

CHAPTER TWENTY SEVEN

Proposals for Change

Introduction

- 27.1 In this Report, I have examined the procedures that were in force within the NHS for the monitoring of general practitioners (GPs) during the whole of Shipman's career. I have also examined the procedures for the handling of complaints against GPs and the way in which concerns raised about a doctor were received and dealt with. My general conclusion has been that those procedures for monitoring were not such as could have been expected to pick up malpractice by a GP in the absence of a complaint drawing direct attention to that malpractice. I have also reported that, until the report made to the Coroner by the late Dr Linda Reynolds in March 1998, no complaints were made or concerns expressed to the authorities about Shipman such as might have given rise to the suspicion that Shipman was killing patients. I have concluded that, even if complaints had been made or concerns raised which might possibly have given rise to such suspicion, it is unlikely that an investigation would have taken place that might have uncovered Shipman's criminality. The system appears to have operated on the assumption that all doctors were essentially decent and strove to do their best for patients; a few would commit some form of misconduct and some might fail to provide an adequate standard of care. Those would be reported to an appropriate authority and would be dealt with. Shipman's was not the only case that demonstrated that these assumptions could not be made. Nor was his the first.
- 27.2 In the second half of the 1990s, the Government, the General Medical Council (GMC) and the medical profession had to come to terms with the unpalatable truth that the existing systems for monitoring the conduct and performance of doctors had failed to detect a number of severely dysfunctional practitioners. The public had been badly let down. Some realised that it must follow that the existing systems were also failing to detect dysfunctionality which was of a less serious kind but which might nonetheless put patients at risk of harm. Many people recognised that the whole system had to be overhauled.
- 27.3 The Inquiry's Terms of Reference conclude by requiring me to make such recommendations for change as I consider are necessary for the protection of patients. To that end, the Inquiry has sought to trace the progress of the overhaul of the systems and procedures by which patients should be protected from dysfunctional doctors. Because Shipman was a GP, the Inquiry was required to focus on the systems and procedures in operation in primary care. My general conclusion is that the overhaul has proceeded a long way, although it is not yet complete. The will to achieve change has been variable. In an organisation as huge and complex as the NHS and in a profession as large as medicine, that is not surprising. My overall impression is that there has been considerable will to bring about change within the Government and in some professional organisations, notably the Royal College of General Practitioners (RCGP). There has been substantial change within the GMC since 1998 and there is about to be more. However, in some quarters of the profession, there has been a disappointing reluctance to recognise the need for change. The view is too often heard that there is no point in change designed to

'catch another Shipman' because there will never be another one. Some within the profession have not recognised that the need for change goes far wider than that.

- 27.4 In this Chapter, I propose to consider how far the overhaul has proceeded and to make recommendations for its further progress in the interests of patient protection. Some of these proposals will be quite detailed while others will be of a more general nature, as I have already made a number of detailed recommendations in the preceding Chapters.

Proposals for Change Affecting NHS Arrangements for Primary Care

Changes and Reforms to Date

- 27.5 In 1997, the Government embarked upon a fundamental review of the operation of the NHS. One of the main aims underlying that review was to place a greater emphasis on quality of care. The corollary of that aim was that patients should not be exposed to avoidable risk at the hands of healthcare professionals. In the course of this Report, I have referred to several of the initiatives considered and the changes which have been brought about. I shall not describe those in detail here. It seems to me that, in the long term, the development of clinical governance, which I described in Chapter 12, could, if carried through with determination and adequate resources, have the greatest beneficial effect of all the changes I have examined.
- 27.6 Another notable development was the change in the structure of the bodies with responsibility for the provision of primary care. Primary care trusts (PCTs) are small organisations, small enough to enable their staff and those GPs who are directly involved in their work to develop personal knowledge of the GPs on their list. PCTs have many new powers. They are entitled to require far more information about a doctor before they decide whether to admit him/her to their lists than used to be the case, including information about his/her involvement in criminal or disciplinary proceedings. They have new powers enabling them to deal with dysfunctional doctors themselves, without having to rely on the Family Health Services Appeal Authority (Special Health Authority) or the GMC. They can remove or suspend doctors from their lists or impose conditions upon their continued inclusion. They are required to undertake clinical governance activities and are being encouraged to set up systems for the detection of poor performance and other forms of dysfunctionality in a GP before such shortcomings give rise to a serious risk of harm to patients.
- 27.7 One aspect of the thinking behind the change from health authorities (HAs) to PCTs was that local practitioners would now be closely involved in the work of the PCT and in making policy decisions affecting local medical services. It is usual for the Chairman of the Professional Executive Committee (PEC) of a PCT to be a GP. The PCT's Clinical Governance Lead is also likely to be a local GP. These arrangements have both advantages and disadvantages. One advantage should be an increased sense of involvement and 'ownership'. As a result, the feelings of tension and division between GPs and the bodies responsible for their monitoring and supervision should be reduced. A significant disadvantage is that there is a potential for conflict of interest for those GPs who are both local practitioners and PCT officers. There is, in any event, an element of conflict

between the roles that the PCT has to fulfil: sometimes offering support, sometimes having to act as an inspectorate.

- 27.8 PCTs have their problems. They are very new and have not yet had time to develop a corporate memory. Many of their staff have very little experience of the kind of quasi-managerial and supervisory functions that they have to perform. One of the problems inherent in the smallness of PCTs is that staff have to cover a wide range of functions and are unlikely ever to acquire real expertise in some aspects of their work; they will not have the opportunity to learn by regular experience. Some PCTs have found it helpful to band together into groups for some purposes. Another problem is that, because there are a lot of PCTs (over 300 in England alone), there are many different ways of doing things; standards are variable. Some PCTs appear to have difficulty in making their resources cover all the functions they are supposed to perform. My overall impression is that there is a real determination to make the new systems work well. I hope that PCTs will be given the chance to settle down; there was a period of almost constant change in primary care organisation for several years before the millennium and for a couple of years after. In my view, further structural change should be avoided for a while at least. PCTs need the opportunity to develop expertise and confidence in using their new powers. I think also that the exchange of ideas and the dissemination of good practice could help to ensure that high standards are developed uniformly across the country.

Areas in Which Further Change Is Needed

- 27.9 I mentioned earlier that clinical governance, if carried through with determination and adequately resourced, could make a very substantial difference to patient safety and to the quality of patient care. There are five particular aspects of clinical governance in its widest sense in respect of which I propose to make recommendations. These are the handling of patient complaints against GPs and of concerns expressed by medical colleagues, fellow healthcare professionals and others, disciplinary proceedings, the use of prescribing information, the use of mortality statistics and appraisal. The other main area in which I wish to make recommendations for change is in the provision of information, both for internal NHS purposes and to patients. I shall also make a number of miscellaneous recommendations about ways in which PCTs might improve patient protection and bring about an improvement in the quality of care provided by GPs.
- 27.10 Ideas for change covering these broad areas of interest were included in a Consultation Paper issued by the Inquiry in October 2003, entitled 'Safeguarding Patients: Topics for Consideration at the Stage Four Seminars'. These topics were the subject of discussion at the Inquiry's seminars held in January 2004. Details of these seminars are given in Chapter 2 and I shall refer to some of the discussions which took place at the seminars, and the points raised by respondents to the Inquiry's Consultation Paper, in the course of this Chapter.

Handling Complaints and Concerns

- 27.11 Several issues relating to complaints were raised in the Inquiry's Consultation Paper. Many organisations and individuals responded. By the time of the seminars, several more

issues had been raised, some by respondents to the Consultation Paper, others by the Inquiry itself as the result of evidence recently received. In this section of this Chapter, I shall discuss a number of these issues. In this discussion, I shall assume that the reader has read Chapters 6, 7 and 11 of this Report and is familiar with the systems in operation at the present time.

- 27.12 As I explained in Chapter 7, the Government has consulted extensively about the reform of the NHS complaints procedures. By the time the Inquiry seminars took place, draft Complaints Regulations had been circulated for consultation purposes. These draft Complaints Regulations proposed changes to both the first and the second stages of the procedures. In general, I considered that the arrangements set out in the draft Complaints Regulations were sensible and helpful and would lead to a substantial improvement in the complaints process as it operates in primary care.
- 27.13 One of the main provisions in the draft Complaints Regulations was the transfer of responsibility for the second stage of the complaints procedures from independent review panels (IRPs) to the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission). That proposal met with general support and the Government was anxious to implement the change. Accordingly, in July 2004, a new set of Regulations, the National Health Service (Complaints) Regulations 2004 (the 2004 Complaints Regulations), came into operation. These effected changes to the second stage of the complaints procedures but, so far as GP practices were concerned, left the first stage of the procedures as it was. The Inquiry was advised that it was the Government's intention to reform the first stage of the complaints procedures insofar as it affected GP practices after receipt of the Reports of this Inquiry and of the Neale and Ayling Inquiries. I was content with that arrangement. However, as a result of the separation of the new arrangements for the two stages of the complaints procedures, the present position and the interconnection between the two stages is perhaps a little confusing. I am confident that that situation will be remedied in the near future.
- 27.14 I will now deal with a number of different issues that arise in connection with the reform of the complaints procedures.

Who Should Receive Complaints?

- 27.15 At present, a person wishing to make a complaint about a GP has to make it, in the first instance, to the practice within which the GP works. Evidence received by the Inquiry and published research suggests that many people who wish to make a complaint are discouraged from doing so by the prospect of having to 'face' a member of staff or a doctor at the practice about which the complaint is to be made. In its Consultation Paper, the Inquiry asked whether such complainants should have the option of lodging their complaints with the PCT, rather than with the GP practice. Some respondents said that a choice would be welcomed by patients for the reason mentioned above. Those who were not in favour of choice preferred to keep the *status quo*, whereby all complaints relating to primary care are handled in the first instance by the practice. Two main reasons were advanced in favour of that arrangement. First, it was said that, if a practice is allowed to handle the complaint, there is a better prospect that the relationship of trust and

confidence between patient and doctor will be maintained. Second, it was said that many complaints in primary care relate to purely administrative matters and/or are extremely trivial; most can be satisfactorily resolved by the practice. It would overwhelm PCTs if they had to deal with large numbers of such complaints. However, by the time of the seminars, the Government had indicated, in the draft Complaints Regulations, its intention to allow patients to choose whether to complain to the GP practice or to the PCT.

- 27.16 It seems to me that the need for patient choice in this respect has been demonstrated by the findings in the research undertaken by the Public Law Project and in the York Report, to which I referred in Chapter 7. Those findings were that many patients were unwilling to complain directly to the doctor's practice. If confirmation of that is needed, it is to be found in evidence given to the Inquiry. I recognise the importance of retaining the relationship of trust and confidence between doctor and patient where possible, and I also accept that many minor complaints can be dealt with quickly and satisfactorily by a practice manager. However, if patients are being discouraged from making a complaint by the requirement to make it directly to the practice, they must be given an alternative. Those who are prepared to make their complaints directly to the practice will continue to do so and it is to be hoped that many such complaints will be resolved quickly and easily without damage to the relationship of trust and confidence between doctor and patient. However, those patients who do not wish to do so – for whatever reason – should, in my view, be able to lodge their complaint with the PCT and, if they wish, to avoid being obliged to enter into direct correspondence or discussion with the practice concerned. I think it likely that it will be the rather more serious complaints – those involving personal criticism of the doctor and/or the clinical care provided – which will be lodged with the PCT. I am not suggesting that this will always occur but I think this is the way in which most patients will behave. Accordingly, I do not think that the result of this change will be that PCTs will be swamped by trivial complaints. Nor do I think that this arrangement will be damaging to the relationship between doctor and patient. If the complaint relates to an administrative matter or some other minor problem, I would expect the PCT to facilitate a solution with a view to maintaining or restoring that relationship.
- 27.17 It is, in my view, desirable that, at the first stage of the procedures, GP practices should continue to deal with most of the complaints that patients bring directly to them. Steps should be taken to improve the standards by which such complaints are handled. The research suggests that the quality of complaints handling within general practice is very variable. GP practices should be helped to adopt a positive attitude towards complaints and to train their staff to handle complaints in an appropriate way.

When Must a Complaint Be Made?

- 27.18 Under the 1996 complaints procedures, a complaint had to be made within six months of the events complained about. Under the draft Complaints Regulations, this period would be extended to 12 months, with the possibility of further extension in some circumstances. In my view, that proposal was sensible. It effectively recognised that complainants may be ill or bereaved and may not be in a fit state to contemplate lodging a complaint until a considerable time after the events in question. Doctors should have good contemporaneous notes of all consultations and, thus, should not be seriously

disadvantaged by the extension of the period. Although one does not wish to encourage delay, 12 months seems to me a more reasonable period to allow. I hope that that change will be incorporated into the next set of Complaints Regulations.

The Reporting of Complaints to Primary Care Trusts

- 27.19 One of the issues raised in the Inquiry's Consultation Paper concerned the lack of information available to PCTs about the nature of complaints received by a GP practice and about the way in which they are handled and resolved. This type of information is important for several reasons connected with the PCT's responsibilities for clinical governance. First, the way in which complaints are handled by GP practices is or should be a matter of interest and concern to the PCT. It is an important indicator of the quality of the relationship that the doctors within the practice have with their patients. Second, as Professor Alastair Scotland, Chief Executive and Medical Director of the National Clinical Assessment Authority (NCAA), said at the seminars, the number and nature of the complaints received by a GP practice is likely to be an indicator of the quality of service it is providing. If either a practice or a particular doctor attracts a number of complaints – especially if those complaints are of a similar nature – alarm bells should begin to ring. At present, as I explained in Chapter 7, PCTs find out only how many complaints are lodged at a practice and know nothing of the content of those complaints unless the complainant proceeds to the second stage. Moreover, the PCT receives information about complaints by way of an annual return, not in 'real time' as the complaints are made. Many respondents to the Consultation Paper favoured the provision of more information to the PCT at more regular intervals.
- 27.20 By the time the issue was discussed at the seminars, it was known that the Government proposed to make changes that would give PCTs improved information about complaints and a discretion to decide how frequently they would require it to be provided. The draft Complaints Regulations would require primary care providers (i.e. GP practices) to provide PCTs with information about complaints at intervals to be specified by the individual PCT. The information would have to include the number of complaints received and their subject matter and would have to specify how the complaints had been handled, including the outcome. The PCT would be required to prepare a quarterly report containing this information for consideration by the PCT Board. At the seminars, there was discussion about the frequency with which GP practices should have to supply the information to their PCT. Some seminar participants thought that complaints should be reported to PCTs as they were made and should not be 'saved up' for periodic reports. Also, the view was expressed that the actual letter of complaint (if the complaint was a written one) or the practice's record of it (if it had been made orally) should be sent to the PCT. Mrs Pauline Webdale, representing the Association of Medical Secretaries, Practice Managers, Administrators and Receptionists (AMSPAR), told the seminars that, at the GP practice where she worked, all complaints were copied to the PCT soon after receipt. This gave rise to very little extra work. The practice did not receive many complaints in a year. My understanding is that the average figure over the whole country is about one complaint per GP per year.

- 27.21 I am impressed by the arguments in favour of the immediate reporting to the PCT of complaints received by a GP practice. I can see that, for some clinical governance purposes, a periodic report (say, quarterly) would be adequate. However, in one respect, immediate reporting would offer a distinct advantage. If the complaint were of a serious nature, the PCT would be able to intervene and to take over the handling of the complaint. I think that it must be recognised that, where a complaint is handled within a GP practice, the prime objective will usually be to 'satisfy' the complainant, in the sense of resolving the complaint in such a way that s/he will not be disposed to take the matter further. Seen in a positive light, that might be described as 'maintaining the doctor/patient relationship'. Seen from another angle, it might amount to 'back covering'. It is asking a lot to expect the complaints manager or a member of a GP practice with responsibility for handling complaints to deal objectively with serious allegations relating to misconduct or incompetence made against a member of a small practice team. In my view, in the unlikely event that a potentially serious complaint will, in future, be made directly to a GP practice (rather than to the PCT), it would be preferable for the PCT to 'call the complaint in' and to take it over from the practice. That could be done only if complaints are reported immediately and if the PCT sees the actual complaint or, if it has been made orally, a full account of it, as recorded by the practice.
- 27.22 Such a proposal could give rise to issues of patient confidentiality. However, in my view, these could be resolved. The patient could be asked to consent to the disclosure to the PCT of the letter or record of complaint. In the unlikely event of a refusal to consent, the letter of complaint could be anonymised and, if the PCT thought it desirable to call the complaint in, it could write to the complainant through the practice, to explain why it wished to investigate the complaint. If the patient refused, which I think would be unlikely, the PCT might well be unable to proceed with its investigation. However, depending on the subject matter of the complaint, it might wish to examine other information which was available about the doctor or to institute its own enquiries to ascertain whether there had been any other incidents of a similar nature reported in respect of the doctor. At least, the PCT would be aware of the fact that a complaint had been made and would be alert to any further complaint of a similar nature. Thus, it would be assisted in its clinical governance role.
- 27.23 Accordingly, I recommend that draft regulation 30 of the draft Complaints Regulations should be amended to require primary care providers to report all complaints to the PCT within, say, two working days of their receipt. The report should comprise the original letter or record of the complaint. It should also be open to a PCT to require delivery of a copy of any correspondence between the practice and the complainant, including the practice's letter of explanation. The PCT should then log the complaint for clinical governance purposes and, if it considers that clinical governance issues arise, the complaint should be 'called in' for investigation by the PCT.

Primary Care Trusts' Responsibility for the Investigation of Complaints

- 27.24 As I have said, I envisage that, in future, most complaints of any gravity will be made direct to the PCT, rather than to the GP practice concerned. The investigation and attempted resolution of complaints will be a new function for PCTs. Until now, they have handled

complaints only administratively. Complaints managers have 'smoothed the way' for patients making a complaint to a GP practice; they have arranged conciliation and, when necessary, they have made the arrangements for independent review. If the draft Complaints Regulations are enacted (as I hope they will be, with some amendment), PCTs will be responsible for some investigations at the first stage of the complaints procedures. If those investigations are not done thoroughly and objectively, the changes currently proposed will not bring the improvements hoped for. Indeed, in relation to complaints received in the hospital service, the Department of Health (DoH) has recognised that good investigation is essential, both out of fairness to both parties to the complaint and for the purpose of learning from experience. In the DoH's framework document, 'Maintaining High Professional Standards in the NHS', published in December 2003, the importance of prompt, thorough investigation of complaints against, and concerns about, hospital doctors is recognised. In each case, a case manager and a case investigator are to be appointed. It is obvious that comparable arrangements must be made for the prompt and thorough investigation of complaints received by PCTs. In my view, the provision of such arrangements is the single most important issue to be tackled in the reform of the complaints procedures.

The Purpose of Investigation

- 27.25 I ought perhaps to explain what I mean by the investigation of a complaint. By 'investigation', I mean the gathering of information and evidence relating to the circumstances giving rise to the complaint. Such an investigation might involve asking questions of the complainant and obtaining a statement from him/her, discovering from the complainant the identity of any potential witnesses and taking statements from them, obtaining a statement from the doctor complained of and from any witnesses whom s/he may put forward, obtaining the comments of the complainant (and possibly of other witnesses) about the account given by the doctor and *vice versa*, and initiating other enquiries (e.g. checking assertions made by the complainant or the doctor with third parties and/or with existing documentation). In the case of a complaint about clinical treatment, an investigation might also involve obtaining any relevant medical records, test results and other documents and obtaining evidence from an expert in the relevant specialty.
- 27.26 Regulation 20 of the draft Complaints Regulations requires the complaints manager of a PCT to investigate a complaint **'to the extent necessary and in the manner which appears to him most appropriate to resolve it speedily and efficiently'**. The complaints manager may request the production of information or documents to enable him/her to consider the complaint properly. No doubt it is intended that guidance will be made available to PCTs and their complaints managers as to how to go about the investigation of complaints. However, I am concerned to see that the words of the draft regulation mention only one purpose behind the investigation, namely the 'resolution' of the complaint. Nothing is said about the need to find out what happened and to establish the facts. Nor is there any reference to using the investigation of a complaint as a learning exercise, for the detection of misconduct or poor practice, or for the improvement of services. I would like to see statutory recognition of the importance of the proper

investigation of complaints to the processes of clinical governance and of monitoring the quality of health care. I also believe that, if PCTs were to approach their new duties in a spirit of learning through investigation, the outcome would be greater patient satisfaction. At present, many complainants feel that they must fight to have their complaint investigated properly. They want to feel that they can tell the NHS that something has gone wrong, in the knowledge that the matter will be fully looked into. I am sure that the Government recognises that the NHS should be able to provide a complaints procedure that does not require the patient to 'do battle'. If the new arrangements are to provide improved patient satisfaction and better learning processes, there must be thorough investigation.

The First Triage

27.27 The Inquiry was concerned to discover how complaints might best be approached so as to satisfy patients and detect poor practice. It appeared to the Inquiry that not all complaints would give rise to issues of misconduct or poor practice or to other issues which have a bearing on the quality of care or patient safety; some complaints might arise from a purely private grievance. I envisage that many 'private grievance complaints' will be of a fairly minor nature and will be made directly to the practice. However, it is likely that, under the new arrangements, some will be made to the PCT. The Inquiry invited discussion about whether it would be possible for a PCT to sort out which complaints it should investigate thoroughly for 'clinical governance' reasons and to differentiate them from ('private grievance') complaints which could properly be handled only with a view to providing 'resolution' for the complainant.

27.28 There was general agreement at the Inquiry's seminars that some sort of 'triage' of complaints would be helpful, although some participants felt that the line between the two types of complaint would not be easy to draw and that a complaint about a 'private grievance' matter might, on further examination, turn out to be indicative of more serious problems within the practice. For example, a complaint that the doctor had been late in arriving at the surgery and had kept the complainant (and possibly others) waiting for an unreasonable time is not likely to give rise to patient safety issues. The desired outcome is probably an explanation and an apology, coupled with an assurance that steps have been taken to ensure that the problem will not arise again. However, the point was made that, if complaints of this nature recurred, they might indicate that there was a problem with the doctor. I can see that. Nonetheless, I think that it will not be difficult for a PCT complaints manager to recognise a single complaint that gives rise or might give rise to clinical governance concerns when s/he sees it. 'Private grievance complaints' of the kind I have just described would not fall within this category, unless the complaints manager became aware of repeated complaints of a similar nature against the same doctor, in which case there would be grounds for investigating further. My reference to 'repeated complaints' implies that the complaint should be viewed in the context of any previous complaints or concerns which had been raised about the doctor, and this must be done. Sometimes, those previous complaints or concerns will have been wholly different and will have no relevance to the complaint under consideration. At times, however, previous complaints and concerns might be highly relevant.

27.29 Professor Scotland was of the view that there would have to be clinical input into any triage decisions to be made by a PCT. I think that he felt that complaints managers would not always recognise patient safety issues. My own impression of, say, Miss Andrea Horsfall (Complaints Service Manager, Oldham PCT) and Mrs Janet Parkinson (Consumer Liaison Manager, former West Pennine Health Authority (WPHA)), both of whom gave oral evidence to the Inquiry, is that they would be perfectly capable of recognising when a complaint raised a clinical governance issue or, at the very least, would recognise when they needed clinical advice before taking a decision. I think that, with appropriate training, they could undertake the first triage quite safely and with the assistance of advice when needed. However, I accept that Professor Scotland has greater experience of complaints managers than I have. In any event, I agree with him that the process of triage would be important and that whoever undertook it would have to be appropriately experienced and to have access to relevant clinical advice.

27.30 The first triage process would therefore result in the division of complaints into those involving purely 'private grievances' and those which required investigation by the PCT.

Investigation and Handling of 'Private Grievance Complaints'

27.31 At present, complaints managers have no experience in the investigation of complaints. However, I think that, with some training, PCT staff who have been accustomed to dealing with complaints administratively could be equipped to handle those types of complaint which do not give rise to patient safety or clinical governance issues. Complaints which give rise to purely private grievances will, in general, require only liaison with the GP practice or, if that fails, conciliation. The objectives should be the satisfaction of the patient and, where possible, restoration of the relationship of trust and confidence between doctor and patient.

Investigation and Handling of 'Clinical Governance Complaints'

The Second Triage

27.32 'Clinical governance complaints' must be investigated with the twin objectives of patient protection and satisfaction and fairness to doctors. PCTs will also wish to ensure that they have a full understanding of the events underlying the complaint in order to comply with their duty in respect of the quality of care provided within their areas. Such complaints will vary greatly in their complexity and potential seriousness. They should not be handled by a complaints manager, but should be referred to a small group formed for the purpose of handling complaints and concerns which raise clinical governance issues. The group might comprise two or three people – for example, the Medical Director or Clinical Governance Lead, a senior non-medical officer of the PCT and a lay member of the PCT Board. The group will have to consider the case (the 'second triage') and decide how it is to be handled. There should be accountability for this process at a high level.

27.33 The first decision will have to be whether the complaint is to be investigated by or on behalf of the PCT itself or whether it would be appropriate for it to be referred immediately to some other body, such as the police, the GMC or the NCA. If the police decide to investigate,

the PCT should put its own investigation 'on hold'. It might be necessary for the PCT to take immediate action for the protection of patients (e.g. by suspending the doctor from its list) or to ask the GMC to take such action. Discussion with the GMC might result in the GMC taking the case over or it might be decided that the complaint should be investigated by or on behalf of the PCT in the first instance. Similarly, with a case that clearly raised issues of poor performance, the NCAA might decide to carry out an assessment of the doctor or it might advise the PCT how to carry out its own assessment. If the complaint or concern suggests that the doctor may have a health problem, the PCT may wish to invite the doctor to be medically examined. Each of these courses of action should result in clarification of the way in which the PCT is to take the complaint forward. As at the first triage, the complaint must be considered in the context of any previous complaints or concerns about the doctor and in the context of the clinical governance information held by the PCT about him/her.

- 27.34 There is, however, a very important class of complaint, where the first priority must be to establish what actually happened. It is in dealing with this type of case that PCTs will face their greatest challenge.

Who Should Investigate a 'Clinical Governance Complaint'?

