [in the NHS] are not cost-effective and that NICE should give more emphasis to examining old technologies to encourage disinvestment”.125

119 Q 42
120 Q 11
121 Q 107
122 The Department announced in 2006 that NICE would be “charged with purging from the NHS treatments that do not improve health or are poor value for money”. Andy Burnham MP, then Minister of State at the Department of Health, stated: “New drugs and treatments are continually emerging, and trusts have to make difficult decisions about how to invest funding. I believe this important new work will show how the NHS can free up millions of pounds from obsolete or ineffective treatments. NICE has an excellent track record in identifying and recommending the most effective new treatments for widespread use in the NHS. But we need to ensure that we balance this with better advice on unnecessary and ineffective interventions that can be stopped.” BMJ, “NICE is to root out ineffective treatments in the NHS”, September 2006.
123 Q 287
124 Q 268
The Pharmaceutical Price Regulation Scheme

105. In our report on NICE, published in 2008, we expressed concern about the affordability of medicines supplied by pharmaceutical companies to the NHS and made a number of suggestions for improving the PPR Scheme to give greater value for money. A new PPRS, agreed between the Government and the pharmaceutical industry, was published in January 2009 and Professor Rawlins claimed the scheme “Is as good an arrangement as there is in the world”. A number of other witnesses however remained sceptical that the new scheme would result in greater cost-effectiveness for the NHS largely because of its continuing reliance on risk-sharing schemes as a means of bringing greater cost-effectiveness for the NHS and failure to implement the recommendation by the Office of Fair Trading that future schemes should include a commitment to value-based pricing.

Patient access / risk sharing schemes

106. Risk sharing schemes have been modified in the new PPRS to become patient access schemes. Dr Felicity Harvey, Director and Head of Medicines Pharmacy and Industry, Department of Health, told us that patient access schemes introduced in the new PPRS would produce benefits because:

the important thing about patient access schemes is that they need to go through an appraisal by NICE in terms of the clinical and cost effectiveness of the scheme and the drug, so it is not just the drug but the drug in the context of the scheme. I think that is going to be very important moving forward.

107. In our 2008 report into NICE we were critical of the risk-sharing scheme for the drugs beta-interferon and glatiramer for patients with multiple sclerosis. Under the scheme, the manufacturers of the drugs came to an agreement with the Department whereby the drug could be used in the NHS as part of a long-term trial. It was agreed that if the drug was less effective than £36,000 per QALY, industry would recompense the NHS. The evaluation was to take 10 years. In 2003 Sheffield University signed a contract with an MS organisation, four medicines manufacturers and the Department of Health (industry division) for an initial three years. Sheffield researchers then wrote a report about the scheme which was submitted in 2006. The next seven year contract then went to tender and Sheffield University did not bid for it. In evidence to the Committee, Professor Jon Nicholl, who led the study, indicated that there were problems with the scheme:

Details of the scheme have not been publicised and the report from Sheffield is not in the public domain, but there are indications that the study will not yield reliable information about the beneficial effects of the drugs.

As we noted in our 2008 report into NICE, there were further problems with the risk-sharing scheme. They included the difficulty of imposing clinical trial conditions in the real world of the NHS. According to Professor Nicholl, the universal availability of drugs used
under risk-sharing schemes meant that there are no comparator groups and no controls. This meant that the uncertainties observed initially were not resolved:

One cannot collect evidence which says that the outcomes for patients who are being treated by the treatments being made available under a risk-sharing scheme are better than for patients not being treated by those drugs. In turn the consequence is that we cannot resolve the uncertainties in the cost and effectiveness as we try to do in the first place.\(^\text{130}\)

108. The Sheffield group subsequently published a report in January 2009.\(^\text{131}\) Astonishingly when we asked Dr Felicity Harvey about the Sheffield study, she denied that there were problems and stated:

It is actually being taken forward through Parexel so actually the study will continue. It continues for ten years; the first set of data has been analysed and is about to be submitted for publication. There are fixed points throughout the ten years where the data will be locked, there will be an analysis and it will be published. The first of those will be published fairly shortly.

109. However Professor Raftery said of the Sheffield University study that:

There are rumours that it is not a success and there are suggestions that lessons should be learned from it. It seems to me that unless those lessons are learned we will repeat the mistakes.\(^\text{132}\)

Conclusions

110. The challenge of making new, often expensive, treatments available quickly to patients within limited resources is faced by health systems around the world. The Department and NICE have introduced two significant initiatives which are aimed at increasing the availability of expensive drugs: the provision of supplementary guidance for end-of-life treatments to NICE Appraisal Committees and the introduction of a new Pharmaceutical Price Regulation Scheme.

111. While Professor Rawlins denied claims that NICE had raised its end-of-life cost per QALY threshold to £70,000, he accepted that NICE Appraisal Committees would be more flexible in the way they appraised expensive treatments. In effect the QALY threshold has been raised for end-of-life drugs. We believe that the decision by NICE to raise its cost per QALY threshold for end-of-life drugs is both inequitable and an inefficient use of resources. By spending more on end-of-life treatments for limited health gain, the NHS will spend less on other more cost-effective treatments.

112. NICE said that that it was important to place clear limits on the numbers of patients who would benefit from the new guidance because the NHS could not afford to apply the guidance for all conditions. However, given that increasingly new drugs are

130 HC (2007–08) 27–I (Q 510)
132 Q 204
‘designer’ technologies for small subgroups of patients many new products can be viewed as treatment for ‘rare’ diseases. We believe that the definition of subgroups of patients suffering from rarer cancers as “small populations” is too woolly and needs more clarity. There is a clear danger that the new arrangements will lead to the system becoming unaffordable as pharmaceutical companies target new drugs on subgroups of diseases.

113. Although we consider it proper that the public’s view on how NHS resources are spent is taken into account, we are not convinced that NICE’s method of doing so is the right one. We recommend that more research is undertaken to determine whether NICE’s favoured method of using citizens’ juries and “willingness-to-pay exercises” is the best way of taking into account the public’s view on this matter.

114. We welcome the Department’s guidance to PCTs for more transparency in the way that they deal with exceptional funding requests for treatments. All decisions on exceptional funding should be consistent with this guidance and PCTs should provide a clear and easily intelligible explanation to patients giving the reasons for any decision to approve or reject an exceptional funding request. PCTs must inform patients of the reasons for rejecting their exceptional funding request.

115. Despite the Department’s proposals, inconsistencies will remain between PCTs about whether or not they fund certain treatments. Those PCTs which do not fund them are likely to come under severe pressure to do so through the exceptional funding request process.

116. The Department maintains that the proposals are affordable if the NHS carries out more disinvestments in technologies which might be effective but which have been superseded by other more cost-effective drugs. In our 2001 and 2008 reports into NICE we called for more effort to be put into disinvesting in obsolete technologies. We are extremely disappointed that little progress seems to have been made in this area.

117. The Department has introduced a new Pharmaceutical Price Regulation Scheme (PPRS) which it claims will reduce the cost to the NHS of purchasing drugs. The new PPRS will also place greater emphasis on risk sharing schemes which it has re-termed as patient access schemes. As we noted previously in our 2008 report into NICE, we have serious concerns about the effectiveness of risk sharing schemes where they place the burden of proving the success of the scheme on the NHS and not on pharmaceutical companies. We repeat the recommendation we made in our 2008 report into NICE that risk-sharing schemes be used with caution and that the risks should be borne by the company concerned.

118. We are surprised by the statement made by Dr Harvey, Director and Head of Medicines Pharmacy and Industry, Department of Health, that the risk sharing scheme evaluated by Sheffield University has been a success as other sources, including our 2008 report into NICE, have indicated that it has been a costly failure. The first published results of the evaluation of the process by the Sheffield group were much delayed and offer little evidence of cost effectiveness.
6 Conclusions

119. In conclusion, although we are not convinced by the arguments that dismiss the threats of establishing a two-tier system or that separation of patients is practicable for only a part of their treatment, we can see no transparent way of rapidly alleviating the problem other than Professor Richards’ Option 3. We recommend that every effort is made to minimise the numbers of patients involved by:

- Speeding up the NICE process.
- Increasing the work on disinvestment on the least useful other treatments.
- Standardising PCTs’ Exceptional Funding Request procedures including the communication of decisions and the reasons for them to patients and families.
- Instructing NICE to issue brief, understandable, accessible and well publicised explanations for lay people to explain the reasons for refusing funding for drugs, to give patients and their relatives clearly spelt out information upon which they can base their decision about paying for some but not all medicines.

120. We recommend that the Department monitors the implementation of the Report’s recommendations by funding research to gather evidence about:

- The actual degree and modes of separation of care achieved by different trusts with and without existing private facilities.
- The support of consultants, especially those who do not normally undertake private practice, and other staff for the scheme.
- The effects on PCTs’ ability to fund other established, essential treatments for other conditions that do not have the benefit of NICE guidance.
- The numbers of patients applying to pay for extra drugs.

121. We recommend that the Department also actively addresses the problems of prioritisation by initiating open discussions about NHS treatments or services that should be reduced or not provided.
Conclusions and recommendations

The nature and scale of the problem

1. The NHS faces growing pressure to make available an increasing number of expensive medicines to patients. The NHS uses two main methods to determine whether or not drugs are sufficiently cost-effective to be funded by the NHS: nationally through the National Institute of Health and Clinical Excellence (NICE) and locally through Primary Care Trusts (PCTs). A number of criticisms were made about the system for making drugs available on the NHS. These related to:
   - The NICE process for appraising drugs for end-of-life conditions, both in respect of the speed of appraisals and the failure to approve drugs of some clinical effectiveness which were not demonstrably cost-effective.
   - The inconsistencies in the decisions made by PCTs in assessing exceptional funding requests.
   - The decision by some NHS trusts to withdraw care for patients who chose to purchase additional drugs. (Paragraph 26)

2. The Department has accepted the Health Committee’s criticism made in 2008 that NICE had, in some cases, been too slow in appraising new drugs. We welcome the Department’s commitment that the maximum time between a drug’s referral to NICE for evaluation and its availability for prescription will be six months. (Paragraph 27)

3. Of the twenty one cancer drugs that NICE considered between 2007–08, the organisation did not approve funding for five on the grounds that they were not cost-effective. Some witnesses argued that patients had been denied drugs that would have benefited them. While some of them do give significant benefits (measured in QALYs) to certain individual patients, they are only marginally, or not at all, beneficial to the great majority of patients. (Paragraph 28)

4. However, owing to the increased number of drugs that it was due to consider over coming months, Professor Richards stated that without closer working between Government and industry, some will fail the cost-effectiveness tests that are currently used and that “it may well be that higher numbers of patients will be placed in a position where their clinician feels that they could benefit from a drug that will not be funded by the NHS”. (Paragraph 29)

5. Currently there are around 15,000 applications per annum made to PCTs for exceptional funding for drugs. The number of cases considered by each PCT varied widely between 1 and 1,000. It is, however, unclear how many of these cases were subsequently approved. For cancer drugs, it is estimated that about three quarters of the 3,000 requests were approved although this figure varied greatly between PCTs. (Paragraph 30)
6. There were a number of criticisms about the lack of information made available by PCTs to patients about the appeal process and the justification for the PCT’s final decision. PCTs themselves estimated that only just over half of patients and the public were aware of the decisions they had taken. (Paragraph 31)

7. Some patients whose funding requests for drugs had been rejected by PCTs had decided to purchase the drug privately. Although we were told that NHS rules about purchasing treatment were clear, PCTs had applied them inconsistently. Some PCTs withdrew funding for patients who chose to purchase additional treatment, while other PCTs effectively subsidised the private treatment. (Paragraph 32)

8. Professor Richards stated that the failure of the NHS to meet the demand for expensive drugs, and concerns that some PCTs had withdrawn NHS funding for patients who had purchased drugs, had combined to result in a loss of confidence in the system for making drugs available on the NHS. Despite much media coverage of the issue, Professor Richards estimated that there were only 18 cases where PCTs had withdrawn NHS funding for patients who had purchased additional drugs. (Paragraph 33)

Addressing the problem

9. Since 2008 the Department made a number of decisions to increase access to drugs. In November 2008, the Department accepted immediately all Professor Richards’ recommendations and made a number of decisions to implement the recommendations:

- Where patients continued to purchase private drugs, the Department published for consultation draft guidance in January 2009 about how to separate NHS and private treatment. Final guidance was implemented on 23 March 2009.

- In December 2008 the Department introduced supplementary guidance to NICE Appraisal Committees to make available a greater range of more expensive drugs to a greater number of NHS patients and thereby reduce the need for patients to buy drugs privately.

- Other measures, including the new renegotiated PPRS aimed at reducing the price of drugs, have been introduced. (Paragraph 54)

The consequences of separating NHS and private treatment

10. The Richards Report was generally well received by witnesses to our Inquiry. Particularly welcome was the statement that NHS care should not be withdrawn from the very small number of patients who purchased additional drugs as long as that care was delivered separately. However some of our evidence expressed concerns about the risks, consequent on the Report, of potential disadvantages to NHS patients including the formation of a two-tier system. (Paragraph 77)

11. Although the Department was confident that its final guidance to NHS trusts would enable the separation of NHS and private care, one witness told us that in practice “it would be a little naive to believe that there would be complete separation. It is simply
not possible”. We believe that separation will be harder to achieve in practice than the Department claims. We believe it would be wrong for very seriously ill patients to be moved from an NHS ward to a different location so as to administer a privately paid for drug separately. This undoubted disruption to a patient’s quality of life just to meet some bureaucratic requirement would not only endanger the patient’s care but would be unjust. We are very concerned that two patients with the same condition on the same NHS ward might receive different treatments because one patient could afford it and the other could not. This must not be allowed to happen except in the circumstances described in the Department’s final guidance. (Paragraph 78)

12. Ensuring that treatment for patients is provided with good continuity of care between the NHS and the private sector will require close collaboration and sharing of information between NHS and private clinicians. This will not be easy and will only be achieved by the establishment of excellent working practices and the goodwill of clinicians. (Paragraph 79)

13. We are surprised that the Department has not made any estimate of the costs associated with separating NHS and private care yet felt able to describe them as “not a major problem”. Other witnesses argue the costs may be significant. We were told by Professor Sikora that it might be possible to establish a tariff for treatments so that the true costs of separation can be identified and so ensure that the NHS does not subsidise private care. It will be important to establish costs without introducing an expensive bureaucratic system. (Paragraph 80)

14. We are concerned that the affirmation of the guidelines regarding the separation of NHS and purchased drugs will establish a precedent that would open up the possibility of a “core service” emerging in the NHS obliging patients to co-fund aspects of their treatment or to go without. We reinforce Professor Richards’ call on the Government to clarify its policy in respect of the arrangements which apply to the separation of NHS and private care in relation to non-drug interventions, including devices and procedures. (Paragraph 81)

The potential consequences of the proposals to make more drugs available

15. The challenge of making new, often expensive, treatments available quickly to patients within limited resources is faced by health systems around the world. The Department and NICE have introduced two significant initiatives which are aimed at increasing the availability of expensive drugs: the provision of supplementary guidance for end-of-life treatments to NICE Appraisal Committees and the introduction of a new Pharmaceutical Price Regulation Scheme. (Paragraph 110)

16. While Professor Rawlins denied claims that NICE had raised its end-of-life cost per QALY threshold to £70,000, he accepted that NICE Appraisal Committees would be more flexible in the way they appraised expensive treatments. In effect the QALY threshold has been raised for end-of-life drugs. We believe that the decision by NICE to raise its cost per QALY threshold for end-of-life drugs is both inequitable and an inefficient use of resources. By spending more on end-of-life treatments for limited
health gain, the NHS will spend less on other more cost-effective treatments. (Paragraph 111)

17. NICE said that that it was important to place clear limits on the numbers of patients who would benefit from the new guidance because the NHS could not afford to apply the guidance for all conditions. However, given that increasingly new drugs are ‘designer’ technologies for small subgroups of patients many new products can be viewed as treatment for ‘rare’ diseases. We believe that the definition of subgroups of patients suffering from rarer cancers as “small populations” is too woolly and needs more clarity. There is a clear danger that the new arrangements will lead to the system becoming unaffordable as pharmaceutical companies target new drugs on subgroups of diseases. (Paragraph 112)

18. Although we consider it proper that the public’s view on how NHS resources are spent is taken into account, we are not convinced that NICE’s method of doing so is the right one. We recommend that more research is undertaken to determine whether NICE’s favoured method of using citizens’ juries and “willingness-to-pay exercises” is the best way of taking into account the public’s view on this matter. (Paragraph 113)

19. We welcome the Department’s guidance to PCTs for more transparency in the way that they deal with exceptional funding requests for treatments. All decisions on exceptional funding should be consistent with this guidance and PCTs should provide a clear and easily intelligible explanation to patients giving the reasons for any decision to approve or reject an exceptional funding request. PCTs must inform patients of the reasons for rejecting their exceptional funding request. (Paragraph 114)

20. Despite the Department’s proposals, inconsistencies will remain between PCTs about whether or not they fund certain treatments. Those PCTs which do not fund them are likely to come under severe pressure to do so through the exceptional funding request process. (Paragraph 115)

21. The Department maintains that the proposals are affordable if the NHS carries out more disinvestments in technologies which might be effective but which have been superseded by other more cost-effective drugs. In our 2001 and 2008 reports into NICE we called for more effort to be put into disinvesting in obsolete technologies. We are extremely disappointed that little progress seems to have been made in this area. (Paragraph 116)

22. The Department has introduced a new Pharmaceutical Price Regulation Scheme (PPRS) which it claims will reduce the cost to the NHS of purchasing drugs. The new PPRS will also place greater emphasis on risk sharing schemes which it has re-termed as patient access schemes. As we noted previously in our 2008 report into NICE, we have serious concerns about the effectiveness of risk sharing schemes where they place the burden of proving the success of the scheme on the NHS and not on pharmaceutical companies. We repeat the recommendation we made in our 2008 report into NICE that risk-sharing schemes be used with caution and that the risks should be borne by the company concerned. (Paragraph 117)
23. We are surprised by the statement made by Dr Harvey, Director and Head of Medicines Pharmacy and Industry, Department of Health, that the risk sharing scheme evaluated by Sheffield University has been a success as other sources, including our 2008 report into NICE, have indicated that it has been a costly failure. The first published results of the evaluation of the process by the Sheffield group were much delayed and offer little evidence of cost effectiveness. (Paragraph 118)

Conclusions

24. In conclusion, although we are not convinced by the arguments that dismiss the threats of establishing a two-tier system or that separation of patients is practicable for only a part of their treatment, we can see no transparent way of rapidly alleviating the problem other than Professor Richards’ Option 3. We recommend that every effort is made to minimise the numbers of patients involved by:

- Speeding up the NICE process.
- Increasing the work on disinvestment on the least useful other treatments.
- Standardising PCTs’ Exceptional Funding Request procedures including the communication of decisions and the reasons for them to patients and families.
- Instructing NICE to issue brief, understandable, accessible and well publicised explanations for lay people to explain the reasons for refusing funding for drugs, to give patients and their relatives clearly spelt out information upon which they can base their decision about paying for some but not all medicines. (Paragraph 119)

25. We recommend that the Department monitors the implementation of the Report’s recommendations by funding research to gather evidence about:

- The actual degree and modes of separation of care achieved by different trusts with and without existing private facilities.
- The support of consultants, especially those who do not normally undertake private practice, and other staff for the scheme.
- The effects on PCTs’ ability to fund other established, essential treatments for other conditions that do not have the benefit of NICE guidance.
- The numbers of patients applying to pay for extra drugs. (Paragraph 120)

26. We recommend that the Department also actively addresses the problems of prioritisation by initiating open discussions about NHS treatments or services that should be reduced or not provided. (Paragraph 121)
Formal Minutes

Thursday 30 April 2009

Members present:

Mr Kevin Barron, in the Chair
Charlotte Atkins     Dr Doug Naysmith
Mr Peter Bone       Dr Howard Stoate
Sandra Gidley       Mr Robert Syms
Stephen Hesford     Dr Richard Taylor

Draft Report (Top-up fees), proposed by the Chairman, brought up and read.

Ordered, That the Chairman’s draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 77 read and agreed to.

Paragraph 78 read as follows: “Although the Department was confident that its final guidance to NHS trusts would enable the separation of NHS and private care, one witness told us that in practice “it would be a little naive to believe that there would be complete separation”. We believe that separation will be harder to achieve in practice than the Department claims. We are very concerned that two patients with the same condition on the same NHS ward might receive different treatments because one patient could afford it and the other could not. This must not be allowed to happen.”

Amendment proposed, to leave out from “claims” to the end and add: “We believe it would be wrong for very seriously ill patients to be moved from an NHS ward to a different location so as to administer a privately paid for drug separately. This undoubted disruption to a patient’s quality of life just to meet some bureaucratic requirement would not only endanger the patient’s care but would be unjust. Wherever possible a drug that is being purchased privately as an addition to NHS treatment should be administered in the location best suited for the patient’s well being. We agree with Sir Len Fenwick, the Chief Executive of Newcastle Hospitals Foundation Trust: “patients first, bureaucracy second.” — (Mr Peter Bone)

Question put, That the Amendment be made.

The Committee divided

Ayes, 1  Noes, 5

Mr Peter Bone     Charlotte Atkins
                Sandra Gidley
                Dr Doug Naysmith
                Dr Howard Stoate
                Dr Richard Taylor

An amendment made.

Paragraph 78 as amended, agreed to.

Paragraphs 79–80 read and agreed to.

Paragraph 81, read as follows: “We are concerned that the affirmation of the guidelines regarding the separation of NHS and purchased drugs will establish a precedent that would open up the possibility of a “core service” emerging in the NHS obliging patients to co-fund aspects of their treatment or to go without.
We reinforce Professor Richards’ call on the Government to clarify its policy on the separation regarding unfunded non-drug interventions including devices and procedures.”

Amendment proposed to leave out this paragraph and insert: “It is unclear what arrangements apply to the separation of NHS and private care in relation to non-drug interventions, including devices and procedures. We reinforce Professor Richard’s call on the Government to clarify its policy on this.” — (Mr Peter Bone)

Question put, That the Amendment be made.

The Committee divided

Ayes, 1
Mr Peter Bone

Noes, 5
Charlotte Atkins
Sandra Gidley
Dr Doug Naysmith
Dr Howard Stoate
Dr Richard Taylor

An amendment made.

Paragraph 81 as amended, agreed to.

Paragraphs 82 to 121 read and agreed to.

Summary agreed to.

Motion made, and Question proposed, That the report be the Fourth Report of the Committee to the House.—(The Chairman)

The Committee divided

Ayes, 6
Charlotte Atkins
Sandra Gidley
Dr Doug Naysmith
Dr Howard Stoate
Mr Robert Syms
Dr Richard Taylor

Noes, 1
Mr Peter Bone

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Chairman make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

Written evidence was ordered to be reported to the House for printing with the Report.

[Adjourned till Thursday 7 May at 9.30 am]
Witnesses

Thursday 29 January 2009

Ms Sophia Christie, Chief Executive, Birmingham East and North PCT, Sir Len Fenwick, Chief Executive, Newcastle Hospitals NHS Foundation Trust, and Dr Alison Jones, Royal College of Physicians

Professor Karol Sikora, Cancer Partners UK, Dr Jacky Davis, and Hilary Whittaker, Chief Executive, Beating Bowel Cancer

Thursday 12 February 2009

Professor Christopher McCabe, Chair in Health Economics at the Leeds Institute of Health Sciences and Director of the Academic Unit of Health Economics, University of Leeds and Professor James Raftery, Professor of Health Technology, University of Southampton

Professor Mike Richards CBE, National Clinical Director for Cancer, Dr Felicity Harvey, Head of Medicines, Pharmacy and Industry Group, NHS Medical Directorate, Ms Una O’Brien, Director General for Policy and Strategy, Department of Health, and Professor Sir Michael Rawlins, Chairman, National Institute for Health and Clinical Excellence (NICE)
## List of written evidence

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The following written submissions were received after the publication of *Top-up fees: Written evidence*, HC 194–II, Session 2008–09. They are reproduced with the Oral evidence in this Volume.

1 Cam Donaldson (TF 9A)  Ev 51
2 National Institute for Health and Clinical Excellence (NICE) (TF 13A)  Ev 53
3 MS Society (TF 37)  Ev 55
4 Dr Clive Peedell (TF 38)  Ev 56
5 Dr Jacky Davis (TF 39)  Ev 60
6 Dr Jacky Davis (TF 39A)  Ev 62
7 Centre for International Public Health Policy (TF 40)  Ev 63
8 Professor Christopher McCabe (TF 41)  Ev 68
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10 Professor Christopher Newdick (TF 43)  Ev 76
11 Centre for Health Economics, University of York (TF 44)  Ev 80
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Oral evidence

Taken before the Health Committee

on Thursday 29 January 2009

Members present

Mr Kevin Barron, in the Chair

Jim Dowd
Sandra Gidley
Stephen Hesford

Dr Doug Naysmith
Dr Richard Taylor

Witnesses: Ms Sophia Christie, Chief Executive, Birmingham East and North PCT, Sir Len Fenwick, Chief Executive, Newcastle Hospitals NHS Foundation Trust, and Dr Alison Jones, Royal College of Physicians, gave evidence.

Q1 Chairman: Good morning. Could I welcome you to what is the first evidence session of our inquiry into top-ups and improving access to medicines. I wonder if I could ask you, for the record, if you could give us your name and the current position that you hold.

Ms Christie: Sophia Christie; I am the Chief Executive of Birmingham East and North Primary Care Trust.

Sir Len Fenwick: Simon Fenwick; I am the Chief Executive of the Newcastle-upon-Tyne Hospitals NHS Foundation Trust.

Dr Jones: Dr Alison Jones; I am a medical oncologist and here for the Royal College of Physicians.

Q2 Chairman: Thank you, and once again welcome. I have got some general questions, and we will start with general questions to all three and then some of my colleagues will get on to specifics to individuals in a few minutes. Why was the Richards Review of patient access to unfunded drugs commissioned? Was it a reaction to pressures from the lobbying of patient groups, the pharmaceutical industry or parts of the media—or a mixture of all three?

Ms Christie: I think there was some general emerging confusion in the system around what the rules governing access to drugs were to the point where, at all levels in the system, there was beginning to be confusion and patients were getting very mixed messages about what they could and could not have access to, so it was probably timely to have something that set out more clearly what the rules were.

Sir Len Fenwick: I think the first point has something to do with it. There were clearly sound voices across the media, and in part that was understandable. I think what we need to strive for is consistency and transparency across the National Health Service, and the report endeavours to bring that about.

Dr Jones: I think there was some general emerging confusion in the system around what the rules governing access to drugs were to the point where, at all levels in the system, there was beginning to be confusion and patients were getting very mixed messages about what they could and could not have access to, so it was probably timely to have something that set out more clearly what the rules were.

Q3 Chairman: Could I ask each of you: what are the strengths and weaknesses of the Richards Report, in your view?

Ms Christie: I think it has reiterated and reminded people of the rules governing access to the National Health Service as a publicly funded service and where the boundaries on that sit with the right to privately spend one’s own money. I think the area of particular concern from a commissioning perspective is the suggestion that came out of it that NICE might raise its threshold for considering what represented value for money and cost-effectiveness. That element did not sit within the original terms that I think people were expecting from the review, and that does hold out some real hostages to fortune in terms of safe use of public money and the sort of messages that we give to patients.

Sir Len Fenwick: I think in very good part the report is to be commended. The key recommendations all have a great deal of mileage to bring about the consistency that we seek. I think it has tremendous strengths right across the report, with perhaps the exception of how can we deal with matters of separation between the NHS and the private care streams. I think that is still highly problematical, and the report does highlight that. The report does not give us solutions, but I think the 14 key recommendations do provide the agenda to take things forward.

Dr Jones: I think the report, in principle, is useful in that it allows patients to have access to a wider range of, in my case, drugs. I think the report has problems in the detail, in the implementation. The concept of separateness is difficult. The concept of billing—because it has to be an episode of private healthcare—which is not only the drug acquisition costs but the costs associated with that, and I suspect neither the media nor the public who would be paying realise how much the administration costs
are and, professionally, there are potential difficulties in that, within the Code of Private Practice, one cannot engage in a consultation with a patient about private healthcare and yet the report is almost inviting us to do so. Professionally there are difficulties in that we would wish to maintain holistic care for patients within the team and, if they wish to have the drug as an episode of private care, there needs to be separateness in terms of how we have the discussion and our professional responsibilities.

Q4 Chairman: Are there any issues you think that the report has not addressed satisfactorily, in your view, any of you?

Dr Jones: I think the report looks at addressing a problem that we have because there is not access to as wide a range of drugs as there should be, and, obviously, it was not within the remit of the report why we were in the position of needing the report in the first place.

Ms Christie: I think it has perhaps side-stepped the issue on whether access is always a good thing. There is an underlining assumption that it is bad to say no to certain drugs and that really what we need to do is make as much as possible as freely available as possible, and that seems to side-step a very real issue about public investment and the health gain that we should be getting for that investment and, on a personal level, whether we are really being honest with patients about the outcomes that they can expect. There has been a lot of discussion in the literature about the particular risks that face patients with poor prognosis, where they are hanging on to a hope that there is going to be a magic bullet that can save them. The reality is that many of the drugs we are talking about will offer maybe six weeks, three months of extra life: that will be life that will continue to be characterised by suffering from a very major disease, with hospital attendances, discomfort and, potentially, a real risk that in extending treatment we are not offering people appropriate palliative care and the opportunity to really plan for their end of life, for where they want to die. We know that over 65% of people express a desire to stay at home, but at the moment, certainly in my patch, we are only managing to achieve 20% of people exercising that choice. That is generally because they have an unplanned admission as part of an extended treatment where there has not been a real conversation with them or their family about the fact that they are now in their final stages of life, and it seems to me there are very real risks underlying the report of a failure to have those conversations and respect people’s right to make real choices at the end of life rather than buying into a belief that one more drug is going to make the difference.

Q5 Chairman: Is it not the case that that has always been a bit of a weakness in our healthcare system? It is not something that has been highlighted by the Richards Report.

Ms Christie: Absolutely, that is a very fair assessment, but we are in the middle of quite an extended public debate now about how do we improve end of life care. It is a major one of our priorities at a local level. One of our major sources of investment last year was: how did we extend palliative care beyond cancer? Historically, we have tended to think that only people who die from cancer need to have proper end of life support, which seems a little unfair for the rest of the population, and it has not been a service that a huge amount of attention has been paid to. We are much more comfortable with the idea of active treatment and rescue, but the reality is that at some point we are all going to die, so we would like to make that as positive an experience as possible.

Sir Len Fenwick: I must say, I am from the North East and we found the report tremendously helpful. We have achieved a great deal in the last three months in respect of both cancer and other top-up treatments, and we have already brought together protocols, standards, better information and, in fact, we are cited in the Richards Report. I think Richards met the objectives that were set and, of course, that is why we are here today—this is on the public agenda; it has been debated in a very meaningful way with good information—but, of course, perhaps he could have extended into the NCPOD findings, published late last year, where only 35% of received care was judged as good. There is quite a bit of rhetoric in the NHS in respect of expectation and policy. I come from the old school of evidence-based practice and I always commend that and, I think, in taking this issue forward, we need to rise above some of the rhetoric and look at good, evidence-based practice. What might work well for one community in one part of the country may be different for another. In very good part, we deliver good services and we can do better. I think my concern is getting back to the need for transparency, consistency where there is fragmentation and we need to move quickly if the options and the choice is going to be available to patients. I hear a great deal, as my colleague on the right, about care in the community and what we can do at home. I have seen a recent experience of care quality with a relative in the NHS, where choice was expressed by the patient and the family but it was the wrong informed choice and the patient suffered accordingly. So it is not all good in the secondary care sector, we need to get more common pathways, and I think Richards directs us there. I think Richards has done the job: it is now for us all to build the arrangements, the protocols and the good governance to bring consistency about. It will not be perfect, but we can certainly do a lot better.

Chairman: Let me tease out the issue of communities versus the individuals in this session. I am going to move on to Doug now.

Q6 Dr Naysmith: I think, Sir Len, you will find that all of us on this committee are in favour of evidence-based medicine and practice wherever we can find it. One of the things that seems to have come fairly clearly out of the Richards Review: talking about the separation of the National Health Service and private treatment, the decision seems to have been made that patients will be allowed to have both National Health Service and private care in parallel, if they can afford it. The reaction to that decision,
which is one of the clearest things that comes in Richards, has been different with different people. Some people have called it the end of equity in the National Health Service and some people have said it is merely a restatement of existing rules which have not been very clear. Which do you think: because you are obviously an enthusiast for Richards?

Sir Len Fenwick: I am not a great enthusiast at all. In fact, this issue is not something that bedevils my organisation. I have one of the largest National Health Service trusts in the country, serving the North East of England and beyond with a range of tertiary and specialist services, and in the main, because we have critical mass, because we innovate, because we are involved in research, many of the issues of the novel treatments and the options that are available we are able to accommodate without fuss, with opportunity, through working with primary care commissioners and the resources that we have to hand. I have got a long time running big hospitals. I have been the leader of the Freeman Hospital in Newcastle for some 32 years and have not really come across these issues in real terms. Where we have had to exercise discretion to look at the well-being of the patient for domestic, social or other reasons, there has usually been a way through, and that has either been thorough a trial, through support from other means or moving the resource around. Where you have the critical mass, you can do this. Where you have got small facilities without the breadth to be able to accommodate the personal requirements of individuals based on good evidence and sometimes good clinical judgment, this can be done.

Q7 Dr Naysmith: There cannot possibly be equity for everyone: some people are going to be able to afford to pay for additional treatment side by side with other patients who cannot pay for that treatment. How can it be equitable?

Sir Len Fenwick: I think that in very, very good part I find that the professionals advise what the expected benefits and what the likelihood of the treatment outcome will be if they wish to opt for a differing pathway of care and treatment, and it is rare that with good communication or with experience and support that difficulties arise in that arena.

Q8 Dr Naysmith: I do not want to trespass into some questions that are coming later, but different PCTs have different levels of resources and sometimes they just cannot find their way to provide the extra money. You are saying this is merely a restatement of existing rules, but, clearly, you were doing it anyway, you were fudging anyway and providing the means for that to happen.

Sir Len Fenwick: I certainly would not fudge. I could give you some case examples, if you wish to test me on them. When you talk about resource, primary care trusts in my region underspent: they sent money back.

Q9 Dr Naysmith: That is not the evidence we get from some PCTs?

Sir Len Fenwick: I can only speak from experience on the ground. I find that primary care commissioners in the North East of England are well informed, they are working together and working on choice, and what we do with clinicians and related professionals across our region through the networks that we have, we have protocols and decision-making trees that ensure a consistency, and it is not so much an issue for the North East as it would appear to be for other parts of country, and I think there are lessons to be learnt in that respect. That is not to say that the top-up is not there, but it is a rare experience in my organisation. I have done some research and over the last six months we have not had a top-up.

Q10 Dr Naysmith: Are you saying that in your organisation the situation has never arisen where someone can get a drug in another PCT and not in yours?

Sir Len Fenwick: Not in the North East. The difficulties that I have found, working with practitioners and others, is the parallel working with the private sector, where part of the treatment may begin in the private sector and then it moves into the NHS and where we have had to use multi-disciplinary teams and improved governance between the two streams to bring a greater, more governed, more consistent approach, and I think that is beginning to improve.

Q11 Dr Naysmith: Sophia and Alison are both indicating they want to say something.

Ms Christie: Can I pick up two points from that? The first one is about the evidence-based practice. As commissioners we are responsible for the wise investment of public money to get health gain, and we pay very real attention to whether commissioning a particular drug or intervention is likely to offer real benefit in terms of outcome, given that anything that we spend money on creates opportunity costs. So if we choose to spend money on a cancer drug that might extend life by six weeks or three months, we do not have that money available to create appropriate palliative care in the community for the six weeks later when that person does die, or we do not have the money available, perhaps more importantly, to invest in the most effective new radiotherapy facilities that might mean earlier intervention and better outcomes for patients. So there is a real issue about what choices the NHS, through commissioners and critically through NICE, makes and what gets into the list for funding. It is each of our individual rights to make bad personal choices, but as public servants we do not have the right to make inappropriate investments. So the decisions about NHS expenditure are very challenging: we have to make, at times, very fine judgments about where we might place limited resources against a whole range of pressures for intervention. The role of private medicine is there so that, if someone wants to make a personal choice about spending their own money on something that might have limited evidence of effectiveness, that choice still exists for them. However, just because they have made that
choice does not mean that we should distort public money in picking up those bad, relatively poor choices going forward. So there are some real issues. If a patient has initiated treatment as a private patient of a drug that has not passed the test of cost-effectiveness for public funding, if they then run out of money or discover that whilst they can afford to pay for the drug they cannot afford to pay for the additional outpatient attendances that might need to go alongside that very toxic substance and they are looking for NHS money to support it, then we are potentially investing money very unwisely at the expense of other choices that we could make, and that will have been judgments that have been distorted by individuals exercising choice about their own finances that then has an impact on, potentially, the public health. So I think there are some real issues here as to being clear about what we mean by evidence and cost-effectiveness evidence and the role of the public sector versus the role of individual choices that we may or may not be in a position to exercise.

Q12 Dr Naysmith: Do you think the Richards Report makes things clearer or makes them more difficult?

Ms Christie: I think on one level it makes it clearer. I think it reiterates that division between the public responsibility for cost-effectiveness and the private right to exercise one’s own resources however one chooses. However, it does raise two issues associated with that. One is the sort of situation that Sir Len was referring to, where someone may have initiated treatment themselves on the private route and where they then get into difficulties maintaining that treatment and expect the NHS to find a way of picking it up and maintaining it, even though it is not a treatment that has been prioritised for public investment. Once we have a situation where people believe that they have the right to co-fund, to initiate their private treatment alongside the public, I think there are increasing risks that there will be a perception that, if that drug is being administered, surely it is a drug that should be available to all and will create a sense of inequity in the local system if some people are receiving a drug and other people are not. I am not sure there is much of a solution to that problem, but it does feel like a continuing problem. The bigger issue is the one I referred to earlier around the proposal to lift the level of what is perceived to be an acceptable ceiling for quality adjusted life years in NICE technology appraisals, and that one has a very significant impact. PCTs have to commission drugs that have been approved through the technology appraisal process in NICE. I think it is well known to this committee that NICE have had to exercise some very fine judgments in their time and tend to be on the receiving end of negative press whatever their decision is.

Q13 Dr Naysmith: We are going to come to one or two of these things later on. There are a lot of things listed.

Dr Jones: The report really is about patients paying for additional drugs, over and above their NHS care, and separating the provision of that drug and the associated costs with that drug from their care. So all patients who are thinking of embarking on this should be in the context of a multi-disciplinary team, looked after by a consultant they know with a team around them, and that should not be broken if patients wish to pay for additional drugs. So I think their underlining care—. I take the premise of this starting as an NHS patient if they find a drug that they wish to have. It may have been deemed effective, because it may have a European license and be deemed effective, it may even be deemed effective through the NICE process; what it has not been deemed is cost-effective in terms of our costing system. It does not mean the drug does not have activity; it just means in this climate in the NHS we cannot afford for that patient to have that drug. I think if they wish to have it, they should be in a position to continue their NHS care but pay for the drug and the associated costs of that drug, with the clear understanding that they would not be in a position, if they run out of money, to have it picked up by somebody else; but they should not lose access to the palliative care and the team that they are in. If it is going to be set up, it needs to be done with continuity of patient care in mind. I am on the sharp end of this—I am not on the sharpest end but I am not a patient and they are really on the sharp end—but I do have these discussions on a daily basis with patients about life expectancy, how long they have got to live and what I can do to prolong that. It is not a choice between supportive and palliative care and a new drug; the two things should run in parallel; so any patient in this position should have access to end of life care while this is going on. None of us know how long the end of life is going be and we should help people do it as they wish.

Q14 Dr Naysmith: But there are some drugs that extend life by merely two or three months, on average. Do you think it is really worthwhile spending lots of resources on that?

Dr Jones: We are not expecting on this report the taxpayer—. It is a question whether the patient wishes to spend a lot of money. For example, if you take a drug that gives a medium survival of three months, that means some patients will die a lot before that and a few patients will benefit, and the other side of this is if we have more investment in identifying which patients benefit from which drugs—

Q15 Dr Naysmith: Is not that what Sophia was saying, that if people can afford to pay for it, the expectation will spread and it needs to be supplied to everyone? That is what you were implying, is it not, that if it is accepted for private patients—

Dr Jones: I live in the south of England where one might expect a lot of people to be doing this. In fact I have been approached about this remarkably few times. I have probably had an approach three times in the last six months about this. I think, potentially, it is not as big an issue as it is considered. If a patient
raises the issue and you have a very realistic conversation about the other options available and the benefits, it is a long consultation but sometimes people decide to go down a different route.