- 27.35 In evidence to the Inquiry, in responses to the Consultation Paper and at the seminars, there was a significant body of opinion expressing the view that, at present, most PCTs lack the resources and the expertise to carry out an effective investigation of a complex or potentially serious complaint.
- 27.36 Ms Linda Charlton, Director of Investigations, Office of the Health Service Ombudsman for England, said that her experience in the Ombudsman's office suggested that such investigative work as was currently carried out by PCTs was of very variable quality. Dr Malcolm Lewis, representing the GMC at the seminars, agreed with that view and said that cases reaching the GMC from PCTs showed a wide variation in depth of analysis.
- 27.37 There was a general view that, being small organisations, PCTs would not have a sufficiently frequent need for a skilled investigator to justify employing anyone in that capacity. It would not be satisfactory to assign the task to someone with many other duties to perform, as s/he would not acquire sufficient experience to carry out the task effectively. However, the contrary view was also expressed. Some PCTs felt that they were able to carry out effective investigation. It appears that, on the occasions when the need arises, such investigation would be carried out by the Medical Director or a Medical Adviser. My clear impression is that most Medical Directors and Advisers do not have the necessary skills. But, in any event, these officers have a very wide range of duties and it would not be feasible to expect them to focus on an investigation to the extent that is necessary once an investigation is underway.
- 27.38 During the hearings, several PCT employees and officers were asked to consider how they would go about investigating a hypothetical case, based broadly on the concerns that might have been reported (if any had been) about the circumstances of the admission to hospital of Mrs Renate Overton; I wrote about Mrs Overton's death in both the First and Third Reports, as well as in Chapter 10 of this Report. The reported concern would have

been that a GP had administered to a 46 year old asthmatic patient 20mg morphine, by injection, as a result of which the patient was deeply unconscious and unlikely to recover. A consultant at the hospital was of the view that the administration of such a quantity of morphine had been **'highly unusual, even dangerous'**. A complaint or expression of concern of this nature would not be easy to investigate well. It is not necessary here to discuss the suggestions that were made by the witnesses as to how they would have approached the task; suffice it to say that it is plain to me that such an investigation should be undertaken by an investigator who is not only trained in the techniques of investigation and case analysis but is also independent to the extent that his/her view of the GP concerned is not coloured by knowledge of the GP's reputation. It is vital that the investigator should adopt an objective and analytical approach and should not automatically accept the account of any witness, including the GP concerned, without testing its reliability against all the other available evidence.

- 27.39 The need for independence was demonstrated in my Second Report, where I described the approach of Dr Alan Banks, then Medical Adviser to the WPHA, to the task of examining the medical records of some of Shipman's deceased patients, with a view to ascertaining whether or not there was a pattern of 'common features' in the deaths. Dr Banks knew Shipman and held him in high regard. As a consequence, he failed to see the unusual features which characterised the deaths and which were evident from the medical records. He could not open his mind to the possibility that Shipman might have deliberately harmed a patient or even that he might have given him/her substandard care. A good investigator must have his/her mind open to all possibilities.
- 27.40 In some PCTs, such investigative work as must occasionally be done is carried out by the committee or group with responsibility for considering how to deal with concerns about a doctor's poor performance. It seems to me that these committees or groups may be well fitted for deciding whether an assessment of a doctor's performance should be undertaken (possibly by or under the guidance of the NCAA), and for considering what should be done when an assessment has been undertaken. However, the functions of assessment and investigation are different. If a PCT seeks advice from the NCAA about how to investigate, say, an adverse incident, the NCAA will do what it can to help by making suggestions. There is, at present, no NHS body with comparable functions in respect of investigation to those of the NCAA in respect of assessment. It does not seem to me that it would be satisfactory to assign the duty of investigating 'clinical governance complaints' of any potential gravity to a committee or group within the PCT, even if there were a suitable advisory body available.
- 27.41 I do not think that the staff of an individual PCT are likely to be satisfactory as investigators of complaints involving disputes of fact, issues of clinical judgement or potentially serious medical errors. At the seminars, there was a general consensus that the investigation of a complaint of any potential seriousness should be undertaken by a person or small team that was dedicated to the task. There was almost universal acceptance that individual PCTs were too small, and that their need for the service would arise too infrequently, to justify the employment of such a team.

Involving Other Bodies in the Investigation of a 'Clinical Governance Complaint'

- 27.42 Respondents to the Consultation Paper had been asked to consider whether there should be an outside body which would have responsibility for advising PCTs on investigations and which could, in particularly difficult cases, take over the investigation itself. Various bodies were suggested for consideration: strategic health authorities (SHAs), the NCAA, the Healthcare Commission and the medical Royal College rapid response teams. Views were also sought on whether a new body, independent of the NHS, should be established to receive and investigate complaints.
- 27.43 A number of respondents suggested that complex complaints should be dealt with outside the PCT. Some said that complaints should be investigated at SHA level, although others said that SHAs did not yet have sufficient investigative experience. Yet others thought that SHAs would not have the necessary independence. At the seminars, Mrs Flora Goldhill, representing the DoH, said that, although SHAs might be able to offer advice, it would not be in keeping with their functions to have responsibility for the direct conduct of an investigation.
- 27.44 Some respondents, including the Consumers' Association (now known as Which?), suggested that the Health Service Ombudsman might investigate complaints. The Ombudsman's office was perceived as being completely independent and its investigative work was recognised to be of a high quality. Ms Charlton said that, although it might be appropriate for some complaints to go directly to the Health Service Ombudsman, the great majority of complaints should be investigated at local level.
- 27.45 Some respondents thought that it might be appropriate for the Healthcare Commission to be involved in the investigation of complaints. However, by the time of the seminars, the Government had announced its intention that the Healthcare Commission should be responsible for the second stage of the NHS complaints procedures. Accordingly, it seems inappropriate that it should be involved at the first stage. I shall return to the role of the Healthcare Commission later in this Chapter.

How Should Specialised Investigative Skills Be Provided for Primary Care Trusts?

- 27.46 Ms Charlton suggested that proper investigative procedures could be put in place at local level, but only if PCTs were to join together, possibly across the area covered by each SHA, to pool investigative resources. She agreed that, if there was a high turnover of staff in a PCT, this would result in a lack of continuity of expertise. The pooling of resources would lessen the impact of this. Professor Richard Baker, Director, Clinical Governance Research and Development Unit, University of Leicester, also supported the idea of pooling resources and suggested that the ideal team might consist of a manager, a nurse or physician assistant and a doctor. The team should be able to call on external advisers when necessary. He thought that PCTs would need to be in groups of at least six to provide those resources. It emerged that the Health Service Ombudsman's investigative team (which is of course much larger than would be required for a group of PCTs) comprises lay investigators. Ms Charlton said that, in recruiting for the team, the Health Service Ombudsman looks for people with experience in dealing with large quantities of

information, with good analytical skills and with the ability to speak confidently to doctors and complainants about the issues involved. The investigators have access to independent clinical advice as and when necessary. The investigators collect and analyse the evidence and write a report setting out conclusions and recommendations. Ms Charlton thought that it would be preferable for the investigation of complaints on behalf of PCTs to be carried out by lay persons with access to clinical advice, rather than by clinicians. She stressed that it was important from the public's point of view that the investigation of doctors should not be carried out by doctors. Dr John Grenville, who represented the British Medical Association (BMA) at the seminars, agreed that investigations should be carried out by lay persons, but said that the provision of expert clinical advice, specifically relevant to the area(s) of complaint, was vitally important. Mrs Goldhill, for the DoH, agreed that it was essential that PCTs should have access to high quality investigative skills and said that the pooling of resources by individual PCTs might be a sensible solution.

- 27.47 There was general agreement that investigators must be properly trained. Mrs Goldhill spoke of the steps to be taken by the DoH to develop such training and mentioned a programme run by Middlesex University. She also said that the DoH was working on a good practice toolkit for the handling of primary care complaints.
- 27.48 Another reason advanced in support of the idea that PCTs should band together to provide an investigation team was that it would reduce the problem created by the perceived conflict of interest if a PCT were to investigate (as it would otherwise have to do) a complaint against a GP on its own list. The potential conflict was said to arise out of the dual role of providing support and assistance to GPs on the one hand and investigating or 'policing' GPs on the other. However, the problem could be more acute than that. The Inquiry has become aware of instances when the GP under investigation has been a member of the PCT's PEC – even the Chairman – or of the PCT's performance group. There is plainly a direct conflict there. Professor Scotland said that the pooling of investigative resources by groups of PCTs would reduce any potential problem of a conflict of interest. I agree, and add that it would also increase the independence and objectivity of the investigation.
- 27.49 I think that the best course will be for groups of PCTs to set up joint investigative teams. I express no view as to how many PCTs should band together; much will depend on the size of the PCTs and the geographical configuration of the group. I say nothing about the constitution of the team, save that it appears to me that it would be sensible for the DoH to take advice from persons such as the Health Service Ombudsman who have experience of this function and to disseminate that advice to PCTs.

The Conduct of the Investigation of a 'Clinical Governance Complaint'

- 27.50 In my view, where it appears to the person or group responsible for carrying out the second triage within the PCT that there is uncertainty about the events giving rise to the complaint, because there is a conflict between the account of events given by the doctor and the complainant, or for some other reason, the complaint should be referred to the inter-PCT investigation team. It should be the task of that team to carry out an investigation

along the lines described at paragraph 27.25. Its objective should be to reach a conclusion as to what happened and to set out the evidence and conclusions in a report which should be delivered to the PCT on whose list the doctor's name is included. There may be cases in which it is quite impossible for the investigators to reach a conclusion about what happened because there is a conflict of evidence. In that event, they must say so in their report.

Deciding Where the Truth Lies in a 'Clinical Governance Complaint'

27.51 At the seminars, there was discussion about how disputed facts should be resolved once an investigation had been carried out by or under the auspices of the PCT. One option was that an oral hearing should be held locally and a panel should decide where the truth lay and make the necessary findings of fact. As I explained in Chapter 6, that is what used to happen before 1996. All complaints that appeared to amount to a breach of the GP's terms of service were heard by a medical service committee (MSC) of the family practitioner committee (FPC) or, later, the family health services authority (FHSA). The MSC was able to resolve any factual disputes. Since 1996, there has been no facility to resolve disputes of fact at the first stage of the complaints procedures. This may well account for at least some of the dissatisfaction felt by complainants. If the doctor gives a different account of events from that of the complainant, it is likely that the practice complaints manager or another member of the practice will accept the doctor's version and will seek to 'resolve' the complaint on that basis. When such complaints are investigated by an inter-PCT team as I have suggested, it is to be hoped that the investigators will be less likely to display any such bias. Indeed, a team of investigators serving a group of PCTs might be expected to approach a complaint with a greater degree of independence than would an officer of an individual PCT. However, there may be circumstances in which a dispute of fact is crucial to the resolution of the complaint and where it is impossible to make a fair determination of the issue without hearing oral evidence.

Acting on the Investigation Report Where There Are Unresolved Factual Disputes

27.52 At the seminars, the view was expressed that it would not be appropriate to convene an oral hearing locally during the first stage of the complaints procedures. It was said that the experience was too stressful. Others favoured oral hearings because they enabled those involved to hear all the evidence. It was said that, if a hearing was held, the PCT should present the complaint to the hearing, rather than leave the complainant to 'prosecute' the complaint. However, I have come to the conclusion that there should not be an oral hearing locally at the first stage. If the report of the investigating team is inconclusive because of a dispute of evidence, the case should, in my view, be referred to the Healthcare Commission, under the power which will, I hope, be included in the amended draft Complaints Regulations which the Government intends to implement in the near future. Later in this Chapter, I shall discuss a provision in the draft Complaints Regulations whereby a PCT would be able to refer a complaint to the Healthcare Commission at any point in the first stage of the complaints procedures.

Acting on the Investigation Report Where All Factual Disputes Have Been Resolved

- 27.53 When the investigation report is complete, it should be considered by the PCT at a high level. I suggest that it would be appropriate for this to be done by the same group that carried out the second triage. The report should be viewed in the context of the doctor's past history. The PCT may wish to take action. It may be appropriate at that stage to refer the matter to the GMC. Referral to the NCAA may be appropriate. If a systems failure has been revealed, referral to the Healthcare Commission might be the best course. On the other hand, the report may reveal misconduct or deficient performance, but not of a sufficiently serious nature as to warrant referral to another body. The PCT might feel able to deal with the matter itself, either through its performance panel or by invoking its list management powers or the disciplinary powers that I shall recommend that PCTs be given. It might wish to liaise with the local deanery about the provision of supervision or retraining for the doctor. The point was made that there was a need for clearer standards to be established for onward referral and it was suggested that protocols should be devised for the guidance of the PCT.
- 27.54 Meanwhile, it is, of course, important that the complainant is kept fully informed about the progress of the investigation and, save to the extent that disclosure would breach the doctor's medical confidentiality, that s/he should be fully informed of the outcome of the investigation and the steps to be taken as a result. If the investigation and decision as to how to proceed could be carried out thoroughly and with a reasonable degree of expedition, it would, in my view, remove many of the causes for dissatisfaction inherent in the present arrangements for the handling of complaints. It would also enable prompt steps to be taken in those cases which raise patient protection issues.

Refusal to Proceed with the Investigation of a Clinical Governance Complaint If There Are to Be Concurrent Proceedings

- 27.55 The draft Complaints Regulations provide for the circumstances in which a NHS body might refuse to proceed with the investigation of a complaint where other forms of proceedings are or might be taking place at the same time. One such other form of proceeding is a civil action for damages.
- 27.56 In Chapter 7, I mentioned that, under the 1996 complaints procedures, a complaint could not be accepted for independent review if the complainant intended to institute legal proceedings or, presumably, if s/he had already done so. In evidence to the Inquiry, Miss Horsfall said that she felt this was sometimes unfair. In my view, not only is it unfair but it is inappropriate.
- 27.57 Although one of the purposes of a complaints procedure is to 'satisfy the complainant', a much more important purpose is to find out what has happened and to decide whether there is a need to take any steps necessary for the protection of patients. Whenever an adverse event has occurred which raises issues of patient safety, the responsible organisation should conduct an internal investigation for that purpose. I cannot see that the position should be different just because a complaint has been made. If a PCT becomes aware of an adverse event affecting a patient, it should investigate the event

whether or not a complaint is made by or on behalf of the patient. That should be done whether or not any person has expressed an intention to take legal proceedings.

- 27.58 Under the draft Complaints Regulations, it was provided that concurrent legal proceedings would not be a complete bar to the investigation of a NHS complaint at the first stage of the complaints procedures. However, NHS bodies would, in certain circumstances, be able to decide not to begin or continue with an investigation. A complaint which was also to be the subject of a civil action was to be designated a **'complex complaint'**. Draft regulation 18 allowed the relevant NHS body to investigate a **'complex complaint'** if it considered that to do so would not **'compromise or prejudice the concurrent investigation'**. Also, a NHS body could discontinue the investigation of a **'complex complaint'** if it considered that **'to continue would compromise or prejudice the concurrent investigation'**. That meant, for example, that if the widow of a patient of a GP intended to sue the GP in respect of the death of her husband, the PCT would be able to refuse to investigate a complaint lodged by the widow in connection with the death. In my view, that is not entirely satisfactory because it might prevent the PCT from carrying out its clinical governance duties. I am aware that, so far as complaints about secondary care are concerned, the 2004 Complaints Regulations (to which I referred in Chapter 7) prevent a NHS body from investigating any complaint if there are any concurrent legal proceedings. For the same reason, that seems to me to be quite unsatisfactory.
- 27.59 If a PCT learns of an adverse incident (either because a complaint is received or in any other way), it should investigate and it should offer to disclose the substance of the report of the investigation to the patient or next of kin, whether or not a complaint has been made and whether or not the doctor is to be sued. The PCT should investigate for clinical governance reasons and should take whatever action is necessary in the interests of patient safety. It should not bow to any pressure not to investigate from the medical defence organisation which indemnifies the GP and which might have an interest in suppressing the information that would come out in an investigation. I hope that the Government will think again about this issue and will decide that a complaint should always be investigated, even where legal proceedings are intimated or underway. I strongly recommend that the fact that such proceedings are proposed or have begun should not be a bar to the investigation of a complaint.
- 27.60 As I explained in Chapter 7, the fact that a NHS body was taking disciplinary proceedings against a doctor would not, under the draft Complaints Regulations, have precluded the furtherance of a complaint brought by a patient. However, the existence of proposed or actual disciplinary proceedings in relation to the substance of the complaint will, under the 2004 Complaints Regulations, now cause a complaint (in relation to secondary care) to be excluded from the operation of the Regulations. In my view, neither the provision in the draft Complaints Regulations nor that in the 2004 Complaints Regulations is satisfactory. If disciplinary proceedings relating to the subject matter of the complaint are contemplated, that presupposes that the event in question has already been investigated. In my view, the complainant should see the substance of the report of the investigation on which the disciplinary proceedings are to be based.

27.61 The draft Complaints Regulations also provide that the NHS body receiving the complaint may defer or discontinue the investigation of a complaint if the matter is being investigated by the police, a regulatory body, a statutory inquiry or some other process. I would accept that, sometimes, in such situations, a NHS body may have to defer its own investigation into a complaint or concern, but it should never lose sight of its duty to find out what has happened and to take whatever action is necessary for the protection of the patients of the doctor concerned. It should also, in my view, provide such information to a complainant as is consistent with the need, if any, for confidentiality in the public interest. I hope that the DoH will redraft these provisions to reflect the principles I have enunciated.

The Role of the Healthcare Commission in the Investigation and Determination of 'Clinical Governance Complaints'

27.62 As I have said, in its Consultation Paper, the Inquiry raised the possibility of complaints being investigated by or with the advice of the Healthcare Commission. From December 2003, it became known that the Healthcare Commission would be responsible for the second stage of the complaints procedure, and it took over that role with effect from 30th July 2004. How these procedures are working in practice, it is too early to say. The Healthcare Commission is a new organisation with many wide-ranging responsibilities, which are designed to encourage improvement in the provision of health care. In order to fulfil its responsibilities for the second stage review, the Healthcare Commission has set up a Complaints Department employing about 70 investigators.

27.63 The view was expressed at the Inquiry's seminars that the resolution of purely 'private grievance complaints' might be a waste of the Healthcare Commission's resources. Mrs Elizabeth Dimond, who had been appointed as Complaints Lead of the Healthcare Commission in advance of the implementation of the reform of the second stage of the complaints procedures, was asked about this. She said that, under what was then draft regulation 23, the Healthcare Commission would not be bound to accept all complaints and, if it appeared that the complaint had been properly handled at the first stage, the request for a review might be refused. I understood from this that, if the complaint was of a minor 'private grievance' nature, the Healthcare Commission might well decline to consider it. On the other hand, if it appeared that the complaint had not been properly handled at the first stage by the GP practice and/or the PCT, the Healthcare Commission might well accept the case with a view to correcting the complaints handling procedures. In those circumstances, it might be appropriate for a 'private grievance complaint' to be considered. In any event, the Healthcare Commission should be well placed to ensure that any lessons that can be learned from its part in the resolution of patient complaints are properly disseminated.

27.64 Under regulation 16 of the 2004 Complaints Regulations, the Healthcare Commission can, on receipt of a complaint, follow one of several different courses, including (as I have said) taking no action. It will be able to refer a complaint back to the first stage of the complaints procedure with recommendations for further action, or to investigate the complaint itself (with or without a panel hearing) or to refer the complaint to a regulator. I expect that the power to refer a complaint to a panel will be used mainly in cases where it is necessary to resolve a conflict of fact by hearing oral evidence.

- 27.65 Under draft regulation 19, it was proposed that PCTs should have the power to refer a complaint (which they were handling at the first stage) to the Healthcare Commission at any time, provided that the complainant and the Healthcare Commission consented. This proposal has not been incorporated into the 2004 Complaints Regulations but I hope that it will be included in the new Regulations. In my view, it is a very good idea, because the Healthcare Commission's investigating facility could be deployed in the first stage of the complaints procedures in difficult cases, as well as (under the arrangements recently introduced) on second stage reviews of less complex cases. It would be particularly appropriate for a case to be referred upwards either if it was necessary to determine a factual dispute or if the complaint was particularly complex, difficult or serious. A referral to the Healthcare Commission should be capable of being made at any point in the first stage of the complaints procedures. That would mean that a complaint could be referred at the time of the second triage, if it was clear that the issues were complex. For example, the complaint might involve issues relating to both primary and secondary care. The referral might also take place later if the inter-PCT investigation team discovered that the complaint raised more complex issues than had been appreciated.
- 27.66 Alternatively, as I said at paragraph 27.52, referral might take place when the inter-PCT team found that it could not reach a conclusion because there remained unresolved disputes of fact. The Healthcare Commission would have the facility to carry out further investigation to the extent necessary and, if appropriate, to set up a panel to hear oral evidence about the facts in dispute and to decide where the truth lay.
- 27.67 On the face of it, referral to the Healthcare Commission would seem to be an ideal way of dealing with complex investigations and with those requiring an oral hearing. Not only would the Healthcare Commission have the necessary resources and expertise, it would also be seen to be independent. However, Mrs Dimond told the seminars that the primary purpose of the provision in draft regulation 19 was to allow the PCT to refer a case during the first stage of the complaints procedures where the complainant had 'lost faith' in the local NHS system, rather than to allow it to pass on cases that were beyond the expertise of the PCT. Indeed, she seemed surprised at the suggestion that cases might be referred because of such a lack of expertise. However, she did say that the Healthcare Commission would probably accept referrals from a PCT where the PCT lacked the necessary expertise to investigate. I hope that the Healthcare Commission will be prepared to accept such cases and that it will have the resources necessary to deal with them.
- 27.68 One potential disadvantage of sending complex complaints and complaints requiring an oral hearing to the Healthcare Commission during the first stage would be that there would then be no second stage or 'appeal' available to the complainant. In my view, that should not matter, because the complainant would already have been able to take advantage of the resources and independence of the Healthcare Commission. Moreover, if s/he remained dissatisfied, recourse to the Health Service Ombudsman would be a possibility. Some complainants might not see matters in that light. Nonetheless, I consider this the best way forward.
- 27.69 At the seminars, there was some discussion about the form of the oral hearings that should take place during the second stage of the new complaints procedures as they are at

present. The draft Complaints Regulations provided for the Healthcare Commission to refer a complaint for hearing by a panel of lay people in an appropriate case. At the seminars, Mrs Dimond said that a case would be sent for a hearing by a panel only if the complainant was 'comfortable with that option'. I was concerned to hear that. In my view, a decision to convene a panel should be taken by the Healthcare Commission (after consultation with those involved); the complainant should not be allowed to exercise a veto. The Healthcare Commission has a duty to be fair to the doctor as well as to the complainant, and there is a public interest to be served in finding out the truth. I am pleased to see that the 2004 Complaints Regulations now provide for the decision whether to refer a complaint to a panel to be taken by the Healthcare Commission after consultation with the parties.

- 27.70 Mrs Dimond also said that, if a panel was convened, it would adopt an inquisitorial, rather than an adversarial, approach. That, I think, is sensible. She said that it would be open to the complainant to request that the doctor be excluded whilst s/he was giving evidence. I hope that that does not mean that, if such a request was made, it would necessarily be granted. If so, I would be concerned about that. Such decisions should be for the panel, after hearing the views of both parties. The complainant should not, in my view, have the right to dictate whether the other party is present during the evidence. However, perhaps this problem will not often arise. Mrs Joyce Robins, who represented Patient Concern at the seminars, said that one of the most unsatisfactory aspects of the IRP process was that complainants were not allowed to hear what the doctor had to say. I would favour a general rule that both parties should be permitted to hear the other's evidence and that of the other witnesses. What should, in my view, be avoided is adversarial cross-examination.
- 27.71 I was also rather concerned to hear from Mrs Dimond that the Healthcare Commission might encourage conciliation in cases in which there was a conflict of fact. Mrs Robins was strongly opposed to such an idea. She said that, where there was a conflict of evidence, a determination of the facts was required. I entirely agree with her. It will be impossible for a PCT to know what, if any, action it should take in order to protect patients unless there has been a hearing in order to determine the factual basis of the events giving rise to a 'clinical governance complaint'.

Private Sector Complaints

- 27.72 Another issue relating to the Healthcare Commission was raised at the seminars by Ms Beverley Cole, representing the National Care Standards Commission (NCSC). She was concerned about the handling of complaints made in the private sector. The NCSC has now been subsumed into the Healthcare Commission. Although the NCSC has jurisdiction to investigate complaints about service provision in the private sector, its powers are limited to complaints that amount to a breach of the relevant Regulations or a failure to comply with specified minimum standards. As Ms Cole agreed, the only recourse for some patients who have been treated in the private sector is to complain to the GMC. However, as the Inquiry has discovered in the context of its examination of the GMC's old fitness to practise (FTP) procedures, the GMC's attitude to a complaint about treatment in the private sector was, after the establishment of the NCSC in 2002, to advise the complainant to make use of the local complaints procedures if these had not been

exhausted. If the local procedures had not been exhausted, the GMC would accept the complaint only if it appeared that the doctor might be a danger to patients or the public or if the complainant insisted on pursuing his/her complaint through the GMC. I have already made it clear that that was not, in my view, a satisfactory state of affairs. No doubt the large private healthcare organisations have systems for the investigation of complaints. How well they operate, I do not know. However, I have grave doubts whether all small commercial organisations, such as slimming clinics or cosmetic surgery clinics, will have adequate systems for handling patient complaints. It seems to me that it might be difficult for a patient dissatisfied with treatment provided by a small private organisation – or, worse, a single private practitioner – to have his/her complaint adequately investigated. Complainants in the private sector are at another disadvantage; they do not have access to the Health Service Ombudsman.

- 27.73 What the position will be under the GMC's new FTP procedures is not completely clear. The available guidance relating to the new FTP procedures suggests that all complaints which do not obviously fall outside the GMC's remit will be accepted for investigation. However, that was ostensibly the position under the old FTP procedures, but it was not the practice. I have carefully examined the Rules governing the new procedures and all the related guidance and instruction of which I am aware. It appears to me that the GMC has decided to discontinue its former practice of advising complainants to pursue their complaints through local procedures. I hope that I am right in reaching that conclusion.
- 27.74 It seems to me that it would be highly desirable for the complaints handling systems in the private sector to be aligned as closely as possible with those in the NHS, so that a complainant who did not receive satisfaction from a private sector body can proceed to a second stage conducted by the Healthcare Commission. Then, the Healthcare Commission could investigate the matter properly, if appropriate. I would also like it to be able to accept and investigate expressions of concern (for example, from colleagues) arising about doctors working in the private sector, other than those concerns which manifestly require the attention of the GMC. I realise that the Healthcare Commission has been charged with a wide range of functions and that it probably has to manage on limited resources. Nonetheless, I hope that, in future, it will be able to develop as an independent centre of expertise in medical investigation.

Should There Be a New Independent Complaints Handling Body?

- 27.75 Because the Inquiry was aware that there was some dissatisfaction with the way that complaints are handled within the NHS, by private sector providers and at the GMC, the Consultation Paper raised the question whether there should be a new independent complaints handling body to deal with all complaints within the NHS and private sector. Those complaints which, in the view of the complaints body, warranted the attention of the GMC could be referred to it after investigation. There was little support among respondents to the Consultation Paper or participants at the seminars for the idea of creating a new independent complaints handling body. The main reason for the lack of enthusiasm was that there has recently been a great deal of structural change in the NHS and there is a widely held view that there should be fewer bodies and organisations in the healthcare system rather than more. I agree with that view. I also think it preferable that

most complaints should be handled locally so that there can be local investigation and, where appropriate, local corrective measures.

Should There Be a New Independent Inspectorate?

27.76 Two respondents to the Consultation Paper, Dr William Pickering and Mr Patrick Tierney, suggested that an independent inspectorate should be established to investigate poor clinical practice revealed through complaints and monitoring. They envisaged that the inspectorate would cover both the public and private sectors. When this idea was circulated for discussion, it received very little support, particularly because it was perceived that the creation of such a body would entail significant reorganisation, or even the abolition, of existing bodies such as the Healthcare Commission, the NCAA and the GMC. A number of participants at the seminars thought that the Healthcare Commission would develop its inspectorate role and would take on the functions envisaged by Dr Pickering and Mr Tierney. I have already expressed the hope that the Healthcare Commission will be able to develop its investigative functions so as to provide expertise and independence, which are, I think, the qualities that Dr Pickering and Mr Tierney wish to see. Of course, if it should transpire over the next few years that the Healthcare Commission does not provide the thorough and independent investigations that it is hoped it will, then it would, I think, be necessary to consider an alternative solution. But, in my view, the Healthcare Commission must be given the opportunity to develop these important functions.

Handling Concerns

27.77 One of the features of the 1996 system of complaints handling which struck me as anomalous and potentially unsatisfactory was that complaints lodged by a patient or his/her representative were in the past handled differently from concerns expressed about a GP by, for example, a fellow healthcare professional. The subject matter of a complaint and that of a concern might be identical; the only distinction between the two would have been the identities of the people who conveyed the information. But the method of handling was quite different. Whereas a concern would in general be referred straight to the PCT committee or group with responsibility for considering how to deal with concerns about a doctor's poor performance, a patient complaint might not even be known to the PCT if it was 'resolved' at practice level. Until July 2004, it would go to the PCT only if the complainant wished to apply for independent review. Since July 2004, however, it has been possible for a complaint to by-pass the PCT entirely and to go straight from the local resolution first stage directly to the Healthcare Commission. At the Inquiry seminars, there was wide acceptance that it is illogical to treat a patient complaint differently from a concern expressed by someone else.

27.78 If and when PCTs have full information about patient complaints and receive the more serious ones directly, this disparity of treatment should disappear. If PCTs or groups of them have access to a team of investigators, it will be possible to refer both complaints and concerns to them. Also, if it is envisaged that the Healthcare Commission is to play any significant role in the investigation of complex, difficult or potentially serious complaints, it

should also be able to undertake the investigation of concerns that raise difficult or potentially serious issues. At the moment, the draft Complaints Regulations anticipate that a PCT will be able to refer a patient complaint to the Healthcare Commission (with the patient's and Healthcare Commission's consent). However, the Healthcare Commission cannot accept a reference that does not originate as a patient complaint unless the reference comes from the Secretary of State for Health (SoS). If it is to be intended that the Healthcare Commission should develop investigative expertise for the benefit of the whole healthcare system, I would suggest that consideration should be given to amending the legislation to permit the Healthcare Commission to accept a concern referred to it by a PCT (or other healthcare body) without the need for a reference from the SoS.

The Standards by Which Complaints Are to Be Determined

- 27.79 One of the (probably unforeseen) consequences of the dissociation of disciplinary proceedings from patient complaints in 1996 was the loss of any (even partially) objective standard by which a complaint could be judged. Before 1996, a complaint was upheld if the doctor was found to have breached his/her terms of service. The sanction imposed depended upon the gravity of the breach and the doctor's past record. To some extent, the MSC had to exercise discretion as to whether a breach had occurred, for example when considering whether the doctor had provided all the services reasonably to be expected of a GP in the circumstances. However, at least there was a legal framework within which the decision was taken.
- 27.80 From 1996, disciplinary proceedings could be taken for alleged breaches of the terms of service but, in fact, they hardly ever were. Complaints could be lodged in respect of all matters, whether or not they were covered by the GP's terms of service. However, there was no framework at all to help the GP practice complaints manager or the IRP to decide whether to 'uphold' the complaint, or to help the convenor to decide whether to convene a IRP. It might be that some IRP members who had formerly sat on MSCs still applied the standards of the terms of service where possible. Since April 2004, when the new General Medical Services (GMS) Contract came into effect, there have not even been terms of service to act as a background framework. In effect, a complaint is upheld if the decision-makers think it should be. At the first stage, the lack of any objective standards or even guidelines must make the task of the practice complaints manager or supervising partner in a GP practice extremely difficult. It is always hard to be objective when judging a close colleague but it must be much more difficult in the absence of any standards.
- 27.81 Now that many decisions about complaints will be taken by PCTs and by the Healthcare Commission, it is to be expected that decision-makers will have greater independence of mind than practice managers and, possibly, than local IRPs. However, in my view, they will need standards by which to decide whether or not a complaint should be upheld. In the past, I suspect that this issue has sometimes been 'fudged' because it has not always been necessary to make a positive decision to uphold or reject the complaint; it has sometimes been sufficient to 'satisfy' the complainant. If, as is contemplated in the DoH publication 'Making Amends', there is to be provision for financial redress, a definite decision will have to be made. It ought to be made whether or not redress is available.

27.82 It is disappointing that the draft Complaints Regulations and the 2004 Complaints Regulations have not attempted to grapple with this issue. In my view, it must be tackled. There must be, at the very least, a standard against which a complaint can be judged. Patients should know what their reasonable expectations are and should be entitled to have their complaints upheld when those reasonable expectations have not been met. I have mentioned elsewhere in this Report the need for standards by which the GMC can decide whether and, if so, how it should take action against a doctor. There is also a need for standards by which PCTs and other NHS bodies can decide whether they should invoke their list management or disciplinary powers or whether they ought to refer the doctor to the GMC. At the moment, all the people who take these important decisions have to do so simply on the basis of what they think is right. There is an urgent need for standards to be established for all these purposes. It seems to me that this should be a task for the Healthcare Commission, in conjunction with the GMC and the DoH, after consultation with patient groups and the wider public. The standards pertaining to patient complaints and those by which PCTs and other NHS trusts should make their decisions should not be set in isolation. They must fit together with the threshold by reference to which the GMC will accept and act upon allegations so as to form a comprehensive framework. I shall return to the issue of standards later in this Chapter.

Support for Complainants: the 'Single Portal'

27.83 It seems to be generally acknowledged that there is some confusion in the public mind as to how to go about making a complaint about a healthcare matter. Many people are under the impression that any complaint about a doctor should properly be addressed to the GMC. In fact, under its old FTP procedures, the GMC would accept only complaints that were (broadly speaking) sufficiently serious to raise a question of serious professional misconduct (SPM), seriously deficient performance (SDP) or seriously impaired fitness to practise due to ill health. Even then, as I have said, if there were local complaints procedures available, the complainant would be advised to pursue the complaint by means of those, unless the doctor was thought to be dangerous or the complainant insisted on his/her complaint being dealt with by the GMC. In future, under its new FTP procedures, the GMC will have a single criterion for acceptance of a complaint or concern, namely that an allegation has been made that a doctor's fitness to practise is impaired. Fitness to practise is to be regarded as impaired only by reason of misconduct, deficient professional performance, a conviction or caution, adverse physical or mental health or an adverse determination by another regulatory body. I think that many people will have difficulty in making up their minds whether the matters of which they wish to complain will fall within the GMC's remit. I think that, unless this remit is explained in ordinary language, it will be difficult for healthcare professionals and healthcare managers – let alone members of the public – to decide whether a case should be sent to the GMC. The fact is that the GMC is not the appropriate recipient for many minor complaints about a doctor.

27.84 It is clear that there is a good deal of confusion about the right place to direct a complaint about a doctor. The Inquiry was told that the NCAA and the Health Service Ombudsman both receive complaints about doctors direct from the public. No doubt there are many other organisations that do so. A patient who asks advice from either

the NCAA or the Health Service Ombudsman about where and how to complain will be directed to the appropriate destination, although the question is not always an easy one to answer, particularly where the complaint involves more than one aspect of a patient's treatment. However, many complainants who think that they know where to lodge their complaints in fact send them to the wrong places. A similar problem exists for persons who wish to make a confidential report relating to some sort of suspected malpractice about which they are concerned. I described the problems they face in Chapter 11. No doubt a sustained programme of public education could improve the position for complainants and those who wish to report a concern, but the problem is bound to persist to some extent.

- 27.85 In the course of the Inquiry, the GMC suggested a possible solution to this problem. It proposed that there should be a 'single portal' or gateway to which anyone who was in doubt about where to lodge a complaint could direct his/her complaint. Any complaint that was directed to the wrong quarter could be referred to the 'single portal'. Advice could be given as to the appropriate destination for the complaint to be received and handled. In other words, the 'single portal' would act as a signpost indicating the appropriate direction of a complaint. Although concerns were expressed about the practicalities of this idea, there was virtually universal acceptance at the seminars that, if it could be made to work, it would be a great improvement on the present position.
- 27.86 Miss Isabel Nisbet was seconded from the GMC to carry out a project on behalf of the Healthcare Commission and the GMC, namely to examine the feasibility of establishing a means of directing patients and others with concerns or complaints about health care towards the most appropriate route to pursue them. In November 2004, Miss Nisbet presented various options to the Healthcare Commission's Commissioners for the provision of such a service. Briefly, the main options outlined were these:
- (a) a website (or single web-based source), giving up-to-date information about complaints procedures in a form that would enable the enquirer to be guided to the most suitable route by a series of questions
 - (b) a website, as in (a), but with a facility to pass the enquirer to the right place by means of email or customised links to the relevant complaints handling bodies (both local and national) and to potential sources of advice and support
 - (c) a website with links, as in (a) and (b), but also with an interactive link to answer enquiries by advisers and intermediaries
 - (d) a website with links, as in (a) and (b), but also with an interactive link to answer enquiries by members of the general public
 - (e) an arrangement as in (d), but expanded to provide advice to complainants, as well as information to help them to select the appropriate route for their complaint.
- 27.87 While (a) provided the cheapest of the available options, Miss Nisbet acknowledged that it had the obvious disadvantage that about half the population do not have access to the internet and would not, therefore, be able to avail themselves of this facility. Miss Nisbet recognised that some patients' organisations would be disappointed if a website of this

kind were the only outcome of the project. She observed that most of the patients' organisations which she had contacted had favoured option (d), in addition to web-based information. They had said that patients, many of whom are elderly, valued contact with a human voice – for example, through a telephone helpline – rather than with a website or an automated message system. When discussing option (e), Miss Nisbet observed that the Independent Complaints Advocacy Service in England (ICAS) provides information and advice and she questioned what would be gained by replicating or replacing the services provided by ICAS. She suggested that options (a) and (b) should be developed. She also suggested that options (c) and (d) should be considered further, with a view to providing a service in conjunction with a patients' organisation or by strengthening an existing helpline facility. The Healthcare Commission has informed the Inquiry that it does not propose to take any decisions on the various options until after the publication of the Inquiry's Report.

- 27.88 In my view, no solution which depends, in the first instance, upon access to a website will be satisfactory. As Miss Nisbet observed, only half the population would have access to it. In addition to any web-based information, with or without interactive links to answer enquiries, there must, in my view, be a telephone helpline with a live human voice to speak to. Otherwise, half the population is unlikely to receive the help it needs. The group without access is likely to include a large proportion of elderly or vulnerable people – the very group most in need of help. I am not opposed to the idea of a website providing information; that might suffice for some purposes. However, in my view, there must be a helpline as well. Miss Nisbet raised the question whether, as ICAS provides information and advice, there is any need to provide advice as well as information about the right destination for a complaint. In my view there is. Very few people who have a problem on their minds about something that has happened at hospital or at their GP's surgery are likely to think that they need an advocacy service. What is needed is a service that not only advises people who have already decided to complain or to raise a concern where to lodge their complaint or concern, but also gives information to people who are uncertain whether or not they wish to complain or raise a concern about where to find the advice that they need. I do not suggest that the single portal service should provide the latter kind of advice but it should be able to refer the caller to, for example, a patients' organisation, an organisation such as Public Concern at Work (which can provide legal advice about the consequences of raising a concern) or possibly to ICAS. I think it would be helpful if, in addition to providing advice about the right destination for a complaint, the single portal service were prepared to forward the complaint to the appropriate body. Whatever form the single portal takes, it must be extensively advertised. It needs to be as well known as NHS Direct and the Samaritans.

Support for Complainants: after the Community Health Councils

- 27.89 As I explained in Chapters 6 and 7, for many years until 2003, Community Health Councils (CHCs) provided advice and support for persons wishing to pursue a complaint. Before 1996, the CHC would correspond with the FPC or FHSA on the complainant's behalf, would advise on the preparation of the complaint for a MSC hearing and would accompany the complainant at the hearing, acting as adviser throughout. From 1996, the

CHC would, on request, assist in lodging a complaint or requesting an independent review. It would also correspond with the HA/PCT making the arrangements for an IRP hearing and would attend and support the complainant at the hearing. Evidence received by the Inquiry suggests that many CHCs did this work well and that their work was greatly appreciated.

- 27.90 In Chapter 7, I also described the provisions that have more recently been made for advising and supporting patients who wish to make a complaint. I said that I did not know how well those arrangements were working. I suggest that an independent review be commissioned into the operation of these arrangements about two years after the new Complaints Regulations come into force in their entirety with a view to ascertaining whether patients are receiving appropriate advice and support and correcting any deficiencies that may be revealed.

Disciplinary Procedures in the Context of Clinical Governance

- 27.91 In Chapter 7, I explained that disciplinary proceedings against GPs at local level fell largely into disuse soon after the introduction, in 1996, of the new complaints procedures. In some places, they were still occasionally used. Their operation depended upon establishing a breach of the GP's terms of service. With the introduction of the new GMS Contract in April 2004, terms of service have ceased to exist. They have been replaced by contractual arrangements. However, as I explained in Chapter 5, from December 2001, PCTs have had new powers of list management. A PCT can remove or suspend a GP from its medical performers' list or impose conditions upon his/her inclusion on the list. There is no power to order a withholding of remuneration; nor is there an official power to administer warnings or reprimands.
- 27.92 Respondents to the Inquiry's Consultation Paper were asked whether they thought it was appropriate that PCTs should be able to deal with misconduct, deficient practice or poor performance falling below the threshold operated by the GMC or below the threshold at which the PCT would exercise its list management powers. They were invited to consider whether disciplinary procedures should be developed at local level to deal with such cases. Views were also sought on the categories of case in which it would be appropriate for local disciplinary proceedings to be invoked and, in particular, whether there should be a code of conduct or code of patients' rights, breach of which might give rise to disciplinary proceedings.
- 27.93 The majority of respondents to the Consultation Paper thought that there was a gap in the powers available to PCTs. There was a substantial degree of support for the idea that PCTs should have a wide range of sanctions available to them. A number of respondents to the Consultation Paper and participants at the seminars suggested that the range of penalties available to the PCT should include 'constructive penalties' (e.g. a requirement that the doctor undergo specific retraining), rather than punitive measures. The Royal Pharmaceutical Society of Great Britain suggested that a wide range of options should be made available to PCTs. Examples given were the issuing to GPs of advice letters containing good practice guidance, advice visits, mentoring, retraining and obtaining written undertakings from doctors. It was suggested that early intervention might serve to prevent a more serious outcome.

- 27.94 In its response to the Consultation Paper, the GMC said that the gap that had been identified in the regulatory system would be narrowed under the GMC's new FTP procedures, which will provide for the issuing of a warning to a doctor where there has been a significant departure from the principles contained in the GMC publication 'Good Medical Practice' or where a GMC performance assessment has indicated cause for concern, but where the GMC does not consider that action on registration is warranted. However, there would still remain a category of cases which might not reach the GMC or which might fall below the threshold for the issuing of a warning. Those cases, the GMC said, should be addressed by PCTs at local level. Mrs Robins, representing Patient Concern, thought that the PCTs' powers should be extended and that the most central and significant problem with the current system was that the PCT does not have the power to impose sanctions to deal with minor matters.
- 27.95 At the seminars, a hypothetical example was considered in order to allow examination of the adequacy of the PCT's powers. It was supposed that the Healthcare Commission had investigated a patient complaint and had made a recommendation to the PCT that it should require the doctor to undergo retraining. If the doctor failed to co-operate with the PCT's request that s/he should retrain, the only sanction available to the PCT would be to direct the removal of the doctor from the list, contingent upon his/her continuing refusal to retrain. It was suggested that, in the case of a failure to co-operate with a recommendation for retraining, the exercising of list management powers might be somewhat draconian and that, in practice, the PCT's list management powers would be imposed only in serious cases. I do not think it would be draconian to impose contingent removal on a doctor who was refusing to co-operate in retraining. It would be an effective means of persuasion as well as protection for patients. However, I can envisage cases in which the gravity of the circumstances would fall below the 'list management' threshold and where a lesser sanction might be appropriate.
- 27.96 Professor Scotland said that there was a need for an extension of the PCTs' powers and stressed that there was a need in particular for a less 'long-winded' disciplinary process to be used in the case of less serious matters. It was acknowledged that procedural complexity was one reason why formal disciplinary hearings had largely fallen into disuse after 1996. Professor Scotland suggested that a system of warnings could be implemented by PCTs along similar lines to the system of warnings which exists in the context of an employer/employee relationship. He suggested that there could be gradations of warning, starting initially with advice given off the record, followed by the giving of oral advice, which would be recorded, and finally written advice. He thought that the PCT list should be able to record information on warnings.
- 27.97 The idea of introducing a system of warnings received widespread support at the seminars. Dr Grenville, for the BMA, welcomed the proposal. He made the point that the complaints system, prior to 1996, permitted PCOs to issue warnings and that the medical profession had been content with that system. Sir Donald Irvine, former President of the GMC, also supported the proposal. He said that the nature of the relationship between PCTs and contracting GPs had been a longstanding problem. By that, I think he meant that PCTs were responsible for GPs but did not have the disciplinary powers of an employer. However, he said that he had known of PCTs which had struck the right balance in the

relationship and had been able to give warnings about matters requiring attention. Mr Martin Staniforth, Deputy Director of Human Resources at the DoH, was also aware of instances of PCTs acting informally to warn GPs about their behaviour and he supported the proposal for a system of warnings to be introduced.

- 27.98 Professor Scotland emphasised that there would still be a need for a thorough investigation and that, where there was a conflict in the evidence, it would be necessary to make findings of fact. There was general agreement among participants that that would be necessary. According to Professor Scotland, the worst thing that can happen is that concerns are not 'bottomed out'.
- 27.99 Mrs Robins suggested that, if a warning system were introduced, the more serious level of warning ought to be made public and should even be posted in the surgery. Dr Grenville did not agree with that. He said that the effect upon the doctor might be very serious. He said that the medical profession has a high suicide rate and that it would be necessary to carry out research into the impact on doctors of publishing such warnings. Dr William Reith, who represented the RCGP at the seminars, said that it was important that the individual patient complainant should be made aware of the outcome of the disciplinary proceedings, whether or not the wider public was made aware.
- 27.100 A number of participants at the seminars said that it would be appropriate for PCTs to have the power to impose financial penalties on contracting GPs. Professor Baker thought that the imposition of financial penalties would be of particular use in dealing with dysfunctional practices as well as with individual GPs. Mrs Robins agreed with that view and said that the imposition of a financial penalty would act as an enormous incentive for a practice to ensure that the problem, whatever it was, was addressed. Dr Grenville said that the imposition of financial penalties would not necessarily lead to a service improvement and that, in his experience, the imposition of financial penalties under the pre-1996 complaints system had not influenced the behaviour of 'problem' doctors. He thought that the most important goal was proper service delivery and that, where problems were identified, it was more important to focus on putting that right. Professor Scotland thought that the imposition of financial penalties might be appropriate in the case of administrative failings but that other forms of sanction (for example warnings, linked to a requirement to undergo retraining) would be a more appropriate way of dealing with performance. He also said that the imposition of a financial penalty should be recorded on the PCT list.
- 27.101 It was suggested by one respondent to the Consultation Paper that involvement in disciplinary procedures should be reported as part of GP appraisal and that the cause of the problem should be addressed in the doctor's personal development plan. A number of participants at the seminars agreed that the disciplinary procedures should be linked with the appraisal system, but that that process should not replace the taking of action at local level by the PCT.
- 27.102 I can see advantages in PCTs having a wide range of sanctions available to them once they have conducted an investigation into a complaint or concern and found that it was justified, although not so serious as to merit the use of their list management powers or referral to the GMC or some other body. It seems wrong that a PCT should not have

the widest range of sanctions available to deal with the situation as it has found it to be. I would favour the extension of the PCTs' powers to include both warnings and financial penalties. That is not to say that I think that PCTs should spend their time conducting disciplinary or list management proceedings if they can deal with matters in a simpler way which is both constructive and effective. I agree with Dr Grenville that the most important aim is to improve clinical performance. I think that PCTs should concentrate on bringing about improvement through the giving of advice – probably by the Clinical Governance Lead – rather than by seeking to punish minor shortcomings. If a doctor will not respond to advice about a matter that needs correction (for example, by undergoing some remedial training) then, in my view, the PCT should use its list management powers to 'persuade' him/her to do so. If s/he is still uncooperative, the PCT should use its stronger powers. I hope that PCTs will gain confidence in using their list management powers. Parliament has bestowed them and it must have intended that they should be used.

The Use of Prescribing Information as a Clinical Governance Tool

27.103 In my Fourth Report, I made a number of recommendations about the ways in which the accuracy and completeness of prescribing information could be improved so as to provide a more valuable tool for the purposes of clinical governance. I shall not repeat those recommendations in detail here. I suggested that every doctor working in general practice should use his/her own prescription pad and that the practice of allowing trainees and locums to use the pad of one of the GP principals in the practice should be stopped. In that way, each prescription could accurately be attributed to an individual doctor. I also suggested ways in which the 'blurring' of prescribing data by the issuing of repeat prescriptions could be avoided. In respect of controlled drugs prescribing, I made recommendations that a special prescription form should be introduced and that private prescribing should also be done on the special form so that it could be included in the analysis carried out by the Prescription Pricing Authority. If those measures are adopted, it should be possible for a PCT to obtain a complete and accurate picture of each doctor's prescribing practice; thus, the PCT will be better able to detect abnormal prescribing. Also, the data available to individual doctors will enable them to undertake a more satisfactory audit of their own prescribing practice.

27.104 In my view, special attention should also be paid to the prescribing of controlled drugs by all doctors. Doctors who have had a problem of drug misuse in the past or who are suspected to have a current problem should be subjected to particularly close scrutiny. Not only should their prescribing data be examined carefully but attention should be paid to information held in the controlled drugs registers (CDRs) kept by pharmacies. In the Fourth Report, I recommended the establishment of a controlled drugs inspectorate. One of its functions would be the scrutiny of CDRs to detect abnormal prescribing of controlled drugs and abnormal conduct by doctors, such as collecting from a pharmacy controlled drugs which have been prescribed for patients. The inspectorate and the PCT would be able to liaise if either had a concern about an individual doctor's prescribing of controlled drugs. I hope that the Government will act upon these recommendations.

The Use of Mortality Data as a Clinical Governance Tool

A National System of Monitoring

27.105 In Chapter 14, I described how the Inquiry commissioned a study of the feasibility of using mortality statistics to detect abnormalities which might indicate that a doctor was failing to provide an adequate standard of clinical care for his/her patients or even that s/he was deliberately harming them. I also described the discussion that took place at a special seminar held by the Inquiry in October 2003. The conclusion reached at the end of that seminar was that it would be desirable to operate a national system for the monitoring of mortality rates in general practice. I agree with that view. It seems to me that such a system (particularly if coupled with the reform of the systems of death certification and investigation that I have recommended in my Third Report) would be likely to deter a doctor from criminal activities such as those of Shipman. Even if it did not, it would greatly improve the chances of detecting those activities. Apart from those potential benefits, however, I believe that the collection and analysis of GP patient mortality data are necessary parts of the clinical governance process and that a greater understanding of that data can only have a beneficial effect on the quality of patient care.

27.106 I recognise that there are practical difficulties in the way of setting up a satisfactory system, in particular the difficulty of linking an individual patient death with an individual GP. However, I recommend that work should be undertaken to find ways of doing this. The DoH will have to take the lead. Some ideas were suggested at the seminar and I am optimistic that, with a will, a way will be found. Once that has been done, I recommend that a pilot scheme for national monitoring be undertaken, along the lines discussed at the seminar. Any national monitoring system must be supported by a proper system of investigating those cases where a doctor's patient mortality rates signal as being above the norm. Those investigations must be well organised, consistent and objective. They cannot be left to individual PCTs, although much of the local knowledge which will inform such investigations will be available from the PCTs.

27.107 At the time of the seminar, it was envisaged that a central analytical unit for carrying out monitoring would be operated by the Healthcare Commission and that investigations would be carried out by local Healthcare Commission offices, in conjunction with the relevant PCT. Since then, it seems that the Healthcare Commission's intentions – both as to the housing of a central analytical unit and as to the establishment of local offices – may have changed. If so, national monitoring and analysis will have to be carried out by another body (probably under the auspices of the DoH), with investigation being done by the skilled inter-PCT investigative teams to which I have previously referred in connection with the investigation of complaints and concerns.

Practice Death Registers

27.108 As I have said, I am of the view that data relating to patient deaths would be of value for clinical governance purposes. The Inquiry was told that some GP practices keep a deaths record or register in which a full copy of each Medical Certificate of Cause of Death (MCCD) issued is maintained. That seems to me to be good practice and would, among

other things, provide the material needed for an audit of deaths. Discussion of such material might be a useful topic at appraisal. In my Third Report, I recommended the reform of death certification. If my proposals are accepted, the form that would be completed by a GP following a death would contain a great deal more information than is currently contained in a MCCD. Such forms would provide an even more useful basis for an audit of deaths and would be an extremely valuable resource in the event that an investigation into a GP's patient mortality rate had to be undertaken as a result of routine monitoring of mortality rates. For patient deaths that occur in hospital or elsewhere, for which the GP does not complete a MCCD, equivalent information should be entered in the register.

Review of the Medical Records of Deceased Patients

27.109 The Inquiry was told on a number of occasions that the examination or review of a GP's medical records is a valuable tool in the assessment of the quality of clinical care and the detection of substandard clinical performance. The process plays an important part in the assessment procedures for the purposes of authorisation as a GP trainer and for Membership by assessment of the RCGP. It could play a part in appraisal. However, I do not think that it will generally be feasible for PCTs to undertake such record reviews themselves; for one thing, there would be problems of patient confidentiality. Nonetheless, it seems to me that use could be made of the records of deceased patients for such purposes. The records of deceased patients are sent to the PCT. It would not be at all difficult for PCTs to review such records. It would be easy for the patient's identity to be removed by one member of staff and for the review to be carried out by a different person, who would of course have to be suitably qualified. It would be necessary to ensure that a full set of records was sent to the PCT, including any records kept only on a computer. The use that would be made of this tool would depend upon the resources that the PCT could apply to the task. Ideally, each doctor should be subject to a periodic review of one or two sets of records, relating to patients who were cared for in the community up to the time of their deaths. My experience on this Inquiry suggests that the care provided to patients in the last few months of life would be a particularly good indicator of the general standard of care offered by the doctor. If resources did not stretch to a periodic review of a few records of all doctors, the process could be limited to those doctors whose performance gave rise to concern in some other respect.