Q16 Dr Naysmith: We are going to have to move on because this is taking a long time. Can I ask you all a couple of very quick questions? Can you see any practical difficulties, and some of them you have hinted at already, but can you see any as being really important and can you see any potential abuses arising from the changes?

Dr Jones: I think absolute clarity about how the conversation is initiated and whether this is a private episode of care in relation to the consultant and the whole process or just for drug delivery. My preference would be that it is just in relation to the drug delivery and the rest of the care of the patient and the consultation process takes place in the context of the NHS, so it is not forcing people who do not want to do it into doing private practice, for example, because I do not think one could do that. The inequities potentially arising from it are not just the drug costs, it is if the patient has a completely different stream of care that is consultant driven rather than perhaps being within the generality of the NHS. Absolute clarity about that and the concept of separateness is going to be difficult in some NHS hospitals that do not have a private facility in which the drug could be administered, in which case it is not realistic to assume there is a separate time of the day or week. We are usually running flat out all week.

Q17 Dr Naysmith: Do you think that will produce pressure to set up a private wing?

Dr Jones: No, there would not be enough to do it, and that raises risks to patients in transferring care at a vulnerable stage.

Sir Len Fenwick: The inter-professional tensions that this can bring across a multi-disciplinary team, where there are many senior clinical practitioners who simply do not get engaged or wish to contemplate any aspect of private practice, can cause difficulty in communication and attitude. I think that is a fundamental issue to be addressed as part of this requirement for separation. I think, in relation to cancer in particular, it is a little naive to believe that there would be complete separation. It is simply not possible. Whether in respect of the therapy administration, the support that is provided in the hospital or in the community, the various disciplines that need to come to work together, there is some difficulty there and it is not straightforward. It is that element of fragmentation that I would believe is something that requires greater tension. There has been comment expressed in relation to documentation—the records and access to the records—if there is more than one provider. If an NHS provider and a private provider are running in parallel, there is a recipe for difficulty there, it is less than ideal, but I think in relation to billing and the documentation, certainly from my experience, my organisation is just a few months away from having any record. We are pursuing a new record outside of the Connecting for Health programme that will support the Connecting for Health programme, and I am confident that this year we will be demonstrating a great deal of integration, and that can include billing—and not just for billing, but also for cost control and awareness and to help primary care colleagues in relation to when they place the order are they getting good value, et cetera. It is the pathway of care and that disjointed break-down in communication and tension that can arise that would worry me.

Ms Christie: I think you have hit the nail on the head with that issue of the multi-disciplinary involvement. It is very difficult to separate paying for a drug from the additional work load that then creates for the NHS. If we do not clearly separate the private episode of care from the public episode of care, we will be, by definition, cross-subsidising private care for some people. I absolutely hear the practical issues that have been raised, but I think that was really the purpose of the report: to clarify that if people are exercising the choice to spend their own money on treatments that have not been deemed good value by the public purse, then there is a very real cost associated to that and they are making a very real choice about a different pathway of treatment. The previous comments perhaps highlight why we needed the Richards Report, which is that clearly there has been cross-subsidisation taking place, driven by the best possible motives on the part of clinicians, but with the effect that people have been benefiting from a range of NHS resources for treatments that they ought to have been paying for themselves.

Q18 Dr Naysmith: Do you think there is potential for abuse in that?

Ms Christie: I think what it is going to do is raise—. We will probably have a difficult 12 months as people get used to the separation. It will make it much clearer where there is a private episode of care being initiated and maintained, and it will require much clearer conversations about where are private patients appearing in the system and what services they would have access to, which is anything that they would routinely get as an NHS patient, but where they require out-patient attendances, or in-patient admissions, or diagnostic tests associated with an additional private treatment, then those costs sit with the private treatment.

Q19 Chairman: If somebody was in a hospital ward having a top-up as a part of in-patient treatment, what is the bed that they are in? Is it a private bed or an NHS bed?

Ms Christie: I think that is probably a question that Len is more qualified to respond on. I am not sure it is that helpful to think of the bed. It is about the episode of care. The patient is a private patient. The point was made by Dr James that just because someone is having their treatment does not mean they should be excluded from the relevant NHS care. They should still have access to whatever they would be entitled to within the NHS, but for those elements of the treatment that are driven by the private
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elements—. It is a little known reality that someone having the breast cancer drug herceptin needs to have four out-patient attendances in cardiology because it is a highly cardio toxic drug. In the period before herceptin became widely available, there was a lot of lobbying for inpatients to pay for the drug. They did not want to pay for the four out-patients attendances in cardiology, but they were entirely driven by the administration of that particular drug. They ought to form part of any private treatment. I think that is where we will begin to see some of the tensions, trying to map out which elements of treatment are driven by the private care and which elements should be routinely available as part of NHS care.

Q20 Sandra Gidley: If somebody has side-effects from a drug that they buy privately, which is quite a common occurrence, who pays for the drugs they need to cope with the side-effects?

Dr Jones: It is very difficult with somebody with advanced cancer to attribute some symptoms to a specific drug or, indeed, the underlying disease, and it would be a very vexed question to try and tease it out because they would be experiencing a number of cancer-related symptoms. In this situation they may be having a drug as an NHS drug and, on a separate day, having a private drug, and I certainly would not want to be the person who tries to attribute and pin down a specific side-effect to a specific drug unless it was absolutely clear. If a patient is in the private sector and they have treatment in London and go up to Newcastle for the weekend and they fall ill, they could easily be admitted as an NHS patient anyway if they are entitled to NHS care. So I think Sophia is right in that the actual drug cost and the costs of tests for that specific drug have to be met privately, which is why it will be about a 70% increase on the actual drug cost for each patient, but complications are sometimes difficult to attribute to a specific drug or disease and they should be managed back on the NHS because they will be ill anyway.

Q21 Sandra Gidley: If it is easy to attribute, what then? That was quite a political answer.

Dr Jones: It is not always easy to attribute.

Q22 Sandra Gidley: No, but there may be a case—

Dr Jones: There may be. If you have got a drug that only turns people green and they go green, then it is obvious. There will be times when you can do it, but a lot of the time it will be a really grey area.

Q23 Sandra Gidley: You have just highlighted the case of somebody perhaps having treatment in one part of the country, then going to another, falling ill and being picked up by NHS care anyway. What are the difficulties with regard to continuity of care? This committee has already looked at the NHS IT project, which is difficult enough within the NHS. When you are adding in the private sector as well, are there problems there?

Dr Jones: I think there are problems with continuity of care, which is why if a patient opts for a top-up drug and its associated costs, it would be ideal that they would stay within the same team that had been looking after them. It is not just the consultant; it is the nursing staff and supportive staff within that team and their palliative team, so their care should be in the same team. We have this all the time with patients falling ill and not necessarily going into the hospital where they had treatment, and that has been highlighted, as Len pointed out, in the NCPOD report and the NCEP report that patients often turn up with complications anyway, about 20% of patients, where they are not being treated, and that highlights a communication issue that is generic and not just specific to this problem.

Q24 Sandra Gidley: Is there not possibly a bigger problem? If somebody is going to a private hospital down the road for their episode of privately funded care, how does that information get back to the NHS?

Dr Jones: That is a two-way exchange. It is absolutely critical that there is a system whereby it does. If they are having one drug on the NHS and the other privately and the drugs have got to be linked in some way to a specific blood count and other supportive drugs, that would be extremely difficult. You have got two prescriptions for one patient; I think the issues in terms of data transfer are really difficult to maintain safety.

Q25 Sandra Gidley: Are you saying that the private sector should be plugged into the NHS IT system?

Dr Jones: I do not think the NHS IT system is entirely plugged into itself.

Q26 Sandra Gidley: No, but let us try not to get into that.

Sir Len Fenwick: Speak for yourself. There are some who are plugging in.

Q27 Sandra Gidley: Are there any other practical difficulties with regard to continuity of care?

Dr Jones: I think it is maintaining the holistic care of the patient with their team. The question is where they get the private care. If you do it in the same hospital in a private wing, it is going to be relatively easy because it will be one data set. If they had it out of hospital, then they could do it with a home care provider, in which case there is very good paper transfer of data back in and that works quite well for patients anyway.

Q28 Sandra Gidley: Does it?

Dr Jones: I have had patients who have wanted to do it for one reason or another. It can work, but it is a problem that we have anyway that patients do have elements of care outside. I think the main one is transfer of information and maintaining the whole team, knowing what is happening with the patient as well as the consultant, but I think data is very problematic.

Q29 Sandra Gidley: Another practical question. If somebody has to have a mixture of drugs, one of which they are paying for themselves, the other is
paid for by the NHS, it is best to give them at the same time. How do you split the difference between the private episode and the NHS?

**Dr Jones**: There are a few schedules where there is a time dependency and a schedule dependency for drugs. That is going to be, practically, very difficult to organise if one drug is available on the NHS and another privately if they are having them on different sites. There will be the issue of putting the cannula in to give the drug, whose responsibility is that, depending on which drug is given first, and, potentially, removing patients between one site and another to receive two elements of care for the same condition. That is a very realistic practical issue.

**Sir Len Fenwick**: It is a challenge across the NHS where there has been good investment in recent years in modern infrastructure and an environment for this client group. In my trust we are just opening a new cancer care centre where the majority of the facilities are single, private rooms for the NHS patients. This will not be an issue for us but, going back to the team working, we are getting so worried about the technical support, the clinical support. For the patient it is all about the personal contact and confidence and communication where you can get fragmentation. A lot of the good work is done, not on the technical side and the administration of the drug, but the support and the ability to work with people, family and carers in a very, very challenging environment, and that is where there can be a breakdown in continuity.

**Q30 Dr Taylor**: If you will allow me, Chairman, I am going to go back a little bit before going on to my questions; I am very conscious of the time. I have been absolutely staggered by this so far, because to you, Len, and to you, Alison, it really has not appeared to be a major problem. Can I clarify? To take a concrete example, you have been funding sunitinib for patients.

**Dr Jones**: I do not actually treat renal cancer; I am a breast cancer oncologist, so I would get asked about different drugs. In my practice I have been asked about drugs that are not available and I have had conversations with patients about what is available, what the realistic benefits of non available drugs are, and I have not had to have that conversation very often.

**Q31 Dr Taylor**: So is the problem rather less with breast cancer than with some other cancers because breast cancer has such a high profile?

**Dr Jones**: I think the problem changes month on month, year on year, depending on the availability of new drugs and the time that they take to go through the approval process. At the minute we have, as it happens, a lot of kidney drugs under consideration. Another year the drugs move on so quickly that it will be a moving field as to which tumour type. I suspect pressure at the minute will be in relation to kidney drugs and bowel drugs, but that pressure could change and it could be a different tumour type another year. Part of it arises if patients have expectations that they are really missing out on something. If you have a consultation with a patient where you explain their options and their realistic outcome in a fashion that they and their family can understand and they understand what is happening and what their life expectancy is, they sometimes make a decision not to opt for a drug that is very expensive or, if they do, they are doing it on the basis of full information. But there are quite a lot of treatments that are available for people on the NHS, and if you explain the relative merits of different treatments carefully (and it is a time-consuming business) I think people feel perhaps less disenfranchised than they do.

**Q32 Dr Taylor**: Have you been providing sunitinib?

**Sir Len Fenwick**: Yes, we have and in very good part, but, again, I come back to critical mass. This is not about cross-subsidy. We spend about six million a year on all of these agents out of a drug bill of over 60 million. So it is 9% of our spend this year in Newcastle, it will be 10% of our spend on drugs, and that is for an organisation with a turn-over in excess of 700 million; so it is not really big beer at the end of the day to my organisation. I think last year, on 107 occasions we sought exceptional circumstances support. Nine out of 10 of the requests were moved very, very quickly through our primary care organisations with understanding and support based on the recommendation of the clinicians. It is still with us and it is a great issue—then this is not a vested interest to promote something—because that is with us and it is a great issue—then this is not a real issue, from my experience. If you wanted to talk about other materials, such as implants, pacemakers and knee joints, that is probably a bigger ticket issue for the coming years, because people are getting much more well informed about the performance of an implant or other support device that can help continuing quality of life, never mind end of life.

**Q33 Dr Taylor**: Because I am going to ask Alison some questions, I have to own up to the fact that I am a fellow of the same college, for the record. A very general question: Is the College happy with the recommendations?

**Dr Jones**: The College sent this out to consultation to the specialist committees and patient and care association, and I think the range of views expressed through the College were as wide as the range of views expressed in the media. There are people who are polarised against it and people who are in favour of it but, overall, most probably broadly in favour of it, provided the issues of continuity of care for the
Q34 Dr Taylor: You have already said that a tremendous amount of information needs to be shared to explain to patients how little the benefits actually are of certain things.

Dr Jones: I think there are different situations. With the kidney drugs I think the benefits are tangible and quite long for some patients, but there is an assumption, because of the perception of rationing and cost containment, that any drug that is not approved is being withheld for cost reasons, and I think we have to sometimes be more transparent about why drugs are not approved. At the end of the day, if somebody wishes to pay for a drug and they have got full information, the feeling is that they probably should be allowed to do so, provided it does not disenfranchise other patients, the ground rules are very clear and it does not disenfranchise patients either in terms of withdrawing, perhaps, consultant time to be doing this.

Q35 Dr Taylor: Len said there are some clinicians who will not contemplate private work. Probably there are quite a number in oncology like that. Is that so?

Dr Jones: I think it was probably about 50:50 in oncology, some of whom will do private work and some who will not.

Q36 Dr Taylor: What will they do under these circumstances?

Dr Jones: There are two options in this. If this is regarded as private care and private prescription, then patients would have to transfer to another clinician who did private care. The other option is to say that you are having a consultation with the patient about care anyway, and if this was not regarded as private care for the doctor, it was just private administration and we did as part of caring for the patient, it would be a lot easier. I possibly would not want to bill for this as a private patient.

Q37 Dr Taylor: Is that not a fudge really?

Dr Jones: Yes, it is, but it is difficult, because you could run into a situation where, if the doctor regards this as private care and some doctors are not doing it, then you are going to get a transfer of patients and their care to different consultants and different teams, which is not good for the patient and, if you do private practice, then you might get overwhelmed by a lot of patients receiving a drug because you are the only person who does it, and that could mean that you were not doing other things that you would wish to be doing.

Q38 Dr Taylor: Although Mike Richards has fallen over backwards not to say so, is not this really the establishment of a two-tier system?

Dr Jones: Patients with cancer in private care do receive palliative care in the NHS and, if they run out of funding, their care transfers back to the NHS. What they cannot do at present is have some elements of care privately and NHS. It creates a situation where some people are getting drugs that are going to be of very limited benefit to them as an individual. The situation where there is a problem is where the drug does have a very overt benefit over a long period of time, which I think would apply to some of the kidney drugs, and I think one of the other risks in this is, if it is used widely, we would not want to take our eye off the ball professionally in pressing for more of the drugs to be available for more patients anyway to avoid the problem in the first place. I think that is where professionally our responsibilities should be.

Q39 Dr Taylor: Will doctors need additional training to carry this out?

Dr Jones: I think if you asked me what my core skill as a medical oncologist is, it is probably communication. That is what my core skill should be. I do not do technical things; I speak to people. I think understanding the data in relation to new drugs as they come through and what it means in the real world: because you have to bear in mind that patients who provide the evidence base are fit patients in clinical trials; they are not the same patients who I necessarily see in the clinic. Only about 10% of patients can go into clinical trials because of the entry criteria; so the patients receiving these drugs are not necessarily representative of the whole population, which is a problem, I think, in its own right.

Sir Len Fenwick: I think that is one of the biggest challenges, and for a hard-pressed service practitioner it is also the time that is required in a clinic setting to do these things.

Dr Jones: There needs to be some extra communication training in terms of not how we talk to patients, because hopefully we have done that already in our qualification in getting our CCST, but possibly we will need to develop some guidelines for new drugs as they come through as to what the real meaning of that drug is for individual patients.

Chairman: I perhaps should have said earlier that I am an Honorary Member of the Royal College of Physicians. There is no causal effect; I just thought I would mention it.

Q40 Stephen Hesford: It is to Len really. These are my words, so do not adopt them if you do not feel comfortable with them. In summing up your position, is it that this kind of whole issue is some kind of PR exercise and a Daily Mail lifestyle issue, because ordinary folk up north are just getting on with things and it has not really made any difference?

Sir Len Fenwick: There are parts of this country still where there is great pride in public service and there is great belief in what local authorities and the NHS can provide and the way that they go about it and the confidence that they have, and I have got to say, in the North East that gives us a head start. We also have, in my view, some excellent provision of services, good communications and networking between the key professionals. As a Chief Executive, I do not apologise: patients first, bureaucracy second. In all my years, if the senior professionals in
healthcare believe that we must do something for a patient and their supporters which will bring benefit, it is my responsibility to ensure the resource and the facility is there to deliver that, and I do that, and that is when I am either working within or without the rules, and I believe that brings success. There are exceptional circumstances. The Daily Mail, yes, there have been siren voices, but there are siren voices always. Going back to the two-tier thing, amenity beds—and Dr Taylor will know this—go back to 1948. I have never seen amenity beds run for many years, but there are still some in hospitals. That is a two-tier system. You come into a maternity department and, if you pay an extra few pounds, you get a nice private room, but you are still on the NHS. That is two-tier. That was in Bevan’s NHS in 1948, so we should not kid ourselves about this. There are the siren voices, and I think some of the case histories that have appeared in the media have been rather dramatic and hyped, and I think in others there has been a case to call, hence the Richards Report has come about. The great thing is we have got focus on this. It has been debated in the public arena, I think, in a very well structured and well informed manner, and this will lead, I believe, to a stronger National Health Service and it will not be a two-tier service.

Q41 Stephen Hesford: Is that a kind of yes?
Sir Len Fenwick: It is a yes, yes.
Stephen Hesford: Thank you very much. I think my questions have been covered by Len elsewhere, so, time pressing, let us move on.

Q42 Dr Taylor: This time it is mostly Sophia because it is about the practical implications for PCTs with the changes of the NICE appraisal scheme. You have already said that life is going to be extraordinarily difficult if the threshold goes up, so it has come across very clearly: life is more difficult for commissioners than providers. Yes?
Ms Christie: I think the NICE threshold potentially makes life more difficult for the entire system. We have been in a very luxurious position in the NHS in the last five years. We have seen unprecedented levels of growth and investment. It has allowed us to significantly raise expectations amongst the public, patients and clinicians of what might be available and what we are able to provide free at the point of use. There have been huge developments in productivity and improvement during that time, but even in that context of 9–10% growth each year, every year has been a struggle to match the demand and the expectations with the reality of delivering a balanced budget. I am in the interesting position of presiding over a £1.2 billion turn-over, and on 31 March at midnight each year I have to have precisely zero pence in my bank account. It is a fine judgment to make it all add up, and the sort of pressures that are exerted are significant, and cancer drugs has been one of the areas that has disproportionately, in my view, in terms of the health gain it offers, taken the bulk of investment over the last five years. In each of the previous three years over 50% of our growth in specialised services has gone exclusively on cancer drugs in the whole of the range of activity across specialised services. It is very difficult to see the extent to which that has really contributed in health gain. The point was made earlier that we do see variation across the country. We see variation across the country because need varies across the country. I used to work in Newcastle, and in Newcastle many of the major health priorities were to do with having a largely disadvantaged white population with a history of smoking and heavy industry where cardiovascular disease was the main cause of premature death. In Birmingham cardiovascular disease is one of two main causes of premature mortality. It is particularly bad in our disadvantaged South Asian population, who die at anything up to 12 years earlier than the national average, but the other big killer is infant mortality. Neither cardiovascular disease nor infant mortality is going to be impacted very much by cancer drugs; so a drive to spend the vast majority of any investment that I have on cancer drugs is counterintuitive in the extreme in terms of a desire to improve the health of my population, but if those drugs have been through the NICE process, they are mandated, and I have to buy those before I can consider investing in appropriate end of life care in the community, in cardiovascular interventions that will make a difference in outcome, very strong evidence-based, or, as I said earlier, in radiotherapy. We are at the point where half of our radiotherapy facilities are on the point of collapse against a pattern of significant investment into cancer drugs. Radiotherapy has much better evidence on outcomes as a cost per QALY. It is entirely counterintuitive that the money has gone into some of the drugs that it has. So there are some real issues here about not underestimating the opportunity costs and setting an opening upper limit, because £70 per QALY is no limit at all. NICE was originally established on the assumption that £20,000 per QALY was a reasonable working assumption: £27,000 you were pushing it and you had to have increasingly strong evidence to justify it. We have seen, on the back of a huge amount of special interest pleading and lobbying over the last few years, that drift up to £36–35,000 and £37,000 makes it virtually impossible to prioritise anything. If NICE are not able to prioritise what they put forward for funding, then PCTs will not be able to prioritise our investment to local health need. We will not be able to deliver wise investment of taxpayers’ money, we will not be able to achieve the stated policy aims of tackling health inequalities and improving mortality and adding years to life as well as life to years, because all of our money will have gone in the last six weeks of people’s lives and potentially—and this is the bit that really worries me—without them getting any better service because it will not necessarily have been in the context of an appropriate discussion of what that treatment really means. So there are huge issues around that £70,000 per QALY, and in the context of an economic environment in which best estimates at the moment suggest we would be lucky to scrape 3% growth in three years’ time, how are we going to afford £70,000 per QALY, and should we?
Q43 Dr Taylor: If we were allowed to discuss rationing, the terrible R word.

Ms Christie: It is not a terrible word; it is a very sensible word.

Q44 Dr Taylor: It is a sensible word; well said. Are there things that could fall off the bottom? Have you examples of things that you would like not to have to pay for?

Ms Christie: I think the issue about rationing and the reason it feel difficult is because what we are talking about is relative value. If only it were as simple as being able to say: that is absolutely useless; we should never even consider it. We are always looking at a package of interventions in which there are always good arguments for just about anything that you could do, but what we are trying to do is get a sense of the relative value that they will give. So it is a prioritisation process; it is more about saying where do we focus the investment than, “We will never ever spend money on X”. Len has already made the point, in individual case discussions you can get exceptional circumstances where something counter-intuitively looks like, in these circumstances, a reasonable approach, but we do have to go through that process of prioritisation.

Last year we sat down with a list of 120 things, all of which had value, but when we had worked through them in terms of how many people were going to benefit, at what level were they going to benefit, to what extent did it contribute to achieving the kind of life to years and years to life agenda, we drew a line at about number 18, and that was a process that clinicians, managers and patients worked through together. We did some work as the Cancer Network earlier this year on a deliberative event, which was entirely members of the public, working through with them a prioritisation process. In each of those events many of the sort of drugs we have been talking about today were the ones that consistently came at the bottom; not that they confer no value—obviously, if you are dying three months seems like a long and positive time—but that they did not confer the same level of value as something that was going to have more prolonged benefits at lower cost. We have talked about some of the sorts of interventions but, going beyond cancer, the ability to really get good at acute treatment of stroke and have the right rehabilitation over the following six weeks that mean that people return to full functioning rather than end up severely disabled for another 10 years, the ability to enable people to die a dignified death in a place of their choosing, with full pain control 24 hours a day seems like a very important investment to be making—the ability to reach out to sections of the population that historically have not made good use of services. We have a telephone-based assertive care management service for people with long-term conditions. It has reduced utilisation by 50%. In hospitals people have better clinical outcomes and symptom control and there is 99% patient satisfaction—fantastic use of money, but not something that has ever been prioritised by NICE.

Q45 Sandra Gidley: One of the tensions is between decisions made by PCTs and national guidance. We have a system of 152 PCTs, all making different decisions using varying evidence bases, and there appears to be no consistency. Is there a need for rationalising that process?

Dr Jones: I think if we are going to have a system of top-ups, then one of the things we have to do is exclude any other route of funding for the patient before they go for self-payment, which means if you do not have a level playing field across the country in relation to funding either through NICE or a consistent approach between PCTs, then it might prove cheaper to move to get your drug than in a PCT that has a more liberal view than not. So there does need to be consistency, and that has been a big problem, and I think that is where a lot of the tensions have arisen. There are attempts to do that. Within London we have a London cancer “new drugs” group and have been through a similar prioritisation exercise to that which Sophia described. To some extent that would almost enable us to have a better discussion with patients about top-ups, because we have actually looked in more detail at the levels of evidence in terms of how long patients might live with and without symptoms; so I think that might make it easier to have a rational discussion with patients. Many of the patients are not actually dying, they are living with cancer, and I think we should bear in mind that for many people cancer is a chronic disease. One in four of us in this room will get cancer, and the improvement in survival over the last couple of decades has been due to new drugs. Inevitably, what we provide in the health system lags behind the development of the drugs, and we are talking today about a situation whereby some patients wish to opt to pay for drugs that are not yet approved and how to create a system where they do not lose equity of care for the cancer which they have still got and is our responsibility and we do not have system where the patients who are not paying for those drugs feel very disadvantaged. I think the problem will be less than perhaps we are all imagining, but I do not see why the patients cannot pay for the drug and still have their care, provided we do not disadvantage the other patients, but they are not necessarily people who are dying. People with cancer die over a period of a very long time and may have secondary cancer for years and years, and some of these people you can go on treating. One of the big problems for these drugs is that they are inevitably very expensive because of development costs, and we tend to give them to the population as whole and only a small number benefit. It is behoven on clinicians like myself, and science and, indeed, all of you, that we should have more investment and teasing out who benefits from an individual drug, both on the basis of their tumour and their own characteristics, so we can focus the money more carefully.

Q46 Sandra Gidley: Sophia, you are in charge of a PCT. Why is the one down the road doing different things to yours? Is there any attempt between PCTs to have more consistency?

29 January 2009 Ms Sophia Christie, Sir Len Fenwick and Dr Alison Jones
Ms Christie: The reason the one down the road might be doing different things is they might have a different population profile.

Q47 Sandra Gidley: I am talking now about decisions made on treatment. You cannot wriggle out of it that easily.

Ms Christie: No, that is about decisions made on treatment. A treatment happens within a context of the whole population spend.

Q48 Sandra Gidley: No; it is supposed to be evidence-based. Are you telling me somebody in Birmingham has somehow a response to a drug differently to somebody in Southampton?

Ms Christie: No, I am not. I am saying that the profile of disease in Birmingham is different from the profile of disease in Southampton. So the decisions that a PCT might make about where they would prioritise investment in Southampton would legitimately be different from the decisions that we might make in Birmingham.

Q49 Sandra Gidley: So it is not about effectiveness then?

Ms Christie: Yes, it is about effectiveness. There is a first test, which is effectiveness, there is a second test, which is cost-effectiveness, there is a third test that is relevance to the local population, “Is this an intervention that is going to make a big difference here?”, there is a fourth test that is about acceptability, “Is it an intervention and a treatment that is really going to resonate with patients and that offers a good personal experience for patients as well as a clinically effective treatment?” It is not a simple kind of, yes/no issue. As I was saying earlier, that test of effectiveness is crucial, but that is not sufficient. They are effective but not affordable.

Q50 Sandra Gidley: Most decisions are turned down on the basis of effectiveness or cost-effectiveness, and so all around the country you have three or four people, sometimes self-selected, it seems, with varying degrees of expertise purporting have great wisdom in these things coming to wildly different decisions on effectiveness and cost-effectiveness. How can that be justified? You cannot wriggle out of it by saying the local needs of the population are different.

Ms Christie: I do not think that is a wriggling out of it by saying the local needs of the population are different. Are you telling me somebody in Birmingham has somehow a response to a drug differently to somebody in Southampton?

Ms Christie: No. I am saying that the profile of disease in Birmingham is different from the profile of disease in Southampton. So the decisions that a PCT might make about where they would prioritise investment in Southampton would legitimately be different from the decisions that we might make in Birmingham.

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Ms Christie: I do not think that is wriggling out of it. In terms of collaboration, we need to improve collaboration. There is a number of initiatives ongoing at the moment to do that. There is a network of the consultants in public health that is looking at how we can share the workload. Typically a PCT might just have a couple of public health people who are trying to assess all of the evidence on what in many cases is very technical information, and we are looking at using the network to be able to share that workload, so we publish for each other the findings and share those. PCTs already collaborate in all parts of the country for a range of specialised services and in many parts of the country at a more local level. In Birmingham, we have a local collaborative commissioning group that covers five PCTs. We collectively commission cancer drugs and a range of other specialist drugs, we work very closely with our clinical colleagues in the cancer network to do a shared assessment of what the priorities for investment are that year, and then we are all working to the same script in terms of what we feel is the best way forward.

Q51 Sandra Gidley: That is all right for cancer, but there are sometimes drugs involved in these decisions that are not necessarily drugs for cancer.

Ms Christie: For that we have an individual cases panel. That is a panel that is made up of clinicians, chaired by a lay member—

Q52 Sandra Gidley: Who usually know little about the subject they are judging.

Ms Christie: I think that is a strong generalisation.

Q53 Sandra Gidley: Sometimes.

Ms Christie: They are highly educated, experienced clinicians who are involved in assessing the merits of the case before them. We receive advice from the referring clinician who is a specialist in the subject. We are paying attention to—

Q54 Sandra Gidley: Who frequently ignore it, I find.

Ms Christie: —the published evidence.

Q55 Sandra Gidley: They frequently ignore the advice of six consultants who might know a particular patient, because these people, who have no expertise in the subject they are deciding on, decide something different. Are you saying that does not happen?

Ms Christie: I cannot comment beyond the area for which I am responsible. In my panel we pay the best possible attention to looking at the evidence in front of us, both in terms of the clinical evidence and the specific patient evidence that is presented by a clinician, and often we have cases referred by clinicians who say, “I don’t think this person is going to benefit from this but they’re giving me a lot of grief about it, so please can you consider it.” There are huge mixed messages in the system and I am hopeful that one of the things that the Richards Review will do—

Q56 Sandra Gidley: I think you had highlighted very well that the system is a complete mess.

Ms Christie: The system is a system of human beings. It is about people who are desperately trying to do the best they can, as a patient for themselves or for their family or as clinicians for the patient in front of them or as commissioners in terms of wiser spend of public money. Yes, it is a messy system. We are talking about life and death. It is a pretty messy process.

Q57 Sandra Gidley: Sir Len has to pick up the process of this dog’s breakfast, because he has two people being treated by the same consultant, who live in different areas and have different decisions made.
Sir Len Fenwick: What do I do? We treat the patient. The real action in the NHS is at my level. That is where the real accountability rests in terms of quality, cost, and performance. When you are a foundation trust, be assured, the buck does stop with the foundation trust. The NHS is improving rapidly, and your questioning is very, very relevant. In the North East—and the Committee may wish to interview and cross-examine the clinicians who are involved in this—across the PCTs, there is a Cancer Drug Approvals Group which gets rid of a lot of this sort of difference between the PCTs—and there are 12 subscribing to this—and then there is a Treatment Advisory Group for treatment, drugs and other treatments outside of the cancer therapy regimes. The great thing about the initiatives taken is that they are healthcare professional lead, they are not led by bureaucrats. That is what brings it together and that is what gets the conference. Step-by-step, patients who are trying to step outside of the evidence-based practice and the appropriate regimes are given good, constant information. Whether they are in Middlesbrough, Sunderland or Newcastle, they get good information, and then they may well wish to make a choice further. That information is also shared with the general practitioners, the specialists in the tertiary centres, and the district general hospitals and others in primary care. I think it is a step forward and I would commend what the North East have done so far. It is by no means perfect but they have grasped the nettle. Just going back to it, it is the professionals, the senior staff, the healthcare professionals, the multidisciplinary team on the ground, that is bringing this about, and they have used the umbrella of an organisation that has been in place for some time, the North-East Cancer Network. We are not adding to the bureaucracy and we are not adding to the cost; we are harnessing the input, the information, the intelligence gathering, the horizon scanning of the professionals on the ground. The better informed, the more consistent the approach, you diminish the issue. I would commend to the Committee to bring them to the table, for you to do as you wish with them.

Q58 Jim Dowd: Could I first apologise to the witnesses and to the Committee Chairman for a conflicting constituency engagement which meant that I missed the first part of your submission. I hope what I am about to say has not been covered. Does the exchange just now not highlight the intractable tension between local commissioning and uniform provision? It is not just a question of cost-effectiveness between people suffering from a similar condition; it is making decisions about people suffering from entirely different conditions. Dr Jones, you were alluding to people moving. I presume the line between the two is that they really should move to areas where there are more people like them, and therefore with the conditions that they have. People have been doing this to find schools for their children for generations.

Dr Jones: I think people go to France as well to get drugs. One of the problems with the relationship between us applying for drugs to primary care trusts is this whole concept of the exceptional circumstance form (or whatever it is called locally). Every patient is exceptional to themselves. If the platform was that certain drugs were approved, but patients who had unusual conditions, particular to them, that meant certain drugs could not be used and certain drugs were better—so it has to be something unusual about the patient, not just the fact that they have cancer that generates an exceptional circumstance application—we would not run into this mess quite as much. I felt that a lot of what Sophie said made the argument for people being allowed to have top-ups, because you would have a bottom line of what people can have and then, over and above that, if they wished to top up they would—but we would get back to the issue of separateness. Part of it is a lack of clarity between the professionals, and, as Sophie alluded to, sometimes pressure from patients saying that they want a drug, please apply for it, when we know it is a futile exercise. Effectively it is precedent setting. Our local rule is that we would apply to the PCT for an exceptional drug if it is an exceptional circumstance based on other characteristics relating to the patient but not if it is a precedent-setting one that either has not been through NICE or has been rejected by NICE. If you just use it to push the window a little further in relation to drugs that have not been proved, you create tension all round which are not helpful.

Ms Christie: I think that is a good setting out of the process. In relation to your point about is it an inevitable tension, I think the answer is yes. We get ourselves into difficulties when we think of it as a problem to solve. I think it is just a tension to manage. There is always a tension between the strategic and the local, between the individual and the population, and that is part of the reason we have a system that helps to recognise that and manage that tension through: the role of government, the role of local commissioners, and the role of local providers. In many ways it can be a healthy tension because it allows for the debate, it allows for the challenge, but we are not going to solve it. There is not a simple answer, other than an exceedingly bureaucratic system which would draw up a list of 100 things that you are allowed to have on the NHS and under any circumstance, if you fall out of those, nothing else is available. If we start to get into absolutely rigid rules we really will struggle to meet local needs and local priorities. Having said that, in response to the earlier question about do we need a more rational approach, that is what NICE was created for and actually it has done a pretty good job in very difficult circumstances, which is why I am particularly worried about the lifting of the threshold, because I think it will make it very difficult for them to continue to have credibility as making any sort of judgment on cost-effectiveness. Effectiveness in the NHS, as a publicly funded system, cannot be separated from cost-effectiveness. Any spend on one activity has a disproportionate impact on everything else. To pretend that is not the case is disingenuous.

Q59 Jim Dowd: I thought you wriggled out of that very well indeed.
Ms Christie: Thank you.

Q60 Chairman: Sir Len, unfortunately constraints of time will make it difficult us to bring your clinicians group down here, but could you pass as a note about how the North East Cancer Drug Approvals Group works and the spread of membership.

Dr Jones: There is one in London as well.

Ms Christie: And in Birmingham.

Q61 Chairman: Could you send that in? We would be more than happy to have a look at the information and see how this PCT interaction works with the local NHS. The last question we have in this particular session is directed to you, Sir Len. It is on the issue of foundation trust private income cap. Do you think there is anything that is going to challenge the boundaries of this private income cap by the introduction of this scheme.

Sir Len Fenwick: I think the answer rests with your good self as the legislators.

Q62 Chairman: We are overseers. We are not legislators.

Witnesses: Professor Karol Sikora, Cancer Partners UK, Dr Jacky Davis, and Hilary Whittaker, Chief Executive, Beating Bowel Cancer, gave evidence.

Q65 Chairman: Good morning. Could I welcome you to this session and ask you to give your name and the current position you hold.

Dr Davis: I am Dr Jacky Davis. I am speaking this morning for the Keep Our NHS Public campaign and for the NHS Consultants’ Association, which is the group of consultants who want to see the basic principles of the National Health Service continue.

Professor Sikora: I am Karol Sikora, Professor of Oncology at Imperial College for 22 years and recently the Medical Director of a private sector organisation working with the NHS called Cancer Partners UK—that Jacky would not like.

Ms Whittaker: I am Hilary Whittaker. I am the Chief Executive of Beating Bowel Cancer charity. We provide education, awareness and support for bowel cancer patients, for health professionals and the general public. Thank you very much for giving me the opportunity to come and give evidence today, particularly this week as this is our biggest public awareness campaign week: Be Loud, Be Clear. I hope I am going to be able to put the patients’ perspective in a Be Loud, Be Clear way.

Q66 Chairman: Thank you very much. You are probably aware that some of us were supporting the campaign here in Parliament last week. Could I ask a question to all three of you. How do you ensure your independence from the interests that fund you or can you ensure your independence from the interests that fund you?

Dr Davis: We have very little funding from anybody and the funding that we have comes from the people who support us. The Keep Our NHS Public campaign is supported by people who sign up to the campaign. Union branches, for instance, give us money and we have had a small amount of money from one union. I believe, but we are supported financially by supporters. The NHS Consultants’ Association is only doctors who work in secondary care, and again that it is only supported by people who belong to the association.

Professor Sikora: Obviously, I belong to a commercial concern and have a vested interest in improving cancer services. I feel that the only way to improve, to bring our cancer care in line with Europe, is to involve the independent sector. It is not an issue for me in the North East, but it could well be a major issue, and I am sure that it is, for a number of the foundation trusts elsewhere in England.

Q63 Chairman: Why is that? Is that because they interact more with the private sector?

Sir Len Fenwick: The cap is 1% of the income stream. It is set very low indeed. But that is the licence that was accorded to us through our regulator and our regulator is tough to deal with. It is a very disciplined approach and I would applaud that.

Q64 Chairman: There has been no debate to your knowledge of lifting that cap due to the Richards’ proposals?

Sir Len Fenwick: With the monitor, the independent regulator, there has been extensive consultation, and the outcome is that it stays as it is.

Chairman: I would like to thank you all three of you very much indeed for coming along and helping us with this evidence session this morning. Thank you.
of a variety of companies, which can vary year on year. A lot of that funding really comes to us for public awareness campaigns, and maybe campaigns that are centred usually around symptoms and early diagnosis of bowel cancer.

Q67 Dr Taylor: I have an extremely broad question which you could all talk about for the whole morning, so, please, a very quick answer because we will be going into the detail. The very broad question is: Do you agree with Professor Richards’ recommendations? Really I am looking for a yes and a very quick reason or a no and a very quick reason, because we are going to go into the detail later.

Dr Davis: I think he has had a jolly good stab at it. He does say we should not have top-ups. He does recognise the threats to the NHS. For our liking, he does not go into alternative ways of doing this. We have heard this morning from two people that this is a very small problem and it seems to us that we are taking a sledgehammer to a walnut here and there are better ways of doing it.

Q68 Dr Taylor: Commendably brief.

Professor Sikora: I agree.

Q69 Dr Taylor: Even better!

Ms Whittaker: We broadly welcome it too. We liked the fact that it was broader than just top-ups, that it did look at the access to drugs for NHS patients. We welcomed the recommendations on exceptional funding and the recent announcement subsequently on high-level principles regarding national guidelines. Of course we want to see how that is going to be interpreted at PCT level. We were very encouraged by the importance given to the NHS becomes a two-tier system. They are the poor, they are the elderly, they are the inarticulate. I work in a hospital where the information sheets are printed in 27 languages. I suggest that we are not hearing from those people who speak those 27 languages about what they would feel when they could not afford these treatments, and I think it is a huge issue.

Professor Sikora: I think we are making a bit of a meal on the logistics. The Richards report is not about how to implement the logistics of top-up payments. That is the next step after the public consultation phase. I think it can all be accommodated. None of us wants to see a lady with a Barclaycard machine following the ward round around, giving a menu of options, and then you give your credit card out and take that. That is not how it can work. Safeguards have to be in place and the paper I submitted talks about the sort of safeguard. Again, the logistics are not that complex. Let us take Erbitux, because you will no doubt be telling us about Erbitux in a moment on—cetuximab is its generic name—it has side-effects. You can cost those side-effects not so much in an individual patient but on an average, so you can add a percentage of the drug’s cost to manage side-effects. Whether they pitch up in Newcastle or London does not matter, that goes into the NHS coffers. I think these sorts of things can be taken care of. The disquiet at a personal level for all of us, and we all feel it, is that you are going to have people knowing that somebody else is getting a different combination. That is difficult. It happens already. I know Sophie has gone, but the private hospital in Birmingham does the cancer drug delivery privately and has done it for top-ups for the last three years under a sort of agreement, so that the Chief Executive in Birmingham can say, “We don’t do top-ups in the foundation trust” but they go across the road to the private hospital. Is that the model? That is really the crux of the logistics: is it a separate model or is it an integrated model? It is safer to be integrated but it may have to be separate.