Appraisal in the Context of Clinical Governance

27.110 I described the present system of appraisal of GPs in Chapter 12 and in Chapter 26. I explained the way in which the GMC's proposals for revalidation came, at least for a period, to rest entirely on the 'successful' completion of appraisal. In my view, that situation was unacceptable. It has now changed in that, in addition to the 'successful' completion of appraisal, a GP seeking revalidation will also be required to produce a clinical governance certificate. I have made recommendations about the way in which I think revalidation should develop. I now wish to discuss the future of appraisal, primarily in the context of clinical governance, but remembering all the while the role that it is expected to play in revalidation.

- 27.111 First, it seems to me that it is essential that the purpose of appraisal should be clear. Is it intended to be a purely formative process or is it intended to be multi-purpose – part formative, part summative, part performance management? In industry and in many employment situations, there is no difficulty about appraisal having several purposes. As I understand it, appraisal of doctors in the hospital service, at least for those in training grades, is intended to be a performance management tool. It is based upon information collected by the employer, and the employer can in large measure dictate the areas covered by that information and the topics to be discussed at appraisal. I believe that it was the DoH's original intention that the appraisal of GPs should be similar and should have both a formative and a summative function. As Dr John Chisholm, Chairman, General Practitioners Committee, BMA, told the Inquiry, even those negotiating on behalf of the doctors expected that appraisal would be based upon hard information provided by the PCT from clinical governance sources. In the event, as it has come to be operated, it is a purely formative process. It is based on material chosen by the appraisee. Much, even all, of that material may not be capable of being verified. It seems to me that, as a formative tool, it is as good as the individual doctor wants it to be. If s/he wants it to be searching, it can be; but if s/he wants it to be little more than a cosy chat about areas of practice that s/he is quite confident about, that can be engineered. I do not suggest that many doctors do that. Indeed, I have the impression that most of them want to make positive use of the opportunity that appraisal offers. But, if appraisal is to be used to any extent as a summative tool, it must be capable of detecting that small group of doctors who have something to hide. It must be a much less 'soft' process than it is at present.
- 27.112 So, somebody must decide whether appraisal is to be a clinical governance tool (in which case it must be 'toughened up') or whether it is to be a purely private opportunity for personal professional development. I have no strong personal view. I can see the benefit of a purely formative session with a colleague, provided that the colleague is someone with high standards, worth learning from. On the other hand, appraisal is a costly business and I wonder whether the money is being well spent, at least unless there can be some guarantee of the quality of the appraiser's contribution. The expenditure of the time and money might be more readily justified if the appraisal were to be based on specific information capable of being verified. It might be more readily justified if more information came out of appraisal for the benefit of the PCT's clinical governance function. These are issues for others, not for me. If I were to recommend that appraisal should contain a summative element, I cannot say whether that would be practicable. I do not know whether the profession would accept such a change. I do not know whether doctors would be prepared to act as appraisers if that were their function. I do not know whether the Government would wish to insist on such a change.
- 27.113 All I can say is that, if appraisal is to remain as it is – an essentially private matter between appraiser and appraisee, based upon material selected by the appraisee – then it must not be regarded as a clinical governance tool. It will be capable of helping a PCT to decide what types of continuing professional development it should provide. That is all. It must not be regarded as being capable of making any useful contribution to the process of revalidation. Revalidation must depend upon something else.
- 27.114 If the Government and the profession were to decide that appraisal should be 'toughened up' so that it is capable of being used as a clinical governance tool, then I would have a

number of suggestions to make as to how that might be done. These ideas come from witnesses to the Inquiry, participants in the seminars and sometimes from published documents such as the Revalidation Toolkit published by the RCGP for Scotland and the recent Consultation Document, 'Portfolio of Evidence of Professional Standards for General Practitioners: a Tool for Continuing Professional Development, Appraisal and Revalidation', also published by the RCGP.

27.115 On that basis, I would recommend first that appraisers must be more thoroughly trained and should be accredited following some form of test or assessment. They would have to be trained to evaluate the appraisee's fitness to practise. GPs should be appraised by an appraiser from another PCT. Second, the standards by which a doctor either 'successfully completes' or fails the appraisal must be specified. At the moment, appraisal is 'successfully completed' unless serious concerns arise and the appraiser stops the process. It is not clear how serious the concern has to be before that happens. Third, all appraisals should be based upon a core of verifiable information supplied to both parties by the PCT. That would not mean that the doctor could not introduce other material in addition; but there would have to be a compulsory core. The list of essentials would have to be agreed nationally. Important categories would be prescribing information, information about complaints, continuing professional development activity, mortality statistics (if a monitoring system is introduced) and audit results. I also consider that it would be appropriate for one particular type of activity to be undertaken and discussed in each year. Given that revalidation will generally take place every five years, there could be a cycle of five different activities. One should be a video film of patient consultations. Another should be a patient satisfaction survey. I am unsure of the value of peer review questionnaires in the context of general practice. If research shows that they are of value, they could be included. Another activity should be a review and discussion of a selection of patient records. Another could be the discussion of a report about a critical or untoward incident and another a discussion about a clinical audit report. In my view, it is important that the whole of Form 4 (the summary of the discussion and the personal development plan) should be made available to those at the PCT responsible for clinical governance. I understand that the DoH intends to ensure that this is done.

27.116 If those changes were made to appraisal, there may be some justification for regarding the process as an evaluation of fitness to practise, such as would provide an adequate basis for revalidation. Whether that is a good idea or whether it is preferable to keep appraisal and revalidation apart, I cannot say.

Miscellaneous Proposals

The Use by Primary Care Trusts of Their List Management Powers

27.117 The list management powers of PCTs are new and the evidence received by the Inquiry suggests that some PCTs are uncertain about when and whether they should be used. At paragraph 5.72, I suggested that it would be useful if the Family Health Services Appeal Authority (Special Health Authority), whose powers are soon to be transferred to the NHS Litigation Authority, were to collect and analyse the information relating to the use of these powers by PCTs. I thought that it would also be useful if PCTs were required to indicate

why they had used their powers in each case. Such analysis would assist the DoH in providing guidance to PCTs about the types of circumstance in which they might properly use their powers. Also, it would draw attention to those PCTs that were using their powers either much more or much less than the average.

Practice Accreditation Schemes

27.118 At paragraphs 5.111–5.119, I described various practice accreditation schemes in operation in England and in Scotland. I expressed the view that it would be valuable if all GP practices could be encouraged to achieve accreditation, as it is intended they should do in Scotland. As remuneration under the new GMS Contract is based upon a series of financial incentives, it seems to me that it would be sensible to provide a financial incentive for the achievement of practice accreditation by means of an accreditation scheme similar to that operated by the RCGP in Scotland. I recommend that the Government consider the feasibility of such an incentive scheme.

Support for Single-Handed and Small Practices

27.119 At paragraphs 9.134–9.135, I wrote about the particular problems of practice staff working in small or single-handed practices. They face problems of isolation; they may not recognise aberrant behaviour or practice in a healthcare professional because they are used to it and do not realise that it is unusual. I have suggested ways in which PCTs could help to reduce the effects of isolation.

27.120 In Chapter 13, I discussed the problems which can be faced by small and single-handed practices. I described a number of initiatives that are already being taken in some parts of the country to resolve or mitigate those problems. I do not propose to repeat that discussion here. At paragraphs 13.69–13.70, I recommended that a more positive approach should be taken to the problems of small practices. The doctors running such practices should be given more support and encouragement and, in return, more should be expected of them in terms of group activity and mutual supervision. I suggested that there should be a pooling of ideas, a willingness to examine the way in which things are done in other countries, such as the Netherlands, and a determination to solve the problems. I recommend that the DoH take responsibility for this initiative.

The Recruitment and Appointment of General Practitioners

27.121 Under current procedures, the extent of the involvement of a PCT in filling a GP practice vacancy varies according to the type of post. The PCT is responsible for recruiting to single-handed practices and salaried posts but, if the vacancy is within an existing partnership, the practice itself selects a candidate, subject to inclusion on the PCT's list. The question was posed in the Inquiry's Consultation Paper as to whether a PCT should have input into the selection process for a vacancy in a group practice and, if so, how and to what extent. As I reported at paragraphs 5.50–5.53, PCTs are entitled to refuse to admit a doctor to their medical lists on specified grounds.

27.122 Those respondents to the Consultation Paper and participants at the relevant seminar who supported the idea of PCT involvement in the recruitment and appointment of GPs did so

for two main reasons: first, because PCTs are responsible for clinical governance and will, therefore, be to some extent accountable for the actions of the doctor appointed and, second, because they felt that GP practices did not have the necessary human resources expertise to recruit and appoint satisfactorily. It was suggested that the necessary expertise might be provided by the PCT, or even the SHA.

- 27.123 Professor Martin Roland, Director, National Primary Care Research and Development Centre, and Professor of General Practice, University of Manchester, emphasised that there were two separate issues relevant to the PCT's involvement in GP appointments. The first was the responsibility which PCTs have for ensuring that only competent doctors are appointed to their lists. The second issue was the role that should be played by the PCT in the appointment of a doctor to a GP practice. Dr Grenville, representing the BMA, also made this distinction and expressed the view that external standards should be set (for example, governing the requirements for acquiring a licence to practise and for joining a PCT's list), but that, provided a candidate met those requirements, the decision to appoint should be made by the GP practice concerned.
- 27.124 There was a consensus at the seminar that the role of PCTs in the appointment and recruitment process should be limited to providing advice. Respondents to the Consultation Paper (including the RCGP) emphasised that professional partnership involves close personal and financial relationships and that, ultimately, the decision as to who should be admitted to a GP practice must be taken by the existing members.
- 27.125 There was, however, widespread support for the proposal that PCTs should provide human resources expertise and advice. The Inquiry heard about some initiatives at PCT level; for example, at the seminar, Ms Fiona Freedland, Legal Director, Action against Medical Accidents (AvMA), described the arrangement in City and Hackney PCT, where a GP vacancy officer had been appointed to help practices which were having difficulty in filling their vacancies. Mrs Webdale, representing AMSPAR, said that, in her experience, many GPs did not have the necessary skills to recruit effectively; however, some did not recognise this and were unwilling to seek help. Dr Reith, representing the RCGP, agreed that GPs were not experienced in recruitment and needed human resources advice. Although he did not believe that a PCT should be able to compel a practice to accept such advice against its will, he recognised that PCTs had a responsibility to ensure that proper recruitment processes were implemented; he accepted that there would be a place for 'robust discussion' between a PCT and a GP practice which was reluctant to accept such advice.
- 27.126 Professor Baker thought that it would be helpful for practices to have input from the PCT in the drawing up of a job description and specification. He suggested that the PCT could also help in sifting applications and in preparing a shortlist. This seems to me a good idea if, given the current shortage of GPs, it is possible to compile a shortlist. Professor Baker also suggested that, at that point, the PCT could check whether any of the candidates were unsuitable before interviews took place. I can see the value of undertaking some of the suitability checks before the interview stage. At present, PCTs might object that it would be too time-consuming to make all the necessary checks for several applicants for a vacancy. However, if the GMC were to put more information about doctors on its website

(as I shall recommend that it should) and if a central database of information about doctors were to be created (as I shall also recommend), it would be quick, easy and worthwhile to make these checks before the interview stage.

- 27.127 The view of Patient Concern was that, in order to ensure an appropriate balance of skills and mix of expertise in a particular PCT area, a PCT representative should be included on the panel which interviewed applicants for a GP post. Dr Reith said that he would not object to PCT involvement in an advisory capacity at the shortlisting or interview stages. In its written response to the Consultation Paper, South West Kent PCT expressed the view that a PCT member should be present during the interview process, but that his/her role should be limited to observing the proceedings. Another respondent to the Consultation Paper suggested that there should be professional input from the PCT at the point of shortlisting and lay input at the interviewing stage.
- 27.128 In my view, PCTs should be willing and able to provide advice on good recruitment practice and should also be willing to offer support in drafting a job specification and advertisements. If the response to an advertised vacancy is such as to give rise to the need for a shortlist, no doubt many practices would welcome help in sifting applications. As I have said, I think it would be useful if preliminary checks on suitability could be made before the interview stage. I would not think it desirable to take up references before a selection had been made. Nor do I think it appropriate that the PCT should play any part in the interview process unless requested by the practice to do so. Selection of the right person from among the suitably qualified candidates must be a matter for the practice concerned.
- 27.129 I also think that it would be sensible if a standard reference form were developed for use in connection with appointments to GP practices. It is not sufficient for a reference to comprise a general statement that the doctor has been satisfactory. Also, in my view, PCTs should insist that a reference be obtained from the previous employer or PCT. In the case of a previous PCT, the reference should be signed by the Medical Director or Clinical Governance Lead, i.e. the person who has access to the clinical governance information held about that doctor.

Involvement of Lay People in the Recruitment of General Practitioners

- 27.130 The Inquiry's Consultation Paper also raised the issue of whether patients should be involved in the process of selection of GPs and, if so, to what extent. It was suggested that there might be patient representation on interview panels. Views were also sought on the type of patient representation; for example, one or more patients at the relevant practice could be involved, or members of the local Patients Forum or some other representative group.
- 27.131 The Inquiry became aware of examples of patient involvement in the recruitment of GPs. The Clinical Governance Review of Harlow PCT, undertaken by the Commission for Healthcare Improvement (CHI) in 2003, reported patient and public involvement in many trust activities, including participation in the recruitment of GPs.
- 27.132 Respondents to the Consultation Paper were divided on the issue of patient involvement. Some respondents were wholly opposed to the idea. Others welcomed the idea in theory

but saw practical difficulties. Many respondents felt that patient involvement was important. A number saw a role for the new Patients Forums, which could be involved directly in the recruitment process, or could at least be consulted on priorities before the practice embarked on the selection process. Others thought that a lay member of the PCT should provide lay input. AMSPAR suggested the setting up of new patient groups covering several PCTs.

- 27.133 Some respondents thought that it would be helpful to have lay input at the stage of shortlisting candidates, while others felt that the most appropriate stage was at interview and that the interviewing panel should include a lay representative. One suggestion was for all shortlisted candidates to meet informally with a group of patients who would give feedback to the interviewing panel. However, there was opposition to this idea on the grounds that it did not give much insight into the quality of a candidate's clinical practice. The need for members of the practice to make the ultimate decision about who was to be admitted was again emphasised.
- 27.134 There was a general view that lay participants would require training in selection and would need to be knowledgeable about issues in general practice. Professor Baker suggested in his written response that low level indirect involvement might be appropriate. Patients at a practice could be consulted about preferences: for example, whether patients would like a woman doctor to be recruited in what had hitherto been an all-male practice. Dr Grenville, representing the BMA, raised a number of potential problems with lay participation. He said that it might be difficult to find a patient or patients who were truly representative of the practice patient list. He gave as an example of the problem the patient representative who had a specific issue on which s/he felt strongly: for example, s/he might want a doctor who would always prescribe antibiotics for a cold, whereas other patients might want a doctor who would not expose patients unnecessarily to the dangers of antibiotics. Like Professor Baker, Dr Grenville was in favour of indirect patient input. He thought that patient participation groups could helpfully inform a practice of broad areas of concern to patients; that information could then be taken into account in recruitment.
- 27.135 Ms Freedland, representing AvMA, stressed that the overriding imperative from the patient perspective is that the doctor be safe, and that other considerations are necessarily secondary to patient safety. She suggested that patient involvement would be of most use in assessing the doctor's communication and interpersonal skills. She thought that it would be helpful to have a patient at the interview so as, for example, to test the candidate's ability to explain to a patient in simple language a complicated diagnosis or prognosis and treatment plan. Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, was supportive of exploring innovative interviewing techniques such as that proposed by Ms Freedland. She observed that lay assessors for the GMC's performance procedures currently test communication skills in a similar way with considerable success. She said that, in certain geographical areas (such as the inner cities where many people do not speak English), the attitude of the doctor is paramount in providing good care to patients. She added that it is important to observe candidates in practical situations, interacting with patients. Professor Aidan Halligan, Deputy Chief Medical Officer for England and Director of Clinical Governance for the NHS, also supported the proposal and said that the principle

of patient participation was a very legitimate one and should be welcomed. Dr Reith pointed out that doctors entering general practice would already have undergone summative testing of their communication skills. Dr Grenville thought that communication skills were central to the work of GPs and that their communication skills should be tested on a regular basis. He envisaged that, in the future, GPs would have a portfolio of videotaped consultations which could be used in applying for a new post. Sir Donald Irvine thought that communication skills would be better tested as part of revalidation, for example, by using videotaped consultations.

27.136 Dr Reith and Dr Sarah Wilson, Director of Public Health and Medical Director, Trent SHA, thought that it would be helpful for research to be carried out to see if patient involvement improved the recruitment process. They thought it should not be built into the process 'for the sake of it'. I think that such research would be a good idea, although it would depend upon the availability of funding for such a project.

27.137 My conclusion about this debate is that there should not be any attempt to be prescriptive about whether or how lay people should participate in the process of selection. I agree with Professor Baker and Dr Grenville that practices really ought to canvass and take account of the views of their patients about the kind of doctor the practice needs. However, I would be opposed to the imposition of any particular format or process by which lay people should be involved in selection. There are obviously a lot of different ideas in circulation. If any GP practice wishes to adopt any of these ideas it should be free to do so, but I do not think it should be under pressure to do so. I must say that I am attracted by the idea that material used in the revalidation process (such as a videotape of consultations) should also be used in the recruitment process. Indeed, it may be that, in the future, doctors will be expected to produce a good deal of clinical governance material for the benefit of a prospective employer or partner.

General Practitioners' Personal Files

27.138 Evidence received by the Inquiry suggests that, at least in the past, it has been the practice for a primary care organisation (PCO) to keep information about individual GPs in different files, dealing with specific topics (such as complaints, remuneration or practice profile), rather than keeping a single file containing everything relating to an individual GP. It may be that the recognition of the importance of clinical governance has led to the adoption of a different practice. For the avoidance of doubt, it seems to me essential that every PCT should keep a separate file (whether on paper or in electronic form) which holds everything in relation to that doctor, or at least everything that could have any possible relevance to clinical governance. A reliable and comprehensive source of information might in certain circumstances be useful to the PCT officer or group responsible for signing the clinical governance certificate for the purposes of revalidation. If a doctor moves from one PCT to another, that file (or a copy of it) should be sent to the new PCT. It should not be possible for doctors with a poor clinical governance record to move on and leave it behind. PCTs should also keep files on doctors who have been admitted to their lists and who work as locums in the area. It might be helpful if the DoH were to establish national criteria for the content of such files.

The Raising of Concerns

Facilitating the Raising of Concerns by Staff in General Practice

27.139 At paragraphs 9.128–9.139, I discussed the need for arrangements to support members of GP practice staff who wish to raise a concern about any matter arising within the practice, in particular about the clinical practice or conduct of a healthcare professional within the practice. I do not propose to repeat the detail of that discussion here. Suffice it to say that I recommend that every practice should have a written policy, setting out the procedure to be followed by a member of the practice staff who wishes to raise concerns, in particular concerns about the clinical practice or conduct of a healthcare professional within the practice. I also recommend that staff should be encouraged to bring forward any concerns they may have openly, routinely and without fear of criticism. However, I recognise that circumstances may arise in which a member of the practice staff feels unable to raise his/her concern within the practice. In readiness for such occasions, I suggested that PCTs should designate a member of staff to act as a point of contact for all practice staff. The contact details for that person should appear in practice ‘whistleblowing’ policies. He or she should make him/herself known to all the practice staff working within the PCT area. If the ‘single portal’ is created, in whatever form, the policy should set out contact details of that also. PCTs should also ensure, through training, that practice staff understand the importance of reporting concerns and know how to do so.

Facilitating the Raising of Concerns by Staff in the Private Sector

27.140 I recommend that the Healthcare Commission should require all private healthcare organisations to have a clear written policy for the raising of concerns. I also recommend that the Healthcare Commission and the GMC should be ‘prescribed persons’ for the purpose of receiving expressions of concern under the Public Interest Disclosure Act 1998 (PIDA), about any healthcare matters, whether arising in the public or the private sector.

Support at a National Level for Those Who Wish to Raise Concerns about Health Care

27.141 In Chapter 11, I discussed the provision of support and advice for those who wish to raise concerns about any aspect of health care. I made a number of recommendations about possible amendments to the PIDA, in particular at paragraphs 11.91–11.115 and 11.124. I shall not repeat the discussion relating to those recommendations here. I also recommended, at paragraph 11.117, that policies for raising concerns in the healthcare sector should be capable of being used in relation to persons who do not share common employment. For example, a doctor or nurse working in a hospital should have a route by which to raise a concern about a GP and *vice versa*. A doctor or nurse working in the private sector should have a route by which to raise a concern about the practice of a healthcare professional working in the NHS and *vice versa*. I also recommended that there should be some provision (probably a telephone helpline) to enable any person, whether working within health care or not, to obtain advice about the best way to raise a concern about a healthcare matter and about the legal implications of so doing. In my view, this should be provided on a national basis. I have not made any recommendation as to the

means by which this should be provided. However, it seems to me that it might be possible to link this helpline with the 'single portal' which is under consideration and which I mentioned at paragraphs 27.85–27.88 above.

The Availability of Information about Doctors

Information Available to Employers and Primary Care Organisations

27.142 One of the issues discussed at some length during the Inquiry was the difficulty experienced by PCTs in verifying information about doctors who apply to join their lists. I listed the checks to be made at paragraph 5.43. One of the witnesses described the process of obtaining this information as a 'real chase-round'. Even the process of checking registration at the GMC, the Criminal Records Bureau (CRB) and the NHS Counter Fraud and Security Management Service can take a good deal of time. Several PCT staff suggested that a more co-ordinated method of making these checks would be very welcome.

27.143 Quite apart from the information that can be gleaned from those three sources, there exists an enormous amount of other information about doctors which would be of value to PCTs and to potential employers. At the moment, there is no way in which such persons or bodies can find out all they would like to know about an applicant for a post or for admission to a list. For example, they will receive a reference from one, or maybe two, previous employers or PCTs but they will have no idea whether there are other employers by whom the doctor may have been dismissed or disciplined. They cannot find out whether a complaint has been made or even a series of complaints. In the Report of the independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling (the Ayling Report), the problem of drawing together and tracking records of separate complaints about the same doctor was highlighted. A similar concern was expressed in the Report of the investigation conducted by CHI into the various complaints made about the GP, Peter Green.

27.144 During the Inquiry, the idea emerged that there should be a central database of information about every doctor working in the UK. This would not be open to the public, but would be accessible to the officers of NHS bodies and to accredited employers in the private sector, as well as to other bodies with a legitimate interest, such as the Healthcare Commission, the GMC, the NCAA and the DoH. Several different classes of information would be fed in. These would include the current records held by the GMC (including any FTP history), although it might be more convenient to create a link to the GMC website, the contents of which I will discuss below. The database would have to contain information provided by the CRB or be linked electronically to that organisation. CRB information would include details of convictions (including those resulting in an absolute or conditional discharge) and cautions; the existence of other, more sensitive, information could be 'flagged' so that further enquiries could be made. In addition, the database would contain information from the NHS Counter Fraud and Security Management Service, a record of any disciplinary action by employers, the details of any list management action by PCTs, any adverse reports prepared following the investigation of a complaint, any adverse findings by a Healthcare Commission panel or by the Health Service Ombudsman and

any findings of negligence in clinical negligence actions and settlements of clinical negligence claims above a pre-determined level of damages. The level of damages should be set at a low threshold, say £5000, so as to catch cases involving the deaths of children, where the damages are unlikely to exceed about £11,000 on full liability and may well be settled for less than full value. In addition, an entry would be made in respect of every post taken up by a doctor in employment, thereby creating a running *curriculum vitae*. For self-employed doctors, an entry would have to be made for each GP practice or deputising service for which the doctor worked. The identity of the doctor's medical defence organisation (if any) could be included. Also, if the doctor had any financial interests which should be declared, they too could be incorporated. Doctors would be able to access their own entries to check the accuracy of the information held.

- 27.145 I would suggest that private sector employers should be required to provide relevant information. The Healthcare Commission could require this as a condition of registration. Also, deputising services should be required to provide information to the PCT with which they are contracted and would then be entitled to access to the information on the database, again through the relevant PCT.
- 27.146 The NHS has already made a start on the collection of information about individual doctors working in the hospital service through the use of NHS Occupational Health Smart Cards. I would have thought that this provision could usefully be extended to doctors working in primary care and that the categories of information that the cards contain might be extended to include those that I have mentioned above.
- 27.147 At the seminars, there was also discussion about whether unsubstantiated allegations should be included on the central database. Not surprisingly, opinions differed. The view was expressed that it would be grossly unfair to include such material. Others thought that, in the light of cases like that of Peter Green, where a number of unsubstantiated complaints had been received but not co-ordinated, it would be in the interests of patient safety if such information were to be included on the database. During the Inquiry hearings, there was discussion about evidence being given to the Independent Inquiry arising from the Soham Murders, chaired by Sir Michael Bichard. The gist of this discussion was that, if Humberside Police had retained information about unsubstantiated complaints against Ian Huntley and had passed them to Cambridgeshire Police when they made their pre-employment enquiries, Huntley would probably not have been employed at Soham Community College and Holly Wells and Jessica Chapman might not have died. Those contributors to the debate who had previously objected to the gathering of information about unsubstantiated complaints or concerns immediately realised that such material might be of great importance to patient protection. The view was that such material should not be entered into the central database, but that the entry should be flagged to indicate that confidential material was held by a named body. Disclosure of that information would have to depend upon who was asking about it and for what purpose, and questions of access would have to be determined at a high level.
- 27.148 Not only would such a central database make it far simpler for an employer or PCT to conduct pre-employment or pre-admission checks, the reliability of those checks would be greatly enhanced. The great majority of doctors would have nothing to fear; their entries

would contain no more than their qualifications and their *curriculum vitae*. However, those doctors who cause problems, and who move on from place to place causing more problems, would very soon be identified.

27.149 The question arose as to who should keep this database. To be useful it should cover the whole of the UK and should include doctors who work in the NHS, in the private sector and in both. That being so, it seems to me that it would have to be funded by Government and a suitable host would have to be found. The Healthcare Commission would seem to be a suitable candidate. It might even fit in with the Commission's own plans for information systems.

Further Information to Be Provided to Primary Care Organisations

27.150 In Chapter 5, I described the information that GPs now have to provide when seeking admission to a PCT list. This includes information about convictions, cautions, various types of disciplinary or FTP findings and ongoing proceedings. Doctors already on a PCT list are under an obligation to inform the PCT about any new relevant information. At the Inquiry, there was some discussion about whether other categories of information should be included, in particular information about clinical negligence claims.

27.151 The debate generated some heat. On the one hand, it was said that a clinical negligence claim was just another way of making a complaint or raising a concern and was of real importance for clinical governance purposes. On the other hand, it was said that many clinical negligence claims are brought which have no merit at all and that, therefore, they should not be reported to the PCT or recorded in any way. It was said that, in many cases, a letter before action was written and then the matter did not proceed further. It was also argued that some clinical negligence claims were settled for quite large sums even though there was no merit in them; this was done for commercial reasons, to avoid costs. My long experience of personal injury litigation teaches me that that is not so. Offers of settlement are often made, it is true, to buy off the risk that the action will succeed but not where it is judged that there is no risk.

27.152 In my view, civil actions are analogous to complaints and concerns. It would be illogical to retain records of complaints and concerns because their clinical governance importance is recognised, and to ignore clinical negligence claims. The fact that the allegations made in some such claims may have little merit seems to me to be unimportant. Some complaints have little merit but that is not a reason for disregarding them; the value of investigating them is recognised. If a record were to be kept of those clinical negligence claims which resulted in a finding of negligence (of which there are very few) and those which were settled for £5000 or above, I do not think any injustice would be done and the PCT would have useful and relevant information on its file. That information should also appear on the central database, if created.

27.153 I consider also that it would be appropriate for PCTs to be given notice when an action is brought. In my view, the trigger for notifying the PCT about a civil action should be the receipt (either by the doctor or by his/her medical defence organisation, or that organisation's legal representatives) of a letter of claim which complies with the requirements of the pre-action protocol in the Civil Procedure Rules. Such letters are sent

only where there is a serious intention to proceed. In my view, doctors should be under a duty to notify any PCT to whose list they have been admitted of the fact that such a letter of claim has been received and the gist of the allegation made. They should also be required to report the outcome.

27.154 As I have said, there is an ongoing requirement under the provisions of the National Health Service (Performers List) Regulations 2004 on doctors to make relevant declarations to their PCTs. In my view, failure to do so, and to do so accurately, should amount to misconduct of sufficient gravity to warrant referral to the GMC.

Information Available to the Public and Patients

27.155 During the Inquiry, there was discussion about how much information about doctors should be made available to the public and to the doctors' patients. This was appropriate in the context of an Inquiry into the activities of a doctor who, 24 years before it was discovered that he was a murderer, had been convicted of a series of offences of dishonesty in connection with his dependence upon a controlled drug. It is entirely natural that the relatives of Shipman's victims should say, 'If only we had known.'

27.156 The information available to patients and prospective patients about an individual GP is very limited under the present system. The public may become aware of a doctor's criminal convictions or about disciplinary matters through press coverage. However, there is no means by which comprehensive information can be obtained. At the time of the Inquiry hearings, the GMC would, in answer to a specific enquiry, provide information to members of the public about current conditions on a doctor's registration and on any previous disciplinary findings. However, that information was not – and still is not – available on the GMC website and will be provided only in response to specific enquiries by telephone. At the seminars, Dr Lewis, representing the GMC, said that the GMC did not at that time have an established strategy on disclosure but was in the process of developing such a strategy through public and professional consultation. That has now taken place and I shall describe the new GMC policy on disclosure later in this Chapter.

The Principle of Disclosure

27.157 Respondents to the Inquiry's Consultation Paper were asked whether patients and prospective patients should be provided with more information about their GPs to enable them to make an informed choice in deciding whether to consult a doctor and whether to submit to treatment by him/her. Respondents were asked what information should be available including, as examples, previous criminal convictions, disciplinary findings and current or past restrictions on a doctor's licence to practise. Respondents were also asked to comment on how the information should be provided to patients.

27.158 Respondents to the Consultation Paper and participants at the seminars were divided on the principle of whether more information should be provided to patients. One of the strongest advocates for complete openness was Sir Donald Irvine. He said that the issue was one of patient autonomy; patients are entitled to have access to information which is already in the public domain. Sir Donald said that he was aware of two cases in which

patients had become aware of a doctor's history after a problem had arisen; they had been angry that information had previously been withheld from them and that they had been denied the opportunity to make a decision in the knowledge of all the facts. The patients had been left with a feeling that there had been a 'cover up'. A number of other seminar participants agreed with that view, including Professor Halligan, Deputy Chief Medical Officer for England and Director for Clinical Governance for the NHS. He said that the need to inform patients and to allow them to make up their own minds about how and from whom they receive treatment arose out of the privileged position of doctors and the trust that patients necessarily place in a doctor.

- 27.159 A large number of respondents to the Consultation Paper expressed the opposing view. Their argument was that it was for the GMC, a PCT or a doctor's employer to decide whether a doctor was fit for practice and that patients should be able to rely on those bodies to fulfil their respective roles. There was (or should be) no need for patients to receive further information about their doctors. The BMA said in its written response to the Consultation Paper that patients should be reassured that minimum standards apply, which reduce as far as possible the chances of patients coming into contact with a GP who might cause them harm. In that context, it was said that the GMC and PCTs should be more robust in their approach to their respective roles of licensing and appointing doctors. Mr Michael Summers, Chairman of the Patients Association, agreed that the responsibility to ensure fitness to practise lay with the GMC and the PCTs. He thought that providing further information might cause patients to worry, which would be particularly damaging to those patients who live in parts of the country where it is not possible to change doctors. With due respect to Mr Summers, it seems to me that the issue is not only one of choosing a doctor. If the only GP to whom a female patient has access is a male one who has been convicted of indecent assault, she might wish to be accompanied when consulting him.
- 27.160 A number of respondents pointed to practical problems associated with the provision of information. Dr Grenville, who represented the BMA, said that the mere knowledge of an event would be insufficient to give the patient informed choice and that the patient would need to be able to ask and get satisfactory answers to questions about a doctor's history. He said that, in practical terms, this would be very difficult to achieve. I see the force of that argument. Some respondents thought that providing some types of information would make it impossible for a GP to continue practising, because patients would be unwilling to be treated by that doctor. My reaction is that, if the doctor's past record is so bad, perhaps the patients might be right and s/he ought not to be practising at all.
- 27.161 Professor Roland said that he had been involved in research into the impact of providing information to the public. The research was aimed specifically at providing information on quality of care. It had shown that publishing the information had made more of an impact on doctors and healthcare managers than on patients. Although he acknowledged that releasing details of, for example, a doctor's criminal convictions might cause patients to refuse to be treated by that doctor, the research suggested that this would not be the case. Ms Freedland agreed, saying that she did not think that the provision of information to patients about a GP would necessarily lead to an exodus of patients. In its written response to the Consultation Paper, CHI said that it thought there was a need for further research on the impact of sharing such information with patients.

27.162 During the course of receiving evidence, the Inquiry was told about the case of a doctor who had been convicted of the manslaughter of a patient and, as a condition of his registration, was required to undergo a period of supervised practice. A suitable supervisor was found but he and other members of the practice decided that they could not keep their patients in ignorance of the situation. A letter was sent to patients setting out the doctor's history, describing the remediation programme he was undergoing and explaining the precautions that were being taken to protect patients. The patients' reaction was good; it appears that they were willing to consult the doctor.

Categories of Information to which Patients Should Have Access

27.163 There are several categories of information to which patients might wish to have access, including criminal convictions and ongoing criminal matters, a doctor's GMC FTP history and ongoing FTP matters, action taken on the doctor's inclusion on the PCT list and findings of clinical negligence. There was broad agreement that information about existing restrictions on a doctor's licence to practise should be available.

27.164 A number of respondents to the Consultation Paper and participants at the seminars thought that the guiding principle should be that any information that has at any time been in the public domain should be available to patients. However, that principle is less easy to apply than it is to enunciate. Criminal convictions are in the public domain at the time they occur but the public soon forgets about them. After some years, they are deemed to be 'spent' under the provisions of the Rehabilitation of Offenders Act 1974 (the 1974 Act). The 1974 Act is designed to allow persons convicted of offences to put the past behind them. Such persons are not in general required to disclose spent offences when applying for jobs. There are, however, certain exceptions to this general rule, one of which extends to work concerned with the provision of health services. Doctors are required to declare any convictions they may have in response to questions from a prospective employer or PCO.

27.165 Of those respondents who thought that the public should have access to information about criminal convictions, some believed that access to such information should be available throughout a doctor's career. Others felt that the information should be available only until the conviction was spent, as defined by the 1974 Act. One respondent thought that there was a need for flexibility about past events and that information about past events should be made available only if it was 'too material/significant not to be shared with patients'. I can see the force of that but think that such a scheme would lead to uncertainty and endless argument. There was broad support among seminar participants for the proposition that matters that were under investigation should not form part of the information available to patients until findings of fact had been made.

27.166 There was some support among respondents to the Consultation Paper for the proposition that information about the outcome of successful clinical negligence claims against a doctor should be accessible to patients. Some findings of clinical negligence against doctors enter the public domain because civil courts generally sit in public and the findings of a judge in a clinical negligence action are publicly available. However, there was some opposition to this idea. It was said that the cases of clinical negligence that go

into the public domain are a minority, and that disclosure of them would therefore be unrepresentative and misleading. It is quite usual for the worst cases of negligence to be settled privately with no public hearing. Also, a claim for damages might fail, not because the doctor was not negligent but because the negligence did not have the consequences alleged. Finally, it was said that negligence on the part of a doctor is often part of a more wide-ranging failure and the contribution of the doctor is difficult to determine.

27.167 Dr Reith suggested that it would be sensible to canvass the views of patients on the sort of information they thought they ought to have.

Methods of Making Information Available

27.168 A variety of different methods of providing information to patients was suggested in the written responses to the Consultation Paper and at the seminars. One respondent argued that the information should be provided proactively so that all patients received it, not only the few who had sufficient determination to seek it out. Another respondent took the opposite view and thought that the information should be provided only to patients who made a specific application for the information. Moreover, that respondent thought that the request for information would have to be justified; in other words, reasons should be given for making the request.

27.169 At the seminars, Dr Wilson said that it would be better if the information were provided to patients on a one-to-one basis by someone at the PCT or from the GP practice, rather than by way of a letter. It seems to me that that ideal would be difficult to meet. Dame Lesley Southgate said that doctors themselves should have the responsibility for providing information about restrictions on their practice. She suggested that one method would be for a joint letter to be agreed between the Chief Executive of the PCT and the doctor, setting out the information that should be disclosed as well as the steps that were being taken to ensure that patients were not put at risk, together with any other matters that might be appropriate in an individual case. Dame Lesley agreed that such a system would be more effective in the case of a GP working at one practice than, for example, in the case of a locum doctor or a doctor working for a deputising service.

27.170 Another possibility is for the relevant information to appear on a website, to which patients and members of the public generally would have access, as is provided in a number of overseas jurisdictions.

International Perspective

27.171 As part of his presentation to the Inquiry, Dr Rocco Gerace, Registrar, College of Physicians and Surgeons of Ontario, Toronto, spoke about the website which is operated by the College. Patients can obtain from the website details of a doctor's referral to the College Disciplinary Committee together with any findings made by the Committee. The College is currently seeking legislative change in order to permit publication of undertakings provided by doctors in cases which do not come before the Disciplinary Committee.

27.172 Dr Gerace said that various categories of information are kept in the public domain for different periods. Findings of the Disciplinary Committee relating to sexual abuse on the

part of a doctor, for example, would remain on the record throughout the doctor's career. For lesser findings, there are fixed periods during which the information will be available, and, for certain categories of activity, the Registrar has a discretion as to how long the information should remain on the website. If a doctor were to go into the equivalent of the old GMC health procedures, then the fact that s/he was in the health procedures would not go on the website, but any restrictions on his/her practice would be published and would remain on the website while the restrictions were in force. I think the practice in Ontario might be worth copying.

- 27.173 Dr Perry Pugno, Director, Division of Medical Education, American Academy of Family Physicians, said that, in the USA, a number of resources providing information on a doctor's fitness to practise were available to members of the public. The State Medical Boards run websites which provide details of disciplinary action against doctors, criminal convictions and other information, such as the status of a doctor's licence to practise. In addition, a number of websites exist which are operated on a commercial basis and contain similar material. One example mentioned by Dr Pugno was 'Choice Trust', which covers the whole of the USA. The website is partially funded by advertising, and the basic service of establishing a doctor's administrative details is free, but a charge is made for information about a doctor's disciplinary history. Dr Pugno said that the information on the commercially run websites is not wholly accurate and, for example, in his own case, some of the practice addresses listed on 'Choice Trust' were incorrect and more than five years out of date.

Information Currently Made Available by the General Medical Council

- 27.174 At the present time, the only official provider of information about a doctor is the GMC. At the time of writing, only information which is on the medical register is available to the public, although, for reasons which I will shortly explain, that may well change in the near future. Of course, anyone who is prepared to use a search facility on the internet will be able to discover a great deal more.
- 27.175 There are two means of access to information held on the medical register. Some information appears on the GMC website. Alternatively, an enquirer can either telephone or email the GMC. I suppose it must also be possible to write. The website contains very limited information. If the doctor is currently registered and if there are no conditions attached to registration, his/her entry will appear on the website. The entry provides basic factual information, states whether the registration is full, limited or provisional and specifies any specialist register to which the doctor has been admitted. If there are any conditions attached to the doctor's registration, the website will indicate that it is not possible to display an entry that matches the request but that this does not mean that the doctor is not registered. A telephone number is provided as well as an email address so that further enquiries may be made.
- 27.176 If the enquirer telephones the number provided and asks about the doctor's registration, s/he will be told whether or not the doctor is registered and whether the registration is full, limited or provisional. Even if the doctor has conditions attached to his/her registration, the caller might well be told that the doctor is 'fully registered'. That means only that the

registration is not provisional or limited. If a lay caller had heard that his/her doctor was or might be subject to conditions and was telephoning to check whether that was so, the statement that the doctor was 'fully registered' might give a misleading impression, even though it would in fact be true. Only if the enquirer asks a specific question, such as whether the doctor has been suspended or whether s/he is subject to conditions, will the enquirer be told of any such matters. The GMC does not volunteer a full account of the doctor's registration status; it waits for the enquirer to ask. Indeed, the person who answers the telephone is able to provide only the level of information that appears on the website. If the enquirer wishes to ask any further questions, s/he is passed to someone else, apparently in another department. The experience of a member of the Inquiry staff who made a registration enquiry (on my instructions) about a doctor whose registration was subject to conditions was that she was kept waiting and that it was necessary for her to be quite persistent in order to obtain the information requested. Indeed, it appeared doubtful that she would ever have been given the information at all if she had not been able to quote the doctor's GMC number. Initially, when she gave the doctor's (correct) name, she was told that no doctor of that name was registered. When she volunteered the doctor's registration number, she was advised that the doctor was registered but his name was hyphenated on the GMC database.

27.177 It seems to me that this process is unhelpful to the public. All information about a doctor's registration is in the public domain and it should be made readily available. For those who wish to access the website, the full information including any history of erasure, suspension, conditions and warnings should be shown. For those who prefer to telephone, the full information should be volunteered, without the enquirer having to ask specific questions. I had hoped that, by now, the GMC would have recognised that this should be done. When Professor Sir Graeme Catto, President of the GMC, gave evidence to the Inquiry in December 2003, he said that, in his view, for the GMC to decline to make available anything that is already in the public domain was a 'weakish stance from which to start'. He accepted that it was not satisfactory that an enquirer had to ask the right questions before s/he would receive full information. However, at the end of October 2004, there had been no change in the amount of information available on the website and no change to the practice of requiring enquirers to ask specific questions before they would be told the full details in respect of the doctor's registration. I hope that that change will be made very soon.

27.178 As I have said, conditions imposed upon a doctor's registration are matters in the public domain. In the past, if conditions were imposed by the Health Committee, only the restrictions upon the doctor's practice were recorded on the register and any conditions of a medical nature were not. That seems appropriate, as any conditions relating to the doctor's health (such as a condition that s/he submit to medical supervision) should, I think, be treated as confidential, at least so far as the public is concerned. For the future, under the new FTP procedures, I envisage that any conditions on registration (other than those relating to medical matters) imposed by a FTP panel will appear in the doctor's entry in the register. However, it seems to me that conditions and restrictions entered into voluntarily ought also to appear in the register. A statement of requirements or a set of voluntary undertakings agreed following a performance assessment is, in reality, every bit

as much a 'condition on registration' as a set of conditions imposed by a FTP committee or panel. If the doctor will not agree to the undertakings, s/he will be referred to a FTP panel. The undertakings would be proposed in the first place only if the view had been taken that the doctor could not safely practise without restriction. Similarly, if the doctor voluntarily accepts a series of undertakings on account of his/her ill health, they are, in effect, conditions on registration. It is verging on sophistry to suggest that restrictions accepted voluntarily are not conditions on registration. I note that the report of the Performance Procedures Review Group suggested that restrictions agreed following a performance assessment should be treated as conditions on registration. In my view, it should be a condition of acceptance of voluntary undertakings that they are to be treated as the equivalent of conditions imposed.

Imminent Changes to General Medical Council Practice

- 27.179 When Sir Graeme Catto gave evidence to the Inquiry in December 2003, he said that the GMC intended to consult publicly in 2004 on questions of public disclosure. That consultation has now taken place and the results were considered at a meeting of the GMC in July 2004. Several new principles of disclosure were established. I do not think that these changes have yet been put into operation but I think that they must be imminent.
- 27.180 First, it was decided that, as a general principle, all information that has been in the public domain should be disclosed to any enquirer. That would include any aspect of the FTP procedures that has been in the public domain, even including the fact that a doctor has been charged with SPM but has been acquitted. Second, as a general principle, historical information that has not been placed in the public domain should be disclosed only in limited, defined circumstances, to the police, a coroner or **'an official inquiry'**. Third, it was agreed that information that has been in the public domain but is no longer of relevance to the doctor's registration should be disclosed for as long as the doctor remains on the register. The transcript of the meeting shows that it was agreed that this type of information should be disclosed to enquirers but that the answer should be accompanied by an explanation that the information is no longer of relevance to the doctor's registration.
- 27.181 The fourth resolution was that any finding of SPM, whether or not that had been followed by the imposition of a sanction, should be disclosed to enquirers. This should continue for as long as the doctor remains on the register. The fifth decision concerned information relating to the findings of fact that had been made against the doctor but had not resulted in a finding of SPM. After some discussion, it was agreed that such information would be provided to enquirers but that it must be set in context so that it would not reflect unfairly on the doctor. It was pointed out that this would be easy in respect of recent and future findings because reasons are now given, whereas, in the past, they were not and it would be difficult to put the information into context. Sixth, it was agreed that, where there had been findings of 'not guilty' and no findings 'in relation to the allegation', the information would be disclosed to enquirers but, again, it would be put in context.
- 27.182 Seventh, it was agreed that, if a warning were to be issued in the future under the new FTP procedures, it should be disclosed to a prospective employer at any time during the

following five years. The Council decided to postpone its decision about whether warnings should remain on the doctor's record indefinitely for some purposes, including enquiries from potential employers. Finally, the Council decided that, during the first five-year period after the issue of a warning, it should be disclosed to any enquirer, not only to prospective employers.

27.183 It appears therefore that, in future, the GMC will give full replies to questions about a doctor's past FTP history. However, it appears that the Council did not question the present practice of giving only the amount of information expressly requested. Mr Finlay Scott, Chief Executive and Registrar of the GMC, told the meeting that the GMC received about 1000 registration enquiries each day but that 999 of them went no further than finding out whether the doctor was currently registered. It does not appear to have occurred to the Council that this suggests that many prospective employers (or PCOs) are not finding out whether the doctor whose application they are considering has a FTP history, or even whether s/he is subject to current conditions. I find this very worrying. Evidence received by the Inquiry suggests that pre-employment checks are made by clerical staff. It would be quite possible to give such staff a list of questions that must be asked, but it appears from Mr Scott's advice to the Council that this is not being done. It seems to me that there ought to be much more information on the website and that, in the interests of clinical governance, much more information should be volunteered to telephone enquirers whether or not they ask the right questions.

Recommended Framework for General Medical Council Disclosure

27.184 I recommend that the GMC should adopt a policy of tiered disclosure. It may already have such a policy; if so, my recommendation is that it should be modified in the following way.

The First Tier

27.185 The first tier of disclosure should relate to information which is relevant to the doctor's current registration status together with certain limited information about his/her past FTP history. First-tier information should be posted on the GMC website and should also be volunteered to anyone who requests registration information, regardless of the questions asked.

27.186 The information to be disclosed in respect of the doctor's current registration status should include not only those conditions imposed by a FTP panel but also those voluntarily accepted by the doctor, save those that relate to the doctor's medical condition or supervision. It should also include the existence of any interim orders in effect. When the provisions for revalidation come into force in 2005, information about a doctor's registration status should include the year in which the doctor is due to be revalidated and, when s/he has been revalidated, the term for which the revalidation will be effective. Thus, it should be possible to see from the register whether the doctor has been revalidated in the year in which revalidation was due.

27.187 The preparation of a list of additional items of information that should be disclosed at the first tier will require public consultation. I shall not attempt to provide a definitive list. However, in my view there are some essentials, which I shall enumerate.

- 27.188 If a doctor has been erased from the medical register and restored, those facts and the circumstances behind them must be included. If the erasure was voluntary, that can be stated. If it was ordered by a FTP panel, that must appear, together with the underlying reason, in summary form. For example, the doctor was erased following his/her conviction for an offence of manslaughter at the XXX Crown Court. The date of erasure should be given. The date of the restoration should be given. In a case of erasure following a finding of SPM, the nature of the misconduct should be explained, for example, 'irresponsible prescribing of controlled drugs' or 'indecentcy with patients'. In my view, such information should be available for as long as the doctor remains on the register.
- 27.189 The fact that a doctor has been erased from the register and the reasons for it should be accessible to the public at the first-tier level for a limited period after erasure even if the doctor has not applied and may never apply for restoration. Now that the minimum period that must elapse before an application for restoration can be made is five years, I would suggest that such information should be available for seven years after erasure.
- 27.190 The fact that a doctor has been suspended from the register should be disclosed at the first tier, not only during the period of suspension, but for a period afterwards. I would suggest that a period of, say, seven years might be appropriate. The fact that conditions have been imposed should also be disclosed. The period of time for which these should remain on the register ought, in my view, to depend upon whether the condition related to some requirement for retraining (in which case a fairly short period would suffice) or whether it entailed some restriction on the circumstances in which the doctor was permitted to practise, in which case a longer period would be appropriate.
- 27.191 The fact that a warning has been given should be disclosed at the first tier. I would suggest that an appropriate period for disclosure would be five years. A brief explanation for the reason should be given: for example, a warning was given after an assessment of performance, or a warning was given following the receipt of a report of a conviction for stealing goods to the value of £20 from a shop.
- 27.192 Past convictions should, in my view, be disclosed at the first-tier regardless of the sanction, if any, imposed by the GMC. The period for which this information should stay at first-tier level should, I suggest, follow the periods laid down in the Rehabilitation of Offenders Act 1974.
- 27.193 In respect of any past FTP history or convictions, when the period of first tier disclosure has expired, a note should appear on the doctor's website entry to the effect that there is further information about the doctor which can be obtained (in effect at the second tier) by telephoning the GMC number. Any person seeking first-tier disclosure by telephone should be told if there is any further information which may be disclosed at the second tier.

The Second Tier

- 27.194 Disclosure at the second tier should be to people who make a specific request for information about a doctor's past FTP history. They should not be asked to identify themselves; nor should they be required to justify their request. The information should be

imparted without more ado to anyone seeking either further or full information about the doctor's FTP history. I do hope that the GMC will instruct its staff to be forthcoming with information rather than waiting for specific questions to be asked. This must not be a game of 'Twenty Questions'.

27.195 At its meeting in July 2004, the GMC accepted as a general principle that it must provide all information about a doctor that has at any time been in the public domain. It has not yet decided what to do about warnings after the expiry of five years. I think that the GMC's decisions were sensible. I quite understand the concerns of Council members that some items of past information should, for reasons of fairness, be put into context. This applies particularly to cases in which the doctor has been found not guilty of an allegation of misconduct but the fact that s/he was charged is in the public domain. It seems to me obvious that information that has been in the public domain should be provided by the GMC for as long as the doctor remains on the register.

27.196 The effect of the second tier would be that any person who was contemplating joining the list of a particular GP or who knew that s/he was about to be referred to a particular consultant would be able to find out what s/he needed to know to make an informed choice, at least so far as any history with the GMC was concerned. For example, if this system had been in operation when Shipman was in practice, anybody thinking of joining his list who had looked him up on the website would have seen that his current registration status was full and unrestricted and that he had no recent disciplinary history. However, they would have been alerted to the fact that there was something more to be known about him and would, by telephoning the GMC, have been able to find out about his convictions in 1976. I think that this arrangement provides a reasonable balance between the interests of the doctor in being able to put the past behind him/her (which would be difficult if full information remained on the website indefinitely) and the right of the public and patients to find out, if they are prepared to make a telephone call, everything that has at one time been in the public domain.

The Third Tier

27.197 The GMC has identified a number of types of information that should be disclosed only to a limited class of persons who have a need to know about it in the public interest. These classes of information must, I think, be matters that have never been in the public domain. I think that this approach is entirely reasonable. I would call disclosure of this confidential information to a limited class of persons third-tier disclosure. If my recommendations for a central database were accepted, it would be appropriate for the GMC to 'flag' the names of doctors about whom confidential information was held.

Information That Ought to Be Given to Patients of a Practice

27.198 So far, I have discussed only information that should be made available to any member of the public who wishes to obtain it. However, there are some situations in which, in my view, a positive duty to impart information arises. I mentioned above the action taken by a GP practice which had taken on, for supervision and remediation, a doctor previously convicted of manslaughter. The action taken was, in my view, exemplary. The

circumstances were rather unusual and it might be said that it would obviously have been wrong to allow the doctor into the practice without informing the patients. However, in my view, the good practice adopted in that case should apply to all cases in which a doctor is subject to conditions on his/her practice. It should also, I think, apply when a doctor has resumed practice following a period of suspension or erasure. In my view, the practice should send a letter of explanation to all patients. The draft should be approved by the PCT. Patients should have the opportunity to refuse to be treated by a doctor who is subject to conditions or has previously been suspended or erased. However, the experience of the practice to which I have referred suggests that they will not necessarily do so.

27.199 It is not part of my remit to make recommendations in respect of doctors working in hospitals. However, having read of the circumstances that arose in the case of Sadler v General Medical Council¹, to which I referred in Chapter 24, I will permit myself to observe that any patient who is to be operated on by a doctor who is subject to conditions should, in my view, be told about them and should be told what arrangements are proposed for the supervision of the operation. This information should not be imparted at a late stage when the patient is asked to sign the consent form. It should be given at a time when the patient can, without throwing all his/her personal arrangements into chaos, exercise a choice not to consent to that doctor carrying out the operation.