Ms Whittaker: There are points there with which I also agree. I think the top-up debate is a complete distraction, which I do not want to talk about today really, because I think that for bowel cancer patients particularly the important issue is access to the drugs. That is the real core. Within the process we are going through at the moment there are very, very few people who are going to be able to afford to have top-ups. This is a minority of people. This is a lot of money people will have to secure to be able to go ahead. We are spending an enormous amount of time talking about something that is going to apply to very small numbers. In fact, I think Len said nobody had applied for a top-up in six months, so it put it into some sort of perspective. I think we have to keep that uppermost in our minds. It is a last
resort for people. I think that continuity of care is a huge issue which patients have too: how this is going to work. They have all sorts of concern around that.

Q71 Dr Naysmith: The evidence of what has emerged from Richards is that the guidance allows patients to receive both private and National Health Service care in parallel. People have interpreted this change in different ways, and I suspect that we have two people who take opposite views sitting in front of us here. Some people have said it is the end of equity in the National Health Service and therefore is a real and significant change. Others say it is merely a restatement of existing rules and fudging practices that were going on anyway. What do you think, Professor Sikora?

Professor Sikora: I think the latter: it is fudging. It has always gone on. The rich get better care than the poor, the educated get better care than the uneducated—and that is a fact in the NHS. The biggest single benefit outside drugs and radiotherapy is your socio-economic class in terms of cancer, and it is not just late stage of presentation but it is how you respond to treatment, and it is because of a whole range of factors within the NHS. In the long term, the biggest weakness in all our arguments is why can we not deliver comparative services to Europe for roughly the same amount of money.

Q72 Dr Naysmith: We will come to that later on.

Professor Sikora: Okay.

Q73 Dr Naysmith: I do not know how much you heard of the previous session—

Professor Sikora: I did.

Q74 Dr Naysmith: —but there was a PCT Chief Executive sitting there saying how difficult it is to balance cancer care against care for somebody with a long-term, disabling disease at home, and the money has to be found for their care as well. Cancer drugs are very high profile, as you will know very well. How do you balance that kind of judgment?

Professor Sikora: You are absolutely right, it is an impossible task. The argument that Sophie gave about local needs is very valid: there are going to be different local needs. You cannot do the balance without having a rapid assessment from NICE to tell you the cost-effectiveness—and we have problems there and I am sure we will come to those. More importantly, if you have top-up, if you allow top-up—which I guess is a foregone conclusion, we are going to allow some form of top-up—it focuses the mind. It focuses the mind of all of us on how can we get the same service for more people so that we diminish the need for top-up.

Q75 Dr Naysmith: But it is on cancer drugs.

Professor Sikora: I agree.

Q76 Dr Naysmith: There are all the other things that the National Health Service has to provide.

Professor Sikora: I quite often get accused by my colleagues at Hammersmith of stealing their budgets for cancer, because over the last 20 years we have seen a tremendous rise in cancer compared to other aspects of health care. One of the problems is that the NHS is based on the people, what the people want, and all the surveys show that cancer treatments are what people want. HIV was a great model from two decades ago: it was something people wanted and it achieved the goal. Things like mental handicap, adolescent care, drug abuse programmes suffer because of this. I think that is where you, as politicians, have to guide the decision-makers to make sure there is no suffering there.

Ms Whittaker: Cancer is going to affect one in three people, as we have heard already, so in itself it is something which we are all concerned about. We all know somebody who has cancer. Bowel cancer is the second biggest cause of cancer deaths, so we are talking about big numbers for the patients I represent. Looking at the proportion of spend on cancer drugs in England, it is 5.7%, in France, it is just under 8%, and the spend on cancer drugs in Germany is just under 10%.

Q77 Dr Naysmith: France and Germany are desperately trying to reduce the cost.

Ms Whittaker: But that is what it is at the moment. I can only base it on information that we currently have and that is the information that is available at the moment. If you think of the number of people who are affected by the disease and the spend, whilst there are all sorts of dilemmas in how money is determined across a PCT and all the different demands on the different disease groups, cancer still in this country does not get its fair share of spend.

Q78 Dr Naysmith: Jacky, I am sure you do not agree with these previous statements. Dr Davis: I seem to be seen as a very disagreeable person this morning. To answer your question, which I think is a really important one: Does this change the nature of the NHS? we would say absolutely. I do not know what you think of Nick Timmins, but the one thing you cannot accuse him of his hyperbole. He wrote a leader in the Financial Times saying that the earth is moving under the NHS. This is an absolutely fundamental change about the way the NHS works. There has been a lot of sophistry about: “Oh well, there’s always been private care”—yes, there has, in the same way that you can buy private schooling for your children—“There have always been user charges and co-payments when you pay prescription charges”—yes, that is true—but it has never been that we are facing a situation within the National Health Service where patients would be on the same ward or in the same hospital having two different treatments based on their ability to pay. There was talk this morning about: “Oh, well, we have amenity beds in hospitals.” Those are hotel services. I have no problem with somebody being able to pay for Sky TV in their room, but there is a problem where people can buy different treatments which are going to affect their life.
Dr Davis: Professor Richards said in the report very specifically that he was not swayed by the minority who wanted to go down the insurance way, but it was interesting that, very soon after it was announced that top-ups would be allowed in some sense, there was an article on the BBC website describing the insurance companies absolutely dancing with delight and saying, "This is a pivotal moment for us. There's a bigger market here than there is in the private health market thus far." Whether we want it or not, they are pretty savvy and they see that this is going to be a big opportunity for people to buy insurance. There will be people who can pay for the extra treatment, there will be people who cannot buy for it out of pocket but who can buy the insurance for it, and there will be people who cannot pay for either of those, and so they are going to fill that gap. Of course, once you are diagnosed with cancer you will not be able to afford that insurance, so those people will be out of that picture. The argument that we cannot afford everything and therefore we have to have insurance I always find a strange one, because, as I understand it, the NHS is the cheapest way of doing things. We might not like many aspects of it, but it is the cheapest way of doing it, and therefore any other way we go is going to be more expensive and so why not just invest that extra money in the NHS.

Ms Whittaker: We have called for the last four years for there to be a lot of debate between the Department of Health and the pharmaceutical companies on the pricing of drugs, cancer drugs for bowel cancer, and to find innovative ways around that to bring the prices down. We continue to call for that and I know there is some movement in that area for patient access and risk sharing schemes and so on which is welcome. The outcome we really want is that these drugs become affordable and that they are readily available on the NHS. Then they would be available for everybody and it would not be a matter of insurance.

Q80 Dr Naysmith: Professor Sikora, you made reference to the national insurance system. Of course our National Health Service is not really a national insurance system, as it is taxation that pays for it. Do you think this change makes it more likely that we will have to move to some kind of proper health insurance system?

Professor Sikora: No, I do not think so. One of the things, listening to everybody, is that we are not alone with this. It is not just the NHS, it is not just Britain. Every healthcare system in the world is struggling with exactly this issue, the high costs of technology and innovation in an area like cancer, with an ageing population so the rate is going up. Second, you have to face up to the fact that you are never going to be able to provide everything and yet you, as politicians, have to try to convince people that your policy will do just that. I think that is where the fault line lies. Top-ups just focus it, make it more obvious that the cost of cancer drugs is really skewing the whole NHS budget. Why would it be right, if you had a child who was going to face their whole life with some problem, to see that money being lost to somebody who is spending that money on the last three months of their life? These are huge issues for society, not for us here this morning. It seems to me that that is the debate we need to be having and that the top-up thing is a distraction, in a sense. Those patients absolutely have to be dealt with who are having their NHS care taken away, but it is a distraction. I did not hear anybody this morning, for instance, talk about bringing the price of drugs down. That is something we really have to look at and that is one of the ways that we can avoid this problem altogether.

Q82 Stephen Hesford: Professor Sikora, could I ask you the Debbie McGee question. Given that you are associated with CancerPartnersUK, which is a private sector organisation, Pharmacia Corporation—

Professor Sikora: I worked for them in 2000, yes.

Q83 Stephen Hesford: They are a private sector company.

Professor Sikora: They are a big multinational pharmaceutical company.

Q84 Stephen Hesford: And Bioscience plc.

Professor Sikora: Yes.

Q85 Stephen Hesford: When did it first occur to you that the NHS should really provide a core service and that independent providers should “. . . bid for contracts to supply a top-up service to cancer centres”?

Professor Sikora: I think that interaction between the private and the public sector is very interesting. If you go around the Hammersmith at the moment,
60% of the staff are private sector employed, although doing tasks for the NHS. Okay, it is all in hotel and cleaning services, nurse agencies and other agencies. In the long term, delivery of care has to be done in the most efficient way, and in some cases the private sector is effective in doing that. The topping up debate in cancer really came at the beginning of 2005, when a whole range of drugs were licensed in Europe which NICE were not taking through because of long-term delays. As we have heard, it is relatively small. It is not an area that we are planning to get into, if that is what you mean. CancerPartners is not about doing top-ups. We are not doing that. It is mainly about radiotherapy expansion, so at the moment I have no conflict of interest in promoting top-ups as a policy.

Q86 Stephen Hesford: It was just a coincidence that in your evidence to us you used “top up” as a phrase.

Professor Sikora: Also, in my experience with pharmacy—I was head of R&D for cancer globally, based in three places—one of the questions for the pharmaceutical industry is “Can you lower the price of the drug?” and the answer is “No, not for a single country because they are global products.” It is like airline tickets: they are global products. You cannot say, “Because we like you and we like the NHS we will lower the price for you.” That is part of the problem. Over the last two years we have seen imaginative schemes of trying to get to value-based pricing, but they do not lower the price of the drug: you either get a refund or something back if it does not work after a certain period of time. The price of the drug to the wholesaler is the same. That is sort of because it is a global business, and I cannot see any way out of that.

Q87 Stephen Hesford: In 1997 the NHS budget was somewhere in the region of £35 billion a year. It is now approaching £100 billion a year. Does that not suggest that there is a move forward to reach European levels and that the NHS, by itself, without any kind of nudging or carving from the private sector, is going to get to where we need to go as long as people all sign up to it and support it?

Professor Sikora: I think there is huge inefficiency—and that is part of the trouble—within the public sector. It needs reform. Both the previous administration and this administration have attempted to do those reforms. I would say they have not gone far enough. There is a lot of efficiency savings to be taken out that could result in these drugs. I think the top-up argument is focusing our minds on how to get more efficient. Whether we use the private sector or do it in-house I do not think matters. We will achieve the same endpoint.

Q88 Chairman: Jacky, do you agree with that?

Dr Davis: I am very much with you, of course, because that is where I am coming from.

Q89 Chairman: Do you mean with the question but not the answer?

Dr Davis: Perhaps you would put the question to me again because I was so busy listening to the answer.

Q90 Stephen Hesford: I cannot really, because you are not in the private sector.

Dr Davis: No.

Chairman: Let us move on.

Q91 Jim Dowd: I was tempted to ask Professor Sikora whether the inefficiencies in the public sector match those in the banking sector.

Professor Sikora: That is not public sector, of course.

Q92 Jim Dowd: Most of it is now. I remember when we wanted to nationalise the banks because they had money. Now they want our money! It is amazing how the world changes. You mentioned the involvement of the private sector in the NHS. This Committee some years ago did an inquiry into the role of the private sector, and of course it goes far beyond the estate or the buildings. The pharmaceutical industry is hugely involved in the private sector. The difference there though is that that is the involvement regulated at the organisational level. With top-up fees, we are talking about contributions made at the individual level for private care. Do you not see that as a considerable change in the aesthetic of the NHS?

Professor Sikora: I think it is relatively small. If you take drug top-ups, is it going to be a separate model, so that the patient goes to a private sector provider, either at home, delivered to them, or at a private hospital or private care unit that is specially set up to do this, or are they going to go down to the pharmacy in the hospital, get the drug, and be given it in the NHS? If one goes down the separatist route, then somehow private sector facilities have to be put in in the traditional private practice type setting to cater for those patients. If it is going to be integrated within the NHS hospital, then it is less of a problem, but even still there may be a need to have a private sector partner that comes and delivers the top-up care. As we have heard, it is going to be small. It is not going to be more than, I would have thought, 5% of all cancer patients who would want to get a top-up drug.

Q93 Jim Dowd: As you have said and as we all know, one of the successes of recent times is increasing longevity, and therefore cancer becomes an ever increasing issue across time and will come to affect more and more people as a proportion of the population. There is no sign that that will ever end until we start losing longevity again, which of course is at a different time. It will come to affect more and more people over time.

Professor Sikora: Absolutely. There are three drivers which you cannot reverse: ageing populations; that there will be new drugs beyond the ones we are talking about today and beyond the ones for bowel cancer that we have heard; and also—which I think is the most powerful driver—the equalisation of information. There are 300 million websites on Google for cancer. You cannot hide in a clinic the fact that these things exist. When I began as a registrar in oncology at Bath, we did not tell people they had cancer. We have come a long way from that.
The quality of information, which may be variable, is easily accessible to most people or to their families, so they know about it. We cannot hide it. I think you are right, there will be an increase. I think the technology driver will be bigger than we will be able to cope with. I think we are being very pessimistic about where cancer is going to go over 20 years. Immortality is not achievable, as you say. We have to die of something. That IS something Western civilisation finds difficult increasingly, this fear of death. The coinage of the term “end-of-life drugs” is a particularly unfortunate one, because you go into a patient in a clinic and say, “Oh, by the way, we’d like to give you this,” and they say, “I’ve read about that and that is an end-of-life drug.” This is not helpful for keeping people’s spirits up.

Q94 Jim Dowd: If it is cyanide, of course, that is probably true. Moving on from there, do you see practical difficulties in separating private and NHS care over time? If so, how would you overcome that?

Professor Sikora: The logistics can be sorted out. I think the key thing is that there is no conflict of interest. If I am sitting in the clinic seeing a patient and I want to give them Erbitux or Avastin and they want to have it or they have come asking for it, I cannot say, “Come to the Sikora Clinic around the corner” and charge a lot of money and make profit out of it. That would be wrong. I think what Alison was saying this morning is very interesting, and it is the way I would envisage it. The patient remains under the care of the same multidisciplinary team. The decision to give the drug, the decision that it is worth exploring, because there the patient does of some benefit to them, maybe not NICE approved, comes from the doctor who looks after the patient but does not charge the patient as a private patient. The money for the drug with the side-effect costs are added to it, and the NHS, the hospital trust, gets the benefit from that. There is no separate moving to another clinic. The current model in Birmingham is worth exploring, because there the patient does move to a separate clinic. The hospital, the private clinic, gets, if you like, a profit or a surplus from the patient coming there, but, interestingly, the doctor signs the prescription but does not make a charge for that prescription. It works very easily for oral drugs. There are some drugs such as Tarceva or Tyverb that are oral. You write a prescription and it is up to the patient to go and find the cheapest way of collecting that drug, whether it is from a retail pharmacist or drug, whether it is from the hospital. It has to be given with other drugs, so the road, so the Birmingham Trust can easily say, “We’re not giving the drugs” but the patients that are getting the top-up, including sunitinib, the drug for kidney cancer that we have heard about, go down the road and get it. The consultant who does the prescription does not make a private charge for the top-up drug. It is a local arrangement which has worked for about three years now. It is one option, but that is the separatist model. It is ethical because there is no profit made by the consultant, so he or she has no vested interest in pushing top-ups to the patients. It is also not using NHS resources.

Q96 Jim Dowd: At what stage is that suggested to the patient?

Professor Sikora: Do you mean when they have chemotherapy?

Q97 Jim Dowd: Yes.

Professor Sikora: Most of the top-ups are drugs that are given with a course of chemotherapy for matters developed with cancer that has spread. At the inception of the chemotherapy, often the families come with internet printouts and say, “I’ve read about this drug”—and Erbitux would be an example if you have colorectal cancer—“can we have that?” That would be the model. The drugs have to go together in that case. The oral drugs are given on their own, and so it is less complicated.

Q98 Jim Dowd: Dr. Davis, on the question of separating private and NHS care?

Dr. Davis: One of the problems we all seem to be suffering with here is that we simply do not know the scale of this problem and how much it would cost to address it. I have been struck, listening to the difficulties of having a true separation as recommended in the report, by how much this is going to cost on a rather individual basis around the country, because some of these will be for patients where there will only be one here and one there. It would be really worth knowing whether the cost of having true separation, as described in the Richards Report, would be greater than the cost of giving those patients the drugs on the NHS because it is possible that that is the case. I suspect that this true separation simply will not be possible for all the reasons we have heard this morning: the difficulty of interrupting the multidisciplinary teams looking after these very complicated patients, the difficulty of giving the drugs separately, the difficulty of costing these thing into separate issues, the complications that arise from being transferred into the private sector. For issues of geography and availability of clinicians, what will happen is that in a lot of hospitals people will just be put in another room and a line will be drawn around it and that will be the private area and the doctor will deal with them: “I’m wearing my NHS hat now, and then I come down the corridor and I put on my private hat and I oversee you having your private treatment.”
am sure the two will just drift together because of all the practical difficulties we have heard of this morning and then we will be down that route of two different treatments in the NHS. Everybody will start out on this with the best possible intentions—and I admire this report and I think he has done a terrific job—but the practicalities of it mean that is where we will end up. I really do think it is worth looking at whether the cost of doing this in the way that he recommends is going to be so great for PCTs in terms of doctors’ time, premises, paperwork, multidisciplinary teams looking after everybody, that it will just be easier to stump up and give the patient the drugs.

Q99 Jim Dowd: Is not the danger of that that you then let the private sector dictate the pace at which drugs become available?

Dr Davis: That is another danger of going down the top-ups route. Once PCTs who are under pressure see that there are mechanisms being set up for drugs to be given to patients under these circumstances, more and more stuff will be pushed into that category. We have not gone down that road of discussion this morning but it is towards the core service model of the NHS, with people having a core service and then there is all sorts of bolt on stuff that you can get, and that will be the temptation. As has been pointed out by your colleague this morning, the NHS has managed to cope with the increasing costs so far. That is really a decision for society to make, we believe, rather than something that just edges in through the backdoor—which is what we are looking at at the moment.

Ms Whittaker: I would like to put this in the context of the patient for a second. From a patient’s perspective, they already have the trauma of dealing with a very serious disease and they are probably aware that they have a limited lifespan. They will be exhausted, having gone through the exceptional funding route first, because all of those avenues have to be exhausted. I think there needs to be lots of clarification on what that means. They are then confronted with this situation, which from a patient’s perspective must be utterly confusing. I think it is very important that this is made very clear, the clarification of what top-ups mean, and, going back, some colleagues this morning mentioned that, even though it might be something that would extend their life for a short period of time, it might not be appropriate for everybody to have top-ups, even though it could perhaps give them some benefit. But patients are going to need an enormous amount of guidance and support—and that has to be a very important part of this process—in order for them to even make a decision with their families about whether they would take a top-up. If they do, one of the big issues is going to be what their belief is, their ethical dilemmas: Do they believe in private care? Are they prepared to pay? Do they want to go into a private hospital? What does continuity of care mean? Clinicians as well are going to need a great deal of help and support in order to be able to explain all of this situation to a patient. I think there is an enormous amount of issues around that which hopefully we will get a lot of clarification on as this unfolds, going forward.

Professor Sikora: In the NHS clinic, time is of the essence. You have a set number of patients, a set time to do it, and the clinic gets taken over after lunch by another consultant. The top-up debate in certain areas is so time consuming. I share a clinic with a consultant who does a kidney clinic and when he is on holiday I have to see the kidney patients. There is no doubt that you spend a lot of time going through the costs/the benefits of these drugs. Not only that, we have a map on the wall of the clinic that tells you which PCT allows it easily and which does not allow it easily. If you are in Oxford, you are not going to get it whatever you do. If you are in Chelsea and Fulham, everyone gets it, as long as the consultant signs a piece of paper—which to me seems a reasonable way, provided the consultant has expertise in kidney cancer management. It is that sort of variation that drives this whole process. The disadvantage to the NHS of a little old man with prostate cancer waiting outside, is that whilst you are going through all this talk, someone is waiting to see you just for routine cancer care. That is one of the ways in which this could absorb a lot of time and some mechanism has to be put to prevent that happening.

Dr Davis: Nobody has mentioned, from a clinical point of view, that as a doctor we have never had to discuss with NHS patients whether they can afford something or not. We are a terrifically lucky generation of doctors since 1948. I work in a part of London where I am sure most people would not be able to afford top-up drugs. Am I going to sit in front of people who I know are on benefits, with their five children around them, and have to go through all the options because that is what the report requires, knowing damn well that those people absolutely are not going to be able to afford those top-ups? I think that is going to be a great strain on clinicians because we have never had to do that before.

Q100 Jim Dowd: The conflict there is between equity at the lowest level and people who can exercise this choice. You say that because not everybody will be able to, nobody should be able to.

Dr Davis: No. I am saying that that is a tension that we all recognise. When my colleague here says, “We will look at it from the patient’s point of view,” she is talking about particular patients, the cancer patients with these very desperate end-of-life requirements, the people who are not sitting here this morning. But we are all patients in this country. There are however many millions of us—everybody in this room—who are potentially going to be disadvantaged by these arrangements, so it is citizenship versus consumer, personal choice versus equity.

Q101 Jim Dowd: De facto, any decision you take closes off further options.

Dr Davis: Absolutely. I suppose I am saying that we always recognise that tension, and that there is nobody speaking for those patients whom I have already mentioned who speak 27 languages but not...
one of them English and who cannot be here today saying “What are the disadvantages to me if you go down this route?”

Q102 Chairman: We heard in the earlier session about the potential associate costs of the National Health Service of this top-up system. I know side effects are a very difficult thing to predict. Is there a comprehensive list or an exhaustive list in terms of what the potential associate costs to the NHS is?

Dr Davis: Not that I know of.

Professor Sikora: You can obtain it from the literature and looking at experience in other countries where the drugs have been licensed and in use. The problem is that clinical trials are not a good way to look at the true cost of giving a drug because they are in very particular circumstances. For Erbitux, which is used I think 10-fold more in France, one would look at French data to see what side-effect cost management is. With Avastin, a drug that has a high level of costly side-effects, again one would look at that. If one is pricing it fairly, I guess you would have to put the side-effect cost for that drug, so for Avastin a 30% mark-up, for Erbitux maybe a 10% mark-up, and so on, and work round. Insurers in Europe have all this data because they keep it and they have enough patients. The British insurers are still relatively small and, although their costs are rising, as I mentioned earlier, they would not have the sort of data we need. I think an oncologist could estimate it and then you could go and validate it against some European insurance scheme where the finances are collected. I do not see that as a logistic problem. I think more of a problem is the thing we were talking about with Mr Dowd, the problem of time and intravenous infusion time. Of the drugs coming through in the next five years, about 20 are tablets and 20 are what are called monoclonal antibodies which have to be given by infusion. There is going to be no way around that. That means that we have 40 compounds coming to be licensed in the next five years of which 20 will have to be given intravenous, and already in certain parts of the NHS access to intravenous infusion is coming to capacity, so we will have to build more specific capacity for topping up if that is how we are going to go. These are the sorts of things that an experienced manager, someone like Len, would have no trouble with dealing with. I do not see it as a logistic problem, because they have been dealing with this over the change in just strict NHS delivery of care, but it is a matter of factoring it in in a way that makes sense.

Q103 Dr Naysmith: One of the things that this whole debate has focused attention on that maybe was not there quite so much before is end-of-life treatment. That has been illustrated this morning with a number of questions that have been asked and answered. I am sure you will all be familiar with the new NICE appraisal system which uses a different cost per QALY threshold. Do you think that this change which means that they have a different threshold for end-of-life drugs is fair? Can it be efficient? Can it be properly cost-effective?

Professor Sikora: It is a horrible word, that is all I can say, “end-of-life.”

Q104 Dr Naysmith: We have been in clinical situations when doctors have talked about it and it clearly has been very much part of the debate.

Professor Sikora: But we are all dying. Everyone is dying. It is a matter of relativity. How long is it that you have! As we heard from Alison earlier, a lot of cancer patients are going to live essentially in an end-of-life state—the disease has spread, so by definition they are not going to be cured of their disease—for 10 or even 20 years. The longest I have had is 22 years. These people are living a normal life and they are accumulating all the morbidities that you accumulate when you get into your 70s and 80s and become frail. The end-of-life drug: it is difficult to define at what point you come to the end of life?

Q105 Dr Naysmith: Somebody is defining it because they are using the different thresholds. Is that a valid decision to make?

Professor Sikora: We have not seen how it is going to be used in practice. I think most oncologists are a bit concerned about this. The cost per QALY is enshrined in how NICE does its assessments. Are you really going to have differential costs per QALY when someone is, you predict, within three months of death? These are the sorts of things that are very difficult to do. At the end of the day, if one just added inflation to the cost per QALY that is allowed from 1997, when NICE started, to 2009, one would find one would be at the reasonable range for most of the drugs we are talking about. The end-of-life concept, to me, is a very tricky area to go down.

Ms Whittaker: On the end-of-life that they are looking at now, which is benefitting “small patient population”, we wanted to have some clarification on what they mean by small patient population, and whether this is to do with the number of people who were diagnosed or whether this is to do with the number of people who would benefit from the end-of-life treatments. Obviously that is a very different area. For bowel cancer patients it would certainly fall into the small patient population for end of life, because of course as a disease it is very large, with 36,000 diagnosed, and half of those are dying, but it would still come into that small patient population, the ones who would benefit from the end-of-life treatments. I do agree with the point that if inflation was added on to the existing 30,000 level over the period of time since it was set, that would be a new parameter for perhaps looking at the QALY measurement. Obviously how it is going to work in practice is another key issue because there are a lot of grey areas in small patient population and how that will be interpreted. It has to be interpreted equally and fairly across the whole of the NHS, so that we do not get the situation occurring again where some patients can get access to the drugs and some patients cannot through what we call the postcode lottery. I think that is terribly important when they are looking at the NICE system. Also, we
welcome NICE speeding up the whole process but, again, we want to see that in practice and see how that is going to resonate.

Q106 Dr Naysmith: Dr Davis, does not the whole situation arise because some of these drugs are quite toxic, the end-of-life drugs, and not effective? Not even the manufacturers would claim they cure the condition.

Dr Davis: That is the difficulty. I think NICE rejects 5% of drugs. I saw a figure that the QALY for some of them is £370,000 a year, so they are obviously very unpredictable and very expensive. As I think Alison said this morning, they do work for perhaps a small percentage of people—we do not know which ones. If they start to be given outside the remit of the NHS, the true NHS, then we may not be able to even monitor how they do, if we start using them for more patients. The other thing is that there will be pressure from the drug companies to push these drugs outside the NICE parameters. I understand that has happened already, that somebody has not submitted their drug to NICE because they understand that it will not be accepted. Now that NICE is admired across the world, to be rejected by NICE will have incredible repercussions, so there will be drug companies who start to bypass NICE and go straight to patient groups, for instance, and put pressure on them to ask for the top-ups outside the NHS. It is a very slippery road to start going down. The other issue that I have referred to before is that it seems to me that end-of-life and cancer drugs in general are really skewing the NHS budget. They are skewing it in an unfair way. It may be that some PCTs have five patients with a condition and another PCT has no patients with that condition, and we should not be denying the patients those drugs. It did occur to me that perhaps if we had some national fund for these drugs, we would not have all this patchy differentiation across the country, with some PCTs saying yes and some PCTs saying no. They are hugely expensive. It was very striking this morning listening to the lady who was sitting in my seat saying, “Do I want to spend this money on a very expensive end-of-life intervention or do I want to spend it on mental health where it will be much more money spread around?” I have just thought of this: take that wretched money out, put it in some national pot, and then have it given out. Then it would be much easier for the PCTs to balance their budgets when they know they are not going to have to face up with somebody like that appearing on 30 March and saying, “I need these drugs.”

Q107 Dr Naysmith: I will open up another whole area here that started with a quotation from Professor John Black, President of the Royal College of Surgeons. He was quoted in The Times as saying, “The importance of surgery seems to have been forgotten at some levels. The common cancers that have a one-in-five chance of killing any of us are dealt with by surgeons. There is a reasonable input from radiotherapy but the input from all these anti-cancer drugs, which cost vast sums, is very marginal.” Do you agree that more work needs to be done to explore the use of radiotherapy and surgery, not to the total detriment of cancer drugs but that the balance has become all wrong?

Professor Sikora: In terms of where cancer research is going, we all realise that the only way to go beyond local control of a cancer with surgery or radiotherapy, is that you have to have something that goes right round the body, so it has to be a drug. The thesis of modern cancer research is about trying to find differences between cancer cells and normal cells to allow you to develop a drug. The future is likely to be more drug-oriented, as it has been in diseases where we have developed drugs: tubercular cancer, lymphomas. The problem is that where the drugs work really well, for those sorts of cancers, it is a relatively small proportion, as you say, of overall cancers. Breast, lung, colon, prostate make up nearly 65% of all cancers, and the drugs there work but they do not work as well as they do in the rarer forms of cancer. I think that all one can do is see where technology takes us. I suspect over the next 20 years it will take us down a more drug-oriented route and the drugs will be much better than the ones we have now, and therefore NICE will be happier with the product, and so it will move forward in alignment.

Q108 Dr Naysmith: That is probably looking towards drugs like Herceptin that go for a specific histotypes.

Professor Sikora: Exactly. The thing about Herceptin is interesting is that it began as an end-of-life drug (using the modern parlance). It was used in women who had disease that had spread to the liver, to the lung, to the brain. That is where it was first tried, it was effective, NICE approved it in that indication. Then two years ago data came showing that it worked early on, after surgery had removed the breast tumour, and so it then came out of the end-of-life box into the active treatment box. That may well happen to many of the drugs we are talking about today, that they are not really end-of-life drugs. They are now, but they will be proven to have benefit earlier in the disease.

Q109 Dr Naysmith: The point I am trying to get at is that there is huge pressure to develop these new drugs from pharmaceutical companies—which is what their business is about. No-one criticises them for that. There are huge improvements possible nowadays in terms of therapy. We heard from one of the witnesses this morning that the radiotherapy department, half of it, is clapped out and needed replacing. Standing beside that—which I know is not true everywhere but happens in some places—we are spending lots of money on developing new drugs. Is that a sensible use of resources?

Professor Sikora: I am a radiotherapist myself and I would agree. The problem you have, if you take the total cancer budget, is where would you spend it? That is what Mike Richards has been doing with the cancer plan over the last decade, trying to find out where to get the most benefit from a certain amount of money. The problem is that the public understand a drug. If you have kidney cancer and there is a drug that you cannot get, you become obsessed with
wanting to get it. Whether you have a fancy type of precision-based radiotherapy compared to normal conventional radiotherapy for your prostate cancer does not have the cachet about it.

**Q110 Dr Naysmith:** We are supposed to be in favour of evidence-based treatments in the NHS.

**Professor Sikora:** Exactly. I think the future is about trying to use the technologies to the maximum and, as they improve, to look at the improvement. NICE is the way forward, there is no doubt, to assess all these technologies, but they have problems all the time: delays, suspension of appraisal for radiotherapy, for example. It is not a smooth transition. We need to get into a smooth transition.

**Q111 Dr Naysmith:** Dr Davis, we have all this focus on drugs purchased by the pharmaceutical companies, and there are other ways, according to some experts, of treating some cancers that get left behind in the priorities.

**Dr Davis:** I guess these are the patients I was talking about this morning, the patients whose voices are not being heard at the moment. If your radiotherapy department is clapped out and you are the patient who is relying on that, who is speaking for you? It seems to me there has been an emphasis on these very dramatic patients. As Karol said, they have become obsessed with drugs. That is one of the problems. It may be that they need protection from a lot of the publicity that goes out about drugs. The media. It is very easy to take up these patients, they are very emotive people, but it may be that somebody else looks at that and thinks, “Oh, that might do good for me.” Who is going to advise these patients if the top-up thing goes mad? The cancer argument has skewed things. We need to step back from it a bit and say, “What about everybody else?”

**Q112 Dr Naysmith:** Do you think that we need to spend more money to explore public attitudes towards whether the funding of expensive treatments that give patients a few extra months to live is a good use of NHS resources? We hear what the papers say, pushed by all sorts of people in the newspapers, but what are the attitudes of the patients in the National Health Service? Is it a good use of resources?

**Dr Davis:** When people answer those surveys they always answer as individuals. The letter that was included in the Richards Report was a very telling letter. It was the only letter, I think, that he did include and he included almost all of it. It was written by a patient who had terminal cancer and who said, “I could not afford these drugs myself, I know I could not, and I ticked the box saying ‘Should other people be able to buy them?’ and I felt very martyred about it and good,” and then he said, “but I went away and thought about it a bit and I thought how miserable all the people would be who could not afford those things.” He was a bit unusual, he answered the question in a citizen sense, he did not answer it in a consumer sense, but when people answer those things, they think: “What would I want?” Perhaps it is right that people answer that, but I think people like you perhaps have to sit back and say what is best for society here.

**Q113 Dr Naysmith:** There are ways of designing questionnaires that can get at people’s views, even, sometimes, when they do not think they are putting them down. Ms Whittaker, do you have a view on this?

**Ms Whittaker:** I think that asking patients their views of these things would be excellent. The more evidence base that you have for making decisions going forward would be welcomed.

**Q114 Dr Naysmith:** This was not so much asking patients but asking the public.

**Ms Whittaker:** Asking the general public is equally valuable. We hold a lot of market research on issues around bowel cancer, awareness of it, and how people would like to go forward and would they accept treatments and so on. I would absolutely welcome it. If I could go back to the previous question for one moment, our aspiration for bowel cancer patients is that they would not need end-of-life drugs. That would be the perfect solution because that would mean that the 50 people a day who are dying from bowel cancer are not. Surgery is usually the first place that a patient will go in terms of treatment for bowel cancer. The advancements on laparoscopic surgery have been absolutely tremendous for bowel cancer patients. Now, where there are centres where laparoscopic surgeons are doing, in some cases, 80% of their surgery for bowel cancer by laparoscope, a patient can be out of the hospital within three days, rehabilitated at home within two weeks, back at work and contributing and for all intents and purposes well. In bowel cancer cases, 90% of patients, if caught early enough, can be successfully treated. I think surgery is still the most important treatment for bowel cancer patients. That would be a wonderful place to be with end-of-life drugs not required for bowel cancer patients. But we have a long way to go, of course, before we are there and so we have to address some of those other issues.

**Professor Sikora:** The largest study that has been done was Cancer Backup two years ago—it is on the web, it is published—looking at attitudes not to top-up but to attitudes to cancer drugs and information. The bottom line was that people want all the information, they do not want things to be hidden from them. If they ask me about a drug, they do not want me to deny the drug exists. They want me to be honest with them, even if they cannot afford to buy the drug for themselves. That transparency is something about the whole consultation process that we cannot take away. It does not matter whether it is in the private sector or the NHS, that is key to good medicine. The question then is: How much would people be willing to spend for a top-up? They did ask a few questions, and that is where it gets a bit different: from social class 1 you get a very different answer than from social class 5. It was of about 3,000 people. It was a donation from the MORI poll people. It is worth looking at that study and I can
send the reference for it to Adrian. But there is very little of that. That is the only study I know of in the whole literature.

Q115 Dr Naysmith: Asking people to understand what it means if you say to them, “There is a one in 10 chance that it might be effective in your case” or “There is a one in hundred chance it might be effective in your case,” with the clinician sitting down and explaining that to a patient, must be a terribly difficult task.

Professor Sikora: Other studies by my colleague Maurice Slevin here in London have shown that, even with a one in a hundred chance of something working for a patient, they are going to take it. Why would they not? Because then they have the perception of cure.

Q116 Dr Naysmith: But then you have to add in, “You might have terrible side effects for a while and it may not work, so you have to weigh up.”

Professor Sikora: Absolutely.

Dr Naysmith: It is difficult.

Q117 Dr Taylor: I am still grappling with the extent of the problem. I wonder if we could be given any idea of the cost of funding drugs for a patient with bowel cancer who is turned down. What sort of figure are we talking about?

Ms Whittaker: I probably do not have that information to hand. I can have a look and see if I can source that information for you, or there may be others who would know what that figure is. I suppose the clinician’s choice is so different for the whole process. Somebody will have worked out. I am quite sure, some measure by which there will be an average, but I do not know what it is.

Q118 Dr Taylor: The Richards Report—correct me if I am wrong—guesses at £8,000 as the basic cost without all the extras. If you add the extras, one is going to be talking about £15,000 or £20,000.

Ms Whittaker: Probably, yes.

Q119 Dr Taylor: That comes back to the previous point: however many people are there who can afford that who are not going down the fully private route.

Professor Sikora: The other problem is that the reason it is relatively low—relatively—is because a lot of patients fail. In other words, after three months the drug is not working, so you can stop, and so they have only had three months’ supply. What do you do with someone who has a dramatically good response? However bad the situation, you get one or two patients who have dramatically good responses, so they are going for a year or maybe a year with the drug, and there the figure could be much greater than that £8,000. I it could be double, because that £8,000 is just an average, and they run out of money. How do you deal with that group of people? That has to be thought of here. Again it can be insured for. The way round it, if you sit down and work it out, you say, “Let’s balance out what the average is and let’s increase that a bit to pay for insurance, to pay for the people who are going to go two or three years down the line and start having to pay for a drug”—which is essentially what the NHS is doing. It is the insurance function of it.

Q120 Dr Taylor: Is there an absolutely huge hidden problem, in that there are a lot of people who would never even dream about affording this amount of money, who are there who would really benefit from some of these drugs? I am talking specifically about the end-of-life drugs that really are proven to have quite a benefit. With the renal drugs particularly it is pretty definite now that they can prolong life. Are there thousands of people who would never even kick up a fuss because they know they cannot afford it at all? Have we any measure on that sort of problem?

Dr Davis: I think part of our problem is that we simply do not know the size of the problem we are dealing with. To come back to your question: What is the average price? I would suggest again that if you add in what it is going to cost the National Health Service to run a parallel system for those patients, it may well be that the problem is small enough so that, cost-wise, it is not worth running that system because of the cost of administering the drugs. The number of those patients who have failed, according to the Richards Report, is very small—I think the Exceptional Cases Committee accepted something between 65% and 75% of cases, the average was £8,000, the overall number in the country was 15,000. Somebody needs to sit down with a calculator and say, “It would have cost this to fund those patients. How much is it going to cost us to administer the system that he is advising?” By the time you have factored in all these different doctors doing things and premises and paperwork and multidisciplinary teams, crossing the divide, perhaps it would cost less money to give the patients the drugs.

Q121 Dr Taylor: Does this number of people who go into Exceptional Case panels probably cover the whole range?

Dr Davis: I do not know.

Professor Sikora: It does.

Q122 Dr Taylor: Probably.

Professor Sikora: It would cover the whole range.

Q123 Dr Taylor: You have mentioned better information, should one of our recommendations be that we suggest to NICE that when they turn down a drug they produce a relatively detailed explanation aimed at ordinary people to explain almost in words of one syllable why they have turned it down so that most people could make up their own minds?

Professor Sikora: And you could translate it into 27 languages. The idea would be that there would be three categories: (1) acceptance for widespread NHS use; (2) acceptance that the drug has value and is probably being used in European systems and there is evidence of benefit but it is not cost-effective used within the NHS; and (3) a recommendation that it is not worth touching with a bargepole, that it has no
real benefit, and therefore do not even go and buy this drug. With a NICE approved drug there is a public leaflet that comes out. You just need to do the same process for the other two categories.

Q124 Dr Taylor: Would you agree with that?

Dr Davis: I think it is going to be necessary to protect patients from predatory drug companies. That seems like a way to do it. As said earlier, if there is a 1% chance patients will take it, but those choices need to be made very explicit. I would really like to see us aiming to offer all drugs that have clinical effect to patients who can benefit from them, like Europe apparently does, and to look at ways in which we can do that rather than through the top-ups. There was a very interesting letter in the

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about three months ago saying that if Europe approached this as a body—and of course we could through the EC—and looked at these very expensive drugs and said, “Europe will buy this drug if you make it value for money, if you bring the price down,” then it may be that a lot of these drugs would start to fall within the price range where we could offer them to everybody, and, as Hilary said, we simply would not have the problem any more because we could deal with it.

Q125 Dr Taylor: If prices came down what could we give up so that we could afford all these things?

Dr Davis: Where could we save money in the NHS?

Q126 Dr Taylor: Yes.

Dr Davis: I believe there is a paper out where we are already identifying places to save money.

Q127 Dr Taylor: Better Care, Better Value.

Dr Davis: That is right.

Q128 Dr Taylor: Which is hopelessly under-used.

Dr Davis: Exactly. We could look at that. I am told by people who understand the pharmaceutical industry that we could, by negotiating with a drug company, bring the prices down. I know Michael Rawlins was quoted as saying that some of these drugs could be sold for one-tenth of the price, so there is a lot of scope there. Of course, coming from where I come from, I would say that a lot of money is being spent in the National Health Service—management consultants, bringing in the private sector and all that kind of thing—where it could have been sent to looking after patients.

Dr Taylor: Thank you very much.

Q129 Stephen Hesford: You argue that the NHS spends less on drug treatments for cancer than some European countries. How robust is the evidence for and should we be suspicious of it when its production is funded by the international pharmaceutical industries?

Professor Sikora: The report comes from the Karolinska Institute in Sweden, which is the main cancer centre in Stockholm. It is true, it is funded through money given to them as a grant, to do this study to look at European comparisons, but the comparisons are based on wholesalers’ returns. It is unlikely that would bias it. The figures are so staggering in terms of Britain Not for all drugs. There are some exceptions. For example, there is a drug called Gleevec for chronic myeloid leukaemia that came out five years ago and the NHS adapted to that very well—just as well as the European system—probably because it was a very well-defined cohort of patients, less than 2,000, who were getting it. When it comes to common cancers, drugs for breast and colon cancer and so on, the graphs are quite staggeringly different. It is unlikely that there is not a difference. A lot of British spend on the drugs is people with private medical insurance. That biases it a little bit. In fact the NHS spending on these drugs is even worse than it looks on the various graphs. These are all drugs that NICE have not approved. That does not mean Europe have got it right, but it suggests that this discrepancy cannot mean that we have necessarily got it right either. There has to be some better formula in between, an average. There is consistency on which countries introduce cancer drugs fastest. Austria, Spain, Switzerland, Germany and France are always at the top of the pile. We are always down the bottom. Interestingly, you start looking at the new countries in the European Union, towards the East of Europe, and they are beginning to catch up with Britain in certain areas of cancer, so there is some fundamental problem. I would say to rectify it—and I would fully agree with Jacky—would not cost an awful lot in terms of the total drug budget of about £9.5 billion. It would not cost a lot to get us out of all this. The difficulty is how to do it.

Ms Whittaker: I think it is clear that for bowel cancer the drugs are readily available in France and Germany and Spain and Italy and most of the rest of Europe, so I suppose if a patient was refused treatment here they could go across there and get it. But that does not seem right at all and, from our point of view, we wonder why the whole of Europe manages to have these drugs readily available for bowel cancer patients but they are not readily available in the UK. I am particularly referring to new innovative treatments that do make a considerable difference to a patient who has terminal bowel cancer. We see the figures printed. We are not party to how they are printed, but we accept that they would be fair and reasonable, and certainly the drugs are available elsewhere and they should be available here from our point of view.

Q130 Stephen Hesford: How do we know that they are cost-effective and that they have any real difference on outcome?

Professor Sikora: They have all been approved by the FDA in Washington and the European Agency. They look at efficacy but not cost-effectiveness. They look at the efficacy, often without knowing what price will be charged for the drug before it is licensed. The European Medical Evaluations Agency based in Canary Wharf. These drugs are approved across Europe. Our Committee of Safety in Medicines does not get involved. It is a European decision to put them in the shops. That means I can write a prescription and the patient can get the drug. Whether the NHS will pay for the drug becomes
NICE’s decision. The reason we have the huge discrepancy in these graphs is simply that NICE take a long time before they are approved. If you look at drugs over the last five years, the drugs that have been approved during that time have been approved by the European Agency in London but not by NICE, so they do not start getting used in the NHS. How do we know they are efficacious? People have done controlled clinical trials. There is a problem. How much is three months of life or six months on average? We have heard about the kidney cancer drugs quite a lot this morning. With some of those you get quite remarkable prolongations of survival but you cannot predict which patients are going to get those remarkable benefits, the two or three years of prolongation of survival. The difficulty we have is that it is all based on clinical trial data before the drug was licensed, then it goes into clinical practice. My colleagues in Europe—and we obviously meet regularly—are astonished that we are not using some of these drugs because they say they have benefit. The difficulty now is how you quantify those benefits and put them against cost. That is the job of NICE, I guess.

Q131 Stephen Hesford: You said before that you could give a drug for, say, three months and then realise it is not having any effect.

Professor Sikora: Yes.

Q132 Stephen Hesford: Is that not a waste of money?

Professor Sikora: No. It is good oncology. You give a drug, you have what is called some sort of marker of response—so it may be an x-ray, it may be a blood test, it may be some other investigation—you repeat it after three months, and you see if it has got better, in which case the drug is working, or if it has got worse. If it has got worse, you stop at that point. Most of these drugs take about three months before you can do the assessment. If you could do it the next day after giving it, it would be wonderful, but you cannot. You usually have to wait three months.

Q133 Sandra Gidley: In terms of outcomes, money spent, survival rates, extension of life, what evidence do you have that Europe is any better?

Ms Whittaker: The figures I can refer to are the 2002 figures that I currently have at the charity, in terms of being able to find out earlier when somebody has bowel cancer. Ms Whittaker: As with all things, it is probably an element of a number of different things, but there is no doubt that if you can get treatment that is very effective early on then the outcome is going to be to your advantage, and there are no other measures that we have that are saying it is any different from that.

Q134 Stephen Hesford: But that is 2002.

Ms Whittaker: Yes. I understand that for part of Mike Richards’ review there is going to be an investigation into some more up-to-date data on those comparisons which of course will be extremely interesting for us to see in due course.

Q135 Stephen Hesford: It will be helpful to you when dealing with your client group to have that up-to-date conversation.

Q136 Chairman: Is that wholly due to the availability of these drugs or is there something else behind survival rates, in terms of being able to find out earlier when somebody has bowel cancer?

Ms Whittaker: As with all things, it is probably an element of a number of different things, but there is no doubt that if you can get treatment that is very effective early on then the outcome is going to be to your advantage, and there are no other measures that we have that are saying it is any different from that.

Q137 Chairman: Would you say that investigating and screening is good in the UK in terms of bowel cancer?

Ms Whittaker: We welcome screening in the UK, of course, because that is a step forward. It is only for people in the 60 to 69 age group, so it has its limit, and of course it is not, as you know, fully rolled out yet. Bowel screening is in the process of being completed. We would be interested to see from the final results as people have been picked up and at what stage they were picked up, but it obviously is an advantage to have the screening. I think the big problem in the UK is awareness of bowel cancer. If we are talking bowel cancer specific, it is that people do not know it is the second biggest cause of cancer deaths. In our market research, less than 50% of people could name a single symptom, so there is no real awareness. Although we were hoping that with screening people would become more aware of this terrible disease that is killing so many people, there is no evidence of that having happened yet, partly because there was no real national awareness campaign that ran alongside screening regrettably, although we did ask for it. It was left to the PCTs to try to do that locally and of course it had very limited funding and it has not necessarily happened.

Q138 Jim Dowd: I heard last week at the reception that it is the second biggest killer. Are you saying that it kills more people than breast cancer?

Ms Whittaker: Yes. More people die from bowel cancer than breast cancer. It is second only to lung cancer. It depends which data you are looking at, but about 16,500 people are dying every year from bowel cancer.

Q139 Jim Dowd: Setuximab was mentioned previously—I am not sure what the other name for it is.
Ms Whittaker: Yes.

Q140 Jim Dowd: Is that what it is called?  
Professor Sikora: Erbitux.

Q141 Jim Dowd: Is that now generally available?  
Ms Whittaker: No. No.

Q142 Jim Dowd: Not at all.  
Ms Whittaker: It is not available.

Q143 Jim Dowd: I had a case with a constituent five years ago over this.  
Ms Whittaker: It is about five years ago that it was licensed, and we are still having this discussion. Avastin was probably four years ago and we are still having this discussion.

Q144 Jim Dowd: And they are still not available.  
Ms Whittaker: They are still not available. In fact, under the exceptional funding possibilities to PCTs, there were about 56 applications for Avastin over a 20 month period finishing in July 2008, of which 41% were positive. There were about 106 for Erbitux and 41% were positive. So even for people going forward for acceptable funding more than half of them are turned down, and of course during that process patients are going through the most traumatic and difficult and stressful time, having to appeal through this exceptional funding process which can be lengthy and very distressing for patients and their families.

Q145 Jim Dowd: I was fortunate five years ago with my constituent because the PCT did agree in the end. Sadly, he died before the first course was supposed to begin.  
Ms Whittaker: This is something, of course, at Beating Bowel Cancer we hear on a daily basis.

Jim Dowd: Thank you, Chairman.

Q146 Chairman: Does the new PPRS scheme which was renegotiated last year represent a good deal for patients on the NHS? I know you have covered this area in many answers to questions in the last hour, but who would like to have a shot at that? Is it a good deal for patients and the NHS?  
Professor Sikora: It is a complex fudge, I think. The difficulty is how is it going to affect the price overall of, say, Erbitux, as we are talking about it? Is it really going to make it cheaper or not? I suspect that in the negotiations on both sides, one side think they have got away with not lowering the price and the other side thinks they have got a big price reduction. I get the feeling that we just do not know—and you will not know until it has been operational. Value-based pricing, which is the other way of doing it, is a better way forward, if one is being logical. If you buy a better car, you expect it to last longer and not to need so many repairs, so you are paying more money to get that. Why does the same not apply to a drug? The difficulty in cancer is that very few cancers can be measured very precisely, so the first value-based pricing model was with a disease called myeloma, with a drug called Velcade. We measured the blood protein level. If it fell below 50% of its start level, you paid for the drug. If it did not, you got the drug for free. That is the ultimate in value-based pricing. That model is still in application. For breast cancer or for bowel cancer it would be very difficult to get such models. Not only that, it requires a bureaucracy to monitor that, how you are going to do it and get the refunds for the drug, so there are hidden costs in that. I am a bit sceptical about the PPRS. It is the most complex scheme and we are talking about a global market all the time. If you take Pfizer or Merck, they are not interested in British sales, they are interested in global sales. To them, this is unimportant. I think that is the problem with the whole thing.

Q147 Chairman: What do you say to that comment in and around the OFT report in 2007 that the issue of prices and PPRS was important to the rest of Europe. People were saying it was keeping the price of drugs up in Europe. Is that correct?  
Professor Sikora: I think value-based pricing would affect the price more than the PPRS. The PPRS is a local agreement, looking at local assets of pharmaceutical companies and not allowing them to make so much profit beyond a certain level and then bringing down the cost. Value-based pricing is how we are used to dealing with the consumer world and would seem to be a much better model for the future—but you have Alan as the expert on this.

Q148 Chairman: Do you think the reason we have drug companies raising prices is "to get profits up so their executives can get better bonuses" and that "the prices the pharmaceutical industry charges are what they think the market will bear". You know who I am quoting on this.  
Professor Sikora: There is definitely an element of what the market will bear. I was involved 25 years ago in the pricing of a drug for cancer—and I will not tell you what it was. The way it was done was just to look across Europe for the three highest cost cancer drugs and take the average for that, and that was the price of the drug. The drug itself has no inherent value—especially if it is a new one. It cannot necessarily be compared with anything else very simply. Value-based pricing gets over that: if the drug works well, you have to pay more for it. The pharmaceutical industry defends itself, saying it is recovering the costs of R&D. I was part of that process for four years and it does spend a huge amount on R&D, but it also has shareholders, so you are working in a capital economy which requires profit for shareholders and that is part of the problem.

Dr Davis: Not being a person who prescribes, that is what I have been told by people who understand the drug industry. One of the important reasons the NHS must stay as a coherent body is that it gives us much greater bargaining power with the pharmaceutical industry. This lies at the heart of resolving this problem. I do not think we are going to resolve this problem in the way that has been suggested in this report. I think we are going to
resolve it by bringing drugs prices down, bringing those patients within the Health Service, and getting rid of all the problems we have discussed this morning. Karol says they are interested in the global industry, certainly looking at it on a European-wide basis and saying, “Okay, we are Europe, we are going to negotiate with you guys, what can you do for us?” and sticking together like that would be in everybody’s interests.

Ms Whittaker: I agree with Jacky. The key here is to get the prices down. The pharmaceutical companies should be working with the Department of Health; the Department of Health should put pressure on them to bring the prices down so that all the drugs can be available at affordable prices where clinicians feel they are appropriate for a patient.

Chairman: You are all agreed that value-based pricing is the way forward and not the scheme that we have now. I do not know how that works on a European scale.

Professor Sikora: Difficult.

Chairman: Yes. Could I thank all three of you very much indeed for coming along and helping us on this, our first day of taking evidence in the inquiry.
Thursday 12 February 2009

Members present

Mr Kevin Barron, in the Chair

Charlotte Atkins
Jim Dowd
Sandra Gidley
Stephen Hesford

Dr Doug Naysmith
Mr Lee Scott
Dr Richard Taylor

Witnesses: Professor Christopher McCabe, Chair in Health Sciences and Director of the Academic Unit of Health Economics, University of Leeds and Professor James Raftery, Professor of Health Technology, University of Southampton, gave evidence.

Q149 Chairman: Good morning. Could I welcome you to what is our second evidence session in our inquiry into top-ups and improving access to medicines? I wonder if, for the record, you could tell us your name and the current position you hold.

Professor McCabe: Christopher McCabe; I am Professor of Health Economics at the University of Leeds.

Professor Raftery: James Raftery, Professor of Health Technology, University of Southampton.

Q150 Chairman: Welcome and thank you for coming along. I have a couple of questions about the Richards Review for both of you. What evidence is there that before the Richards Review significant numbers of people were not able to purchase drugs not funded by the National Health Service? Is this well evidenced?

Professor McCabe: I do not actually think it is well evidenced. There was a large amount of media coverage of a relatively small number of cases. Searching through the media coverage I identified about 18 distinct named cases. When you look into what evidence there is about how many people are going through the individual appeal processes, it is not huge numbers and the average success levels look quite high. None of it is well-evidenced, but what evidence there is out there suggests that it is not a huge problem.

Professor Raftery: I agree with that.

Q151 Chairman: Could you tell me what impact you think the Review will have and the consequent changes to the NICE appraisal process on NHS and patients?

Professor Raftery: The main effect on NICE has been the end of life new supplementary advice to the appraisal committees. It has already led to a drug being approved—Sunitinib—for renal cancer, explicitly under those four conditions.

Professor McCabe: The thing about the Richards Review is that it was a set of recommendations and not actually a statement of a new policy. Those recommendations can be interpreted in a number of different ways and we are probably seeing PCTs interpret them in different ways in the absence of a clear specification of how the department wants them to respond to the Richards Review. At the NICE level clearly the most direct and obvious effect is the implementation of the end of life premium and whilst we have the four very clear criteria for the operation for the end of life premium, what we do not know is how many technologies are going to be able to tick the boxes and therefore qualify for that special consideration. What do we mean by the lack of an equivalent alternative technology? That is not well described yet or well understood. What do we mean by a small study population? Again that is not well-specified. So the impact could be large, it could be small, depending on how the criteria are operationalised.

Q152 Stephen Hesford: On your previous answer about the evidence, if it was not well-evidenced but there was obviously a storm about it, have you researched that media storm? Is there an argument for not doing what we did and not having the Richards Review?

Professor McCabe: We have the Richards Review. A perfectly reasonable response from the Department of Health to the Richards Review would be to shift the guidance statements with regard to how private and public funded healthcare should not be mixed into direction so it has legal force and trusts have removed from them the ability to read it and say, “Thank you very much, I have taken notice of it but actually I am going to mix public and private healthcare within the NHS hospital”. If the Department of Health wished to make it a directive then that would protect people from being charged for care which the NHS routinely provides in response to them buying their own drugs. Has that answered your question?

Stephen Hesford: I am not sure it did, but it was an answer.

Q153 Chairman: The Richards Review itself has been described as opening the door to co-payments and a core service National Health Service. Others have described it as a bit of a fudge actually. What do you think about it? Where are you in this debate?

Professor McCabe: I think it could be operationalised so that it was either: what we do not know is how it will be operationalised, how PCTs and how foundation trusts will use the recommendations of the Richards Review to either actively pursue the opportunity to generate an additional revenue stream from top-ups. However,
they could look at it and say, “Essentially this is a clear re-statement that we do not mix public and private healthcare in NHS hospitals” and not go there. In the current environment either of those is possible.

Professor Raftery: I think there is a big distinction between top-ups and co-payments. I think co-payments are common in insurance based systems and they seem to have fewer problems with top-ups, particularly if there are a variety of schemes on offer. The thing I thought was really interesting and valuable about the Richards Review was the variety of mixes of public and private that exist in the NHS and that had not been listed comprehensively before, let alone quantified. I think quantifying those is tricky. The Richards Review then clarifies the background and confines the issue to drugs that had been refused by NICE. That is a very small subsection of that whole complicated area of the mix of public and private, but I think it also clarified the ground rules for public and private.

Q154 Stephen Hesford: Could we have done without it?

Professor Raftery: I think the issue was one of perception and the media. Patients with terminal cancer or other illnesses are unusual in the sense that most cost-effectiveness analysis or cost-benefit analysis do not ever confront the people who are not going to be treated as a result. For instance, if there is a scheme about fixing a traffic problem the decision not to proceed with it may mean that lives are lost there but those people never come and confront the decision maker, whereas in the situation of NICE and end of life patients they are going to challenge the decision and appear on television and make a disproportionate amount of noise. It is hard to disagree that they have a right to do that and that it is a particularly gripping story.

Q155 Chairman: How easy do you think it will be for the National Health Service to separate the NHS costs and the private costs associated with administering additional drug treatments? Is there a danger that under the scheme the NHS will end up effectively subsidising private healthcare? This is an accusation that has been in the media. How do you feel about the separation of costs and whether that accusation would stick?

Professor McCabe: I think it will require a significant amount of data collection. As I understand it, co-NHS contracts are mainly on volume and quality basis; we do not do a great deal of collecting patient level resource use in a way that would enable the NHS to easily start issuing accurate bills to patients or their insurance companies. Therefore if we are to be confident that the NHS is not subsidising private care we will have in some way to create that infrastructure which will be expensive. We only need to look to the administration cost of insurance based healthcare systems to be quite confident that we will have to spend a lot of money. If it is the NHS that spends that money then that will be a form of the NHS subsidising the healthcare of those who are fortunate enough to be able to afford private healthcare. If that is charged onto the patients who access top-ups then that will drive down significantly the proportion of patients who can access top-ups because the costs will exclude them from it. That is a major issue.

Q156 Chairman: Do you agree with that, James?

Professor Raftery: I have two points to make on that. If the numbers are relatively small—which was the discussion we were having earlier—then I think there is less of a problem. A lot does depend on what the numbers are and I think the Richards Review, by encouraging a variety of methods that would reduce the numbers, should enable those numbers to remain small, particularly speeding up the NICE processes, PCTs being more transparent and so on. If they work then I think the numbers will stay small. I agree that the cost per individual patient may be considerable and if it is very ad hoc and occasional then costing them is a new exercise every time. If the numbers are relatively small—which was the discussion we were having earlier—then I think there is less of a problem. A lot does depend on what the numbers are and I think the Richards Review, by encouraging a variety of methods that would reduce the numbers, should enable those numbers to remain small, particularly speeding up the NICE processes, PCTs being more transparent and so on. If they work then I think the numbers will stay small. I agree that the cost per individual patient may be considerable and if it is very ad hoc and occasional then costing them is a new exercise every time.

Q157 Dr Naysmith: Professor McCabe, in answer to the Chairman’s first question you implied—if you did not say directly—that the Richards Review, as well as not being a statutory thing that would direct people to take action on it, it was a little bit vague in the recommendations and not very positive. Do you think that was deliberate or do you think it was just written that way?

Professor McCabe: I do not think the Richards Review is vague in its own terms but it did make some principal level recommendations. How you operationalise those recommendations has not subsequently been set out by the Department of Health. That gives the people running the trusts a reasonable amount of space and freedom to interpret them as fits best with their strategic objectives. Whether that was a conscious decision, I think it was quite appropriate for the Richards Review to make principal level recommendations and handing onto the Government to then decide how to operationalise and which ones to operationalise.

Chairman: We will later ask Professor Richards, who is in the room, about this. We are now going to move on to look at NICE thresholds and the end of life technologies.

Q158 Mr Scott: Is the new NICE threshold for end of life treatments merely a public relations exercise or will it lead to patients receiving drugs that they had been denied previously by the National Health Service?

Professor Raftery: I think patients are already going to receive drugs under the end of life arrangements based on the Sunitinib guidance that was issued last week.

Professor McCabe: It will undoubtedly lead to patients qualifying for treatment with drugs that are in that small selection reviewed by NICE. They will receive treatments they would not otherwise have received. Of course other patients are likely to not receive treatments that they would otherwise have received because of the displacement of the opportunity costs of those NICE recommendations.
Q159 Mr Scott: Do you have an estimate of the number of cases that will qualify under the new criteria and how much will it cost to provide these drugs?

Professor Raftery: On a case by case basis it will be quite simple to multiply up the numbers, the maximum costs of the Sunitinib judgment. I think the NICE guidance said that it was a max of 4000 patients and the cost is £20,000 to £30,000 per patient so you can work out the numbers quite easily. How many of those patients would actually take up the drug remains to be seen.

Q160 Sandra Gidley: Professor McCabe, you said that if some people receive the end of life drugs then others would not receive the drugs that they might want. The question I have to ask is, is this decision fair and is it efficient?

Professor McCabe: Fairness is about values. If we are confident that the end of life premium is consistent with society’s values then it is fair. Definitionally, when we make decisions based on considerations of fairness, we are departing from a purely efficiency perspective, so we are making a trade-off knowing that we may generate fewer health gains for the population but we are doing it because some of the healthcare we value more highly.

Q161 Sandra Gidley: If I was a patient who can now receive Sunitinib I might think that was fair; if I was a patient who was not receiving some treatment because others were receiving Sunitinib I would not think that was fair at all.

Professor McCabe: That is an issue of whose values should guide the decision, is it not? On any decision which is about allocating resources between two competing groups there are at least two sets of patients who will be affected. There are those who will gain if a positive decision is made and those who will bear the opportunity cost. They have different values probably. If you give preference to patient values then an issue of whether you can identify the patients who bear the opportunity cost becomes crucial and the fact is that we cannot. That is one of the reasons why the values that are recommended for use in these types of public resource allocations decisions are not being valued at the identified patient but the values of society at large and so it is society’s values, and if society takes the view that it values the health gain that is generated at the end of life—that is life extending at the end of life—more highly than health gain elsewhere then that is fair.

Q162 Sandra Gidley: I do not think they have been asked to prioritise it in the way you say. We seem to have NICE playing a sort of arms-length god here.

Professor McCabe: I would say that one of the ways in which society expresses its values is through the democratic process and in the absence of evidence to the contrary it is legitimate for values expressed through Parliament and through the minister to guide these sorts of decisions. It would be nice to have more evidence, but in the absence of evidence it is legitimate for Parliament to be the source of value. Indeed, even in the presence of the evidence, it is legitimate for Parliament to be the source of value.

Q163 Sandra Gidley: Professor Raftery, do you agree?

Professor Raftery: If I can go back to your earlier question about the patient who is denied treatment versus the patient who gets Sunitinib, I think there is fundamental asymmetry here. The health service as currently structured is not going to identify the patient who does not get treated. The patient who does not get treated will not know that they were not treated or were treated more slowly because the money was spent elsewhere. That is fundamental asymmetry in terms of looking at the fairness issue.

Q164 Sandra Gidley: Are either of you concerned that the decision to raise the threshold for end of life drugs will set a precedent for raising the threshold for other categories of drugs or treatments? Or do you think that this threshold could possibly do to be raised?

Professor Raftery: I have written some stuff on this and I think there is a danger of a precedent and the wording of the supplementary advice has been very careful not to raise the threshold. It has emphasised that it is looking at a premium on the quality of life of those patients whose life is extended and it is the amount of the premium on the quality of life that matters and the question is whether or not such premium would be justified in order to bring the consideration of any particular drug below the existing thresholds. I think the supplementary advice tries to maintain the existing thresholds and puts the pressure onto the quality of life issue which has a couple of effects. It means that it is possible to research the quality of life of those patients who get treated and that could in turn lead to revisiting the decision to say yes, whereas attempts to research what the threshold should be is a much more difficult question.

Q165 Sandra Gidley: Are there perverse incentives for manufacturers to concentrate research on end of life drugs if they are going to be able to charge a lot more for them?

Professor McCabe: Yes. They are not perverse, they are incentives to do what we want profit maximising companies to do which is to maximise profits. Whether those incentives are perverse from the perspective of what the NHS would like industry to put its money, investment and research and development efforts into, they may not be what we want to do.

Q166 Dr Taylor: Moving onto rarer cancers, “to be licensed for treating a patient population not normally exceeding 7000 new patients each year”, where did the figure of 7000 come from? Was it based on evidence? Is it going to be practically easy for it to be used?

Professor McCabe: I think in the final version the 7000 had been changed to “a small population”.

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Q167 Dr Taylor: Without a figure being put on it.
Professor McCabe: Yes. That kind of gets us off the hook about where 7000 comes from but puts us on another concern which is, what is small? I guess we will observe by a precedent what is small.

Q168 Dr Taylor: If you take Sunitinib as an example, is it just the people with renal cancer who would benefit from this who count as the small population or is it everybody with renal cancer?
Professor McCabe: I think it is the population for which it is indicated. My understanding is that it is the population that meet the criteria in the summary of product characteristics for a specific drug, but I could be wrong.
Professor Raftery: The phrasing is, “the treatment is licensed or otherwise indicated for small patient populations”.

Q169 Dr Taylor: Does that mean that it is the appraisal committee who will decide what is a small population?
Professor McCabe: I would not be surprised if that is what happens, given the “otherwise indicated” phrase. The first half was driven by the licensing but the “otherwise indicated” opens that up. I am sure there are very good reasons to do with not all product technologies they consider are in fact drugs and have that licence indication.

Q170 Dr Taylor: Professor McCabe, you have talked a little bit about society’s values; does consulting the public on willingness to pay exercises have a valid role? I think you have argued, “In a system where Parliament allocates the budget for the NHS, survey based estimates of society’s willingness to pay for health gains are not relevant to establishing the cost effectiveness threshold for resource allocation decisions”. I think that was yours.
Professor McCabe: That is most definitely mine and I can say it again if it helps. Willingness to pay tells us how much society, if they are well done, can give us some insight into how much society values healthcare. However, once a budget has been allocated to the NHS, the NHS has a whole load of things (according to the Office of Fair Trading I think it is 25,000 different interventions) it provides and these give varying amount of health per pound spent. When we are faced with decisions such as PCTs and NICE are faced with which is: “Should we bring a new technology into the portfolio of therapies provided?” the question is, what would we give up, what would we exclude in order to pay for it? Hopefully, in a rational world, we will exclude the things that produce less help per pound spent, so have a higher cost per QALY produced with the new technology. That is what the threshold is, it is the estimate of the cost per QALY of the least efficient thing that the NHS currently does and it is the appropriate thing so that we are confident at the margin when we bring the new technology in because it displaces and generates less health.

Willingness to pay is to do with how big the budget that is allocated to the NHS should be and it is information that Parliament should be interested in.

Q171 Dr Taylor: I think we are going to come onto the whole issue of rationing in the second part. You suggested that there are not huge numbers and that the average success of the appeals process is quite high. I come from an area where the average success of the appeals process is absolutely nil so I have a false view that this is a much greater problem than many other people see it.
Professor McCabe: I think you have a view based upon the data that you have personally. What I have looked at is the data that is in the Richards Review and the data that is interpretable are for those where we know how many are put in and how many are approved. That data suggests that it is actually not a huge number of people who, having exhausted all available avenues funding in the NHS, are ending up without access to the therapy that their doctor is the best treatment for them. There is a footnote where they say the range they observe is nought to 100% success rate but without the information about whether there were two submissions in the place that gave nought or were there a thousand and they still got nought, it is not possible for me to interpret that.

Q172 Dr Taylor: If PCTs are running toward deficits are they likely to be stricter on these sorts of panels?
Professor McCabe: I think actually the new NHS Constitution is what is going to make PCTs much more strict, and the direction to do with commissioning is in the booklet that has come out the National Prescribing Centre. That sets out very clear processes and if PCTs implement them I think you will find that that will on the one hand protect to a degree the decision making from short term budgetary considerations and so they have to make the decisions they make almost irrespective of budget if they abide by their rules, but I suspect abiding by their rules will push down the success rate.

Q173 Dr Taylor: If the constitution could standardise the process—
Professor McCabe: That is its objective, yes.

Q174 Dr Naysmith: Professor McCabe, when you were talking about the public’s willingness to pay I agree that sometimes the results you get are pretty useless, but do they improve if you ask people to rank the choices they would make?
Professor McCabe: This is purely my own personal experience of working with a couple of PCTs doing exercises with their population where you get people in and you run a workshop. If you ask them to rank treatments for investment it is interesting that over the day they become (a) more consistent and (b) are less likely to say yes to high cost, innovative new technologies because they see things in the context of what has to be sacrificed to pay for it.
Q175 Dr Naysmith: If you are doing that kind of survey you can get more useful information and it may be worthwhile doing.

Professor McCabe: Yes, I strongly believe that those things are very valuable and give very strong insights into what the population you serve want you to spend your money on.

Professor Raftery: There was some recent work published, partly commissioned by NICE, on the willingness to pay and the social value for QALY. The thing that was striking in that was that the results were very sensitive to the methods used which I think was your question. If you have one method you will get one set of answers, if you have another you get a different set of answers and nobody is sure which is the right way to do it. Unfortunately the research project did not plan how it would reconcile the differences.

Q176 Dr Naysmith: My question really is whether one way of doing it is better than the other.

Professor Raftery: Ranking was one of the methods tested but whether it is better or not, I do not know.

Q177 Dr Naysmith: I do not know what better means in this context. Is it more useful?

Professor Raftery: Maybe.

Q178 Charlotte Atkins: Following on from that, do you think there should be more research to explore public attitudes about funding priorities? We are told by many commentators that the lobbying by patient groups, particularly around new cancer drugs, is distorting healthcare priorities? Do you agree with that?

Professor Raftery: I agree that more research is needed. I think there is a danger of pressure groups particularly focussing on their disease or their client group. There are issues also about the funding that some of those patient groups get from pharmaceutical companies. I know there has been work done on that which has not been published and I know there is an on-going controversy on that. I would argue that there should be complete transparency on that issue. The sort of research I would like to see relates to the question we had earlier about the opportunity costs of NICE saying yes to a particular drug or other intervention. It is that opportunity cost—or the cost per QALY of what is displaced—that should be setting the threshold for the NHS. I think that is the focus of what Chris has written and that is a very different research question. I would argue that the attempts to research the social value of QALY have shown that you get a very wide variety of answers depending on the method you use. I would be in favour of research to identify what that displacement effect is. The problem is that the services that are displaced would be very different in different parts of the country so there is not a single answer.

Q179 Charlotte Atkins: That was the point I was going to make. I think there would be very different solutions in different parts of the country. In my area the whole controversy around use of Herceptin for the early onset of breast cancer had the intervention of the secretary of state to persuade the local Stoke PCT to fund that particular drug. Certainly, when you are talking about a very deprived area, then clearly there was going to be significant displacement of hip replacements, cardiac surgery, smoking cessation and I just wondered whether you considered the present balance with individual cases highlighted by the local press and the national press really is distorting health priorities because I saw the tremendous pressure on a number of local PCTs to make a decision because they were in the headlines.

Professor McCabe: It is strange for an economist to say that it is not an either or, that actually we need both, recognising that we cannot have everything. I think for the electorate to accept the inevitable rationing we make in those decisions they have to be confident that the values that are driving those reflect and are built upon what society values and we do not have the information to allow us to give them that reassurance. When it is this sort of money that we are spending and it is people's health, people can understand that rationing happens—they can accept it, they do it in every day lives—but they want to know it is consistent and they want to know what the values driving it are. We need that research. It is very difficult but important things often are very difficult. We also need to know where the opportunity cost falls. The thing is, because of devolved budgets of PCTs and the fact that they have different historical patterns of care, their population healthcare needs are different, actually their thresholds are going to be different and are going to be appropriately different. It is not evidence of poor practice and bad decision making if Lincolnshire, which has a much lower funding per head of population, has a much lower threshold than Kensington and Westminster. That is rational and appropriate. Looking at where the opportunity cost falls we would expect to find differences; what we want to know is that those differences are appropriate. Research is necessary at a population level. The approaches in the work by Martin and colleagues at York do give us some insight. The fact that they demonstrate that the threshold within disease areas ranges from around 7000 up to 28,000 gives us insight. If all of this investment in oncology drugs takes place in oncology it is probably okay because it is around that threshold, but if it is paid for out of mental health—which is around the 7000—then that is not okay, we are reducing population health. There are ways into this. It is difficult stuff but we cannot do one and not the other. I think they serve different purposes and we need to do both.

Q180 Charlotte Atkins: Is the problem that when PCTs are faced with very difficult choices they are getting expert opinions but they have lay people on those bodies who are not immune from the sort of pressures they are getting perhaps from individual patients who are talking about heart rending cases, and then we have the media making it even more difficult for them to say no to a heart rending case; then you might even have public demonstrations as
well, as has happened. How difficult is it for PCTs to make rational decisions which do not distort properly considered healthcare priorities, particularly after Professor Raftery’s comment which I certainly am concerned about which is the lack of knowledge about the linkages between patient groups and the pharmaceutical companies?

Professor Raftery: I think it is terribly difficult for PCTs. They came on the scene after NICE came into existence and they have been re-organised several times. In terms of their opportunity to be on top of that game it’s difficult. I have worked for a health authority for 10 years as a health economist so I am pretty familiar with the difficulties they face. One of the things that became very clear to me was that the decisions are often made not at PCT or health authority level, they are often made in the hospital and they are often made by clinicians at speciality level. So there is a big issue about how budgets are allocated within hospitals. If there is an oncology budget then you are likely to have the oncologists making the decisions and the opportunity cost is within oncology. I think they are best placed to make it because using cost effectiveness analysis to make those decisions is a pretty crude tool. There are going to be all the varieties of different patients and different circumstances that need to be taken into account. I would be very much in favour of seeing exploration at least of having that decision making delegated closer and closer to the clinical interface and made by clinicians. The trouble is, at some stage they would prefer not to make it and pass it back up, and the further it is passed up from the direct contact with the patient, the more difficult it gets and the more demanding the information requirements.

Q181 Charlotte Atkins: Is that not happening already with oncologists saying, “I would give you that drug but I know that the local PCT won’t fund it”? Does that not happen already?

Professor Raftery: I do not think it does. In my experience clinicians are aware of the opportunity costs of them doing something within their territory but they have no awareness of the opportunity cost of the clinic next door or the other speciality.

Q182 Charlotte Atkins: When you are talking about some of these really high cost drugs, you are saying there obviously opportunity costs within the speciality, does it not go outside that?

Professor Raftery: It depends on how the budgets are structured. PCTs do not, at the moment, decide how much they are going to spend on cancer or on anything else. Those decisions are made largely within the hospital rather than at PCT level. PCT level is a very crude, overall contract for hospital services which is mainly in-patient episodes.

Q183 Charlotte Atkins: If one is talking about an expensive drug and the patient is not an exceptional case or one of the oncologists or other specialist might say that they want this particular drug for this particular patient but they do so knowing full well that the PCT policy is not to fund that drug unless it is an exceptional case. Unless the specialist is going to make the case for that patient to be an exception or they make it in such a way that it is not convincing, then of course what they are doing is sidestepping the issue by saying, “I would love you to have that drug but actually the nasty PCT down the road won’t give it to you because they are playing God”. Is that not unacceptable?

Professor Raftery: I think that is unacceptable and I think it is a version of passing the buck.

Q184 Charlotte Atkins: Absolutely.

Professor Raftery: What I am trying to argue for is some greater coherence between the PCT and the clinicians about what is the size of the budget, what is the scope for efficiency increases in it and what are the priorities.

Q185 Charlotte Atkins: It is not helped when you have consultants who are working with pharmaceutical companies trying to pursue a particular drug.

Professor Raftery: I agree.

Q186 Stephen Hesford: Professor McCabe, you talked about values before and you have spoken about values a number of times and how to quantify them, but we cannot quantify them is basically what you said or it is difficult.

Professor McCabe: It is certainly difficult.

Q187 Stephen Hesford: To the point where we cannot make a decision as to what the value is and then proceed based on that value. Have I understood you correctly?

Professor McCabe: I would say that is quite a strong interpretation. We make decisions about values implicitly all the time. Whenever we choose to say yes to this intervention and not to that there are values in play there. When we gather evidence we will never have the evidence to the level that actually there is not a role for the decision maker; the evidence will never make a decision. However, the more evidence we have, the more guided the decision maker can be by that evidence, the greater the ability of the decision maker to say, “Look, we have gone out to the public and we have asked them to prioritise between treatments which extend life at the end of life and treatments which prevent major morbidity in mid life or critical care facilities at the beginning of life”. We have gone out and asked them to trade these things off to gain insight into the relative importance or the relative value that the population attaches to those things. There is a whole list of values or value bearing characteristics that society might want decision makers to take account of. We do not know at the moment how important they are but if decision makers want to be able to be transparent in the rationale for their decisions which are driven by value judgments then they need to get that information; they need to gather evidence so that they can be transparent, explicit and, most desirably I think, consistent so that where they play values in one decision it is given the same weight in the next 200 decisions.
Q188 Stephen Hesford: Are you saying that it is important that a decision maker has a clear understanding of what those values are?

Professor McCabe: I cannot see how you can truly justify a decision if you do not understand the values that you have brought to bear on that decision.

Q189 Stephen Hesford: Given that the NHS is consistently the most popular government institution—it has been for the past 60 years and as far as one can see will be for the next 60 years—that would seem to be a consistent expression of value that the population places in the NHS. What is the problem?

Professor McCabe: I may be interpreting you incorrectly so correct me if I am. I think you are speaking to the idea that the need to prioritise and ration—which is where values come in—is driven by budgetary constraints that do not in fact reflect the value that society attaches to the NHS and therefore if the budget reflects the value that society attaches to the NHS we would not have that problem. Is that what you are saying?

Q190 Stephen Hesford: I am asking you.

Professor McCabe: I cannot answer a question if I am not sure what it means.

Q191 Stephen Hesford: You posed the question that we may be making some decisions which, if we knew what the public valued, we would not be making those decisions.

Professor McCabe: Yes, within the NHS budget. You posed a question back at me which was to do with the NHS as a whole.

Stephen Hesford: So I am asking you, given that we have not one day, not one month, not one year but 60 years of consistent high value and appreciation of what the NHS does, it does not really matter because overall the population thinks the NHS is getting it right.

Q192 Chairman: Overall we are a group of individuals and I think the issue is about the effect on individuals as opposed to others. Maybe we could have this debate later, Stephen.

Professor McCabe: There may not be a problem; I am open to that. However, all the evidence is that there is.

Q193 Chairman: Professor Raftery, I think you suggested the potential for pharmaceutical companies to influence patient groups and then the potential to, if you like, distort healthcare priorities, that work has been done on this but unpublished. Did you say that or words to that effect?

Professor Raftery: I did.

Q194 Chairman: Could you make it any clearer to us who did it, why it is unpublished and whether it will ever see the light of day.

Professor Raftery: I do not have the details to hand but all I would be happy to say is that at a general level I know that some work has been done and there is an on-going controversy among the medical research charities about disclosure of the degree of funding that each charity receives from commercial companies. I think that is the place to look.

Q195 Chairman: If somebody has done some work on this there could be some conclusions. Are you saying that there are conclusions, whatever they are, but they are not published?

Professor Raftery: My understanding is that the percentages are quite low and I would expect them to be quite low, that is the percentage of total funding coming from companies. However, that is only one measure of what the influence might be.

Q196 Dr Naysmith: Can we turn to another area of controversy that bedevils this whole discussion? People often argue that things are done better in other countries and drugs are available in other countries that are not available here. Putting it more succinctly, patient groups, often encouraged by pharmaceutical companies, argue that European countries spend more on cancer drugs, for instance. Do you think that this is true, that other European countries spend more on cancer drugs than we do? If so, do you think these countries achieve a better patient outcome as a result of their extra spending?

Professor Raftery: I think there is quite a lot of literature on this within health economics which shows very weak relationships between levels of spending in healthcare systems and healthcare outcomes. The US has the highest level of healthcare spending and some of the worst outcomes. There is not an easy relationship between spend and outcomes; that is the key issue. When you get down to detailed levels of comparison it is very difficult to get accurate data. On cancer, for instance, a lot depends on when patients become known to the healthcare system. I regard the attempts by particularly the cancer charities who argue that cancer is treated better elsewhere with quite a degree of scepticism.

Q197 Dr Naysmith: There is some evidence that there is higher spending in Germany and France on cancer treatments than in this country, although I know that France is trying hard to reduce its costs on its healthcare system. Nonetheless there seems to be reasonable evidence in France and Germany that spend is higher. Do you think the National Health Service should try and match these levels of funding?

Professor Raftery: It is very easy to spend it, it all depends what you are spending it on and whether it has been spent effectively. I think that is the crunch issue from an economics point of view.

Q198 Dr Naysmith: Is it not cost effective?

Professor Raftery: I do not know and I would not want to advocate it unless I knew that it was cost effective otherwise it would be a waste of money.

Q199 Dr Naysmith: Professor McCabe?