Proposals for Change Affecting the General Medical Council

The Fitness to Practise Procedures

27.200 In Chapter 25, I explained why it had been necessary for the Inquiry to examine the GMC's proposals for its new FTP procedures in some detail. I said that my examination of the old FTP procedures had identified a number of shortcomings and that it was important to find out whether those shortcomings would be remedied under the new procedures. In the course of Chapter 25, I reported my view that some of the defects of the old procedures had been remedied but that, in other important respects, the old shortcomings were to be perpetuated. I also found that some changes had been retrograde. I have already made a number of suggestions as to how the new FTP procedures might be improved. I have made these detailed recommendations because the Inquiry's Terms of Reference require me to make such recommendations as I consider necessary for the protection of patients in future and because I do not intend to recommend that the GMC should be deprived of its FTP function. In this section of this Chapter, I shall draw together those recommendations. In some cases, I shall only refer back to the passage at which the original recommendation was made.

The General Medical Council's Role in the Wider Regulatory Framework

27.201 In Chapter 18, I referred to the ambiguity in the GMC's perception of its role in the wider regulatory framework. In the past, it encouraged the public to see it as a repository for all complaints about doctors but did not have the resources to investigate all the complaints

¹ [2003] 1 WLR 2259.

it received. The result was that it sought to divest itself of many complaints that had not already been investigated by other bodies, often without even considering whether they raised a question of SPM. In effect, it was behaving as if it were a secondary referral body rather than an initial recipient of complaints. It does appear that this problem may have been resolved. First, the GMC has taken on a substantial number of investigators and should be in a position to deal with all allegations that it receives which fall within its jurisdiction. Second, as I have said at paragraphs 25.118–25.119, it appears that the GMC will no longer close cases, and advise complainants that they should pursue their complaints through local complaints procedures, before it has decided whether or not the allegation falls within its jurisdiction. It will give advice to that effect only after it has decided that the case does not fall within its jurisdiction. If that is indeed the case, it will be satisfactory.

27.202 It is inevitable that there will be complaints that are directed to the wrong destination. No doubt the GMC will continue to receive some that do not fall within its jurisdiction and other organisations will receive complaints and concerns which ought to be directed to the GMC. As I have said, the GMC has suggested that there should be a ‘single portal’ to assist persons who wish to make a complaint or raise a concern in directing that complaint or concern to the correct complaints handling body. This seems to be a good idea and, as I have already said, the Healthcare Commission is considering various options for the provision of such a service. However, the number of misdirected complaints would, I think, be reduced if the GMC were to ensure that its publications contained accurate and readily understandable guidance as to the types of case that do and do not fall within its remit.

27.203 The GMC has said that, where a case is referred to it by a person acting on behalf of a public body (usually an employer or a PCO), it may suggest that that body investigates the allegation before the GMC takes over the case. This may be done even though the allegation does, or might, fall within the GMC’s jurisdiction. However, I presume that this procedure would not be followed if the case required urgent interim action by the GMC. This procedure is acceptable provided that the other body, the employer or PCO, is content to investigate it and has the expertise and resources to do so and provided also that the GMC does not lose sight of the case. The GMC has said that it recognises the importance of bringing such cases back for further consideration after they have been investigated. In fact, the GMC should be able to use its influence with the PCT or NHS body to ensure that the investigation progresses satisfactorily. As these procedures will be new to GMC staff, I recommend that their operation should be audited, especially in the early days. As I understand it, it is not the GMC’s intention that this procedure should be applied to allegations made by private individuals. That would not be acceptable in my view.

Separation of Functions

27.204 In Chapter 25, I reported that, despite the GMC having recognised the need for separation of the investigation and adjudication functions, both the investigation and the adjudication stages of the new FTP procedures are still to be under the control of the GMC.

27.205 At the investigation stage, there is a casework function, which will be undertaken mainly by members of the GMC staff and case examiners. The Investigation Committee (IC) will

also undertake some casework in cases where the case examiners disagree and in cases where there is an oral hearing to decide whether to issue a warning. The IC's casework will be carried out by panels. At the moment, the Rules allow GMC members (as well as associates) to sit on IC panels. However, the GMC has told the Inquiry that the 'operational intention' is that they should not. If it is indeed intended that membership of IC panels should be limited to non-members of the GMC, the Rules should be amended to reflect that. There are also governance functions within the investigation stage. These include the setting of standards, criteria and thresholds, general supervision of the investigation stage and audit of the casework done by members of staff and case examiners and of decisions taken by IC panels. It was originally intended that the IC would undertake all these governance functions, in addition to its casework function. Recently, however, it has been recognised by some within the GMC that this would not be appropriate. In the immediate future, the governance functions relating to the investigation stage will be undertaken by the Fitness to Practise Committee. As I explained in Chapter 25, there is uncertainty about the future role of the IC. Whatever the eventual outcome, in my view, there must be complete separation of the casework function and governance function. It is inappropriate for one committee to have complete control of all aspects of the investigation stage.

27.206 The adjudication stage presents much greater problems of separation of function. The GMC initially considered hiving off the adjudication stage altogether but decided against it, preferring to keep both adjudication and investigation within the GMC and intending to introduce a measure of separation by using only non-members of the GMC for its adjudication stage casework. However, it appears to me that there is no real separation at all. As I have observed, under the present proposals, the GMC will select the FTP panellists (both for inclusion on the list of panellists and for inclusion on a panel in an individual case), train them, provide them with guidance, audit their decisions, appraise their work, and call them in for discussions about decisions with which it disagrees; it will also have the power to dismiss them if dissatisfied. The GMC is also proposing that, in future, it will or might indicate to a doctor, in advance of a hearing, the outcome that the GMC will seek in his/her case. If done, that might well have the effect of restricting FTP panels to the sanction sought by the GMC. Even without such a restricting indication, panellists will have very little independence. The GMC will also select the legal assessors and any specialist advisers or assessors who may be required. In 2000, the GMC rightly recognised that, under the Human Rights Act 1998, doctors were entitled to a fair and public hearing by an independent and impartial tribunal. I think that, in the future, it might well be alleged against the GMC that its FTP panels are not independent of the 'prosecuting' authority. Whether that allegation were to come from a dissatisfied doctor or a dissatisfied complainant does not really matter. The process would be much more satisfactory from the points of view of both patient protection and fairness to doctors if separation were to be achieved.

27.207 I realise that a great deal of effort has gone into the selection and training of the FTP panellists but I regret to say that I do not think the present arrangements are satisfactory. I must recommend that some mechanism be found for the appointment, training and management of both lay and medically qualified FTP panellists by a body that is independent of the GMC. That body would also have to provide administrative support for

hearings. I recommend that consideration should be given to the idea of appointing panellists who could sit full-time or nearly full-time on disciplinary or FTP panels for all healthcare regulators. They would acquire far greater experience than GMC panellists currently can. If this idea were adopted, it would be possible to have full-time legally qualified chairmen. The GMC should also divest itself of the right to appoint legal assessors; in any event, if legally qualified chairmen were to be used, legal assessors would not be required. Legally qualified chairmen could also undertake case management work. In any event, it would not be appropriate for the GMC to appoint case managers.

27.208 Precisely how this separation should be achieved, I cannot say. I have heard no evidence about the way in which other regulatory bodies arrange matters. It occurs to me that the other healthcare regulators may also have a need for independent panellists. It may be possible to set up a joint facility. I had thought that the Council for the Regulation of Healthcare Professionals, now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE), might be able to undertake this function but, on reflection, I do not think that it could. I think that there would be a conflict between its role of appealing unduly lenient decisions and a responsibility for appointment of the panels whose decisions it might wish to appeal. Having ruled the CRHP/CHRE out, I am unsure which other existing body could undertake the task. However, I consider that some way must be found because this is the only means by which the GMC can avoid the charge of being prosecutor and judge in the same case.

27.209 Hiving off the adjudication function would not deprive the GMC of all interest in the adjudication process. The GMC would still be involved in the development of standards, criteria and thresholds for all stages of the process, including the adjudication stage. It would also be able to monitor the outcomes of cases and thereby to inform itself of the need for any adjustment in the standards, criteria and thresholds. At paragraphs 27.213–27.230 below, I shall discuss the possible methods for the development of standards, criteria and thresholds.

27.210 If adjudication were to be hived off, as I have recommended, some of the recommendations that follow will be irrelevant. I shall make them nonetheless, in the event that this is not done.

The Statutory Tests

27.211 At paragraphs 25.41–25.69, I explained why I consider that the statutory test for the adjudication stage and the GMC's formulation of the investigation stage test will both give rise to difficulties of operation. I do not propose to repeat those reasons here or to restate what I think should be done to alleviate those difficulties. I recommend that the tests I have suggested be adopted.

A New Route to Impairment of Fitness to Practise

27.212 At paragraphs 25.70–25.71, I have explained why I consider that it would be desirable for section 35C of the Medical Act 1983 (the 1983 Act) to be amended to add a further route

by which there might be a finding of impairment of fitness to practise. This would be 'deficient clinical practice' and would be designed to cover those cases which involve, say, one or two incidents of negligence or poor clinical practice which do not amount to misconduct and which also do not show the pattern of poor clinical performance which is necessary in order to trigger a performance assessment. I recommend that that change should be made on the next occasion when the 1983 Act is amended.

Standards, Criteria and Thresholds

The Need

- 27.213 The need for the setting of standards, criteria and thresholds to be applied by those taking decisions at each stage of the GMC's FTP procedures runs as a thread through almost all of the last ten Chapters of this Report. Indeed, as I have said earlier in this Chapter, the need for agreed thresholds for the standards of professional conduct and medical care goes beyond the GMC. Patients should know what they are entitled to expect from the healthcare system. Those are the standards by which patient complaints should be judged. People working in healthcare management – and I include those working in PCOs – need standards by which they can decide whether they should take disciplinary action against a doctor or invoke their list management powers. At the moment, such managers have to make up their own minds about whether the conduct or practice under consideration is acceptable or not. They have to make up their own minds whether unacceptable conduct or practice is serious enough to justify a report to the GMC.
- 27.214 Elsewhere in this Report, I have referred to the occasions on which the GMC has been urged to formulate standards, criteria and thresholds for use by its decision-makers. In 1996, 2000 and 2003, Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute, urged the GMC to produce agreed standards, criteria and thresholds by which decision-makers could determine whether a set of facts amounted to SPM. Until recently, the response of the GMC has been that, at least until 2000, all decisions about SPM or SDP were being taken by highly qualified and experienced members of the GMC. There was no need for them to have standards, criteria or thresholds because they could recognise SPM and SDP when they saw them. They were also able to apply the appropriate tests at the preliminary stages of the FTP procedures. I cannot accept that that was so. In Chapter 17, I described the difficulties that had arisen in defining SPM. I reported that Sir Donald Irvine, who had very long experience as a member of the GMC, culminating in six years as its President, had said that disputes about whether a particular set of facts amounted to SPM gave rise to much 'heat' and 'emotion'. In addition, the need for standards, criteria and thresholds has been underlined by the many occasions on which, in this Report, I have drawn attention to inconsistency in decision-making at every stage of the old FTP procedures.
- 27.215 SPM and SDP as concepts have now disappeared, but I am convinced that the concept of 'impairment of fitness to practise' will be even more difficult to define and recognise. I accept that most doctors may believe themselves to be able to recognise impairment but, in doing so, they are applying their own personal standards. They are not applying agreed standards and, unless standards, criteria and thresholds can be agreed,

decisions on 'impairment of fitness to practise' will be inconsistent, as decisions on SPM were in the past. There will be no diminution in the 'heat' and 'emotion' of the debate or in inconsistency of outcome unless and until there are some agreed standards.

- 27.216 The GMC also argues that it provides standards and criteria in its publication 'Good Medical Practice'. Its stance is that departures from those standards might result in referral into the FTP procedures, with the possibility of action on registration. Yet it is clear that not every departure from the standards in 'Good Medical Practice' will result in referral into those procedures. The problem is that no one knows how serious a departure from 'Good Medical Practice' has to be before disciplinary action will be taken or action on registration will follow.
- 27.217 Another objection raised by the GMC to the suggestion that it should prepare agreed standards, criteria and thresholds for approaching decisions about SPM was that the process of doing so was difficult to the point of impossibility. SPM, the GMC argued (and I paraphrase) was capable of covering a very wide range of conduct and practice. It was not possible to devise a threshold for every single circumstance in which SPM might be found. I agree that the task in respect of SPM in the past would not have been an easy one. The task for the future, in respect of 'an impairment of fitness to practise' and 'an impairment of fitness to practise to a degree justifying action on registration' will be even more difficult. But just because it is difficult does not mean that it must not be tackled. The new FTP procedures have now come into operation and decision-makers will have very little help in deciding on which side of the various 'lines' a case will fall. The GMC has produced some draft guidance for case examiners and panellists at the investigation stage and for panellists at the adjudication stage. This guidance is in many respects sensible and helpful; it identifies relevant factors for decision-makers to take into account. But it does not go far enough; it does not help them to decide where to draw the line. They are still left to apply their own personal standards.
- 27.218 At the Inquiry hearings in December 2003, Sir Graeme Catto and Mr Scott said that it was the GMC's intention to provide a series of 'case reports' which would contain examples of circumstances in which SPM had or had not been found in the past. It was hoped that these would prove useful for decision-makers in the future. As I reported in Chapter 21, nine months later, five very brief case studies were published. These are so brief as to be 'unfit for purpose'. In addition, two of the five appear to be mutually inconsistent.
- 27.219 In Chapter 25, I have suggested tests for the investigation and adjudication stages which would, if adopted, make the task of decision-makers easier. These tests would help decision-makers to analyse the allegation or the established facts to see whether what is alleged would, if proved or admitted, amount to impairment of fitness to practise. However, I do not suggest that the new tests will remove the need for standards, criteria and thresholds. If the existing guidance, the case studies and my proposed tests are all that is to be provided (and these last may be rejected by the GMC), I foresee real problems of inconsistency at each stage of the process because individuals will be applying their own personal standards.
- 27.220 In the area of guidance on the imposition of sanctions, the GMC has made some progress, in that it has published Indicative Sanctions Guidance (ISG). This is helpful; it provides a

general idea of what kind of sanction is appropriate where certain features are present in a case. The guidance is particularly helpful where it descends into the detail of how to approach a particular class of case. However, although the ISG is helpful, in my view, panellists need more help. I recognise that there is now a means by which any decision on sanction can be appealed, either because it is too severe or because it is unduly lenient. However, I think the GMC would agree that it would not wish to rely upon the appeal process in order to establish a proper framework for the imposition of sanctions. I am sure that it would agree that it would be preferable if the decisions were right in the first place.

What Should Be Done?

27.221 I have said enough about the need for the development of agreed standards, criteria and thresholds. I accept that the task of development is not easy. I have observed earlier in this Report that it is easier to criticise the work of others than to propose a better way. I do wish to be constructive. It appears to me that there are two possible ways of approaching the problem of standard and threshold setting.

27.222 One method would involve analysing a number of sets of circumstances (topics) that might be expected to arise in FTP procedures and envisaging gradations of increasingly serious examples of conduct or practice within that topic and deciding where the thresholds should lie. I did not know whether this idea would be feasible. Accordingly, the Inquiry invited Professor Baker to produce a paper setting out his ideas about how the task of analysing topics and setting standards, criteria and thresholds might be tackled. His work has now been published on the Inquiry website. I shall summarise his suggestions as briefly as I can.

Professor Baker's Paper

27.223 Professor Baker envisages that research would have to be done into the likelihood that certain features in a particular case are valid indicators of a doctor's fitness to practise. Conduct of the research would require the collection of evidence from a wide variety of sources. The starting point would have to be actual cases in which decisions had been made, either by the GMC or by NHS trusts, about allegations of misconduct, etc. There would have to be systematic follow-up of such cases to find evidence of the likelihood of further complaints or problems associated with particular categories of complaints. There would also have to be comparisons between doctors with selected characteristics who have or have not had complaints made about them. In addition to evidence derived from actual cases, Professor Baker suggests that further information would also be required about public expectations and about the ethical codes of healthcare professionals, including international codes. When all this information and evidence has been assembled, some means would have to be found of combining it so as to produce a set of standards and criteria suitable for use in medical regulation. That process would involve the making of value judgements. Accordingly, in Professor Baker's view, the public and healthcare managers should be involved, as well as members of the medical profession.

27.224 Professor Baker then considers a number of options by which this process might be undertaken. He discusses the advantages and disadvantages of the various methods,

including their validity, feasibility and cost. He considers options for the scope of the standards and criteria, for example, whether the scope should be limited to the issues covered by 'Good Medical Practice' or whether it should cover issues raised in wider consultation within and outside the GMC. Another set of options relates to the classes of people who might be involved in the standard-setting process. He assumes that the GMC will be at the heart of the process but considers the advantages and disadvantages of involving other groups. He examines various options for discussion and decision-making in the standard-setting groups. He considers different options for the testing and updating of the standards and criteria that would result from the initial standard-setting process. Professor Baker does not say which of these various options should be adopted, although he expresses a preference for processes which involve a wide range of consultation, as he considers that the results would be more likely to attract and retain public confidence.

27.225 Finally, Professor Baker gives some hypothetical examples of the way in which standards might be set on various specific topics, all taken from the principles set out in 'Good Medical Practice'. These include establishing a clinical history, taking suitable and prompt action, keeping clear records, taking part in audit, dealing with patients who decline to take part in teaching or research, raising concerns about fellow healthcare professionals and the duty of honesty in record keeping, document preparation and certification. The resulting hypothetical standards do not demonstrate actual thresholds but they do produce categories of conduct which are to be regarded as 'acceptable', 'unacceptable' and 'seriously unacceptable'. It seems to me that, if standards of this kind could be produced for a large number of topics, the task of decision-makers both within and without the GMC would be made very much easier.

An Alternative Approach: the Use of Case Summaries

27.226 Another possible approach would be to use a collection of case summaries, in which decisions that are agreed to be 'correct' could be collated into topic groups and published. Such collections of cases would not seek to define thresholds but would, rather, seek to illustrate where the threshold had been (correctly) set on other occasions. It would be necessary to have examples that fall on either side of any dividing line so that the decision-maker is able to 'get his/her eye in' as to which side of the line the particular case under consideration should fall. This is a process which is used extensively in legal work. For example, there exist two encyclopaedias on employment law, containing a large number of case summaries from which practitioners and decision-makers can develop a 'feel' for whether a dismissal has been fair or unfair. There is a book containing cases about road traffic accidents; the decision-maker can 'get his/her eye in' about whether, in a particular set of circumstances, a driver, cyclist or pedestrian has been negligent. There are encyclopaedias on sentencing in criminal cases and on awards of damages in personal injury cases. None of these case collections seeks to provide the 'right answer' in any particular case because the facts of all cases are different and because there must be an element of discretion for the decision-maker. But they do enable practitioners and decision-makers to 'get their eye in'.

27.227 Because it is important that the GMC decision-makers should have guidance on thresholds for use at both the investigation and the adjudication stages, the preparation

of the case summaries would entail the examination of quite a large number of cases which had come into the FTP procedures. For a start, all the cases entering the procedures during a three-month period might be examined. All would be anonymised and the available information summarised using a standard template so that different cases could be readily compared one with another. After the investigation stage decision had been taken, all cases would be considered by a group of assessors who would decide whether, in their view, the decision taken was 'correct'. Cases with 'incorrect' decisions would be discarded; cases with 'correct' decisions would be used as guidance on the investigation stage test. Cases which had gone before FTP panels would also be considered by the group of assessors. If a decision on 'impairment of fitness to practise' and/or 'impairment of fitness to practise to a degree justifying action on registration' was considered 'incorrect', the case would be discarded. Those cases with 'correct' decisions would be used as guidance. The assessment group would also consider any sanctions imposed or decisions not to impose a sanction. Once again, 'incorrect' or inappropriate decisions would be discarded and 'correct ones' would be kept as guidance. As more cases were collected, it would be possible to divide them into groups and subgroups relating to different types of commonly occurring case. For example, it would not be long before there were groups of cases involving the abuse of drugs, dishonesty, indecency and improper relationships with patients. In due course, there would be groups of cases of many different types, including health and performance cases.

- 27.228 If this approach were to be adopted, the assessment group should, in my view, comprise some doctors, other healthcare professionals, healthcare managers and some lay people from a variety of backgrounds. In Chapter 21, I mentioned the Sentencing Advisory Panel, which advises the Court of Appeal (Criminal Division) on sentencing policy. Some of its members are judges, barristers and solicitors but there is also a strong non-legal membership. I have in mind a comparable mixture of medical and lay members. I would expect the GMC to have a major voice within the group but the objective would be to reach a consensus acceptable to both the medical profession and the public.

The Way Forward

- 27.229 It is not my intention to recommend either the use of Professor Baker's suggested method or the alternative method of collecting case summaries. It seems to me that the advantage of Professor Baker's method is that the results would be soundly based in scientific evidence. The major disadvantage is that I think it would take a long time to produce results that could be used by decision-makers. The advantage of the case summary method is that it would be easier to set up and results could be expected in a shorter time. The results would be based on actual cases and would therefore soon provide guidance on the kinds of case that crop up regularly. The GMC Presenting Officers and the doctors' representatives would soon become familiar with the published case studies and would be able to draw a FTP panel's attention to any that were comparable to the case under consideration. Panellists would not be expected to become familiar with all the case summaries. Such case summaries would also be useful for the courts when dealing with appeals. The GMC might have other ideas about how this work should be done. Yet more ideas might come from other quarters. I hope that there will be a debate about the best

way forward. However, it is vital that this problem must not be shelved. Some way must be found – soon – to provide guidance on standards, criteria and thresholds so that decision-makers will be able to reach reasonably consistent decisions at both the investigation and the adjudication stages.

27.230 It appears to me that, whatever method of standard setting is to be adopted, a panel or group of people will be required. This is essential if the public is to have confidence in the results. It seems to me that the CRHP/CHRE could play an important role here. Indeed, it may be that it would welcome the opportunity to facilitate the setting of standards across the whole field of healthcare regulation. Many of the issues that arise in GMC cases, such as dishonesty, indecency, breach of confidentiality and failure to obtain proper informed consent, must arise in other contexts. I recommend that the CRHP/CHRE be invited to set up a panel of professional and lay people, similar in nature to the Sentencing Advisory Panel, which would be the vehicle for whatever method of standard setting is eventually adopted. It could remain in existence and review standards periodically.

Standards in Relation to Performance Procedures

27.231 In the passage above, I have discussed the need for the setting of standards in respect of many aspects of misconduct and clinical practice. In the past, the problem has been lack of agreement as to what amounted to SPM. However, a different problem arose in respect of the GMC's performance procedures. There, a standard had been set. The GMC performance assessment tools (for GPs) are calibrated against the standard of summative assessment, the process used to assess whether a doctor's competence and performance are adequate for him/her to be admitted to general practice. The problem is that, in the past, panels of the Committee on Professional Performance (CPP) appear on occasion to have applied their own personal standards (rather than the standard at which the performance assessment tools are set) when considering whether a doctor's performance was seriously deficient. I have mentioned more than once in this Report the fact that the standards applied within the GMC's performance procedures have been very low. I shall not quote the evidence relating to this again. There is no indication of an intention to raise them under the new FTP procedures. This low standard will, to a very large extent, underpin revalidation. In my view, for reasons of patient protection, there is an urgent need for this standard to be raised. There can be no justification for judging the performance of an experienced GP by a standard lower than the equivalent of the standard set for admission to general practice. I do not know how this problem should be solved but I recommend that the GMC should give urgent attention to it. Unless this is done, patients will be left at risk and revalidation will be without value.

The Investigation Stage

The Preliminary Sift: the Test for Jurisdiction

27.232 At paragraph 25.115, I have expressed the view that the rule which sets out the test to be applied by the Registrar (or by a member of the GMC staff, exercising his legal powers) on receipt of an allegation should be amended to give greater clarity. I have suggested an appropriate wording. It may be that there is no confusion within the GMC about the

meaning of the rule. However, the meaning of the words should be clear to all. There is a need for decisions taken at this stage to be audited to ensure that the test is being correctly applied. I also recommend that criminal cases in which a doctor has been conditionally discharged should be treated as convictions.

Advising the Makers of an Allegation to Use Local Complaints Procedures

27.233 At paragraphs 25.116–25.120, I discussed the practice (which, so far as I know, was followed until the termination of the old FTP procedures) of closing cases in which local complaints procedures had not been exhausted, without considering whether they raised a question of SPM. I have said that, in my view, this practice was not only unlawful but also not in the interests of patient protection. I had hoped to see a clear and unequivocal statement that the practice had been abandoned under the new procedures. No clear statement has been made. As I have said, I have examined the Rules, the draft Guidance, the November 2004 draft Investigation Manual and the initial processing and assessment form. The only reference to the giving of advice about the use of local complaints procedures appears in a context which suggests that such advice will be given only in cases in which the GMC has already decided that the case does not fall within its remit. I would feel completely reassured by that state of affairs, were it not for the fact that there was no reference to this practice under the old Rules. The practice went on ‘outside the Rules’ and was followed in hundreds of cases every year. I want to give the GMC the benefit of the doubt. I want to conclude that the GMC has indeed abandoned this bad practice under the new FTP procedures. I do not feel that, at present, I can do so with confidence. It would have been quite possible for the GMC to put an immediate stop to the practice at any stage; no legislation would have been required. I hope that this practice has stopped with effect from 1st November 2004. However, there is a danger that the practice will linger on because staff are so used to it. I recommend that there should be an audit of the reasons why cases are closed and of cases where consideration by the GMC is deferred. That audit should take place quite frequently.

Preliminary Discussions and Disclosure to Employers and Primary Care Organisations

27.234 At paragraphs 25.122–25.126, I discussed the practice, introduced in May 2004, whereby the GMC communicates informally with employers and PCOs before deciding what action, if any, should be taken in response to an allegation. Such communications should be an important source of information to the GMC. The idea of adopting this procedure was discussed in evidence at the Inquiry hearing when Mr Scott said that the GMC would consider it. He has since reported to Council that the practice is yielding useful information. I have noted that it has been reported that some of the medical defence organisations have objected to this new procedure but, as the November 2004 draft Investigation Manual provides for staff to communicate in this way, I assume that the GMC has decided that it should continue. I recommend that the Rules be amended to make formal provision for this practice, and to give the GMC power to require from the doctor the necessary details to enable it to make such a communication.

The Power to Direct Investigations

27.235 I recommend that case examiners should have the power to direct that particular investigations should be undertaken. They would have had that power under the 2003 draft Rules. Under the November 2004 Rules, the power to direct investigations lies solely with the Registrar, which, in practice, means that it lies with the GMC staff. I also recommend that IC panels hearing cases where the case examiners have disagreed should have the power to direct investigations.

Case Examiners

27.236 I recommend that case examiners, who are not lawyers, should be given advice about two matters. They should not take into account mitigation advanced by or on behalf of the doctor. It is not relevant to their decision at the investigation stage: see paragraph 25.163. Also, they should be advised to consult a lawyer if they are in any doubt as to whether there is a realistic prospect of proving the allegation: see paragraph 25.169.