Professor McCabe: We cannot argue that historically other European countries have spent more on cancer drugs than we have. However, our
funding of healthcare across the board has been lower, that is why we have had this massive expansion—almost doubling—of the NHS budget in the last decade. I think we are now at the European average. Obviously there is a lag between putting the funding up and then seeing the improvement in outcomes, but as James has said the link between level of funding and outcome is not strong. I do not think it is very long ago—six or 12 months ago—that the chief executive of GlaxoSmithKline admitted that their old cancer drugs were not very good. In Europe they bought a lot of them and we bought less so with hindsight maybe we were a bit smarter. We have a whole new batch of new cancer drugs. The underlying science is a lot better so our confidence that they will be as good as they say on the packet is higher, but it is a long way short of absolute because the trials tended to stop early. Given history, some continued caution by the NHS on getting into widespread utilisation of these new cancer therapies would seem reasonable.

Q200 Dr Naysmith: What you have actually said is that we, in this country, have allocated drugs for cancer treatment more cost effectively than some other places have done.
Professor McCabe: Without having seen the figures I cannot say that that is absolutely true but my expectation is that that is likely to be true.

Q201 Dr Naysmith: Turning to the question of risk sharing and the pharmaceutical price regulation scheme, is the proposed risk sharing scheme between the National Health Service and pharmaceutical companies likely to bring about a better deal for the NHS?
Professor McCabe: It depends what we are trying to achieve with these risk sharing schemes. If the objective is to maximise healthcare for the population to the degree that we are negotiating a price discount it is likely to be better than if we just said yes to them at their list price. However, we still need to look and ask the question at the discounted price, are they good value? If it is that we want to learn more about these technologies as we go along then the characteristics of a risk sharing scheme that have that objective would be very different to the characteristics of a risk sharing scheme that is about keeping the price down or the budget impact under control because you are going to have to collect data and analyse it at a population level rather than looking at what happens at the individual patient level. I do not think—I am not an expert on the details of the proposed risk sharing agreements—there is sufficient sophistication and clear specification of the details for us to say that risk sharing is a good think here in the UK or not. They certainly get in the way of pursuing the opportunities that are in value based pricing which were recommended by the OFT because value based pricing would allow us to signal to the pharmaceutical industry what we want them to invest in in the future and discourage them from developing technologies which are unlikely to be good value for money. By going into these risk sharing schemes we give up our ability to signal to them what we would like them to be doing in the longer term; I think that is a price that is little recognised.

Q202 Dr Naysmith: How do you think the department can be persuaded to introduce value based pricing in line with what you have just said?
Professor McCabe: The department has a problem. In its duties, as I understand it, the NHS has a role as an instrument of industrial policy and that is a different objective from the NHS’s primary objective which is the health of the population. The department will be interested in going with value based pricing if it can see that it makes good industrial policy sense or for some reason is no longer responsible for industrial policy around the pharmaceutical industry.

Q203 Dr Naysmith: Do you think that gets in the way?
Professor McCabe: It is not in the way, it is about the department’s legal duties; it has to deliver both of them and it balances them in a certain way.

Q204 Dr Naysmith: Professor Raftery, do you want to add anything?
Professor Raftery: If I could, yes. You asked about risk sharing schemes and I think we need to learn from the one that we have which is a multiple sclerosis risk sharing scheme. No reports have been issued; reports have been due for several years. There are rumours that it is not a success and there are suggestions that lessons should be learned from it. It seems to me that unless those lessons are learned we will repeat the mistakes.

Q205 Dr Naysmith: Do you think value based pricing would bring significant benefit?
Professor Raftery: Yes I do. I think that it would probably, as envisaged in the Office of Fair Trading report, involve the wider use of cost effectiveness analysis of the sort that NICE already does. I think the PPRS209 which was published in December does not go as far as it might towards value based pricing but it does emphasise both flexible pricing and what they call patient access schemes which are divided between financially based schemes and outcome based schemes and the classification of those. They are very clear that these would be only for drugs that have been refused by NICE so it is quite limited in its scope.

Q206 Dr Naysmith: It is supposed to improve incentives for industry to develop products of high value to patients. Do you think it would do that?
Professor Raftery: Frankly, no; I think it is much too limited. If it is meant to be sending a signal to industry about these being the therapies we want, if it is confined to drugs that have been turned down by NICE then that is sending a very limited signal. I think the direction of travel is in that direction but I think the challenges about assessing the cost effectiveness of the whole range of drugs are considerable but some countries do try.
Q207 Dr Naysmith: Is it worth doing?
Professor Raftery: I think so, yes. From my experience of looking at Australia and New Zealand, they seem to have got better value than we did for some of the drugs.

Q208 Dr Naysmith: One of your academic colleagues, Professor Alan Maynard at York University, has suggested that we would receive more benefits if agreements were back loaded so that manufacturers received low initial prices and then, if the benefits exceeded expectations, they could charge more. Is there any merit in that scheme?
Professor McCabe: I think the number of individual cases reported in the media is quite small and Professor McCabe earlier on was quoting a figure of 18 and that is about right. Some of those were about patients who had actively been denied NHS care when they chose to pay for a drug privately. The case of Linda O’Boyle, which was one of the central cases that stimulated the setting up of the review, was one such case. That is quite different from the number of cases that are being referred to PCTs for exceptional case funding or individual funding reviews. From the survey we did of PCTs we estimate across the country there are about 15,000 patients per annum who are being referred to those exceptional cases panels. I think it is very important to say that that is not just cancer; in fact three times as many of those were for non-cancer as they were for cancer. Over the course of a year it probably relates to about 50 different drugs and they fall into a number of different categories. There are those drugs which are

Q209 Dr Naysmith: Professor McCabe, do you have any comments on that?
Professor McCabe: No, I agree with what James has said.
Chairman: Could I think both of you very much indeed for coming along this morning and helping us with our inquiry.

Witnesses: Professor Mike Richards CBE, National Clinical director for Cancer, Dr Felicity Harvey, Head of Medicines, Pharmacy and Industry Group, NHS Medical Directorate, Ms Una O’Brien, Director General for Policy and Strategy, Department of Health and Professor Sir Michael Rawlins, Chairman, National Institute for Health and Clinical Excellence (NICE), gave evidence.

Q210 Chairman: Good morning. Could I welcome you to our second evidence session in our inquiry into top-ups and access to medicines? For the record could you give your name and the current position that you hold, please?
Dr Harvey: Dr Felicity Harvey, I am Head of Medicines, Pharmacy and Industry Group within the Department of Health.
Ms O’Brien: I am Una O’Brien; I am the Director General for Policy and Strategy, responsible for taking forward the Government’s response to the Richards Review.
Professor Richards: I am Professor Mike Richards; I am National Cancer Director and I led the recent review for the Government.
Professor Sir Michael Rawlins: I am Michael Rawlins, Chairman of NICE.

Q211 Chairman: Welcome once again. We have specific questions for individuals in this particular session and I would like to start with the reason we are here and put a question to Mike Richards. It took you just four months between starting the review and publishing your conclusions. How do you respond to the criticisms that your review was insufficiently rigorous?
Professor Richards: I believe it was a rigorous review. There were time constraints but those time constraints were set by the fact that there was such a demand for clarity on this issue as quickly as possible. That demand was coming, as you know, as much from parliamentarians as from other sources. We had a fixed time for the review and during that time we engaged with a very large number of people and sought a great deal of evidence. In total we engaged with over 2000 individuals and a lot of organisations during that time and that included focus groups with the public, it included working with patient groups whether they were cancer or non-cancer groups, with charities, with clinicians, with NHS managers, with the pharmaceutical industry, with the insurance industry, with academics and, indeed, with parliamentarians early in the review. I think we sought a great deal of opinion from that. We also undertook a number of specific pieces of work to try to find out the facts, one of those obviously related to the issue you were discussing earlier on this morning about what is the size of the problem.

Q212 Chairman: You think overall, in view of the width and breadth of your review, that the time constraint did not in any way undermine the outcome and the conclusions.
Professor Richards: I do not believe it did, no.

Q213 Chairman: What was the scale of the problem that was identified? For example, how many patients were being denied access to drugs recommended to them by their doctor or even having their NHS care withdrawn because they had chosen to buy additional drugs privately? We hear cases about this in the media, what was it like out there before your review?
Professor Richards: I think the number of individual cases reported in the media is quite small and Professor McCabe earlier on was quoting a figure of 18 and that is about right. Some of those were about patients who had actively been denied NHS care when they chose to pay for a drug privately. The case of Linda O’Boyle, which was one of the central cases that stimulated the setting up of the review, was one such case. That is quite different from the number of cases that are being referred to PCTs for exceptional case funding or individual funding reviews. From the survey we did of PCTs we estimate across the country there are about 15,000 patients per annum who are being referred to those exceptional cases panels. I think it is very important to say that that is not just cancer; in fact three times as many of those were for non-cancer as they were for cancer. Over the course of a year it probably relates to about 50 different drugs and they fall into a number of different categories. There are those drugs which are
Q215 Chairman: Did we need a review to change the guidance?

Professor Richards: Absolutely yes because there were those variations in interpretation. There was a great deal of concern amongst the public, amongst clinicians, amongst parliamentarians. Yes, we needed a review to come to some firm conclusions about that.

Chairman: We will pick up on one or two of those issues with yourself and other witnesses. We will move over to Richard now.

Q216 Dr Taylor: I want to look at the practical implications of separating care, and I am looking in particular at Una and at Mike. We have had many concerns about continuity of care, about the consultants who, by principle, will not do anything to do with private work. We had Len Fenwick at one of our sessions saying, in relation to cancer in particular, that it is a little naïve to believe that there would be complete separation; it is simply not possible. Mike, you have just used the words “pay privately on top”. Are we not in fact moving some people straight into the private sector and other people who cannot afford are being left in the NHS?

Professor Richards: I gave this extremely careful thought during the course of the review and discussed this with a lot of clinicians and with a lot of different NHS trusts before coming to my conclusions on this. The first thing we were trying to achieve was that there would be fewer occasions when patients would feel the need or wish to pay for drugs and half of this report is about improving access to medicine for NHS patients, and that is its title. Trying to reduce the number is very important. However, what we also heard from all the people we engaged with was that surely some of these drugs should be available to people, that they should be allowed to pay for them if they could not be afforded by the NHS. Comments were coming out earlier this morning about the fact that we do have a mixed economy; people are paying for private physiotherapy and then having a hip replacement on the NHS but those can be kept separate. Indeed, you can have IVF privately and then have your maternity care on the NHS. That is again separate. We considered this carefully and what I set out in my report were four different ways in which separate care can be delivered and delivered safely. You can do it by getting a private hospital—maybe one that is across the road—to deliver that private care. About half of our hospitals have a private facility and the private care could be given in the private wing or facility of that hospital. We have also said that the drugs could be given by a private home healthcare provider and we know that is already happening around the country anyway. The fourth thing we have said is that you can designate an area of an NHS hospital as private for a specific period of time in the same way as you have a patient in an NHS hospital but in the private wing and they need a CT scan you do not have a separate CT scanner for that patient but that CT scanner is being used in private mode for the time the patient is having it. We set those out but very deliberately did not say that there was a one size fits all solution because it will vary across the country. I know, for example, that in the north west they are opting to go for the home help care providers in some parts of the area because they believe the demand is going to be very small for this and they do not want to set up a separate facility; they believe it can be very safely done that way. In the north east they have taken a different approach; they have designated three hospitals—Carlisle, Newcastle and Middlesbrough—that will do this work. They all have a private wing already and they
feel that is the safe way that they can manage this. Solutions can be found that are entirely consistent with the principles of separate care.

**Ms O’Brien:** I think I can re-enforce what Professor Richards has said. It is very clear from the consultation responses we have had that there are some issues about how you deliver this in practice but because we have some worked examples—as Mike has cited—we already know that it will be possible for localities, if they take the time, to work this through. We have asked strategic health authorities in their system oversight role to really get involved and take soundings locally, to work with local providers and local commissions to ensure that arrangements are put in place that are locally sensitive to the delivery of separate care. While I appreciate and am aware of some of the evidence that you were given in your previous session—we have had some of these points raised with us during the consultation on the guidance—we will be taking account of those and working with them through SHAs to make sure there is a transparent system organised and delivered locally.

**Q217 Dr Taylor:** Going back to Mike, your example of private physio after a hip replacement, I do not think that really comes into the same category as having or not having a drug that has a good chance of extending life. I do not think they are very comparable.

**Professor Richards:** What I said was that one of the things that was drawn to our attention during the course of the review is that patients have, for a long time, been having some care privately and some care on the NHS; that has always been accepted as long as the two are separate.

**Q218 Dr Taylor:** Because of the shortage of resources, the shortage of single rooms in hospitals that do not have a private facility, is it going to be acceptable for those rooms to be used for this sort of purpose?

**Professor Richards:** It would be possible to designate a chemotherapy unit out of hours at five o’clock on a Tuesday afternoon to be the place where you do the private chemotherapy. If that is kept separate then that is perfectly acceptable.

**Q219 Dr Taylor:** As you know from our talks I am not happy that somehow this is not producing one NHS for those who have that little bit of extra money and a slightly different NHS for those who cannot. Unintentionally do you not think that this has opened the way for further inequity and certainly further inefficiency because of the huge amount of work that is needed to create these separate units?

**Professor Richards:** I do not believe that that is the case. I think it can be managed perfectly effectively and I think we have set out the different ways in which it can be done. We must remember that we were looking at what the two extremes were. One extreme was that you say to patients, “Sorry, if you have any private care you cannot come to the NHS” and we got a very, very clear message from the public, from patients, from a whole lot of people that that was utterly unacceptable. At the other end of the spectrum we could have gone down a route—we looked at this and rejected it—of saying that effectively the NHS can have a set of basic care that you get free and then on a sort of top-up basis you can pay for extra things on top of that and then there would be a lengthy menu of things you could pay for on the NHS. We rejected that as well because that is not the NHS that I certainly want to see. I think what we have found is a way of enabling people to have that private care while at the same time preserving the fundamental principles of the NHS.

**Q220 Dr Taylor:** If they have gone to the separate unit or separate facility for this bit of their treatment, how and when do they come back to the NHS?

**Professor Richards:** They can come back at any time and that has always been the rule. The old wording was “as long as it is not in a single visit”. You can always come back. That may have been misunderstood but that is what has been there since 1986.

**Q221 Dr Taylor:** I quite understand your aim for improving access and speed and battling with the pricing and the drug firms. Was there widespread acceptability among all the people you talked to that this was not causing a two tier system?

**Professor Richards:** I think there was a very widespread view that we should avoid creating a two tier system. We heard that loud and clear from a lot of different places and when we talked through these options with people they felt that this was the best approach that combined, as I said, the ability for people still to get private drugs if that is what they want and, at the same time, not to change the fundamental principles of the NHS.

**Q222 Dr Taylor:** The best approach but a compromise and not avoiding the two tier system entirely.

**Professor Richards:** I believe it has avoided a two tier system because the two are kept separate and people have always had that right to have private care. I think it does avoid that.

**Ms O’Brien:** The whole thrust of the Government’s response to Professor Richard’s report is a pro-NHS response. The NHS, as we all know, is a comprehensive and universal service free at the point of use based on clinical need. What Mike’s report showed us was that on the outer fringes—a very, very important area of care—there were some issues that had to be addressed about access to medicines. That was one of the most powerful set of recommendations that he brought. I would really like to emphasise that both within the draft guidance and in the chief executive’s letter to the NHS we are very, very clear that this was about minimising the circumstances in which people would ever have a need to seek to have drugs provided privately. However, in those circumstances which might remain it is very important for care to be delivered
separately. So I think it is about the proportionality of this and also about the thrust of the Government’s response. It is not about setting up a parallel private system but actually driven towards reducing the circumstances in which this would be necessary.

**Q223 Dr Taylor:** Do you think it is actually only the tip of the iceberg? Do you think there are a large number of people who would never consider because they do not have the money at all—the silent voices who would never consider top-ups or increasing their healthcare spending—that we have not even touched?

**Ms O’Brien:** I am sure that Professor Richards would comment on that, but in general terms what I would say is that the NHS works at the boundaries of science. I think this is very clearly stated in the NHS Constitution. There are always going to be new forms of treatment, new medicines that are becoming available and the pace of the system to keep up with that will always be a challenge on the fringes as that happens in terms of time. The fundamental point connecting back with a question the Chairman asked at the beginning is, are these the same principles applied? In fact they are and it is about adapting the guidance to different and more modern circumstances. However, there is a real continuity about the comprehensive nature of the NHS and about the NHS itself in not charging except where there is parliamentary agreement for doing that.

**Q224 Dr Taylor:** I think you said you had adapted the principles.

**Ms O’Brien:** No, I think the principles are true and we have to adapt the guidance as circumstances change and also as pathways of delivering care change over time.

**Professor Richards:** The fundamental element of the new guidance is that patients should not have their NHS care withdrawn if they choose to pay privately for other treatments. That is something that is very important that is stated. It was one of my key recommendations and one which I was extremely pleased that the secretary of state readily adopted.

**Q225 Dr Taylor:** One of the witnesses we had at our last session has since sent in an entirely different proposed solution, a central funding mechanism for additional cancer drugs. Money for this could come from top-slicing PCT budgets to the tune of the amount that is spent now by exceptional funding reviews. Is there a real alternative?

**Professor Richards:** Personally I do not see what the advantage is in that as long as we get clear guidance from NICE as quickly as possible on these drugs so that the NHS will then adopt standardised responses to it. That is what we need to get to and, after all, it is NHS policy to devolve as much responsibility to the front line and therefore not to have large central pots of money.

**Q226 Dr Taylor:** The advantage of it would be that there would be absolutely equal access for all patients to all the drugs. That is the theoretical advantage.

**Professor Richards:** Yes, I believe we can achieve the same objectives through the combination of measures that we have set out. One of those is about getting more timely advice from NICE, which is happening anyway. A second is about improving the processes at the PCT level, and that is being taken forward as part of the NHS constitution. There is a firm recommendation from me that PCTs should work together on this. The reason for that is that a PCT may only have to deal with a particular drug once or less often a year; to do a full health technology assessment at an individual PCT level is crazy and therefore it makes very good sense for PCTs to collaborate on this, which they are doing in certain parts of the country. The north east has been leading on this, as has London. There are a whole number of processes that we put in place that will mean that we have far more standardised approaches and far quicker advice on which drugs are good value for money and should therefore be made available on the NHS.

**Q227 Chairman:** Could I ask you whether you could see a situation where you would have two patients presenting with the same problem in an NHS hospital and one of them goes for chemotherapy which is different to what the other one gets on the basis that they can afford it and that would be acceptable?

**Professor Richards:** I think that is an absolutely logical conclusion from this report, that there may be people who decide on the basis that they can pay that they will pay, but they will be paying for that element of care privately.

**Q228 Chairman:** It could be on the same ward in the same hospital.

**Professor Richards:** With the arrangements we have said it will not be on the same ward, it will be, as I said, either in private facilities or through home help care or through specially designated areas. That is what we have set out, the principle of separation.

**Q229 Chairman:** Do you agree with that?

**Ms O’Brien:** I think it is theoretically possible but I would stress again that the thrust and intention of the policy overall is to reduce the circumstances in which that is ever likely to arise. The key thing would be that the circumstances in which someone was choosing to have additional medicine privately ought to be those circumstances where the choice of medicines is for something where it has been decided that it is not cost effective for the NHS to fund. We ought to be in a situation with the new arrangements as they come on board where those circumstances are more and more rare. I think that is the important thing to get the perspective around; it is not about arranging a completely new set of possibilities to open up private provision in the NHS but it is about
being clear about people’s rights to maintain their access to NHS care and also about implementing the principle of separateness in practice.

**Dr Harvey:** From our perspective it is also very important that we get NICE appraisals to the NHS in as timely a fashion as possible. As you will be aware there are various things we are doing with NICE to actually ensure that that happens. We will be aiming to get all new drugs with better horizon scanning into the NICE work programme at least 15 months prior to market authorisation. That means that as we go forward we should have the technology before we make a decision at market authorisation. That does actually start making the problem less of a problem where those drugs are deemed to be clinically and cost effective by NICE looking at the value of drugs to patients.

**Q230 Chairman:** The issue of the speed of NICE is something that this Committee has called for on more than one occasion.

**Professor Richards:** It is happening in practice already. Cancer has been the area where we have been piloting the new approaches and I chair the panel for NICE that looks at what cancer drugs will be considered by NICE and already we are seeing a marked shift, so we are beginning that process early.

**Q231 Dr Naysmith:** Dr Harvey mentioned just now the recommendations of this Committee on previous occasions when we have been looking at NICE; it is good to hear that we are having some influence.

**Professor Richards:** You always do.

**Q232 Dr Naysmith:** Thank you. Professor McCabe was here in the previous session argued in his written submission to us that allowing private top-ups within the NHS would have number of undesirable effects including a substantial increase in the administration cost of the healthcare system. Has anybody made an estimate of the administrative and other costs to the NHS associated with separating care and the recommendations made by Mike?

**Ms O’Brien:** Can I just be clear on the use of the words “top-up”? In the way that we use the term that is something we are not allowing, ie topping up NHS care or the NHS itself charging. Just to be clear, when we are talking about charging mechanisms what we are actually talking about are those circumstances in which the NHS would charge for privately provided care. So it is either one or the other; there is no middle position.

**Q233 Dr Naysmith:** You may find that from the top you are not allowed to use that phrase but I bet you find on the ground many people will be using it.

**Ms O’Brien:** I appreciate that and I think that is why it has actually caused some degree of confusion, and I think Mike’s report has really helped to bring that out. The key thing to say is that there are no detailed estimates of the administrative overheads, if you like, involved in charging but a number of hospitals do this anyway because they have to, for example, charge for overseas patients; it is not at all uncommon in NHS hospitals. So there are methods for doing this; it is not something that has been brought to our attention as a major overhead or a significant cost that would be brought to bear on the NHS as a result of Mike’s report. I am confident that we will be going in the direction of reducing the circumstances in which this is necessary; I would not see it as a major problem.

**Professor Richards:** The principle is there that the NHS should not subsidise the private element of care so yes, we would expect the NHS to charge for the drug, we would expect the NHS to charge for the time of the pharmacist preparing the drug, the time of nurse delivering the drug. If there are costs of administration and billing that should be built in as well so I think we can say those are all elements that we would expect the NHS to take in order to fulfil that principle of not subsidising.

**Q234 Dr Naysmith:** The point is that no estimate has been made of how extensive this is likely to be.

**Professor Richards:** As Una has already said, this is already happening. A lot of hospitals have private facilities and hospitals have overseas visitors so I do not think this is something that is beyond the wit of man.

**Q235 Dr Naysmith:** The other aspect of this which is perhaps a bit worrying is that if the private care treatment was wrong in any way then presumably it will revert back to the National Health Service. Does this pose any kind of problem?

**Professor Richards:** That has always been the case. Patients who have chosen to go privately for any care, if they then have a problem and present as an emergency to the NHS, the NHS has always taken that on and that has been going for the 60 years of the NHS.

**Q236 Dr Naysmith:** Is that going to become any more difficult or any more of a problem in the future?

**Professor Richards:** It is no more or no less of a problem than it has been in the past. It is something we expect to do.

**Q237 Dr Naysmith:** If some of these patients are being treated in a facility that currently does not exist—which is happening in some places—you are saying that people will not be treated in the same ward as another patient, which means providing in some cases which may not have a private wing or facility at the moment for administering a drug privately. Does that not follow from what you have said?

**Professor Richards:** What I was equally saying is that we believe that the other measures in my report will reduce the total number of people who are currently choosing to pay privately for their care. There are patients who are paying privately for their care and if we reduce that need because we make more drugs available at an affordable cost to the NHS, then this will not arise.
Q238 Dr Naysmith: There will be a pressure to try to keep the patient in the same institution I am sure. In fact we had the chairman of a trust here a couple of weeks ago saying that he felt it was impossible to separate in practice and where it does occur that will incur expense that was not there before.

Professor Richards: Not to the extent that some of these patients are having these drugs anyway and funding them and when they get complications they can come into the NHS. That is already happening within the NHS and we believe the extra burden of this will be minimal because we believe that the number of patients who are choosing to buy drugs will be a very small number.

Q239 Dr Naysmith: I think Professor Richards has already answered this question but I will ask it anyway and probe it a bit further. Having accepted the principle that there will be this element of separation of care, no matter how it is done, would it not have been simpler to allow the alternative option for purchasing additional treatment such as top-ups in the NHS or voucher schemes? You said this had been considered; could you tell us how seriously it had been considered. You also said there were many noises against it or words to that effect. How thoroughly was it considered and what was the evidence that made you reject it?

Professor Richards: It was considered and in fact the option appraisal is set out in my report. We believed the voucher scheme was the worst of all options in fact largely because it would take money out of the NHS and also if people then went to a private hospital their NHS element would have transferred them into the private sector but they would be paying more for that same element in the private sector than they would in the NHS. So it would be bad for the individual and it would be bad for the NHS. We looked at that and we set out all the different reasons in the report why we rejected that. In terms of the option what might be called the full top-up scenario which is saying that the NHS has a schedule of things that you can get on the NHS but here are all the other things which you might want to pay for, I can tell you there was very little enthusiasm for that amongst the great number of people that I talked to. Again it would be an administrative nightmare. If somebody said, "I want to have a slightly different sort of artificial hip joint" we would look at the scale of charges and we would be billing every patient. Compared with your previous question about billing which I think will be a very, very minor impact on the NHS, if we had gone down that route of saying that there are full scale top-ups for everything it would have been a billing nightmare.

Q240 Dr Naysmith: Are you confident that your solution will end the top-ups debate? I do not just mean by banning the use of the term in official documents.

Professor Richards: I do not have a crystal ball but I think what I can say is that there has been a huge amount of public concern about this, parliamentary concern, media concern and very rapidly after 4 November when the report was published that concern seems to be resolved. Many of my colleagues, including the Royal College of Physicians, have broadly welcomed the findings and most people are saying that it can be done; where there is a will there is a way and this is a good way of going forward.

Q241 Charlotte Atkins: We are now going to move over to talk about the NICE thresholds for end of life treatments. Professor Rawlins, how do you react to criticisms that the reported decision to raise the cost per QALY threshold to £70,000 for end of life treatments demonstrates that NICE decision making favours inefficient and inequitable treatments?

Professor Sir Michael Rawlins: There is a bit of a misconception here. We have not raised the threshold to £70,000; that is the first point to make. We have always stated that we have a threshold range of somewhere between £20,000 and £30,000 per QALY but we have always given our advisory committees latitude to go above and below it. For example, when the effect of a treatment on the quality of life has been inadequately captured by the conventional techniques, as is the case in mesothelioma, the appraisal committee took account of that and said yes at £37,000. When a new innovative treatment comes along with very real and unique benefits like glyceremic for chronic myeloid leukemia the appraisal committee accepted that at £34,000 this was a significant benefit. Sometimes there are equities like the blast cell phase of chronic myeloid leukemia where the appraisal committee said yes at £48,000. There has been an incident going up as far as £60,000, a particular treatment for children undergoing renal transplantation. The idea that we have a fixed threshold is wrong. We try to balance equity and efficiency. This is very difficult and in fact there have been discussions amongst political philosophers since the time of Plato and I am afraid I have not resolved this difficulty. You do it all the time in Parliament; that is your job as politicians. It is a balance. David Hunter said I was muddling through elegantly and that is as a kind a description as I will probably ever have. The one bit we do not do in our healthcare system is go to the libertarian approach where it is your responsibility to look after your own healthcare and your family’s healthcare. That is the American approach and having seen quite a bit of it over the last few years I hope we never even begin to get near that.

Q242 Charlotte Atkins: Where does this £70,000 come from?

Professor Sir Michael Rawlins: I think a journalist attributed it to me but I do not know where it came from.

Q243 Charlotte Atkins: There seems to be quite a lot of leeway from £30,000 up to £70,000.

Professor Sir Michael Rawlins: We have not got to £70,000.
Q244 Charlotte Atkins: I am interested to hear that. Then we have the issue around so-called rarer cancers and how you define that. We have already heard this morning that the population of 7000 people has now been redefined to mean smaller populations which seems to me even more woolly and more difficult for organisations within the NHS to define it or to make a decision. What are you saying around that?

Professor Sir Michael Rawlins: We did originally say 7000 and the reason why we did it was because there is a very clear distinction between the incidents of the four big common cancers—colon, breast, prostate, lung—and the rest. It is a big jump and it is quite clear it is around 7000. That is why we did it in the first version. However, although that is very clear for cancer, many commentators felt that we should be less restricted than this. Although it is very clear for cancer it is less clear for other conditions and our guidance is not cancer specific, it is all lethal conditions which have the properties and the characteristics that we have specified. People said, “We get what you’re getting at but don’t box people in with 7000 otherwise you will find 7100 and then what do you do?” So we have given some latitude to our appraisal committees on that. All this recognises what do you do?“ So we have given some latitude to our appraisal committees on that. All this recognises that the development costs for treatments for less common conditions are going to be pretty well the same as development costs for common conditions which have the properties and the characteristics that we have specified. People said, “We get what you’re getting at but don’t box people in with 7000 otherwise you will find 7100 and then what do you do?” So we have given some latitude to our appraisal committees on that. All this recognises that the development costs for treatments for less common conditions are going to be pretty well the same as development costs for common conditions but the market will be smaller and therefore the unit cost is likely to be higher. We recognise that manufacturers may well have to charge more for treatments for less common conditions. I want to be very clear that we are limiting it to small populations; we cannot do this for common lethal conditions. It would cost the health service hundreds of millions of pounds a year.

Q245 Charlotte Atkins: Where would you draw the line? Take oral cancer, for instance, which is about the sixth most common cancer I believe. 

Professor Richards: If you put all head and neck cancers together that would probably be about right. If you take oral cancer per se it would be considerably lower down the list.

Q246 Charlotte Atkins: So it is going to be very difficult for people to be able to define what a rarer cancer is.

Professor Richards: I think in cancer terms, as Sir Michael has said, we have four very common cancers and all the rest we can call less common or rare. Equally in the number of deaths that there are from these cancers there is a distinction as well. Oral cancer will undoubtedly be a less common cancer and would undoubtedly come within the small or 7000. I am sure it would be covered by that, as would conditions like myeloma or kidney cancer. All of those would be captured by the small population or 7000.

Q247 Charlotte Atkins: Professor Rawlins, you said that you have not raised the threshold but it does appear that the threshold is rising over time and of course the implications are that this then has a direct effect on PCT budgets. If they are supposed to suddenly fund something which has a higher threshold and that becomes more common, if they still have the same budget—given the present economic situation they are not likely to have big increases in their budgets—what impact does that have in terms of NICE guidance to PCTs?

Professor Sir Michael Rawlins: We have maintained the threshold range for a number of years now. I have always said that this is not an empirically devised number and you have heard from the previous health economists that it is very difficult to know what that should be. People have been asking us whether it should be raised in line with inflation. Health economists are completely divided over this. James Raftery has been published saying that the threshold is too high and should be lowered. In the same edition of the British Medical Journal there was another health economist saying that it was too low and should be increased and Professor Karl Claxton from York thinks it is about right. It is a great uncertainty and 10 days ago we were planning to have a meeting which many members of this Committee were going to come to at NICE to talk about this and hear some of the experts but unfortunately the weather was so awful that only Dr Naysmith managed to make it.

Chairman: It is back in the diary I understand, Professor Rawlins.

Q248 Charlotte Atkins: When we look at that clearly any increase in the threshold will have an impact on the normal procedures which PCTs fund. 

Professor Sir Michael Rawlins: I think we have to be very careful there because although the previous speakers spoke about the opportunity costs and that the expense here would deprive other patients of care I think it is important to ask Professor Richards about this because in his previous cancer report he pointed out areas where there were very considerable savings to be made in cancer care.

Professor Richards: If you look at the total cancer spend in this country, £4.5 billion out of the roughly £100 billion that we spend on the NHS goes on cancer. The first thing to say is that less than 20% of that is on drugs, less than a billion. That is an important element of cancer spend but a minority. The large element of cancer spend is on in-patient care; that is probably about 50% of the total spend. What we pointed out in the Cancer Reform Strategy is that there are huge opportunities for rationalising that in-patient care which would benefit both patients and the NHS. That is where I would really like commissioners really to target their efforts ensuring that their local provider hospitals are using in-patient beds as effectively as possible. We did some studies looking at individual hospitals around the country, getting experts from overseas to come and work with clinicians and managers in this country and in every one that we went to by the end of the session the people from this country recognised that there was a lot they could do to reduce their in-patient care. We have set up a
programme through NHS Improvement which is piloting this across the country; I would just encourage commissioners to get involved with this because we estimate that there is £350 million worth of in-patient care that could be released for other purposes. That is where there is headroom to do a lot of the things that we need to do.

Q249 Chairman: Presumably that would be balanced by primary care.

Professor Richards: That is net saving. Yes, there are things you would have to invest in in order to make that saving, but that is the net saving we believe would be possible.

Dr Harvey: At the moment the NHS spends about 12% of its budget on drugs and, as Professor Richards has said, a lot of the rest of the care is the non-drug care. Through the work that Lord Darzi is doing, and his next stage review of the recommendations that we have that is currently being implemented is the development of NHS Evidence. One of the issues that came up from a huge amount of evidence both in this country and abroad about barriers to innovation was the fact that there is a lot of information for the NHS, but it was all in different places and was quite difficult to access. NICE provide a lot of it but there is a huge amount of evidence elsewhere. What we will have through NHS Evidence—which will be hosted by NICE and is being developed by NICE—is a single portal for the NHS for patients, commissioners and for clinicians etc., one place where all of that evidence can be established. NICE guidelines in terms of its drugs will be on there but also clinical guidelines from NICE and many other places, as well as allowing a place for clinicians that are, for example, looking at new pathways of care to actually have that in one place as well. I do think we need to remember that the drugs are important but it is actually 12% of total spend. That may vary over time but there is actually an awful lot we need to do about care in its totality as Professor Richards has said within the Cancer Reform Strategy.

Q250 Dr Taylor: The previous witnesses rather cast doubt on willingness to pay as a valid role in shaping NICE policy. I was going to ask exactly how you asked that question and whether it took into account opportunity costs although you have rather pooh-pooed the idea that opportunity costs are much of a problem. When you put this to the public survey did you make the point that if you get more of X you have probably got to get less of Y?

Professor Richards: The first point to say is that opportunity costs obviously do matter. What I was trying to do was point out that there are areas where there is very little health gain in patients spending unnecessary time in hospital; it may be the opposite of health gain. Those are the areas that we ought to be looking to decrease our expenditure. That is where I would see that there is the headroom to move forward. We approached the issue of willingness to pay in a number of different ways. First of all, would people want to be allowed to pay and all the evidence there is that four-fifths of the population are saying they would want to be allowed to pay on top of NHS care. Cambridge University Hospital did some work where they asked people how much they would be prepared to pay. Only 120 people responded to this but over 50% of them said they would pay up to £10,000 and 30% of them said they would pay £30,000.

Q251 Dr Taylor: That is Cambridge, mind you.

Professor Richards: I accept that but interestingly my colleagues, the oncologists, did a survey of their own members and asked what happened to people when the PCTs had said no. This is only one survey but around half of those patients were ending up paying themselves. That came as a shock to me that it was at that level. I think we would need to try to replicate that data and see if that is happening and we plan to do that through auditing unfunded drugs in the future. If that is the case it does show that the people who are in this situation themselves are willing to pay. Indeed, that builds on research that was done almost 20 years ago that I was involved in where we ask cancer patients who are in the situation that these patients are, where they are facing life and death, about their willingness to go through intensive treatment—we were not asking them to pay for it at that stage—and is very much higher than if you ask the same question to age-match controls in the population. So I think we do know some things about this. Equally, during the course of the review, the message that came through in a number of different ways from a lot of different people was that we do expect the NHS to look after people who are in extreme situations. Whether that is very disabled children, we would not want to put a limit of £30,000 on their care each year; we would spend a lot more than that. If it is premature children we may spend more on that. If it is people who come in following a road traffic collision we would spend more on that. We do believe that there is some particular value for people approaching the end of life. I do not have numbers for that but that was the message that was coming through from the engagement exercise we were involved in.

Q252 Dr Taylor: The end of life drugs, these are technology appraisals so they will be mandatory.

Professor Richards: Yes.

Q253 Dr Taylor: Professor Rawlins probably remembers the very first inquiry we did into NICE which is going back some years, but I shall never forget the people from across the River at St Thomas’s when you were talking about implantable defibrillators they said quite clearly they would far rather have more nurses in the A&E Department than the implantable defibrillators. Even though these are mandatory, if a given PCT feels very strongly that it has a much more important priority, what will be the position for that PCT?
Professor Sir Michael Rawlins: They will be in breach of the law. There is a direction from the secretary of state that they should provide them; it is enshrined in the Constitution.

Q254 Dr Naysmith: Following up on that exchange Professor Richards, some people have suggested that instead of increasing expenditure on cancer drugs that only prolong life for a few weeks or a few months, PCTs would be better to spend their money on more cost effective areas such as prevention or services such as palliative care. From what you have said I think you probably do not agree with that.

Professor Richards: Far from it.

Q255 Dr Naysmith: Taken together the money would be better spent on these things.

Professor Richards: My job as National Cancer Director is to maximise the benefit for all people who may now or in the future develop cancer. I certainly want to see investment wherever we have evidence that it is going to be of benefit. We have evidence of cost effectiveness on things like screening programmes. We know those are highly cost effective; we are extending the breast screening programme and the bowel screening programme so we are doing a lot in those areas. I would be very worried if we were not able to do that because those do undoubtedly save lives in the long term. Equally we need to put more investment into encouraging patients to come forward earlier for diagnosis when they do get symptoms because we have heard a lot of references between our

Q256 Dr Naysmith: If that is the case and the evidence suggests that, would it not be better to spend this extra money that we are spending on this on earlier diagnosis in this country?

Professor Richards: I think there is always a balance and what I am also saying is that we believe there is an even larger chunk of resource that can be released to do both of these and that is the resource that is currently tied up on in-patient care for cancer patients. That is why we set that out very carefully. The whole of chapter seven of the Cancer Reform Strategy tells people that that is what they can do.

Q257 Dr Naysmith: Yes, but what you are doing is telling somebody else to save the money.

Professor Richards: I am telling the health service and telling local health economists that these are areas where they can relatively simply save a great deal of money for the benefit of patients and, at the same time, that will then release the resource to save lives through earlier diagnosis and to improve the lot of people who are coming towards the end of their lives.

Q258 Dr Naysmith: Given the recession and reduced future funding of the NHS, which is almost inevitable, is it time to alter the NICE legislation to make it responsible for its own budget and for the budgetary consequences of its guidance?

Professor Richards: I have to say from my point of view, particularly with this new scheme that has come in, I believe that working with NICE is working very well. I have had a very fruitful relationship working with NICE over the last nine years since I have been in my post. There are things we have had to improve—the timeliness of NICE we have already talked about—but I believe we have it just about right at the moment.

Professor Sir Michael Rawlins: I think what you are suggesting is that there should be a pot of money.

Q259 Dr Naysmith: There is one country that does it.

Professor Sir Michael Rawlins: I do not know, but it has been suggested before. There are several problems with it actually, one is, how big is the pot? One year you might want a slightly bigger pot than another year. That is one problem; nobody knows how big the pot ought to be. Should it be £100 million or £150 million? We do know that if NICE’s advice is taken up completely the consequence in budgetary terms is about £1.5 billion. We are talking, on average over 10 years, £150 million. I am not ashamed of that; it is money, in my view, well spent; it is demonstratively clinically cost effective. The other problem with having a pot is that the appraisal committees would be more tuned into the budgetary impact of their decision rather than cost effectiveness.

Q260 Dr Naysmith: Somebody has to take account of it.

Professor Sir Michael Rawlins: Parliament has specifically said in our statutory instruments that we are not to take into account the budgetary impact. One of the dangers of course is towards the end of the financial year, having a discussion about something that really is rather expensive and fairly cost ineffective but it is March, there are £10 million left, let us stop the argument, say yes and go ahead. I have worked with committees for 30 or 40 years now and I know how they behave and if there is an easy way out they will use it.

Q261 Dr Naysmith: We have had a lot of experience of committees here too and we know how they work. PCTs work in a similar sort of way; come about January they are stopping things they were funding or they are funding things they would not otherwise fund.

Professor Sir Michael Rawlins: I think the real problem is that one year it might be £100 million and another year it might be £200 million. It is very difficult to work it out that way.

Dr Harvey: I think the point that Sir Michael makes is very apt. If there was an issue about affordability would NICE actually take a slightly different view
from the view it takes now? Our view is that in terms of negotiation, in terms of pricing et cetera, those issues are for government. However, in terms of actually having a view on clinical and cost effectiveness and now, as we have in the PPRS, value, we think it is very important that they have that role, that they do not have a role in negotiation et cetera which properly sits with us. The other issue is that NICE will look at technology appraisals as just one part of their business and, as you know, the NICE work now is extraordinary broad over technology appraisals, over clinical guidelines, interventional procedures and indeed now they are taking on quality standards for the NHS. There certainly is no intention at the moment that we would change the legislative base to give them affordability as well.