Performance and Health Assessments

27.237 The November 2004 Rules provide that the Registrar may direct a performance and/or health assessment during the investigation stage. I recommend that case examiners and the IC should also have that power. I do not know what the policy will be for directing such assessments. I know that a full performance assessment is expensive and time-consuming. The Inquiry heard evidence that the GMC was considering the possibility of devising an abridged assessment and there were also suggestions that the work of assessment might be undertaken on a modular basis or that it might be 'outsourced'. I do not know what developments there have been in these respects. In my view, it would be highly desirable for there to be an abridged form of assessment which could be used as a screening tool to detect whether there is a problem with the doctor's performance, rather than seeking to measure the extent of it, as the full assessment does. I would have thought that an adaptation of the Professional and Linguistic Assessment Board test, or possibly a modified version of Phase II of the current performance assessment, might suffice. In my view, such an abridged assessment should be ordered in any case in which an allegation is made which potentially calls into question the doctor's clinical practice, either because there are one or more allegations of bad clinical practice (such as perhaps a prescribing error) or because there are allegations that raise more general issues of poor performance. If the work has not already been undertaken, I recommend that the GMC should develop an abridged performance assessment and should use it as a screening tool. The GMC will, of course, also need a full performance assessment tool, on which to rely as evidence to place before a FTP panel. In order to avoid multiple assessments, I also recommend that the GMC should investigate the development of a modular assessment: see paragraphs 24.200–24.205.

27.238 As I explained at paragraphs 25.240–25.241, the draft Rules published in May 2004 would have provided that, on receipt of the report of an assessment of a doctor's performance, the Registrar should send a copy to the doctor's employer or PCO. The effect of this would have been to ensure that those with responsibility for clinical governance were fully aware

of any problems of performance which might affect the doctor's fitness to practise and which thus might have an impact on the safety of patients. However, the provision does not appear in the November 2004 Rules and it appears that it has been dropped.

27.239 I do not see how local NHS bodies can properly discharge their clinical governance obligations if they do not have access to this kind of information about the doctors for whom they are responsible. I therefore recommend that the provision should be reinstated as soon as possible.

Criteria for Letters of Advice

27.240 At paragraphs 25.174–25.180, I observed that the circumstances in which letters of advice were to be sent to doctors under the new procedures had remained as obscure as they were under the old procedures. The GMC recognised the need for greater transparency in this respect but has not made any changes to improve the position. I recommend that criteria for the sending of letters of advice should now be prepared and the power to send letters of advice should be incorporated into the Rules. The need for transparency is related to patient safety. If there are no clear criteria for the sending of letters of advice, there is a danger that this procedure will be adopted in cases which should be dealt with more severely; in other words, it may be used as a 'soft option'. The use of letters of advice should be audited to ensure that this does not happen.

The Issuing of Warnings at the Investigation Stage

27.241 At paragraphs 25.181–25.196 and 25.204–25.218, I have discussed the difficulties which I think will arise in connection with the GMC's proposals to issue warnings at the investigation stage. I fear that the proposed procedures for a 'summary' oral hearing will be almost unworkable. I recommend that the GMC should reconsider these proposals in the light of my observations. I think that, in most cases in which a warning might be given at the investigation stage, it would be more appropriate for there to be a full hearing before a FTP panel which should decide whether the doctor's fitness to practise is impaired. In the event that the GMC decides to proceed with its proposals as planned, I consider it important that the issuing of warnings by case examiners and the IC should regularly be audited. In particular, the question of whether it would have been more appropriate for the case to proceed to a FTP panel should be considered. There should also be audit of those cases in which an invitation is issued to a doctor to make written representations about the giving of a warning but where, on receipt of the representations, no further action is taken after receipt of the doctor's representations.

The Procedure for Cancellation

27.242 At paragraphs 25.243–25.250, I reported on the GMC's proposals for the cancellation of cases which have already been referred to a FTP panel. These provisions lack transparency and are open to abuse. I recommend that they be changed in the way that I have suggested, so that decisions on cancellation should be taken by panels of the IC and the reasons for the cancellation formally recorded. Both applications to cancel and cancellation decisions must be monitored and audited, and the reasons for the

applications and decisions should be scrutinised with a view to steps being taken to minimise the number of cases in which referrals are subsequently cancelled. The number of cancellations and the reasons should be published in the GMC's annual report.

Consensual Procedures

27.243 At paragraphs 25.251–25.253, I have sounded a note of caution about the GMC's intention to introduce consensual procedures for cases other than those raising problems of adverse health or deficient performance. There is a danger that such procedures might lead to the 'fudging' of factual issues. Such procedures could be open to abuse, as I explained in Chapter 25. I recommend that, if the GMC pursues its present intention to extend consensual procedures to all categories of cases, the disposal of such cases should take place in public at the adjudication stage and not in private as part of the investigation stage.

Revival of Allegations

27.244 At paragraphs 25.254–25.256 I mentioned that the practice of 'reviving' closed cases was to be discontinued under the new procedures. I recommend that there should now be proper provision, enshrined in the Rules, whereby closed allegations can be revived. I have suggested that the usual 'cut-off' period should be five years but that it should be possible, in exceptional circumstances and in the interests of patient protection, to reopen a case at any time.

Review of Investigation Stage Decisions

27.245 At paragraphs 25.257–25.264, I have welcomed the GMC's proposal to introduce a review of investigation stage decisions, albeit only in limited circumstances. However, I recommend that the review should be carried out not by the President of the GMC, as is currently proposed, but by an independent external commissioner, appointed for the purpose. The commissioner could be appointed by the SoS. I also recommend that the right to a review should be extended to decisions of members of staff to reject an allegation rather than refer it to a case examiner.

Voluntary Undertakings in Cases with a Health Element

27.246 In Chapter 25, I have expressed a number of concerns about the way in which the giving of voluntary undertakings in cases with a health element will operate in future. First, at paragraphs 25.223 and 25.232, I lament the decision to remove responsibility for the operation of many aspects of the voluntary procedures from case examiners to GMC staff, who are not medically qualified. Under the 2003 draft Rules, it appeared that the voluntary procedures would be operated very much as they had been under the old health procedures, with an appropriately medically qualified case examiner taking over all the responsibilities formerly held by the health screeners. Those old arrangements were working well and it seems to me wrong to change them without good reason. I recommend that the GMC reverts to its original intention in this respect and employs one or two case examiners suitably qualified to carry out the former role of the health screeners.

I recommend that the November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of health assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to health should be directed by a medically qualified case examiner. If a case is to be closed on the basis of a health assessment, the decision should be taken by two case examiners, one medically qualified and one lay and, if they disagree, by an IC panel.

27.247 If that recommendation were to be accepted, my only other recommendations in respect of cases involving a health element concern various issues arising out of supervision and the cessation of supervision. As these issues arise both in cases which will be dealt with by way of voluntary undertakings and in cases where conditions are imposed by a FTP panel, I shall deal with them later in this Chapter.

Voluntary Undertakings in Cases with a Performance Element

27.248 At paragraphs 25.238–25.239, I expressed my regret that most of the functions that used to be performed by medically qualified performance case co-ordinators will now be carried out by GMC staff, who are not medically qualified, rather than by medically qualified case examiners. Under the 2003 draft Rules, the functions of case co-ordinators were to be transferred to case examiners but, in 2004, most of them were transferred to members of staff. In Chapter 25, I have explained why I regard that change as retrograde. I recommend that the November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of performance assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to performance should be directed by a medically qualified case examiner, who should fulfil the functions previously carried out by a performance case co-ordinator. If a case is to be closed on the basis of a performance assessment, the decision should be taken by two case examiners, one medically qualified and one lay and, if they disagree, by an IC panel.

27.249 In evidence, the Inquiry was told that, in the future, the GMC intended to concentrate on regulation and not to become involved in the long-term remediation of doctors whose performance was deficient. I am not sure whether that remains the GMC's intention. It appeared to me to be an appropriate change of approach.

The Adjudication Stage

Fitness to Practise Panels and Procedures at Panel Hearings

27.250 I recommend that there should be an explicit power in the Rules to allow the GMC to undertake any further investigations it thinks necessary after a case has been referred to a FTP panel and before the hearing. Such a power may be implicit but the position should be clear.

27.251 I have already recommended that the GMC should think again about its decision to retain control of the adjudication stage and should divest itself of the right to appoint, train and manage panellists. However, in the event that the GMC resolves to continue on its present course, I have some recommendations to make in respect of the adjudication stage.

- 27.252 I have welcomed the introduction of case management provisions, although I must point out that it is inappropriate that the GMC should have responsibility for 'management' of case managers. I recommend that the committee charged with governance of the adjudication stage should audit the work of case managers to ensure that the orders made are adequately tailored to the needs of individual cases and to achieve the desired effect. I recommend also that case management should apply to cases with a performance element.
- 27.253 For reasons I explained in paragraph 25.285, I recommend that panellists should be advised to exercise caution about drawing adverse inferences from the failure to comply with case management orders.
- 27.254 In the event that the GMC decides to continue to be responsible for adjudication, notwithstanding my recommendation that it should be hived off, I recommend that the GMC should appoint a number of legally qualified chairmen who should, as an experiment or pilot scheme, preside over the more complex FTP hearings. The results of the pilot scheme should be scrutinised to see whether there are benefits in terms of the improved conduct of hearings, more consistent outcomes, improved reasons and fewer appeals.
- 27.255 I recommend that, as part of their training, FTP panellists should be advised about their discretion to admit hearsay evidence and other forms of evidence not admissible in a criminal trial. Panels have had such a discretionary power for many years but the evidence received by the Inquiry suggests that it was not used as flexibly or frequently as it should have been. Panellists should also be advised, during training, that it is entirely appropriate for them to intervene and ask questions if they feel that any issue is not being adequately explored. The proceedings should not be strictly adversarial; the FTP panel has an inquisitorial function.
- 27.256 I recommend that the GMC should reopen its debate about the standard of proof to be applied by FTP panels. The GMC has recognised that, in the future, FTP panels will sometimes have to consider allegations of misconduct and deficient performance at the same hearing. The application of different standards of proof may cause difficulty. Also, there should be full recognition that the GMC's primary function is to exercise a protective jurisdiction and not a punitive one. That means that the civil standard of proof will usually be appropriate. I recommend that the GMC should introduce the civil standard of proof for all FTP decisions. However, I do accept that it is arguable that, for allegations which also amount to a criminal offence, the criminal standard of proof may be appropriate.
- 27.257 For reasons that I explained at paragraphs 25.274–25.279, I recommend that the GMC should abandon its intention to inform the doctor of the desired outcome of a case in advance of the hearing. It is not inappropriate for a GMC representative to make a submission as to outcome after the evidence has been heard, but it must be plain that this is only a submission and cannot in any way bind the panel.
- 27.258 For the reasons given in paragraph 25.309 I recommend that FTP panels should be required to give brief reasons for their main findings of fact.
- 27.259 At paragraph 25.310, I noted that, before deciding whether a doctor's fitness to practise is impaired, a FTP panel will have the power to order a health or performance assessment.

That power arises under rule 17(4). I welcomed that development. However, I expressed concern that, under rule 17(5)(b), on receipt of the assessment report, the FTP panel is empowered (without deciding whether the doctor's fitness to practise is impaired or even without making findings of fact) to send the case back to the investigation stage so that case examiners can consider whether it would be appropriate for the doctor to be dealt with by way of voluntary undertakings. I said that such a course would not be satisfactory and explained why. Rule 17(5)(b) deprives the proceedings of transparency. I recommend that rule 17(5)(b) be revoked.

27.260 At paragraphs 25.313–25.315 and 25.317, I drew attention to the fact that there is no specific provision in the November 2004 Rules which requires or enables a FTP panel to take into account a doctor's FTP history when considering the issues of impairment of fitness to practise and of sanction. The 2003 draft Rules had included such a provision. The omission in the November 2004 Rules is puzzling since it surely cannot be intended that FTP panels should not consider this information. It is all the more surprising since the rules governing the procedure of IC panels specifically empower them to take into account a doctor's FTP history with the GMC or any other regulatory body when deciding whether to issue a warning. I recommend that rule 17(2)(j) should be amended to make clear what types of further evidence should be received before the panel decides whether the doctor's fitness to practise is impaired. In my view, that should include evidence of the doctor's FTP history. I had also envisaged that it would include any evidence the doctor wished to advance in mitigation, including purely personal mitigation. Also, rule 17(2)(l) should be amended to make clear what categories of evidence might be received after a finding of impairment of fitness to practise but before determination of sanction. I do not know what further evidence the GMC contemplates might be admitted at this stage.

27.261 At paragraph 25.316, I referred to the inconsistency between, on the one hand, the provisions of section 35D of the 1983 Act and rule 17(2)(k) of the November 2004 Rules and, on the other hand, the contents of the September 2004 draft Guidance for Panellists. The draft Guidance must be corrected as it will confuse panellists. I have also referred to what I consider to be the illogicality of the various outcomes open to a FTP panel. As I have explained, the November 2004 Rules require a FTP panel to decide whether the doctor's fitness to practise is impaired. If the FTP panel decides that his/her fitness to practise is *not* impaired, the FTP panel has the power, under the 1983 Act, to give the doctor a warning as to his/her future conduct or performance. Although at first sight this appears odd, I can understand that a warning might be appropriate in a case where a doctor has done something wrong in the past but where the panel considers that there is no current impairment of fitness to practise. However, if the FTP panel finds that the doctor's fitness to practise is impaired, it has no power to issue a warning. The options open to it in that event are to take no action at all, or to take action on the doctor's registration – by imposing conditions on or suspending registration, or by erasing the doctor's name from the register. I recommend that the legislation be amended to permit a panel to issue a warning where it has found an impairment but one that is not of a degree justifying action on registration.

27.262 At paragraphs 25.324–25.326, I referred to the new provision (rule 17(2)(m)) which would permit a FTP panel to 'take into account' any written undertakings (including undertakings

relating to limitations on his/her practice) entered into by the doctor which the FTP panel considered to be sufficient to protect patients and the public interest. I said that it was not clear to me at what point in the proceedings it was intended that such undertakings should be taken into account. If the FTP panel were to take undertakings into account at the stage of deciding what sanction to impose (e.g. by accepting the undertakings rather than imposing formal conditions), that might be acceptable provided that there was provision within the Rules for supervision of the doctor to ensure compliance with the undertakings and for dealing with a breach. There would also have to be provision for review hearings in cases where undertakings had been given. At present, there is no such provision and I recommend that, if rule 17(2)(m) is to be retained, the Rules should be amended as a matter of urgency to include such provision. If there is no means of ascertaining whether a doctor is complying with undertakings which s/he has given and no means of dealing with him/her if s/he is not, patients cannot be adequately protected. That said, I do not see the necessity for undertakings to be given at the sanction stage. By that time, the FTP panel will have made its findings in relation to impairment of fitness to practise and action on registration and will have heard evidence and/or submissions. It will be in a position to impose conditions of its own choosing. If it does so, provision for review hearings and for action in the event of breach are contained within the existing Rules. I cannot see anything to be gained by the new provision and I recommend that the best course of action is for rule 17(2)(m) to be revoked.

- 27.263 My concern is that it may be intended that undertakings should be 'taken into account' by a FTP panel before it has made findings of fact and/or a decision on impairment of fitness to practise. The provision is wide enough to permit this. That could lead to the 'fudging' of these important issues and would be most unsatisfactory. I recommend that, if it is to be retained, the rule should be redrafted to make clear that undertakings can be taken into account only at the stage of deciding on sanction after findings of fact and of impairment of fitness to practise have been made.

The Need for Supervision

- 27.264 I recommend that, throughout the period that a doctor's registration is subject to conditions, someone within the GMC (I would suggest a case examiner) should take responsibility for monitoring the doctor's progress and for ensuring, so far as is possible, that s/he is complying with the conditions imposed. That is vital for the protection of patients. I further recommend that, in every case where a doctor is continuing to practise subject to conditions, a professional supervisor should be appointed to oversee the doctor's progress. I recommend that such professional supervisors should be in direct contact with the case examiner appointed by the GMC and should be required (like medical supervisors under the old voluntary health procedures) to provide regular written reports on the doctor's progress and on his/her compliance with conditions and restrictions on practice. I consider that the direct contribution of the professional supervisor would enhance the quality of the overall supervision and thus reduce the risk to patients of allowing such doctors to continue in work. In a case where the doctor's health is an issue, a medical supervisor should be appointed as under the old voluntary health procedures.

- 27.265 Any breach of a condition imposed by a FTP panel (save for the most minor breach) should result in the doctor being brought back before the panel so that consideration can be given to imposing a sanction which affords a greater degree of protection to the public.
- 27.266 So far, I have referred to the need for supervision of doctors who are subject to conditions imposed by a FTP panel. However, the same considerations apply to doctors who have given voluntary undertakings or had undertakings 'taken into account' by a FTP panel. Where the case raises issues of health, the doctor should be subject to medical supervision as under the old voluntary health procedures. In all cases where voluntary undertakings are in place and the doctor is continuing to practise, a professional supervisor should be appointed. I recommend that such professional supervisors should be in direct contact with the case examiner appointed by the GMC, even in health cases where, in the past, the arrangement has been for a professional supervisor to be in indirect contact only, through the medical supervisor.

Review Hearings

- 27.267 The most recent guidance from the GMC suggests that, where a period of suspension of or conditions on registration has been imposed, there will '**generally**' be one or more review hearings at which the FTP panel may, *inter alia*, extend the period of suspension or conditional registration or revoke or vary the conditions or permit the doctor to resume unrestricted practice at the expiry of the period of suspension or conditional registration. Review hearings are extremely important. They are the 'teeth' behind the sanctions other than erasure and should focus the doctor's mind on the need to undertake any necessary remediation. I recommend that the Rules should be amended to ensure that there is at least one review hearing in all such cases, unless there are exceptional reasons why no hearing should take place. The period within which the first review hearing is to be held should be set at the original hearing and should be within a reasonably short period (no more than a year in a case where conditions have been imposed); this will enable the FTP panel to ensure that the doctor is complying with his/her conditions and making progress. A second review hearing can then be fixed for a time near to the expiry of the period of conditional registration at which the fitness of the doctor to return to unrestricted practice can be considered. There should be an expectation that the doctor will give evidence and answer questions from the FTP panel.
- 27.268 The November 2004 Rules provide that the Registrar (in practice, the staff exercising his legal powers) may carry out any necessary investigation and obtain any expert or other evidence that he considers necessary in preparation for a review hearing. He may also invite the doctor to undergo an assessment of his/her performance or health. Under the 2003 draft Rules, these functions would have been carried out by a designated case examiner. I recommend that the arrangements set out in the 2003 draft Rules should be reinstated. The kind of investigations to be undertaken (in particular, the commissioning and consideration of expert reports and assessments) should be undertaken by medically qualified case examiners. Of course, they will require the support of staff in administering the arrangements but a case examiner should take the decision about the type and extent of evidence that will be required by the FTP panel at the review hearing. If, as I have suggested, the case examiners are to have responsibility for monitoring the progress of

doctors who are subject to conditions, it will be even more appropriate for them to direct the preparations for review hearings.

- 27.269 In the past, doctors have been permitted to return to practice after the expiry of a period of suspension or conditional registration without any further hearing of their cases by a panel of the Professional Conduct Committee (PCC). Sometimes, the doctor has been released from conditions on registration on the basis of a report from the person overseeing his/her remediation. It has not been unusual for the PCC and the CPP to allow a doctor to return to unrestricted practice without any objective assessment being made to ensure that the deficiencies which led to the original sanction being imposed have been cured and that the doctor is indeed fit to practise. Under the November 2004 Rules, as I have said, the Registrar has the power to invite the doctor to undergo a performance or health assessment but there is no requirement that the Registrar should do so. In my view, this is unsatisfactory and does not afford adequate protection for patients.
- 27.270 I recommend that, in all but exceptional cases, a doctor whose registration has been suspended should be required to undertake an objective assessment of his/her fitness to practise before being permitted to return to practice. The kind of exceptional circumstances I envisage are where the doctor has been subject to a short period of suspension which was intended to be a 'sharp rap on the knuckles' for an incident of misconduct which did not affect his/her clinical competence or performance. In all other cases, it is likely that the doctor will have been found to have a serious impairment of fitness to practise and that the period out of practice will have rendered him/her even less fit to practise than hitherto. An assessment is, therefore, imperative. That assessment should be considered by a FTP panel and a decision taken as to the doctor's fitness to practise. Even when a doctor who has been the subject of a suspension is deemed fit to return to practice, it will in most cases be appropriate for him/her to be subject to conditions (in particular a condition of professional supervision) for a period after s/he resumes practice and for a further hearing to be fixed at which his/her progress in practice can be considered and a decision taken as to whether s/he is fit to practise unrestricted.
- 27.271 Where a doctor has been subject to conditions on his/her registration, s/he should be required to undertake an objective assessment of his/her fitness to practise before being permitted to return to unrestricted practice. That assessment should be considered by a FTP panel at a review hearing in the way that I have described above.
- 27.272 The nature of the assessment will vary according to the aspects of the doctor's performance, health or conduct that gave rise to the suspension or conditions. It will not necessarily be the full performance assessment although, in cases where there has been a multiplicity of deficiencies, this may be necessary. In a case where the doctor's competence has been deficient, it may be appropriate for him/her to undertake an assessment comprising all or part of Phase II of the performance assessment. Where a doctor has been required to undergo a specific type of retraining, an assessment based on his/her competence and performance in that particular area of practice might be suitable. What is essential is that the doctor should not be allowed to return to unrestricted practice unless and until the deficiencies which led to action being taken on his/her registration have been successfully addressed and s/he meets an acceptable standard

of practice. At present, the appropriate standard for GPs is that set for summative assessment; it is to that standard that the performance assessment instruments are calibrated.

27.273 If a doctor undergoes an assessment to ascertain whether s/he is fit to resume practice or unrestricted practice and the assessment reveals that s/he does not meet the required standard, it is undesirable that s/he should 'limp on' with repeated periods of conditional registration. The time will come when it becomes apparent that the doctor is unlikely ever to meet the standard for unrestricted practice. At the time of the Inquiry hearings, the GMC appeared to have recognised that, if a doctor has been given a chance to improve and is unable or unwilling to do so, the GMC's primary duty to protect patients requires that it should remove him/her from practice. I am uncertain whether or not this remains GMC policy. I thought that that was the right policy and recommend that it should be adopted. In cases of this type, it might be necessary to commission a new full assessment with a view to the doctor's erasure. I do not suggest that this policy should be adopted in respect of impairment caused by adverse health. In such cases, erasure is rightly not available and indefinite suspension may be appropriate.

27.274 It is, in my view, important that the same standards of supervision, review and reassessment should apply in cases in which voluntary undertakings have been accepted or 'taken into account' by a FTP panel as apply where conditions have been imposed. Any breach of such undertakings should be referred to a FTP panel; that should happen now, although the Inquiry heard evidence that it does not always happen when it should. There should be a reassessment before voluntary undertakings are allowed to lapse. Moreover, voluntary undertakings should not be allowed to continue in force and be renewed indefinitely. The time should come when enough opportunity for improvement has been given. In my view, if undertakings have been given at the investigation stage, it should be for the case examiner to decide when the time has come for the doctor to be referred to a FTP panel with a view to further action being taken.

Applications for Restoration to the Register

27.275 The 2003 draft Rules provided for a case examiner to be appointed to consider and prepare the evidence to be placed before a FTP panel at the hearing of a doctor's application for restoration to the register. The case examiner was to have the same powers to procure expert and other evidence as in relation to a review hearing. Subsequently, these proposed arrangements underwent change and, under the November 2004 Rules, the functions which were previously to have been undertaken by case examiners will be given to members of the GMC staff. I recommend that the arrangements contemplated under the 2003 draft Rules should be reinstated. I do so for the same reasons as I have previously outlined in relation to review hearings. Preparation will include the commissioning of an appropriate assessment dealing with the doctor's fitness to resume practice and may also involve obtaining other expert evidence. It might also involve the consideration of complex evidence relating to the events giving rise to the original erasure. All these functions, it seems to me, require the input of a case examiner, preferably one who is medically qualified. Support from the administrative (and probably legal) staff of the

GMC staff will obviously be needed, but the preparations for the hearing should in my view be directed by a case examiner.

27.276 My understanding is that, since 2000, every doctor whose application for restoration to the register has reached the second stage of the procedure has been required to submit to an assessment for the purpose of satisfying the PCC panel as to his/her good character, professional competence and health. I entirely agree that it is essential that there should be an independent objective assessment of the doctor's fitness to practise. This should be directed in part at the deficiencies which led to his/her original erasure but must also take into account that, even if the problem was not one of poor performance, following a period of more than five years out of clinical practice, his/her competence and clinical skills must also be in doubt. The assessment must, therefore, be directed at every aspect of fitness to practise and the doctor should not be restored unless s/he has met the required standard. Panels considering restoration need guidance as to the standards and criteria to be applied. I recommend this be provided through a collection of case summaries.

27.277 I understand the reasons why the GMC has decided against the automatic imposition of conditions on the registration of a doctor who has been restored to the register and I do not propose to recommend that course. Instead, I recommend that, as an additional safeguard for patients, doctors who are restored to the register should be required to have a mentor whose task it will be to monitor their progress in practice and to report to the GMC on their progress. I suggest that those reports should be considered by the case examiner appointed to deal with the restoration application. If it appears from the mentor's reports that further problems are arising, s/he will be able to take appropriate action within the FTP procedures.

Cases Involving Drug Abuse

27.278 In Chapter 23, I have discussed the need for a more searching examination of the circumstances underlying allegations of drug abuse by doctors, and convictions for offences related to drug abuse. I have said that any factual disputes must be resolved and that there must be a more thorough investigation of how the doctor's drug abuse began. I also recommend that the GMC should commission research into the outcomes of the cases of those doctors who have gone through the GMC health procedures. In past cases, the GMC has access to a pool of valuable information. The research might well inform the development of new or improved methods of supervision; the GMC would be able to find out what had worked best in the past. Also, by finding out which drug abusing doctors had relapsed or had otherwise not 'done well', the GMC would gain valuable insight into the characteristics of drug abusing doctors.

Transparency

27.279 I have said that it is important that the GMC's processes should be transparent. Doctors, those representing them and the public should be able to understand exactly what the GMC does and why. There are several respects in which the present arrangements should be improved. First, there are some matters that should be covered in the Rules but are not.