Q262 Chairman: Looking at this debate we have just had for the last few minutes, you have obviously looked at comparable systems in terms of access to medicines throughout the world. One of the comparable health services I have come across from personal experience is New Zealand in terms of what happens there and how it is funded overall. They have a Crown entity system which decides where the priorities are and subsidises medicines for the general population. I do not know whether that is in all areas of medical care. Its remit is prioritising which medicines are publicly subsidised which they believe is crucial to ensuring that the best health outcomes are obtained from medicines and those outcomes provided the best value for money. I hear what you say about having £10 million and it is heading towards the end of March but that is an accountant’s view of society. If you could take the £10 million into next April it does not mean that you have to take a decision. Have you looked at these types of comparable systems?

Professor Sir Michael Rawlins: Yes, and we have a lot of links with the Australian system. They invited me over there last year to celebrate their 60th anniversary. They have a similar sort of process to our technology appraisals but they do not do anything else. They do not do devices, they do not do diagnostics and they do not do guidelines. It is a very circumscribed field but they do very similar things and they usually come up with very similar conclusions, although not always because pricing is different.

Q263 Chairman: Have you looked at New Zealand?

Professor Richards: Not in detail but I have been to New Zealand to talk about Cancer Matters in the past and the conclusion I came to from talking to both parliamentarians and clinicians in New Zealand is that their regime is rather a lot stricter in terms of availability of drugs than ours is. That was certainly true two or three years ago when I was last there. In the course of my review I have talked to people from Canada, from Italy, from Australia. We engaged through the London School of Hygiene and Tropical Medicine and commissioned a report on what the approaches were in different countries. One of the recommendations I made in my report was that that work should be taken further forward looking in more detail at international comparisons and we will be taking that forward this year.

Q264 Charlotte Atkins: Should there be a different threshold for end of life care or should it be the same as any other threshold?

Professor Sir Michael Rawlins: We use the same threshold. For those treatments that fall into the category we take account of the weighting of the QALY and the appraisal committees have been doing this since the beginning of January. They have made two positive decisions relating to end of life treatment. We make sure that the quality of life weighting they are prepared to accept brings it broadly within the normal threshold range.

Q265 Charlotte Atkins: So it is not at a much higher level.

Professor Sir Michael Rawlins: No. Under some circumstances one might want to double the QALY.

Q266 Charlotte Atkins: That is because we are only talking about a few weeks or months of life.

Professor Sir Michael Rawlins: Exactly, yes.

Q267 Charlotte Atkins: The other issue which this Committee has looked at, as you will know from our 2008 report into NICE, is the whole issue of disinvesting from interventions where they are not effective or cost effective. That was a recommendation we made in 2008; what progress have you made in terms of making sure that that happens?

Professor Sir Michael Rawlins: You may recall our response to you when you made that recommendation. We have actually got a pretty formidable disinvestment programme but it is not labelled as such. Much of the disinvestment opportunities actually arise from our clinical guidelines, not from the technology appraisals. There are not actually in the British National Formulary useless drugs; I would be ashamed if there were because I was Chairman of the Committee on Safety of Medicines for six years. There are some rather old fashioned drugs which people do not use very much now.

Q268 Charlotte Atkins: There are plenty of old fashioned GPs and doctors are there not? When you have old fashioned doctors you may well have old fashioned prescriptions.

Professor Sir Michael Rawlins: Yes, and there will be people using methyldopa for the last 30 years who will be very cross if we take it away because it is effective but has associated side effects for many people. It is really in the clinical guidelines where the opportunities for disinvestment occur. It is not usually so much a question of stopping doing things
altogether, it is refocusing and making sure that children with sore throats only get antibiotics under some special circumstances and not as a routine. These are the rather more subtle things. In 2007 we counted there were over 150 disinvestment opportunities from the guidelines and we keep on recycling these to remind people. So we do have disinvestment. We have not forgotten it but it is a bit like the problem with the bed occupancy in the oncology units, that sort of subtlety.

Q269 Charlotte Atkins: You have not been successful in getting doctors on side. If you take something like generic prescribing, for instance, attempts to get doctors to move in that direction have not been particularly fast.

Professor Sir Michael Rawlins: I beg your pardon, we have the highest rates of generic prescribing in Europe.

Q270 Charlotte Atkins: There is still a wide variation between doctors.

Professor Sir Michael Rawlins: Actually there is very little variation. One reason why there is no much variation is the repeat prescribing systems that are computerised which all do it under the generic names so even if the doctor cannot remember the generic names and can only remember the brand name it actually comes out as a generic. We have very, very high rates of generic prescribing in Britain.

Q271 Charlotte Atkins: I am pleased to hear that.

Dr Harvey: There is about 83% of generic prescribing on prescriptions dispensed in the community in England. Even if there is no generic because it is actually a branded product that has not come of patent, nonetheless the prescriptions are written in the generic form for 83% of prescriptions and it is the highest in Europe.

Q272 Jim Dowd: Before I go onto the substance of my question, Professor Richards, you mentioned New Zealand and the drugs regime there. When we were in Australia a few years ago it was drawn to our attention that they allow direct to patient advertising by the drug companies in New Zealand. I wondered if you knew anything about that and felt that it was a good or a not so good scheme.

Professor Richards: I do not personally support direct to patient advertising. I think that is one of the things that a clinician meeting with a patient can explain what he or she thinks is in the patient’s best interests and explain all the pros and cons of different treatments. I personally think that is the right way forward. I do not know about that particular aspect of what might be happening in New Zealand. All I can say is that when I was in New Zealand the very clear impression I was given was that on cancer drugs they were more restrictive than we were.

Professor Sir Michael Rawlins: There is a lot of direct to consumer advertising in the United States of America. It makes for very boring television to keep on seeing different drugs for erectile dysfunction which seem to be the predominant adverts on American television whenever I watch it.

Q273 Jim Dowd: I want to move onto risk sharing schemes. The experience in Sheffield has been described variously but I think the kindest euphemism one can use is "unfortunate". That was the study over the MS drug glatiramer. Is there any future for risk sharing schemes and, if so, what framework should they be conducted under?

Dr Harvey: I think you may be referring to the MS risk sharing scheme which was started back in 2002. There are four drugs involved and that is between government and the manufacturers of those four drugs. That study is continuing.

Q274 Jim Dowd: Sheffield is not going ahead with the second stage of it, is it?

Dr Harvey: It is actually being taken forward through Parexel so actually the study will continue. It continues for 10 years; the first set of data has been analysed and is about to be submitted for publication. There are fixed points throughout the 10 years where the data will be locked, there will be an analysis and it will be published. The first of those will be published fairly shortly. In terms of the risk schemes going forward, we have referred to them within the PPRS scheme as patient access schemes. They are not likely to be in the same way as the outcome guarantee scheme. The sorts of things we are likely to see are responder schemes, discount schemes et cetera of the sort we saw before the PPRS was agreed for Lucentis and Velcade but those are the sorts of schemes we are likely to see in the future as patient access schemes, so slightly different.

Q275 Jim Dowd: Professor Nicholl, who was leading the scheme in Sheffield, told this Committee that they pulled out because they felt that the structures were weak and it was not going to provide the science they hoped it would. Have you discussed these reservations with them to decide whether they are valid and what actions you need to take to address them?

Dr Harvey: When we re-tendered for this second part of the scheme they in fact did not put in for that tender and therefore we are now working with Parexel as well as the neurologists, the MS Society, MS Trust et cetera and we have a scientific advisory committee that is chaired by Professor Richard Lilford and I think it is the scientific advisory committee that recommends to the funders, trying to ensure that the scientific validity of the study as it moves forward, is as good as it possibly can be. I think we are confident that it is robust. We have a cohort of about 5000 patients who are being studied over the course of this 10 year scheme and there is a collection of data from their outcomes being collected. Clearly the first of the publications from that will be submitted for publication imminently. It
will depend on how long the peer review journal takes before it is actually published but it will then come out into the public domain.

Q276 Jim Dowd: What about the previous view of this Committee that risk sharing should operate under a system whereby the burden of proof will be on the drug companies to demonstrate that a drug provides adequate benefits?

Dr Harvey: I think that is really more in the sort of risk sharing/patient access schemes that we are moving towards as part of PPRS which are less likely to be of the outcome guarantee scheme. In the case of Velcade, for example, if there is something that is measurable in terms of a responder scheme but, if not, it might be a simple discount scheme as a way of getting access to patients for innovative drugs that could actually have benefits for them. I think the important thing about patient access schemes is that they need to go through an appraisal by NICE in terms of the clinical and cost effectiveness of the scheme and the drug, so it is not just the drug but the drug in the context of the scheme. I think that is going to be very important moving forward.

Q277 Chairman: To what extent does the debate about top-ups obscure the real issue that the NHS has failed to get cheaper drugs available more quickly?

Professor Sir Michael Rawlins: In the sense that we have been too slow at producing guidance I have held my hands up to this Committee before and we have put in train measures to try to make sure that does not happen again. If you like, that is my failure.

Professor Richards: I think all the measures that are being taken through the next stage of the review, through the Cancer Reform Strategy to make sure that NICE guidance and the technology appraisals are done in a more timely fashion is extremely welcome. As I said earlier, we are beginning to see the benefit of that in cancer anyway. That particular problem of there being long delays is likely to become a thing of the past quite soon.

Q278 Chairman: Professor Rawlins, you have had some sharp comments to make in relation to how you feel the system works in terms of the pharmaceutical industry and what we pay. I am not going to ask you to repeat them here today but the real issue is around whether the National Health Service could use its bargaining power with the industry more effectively by becoming a price maker as opposed to a price taker?

Professor Sir Michael Rawlins: The difficulty is that the National Health Service is actually only a very small market; we are roughly about 3% of the world market. People think that because the National Health Service is a monopoly buyer it can be a price maker but it is not, it is a 3% market; it does not have the clout to be able to do that. Many companies have told me privately that sometimes they would rather take the business out of the UK because of the danger that if they sold it at half price in the UK the rest of the world would want half price too. We have to have arrangements that meet their aspirations and our aspirations. The PPRS I think is as good an arrangement as there is in the world.

Q279 Chairman: Do you agree with that, Professor Richards?

Professor Richards: I do, yes. This issue of it being only 3% of the world market keeps coming up and the pharmaceutical industry can decide just not to play ball in that way.

Q280 Dr Naysmith: Professor Richards, does it matter that some European countries spend proportionately more on cancer drugs than the NHS does? We heard in the previous session that there is some doubt about the figures but there seems to be some feeling that it is true that they spend more than we do on some cancer drugs.

Professor Richards: The first point to make is that I think there is clear evidence that overall we spend less on cancer drugs than some European countries. We published that figure—about 60% of the EU average—in the Cancer Reform Strategy. I think the issue we need to get behind is why and does this relate to some drugs and not other drugs and what factors may be behind it? That is the work we want to do this year because I do not think it is as simple as having a yes or a no from NICE. Also, what are the views of clinicians of the relative benefits and the relative harms? Most of these drugs have quite considerable side effects as well as benefits and in general I would say that clinicians in this country are more cautious in their use of the drugs than clinicians elsewhere. I am sure it does not necessarily feel like that to PCTs who are getting all the requests for these drugs, but I can assure you that that is my assessment of it. As you probably know we have done extensive look-backs in this country to see what variation there is within this country. I think we want to build on that and we want to look at a range of products within cancer—although this can go beyond cancer—and those products that were licensed within the last five years, those that are six to nine years old and what about the drugs that have been around for ages where cost is not usually the main limitation. I think we need to look in detail at that to get a clear idea. I think we need to work with clinicians from other countries to find out whether the comparisons are valid because there is always that question of whether we think the comparisons are valid.

Q281 Dr Naysmith: I think you said earlier that there was some element of earlier diagnosis giving better results in some countries.

Professor Richards: We are doing two different international bits of work, one is on the early diagnosis side which we are doing in collaboration with Cancer Research UK and a completely separate one which flows on from my review which is looking at usage of drugs and trying to find out what is, as near as one can get, optimal usage of those drugs.
Ms O’Brien: Perhaps I could add to that on a more general level that this is precisely the question that we need to ask ourselves across all the different dimensions of care in relation to achieving better outcomes for our population. I think it is one of the reasons why Lord Darzi places it so central in his review. As we look forward into 2009 we will be establishing the National Quality Board chaired by the NHS chief executive which, really for the first time, is going to bring together—looking at the comparison and performance of the English NHS with the health systems of other western developed countries—all the differences that there are between them, trying to get behind in more depth and to share systematically the evidence about the bad outcomes and to see what we can do to up our game here. I think that is a really significant development in being honest that we have some really important things to learn and we need to get smarter international comparisons. They are fraught with difficulty which I think the evidence in the session before indicated. We are not necessarily comparing like with like. The point really to make is that we know that this is the next place we have to go.

Q282 Dr Naysmith: Professor Richards, the October 2008 report by the London School of Hygiene and Tropical Medicine which looked at how other countries fund expensive drugs, did that influence your recommendations at all?

Professor Richards: Up to a point. What it did show was that there are different approaches both for the assessment of these drugs and there are differences in which drugs are available. What it showed was that we needed to go even further beneath that to understand these variations and that we also needed to look quite separately at the data on drug utilisation per thousand population in these countries and that is what we will be doing. I think it is a useful foundation for the work that we are going to be doing this year looking at variations in drugs.

Q283 Dr Naysmith: I think that report showed that some countries have found it difficult to separate public and private healthcare. What makes you think that the NHS will be able to succeed where other countries have failed?

Professor Richards: They are completely different systems of healthcare; they are radically different. However, we will look at all of those things in terms of whether we are really counting like for like. That is the important point. If we are going to come out with any statements about where we are on an international league table we do need to know whether that is a fair comparison or not.

Q284 Dr Taylor: Right at the end we are coming to the dreaded word, the “R” word—rationing. I think everybody agrees with the increasing longevity and increasing possibilities for treatment there is no way the NHS is going to be able to go on affording absolutely everything. NICE is the first excellent beginning of healthcare rationing in a particularly limited field really. I am delighted to have two top officials from the department here because they can tell me why an adjournment debate I tried to have some months ago entitled “NHS Rationing” was changed to “NHS Prioritisation”. Why will the Government not face up to the fact that we have to start having an open discussion across the whole country about what the NHS must afford and what is possibly going to fall off the bottom? One of our first witnesses said that there are 25,000 interventions in the NHS and obviously some of those are of enormous value, cost effective, very low figures. Why can we not start an open debate on what perhaps we should not be affording because we cannot afford everything? Can we use the word “rationing”?

Dr Harvey: I cannot comment on that because I do not know about the background. However, I would say that having NICE as an organisation is extremely valuable for the NHS because, as you know, their remit is much, much wider than just the technology appraisals and I think, as I said earlier, the fact that they now have NHS Evidence which they are developing as well to look across the piece in terms of the best evidence there is that clinicians, commissioners and indeed the patients will be able to access I think is very important. As you know, NICE does not just look at clinical care and technology appraisals, it also looks at public health. What we need to be doing is looking right the way across public health disease prevention as well as the treatments for people who actually have active disease. Looking at the clinical and cost effectiveness of those within the NHS budget which is sizeable—it is about £96 billion this year—is, we feel, the way we need to go. Also, as the Chairman raised earlier, there is the issue of disinvestment. Where we think there is care that is actually outmoded and there are better ways that care can be provided, then that needs to be taken forward. The other thing we do need to remember is that there is a lot of emphasis on new drugs that come forward which are an added cost to the NHS. I think we must remember that actually a number of these innovations will actually change a pathway of care and change a pathway of care quite dramatically which can then use less bed days which can actually make a patient pathway very different, we be able to move secondary or tertiary care into the community. All of those things are things that we need to be looking at together in terms of how care is provided.

Ms O’Brien: There is little that I would add to what Felicity has said. I think these things come back fundamentally to what is the Government’s policy towards the NHS as a whole and how do we best preserve the principles and the universality of the NHS in the context of the fast moving developments in technology. I would re-enforce what Felicity said about NICE. This is not really so much about rationing as about getting smarter and better at disinvesting and stopping doing things that are ineffect and finding and harnessing those
technologies that will enable people to stay healthier for longer. Many things that on the face of it appear expensive are in fact effective in terms of maintaining people’s health in the longer run. I think it is about our purpose and our overall objectives. How do we find a way through this? I was very struck by the comments that Bill Gates made at Davos when he talked about the three drivers for economic development over the next 10 to 15 years would be medicine, technology and software and really they are three things that come together very powerfully in relation to health systems. It is not just who we are faced with this challenge, all health systems are looking at ways in which they can harness technology in order to use the resources most effectively. I do not see it really as a situation where the resources are all allocated and now we are going to have to rush them back in order for them to be affordable, it is actually about how we can use innovation in order to get more effective use of our resources and better health at the same time.

Q285 Dr Taylor: Whatever you call it, how should the public be involved in this? I know NICE has their citizen’s panel but that is relatively small in the amount it can do. How should a widespread public debate be stimulated? Or should it be?

Ms O’Brien: Obviously Professor Rawlins can speak about the approach that has been developed by NICE which, particularly in relation to patient and public involvement, I think is absolutely showing the way not only for organisations similar to NICE elsewhere in the world but actually showing to the NHS just how you can really start to involve public and patients. The key development in terms of public involvement now is very much focussed on PCTs and the role of PCTs in facing out to their local population. We have clearly set a course there with the approach of world class commissioning and we have a long we to go. However, I think the absolute importance of the PCT linked with, for example, local authorities and other partners, is to be much more engaged with and facing up to the needs of the local population and really listening to what people want and need and engaging them in that debate. It is the direction of policy even though we have much to do in order to improve the practice. We have some really great PCTs on that front and others who have a way to go.

Professor Sir Michael Rawlins: I have never liked the “rationing” word because I am old enough to remember ration books and sweet rationing and things like that, but if you want to use it let us call it rationing. People generally do now understand that rationing in healthcare is necessary, that there is not a bottomless pit of money. It is not a matter of whether we do it but how we do it. How do we do it fairly? I think we need to learn more how to do it. We have our citizens’ council and that is there to help us with the social value judgments that you were talking about earlier. The great fault with it is that it is only 30 people and they are drawn roughly at random but do they really reflect everybody’s views? I am not a social scientist but we do need to develop better mechanisms and methods. I feel that things placed on the internet might well have great possibilities for the future. I am struggling to think of a way and nobody has really come up with a sensible one. The only thing I can say about the citizens’ council is that we put the reports out for consultation before they come to the board and interestingly enough nobody has really criticised any of their reports; there has been no major hoo-hah about what they have said.

Q286 Dr Taylor: Surely it has to be a national debate because if it is left to PCTs then we really will be down to postcode differences.

Professor Sir Michael Rawlins: How do we have a national debate? It is not easy. It is the Daily Mail arguing with the Telegraph, with the Guardian, the Times and the Financial Times. That is what happens.

Q287 Dr Taylor: At the risk or raising a complete red herring, it is patient and public involvement in health which has been ruined?

Professor Richards: During the course of the very large scale engagement exercise that I was engaged with for my review we did hear a very large majority of people say that they did accept there is a limit. That was the way it was being phrased by the public. Not everybody; there were some people who thought we should pay for everything. Wherever we went there were one or two saying that, but by far the majority said that they did accept there is a limit. I think also people were saying that they do expect the NHS to get rid of any waste as one of its first priorities. In its prioritisation I would prioritise getting rid of the waste and driving that efficiency and there is still a lot more we can and should do on that.

Q288 Jim Dowd: On the 3% figure for the drugs use in the UK, is that by volume or by value?

Dr Harvey: I think so but we will have to come back to you. We were 3.3% of the global market for pharmaceuticals in 2006. I have just been told it is 3.3% by value.

Q289 Jim Dowd: Also we are only less than 0.1% of the world’s population.

Dr Harvey: We do have 9% of global R&D for pharmaceuticals in 2006. I have just been told it is 3.3% by value.

Q290 Jim Dowd: How has that figure changed over time?

Dr Harvey: It has stayed roughly the same. Some people say 3%, some say it is 3.5%. It is in the region of 3% to 3.5% and it has stayed, as far as we know, roughly about the same. I think that is why we cannot be a price maker.

Q291 Chairman: Professor Richards, is it true that we all accept there are limits in health service expenditure until we are ill? The real issue is not
about the generality of the public because they are not the ones who are batting around between the *Daily Telegraph* and other tabloid newspapers and broadsheets. That is the hard reality of it. Looking at it from the base of the community is not looking at it from the base of the individual concerned. That is the problem you have and we have in coming to decisions, is it not?

**Professor Richards:** You have to remember the engagement exercise that we are going through, yes we did engage with the public through focus groups but we also engaged with a lot of patient groups and even within those patient groups there was an acceptance by and large that there is a limit. I am not saying that everybody accepted that but there was an acceptance by and large. The difficulty in trying to find out from large scale polls of the public is that it does depend how you frame the question. Just before my review started there were different papers that conducted different reviews and came to diametrically different results, but that was dependent on how the question was framed.

**Professor Sir Michael Rawlins:** I think one can easily underestimate people’s generosities. Years ago when the beta interferon thing was happening I was asked to go and speak to the Multiple Sclerosis Society in Newcastle. I went in fear and trepidation and they were very kind. Afterwards I found myself ringed by four or five men in wheelchairs who said, “We want to talk to you”. I thought, “Oh dear” and then they said, “We realise there is a problem about this drug. We want you to know that we all think that the kids over there who are still walking should have priority, not us.” I thought that was an extraordinary statement.

**Chairman:** That is a nice statement to finish on. Could I thank all four of you for coming along this morning and helping us with this evidence session.
Health Committee: Evidence

Written evidence

Further memorandum by Cam Donaldson (TF 09A)

NICE COST-PER-QALY THRESHOLD

It is not clear if NICE has created a new cost-per-QALY threshold for life-extending pharmaceuticals for people with kidney cancer who are close to death. This is reminiscent of the period after NICE’s creation during which it denied having any kind of threshold at all. This was never made public until the famous Rawlins and Culyer paper in the British Medical Journal in 2004.

Multiple thresholds may solve the problem

Generally, I am not unhappy with an admission of the possibility of multiple thresholds. It reflects my own position that not all QALYs are the same; that we are buying different “goods” when buying different types of health gain for the population. So, NICE needs to work with more than one threshold.

The response to this from those who seek to retain one threshold value might be that issues about who is gaining a QALY are dealt with through the deliberation process on the NICE Appraisal Committees. The deliberation process, in a sense, deals with “additional” issues such as who might be gaining QALYs and, particularly, what their characteristics are—for example, we may pay more for QALYs gained by a young child.

However, what this misses is that health itself can be gained in different ways, which the current process ignores. QALYs have two dimensions, which mean health gains can be represented by gains in health-related quality of life alone or through gains in survival, or, of course, through combinations of the two. These may be viewed very differently by members of the public. If so, this would mean that the debate about one threshold, and whether to raise it or even lower it, is irrelevant. It could be that gains in the form of short life extensions for people with serious conditions, such as cancer, are valued highly by the public, but this does not mean the threshold should be raised for all therapies. It is conceivable that quality-of-life gains which come with no corresponding life extension are valued much less by the public, and even at a level which is lower than the current threshold. If this were the case, then the raising of the threshold being proposed for kidney cancer drugs would not only reflect the preferences of the public but would be affordable if we were harder (ie imposed a lower cost-per-QALY threshold) on interventions which are quality-of-life-enhancing only.

This does also raise the subtle point about whether the kidney cancer drugs issue is a question of who is gaining or of the type of QALY being gained. In the case of the former, NICE might contend that any variance from the threshold (ie a weighting of the threshold) be left to the deliberation process, as currently happens with any other intervention NICE evaluates. If defined along the latter lines, then it would be useful to know the differential value of such QALY-types.

How might we address the valuation issue?

One way of addressing the valuation issue is to survey the public according to what is their willingness to pay for different QALY improvement scenarios, from which a value of a QALY can be inferred. There is a precedent for this, in that the value of a prevented fatality currently used in road safety evaluations by the Department for Transport is based on asking members of the public about their willingness to pay for small reductions in risk to their life, which, when aggregated over a large population, can be used to infer a value of a “statistical” life. Indeed another route to the value of a QALY would be to take the Transport value of life and, from that, “model” a value of a QALY by making different assumptions about (1) how long a person may have otherwise expected to live and (2) quality of life scores across the life course.

Recent work, through the Department of Health-funded Social Value of a QALY (SVQ) project, has provided initial estimates of the value of a QALY (SVQ) project, has provided initial estimates of the value of a QALY (SVQ) project, has provided initial estimates of the value of a QALY (SVQ) project, has provided initial estimates of the value of a QALY (SVQ) project, has provided initial estimates of the value of a QALY. A modelling approach was used to give some quick and initial indications of what the value of a QALY might be. Through the use of different assumptions about the data, it also allowed an initial investigation of the issue of the value of different QALY types as outlined above. The survey approach, being new and more developmental, took longer, and did not address the issue of QALY types, but rather whether we could arrive at a single value.

The results of each of these will be briefly discussed in the next-but-one section, but, first, it is important to defend the willingness-to-pay approach against three common criticisms.
In defence of willingness to pay

The first criticism of willingness to pay is that it associated with ability to pay. Thus, it is natural to think that defining the value of a QALY in terms of individual willingness to pay would result in higher values for the better-off and lower values for those on lower incomes. However, the point of asking a cross-section of the population about their willingness to pay is not to differentiate between income groups but to obtain a value which takes proper account of society’s overall budget constraint. Advocates of the approach would tend to argue for one value, based on some measure of central tendency, to be applied to each member of society regardless of income. Indeed, public sector agencies that employ such values (for example, the Department for Transport) invariably do apply the same value, based on the population average, to all income groups.

The second criticism is that, as the NHS budget is set through negotiation between the Treasury and the Department of Health, individual willingness-to-pay values have no relevance for health service resource allocation as they are somehow detached from the budget-setting process. This is a strong argument, but it can be countered in two ways. When answering willingness-to-pay questions in surveys, it is conceivable that respondents think of the NHS as being at full efficiency whereby it is unable to provide more services (or more QALYs) without extra payments being made. If this is the case, expressed willingness-to-pay amounts would be a reasonable representation of a value of a QALY at the margin for the NHS and may not be far away from what an individual budget-holder, like a primary care trust (PCT), might say is the value (if they used QALYs and if they behaved in an economically rational fashion!). Moreover, NICE can be subjected to the same criticism of being detached from the NHS budget. NICE does not have a budget and PCTs constantly complain about decisions being imposed upon them from NICE. Such complaints, if valid, would mean that the current threshold is leading to a misallocation of NHS resources which, ultimately, means we are getting less health for our tax £s spent.

Recent arguments that somehow NICE can search for a threshold, via a series of decisions it has made and will make, would seem odd to me. The value that emerges from this is likely to be around £30,000 per QALY because that is what NICE already operates at! The literature abounds with decision-makers getting these things wrong in the past. It may well be that £30,000 is the correct number because it was made on the basis of intelligent guesses by experts at NICE’s outset. But, we can never know if this is the case or whether there is a path dependency towards £30,000 because that is the number that is now “out there”.

The related idea that PCTs can somehow iterate towards such a value would also seem to be rather farfetched at the moment. To date, in the NHS, no systematic framework for commissioning, which recognises scarcity and can explicitly address trade-offs, has been implemented. I know this as a health economist who has done more than most in terms of working with the NHS on trying to improve its decision-making processes. It would seem that the development of such a framework is essential for matching national priorities (and successes) with local needs and to provide local health organisations with a defensible mechanism for (occasionally) justifying a focus on the local as well as the national agenda. When in place, perhaps we could iterate towards the value of a QALY at the margin. However, only a few years ago, this very Committee stated that practical systems and structures should be put in place to improve capacity to implement guidance, as implicit prioritisation is insufficient, and the Government must work towards “a comprehensive framework for health care prioritisation, underpinned by an explicit set of ethical and rational values to allow the relative costs and benefits of different areas of NHS spending to be comparatively assessed in an informed way.” The more recent assessment of PCTs, through the World Class Commissioning initiative, would seem to show little movement towards this ideal.

Thirdly, the willingness-to-pay approach has even been described as a threat to constitutional jurisdiction of Parliament! The simple answer to that is to ask what can be more legitimate than asking those who pay for services and who stand to gain or lose from different allocations of NHS resources—ie the public—what are their views about what should count. NICE does this anyway, as the quality-of-life “tariff” that it uses to calculate the cost per QALY of interventions is based on a survey of the general public. I would contend that, if we want to go beyond having a single value of a QALY to valuing QALY types, the only legitimate way of doing this (and of avoiding politicians and decision-makers being criticised for the decisions made) is to establish more thoroughly the preferences of the public.

What does the evidence say?

The only rigorous UK-based evidence on the value of a QALY is that provided by the SVQ project. Having said that, the complexity of issues and the nature of the wider ethical issues involved means that there is more developmental work to be done. As an analogy, it took several years of painstaking research to establish the value of a prevented fatality used by the Department for Transport.

What you are getting here is my interpretation of the work to date, and not necessarily that of my colleagues on the SVQ Team, and because some of the details have been set up in the preceding material, this part will be brief.1

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1 Full report: http://www.pcpoh.bham.ac.uk/publichealth/methodology/projects/RM03_JH12_CD.shtml
Generally, what the research shows is as follows:
— although the results from our survey work are not as stable as one might wish for, using reasonable
measures of central tendency and aggregation across respondents, the value of a QALY is not far
off that currently used by NICE; and
— the modelling work indicates that the above patterns, where some QALYs are valued differently
to others, are borne out.

This may allay the fears of some of my colleagues who have read press reports that the research shows
the threshold should be raised. Furthermore, and sadly, at this point in time there is no specific evidence on
the value one might attach to QALYs gained over a short period by those near to end-of-life as a result of
a condition such as kidney cancer.

What is needed now?

I can only talk about this in research terms.

However, what is required is more work, building on earlier and current research, on the public’s views
on the value they might attach to the different ways QALYs can be generated and on the relative importance
that might be given to the characteristics of potential beneficiaries of NHS services.

Research to encourage improved and more-systematic decision-making by PCTs would also help, and,
eventually, would permit reasoned comparison with the views of the public.

More generally, we need, in the UK, the ability to fund specific pieces of work quickly which would lead
not only to scientific advancement in the methods available to inform decision-makers but useful real-time
data for these decision makers—end-of-life cancer drugs being a case in point. Some of the most valuable
products of the public sector (eg safety, health) are seen as being intangible which creates great challenges
and evidence-free debates about their value. There is no research centre currently available to us which
conducts inter-disciplinary research on “valuing the public sector” which would permit progress, and even
some resolution, on these hugely important issues.

Cam Donaldson
Health Foundation Professor in Health Economics
NIHR Senior Investigator
Director, Institute of Health and Society
Newcastle University

February 2009

Further memorandum by the National Institute for Health and Clinical Excellence (TF 13A)

TOP-UP FEES

The supplementary advice for NICE appraisal committees presented below was approved by NICE’s
Board at a meeting on 17 December 2008. It takes account of responses to a public consultation that closed
on 10 December.

This advice forms an addendum to section 6.2.25 of NICE’s “Guide to the Methods of Technology
Appraisal”.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

APPRASING LIFE-EXTENDING, END OF LIFE TREATMENTS

1. Summary

1.1 This document sets out supplementary advice to the Appraisal Committees, to be taken into account
when appraising treatments which may be life-extending for patients with short life expectancy, and which
are licensed for indications affecting small numbers of patients with incurable illnesses. The additional
advice will apply when such treatments have an incremental cost effectiveness ratio (ICER) in excess of the
upper end of the range normally approved by the Appraisal Committees, using the “reference case” outlined
in the Institute’s Guide to the Methods of Technology Appraisal, and which may offer demonstrable survival
benefits over current NHS practice.

1.2 The current appraisal methodology recognises that there will be circumstances in which it may be
appropriate to recommend the use of treatments with high reference case incremental cost effectiveness
ratios. It states (with reference to the Institute's standard appraisal criteria) that: “Above a most plausible
ICER of £30,000 per QALY gained, the Committee will need to identify an increasingly stronger case for
supporting the technology as an effective use of NHS resources.” The Appraisal Committee has, in the past,
made recommendations above the normal threshold range when it has explicitly identified additional benefits not readily captured in the reference case. This has occurred when the treatment involved has been life-extending, licensed or otherwise indicated for small populations with incurable illnesses.

1.3 In developing this supplementary advice, the Institute has taken account the Appraisal Committees’ previous decisions, together with the relevant principles in the guide to the use of Social Value Judgements. It has also had regard to the consideration given by the Citizens Council, at its meeting in November 2008, to the circumstances in which it might be appropriate to support the use of treatments outside the Institute’s cost per quality adjusted life years (QALY) threshold range. In addition, the Institute has taken account of its responsibility to recognise the potential for long term benefits to the NHS of innovation. In this context, it considers it appropriate for its Appraisal Committees to have regard to the importance of supporting the development of innovative treatments that are anticipated to be licensed for small groups of patients who have an incurable illness.

1.4 The objective of this supplementary advice is to ensure that the Appraisal Committees fully consider all the benefits which it is appropriate to take into account in appraising treatments designed to extend life, at the end of life for small populations and in particular to ensure that where benefits are not, or not adequately captured in the reference case, that the Appraisal Committees are provided with an appropriate supplementary analysis. For this supplementary advice to be applied, a treatment will need to have been through an appraisal by NICE where the most plausible reference case point estimate for the ICER exceeds the upper end (£30,000) of the range normally considered by the Appraisal Committees to represent a cost effective use of NHS resources. Each candidate treatment will also need to meet the criteria set out in section 2.

1.5 The Institute will normally recommend to the Department of Health that it should give consideration to a data collection exercise for treatments recommended for use on the basis of the criteria set out in section 2. The purpose of this will be to assess the extent to which the anticipated survival gains are evident when the treatments involved are used in routine practice. The outcome of this exercise will be evaluated when the guidance for that treatment is reviewed.

2. Criteria for appraisal of end of life treatments

2.1 This supplementary advice should be applied in the following circumstances and when all the criteria referred to below are satisfied:

2.1.1 The treatment is indicated for patients with a short life expectancy, normally less than 24 months; and

2.1.2 There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional three months, compared to current NHS treatment; and

2.1.3 No alternative treatment with comparable benefits is available through the NHS; and

2.1.4 The treatment is licensed or otherwise indicated, for small patient populations.

2.2 When the conditions described in 2.1 are met, the Appraisal Committee will consider:

2.2.1 The impact of giving greater weight to QALYs achieved in the later stages of terminal diseases, using the assumption that the extended survival period is experienced at the full quality of life anticipated for a healthy individual of the same age; and

2.2.2 The magnitude of the additional weight that would need to be assigned to the QALY benefits in this patient group for the cost-effectiveness of the technology to fall within the current threshold range.

2.3 In addition, the Appraisal Committees will need to be satisfied that:

2.3.1 The estimates of the extension to life are robust and can be shown or reasonably inferred from either progression free survival or overall survival (taking account of trials in which cross-over has occurred and been accounted for in the effectiveness review); and

2.3.2 The assumptions used in the reference case economic modelling are plausible objective and robust.

3. Review of the resulting guidance

3.1 The guidance produced using these criteria will be subject to review in accordance with the Institute’s current arrangements. The review will normally take place no later than two years after the guidance has been issued. The review can be either brought forward or delayed, depending on the outcome of any data collection exercise or the availability of other new evidence.

3.2 Treatments approved following the application of the supplementary advice will not necessarily be regarded or accepted as standard comparators for future appraisals of new treatments introduced for the same condition. Second and subsequent licences for the same product will be considered on their individual
merits. The Appraisal Committee will take into account the cumulative population for each product in considering the strength of any case, for justifying decisions which employ, in whole or part, the supplementary criteria outlined above.

4. Implementation and evaluation

4.1 This supplementary advice will be effective from 5 January 2009.

4.2 The Institute intends to ensure that this supplementary advice is robust for the long-term and that it achieves its intended purpose. It will therefore be subject to a methodological evaluation. The Institute will design and manage this evaluation, the results of which will be published and used to make modifications to the supplementary advice, if necessary.

NICE
6 January 2009

Memorandum by the MS Society (TF 37)

TOP-UP FEES

1. Thank you for this opportunity to submit evidence to your inquiry into the purchase of additional drugs by NHS patients—"top-up fees". The MS Society welcomes the contribution this inquiry will make to the continuing debate about top-up fees, especially to explaining why many people feel the need to pay for drugs not available from the NHS and the actions the Department of Health could take to minimise this demand. The MS Society's submission to the Department of Health's inquiry in the summer of 2008 incorporated the results from a survey of people with MS. It is available from the MS Society website: www.mssociety.org.uk/get_involved

2. The main drivers for the introduction of top up fees are escalating costs of drugs, in the context of limited resources within the NHS and a regulatory process that fails to ensure the early or efficient entry of drugs into the NHS. Our evidence therefore covers three topics:
   a. implementation of NICE technology appraisals;
   b. timely appraisal of new drugs and treatments; and
   c. the operation of the Risk Sharing Scheme for MS drugs.

3. IMPLEMENTATION OF NICE TECHNOLOGY APPRAISALS

When a drug or treatment has been granted a licence and judged cost effective by the National Institute for Health and Clinical Excellence (NICE), a "postcode lottery" may persist nonetheless. NICE's technology appraisals have proven to have no practical force in law, in terms of compulsion or penalties for failure to comply. Local implementation may be slow or non-existent. In this climate, patients may struggle to gain access to those drugs to which they should rightly have access on the NHS. A recent example reported in the media is detailed at http://www.guardian.co.uk/science/2008/dec/16/multiple-sclerosis-drugs-tysabri.

4. TIMELY APPRAISAL OF NEW DRUGS AND TREATMENTS

The escalating cost of drugs is a driver for people's decision to pay for drugs privately and therefore for this inquiry. Other witnesses will be in a position to detail the reasons for the escalating costs of drugs; the MS Society wishes to ensure that the current provisions for regulation are included in this debate. Emphasis should be placed on bringing new drugs to the market as efficiently as possible. In particular, mechanisms to allow for early or conditional licensing (and streamlining or coordination of this process with the NICE appraisal process) should be explored, particularly where alternative effective treatments are not available.

5. RISK SHARING SCHEMES

The development of innovative schemes for risk sharing in the context of new drugs is welcome. However, there are significant issues relating to measuring long-term efficacy of drugs for chronic conditions such as multiple sclerosis. Research is needed into the methodology used and as to suitable outcome measures. The outcome measures used in clinical trials of drugs (where follow-up is limited to perhaps as little as six months) are not necessarily relevant to measuring longer term efficacy. Sufficient flexibility needs to be built into any risk sharing scheme for drugs for chronic conditions to take account of new developments, in order for healthcare system to remain flexible in prescribing and driven by the best interests of the patient. This is needed for delivery of the right drug to the right patient at the right time.
6. In this respect, it would be helpful to review the lessons learned from the Risk Sharing Scheme for MS disease modifying drugs. Such difficulties are exemplified by this Risk Sharing Scheme, which was established in 2002 but which has yet to report. The Health Committee commented on this delay in its 2007 inquiry into NICE.

7. **ABOUT MULTIPLE SCLEROSIS AND THE MS SOCIETY**

Multiple sclerosis is the most common disabling neurological condition affecting young adults. At least 85,000 people in the UK have MS. For some people MS is characterised by relapses followed by periods of remission while for others it follows a progressive pattern. The causes of MS are unknown, there is no cure and the treatments that are available are effective in only certain cases and for some of the time. MS symptoms include loss of mobility, pain, fatigue, visual impairment, numbness, loss of balance, depression and cognitive problems. MS can lead to severe and permanent disability. The MS Society is the UK’s largest charity for people living with MS, with over 43,000 members, 300 local branches and four respite care centres. The MS Society is the UK’s largest funder of research into MS, investing approximately £8 million in 2008 alone.

8. The MS Society would be pleased to give oral evidence to the committee if it would be helpful to the inquiry.

**MS Society**

*December 2008*

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**Memorandum by Dr Clive Peedell (TF 38)**

**THE PURCHASE OF ADDITIONAL DRUGS BY NHS PATIENTS (“TOP-UP FEES”)**

1. **INTRODUCTION**

1.1 I am a Consultant Clinical Oncologist at the James Cook University Hospital in Middlesbrough and sit on the North of England Cancer Network Lung Cancer Group Executive Committee.

1.2 I have personal experience of the funding problems for cancer drugs and have been involved in many requests for exceptional funding of cancer drug from PCTs.

1.3 I have a major interest in medical politics and I am a member of BMA Council and the (Hospital Consultants and Specialists Association) HCSA Council. I am currently researching the effects of neoliberal policies on medical professionalism and NHS reforms, and hope to publish a paper on the subject soon.

1.4 I strongly believe that a well run, fully tax funded healthcare system is the fairest, and most efficient way to deliver universal healthcare. I also believe that the broadly neoliberal policies that have been inflicted on the NHS over the last 30 years have resulted in the need for this inquiry.

2. **EXECUTIVE SUMMARY**

2.1 The founding principles of the NHS state that it should be universal, free at the point of delivery, equitable and paid for by central funding (taxation). Although dentistry, long term care for the elderly, prescriptions and some forms of eye care have slipped through the net, the founding principles of the NHS remains remarkably intact 60 years down the line. However, the proposals of the Richards Review, “Improving Access to Medicines to NHS Patients”, in combination with other NHS reforms will have far reaching consequences that will signal the demise of these core principles of the NHS.

2.2 Allowing patients the option to pay privately for new drugs and technologies not available on the NHS opens the door to the insurance industry and private sector providers. Over time, more and more treatments/technologies will become unavailable on the NHS and increasing proportions of the population will take out health insurance. This may eventually result in a “Snowball effect” with the potential of creating a US style “medical industrial complex”.

2.3 As the poorest members of society tend to be the most unhealthy, they will also be the most expensive to insure, and therefore the least likely to obtain health insurance and gain access to these treatments. This is an example of the “Inverse care Law”, which is most powerful where healthcare markets exist.

2.4 Governments will come under increasing pressure to subsidise insurance for the poor. This by definition means diverting taxpayers money directly to the insurance industry and private providers. This money may be diverted out of the UK if foreign companies take a significant foothold in these industries. This is not good for the UK economy and unemployment.

2.5 The Richards Review proposals have far reaching consequences in the context of current healthcare reform. They should be rejected.
2.6 Ideally, the Government should abandon its market style reforms and stay with a fully tax funded, universal healthcare system. At the very least the Health Select Committee should recommend that the Government orders a Royal Commission.

3. BACKGROUND INFORMATION TO THE TOP UP DEBATE: HOW NEOLIBERALISM, THATCHERISM, AND THE THIRD WAY HAVE INFLUENCED NHS POLICY

3.1 Following major worldwide economic crises in the 1970s, the Keynesianism economic model was abandoned in favour of the political, economic and philosophical doctrine of neoliberalism. In short, neoliberal theory claims that the role of the state should be restricted to creating and defending markets and protecting private property. The main features of neoliberalism include: the promotion of economic growth through introduction of business friendly policies aimed at freeing up markets by abolishing capital controls, removing trade barriers, expanding public choice, ensuring economic stability for the private sector’s planning environment, strict financial management and control of public expenditure, the defeat of inflation, privatising a vast array state-owned enterprises, premises and public services, introducing users charges for public services, and remodelling the state’s internal operations along business lines (New Public Management).

3.2 Neoliberalism formed the basis of “Thatcherism” in the UK and “Reaganomics” in the USA and has been heavily promoted by the World Trade Organisation (WTO), World Bank, Organization for Economic Co-Operation and Development (OECD), International Monetary Fund (IMF) and other economic bodies. Thatcher’s NHS reforms included the introduction of the NHS Internal Market and the PFI, but a full dose of neoliberalism was not administered to the NHS because of its “sacred cow” status with the public. This should be contrasted with healthcare policy in the United States, which was subjected to the full free market treatment. An article in the New England Journal of Medicine last year, stated that “the United States spends twice per capita what other major industrialized countries spend on health care, but is the only one that fails to provide near-universal health insurance coverage”. We should take note.

3.3 New Labour accepted neoliberalism as the “New Reality”. Peter Mandelson famously said, “We are all Thatcherites now”. Two Labour MPs, John Cruddas and Jon Tricket summarised what this change of policy direction meant:

“After years in opposition and with the political and economic dominance of neoliberalism. New Labour essentially raised the White flag and inverted the principle of social democracy. Society was no longer to be master of the market, but its servant. Labour was to offer a more humane version of Thatcherism, in that the state would be actively used to help people survive as individuals in the global economy—but economic interests would always call all the shots.”

3.4 So whilst the Labour Government retained it’s social democratic commitment to maintaining public services, its main logic was neoliberal: to spread “the gospel of market fundamentalism”, promote business interests and values and hollow out the welfare system.

3.5 The PFI and Public Private Partnerships (PPPs) have been a key part of the Labour Government’s broad political strategy. The internal market was modified rather than scrapped. The Winter crisis of 2000 and the subsequent Wanless report led to a massive increase in NHS funding. In return, the NHS was “modernised” and “reformed” through a performance driven managerialist assessment framework, which included a “target culture” and a new ratings system for NHS Trusts. Further reforms have introduced patient choice, payment by results, and competition between healthcare providers (NHS, private and 3rd sector) with the aim of creating a consumerist healthcare market in the English NHS. Publication of the “NHS Improvement Plan” in 2004 prompted former DH Director of Strategy, Professor Chris Ham to state:

“The foundations have been laid for the complete transformation of health care delivery. We are shifting away from an integrated system, in which the NHS provided virtually all care, to a much more mixed one, in which the private sector will play an increasingly major part. The government has started down a road which will see the NHS increasingly become a health insurer.”

3.6 Further evidence for the neoliberal agenda came from placement of an advert in the European Journal by the DH Commercial Directorate inviting expressions of interest in managing the purchase of clinical services from health care providers in the UK. This prompted former SoS for Health, Frank Dobson to say:

“If this is not privatisation of the Health Service, then I don’t know what is.” (Guardian 30 June 2006)

3.7 Lord Darzi’s Next Stage Review shows no sign of reversing the trend. In fact the polyclinic model and the pilot for patient held budgets suggests even an even greater market style approach to healthcare delivery.

3.8 “Top ups” payments are a form of “user fees” and entirely in keeping with the neoliberal agenda to increase the role of the private sector in public services. This places the founding principles of the NHS under an unprecedented threat and elevates the “Top ups” debate to extreme importance.
4. CONSEQUENCES OF “TOP UPS” FOR THE NHS, THE INSURANCE INDUSTRY AND PRIVATE SECTOR—“THE SNOWBALL EFFECT”

4.1 Allowing patients to “top up” their care in the private sector opens the door to the Insurance Industry with the longer term potential of a system of “managed care” much like that in the US where it is the insurers and not doctors who decide who gets treated, where they get treated, how they get treated, who gives the treatment and how much it costs.

4.2 New healthcare providers will be encouraged to enter the system. Standards of care may be compromised in order to remain competitive and increase profit margins eg, using the cheapest possible staff to deliver care.

4.3 The poorest and most vulnerable (eg, elderly) sections of society have the greatest healthcare needs and the most risk factors for disease. They will therefore attract the highest insurance premiums. In fact, the most needy in society will be uninsurable. This is an example of the “inverse care law”, which holds truest where healthcare markets exist.

4.4 If the state subsidises healthcare insurance for the poor, then it is in effect paying not only for the costs of treatment, but also the administrative costs, which include payments to tens of thousands of telephone and computer operators, claim payers, insurance salespersons, actuaries, benefit managers, consultants, and other low- and middle-income workers. Money that could have gone to direct clinical care will be siphoned off into the private sector and shareholders pockets.

4.5 The “Snowball effect”. Over time an increasing number of treatments and technologies will no longer be available on the NHS, and increasing proportions of the population will take out healthcare insurance. More and more care will be siphoned off into the private sector, with less money available to treat NHS patients, who will increasingly be offered falling “basic” standards of care. Many more doctors will go into private practice with less time available for NHS patients. NHS staff will be transferred to the expanding private sector, which will take advantage of the removal of the “additionality” rule. In the longer term there is a significant risk of developing a “medical industrial complex”, which has spectacularly failed the US healthcare system. This could be very damaging to the UK economy, because many of the private providers will be from overseas and therefore income from UK citizens and taxpayers (via the state) will flood out of the UK to the economies of other countries. With manufacturing industry in decline and trade deficits worsening, selling off of great chunks our healthcare system is pure folly.

5. POTENTIAL DETERIMENTAL EFFECTS ON THE CARE OF CANCER PATIENTS

5.1 Cancer treatment requires a multi-disciplinary approach. Most patients receiving systemic therapies for cancer have advanced disease and complex needs. They are best managed by a team of professionals and carers. Some patients live with cancer for many years and over that time may form very important trusting relationships with certain members of the professional teams (especially specialist nurses). The separation of care suggested by Professor Mike Richards completely undermines the basic tenet of multi-disciplinary professional support structures that is so fundamental to high quality care. In addition the separation of care will not be possible for certain patients undergoing treatments such as concurrent chemoradiation.

5.2 The vast majority of Consultants super-specialise into managing two or three cancer sites. Since many Consultant Oncologists do not do private practice, it is inevitable that situations will arise where a patient wants to pay privately for a new drug, but will need to be transferred to another cancer specialist in another Cancer Centre or Cancer Unit. This could be particularly damaging to patient care if this involves loss of the crucial professional support structures. It could also include long distance travel, meaning family cannot easily visit and support the patient. Also problems with travel expenses.

5.3 Patients who are already diagnosed with cancer are uninsurable. Most of them thought that the NHS would take care of their needs and would never have felt the need to take out health insurance. It is therefore extremely unfair that they have to consider spending their own money on expensive treatments. This can grossly increase the levels for stress for patients and relatives.

5.4 This issue of what happens when patients who do pay for treatment privately and then develop serious complications has not been adequately addressed. Should they continue to receive treatment privately or re-enter NHS care? What happens if the complication occurs in a private facility or a different cancer centre/ unit to where they were receiving NHS treatment?

6. CONSEQUENCES FOR DOCTORS AND MEDICAL TRAINING

6.1 Doctors who don’t do private practice may be encouraged to do so by their Trusts due to worries about income streams with Payment by Results (PBR). Some Trusts whose consultants don’t do private practice will clearly lose out financially. This may be a particular problem in poorer parts of the country. Again the “Inverse Care Law” comes into play.

6.2 Private providers offering services will take some of this income flow. This problem will increase over time as more and more treatments become unavailable over time. In future years this could destabilise some departments.
6.3 Cream skimming by the private sector may be a problem, because patients who have insurance have the least medical co-morbidity (otherwise they could not get insurance).

6.4 Doctors who don’t do private practice will not get experience in using new drugs and technologies. Trainees will also miss out on this experience. Opportunities for research may be lost due to NHS doctors no longer being at the “cutting edge” of oncological practice.

6.5 Doctors who choose to take on private practice will have less time for their NHS work. This problem will be exacerbated by the “Snowball effect”. Care will be increasingly fragmented especially if there is split site working arrangements.

6.6 There is good evidence from the USA that commercialisation of healthcare has had damaging effects on medical professionalism and values. “Knights become knaves”, which I call the “Le Grand paradox”.

7. CONSEQUENCES FOR OTHER HEALTH CARE PROFESSIONALS AND HOSPITAL MANAGERS

7.1 There will be major issues regarding separation of care including bed allocation, nursing care, and pharmacy procedures.

7.2 New clinical governance structures will need to be put into place.

7.3 Finance departments will need to assess income projections. They will need to do appropriate horizon scanning to assess financial risks to their organisations as new treatments and technologies become available.

7.4 New hospital space will have to be found, built or developed to allow the separation of care. This may well involve significant capital and revenue costs. Other clinical services may be detrimentally affected.

7.5 Specialist nurses and other professional groups will find it much more difficult to support their patients, especially if they are being treated elsewhere.

7.6 Transfer between different hospitals and departments may increase the risk of Hospital Acquired Infections.

8. WHAT ARE THE POSSIBLE SOLUTIONS?

8.1 The current proposals of the Review in the context of the current market style reforms could signal the demise of the English NHS. The implications are so serious and wide ranging that I believe it would be a serious mistake to accept the proposals.

8.2 The current status quo of not allowing patients to pay for effective new treatments is also unethical and unacceptable.

8.3 The only sensible solution in my opinion is to continue to provide a fully tax funded system according to the founding principles of the NHS.

8.4 At the very least a Royal Commission is required.

9. A FULLY COMPREHENSIVE AND TAX FUNDED NHS. HOW IT COULD BE ACHIEVED

9.1 The total NHS spend on cancer drugs including hormonal therapies is £1 billion (personal communication with Mike Richards). According to the Association of the British Pharmaceutical Industry, over the next four years, seven out of the top 20 medicines are going off patent and will be replaced by generic copies which are much cheaper. The drugs industry estimates this will save the Department of Health £2.9 billion by 2012. This money could be used to fund new drugs/technologies.

9.2 The healthcare market with its huge associated administrative costs should be abandoned, with a return to block contracts and high quality local and central planning with collaboration between Government, SHAs, PCTs and Trusts.

9.3 Instead of using financial competition to raise standards, I believe that “professional pride” should be used to incentivise high quality, efficient care. The publication of high quality outcome data alongside a powerful Peer Review process “with teeth” could be used to identify and address failing individuals, teams, departments and Trusts. Community Health Councils could be re-established to ensure accountability.

9.4 The PFI (and most PPPs) should be abandoned across the entire public sector. The Connecting for Health programme should also be abandoned.

9.5 Dramatically cut the use of management consultants in Government business.

9.6 The Government could encourage the growth of the private sector by offering incentives for the wealthy to pay for private insurance rather than use the NHS. I foresee a situation where clinical care between the private sector and the NHS would be no different in terms of quality, but private patients could pay extra for “hotel type services” such as “home entertainment” and top restaurant style food etc. This
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would avoid a “two tier” system in terms of quality of clinical care, but allow the wealthy to enjoy more comfortable surrounding by paying for various extras. Some NHS Trusts could provide these services to generate extra income. This would allow “total separation of care”.

9.7 By avoiding fragmentation of the NHS, an NHS Monopoly will be able to bargain more effectively with the Pharmaceutical Industry over drug costs. “Hard bargaining” should be used for drugs with a “Class effect” to get the best possible deals.

9.8 Preventative medicine and promotion of healthy lifestyles should be encouraged.

9.9 All the political parties need to start a debate on the role of increasing the age of retirement. The increasing elderly population with its associated health related problems is going to be unsustainable in the long term unless. We increase the length of our working lives, so the number of pensionable years remains stable.

January 2009

Memorandum by Dr Jacky Davis (TF 39)

ENQUIRY INTO THE PURCHASE OF ADDITIONAL DRUGS BY NHS PATIENTS

1. INTRODUCTION

I am a consultant radiologist at the Whittington Hospital in London. I am a member of the BMA Council, Co Chair of the NHS Consultants Association and I am a founder member of the campaign to Keep our NHS Public. I believe the NHS functions best as a publicly funded and delivered service and that the introduction of top up payments has the potential to undermine the founding principles of the NHS, creating a two tier service.

I welcome the following points in the report:
— the recommendation that the option of NHS top ups should be rejected;
— a recognition of the dangers to the principles of the NHS in introducing top ups;
— the unequivocal statement that no solution should lead to an insurance based system;
— the wish to keep the number of patients involved in treatment outside the NHS to a minimum;
— the belief that this can largely be dealt with by improved drug access within the NHS through improving NICE and working with the pharmaceutical industry; and
— the acknowledgement that the extend of problem is unknown.

2. THE EXTENT OF THE PROBLEM

The extent of the problem is unknown and may have been exaggerated by those who believe that the NHS should move towards an insurance based system. Their hope is that the introduction of top ups will precipitate a move in that direction

http://www.bmj.com/cgi/content/full/336/7656/1265?maxtoshow=
(for role of Doctors for Reform)

The report states that requests for exceptional funding number 15,000 cases a year (P 15, 2.4). Most of these are for drugs waiting for NICE approval (P 16).

Average cost/patient varied between £8,000 and £20,000 (unfunded cancer treatment)
65–75% were approved (P 18, 2.12)

The number of patients are thus relatively small, as are the sums of money involved compared with the overall drugs budget. Patient charges are currently only 1.3% of current NHS spending (P 27, 3.22) and thus peripheral to the core function of the NHS. The solution to this problem does not require a change in the basic principles of the NHS, but rather improvements in the function of NICE and better liaison with the pharmaceutical industry.
3. THE ROAD TO AN INSURANCE BASED SYSTEM

While Professor Richards states that he does not want any solution to precipitate a move towards an insurance based system, the insurance companies themselves see great potential in any change. http://news.bbc.co.uk/1/hi/health/7714039.stm

“‘The potential for this (insurance) market is phenomenal’

“One firm said it could be bigger than the private medical insurance market, while analysts predicted the top-up ruling could mark a “pivotal point”.”

4. STAKEHOLDER OPINIONS

While many different groups contributed to this report, the voice which is almost always lacking in this debate is that of those who will not be able to afford the top ups or even the relevant insurance—most often the elderly, the poor, the chronically sick and the inarticulate. The tension in the debate is between personal autonomy and principles of equity and inevitably the consumer has thus far spoken louder than the citizen.

The welcome inclusion of the letter (P 34) is indicative of how this group—likely to significantly outnumber those who would benefit from a change of practice—might feel.

The funding of patients groups by the pharmaceutical industry is also of note in this context. http://blogs.independent.co.uk/openhouse/2008/10/why-nice-gets-b.html

5. LOSS OF EQUITY

The statement is frequently made that no solution should be to the detriment of those NHS patients who cannot pay for additional unfunded treatments or insurance. Little is known however about the effects upon this group of the availability of treatments which they cannot afford. They are likely to significantly outnumber those who benefit from top up arrangements. Research is needed about the effects—clinical and psychological—on those who are, or will perceive themselves to be, second class citizens with the health service.

The poorest members of society tend to be the least healthy and will thus have the most difficulty in either paying for additional treatments or obtaining insurance to cover them, especially should the range of unfunded treatments and interventions increase. Any move in the direction of top ups within the NHS will increase health inequalities, which are already a continuing source of concern.

There has been some work on the adverse effects of the introduction of co-payments, for example: http://www.rand.org/pubs/research_briefs/RB9169/index1.html http://www.publications.parliament.uk/pa/cm200506/cmselect/cmhealth/815/815ii.pdf. (ev 49, ref 22)

6. PRINCIPLE OF "SEPARATEDNESS"

While the principle is a good place to start it is difficult to see from a clinical perspective how it will always be maintained in practice.

Medical care, particularly cancer care, requires a multidisciplinary approach and team work which may be undermined by “separatedness”. Some treatments may not be able to be separated physically, and local expertise may mean that they have to be given by the same clinician.

Local considerations may mean that treatments have to be given in the same establishment, leading inevitable to a two tier service within the NHS. Having a treatment down the corridor as an NHS patient will not appear very “separate” to another patient on the ward who cannot afford it.

It may not be easy to separate complications arising from NHS v privately purchased drugs.

It thus seems inevitable that NHS patients will on occasion end up having different treatments in the same establishment, based on ability (or inability) to pay.

7. SAFEGUARDS FOR THOSE WHO CAN’T AFFORD TO PAY

As mentioned above, insurance is already available for those who can’t afford to pay out of pocket. The government might wish to provide cover for those who can’t afford the insurance (we have no idea what percentage of the population this would be) but this is likely to prove difficult to administer and possibly more expensive than providing the treatment on the NHS in the first place.

P 70 of the report states that:

“patients should only be able to supplement their NHS care with additional private care where a clinician agrees that this is clinically appropriate”.

It would be better to aim to have all clinically appropriate care available for all patients in the NHS.
8. OTHER DIFFicultIES

The NHS Confederation has identified a list of practical difficulties, mostly centering on the financial administration of such an arrangement (P 35, 4.26). No answers to these difficult questions are contained within the report.

9. EFFECTS OF PROPOSALS ON HEALTHCARE WORKERS

Much of the burden of applying the recommendations appears to fall on frontline workers. For instance (recommendation 12) doctors’ communication skills are to be improved so they can discuss all options, funded and unfunded, with patients. The problem (for clinician and patient) of fully discussing unfunded options with those who cannot afford them is not addressed. The report recognizes that there will be increased communication problems for the clinicians. (P.37, 4.34)

There is also an inherent contradiction, as doctors are expressly forbidden to discuss private treatment with patients (paragraph 2.9 of the Code of Conduct for Private practice):

“In the course of their NHS duties and responsibilities consultants should not initiate discussions about providing private services for NHS patients, nor should they ask other NHS staff to initiate such discussions on their behalf.”

The requirement that clinicians “exhaust all reasonable avenues to secure NHS funding” will also be time consuming, taking skilled workers away from clinical work.

Managers will need to put in place arrangements for separate facilities for delivering private treatment, and governance arrangements to ensure continuity of care. The cost of this extra activity is unclear. Would it be greater than the money saved by not funding the small range of drugs in question?

CONCLUSION

The need for this report has arisen because not all clinically appropriate drugs are available on the NHS. It is frequently said that the NHS can no longer afford to be comprehensive. The observation is traditionally made by those who would like to dismantle the NHS and replace it with another system. It is however a dangerous starting point for this debate, and needs challenging. It is worth asking as part of this exercise whether the NHS could in fact offer all clinically appropriate drugs to patients and thus avoid the problem of top ups altogether.

The report identifies ways of working with the pharmaceutical industry and NICE to increase the number of drugs available. In addition the DoH has identified savings elsewhere in the system (“Better care, better value indicators”) which could be used in this context. Is it possible that through these mechanisms we could offer all clinically appropriate drugs to NHS patients, thus avoiding the inevitable two tier system which will result from even Professor Richards’ thoughtful approach.

The reality of “separate care” is apparent on P 51, “option appraisals for separate care”. Steps will have to be taken to ensure continuity of care as patients will be receiving different care from the NHS and the private provider (although this will often be in the NHS).

The NHS is a vital act of social solidarity and equity lies at the heart of it. We must not move towards a two tier system. The only solution which avoids a two tier system and which remains fair to the minority of patients who need clinically appropriate drugs not currently available is to work towards making all clinically appropriate drugs available to NHS patients. Mechanisms have been identified and may indeed cost less than the (uncosted) alternatives proposed.

January 2009

Supplementary memorandum by Dr Jacky Davis (TF 39A)

SUGGESTION FOR FUNDING OF ADDITIONAL CANCER DRUGS

While listening to the evidence at the HSC on 29 Jan several facts emerged:

— The problem of top ups is “not a big issue” and “not a real issue”.
— For the patients’ representative the problem is equitable access for patients to clinically effective drugs which are currently not available—either because they have not yet been assessed by NICE or are too expensive by NICE criteria.
— The number of patients involved in buying top ups is likely to be small “because of the expense”, and the true number is unclear.
— The cost of setting up a parallel system (as recommended by Professor Richards) has not been assessed and is likely to be high.
— There will be many practical difficulties in setting up this system which have not yet been resolved. The many questions raised by the NHS Confederation, particularly around the financial aspects, have not been answered.

— Exceptional funding reviews are expensive and time consuming for PCTs. There is a wide variation between PCTs which may approve between 0% and 100% of requests. This leads to delay and anxiety for patients and unfairness in regard to access to additional drugs.

— Cancer drugs, even when approved, take a large and unpredictable slice from PCT budgets.

PROPOSED SOLUTION

A central funding mechanism for additional cancer drugs should be established. This would include drugs which are either in the NICE pipeline, and/or are clinically effective (and considered [clinically beneficial] by the patient’s clinician) but judged by NICE to be too expensive by current criteria.

The money for this central fund could come from several sources:

— top slicing the PCT budgets to the tune of the amount that is spent now by exceptional funding reviews, plus the money spent on administering the reviews themselves.

— Additional money could be provided centrally to reflect the potential cost of administering the parallel system proposed by the Richards report.

— Money could be used from the NHS surplus (£1.7 billion last year).

ADVANTAGES OF A CENTRAL FUND

— Cancer patients would have access to all cancer drugs considered sufficiently likely to be clinically effective in their particular case by their treating doctor. There would be no “two tier” system for NHS patients.

— Patients being treated would remain within the NHS, thus avoiding all the clinical and personal difficulties of transferring between clinical teams.

— Clinicians and patients would not have to spend time—“exhausting all avenues”—to access these drugs.

— PCTs would not have the responsibility for exceptional funding reviews. This would save them time and money.

— The unpredictable and high costs of granting exceptional funding would be removed from PCTs.

— Patients being treated with new drugs would remain with the NHS, thus allowing better monitoring of these drugs.

— Better “bargaining powers” about the cost of new drugs if they remain within the NHS rather than being paid for by individuals.

— It is possible that this method would cost less than administering the system proposed in the Richards report, while removing the contentious aspects of running a parallel system.

— It is understood that there is already a similar system in place for the funding of “orphan drugs”.

This is of necessity a brief and broad outline. The proposals in it are supported by the

The NHS Consultants Association
The NHS Support Federation
Keep Our NHS Public

Jacky Davis

February 2009

Memorandum by the Centre for International Public Health Policy (TF 40)

THE PURCHASE OF ADDITIONAL DRUGS BY NHS PATIENTS

1. EXECUTIVE SUMMARY

1.1 This policy is contrary to the goals of the NHS and the principles of universality, equity and service provision on the basis of need rather than ability to pay, and should be withdrawn.

1.2 The Department of Health guidance on this policy claims that it is possible to separate public and private funding and delivery and put in place mechanisms and safeguards for this. All the evidence shows that it is not.
1.3 Recommendations:

— Treatments and services that are deemed to be effective should be available free at the point of delivery on the NHS. This founding principle of the NHS is inviolable.

— In the light of comments by the Chairman of NICE on excessive prices by pharmaceuticals and the OFT inquiry into the PPRS\textsuperscript{3,3} the government should investigate the price and costs of drugs and seek to control NHS drugs expenditure by more efficient price regulation, not by opening up new funding mechanisms. It should explore the potential of the revised Pharmaceutical Price Regulation Scheme, in effect since 1 January 2009, to lower prices on oncology drugs.

— The government should also explore other measures for the control of prescription costs, such as the use of generics and the restriction of the pharmaceutical industry’s attempts to influence GPs prescribing patterns, as highlighted by the National Audit Office\textsuperscript{4}.

2. Background

2.1 On 4 November 2008, the Department of Health published its Guidance on NHS patients who wish to pay for additional private care—A consultation\textsuperscript{5}, closing on 27 January 2009. On 12 December 2008, the Scottish government published draft guidance on Arrangements for NHS Patients Receiving Private Healthcare for consultation, with comments to be returned by 12 January 2009\textsuperscript{6}. We have responded to both of these consultations.

2.2 The key policy change addressed by the English guidance is that patients are now allowed to mix private and publicly funded care during the same NHS treatment episode: “Patients may pay for additional private healthcare while continuing to receive care from the NHS”\textsuperscript{5}. In Scotland, this policy has not yet been approved but is being consulted on.

2.3 A crucial issue is that the guidance will allow patients to top up publicly funded NHS care with private funding for services other than drug prescribing.

3. Issues Raised by the Purchase of Additional Private Healthcare Services by NHS Patients

3.1 Adherence to the principles of the NHS

3.1.1 Comprehensive service with access based on need:

3.1.1.1 The guidance undermines the principles of the NHS which are that “the NHS provides a comprehensive service available to all” and that “access to NHS services is based on clinical need, not an individual’s ability to pay”\textsuperscript{5}.

3.1.1.2 This policy also undermines Professor Mike Richards’ report, which states that a system of NHS top-ups whereby patients would pay a user charge to receive additional drugs “presents significant challenges and is inequitable for those NHS patients who could not afford to top up.”\textsuperscript{7}

3.1.1.3 Combining public and private funding of treatment creates a two-tiered system of care, where patients who can afford it may top up publicly funded NHS care. This position is endorsed by witnesses to the Scottish Public Petitions Committee who included Deputy First Minister and Cabinet Secretary for Health and Wellbeing, Nicola Sturgeon; Professor Peter Johnson, chief clinician of Cancer Research UK; MSP Rhoda Grant; and Professor Alan Rodger, medical director of the Beatson Oncology Unit\textsuperscript{8,9}.

3.1.1.4 As stated by NHS Grampian\textsuperscript{10}:

“It seems neither ethically nor morally appropriate that patients should self-fund in a national health service that espouses to be free at the point of delivery. An anomaly is created between those who can afford to pay potentially being advantaged over those who cannot.”

\textsuperscript{1} Hinsli G. Health chief attacks drug giants over huge profits. The Observer 2008 August 17.
\textsuperscript{6} Richards M. Improving access to medicines for NHS patients: A report for the Secretary of State for Health by Professor Mike Richards CBE. November 2008.
\textsuperscript{9} NHS Grampian, Office of Chief Executive. Public Petitions Committee inquiry into availability on NHS of cancer treatment drugs. 7 April 2008.
3.1.2 The evidence behind cost-sharing and its impact on the poor:

3.1.2.1 The NHS Plan 2000 for England states:

“Charges are inequitable in two important respects. First, new charges increase the proportion of funding from the unhealthy, old and poor compared with the healthy, young and wealthy. In particular, high charges risk worsening access to healthcare by the poor. As the World Health Organisation report—which assessed the United Kingdom as having one of the fairest systems in the world for funding healthcare—concludes: ‘Fairness of financial risk protection requires the highest possible degree of separation between contributions and utilisation’. Second, exempting low income families from user charges can create inequities for those just above the threshold. High user charges with exemptions can create disincentives to earning and working through the imposition of high marginal tax rates.”

3.1.2.2 In their 2005–06 report *NHS Charges*, the Health Select Committee’s view was that private health funding is regressive and acts as a barrier to treatment. The report cites a UK survey conducted in 2001 which indicated that 28% of individuals liable for the prescription charge did not have all of their medications dispensed in full. Further, a survey of people in England and Wales estimated that each year 750,000 people did not have their prescriptions dispensed due to the cost of the co-payment. They also stated that UK evidence indicates that single parent households and individuals with long-term conditions face stronger barriers due to the costs of prescriptions. Further, the Committee’s document on NHS Charges states that there are no comprehensible underlying principles guiding charges in the NHS and that the system has many anomalies.

3.1.2.3 In the US, cost-sharing and co-payments are associated with risks of catastrophic health costs. Half of American families that filed for bankruptcy in 2001 cited medical costs, with 47.6% of those families listing drug costs as a contributor to these. Further, prescription medications were listed as the biggest contributor to medical expenses by 22% of those who filed for bankruptcy due to medical costs, and by almost all those with Medicare coverage.

3.2 The separation of responsibility for public and private provision

3.2.1 The Department of Health guidance states that:

— the NHS should never subsidise private care with public money, which would breach core NHS principles; and therefore; and

— it should always be clear whether an individual procedure or treatment is privately funded or NHS funded.

3.2.2 However, the document does not provide specific guidance on how trusts shall maintain the distinction between public and private care, nor does it explain how this will be monitored. NHS Grampian advised the Scottish Public Petitions Committee that “it is not practically possible to make the separation in the way the health department letter suggests—we have difficulty with this because it places us in the difficult position of having to make judgments on a case-by-case basis”. Further, the Public Petitions Committee acknowledge in their report “that it is simply not possible to split pro rata a patient’s treatment costs between that received privately and that on the NHS”.

3.3 Conflicts of interest—both public and commercial

3.3.1 NHS staff could find themselves compromised by advising on privately funded care within the same NHS treatment episode, especially where they have private practice interests. Clinicians with a pecuniary interest may find their own judgement is clouded. The guidance includes a cursory call for NHS clinicians who carry out private care to avoid any actual or perceived conflict of interest, however it does not describe how this will be monitored and regulated.

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15 Harding M. Payment by results wide open to fraud, say commissioners. Health Services Journal 2006; 23 Feb: 10.
3.4 Clinical accountability

3.4.1 The guidance states that “there should be clear separation of legal status, liability and accountability between NHS care and any private care that a patient receives.” However, it does not provide further clarification of how separation will be achieved.

3.4.2 For example, if a patient is prescribed a drug privately and subsequently experiences a serious adverse reaction which requires treatment, is the NHS responsible to pay for the services required by the patient, or should they be charged to the private provider? Who will be responsible for monitoring these situations to ensure that the appropriate provider bears the risks and costs? How will the patients and physicians deal with allocation of risk and responsibility for combined therapies, such as cancer treatments, where some drugs are provided by the NHS and others through the private sector?

3.4.3 Nicola Sturgeon, Scotland’s Deputy First Minister and Cabinet Secretary for Health and Wellbeing, raised these concerns in her testimony to the Public Petitions Committee, stating that “if treatment is divided between the NHS and the independent sector, the lines of clinical accountability become blurred, which can have serious implications.” Ms. Sturgeon made it clear that this possibility presents “real dangers” for patients.

3.4.4 Professor Rodger, medical director of the Beatson Oncology Unit in Glasgow, expresses this issue as one of clinical governance:

“Someone might get three drugs through the NHS and one through the private sector. They might all have to go in through an intravenous line. That costs money. The NHS would put in the line. If it got infected, would it be the NHS’s responsibility or the private sector’s responsibility? If the patient becomes severely ill as a result of the combination of drugs, would they go into the private sector because it was the expensive, non-approved drug that caused the trouble? It might not have been the expensive drug that caused the trouble. How do you work that out? I can tell you that, in such circumstances, the patient would come straight back into the NHS under ‘unscheduled care’.”

3.4.5 The guidance states that the NHS should not be expected to meet any predictable costs from the private element of care, yet it should continue to treat patients in an emergency. This means that the public sector’s tax-funded budgets will be expected to absorb the costs of treating side effects of privately-provided drugs.

3.5 Legal liability

3.5.1 It is unclear how legal liability will be determined when treatment is mixed between public and private. The guidance states that “it should always be clear which clinician and which organisation are responsible for the assessment of the patient, the delivery of any care and the management of any complications”, however it does not explain precisely how this can be done.

3.5.2 As Dr. Jean Turner of the Scotland Patients Association stated, “I can see the difficulties with mixing NHS and private care, which include difficulties with insurance and risk. If treatment takes place wholly within the NHS, the NHS carries all the risk. When treatment is part private, that is difficult.” How will patients determine which sector is liable if and when things go wrong? How will they navigate the complaints and litigation processes?

3.6 Transaction costs

3.6.1 According to the guidance, “The patient should bear the full costs of any private services.” Administrative costs will be incurred for the public sector as a result of new billing arrangements, as well as the costs of monitoring and regulation. How will these costs be met and how will they be budgeted for?

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3.7 Erosion of entitlements to NHS care will lead to a parallel private healthcare system

3.7.1 This guidance sets a precedent, leading to the extension of this policy to other treatment areas and the loss of entitlements across the NHS. The loss of entitlements, known as delisting, could lead to more patient charges for the public, a policy that is regressive and has had demonstrable negative effects around the world. The practice of delisting or removal of entitlements to NHS care is best exemplified in the NHS in long-term care and dentistry, where increasingly the risk and the responsibility for funding is devolved to individuals and where there are widening inequalities in access to care22,23,24,25,26,27,28.

3.7.2 In the US, where the policy of mixing funding originates, co-payments are used by HMOs to reduce service costs. The ability to charge inevitably results in delisting, limiting eligibility and entitlement to public services or the introduction of private insurance policies. The US has a large body of evidence showing the way in which HMOs engage in fraud and denial of care when the option is open to restrict eligibility29.

3.7.3 The implications for the NHS are that enabling private funding of treatments and services will result in the creation of a parallel private healthcare system. In England, Europe’s largest pharmaceutical distribution and retail company, Celesio, has launched a service company, Evolution Homecare, that not only delivers privately funded drugs to patients’ doors, but will organise privately funded nurse visits to guide patients through their treatment30.

3.8 Cost control in the NHS

3.8.1 This policy has primarily emerged out of the controversy and criticism surrounding the rationing of pharmaceuticals by NICE. Mike Rawlins, the Chairman of NICE, has stated that the drugs industry overprices vital new medicines in order to boost profits31. The Office of Fair Trading report on the Pharmaceutical Price Regulation Scheme32 criticized the failure of the PPRS to achieve its objectives with respect to clinical value: “We recommend that government reform the PPRS, replacing current profit and price controls with a value-based approach to pricing, which would ensure the price of drugs reflect their clinical and therapeutic value to patients and the broader NHS.”

4. Conclusions

4.1 The evidence supports the testimony of the Scottish Cabinet Secretary for Health and Wellbeing, Ms. Sturgeon, to the Public Petitions Committee report33, in which she stated:

“The NHS provides health care free at the point of need, and equity of access is the fundamental principle of the NHS. A system that in effect allows people to top up the care that they get on the NHS by paying privately for part of their care raises the danger of a two-tier system in which people who can afford to pay for bits of their care privately do so and people who cannot afford such care are denied it.”

4.2 This policy is contrary to the goals of the NHS and the principles of universality, equity and service provision on the basis of need rather than ability to pay, and should be withdrawn.

4.3 The guidance claims that it is possible to separate public and private funding and delivery and put in place mechanisms and safeguards for this. All the evidence shows that it is not.

31 Hinsliff G. Health chief attacks drug giants over huge profits. The Observer 2008 August 17.
5. **Recommendations**

— Treatments and services that are deemed to be effective should be available free at the point of delivery on the NHS. This founding principle of the NHS is inviolable.

— In the light of comments by the Chairman of NICE on excessive prices by pharmaceuticals and the OFT inquiry into the PPRS, the government should investigate the price and costs of drugs and seek to control NHS drugs expenditure by more efficient price regulation, not by opening up new funding mechanisms. It should explore the potential of the revised Pharmaceutical Price Regulation Scheme, in effect since 1 January 2009, to lower prices on oncology drugs.

— The government should also explore other measures for the control of prescription costs, such as the use of generics and the restriction of the pharmaceutical industry’s attempts to influence GPs prescribing patterns, as highlighted by the National Audit Office.

*Prof Allyson Pollock*

*Megan Arthur*

*David Price*

*February 2009*

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**Memorandum by Professor Christopher McCabe (TF 41)**

**Summary**

Careful consideration of the events leading up to the Richards Review, the Review itself and changes in the NICE methods subsequent to the Richards Review, gives rise to the following observations:

— The attempts to charge people for NHS care was based upon an extreme misinterpretation of the Guidance issued by the Department of Health relating to private practice and the NHS.

— Richards review did not find any evidence to support the view that a significant number of patients are being failed by the current funding arrangements.

— Allowing private top-ups within the NHS would have a number of undesirable effects, including a substantial increase in the administration costs of the health care system; the redistribution of NHS resources towards people who can afford some private health care; and the promotion of geographical inequity in the quality of care provided by the NHS.

— Allowing private top-ups in the NHS would be unlikely to significantly increase the resources available for front line health care in the UK and may be unsustainable in the long term.

— There is a lack of strong evidence supporting the presumption that society attaches a special value to health care interventions that extend life at the end of life.

— There is a tension between rapid appraisal of new technologies by NICE and the quality of NICE’s decision making. The current presumption that rapid appraisal is good appraisal is in denial of this tension.

— In a system where Parliament allocates the budget for the NHS, survey based estimates of society’s willingness to pay for health gains are not relevant to establishing the cost effectiveness threshold for resource allocation decisions.

— The end of life premium recently implemented by NICE creates incentives for manufacturers that are not consistent with promoting the health of the UK population.

— There is a risk that the end of life premium will be funded at the expense of interventions that improve the quality of life at the end of life.

— Both top-ups and the end of life premium reduce the incentives for manufacturers to engage with the “Value-Based Pricing” initiative at the heart of the renegotiation of the PPRS.

**Personal Statement**

The following evidence reflects my personal views on the implementation of top-ups within the NHS and the use of an end of life premium in the NICE Technology Appraisal Programme. These views draw upon my professional expertise as a health economist and my extensive experience of working with the National Institute for Health and Clinical Excellence, local commissioners across the UK; national and international pharmaceutical companies; patient groups; and health care reimbursement organisations in Europe and North America.

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34 Hinsliff G. Health chief attacks drug giants over huge profits. The Observer 2008 August 17.


I have worked in health economics for nearly 18 years. I hold a PhD in Health Economics. I have held chairs in health economics at the Universities of Sheffield, Warwick and Leeds as well as being a Visiting Professor in Health Economics at the University of Alberta in Canada. I am a Scientific Advisor to the Biotherapies Development Association, a body committed to promoting access to innovative effective new therapies. I also sit on the Health Care Committee of the Faculty of Public Health.

BACKGROUND

The current review of how the NHS should be funded and the role of individual patient’s private financing is a response to the high profile “Withdrawal of Care Crisis”, which started in Spring 2008.

A number of newspapers reported cases where individuals who had paid privately for drugs not funded by their local NHS were told that this had the effect of making them private patients for all of their NHS care and thus they would therefore have to pay for some treatments that were free to NHS patients.

After extensive media coverage and a call from the BMA conference, the government commissioned the Cancer Tsar, Professor Michael Richards to review the NHS policy on mixing NHS and privately financed health care in the NHS. It is worth noting that whilst the media coverage was large, the actual number of cases identified was small, perhaps fewer than 20.

RICHARDS REVIEW

The terms of reference for the Richards Review are reproduced in Box 1. The key elements are (1) the presumption that patients who pay privately for drugs are required to pay for care they would otherwise have received free on the NHS; and (2) the requirement to uphold the principle that “treatment is based upon clinical need not ability to pay”.

The first point was expressed in a slightly misleading and tendentious way. The Guidance from Department of Health over many years (dating at least from the Green Book in 1986) was that a patient was required to either be an NHS patient or a private patient for an episode of care, but could switch between these statuses at will and without prejudicing the care available as an NHS patient. In practice, problems only arose if the privately funded treatment was required to be given simultaneously with NHS care. Thus the problem identified in the Richards Review was very rare indeed.

The timeline for the Richards Review was notable. Submissions could be made over a seven week period and recommendations to the minister were due approximately 10 weeks later. The last time the fundamental principles of funding health care in the UK had been reviewed, the discussion had taken place over a number of years.

In addition to taking submissions on the desirability of allowing top-ups within the NHS, the Richards Review examined the regulatory framework for private health care in the NHS, and looked for evidence that a substantial number of patients were unable to access cancer drugs their doctor recommended for them, through the NHS.

Box 1

TERMS OF REFERENCE FOR THE RICHARDS REVIEW

“To examine current policy relating to patients who choose to pay privately for drugs that are not funded on the NHS and who, as a result, are required to pay for the care that they would otherwise have received free on the NHS.

2. To make recommendations on whether and how policy or guidance could be clarified or improved.

3. In making recommendations, to take into account:

a. the importance of enabling patients to have choice and personal control over their healthcare; and

b. the need to uphold the founding principle of the NHS that treatment is based on clinical need not ability to pay, and to ensure that NHS services are fair to both patients and taxpayers.

The Review will take account of:

— the Government’s wider strategy for improving the quality and effectiveness of NHS services; and

— developing policy and practice arising from the NHS Next Stage Review and Constitution.”

On examination it is clear that Guidance from the Department of Health explicitly forbade charging patients for their NHS care if they had paid privately for some health care. [Box 2] However the NHS/private patients regime was never set out in Regulations or Directions and thus NHS bodies, and in particular acute trusts had the legal right to consider and then reject the Guidance.
Exercising these discretionary powers may have been a more effective solution for Trusts than allowing the medical and specialist patient lobby to change the approach to cost effectiveness for end of life care.

There were a small number of providers who exercised their legitimate freedoms to refuse to follow the Guidance and charge patients for private drugs delivered alongside NHS care. This was legally permissible albeit in direct contravention of the Guidance. The Richard’s Review suggested that this might have arisen from a confusion between the “a visit to an NHS organisation” and an “Episode of Care”. An episode of care can consist of many visits to an NHS organisation. In principle, the Secretary of State could have issued Directions to replace the Guidance which would have delivered clarification for Trusts on what they could and could not do in this area.

Box 2
REGULATION OF PRIVATE PRACTICE IN THE NHS

“A patient cannot be both a private and a NHS patient for the treatment of a single condition during one visit to an NHS organisation…”

…any patient seen privately is entitled to subsequently change his or her status and seek treatment as an NHS patient;

….any patient changing their status after having been provided with private services should not be treated on a different basis to other NHS patients as a result of having previously held private status;”

UK Dept. of Health. Code of conduct of private practice. 2004

Unmet clinical need is difficult to establish. The Richards Review consulted with NHS hospitals providing cancer care to establish how often patients were unable to obtain the drug recommended by their doctor within the NHS. When a treatment was not routinely funded as part of the contract between a PCT and the hospital, doctors must make a specific request to the PCT for funding. These processes are referred to as Exceptional case or Individual Funding Request (IFR) Panels. These PCT IFR systems are being standardised as a result of the recent NPA Guidance. Box 3 summarises the findings.

Box 3
EVIDENCE OF UNMET CLINICAL NEED FOR CANCER DRUGS UNDER CURRENT FINANCING MODEL

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Number of applications per month</th>
<th>Approval Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leeds Teaching Hospital</td>
<td>45</td>
<td>90% approved</td>
</tr>
<tr>
<td>Christie Hospital (Manchester)</td>
<td>5</td>
<td>75% approved</td>
</tr>
<tr>
<td>Royal Marsden (London)</td>
<td>27</td>
<td>65% approved</td>
</tr>
</tbody>
</table>

Note: Richards Review reports the range for successful applications was 0 to 100% but without knowing how many applications were made, these figures are meaningless.

The evidence provided by the Richards Review does not appear to support a conclusion that there are large swathes of people being denied access to the care their doctors recommend for them; ie the current financing arrangements are not failing even a substantial minority of people with cancer.

In the submissions to the Richards Review a number of advantages and disadvantages of allowing top-ups in the NHS were identified. The primary advantages advanced were:

— the respect of an individual’s freedom to spend their money how they wish;
— releasing the financial pressure on NHS resources by injecting additional money into the health care system; and
— providing a reward to pharmaceutical innovation thus ensuring that investment in research and development was maintained.

Whilst the principle of individual freedom is important, in this context it conflicts with the principle of access to care being based on clinical need rather than ability to pay. Top-ups, by definition, conflict with this principle. Furthermore, unless the top-ups were cost neutral to the NHS; ie all costs to the NHS associated with the private treatment were reimbursed by the patient, then patients able to take advantage of top-ups would have unequal access to NHS care. For Top-ups to be cost neutral to the NHS a new patient level resource use monitoring system would have to be created. Otherwise the NHS would not know who to bill for what.
The costs of this monitoring system would likewise have to be met by the patients receiving private care within the NHS. This in itself would likely price many potential beneficiaries of a top-up system out of the market. If the system was created, the effect would be to see a large increase in total expenditure on the health care system without a corresponding increase in frontline funding. The absence of such a system would mean that NHS patients would be subsidising the care of private patients within the NHS.

The extent to which top-ups would represent a significant increase in the health care resources is a key issue. The Richards Review does not suggest that there are large numbers of people being denied access to their recommended treatments by the NHS. In the absence of a substantial demand for top-ups, it is unlikely that the additional resources generated by top-ups would be large. It is perfectly feasible that the cost of setting up the administration system for top-ups could negate these financial benefits. Privately financed health care systems often spend \( > 10\% \) of their budgets on administration.

There is also a question over the long term sustainability of private funding for expensive end of life drugs. The experience of the United States is that the costs of modern drugs are so high that the majority of private individuals cannot afford them in the long term. As a result the Government in the United States have had to reimburse the cost of pharmaceuticals for retired populations through the Medicare system. Employers carry the majority of the burden for the employed population of working age. These costs are recognised as a major factor in the productivity challenges faced by major US employers such as General Motors and Ford. The implication for the UK is that, if contrary to the Richards’ Review evidence, there is significant unmet need within the NHS, the financial benefit to the NHS of allowing top-ups within the NHS might be short lived and more broadly there may be an increase in employment costs for British industry.

Whilst allowing top-ups would provide some additional revenue to the pharmaceutical industry, the scale of unmet need identified by the Richards Review, does not suggest it would be of sufficient scale to influence a global industry’s investment behaviour. Thus the argument that allowing top-ups would encourage continued investment in the development of future treatments is less than convincing.

In addition to the likely costs of establishing a top-up administration system and the departure from the founding principle of the NHS, the most significant disadvantages of allowing top-ups, identified in the consultation were:

1. the difficulties in ascribing legal responsibility for clinical negligence when the care package is a mixture of private and NHS funding;
2. the difficulty of stopping the top-up treatment if the individual runs out of money;
3. the potential for unethical decision making for a highly vulnerable group of patients; and
4. the impact on the geographical equity in health care.

The first two are self-explanatory. The third and fourth may not be so obvious.

Patients facing the end of their lives are incredibly vulnerable. Top ups encourage patients to spend a proportion of their assets (maybe by mortgaging a house) on purchasing “hope value” of a limited extension to life which can be of a marginal quality. Relatives and loved ones cannot be seen other than to support the expenditure and yet, for many, this will be a complete waste of time. The drivers here may be as much about satisfying the clinician’s professional commitment to do everything medically possible for the patient, as delivering care which is the in patient’s overall best interest.

The fourth argument goes that people who have the wealth to take advantage of top-ups are not uniformly distributed across the health care system. Some hospitals may see very few patients with the necessary resources, whilst other hospitals may see many. If there were in fact significant unmet need for access to innovative new technologies through the NHS and that hospitals charge for the private health care provided as part of the top-up, revenue to hospitals serving socio-economically advantaged populations will be greater than revenues to hospitals serving less affluent populations. Overtime, the hospitals serving advantaged communities will be able to provide a better standard of care reflecting their greater resources and thus a community’s access to health care would be influenced by their ability to pay, rather than clinical need.

Recommendations of the Richards Review

Box 4 reports the key recommendations from the Richards Review. The recommendations effectively restate the Guidance from the 2004 Department of Health document, emphasising that private funding of drugs should be a last resort and making no change to the underlying system. They then encourage the government to pursue pricing negotiations to make innovative new drugs available within the NHS.

The two most interesting recommendations were that government pursue affordable measures to make available drugs used near the end of life, and that the Department continue to attempt to speed up the timelines of the NICE Technology Appraisal process. Both of these recommendations may have unintended and not necessarily desirable consequences.

The NICE Technology Appraisal process can be thought of as a diagnostic procedure. It assesses the likelihood that a technology will prove to be a cost effective use of limited health care resources—its introduction will lead to an increase in the net value of the health produced by the NHS. Inevitably, the
process will not be perfect, it will have both a false positive rate (approving technologies that do not prove to be cost effective) and false negative rate (refusing technologies that would in fact have been cost effective).

The quicker the appraisal process becomes, the greater the risk that treatments that would be a good use of NHS resources are rejected and treatments that would not be a good use of resources are recommended. The level of care in the appraisal of a technology should reflect the magnitude of the cost of making the wrong decision. Thus, the greater the expected budgetary impact of a technology, the more care is justified to avoid a false positive recommendation.

**Box 4**

**KEY RECOMMENDATIONS OF THE RICHARDS REVIEW**

- pursue affordable measures to make available drugs used near the end of life;
- continue to renegotiate the Pharmaceutical Price Regulation Scheme (PPRS) allow flexible approaches to the pricing and availability of new drugs;
- make clear that no patient should lose their entitlement to NHS care they would have otherwise received, simply because they opt to purchase additional treatment for their condition;
- ensure clinicians exhaust all reasonable avenues for securing NHS funding before a patient considers whether to purchase additional drugs; and
- establish clear clinical governance arrangements to ensure that patients who do elect to purchase additional private treatment receive good continuity of care to improve the timelines of the NICE decision making process.

**THE END OF LIFE PREMIUM**

Richards advanced two pieces of evidence to support a special status for treatments as the end of life [See Box 5]. Subsequently, a paper by Mason et al reported findings which they argued supported a conclusion that society was willing to pay up to £70,000 per QALY for life saving treatments.37

The two studies quoted by Richards, report patient preferences and thus may not be relevant to the type of resource allocation decisions made by NICE. When NICE issues guidance on a new technology, there are (at least) two groups of patients who will be affected by the decision and whose values, in an ideal world, would be considered in the decision: those who would benefit from a positive recommendation and those who would bear the opportunity cost of that positive guidance i.e. those whose treatment will not be funded because the money has been spent on the new technology.

It is inequitable to give preferential status to the values of the patients who will benefit from the technology whilst ignoring the values of the patients who will have to pay for the decision. In reality, the evidence base to support a claim that society attaches a special value to interventions which extend life at the end of life is notable by its absence.

**Box 5**

**EVIDENCE FOR AN END OF LIFE PREMIUM**

“There is evidence that patients are willing to undergo further treatment for relatively small gains in survival….42% of cancer patients said that they would accept an intensive treatment even if it only prolonged their life by three months, whilst only 10% of controls said they would.” Slevin et al 1990

and

Many (patients) would not choose chemotherapy for a survival benefit of three months, but would if it improved quality of life. The median survival threshold for accepting chemotherapy was 4.5 months for mild toxicity and nine months for severe toxicity.” Silvestri et al 1998

Those who argue that the findings of Mason et al. represent a strong reason to raise the cost effectiveness threshold are for end of life treatments, do not unfortunately understand what the cost effectiveness threshold is. [See Appendix 1] Mason et al report estimates of society’s willingness to pay for health gain. However, Parliament has already expressed a willingness to pay for health gain through the budget it allocates the NHS. Once the budget has been set by parliament, the cost effectiveness threshold is used to allocate the resources in line with the objectives of the NHS—providing a comprehensive health care service, free at the point of consumption, with access based upon clinical need rather than ability to pay in order to promote the health of the population. It would only be rational to use an estimate of societal willingness to

37 There are concerns about the validity of the results from this paper.
pay for health gain as the cost effectiveness threshold if Parliament committed to increase the NHS budget to cover all treatments that has an ICER at or below this value. Appendix 1 gives a detailed account of the nature of the cost effectiveness threshold and its use in resource allocation decision making.

In response to this recommendation from Richards, following instructions from the Secretary of State for Health, NICE have adopted an amendment to their Methods of Health Technology Assessment. [See Box 6]

This amendment to NICE’s methods raises a number of concerns including: “Why is the focus on treatments for small populations?” and “Why are treatments that improve the quality of life at the end of life excluded?”

It is not intuitively obvious that society would attach a different value to health gain on the basis of how many people have the condition in question. The NICE consultation document argued that the reason for the premium was that treatments for rare conditions cost more per person to develop and the NHS should be willing to pay more for them to ensure that the treatments became available. Whilst this approach is consistent with a principle of social solidarity, it may well have unforeseen consequences.

**Box 6**

NICE’S END OF LIFE PREMIUM

For:

- Treatment indicated for patients with a short life expectancy, normally less than 24 months and;
- There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional three months compared to current NHS treatment, and
- No alternative treatment with comparable benefit is available through the NHS, and;
- The treatment is licensed or otherwise indicated, for small patient populations.

Consider

- The impact of …the assumption that the extended survival period is experienced at the full quality of life for a healthy individual of the same age, and;
- The magnitude of the additional weight that would need to be assigned to the QALY benefits in this patient group for the cost effectiveness threshold of the technology to fall within the current threshold range.

First, it provides an incentive for manufacturers to license new products for rare conditions first, in order to maximise their income. As treatments are increasingly active across many indications, society might prefer that innovative therapies are made available for the more prevalent conditions first.

Second, there are a large number of patients with rare diseases. The numbers for each rare disease may be small but the number of rare diseases is high. Hence the number of patients affected by the proposals is (a) large and (b) uncosted.

The implicit assumption in the Richards Review that total budget impact of a premium for rarity will be small is likely to prove wrong and the Review has not asked the question what should be cut to pay for this investment. Further, developments in genomics and proteomics are leading to disaggregating of once common disorders into multiple much rarer disorders with a shared clinical presentation; eg Breast Cancer is now differentiated into three distinct conditions for treatment purposes and six distinct genotypes. This process is likely to further exacerbate the budgetary implications of providing a premium for rarity.

The operation of an end of life premium will necessarily divert resources away from preventive and chronic treatments. The most recent estimates indicate that, in the UK, individuals consume approximately 64% of their lifetime health care in the last year of life. By implication, chronic and preventive health care already receive a relatively small share of the health care budget. The end of life premium is likely to maintain if not increase this divergence. A second implication is that the people who bear the opportunity cost of the end of life premium are ceteris paribus, likely to be in the last year of life. This makes the focus of the premium on treatments that extend life at the end of life particularly challenging. There is a substantial probability that cost will be met by not funding or reducing funding for treatments that improve the quality of people’s lives at the end of their life.

**A Personal Observation**

There is a larger issue which appears to have driven the Richards Review; the frustration of specialist clinicians who felt it was possible to provide treatment of some efficacy, or that might deliver some life extension to patients, but were prevented from doing so by PCT commissioning policies, unless they supported exceptionality applications. Doctors wished to be able to prescribe these drugs whenever they believed they were clinically indicated and not be subject to individual applications to PCTs. These concerns were understandably supported by the specialist cancer patient lobby groups.
Thus what started as a concern raised by a very small number of individual patients became, as the Review developed, a political drive to give cancer doctors the freedom to prescribe drugs which were, according to the standards applied in the rest of the NHS, poor value for money.

Whilst such a drive may be consistent with the doctor’s duty to “Make the care of your patient your first concern,” it is in direct conflict with the doctor’s duty “Work with colleagues in the ways that best serve patients’ interests.” [GMC Good Medical Practice 2006]. Good husbandry of the NHS’s resources depends upon the recognition by frontline clinical staff of the importance of their role as stewards of our health care system as well advocates for their patients. The experience of recent months suggests that key medical personnel within the NHS have yet to understand this.

Christopher McCabe, PhD
Professor of Health Economics
University of Leeds

February 2009

Memorandum by GlaxoSmithKline (TF 42)

TOP UP FEES

INTRODUCTION

GlaxoSmithKline (GSK) welcomes the opportunity to contribute to the Health Select Committee’s inquiry into “top-up” fees in the NHS. We have taken the opportunity to comment on this and the wider issues we believe need to be addressed to ensure British patients have early and equitable access to innovative new medicines.

GSK is one of the world’s leading research-based pharmaceutical and healthcare companies, developing and supplying medicines to improve patients’ quality of life. We make prescription medicines, vaccines, over-the-counter medicines and oral care and nutritional healthcare products. We are proud of our strong, open relationship with the NHS and our British heritage. We employ more than 19,000 people across the United Kingdom and spent over £1 billion on Research and Development (R&D) in the UK in 2007. This equates to over 40% of our global R&D spend. GSK is the largest private sector funder of R&D in the UK.

This paper provides comments on top up fees and the recommendations set out by Professor Mike Richards in his report “Improving access to medicines for NHS patients”.

COMMENTS ON TOP UP FEES AND PROFESSOR RICHARDS’ RECOMMENDATIONS

The UK Government, like others around the world, faces significant funding pressures, caused by demographic ageing, technological advances creating a new generation of leading-edge medicines, and essentially limitless demand for healthcare. Governments must allocate their resources efficiently and effectively to provide the best health outcomes for their citizens and to align limited healthcare budgets with health priorities. Coupled with these demands is the realisation that patients are becoming much more informed, not only about their conditions, but also about the range of treatments becoming available to them and their potential value to improve their quality of life. In some cases, this has led to a willingness to top-up or pay for treatments which are otherwise unavailable to them.

The subject of “top-up fees” is highly sensitive, particularly with regard to issues of equity, health equality, and access to medicines. GSK believes that top-ups are not the strategic answer to the fundamental challenges within the current health system, and must not distract stakeholders from searching for solutions to the wider systemic problems surrounding universal access to new and innovative medicines.

Professor Mike Richards’ report marks an important first step to addressing some of the issues around improving access to new medicines and provides some clarity on situations whereby patients may wish to purchase additional treatment but obtain core NHS care. We agree that all reasonable avenues for securing NHS funding should be exhausted before suggesting that a patient’s only option is to pay for care privately.

GSK believes that there are two distinct, but connected issues that need to be addressed to ensure good access to new medicines for British patients. First, industry and Government should work together to ensure that once NICE has recommended that a medicine be used in the NHS, that the system supports this recommendation through widespread use of the medicine in the appropriate patient population. Second, there needs to be thoughtful consideration given to the way NICE currently reviews new medicines. The Richards Review was a first step in the right direction in this regard, but there remain other areas that should be considered to ensure that NICE decision-making reflects the broader goals of stimulating innovation and giving patients in the UK access to medicines that their European counterparts enjoy.
DRIVING UPTAKE IN THE NHS OF COST-EFFECTIVE MEDICINES RECOMMENDED BY NICE

All stakeholders (Government, NICE, industry and patients) should focus on a collective response to improve rapid, universal access to innovative medicines for patients in the UK, in a cost-effective way. The Government has acknowledged that more needs to be done to remove barriers to access and improve uptake of innovative medicines within the NHS. Some progress has been made through joint working between the Government and industry under the Ministerial-Industry Strategy Group but the UK still lags behind Europe on uptake of new medicines and significant variations remain across the UK.

As part of the PPRS settlement, industry and Government agreed to a series of measures in an “innovation package” that, if implemented well, should drive uptake of NICE-recommended medicines. These measures were also featured in Lord Darzi’s recommendations in his recent Review.

GSK believes that there is commitment in Government to drive uptake of NICE-approved new medicines and is keen to work with the Department of Health and the NHS to ensure that improvements are made.

REVIEWING THE VALUE JUDGEMENTS NICE MAKES WHEN ASSESSING NEW MEDICINES FOR USE ON THE NHS

The “Improving Access to Medicines” report addresses some key issues particularly around access to end of life medicines but there remain some outstanding concerns with the way NICE assesses new medicines.

Professor Richards has acknowledged that increasingly we are seeing the emergence of drugs which, in their first indication, are likely to benefit only a small number of patients, usually towards the end of their life. Often it has been difficult for these drugs to achieve cost-effectiveness within the original process/criteria. There have been recent NICE judgements (eg Avastin, Nexavar and Torisel [renal cancer]) which acknowledge that a particular medicine does bring clinical benefits to appropriate patients but recommend the drug be excluded from use in the NHS on the basis of not being cost-effective.

While a negative decision on this basis can be logical with respect to short-term NHS efficiencies, it fails to take into account that the innovation is meeting an unmet medical need, that reward for clinical improvement is a fundamental part of incentivising innovation, and that in due course the innovative technology will also, in time, be available as a cheaper generic.

In line with Professor Richards’ recommendations, GSK was encouraged by the guidelines NICE has issued to appraisal committees on the criteria to be considered when making recommendations on the use of medicines which extend life at the end of life. We support these new guidelines and hope that their implementation will deliver on Professor Richards’ intended vision of ensuring that as few patients as possible feel the need to top up their care, as medicines that provide additional clinical benefit will be available on the NHS.

Although the additional measures on end of life medicines mark an important step in the right direction, the new criteria have yet to be tested extensively in practice.

It is important that the appraisal committees remember that data generation in the end of life setting can be challenging, particularly when ethics committees involved in drug trials recommend patients on control arms have access to the trial drug, following signs of significant benefit. Ethically, this is clearly appropriate but it can limit the generation of good survival data for new medicines that clearly have significant clinical benefit.

We hope that the new guidelines will be sufficient to ensure that Professor Richards’ vision is realised but remain concerned that this may not be the case. Often the Cost per QALY is significantly above the threshold and we anticipate that these new criteria will impact only a few medicines a year, rather than provide a complete solution. Of the first batch of medicines to be assessed by NICE under the new guidelines, only those where the manufacturer had been prepared to discount heavily have been recommended (Revlimid for blood cancer and Satent for renal cancer). Others, with clear clinical benefit, have been rejected on the grounds of cost-effectiveness.

Clearly, industry needs to be flexible and has a role to play in adopting new approaches to making drugs available to the NHS on cost-effective terms and it is important that we work in partnership with relevant bodies to ensure this occurs. We welcome proposals in the PPRS to help facilitate this. However, greater flexibility is also needed by NICE and the appraisal committees.

We are pleased that NICE has recently announced an independent study, chaired by Sir Ian Kennedy, to assess how value is taken into account when looking at new health technologies. This announcement comes at an important juncture. The adoption of guidance on end of life drugs acknowledges that the original approach did not fully reflect the value that patients and their families place on relatively small extensions to survival at the end of life. Building on Professor Richard’s recommendations, this review could provide further progress on improving access to medicines.

GSK believes that further improvements could be made by reviewing and broadening the definition of value to ensure that the cost-per-QALY measurement is not the sole factor in determining patient access. The current framework for estimating cost effectiveness and NICE’s preferred questionnaire to measure quality of life do not fully capture all the benefits likely to be important to and valued by patients and their carers and dependants, including reducing the severity of the disease, an improved safety profile or providing...
therapy in an oral rather than intravenous form, which may allow a patient to be treated at home. The potential to alleviate the stress, anxiety and burden of care imposed on relatives and carers of patients is another significant benefit not routinely included in decision-making. Similarly, benefits relating to mental health, cognitive function, and improved tolerability are not well-captured.

It is also worth remembering that there are other reasons why a country such as the UK should be an early adopter of new medicines, in particular in their first indications. Clinicians, in particular in a hospital setting, need the ability to use and experiment with new medicines, to ensure that the UK’s leadership position as a location for early-phase experimental medicine is maintained. The market environment is also a factor companies consider when placing investment in research, development and manufacturing.

Finally, GSK believes that if patients are going to be able to top-up their care by paying more to continue to take a medicine of their choice, they should receive all of the information necessary to make that choice as rationally and well-informed as possible, including clear information about the full costs which they will bear.

**Conclusion**

GSK believes that there is much that could be done to improve patient access to new and innovative medicines and welcomes Professor Richards’ recommendations. All stakeholders should focus on how the system can be improved to ensure universal access to such medicines, irrespective of where in the UK a patient lives.

The guidance on appraising end of life drugs, developed by NICE in response to Professor Richards’ recommendation, is a step in the right direction but is unlikely to be the complete solution to issues of access near the end of life. Further improvements could be made by reviewing and broadening the definition of value to ensure that the cost-per-QALY measurement is not the sole factor in determining patient access. We are pleased that NICE has recently announced an independent review of how value is taken into account when looking at new health technologies and we look forward to contributing to the debate.

Furthermore, we agree that the industry has a role to play in working in partnership with the Department of Health and NICE and agreeing flexible approaches to ensure that patients have access to cost-effective medicines. The recent PPRS negotiations also produced a balanced outcome and patients will undoubtedly benefit if the Innovation Package and approach to flexible pricing is implemented in full.

The ultimate goal should be for industry and Government to work together to generate a pattern of usage of all medicines that is more in line with value generated—in other words, to ensure that the right medicine is prescribed to the right patient at the right time.

*February 2009*

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**Memorandum by Professor Christopher Newdick (TF 42)**

**NHS PRIORITY SETTING—ASSESSING THE RISKS OF THE NHS CONSTITUTION**

This paper assesses the risks presented to PCT priority setting policies by the *NHS Constitution*.

1. **The Risk of the NHS Constitution**

The NHS Constitution, and the documents which support it, explain rights within the NHS. It has a particular focus on patients’ rights within PCT priority setting. Although it does not intend to change National Health Service legislation, or the cases which have considered it, in practice it is likely to have a significant impact on the relationship between patients and PCTs.

I am concerned that the *NHS Constitution* clarifies the rights of patients without explaining the duties from which those rights arise, ie the statutory duties imposed on PCTs. To explain one side of the equation without considering the other gives patients a sword with which to attack the hard choices made by PCTs, without giving PCTs an adequate shield with which to explain themselves. This will benefit patients who are able to challenge PCT decision-making, but it will lead to “disinvestment” from patients who do not have the capacity to do so.

The *NHS Constitution* enhances patients’ rights at the “macro” and “micro” level.
2. The NHS Constitution on Patients' Macro-Rights

At the “macro” level, i.e., with respect to allocating resources to a community of patients, the following two rights in the Constitution should not give rise to particular concern because PCTs should be capable of explaining why hard choices are necessary. Thus, it is reasonable to advise patients that:

- You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you. (NHS Constitution, Principle 2a).

This general principle will become mandatory upon PCTs under Secretary of State’s “Directions” which require that:

- Each PCT must have in place arrangements for making decisions and adopting policies on whether particular healthcare interventions are to be made available for patients for which the PCT is responsible… Each PCT must compile and publish clear written information outlining the arrangements specified… (Draft Direction to PCTs and NHS trusts concerning decisions about drugs and other treatments 2009).

This requires PCTs to implement fair procedures that respond to patients equally and consistently. Such a requirement is reasonable and complies with existing law.

3. The NHS Constitution does not Recognise the Limitations on PCTs Macro-Duties

However, I am concerned the NHS Constitution does not properly explain the finite nature of PCTs’ duties in respect of priority setting.

If I have a right to NHS resources, it is because PCTs have a duty. The nature of my right depends on the extent of the duty. The duties imposed on PCTs in respect of priority setting are not infinite. They are, amongst other things:

- to promote a comprehensive health service for the entire community,
- not to exceed finite annual budgets, and
- to have a reasonable system for prioritising resources.

This recognises that very expensive treatments offering limited health gain to small numbers of patients may not always be funded. Put the other way, if such treatment is funded, it will be at the cost of less expensive treatments which would otherwise be available for patients (what health economists call “opportunity cost”).

However, this fact is not properly acknowledged in the NHS Constitution. It says, for example:

- The NHS is committed to providing best value for taxpayers’ money and the most effective use of finite resources (NHS Constitution, Principle 1(6)),

And:

- The Constitution sets out expectations of how patients, the public and staff can help the NHS work effectively and ensure that finite resources are used fairly (NHS Constitution Handbook, 5).

Only one document begins to address this issue, although it is intended for PCTs (not patients). It says:

- Like all public authorities, PCTs are required to operate within finite budgets and, therefore, have to prioritise some treatments over others according to the needs of local communities… (Defining Guiding Principles for Processes Supporting Local Decision Making About Medicines, 3).

None of these statements, however, candidly address the problem of finite resources, opportunity costs and the need for hard decisions between competing demands. Explaining the duties of PCTs to “prioritise” (sic, “ration”) resources is sensitive in party politics, but if one side of the rights-duties equation is ignored, the NHS Constitution will confer disproportionate benefit on complainants. By emphasising patients’ rights alone, the new regime is likely to generate more claims for access to funding, yet leave PCTs without equivalent tools with which to defend the hard choices they are required to make.

PCTs are unlikely to develop a new appetite for judicial review. Consequently, many of these claims will be conceded without litigation. Since hard choices will still be required, the net losers will be the inarticulate and unpopular groups that tend not to complain; most commonly this means elderly and disabled patients. This will undermine the public health objective of promoting equality of access to NHS care and worsen the problem of “institutionalised ageism” recognised in recent reports.
Instead, the **NHS Constitution** should recognise that PCTs are duty-bound not to exceed their annual financial allocations (see s 229, National Health Service Act 2006), and, perhaps, incorporate the statement of the Court of Appeal in Jaymee Bowen’s case (Girl B), *R v Cambridge DHA, ex p B* (1995) that:

…in a perfect world any treatment which a patient, or a patient’s family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however be shutting one’s eyes to the real world… to proceed on the basis that we do live in such a world… Difficult and agonizing judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients.

By doing so, the **NHS Constitution** would acknowledge that PCT resources are finite, that priority setting is inevitable and that hard choices are sometimes required. In this way, the argument about balancing the needs of individuals with those of the community will be recognised and understood.

4. **The NHS Constitution at Micro-level—Individual Funding Requests (IFRs)**

This imbalance between rights and duties is exacerbated at the “micro”-level by the new approach to individual funding requests. Since 1999, the Court of Appeal has required PCTs to have procedures for dealing with exceptional cases. However, the **NHS Constitution** tips the balance in favour of IFRs.

(a) *The Law on Exceptional Cases*

Existing law is unsettled on exceptional cases. Should the PCT’s duty be to respond to the needs of the individual patient, or only to reconsider the policy about which complaint is made?

Some cases say that the duty to exceptional requests should be at policy level. This has the advantage that individuals will not receive an inconsistently favourable response which is unfair to the majority. On this view, public authorities should modify a policy in response to pressing need (even by a small number of patients), but should not normally respond to individuals requests. Thus, in *R v Ministry of Agriculture, Fisheries and Food, ex p Hamble (Offshore) Fisheries Ltd* (1995) the judge said:

While the framer of a policy for the exercise of a government discretion must be prepared to consider making exceptions where these are merited, the inclusion of thought-out exceptions in the policy itself may well be exhaustive of the obligation. While any further candidates for exemption must be considered, it will always be a legitimate consideration that to make one such exception may well set up an unanswerable case of partiality or arbitrariness. The decision-maker must therefore balance the case for making no such exceptions against the case for generalising it.

This promotes consistency for all and saves the time and other resources diverted into managing large numbers of individual funding requests.

However, other cases (especially *R v N Lancashire HA, ex p A, D &G* (1999)) seem to favour a more individualistic approach so that “blanket bans” will generally be unlawful.

(b) *The NHS Constitution and IFRs*

The **NHS Constitution** offered the opportunity to rationalise this process by recommending that “exceptionality” should generally apply at the level of policy-making (even if the number of patients concerned was very small). However, it has not taken this opportunity. Instead it says:

…a PCT can have a policy not to fund a particular treatment (unless recommended by NICE in a Technology Appraisal), [but] it cannot have a blanket policy, ie it must consider exceptional individual cases where funding should be provided (**NHS Constitution Handbook**).

This will be given statutory force in Secretary of State’s “Directions”:

… each PCT must have in place arrangements for making decisions and adopting policies on whether particular healthcare interventions are to be made available for patients for which the PCT is responsible [and include] arrangements for the determination of requests for the funding of a healthcare intervention for an individual, where the PCT’s general policy is not to fund that intervention (*Draft Direction to PCTs and NHS trusts concerning decisions about drugs and other treatments 2009*).

This will surely encourage everyone refused access to treatment to consider going to an IFR Panel. Hospital doctors and pharmaceutical companies will use the **Constitution** to persuade patients to do so. This will generate considerable extra activity in IFR Panels. And as PCTs come under pressure to concede these claims, resources will drain away from other areas of patient care.

“Top-up” payments for NHS treatment also make IFRs more likely. Top-up payments may give patients access to care that would not otherwise have been available within the NHS and on which further claims to “exceptionality” may be based.
My point is not that IFRs should not exist. It is that they contain “opportunity costs” of their own. If IFRs become the norm whenever PCTs consider a treatment to be low-priority, the impact on the time and resources available for other patients will be considerable.

(c) A Right to Attend IFR Panels?

Existing law does not require IFR proceedings to be open to patients and the public. Rejecting such a right to appear in person, in R(F) v Oxfordshire Mental Healthcare NHS Trust, (2001), the court said:

A meeting of the forum is essentially a discussion between medical experts. It is not to be equated with a contested hearing, and rules of disclosure which might be appropriate for such a hearing should not be imposed upon the Forum’s deliberations … Decisions on funding affect lives [but] that is not a good reason to judicialise them. They are agonisingly difficult decisions, and they will not be made any easier or better if they are encumbered with legalistic procedures.

However, the NHS Constitution appears to promise that patients will have access to IFR panels.

You have the right to be involved in discussions and decisions about your healthcare, and to be given information to enable you to do this (Principle 2b, NHS Constitution).

Indeed, the National Prescribing Centre recommends a further level of appeal against the decision of the IFR, again, to which the patient should have access.

PCTs should establish an appeals process for decisions made on individual funding requests, including clearly defined grounds of appeal, independent of the original process and open to patients and the public. (Defining Guiding Principles for Processes Supporting Local Decision Making About Medicines, 23).

(Note, however, that the draft “Directions” do not go so far and say only that:

Where a PCT makes a decision to refuse a request for the funding of a healthcare intervention, where the PCT’s general policy is not to fund that intervention, the PCT must provide that individual with a written statement of its reasons for that decision. (Draft Direction to PCTs and NHS trusts concerning decisions about drugs and other treatments 2009).)

This “legalises” and “proceduralises” the process. It intensifies the problems inherent in these “agonisingly difficult decisions” and exposes PCT chief executives and medical directors to extreme pressure. Patient groups, the press and the Department of Health, will tend to press for treatment to be funded and many PCT board members will give way. Without support from the NHS Constitution, they will not have the time, or fortitude to argue the complex issues of opportunity costs and community interests. Many claims will be conceded and resources will be disinvested from planned uses to pay for treatments previously considered too expensive to merit funding.

Conclusion

The NHS Constitution explains the rights of patients without reference to the finite duties of PCTs. This is likely to generate unrealistic expectations of PCTs. If the imbalance is not redressed, we should expect more IFRs appeals and, in reality, a shift of finite resources toward vocal and well-represented groups. Inevitably, this will disinvest resources from planned uses and undermine policies that promote equality of access to NHS treatment.

Eight years ago, Professor Sir Ian Kennedy criticised the Department of Health. In Learning from Bristol he said:

Governments of the day have made claims for the NHS which were not capable of being met on the resources available. The public has been led to believe that the NHS could meet their legitimate needs, whereas it is patently clear that it could not. Healthcare professionals, doctors, nurses, managers, and others, have been caught between the growing disillusion of the public on the one hand and the tendency of governments to point to them as scapegoats for a failing service on the other … (Learning from Bristol, 2001, 57, para 31).

The NHS has received substantial new investment, but priority setting remains endemic to the work of PCTs. The NHS Constitution should be sensitive to Sir Ian’s criticism.

February 2009
Memorandum by the Centre for Health Economics, University of York (TF 44)

TOP-UP FEES

Benjamin Franklin remarked in 1789 that “in this world nothing can be said to be certain, except death and taxes”.38 To these certainties the economist would add the scarcity of resources, and the consequent need for careful resource allocation, which in health care is usually labelled “rationing”. The fiscal and monetary stimuli introduced to mitigate the global recession will mean that in the UK, after the next election, scarcity in public services will be acute. In these circumstances, the role of the National Institute for Health and Clinical Excellence (NICE) as a rationing body for the NHS becomes even more important.

At the same time, NICE is exhibiting continued and new problems in rationing access to health care. Industry, ably supported by patient groups they fund directly and Clinical Excellence (NICE) as a rationing body for the NHS becomes even more important.

The top up debate has raised two central issues about the regulation of the pharmaceutical market and the role of NICE: how to determine drug prices and how, if at all, to deal differently with “rare” and “end of life” interventions when making resource allocation decisions in health care.

Various forms of the Pharmaceutical Price Regulation Scheme (PPRS) have, since 1957, regulated companies’ rates of return on historic capital, but left companies virtually free to set prices. If profits exceeded a generous rate of return, usually around 21%, government has sought repayments and price cuts. Such action has been unusual. The Office of Fair Trading40 criticised PPRS and argued that “value based pricing” could save the NHS half a billion pounds. This intuitively appealing concept has influenced the design of the new PPRS, operational since the start of 2009.45

However, the government has proceeded with a level of caution and ambiguity that may undermine the rationing capacity of NICE. Part of the new PPRS establishes a “Patient Access Scheme”, whose role is “to facilitate early patient access to medicines that may not, in the first instance, be found to be cost and clinically effective by NICE.”46 This has resulted in draft proposals for a Patient Access Scheme Liaison Unit within NICE, which will advise Ministers about whether to allow early introduction of such products. Industry may be able to take advantage of either front-loaded schemes, which allow high price introduction but with agreement of repayments if evidence fails to demonstrate improved cost-effectiveness, or back loaded schemes which introduce the products at a lower price but allow prices to increase if research subsequent to launch demonstrates improved clinical and cost-effectiveness.

Great caution is needed with such schemes. For instance, the front loaded scheme adopted for beta interferon for multiple sclerosis, after NICE rejected the product, remains somewhat clouded in mystery, with the initial research team at Sheffield University ceding its evaluative role less than four years after the launch of the planned 10-year evaluation.47 There has been little reporting of evaluative data and no consideration so far of reimbursement of the NHS. Should drugs of unproven clinical and cost effectiveness be made available to patients with financial risk shared by the NHS, rather than increased investment in more definitive clinical trials being the obligation of industry? NICE has been parsimonious in its referral of unproven products for more research evidence, and should perhaps be more robust with industry, requiring it to provide good evidence of cost effectiveness or face rejection of NHS reimbursement.

Instead, the usual response by industry is advocacy of consideration of incentives for investment in “rare diseases” and “end of life care” both of which may in principle generate a lower return on investment. But given that increasingly new drugs are “designer” technologies for small subgroups of patients, often with particular genetic characteristics, many new products can be viewed as treatment for “rare” diseases. For example, while breast cancer is not a particularly rare condition, treatments such as trastuzumab (Herceptin) are clinically effective only for a sub-group of patients—in this case those who have HER-2 breast cancer.

46 Ibid.
Does this make it a rare condition? For the “rarer” cancers, the argument is that there should be special consideration of patient sub-groups of 7,000 or less. Again, the central issue is demonstrable cost-effectiveness rather than special consideration.

The concept of “end of life” care is equally debatable. How is “end of life” defined, and is it reasonable to prioritise more highly products that may extend the life of those with a terminal illness for perhaps a few months than products that, for example, improve quality of life over very many years? For both end of life care and rare diseases, the argument is essentially advocacy of investment which may be viewed as inefficient, and consideration must be given to whether these arguments are robust enough to justify inefficiency in order to achieve other desired objectives.

NICE uses, de facto, a rationing cut off of £30,000 per QALY.48 The “top up” debate and the discussion of “rare” diseases and “end of life” care have given rise to suggestions that this cut off be raised to circa £70,000 for these “special cases”.49 This would mean that some patients would be treated very differently from the majority of patients. This inequity would be compounded by inefficiency: funding at £70,000 per QALY would displace existing procedures which may be far more cost-effective.50

Instead of confused advocacy of more generous rationing criteria for sub-groups of patients, NICE and government should implement more parsimonious criteria. Research into rationing criteria use by PCTs indicates that their cut off is below £20,000 per QALY.51 The case for NICE-PCT consistency in rationing is as strong as the need to be even more rigorous in funding marginal technologies for use in the NHS.

These “wobbles” in NICE procedures are a product of the political consequences of the “top up” debate and confusion in the Department of Health, which is both the guardian of value for money in the NHS and the Whitehall sponsor of the pharmaceutical industry. NICE resistance to these pressures is essential as the NHS and its patients can not afford it departing from rigorous appraisal of the clinical and cost effectiveness of new procedures in a period of acute economic crisis.

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