Examples include the tests that are to be applied at each stage of the process and the provisions for the issue of letters of advice. I recommend that every aspect of the procedures in which either doctors or makers of allegations have a direct interest should appear in the Rules. So far as purely internal procedures are concerned, I can see that it would be impractical and restrictive if every aspect of the procedures had to be enshrined in the Rules. However, that is not to say that the internal procedures should be shrouded from the eyes of the public. They must not be. I recommend that the GMC should publish a FTP manual containing all its relevant Rules and guidance for panellists, case examiners and staff and any relevant Standing Orders. This would include such documents as the ISG and the standard forms used by staff and case examiners when recording their decisions. It may be sensible for this to be produced in loose leaf form so that it can be amended periodically. It could also go on the GMC's website so that it could readily be accessed by anyone who needs to use it.

27.280 At various points in this Report, I have mentioned the need for clear statistical information to be provided by the GMC. For example, at paragraph 25.148, I said that the way in which reports of convictions are dealt with should be made clear to the public. Other categories of information that should be made public in a clear and comprehensible form are the numbers of cancellations of referrals to a FTP panel and reviews of decisions made at the end of the investigation stage. I recommend that the GMC should publish an annual report which should amount to a transparent statement of the year's activities in relation to the FTP procedures and revalidation.

Revalidation

27.281 In Chapter 26, I expressed my concern and dissatisfaction about the GMC's current proposals for revalidation. The GMC has told the public that revalidation will require every doctor to demonstrate that s/he is up to date and fit to practise. Section 29A of the 1983 Act imposes a duty on the GMC to make regulations providing for the revalidation of doctors. At section 29A, revalidation is defined as an **'evaluation'** of a doctor's fitness to practise. I have explained that the process that the GMC intends to use for revalidation does not entail an evaluation of fitness to practise. In my view, this process is not fit for the purpose for which it is intended.

27.282 At paragraphs 26.191–26.197, I have set out some suggestions for the way in which the revalidation of GPs could be carried out. In brief, I suggest that the folders of evidence that all doctors working in the NHS have to compile for the purposes of appraisal should be examined by a panel of at least three assessors. One would be the clinical governance lead of the doctor's PCT. Another would be a GP from another area, accredited by the RCGP as an assessor to standards approved by the GMC. The third would be a lay person. The folder would have to include certain specific items of evidence, to be determined by the GMC in consultation with the RCGP. I have also proposed that there should be various 'proxy' methods of achieving revalidation.

Recommendation Relating to the Council for Healthcare Regulatory Excellence

27.283 At paragraph 21.187, I observed that the provisions of section 29 of the National Health Service Reform and Health Care Professions Act 2002 had given rise to considerable

difficulty of construction in the case of Ruscillo. I recommend that, on the first occasion that the Act is to be amended, the opportunity should be taken to clarify that the Act provides for the CRHP/CHRE to appeal against 'acquittals' or findings of 'no impairment of fitness to practise' as well as in respect of sanctions which it believes were unduly lenient. There should in the future be a review of the powers of the CRHP/CHRE with a view to ascertaining whether any extension of its powers and functions is necessary in order to enable it to act effectively to ensure that patients are sufficiently protected by the GMC.

The Culture within the General Medical Council

27.284 In considering what recommendations I should make for the protection of patients in the future, I have had to consider whether, in my view, the GMC should retain responsibility for the conduct of the FTP procedures which, as I explained in Chapter 2, form an integral part of the present systems of monitoring and supervision of doctors, including GPs. These are the procedures by which the GMC should protect patients from dysfunctional doctors, i.e. doctors who, by reason of their misconduct, adverse health or deficient performance, put patients at risk of harm. The Inquiry has received evidence and submissions from some quarters suggesting that the GMC should no longer carry out that function. It has been suggested that the GMC does not have the protection of patients as its first priority; it is said that, rather, its priority is to safeguard the interests of the medical profession. I have already indicated that it is not my intention to recommend that the GMC should be deprived of its FTP function. It is important that I explain my reasons for reaching that conclusion.

27.285 The words that have appeared in the top right-hand corner of virtually every communication disseminated by the GMC in the recent past are 'Protecting Patients – Guiding Doctors'. In modern parlance, this has been the GMC's 'strapline'. The words are intended to encapsulate the aims and philosophy of the GMC. I understand they may shortly be changed, although I do not know what form of words is proposed. Those aims and philosophy should have applied to all the GMC's activities but they were perhaps of greatest relevance to the operation of the FTP procedures. In this Report, I have described the FTP procedures as they have been operated over the last 30 years. I have sought to examine the extent to which their operation has protected patients in accordance with the GMC's primary purpose. For those who have had the patience and endurance to read Chapters 15 to 24, it will come as no surprise that I have reached the conclusion that the GMC has not, in the past, succeeded in that primary purpose. Instead, it has, to a significant degree, acted in the interests of doctors. Of course, I accept that the GMC also has a duty towards doctors; it must be fair in all its dealings with them. But, in the past, the balance has been wrong and, as I have illustrated, the imbalance was due to a culture within the GMC, a set of attitudes and an approach that put what was seen as being 'fair to doctors' ahead of what was necessary to protect patients. Chapters 15 to 24 contain many examples of the way in which this culture operated. I do not propose to repeat them here.

27.286 It is important for the Inquiry to consider whether the culture within the GMC has changed. The GMC's corporate attitudes and culture are fundamental to its capacity to function in the best interests of patients and of the public, as it is under a duty to do. It is also important

that the GMC should recognise the shortcomings of its old FTP procedures and its inability to detect doctors whose practice was either aberrant or substandard. If, at the GMC, there had not been some change of culture and a recognition of the need for change, I would have had little hesitation in advising the SoS that he must make provision for some other way of dealing with doctors whose fitness to practise had been called into question. However, the need for changes to the FTP procedures was recognised, as was the need for an improved method of detecting aberrant behaviour and poor performance. Also, for reasons that I shall explain, I think that there has been some change of attitude and culture, although that change is by no means complete.

27.287 It is clear that the GMC did not recognise the need for change without some prompting from outside. The emergence of a number of medical scandals during the late 1990s must have played a significant part in the development of a resolve to reform. I have no doubt that there were, in the GMC, some who had for many years wished to see a change of both culture and practice. However, scandals such as those involving Shipman, Ledward, Green and others appear to have had the effect of bringing the majority within the GMC to the view that reform was necessary. Since that time, the GMC has been in a state of transition.

27.288 The transition has comprised three major reforms. First, the GMC's constitution was changed with effect from July 2003. The Council was reduced in size from 104 to 35 members and the proportion of lay members was increased from 25% to 40%. However, elected medical members still wield an overall majority. I shall return to constitutional issues later. The second main reform was the development and introduction of the new FTP procedures, which came into effect on 1st November 2004. The third was the development of the process of revalidation, which is due to come into effect in April 2005. The practical effects of the new FTP procedures and revalidation cannot yet be known. In addition to making preparations for those major reforms, during the last five years, the GMC has introduced some more modest changes to its FTP procedures. These were not dependent upon the introduction of the new procedures. I shall list a few because the circumstances in which these changes were introduced is of some significance in considering the extent of the culture change during the last five years.

27.289 In late 1999, the GMC discontinued the practice whereby medical screeners could also sit on the Preliminary Proceedings Committee (PPC); thereafter, screeners could not fulfil both functions. It appears that this change was made in anticipation of the coming into force of the Human Rights Act 1998, which was to take place in October 2000. In 2000, the GMC took greatly increased powers to make interim orders suspending or imposing conditions on a doctor's registration in a case in which it is necessary for the protection of members of the public, or in the public interest or in the interests of the doctor concerned. This change was made because the GMC had been unable to take action to suspend Shipman from the register in August 1998, when he was under investigation for murdering his patients. At about the same time, in 2000, legislation was also introduced to require the GMC to disclose certain adverse information about doctors to employers and PCOs. Hitherto, the GMC had been reluctant to disclose such information as it had been thought that this might be unfair to doctors. The Government had insisted upon this change; as the

major employer of doctors, the NHS wanted the information. No doubt that change too was precipitated, in part at least, by Shipman's case.

27.290 In November 2002, the rule requiring a complaint from a private individual to be supported by a statutory declaration was abolished. That change had been recommended by Professor Allen and her colleagues in 1996. Mr Alan Howes, who was employed by the GMC between 1977 and 2002 and was Head of the Conduct Section from 1987 to 1994, told the Inquiry that there had been tension on this issue between some members of the Council who wanted the rule to be abolished and other members who wanted to keep the rule for the protection of doctors against false or frivolous complaints. It had taken a long time for the majority to accept the need for abolition. In the same month, November 2002, the Registrar was given power to send reports of serious convictions straight to a PCC panel, unless there were public interest reasons for not doing so. Previously, such cases had had to be considered by a screener and the PPC. This change had been recommended by Professor Allen in 2000.

27.291 In May 2004, the GMC introduced the practice of having an informal dialogue with the employer or relevant PCO in respect of doctors about whom complaints had been received. This had never previously been done and was perceived by some to be unfair to doctors since it involved disclosing to the employer or PCO the fact that a complaint had been received. Mr Neil Marshall, who has been employed by the GMC since 1996, told the Inquiry that, between December 1998 and April 2000, there had been a debate within the GMC about the seeking of background information about a doctor. He said that it had become apparent that, by not carrying out such searches, the GMC might be failing in its duty to protect the public. Eventually, it was decided that discussions should take place, but only in 'more performance-like cases'. It was clear from the evidence, however, that it was common for no such discussion to take place. It appears that the change was made as the result of evidence given to this Inquiry. Another change was made as the result of observations made at Inquiry hearings. Until recently, doctors charged with or convicted of a criminal offence had not been required to report the fact to the GMC. The GMC now requires doctors to report these matters and a doctor would be guilty of professional misconduct if s/he failed to do so. A further example of a change brought about as the result of evidence given to the Inquiry relates to the identification of doctors against whom complaints have been made. In 2003, Professor Allen and her colleagues reported that 25% of doctors about whom complaints had been made in 2001 had never been identified. That meant that the GMC was unable to ascertain whether the doctor had a previous FTP history and that, if another similar complaint about the same doctor were to be received, the two could not be linked. The GMC could not even confirm that the 'doctor' complained of was in fact on the medical register. At the Inquiry's hearings, Mr Marshall acknowledged that the GMC should consider making more effort to ascertain the identity of doctors against whom complaints were made. It was clear from the evidence that, in some cases, all that was required was a telephone call. The Inquiry has been told that, since the hearings in December 2003, the GMC has taken steps to improve its systems for identifying doctors reported to it.

27.292 All those changes were for the better. They improved the position of complainants and the ability of the FTP procedures to protect patients. To some extent, the GMC is to be

congratulated on making those changes. However, the disappointing feature is that all the changes appear to have been made as a reaction to some form of external pressure or advice. None of them appears to have been made because the GMC realised for itself that it was not acting in the best interests of patients and the public. Those changes do not demonstrate that there has been much of a change of culture within the GMC.

27.293 During the same period, the GMC failed to make a number of changes which, in my view, it would have made if it had had patient protection at the forefront of its collective mind. I shall mention four. Until very recently, the GMC has not employed staff for the purpose of investigating complaints or allegations against doctors. In general, in a conduct case, it has accepted the complaint, obtained the doctor's response, obtained the complainant's response to the doctor's response and then decided whether to send the case through to the PCC for hearing. Thereafter, if the case was to go forward to the PCC, it would be investigated. As Mr Scott observed at the Inquiry, that was to 'put the cart before the horse'. The GMC knew that this was the practice and should have realised that it was not satisfactory in the interests of patient protection. As a consequence of the practice, it was inevitable that some complaints against doctors would fail at the early stages for lack of investigation. Professor Allen had made this point in 1996. It is true that the GMC did not have statutory powers to compel the production of evidence before the stage when a case was referred to the PCC; but that was no bar to investigation. Only now, under the new FTP procedures, is it intended that the GMC should investigate cases at an early stage.

27.294 My second example relates to the GMC's practice of closing complaints from private individuals and advising the complainant to use local complaints procedures; this was done without considering whether the complaint raised an issue of SPM and in the knowledge that NHS complaints procedures were profoundly unsatisfactory. It was a practice that plainly disadvantaged complainants and reduced the ability of the GMC to protect patients by dealing promptly with all potential allegations of SPM. Mrs Jean Robinson, formerly a lay member of the GMC, had, in 1988, drawn attention to the practice and its effects. Professor Allen had drawn attention to it again in 1996 and pointed out that some of the complaints being redirected were of a serious nature. It was not stopped, although it could have been stopped at any time as it was not sanctioned by the Rules; indeed, it was a breach of the Rules. Far from being stopped, in November 2002, the practice was extended to complaints about treatment in the private sector. The practice was the subject of discussion and some criticism at the Inquiry in December 2003. The briefing papers for the Council meeting in July 2004 suggest that the practice was still in operation at that date. So far as I am aware, it remained in operation until the demise of the old FTP procedures at the end of October 2004.

27.295 My third example relates to the GMC's unwillingness to establish agreed standards, criteria and thresholds by which the FTP procedures, and particularly the old conduct procedures, could operate. Professor Allen and her colleagues drew attention to the need for them in their Reports of 1996 and 2000 and in their Paper of 2003. They made it plain that the absence of standards was resulting in inconsistency of decision-making and lack of transparency. The implications for patient safety were obvious. No real progress has been made.

- 27.296 Finally, I refer to the disclosure of information relating to a doctor's registration status to persons making enquiry of the GMC. I described at paragraphs 27.174–27.178 how this information is imparted. I explained that, at the Council meeting of July 2004, Mr Scott explained that information was imparted only in response to specific questions, and that 999 out of 1000 callers asked only whether the doctor was registered. No further questions were usually asked. No member of Council made any observation about this. Nobody remarked that it appeared therefore that many prospective employers were receiving incomplete information about the registration status of the doctors they were about to employ. They were putting down the telephone having assured themselves that the doctor was registered, but they had not discovered whether the doctor was subject to conditions or even whether s/he had a recent FTP history. Similarly, it did not appear to be appreciated that members of the public might not be getting the information they were seeking. In short, nobody seems to have noticed that the way the GMC handles these enquiries is not in the best interests of patient protection.
- 27.297 My examination of the events of the last five years leads me to conclude that, although the GMC has made a number of beneficial changes, its culture has not altered radically. However, the GMC would have me believe that, insofar as there ever was any need for a change in culture, it has already occurred. In his opening submission to the Inquiry, made in November 2003, Leading Counsel for the GMC, Mr Roger Henderson QC, accepted on the GMC's behalf that, in many ways, its FTP procedures had not been as they should have been. There had been problems of inflexibility, inadequacies of training and guidance and resulting inconsistency of decision-making. It was, I think, accepted that these shortcomings must at times have resulted in the GMC failing to act in the best interests of patients and for their protection. Mr Henderson acknowledged that some cases had been closed that should not have been closed. However, he did not volunteer any acceptance that there had been anything fundamentally wrong with the GMC's attitudes or culture. The thrust of the evidence presented to the Inquiry by the GMC was that its priorities were clear; its primary duty was to protect patients and that is what it was doing.
- 27.298 The most important transitions effected in the last few years have been the preparations for the introduction of the new FTP procedures and of revalidation. I turn to consider whether the GMC's approach to those important innovations demonstrates a change of culture and attitude.
- 27.299 In Chapter 25, I examined the development of the proposals for the new FTP procedures in detail – some might say in too much detail. I wished to understand the thinking behind that development. The GMC's vision for the future procedures was clearly set out in its Consultation Paper published in 2001. That paper demonstrated a firm commitment to FTP procedures that would operate for the protection of patients, without compromising the need to be fair to doctors. On the basis of that document, I would have said that there had indeed been a change in the culture of the GMC. However, the translation of the vision into reality has been, in some respects, disappointing. As I explained in my conclusions to Chapter 25, I found that there had been no consistent transition from the initial vision to the implementation of the new procedures. The major change is that the old 'silos' of the conduct, health and performance procedures have gone and are to be replaced by a single basis for the GMC's powers to erase, suspend or impose conditions on a doctor's

registration, namely 'impairment of fitness to practise'. There have been many other changes, some for the better, some for the worse. There has been a good deal of 'chopping and changing' in the detail of the proposals and it is often hard to see any coherent principle behind the changes. The GMC has adopted a number of suggestions that have been made in evidence to the Inquiry. It has reacted positively to some of the criticisms and concerns about which the GMC witnesses were asked. But I do not feel confident that the GMC has maintained the clarity of purpose that it exhibited at the time it published its Consultation Paper in 2001. I do not feel confident that there is currently a determination that the new procedures will be operated with the primary objective of protecting patients.

27.300 Examination of the development of the GMC's proposals for revalidation leads me to a similar conclusion. In Chapter 26, I described how, in the late 1990s, the GMC recognised that, in order to protect patients adequately, it must take proactive steps to identify under-performing doctors, instead of waiting for someone to make a complaint or allegation. It set out its principles with clarity in the Consultation Paper of 2000. This was another seminal document, setting out proposals that were manifestly designed to protect patients. Again, on the basis of that document, I would have said that the GMC had changed its culture. But again, implementation has been a disappointment; there has been a retreat from the early ideals. Revalidation was to involve the evaluation of the fitness to practise of every individual doctor who wished to hold a licence to practise. A method was devised and pilot studies were carried out. Then it became apparent that the task of evaluating every doctor every five years was more daunting than had been thought. The process would be expensive and the doctors would have to pay for it. Moreover, the proposals were unpopular with a powerful section of the profession. So the GMC retreated from its earlier vision and devised a system that it calls 'revalidation' but which does not involve any evaluation of the individual doctor's fitness to practise, certainly so far as GPs are concerned. I know that that retreat caused dissent within the GMC but it was accepted by the majority. I am driven to the conclusion that, for the majority of GMC members, the old culture of protecting the interests of doctors still lingers on.

27.301 It is not possible for me to understand the internal dynamics of the GMC. I can see from the transcripts of the public discussions in Council that there is sometimes a lively debate. That is, of course, as it should be. I do not know and cannot tell when or why the GMC takes some of its decisions. For example, in 2003, the GMC decided that, under the new FTP procedures, when a performance assessment report was obtained, it would be sent to the doctor's employer or PCO. At some time, that decision has been reversed; it will not now happen. That is a retrograde decision but I do not know when or why it was taken. Similarly with the decision to allow FTP cases to be cancelled on the say-so of a single member of the IC, to which I referred at paragraphs 25.243–25.250. I do not know when or why that decision was taken. In short, I do not know what goes on but I do gain the impression that the old culture has not entirely disappeared.

27.302 Why then have I not recommended to the SoS that the GMC should no longer be responsible for the FTP procedures? In fact, I have recommended that responsibility for the adjudication stage should be hived off to an independent organisation. However, I have recommended that because it is inappropriate for the GMC to control both the

investigation and the adjudication stages of the process. I would have made that recommendation even if there had been no suggestion that the GMC's culture could be criticised. There are four reasons why I have not recommended that the GMC should cease to be responsible for the FTP function.

27.303 First, fitness to practise and revalidation are closely linked. Revalidation and registration are closely linked. It is preferable therefore that fitness to practise and registration should be under the control of the same body. I do not consider that my Terms of Reference permit me to consider whether the GMC might lose its responsibility for registration (or indeed for setting the standards for admission to the register and all the educational responsibilities that accompany that function). That would, in effect, be to recommend the abolition of the GMC. I could not do that. This is a Public Inquiry, not a Royal Commission on the regulation of the medical profession. If I were to recommend the detachment of the FTP function, it would create practical difficulties for the future, although I do not think they would be insurmountable.

27.304 Second, the task of creating a body to take over the FTP function would not be an easy one. If improvements to the GMC could be effected, so that it acted more consistently in the interests of patients and the public, that would seem to me to be a preferable course to take.

27.305 So far, I have given two reasons; both are negative. There are some positive reasons for my conclusion. The GMC has just introduced a new set of FTP procedures. I do not know how well they will operate in the interests of patient protection. Broadly speaking, the new procedures are an improvement on the old. Change has been in the right direction. No doubt the new procedures will be changed in some respects during the next few years in the light of experience. It seems to me to be sensible that the new procedures should be allowed to develop and to settle down before their adequacy and fitness for purpose is judged. It will be important to see whether any future changes move in the right direction.

27.306 There is a major reason to hope and expect that change for the better might continue. The CRHP/CHRE may be expected to play an important role in the further development of the new FTP procedures. The CRHP/CHRE is a new body; it came into existence in 2003 as the result of a recommendation of Professor (now Sir) Ian Kennedy in his Bristol Inquiry Report. The CRHP/CHRE has already made its mark by exercising its power to refer to the High Court any decision of the GMC which it considers to be unduly lenient and which should be reviewed in the public interest. It also has the power to refer to the High Court cases in which a doctor has been 'acquitted' of SPM and it will in the future have the power, in some circumstances, to refer cases in which a FTP panel's failure to find that a doctor's fitness to practise was impaired, or its failure to find impairment of a degree justifying action on registration, was 'unduly lenient'. However, the CRHP/CHRE's powers are not limited to referring individual decisions to the Court. It has wide powers of oversight of the GMC's FTP function. It can audit outcomes of cases; it can examine processes and it can require rule changes. That is not to say that the CRHP/CHRE could or should attempt to 'manage' the GMC. That would be impractical and inappropriate. But the fact that it exists and that it has shown that it intends to use its powers will, I believe, have an important effect on the GMC. The GMC must know that, if it fails to act in the best interests of patients and

the public, the CRHP/CHRE will intervene. Moreover, this Inquiry has shed a great deal of light on GMC practices, particularly on those that are not usually open to public scrutiny. I hope that what the Inquiry has revealed will help the CRHP/CHRE in that it will know where to look to see how well the GMC is doing its job.

- 27.307 The Inquiry has revealed many shortcomings in the GMC's operation of its old FTP procedures. How the new procedures will operate in practice it is not possible to say. In my view it is important, in the public interest, that, in about three or four years' time, there should be a thorough review of the operation of the new procedures, to be carried out by an independent organisation. It seems to me that that task should be undertaken by or on the instructions of the CRHP/CHRE. The cost should, in my view, be borne by public funds. That review should not be limited to consideration of administrative systems, but should be empowered to examine casework decisions at all levels as well.
- 27.308 I would like to believe that the GMC's culture would continue to change in the right direction by virtue of its own momentum. However, I do not feel confident that it will do so. I am sure that there are many people within the GMC, both members and staff, who want to see the regulation of the medical profession based on the principles of 'patient-centred' medicine and public protection. Indeed, I think it is likely that all members are theoretically in favour of those principles. The problem seems to be that, when specific issues arise, opposing views are taken and, as in the past, the balance sometimes tips in favour of the interests of doctors.
- 27.309 In Chapter 15, I observed that, for an organisation like the GMC, issues are bound to arise in which there is a conflict between the interests of doctors and those of patients and of the public. Members have to deal with that conflict. To do their work properly as members of a regulatory body, they have to put the public interest first. That is very difficult for a member who depends for his/her position on an electorate of doctors. I am sure that some manage to do it. I think that others find it more difficult. At present, the GMC is effectively controlled by elected members. It seems to me that one of the fundamental problems for the GMC is the perception, shared by many doctors, that it is supposed to be 'representing' them. It is not; it is regulating them. It may be that this perception goes back to the 1970s, when the profession objected to being asked to pay an annual retention fee and raised the cry of 'no taxation without representation'. If the profession perceives that the GMC is supposed to represent it, that would explain why some GMC members tend to adopt a representative role. In fact, the medical profession has a very effective representative body in the BMA; it does not need – and should not have – two.
- 27.310 I have come to the conclusion that one of the reasons why the GMC has not been able to rid itself of the old culture lies within its constitution and the overall majority of elected 'representative' members. I think that the GMC should look again at its constitution. I know that the constitution was changed as recently as July 2003. I realise that further upheaval would be unwelcome. However, my considered view is that it is not appropriate that the GMC should be dominated by elected members. It should certainly be dominated by medical members; I am not suggesting that there should be any increase in the proportion of lay members. But I do suggest that there should be more appointed medical members – people who are not beholden to an electorate and do not see themselves in the position

of representatives of the profession. Rather, they should see themselves as servants of the public interest.

27.311 Accordingly, I recommend that the constitution be reconsidered. It occurs to me that the sharp reduction in size that occurred in 2003 might have gone a little too far. The GMC may wish to consider whether it needs a few more medical members than it has. It needs medical members for many tasks that cannot be carried out by lay people, such as the development of policies and medical guidance. That is not a recommendation, merely a suggestion. As Sir Donald Irvine observed, it may be preferable for the GMC to 'hire' the medical expertise it needs from the experts in particular fields. What I do recommend, however, is that the balance of the Council should be changed so that the elected members do not have an overall majority.

27.312 I also recommend that medical and lay members who are to be appointed (by the Privy Council) should be selected for nomination to the Privy Council by the Public Appointments Commission following open competition. It would seem sensible for the universities and medical Royal Colleges to have the right to nominate medically qualified candidates for consideration. However, the competition should also be open to medically qualified persons who wish to put themselves forward. I have seen, from the DoH prospectus inviting applications for the position of lay membership in 2003, the emphasis that was laid – quite rightly – on the lay members' duty to safeguard the public interest. I would like to see the same emphasis on the public interest applied to the appointment of medical members.

27.313 During the course of the evidence, concern was expressed about the number of lay members who have a background in health service management. In Chapter 15, I expressed the view that it would be desirable that lay members should come from a wide range of backgrounds.

Public Accountability

27.314 In the past, the GMC has been accountable to the public only in very general terms. It has had a duty to regulate the medical profession in the best interests of patients and the public. However, there has been no person or body to whom the GMC has been directly accountable. Since 2003, the CRHP/CHRE has had the power to oversee and correct some aspects of the GMC's work. The GMC itself recognised and drew the Inquiry's attention to the fact that, although the GMC derives its powers from Parliament, it is not directly accountable to Parliament for the way in which it exercises its powers. The GMC suggested that it might be appropriate if it were to be directly accountable. I think that that is a good idea. I have in mind that the GMC would be required to publish an annual report of its activities, which could be scrutinised by a Select Committee. For this to be a worthwhile exercise, the report would have to contain specified categories of information, including statistical information, in a form that was readily understandable and, in effect, transparent.

Conclusions

27.315 In the course of this long Report, I have on many occasions been critical of the GMC, its procedures and its attitudes. I realise that the fact that this Inquiry has been conducted in

public and that my Report will be in the public domain must make those criticisms even more unwelcome than they would have been if made in private. Indeed, I recognise that their effect is likely to be bruising. It has not been my intention to be hurtful or indeed to be critical of any individual at the GMC. My criticisms have been of the corporate body and its collective actions. I have made a large number of recommendations affecting the GMC and I realise that some of them will be unwelcome. However, I hope that it will be accepted that they have been made in a constructive spirit and with the intention of helping the GMC to achieve its primary purpose of 'Protecting Patients – Guiding Doctors'.

27.316 In this Stage of the Inquiry, I have examined the parts that are or could be played by Government, the GMC, the Healthcare Commission, the CRHP/CHRE, NHS organisations, practice staff, patients and members of the public in protecting patients who might be at risk from an aberrant or poorly performing GP. In this Report, I have made a large number of recommendations which, together with the recommendations in my Third and Fourth Reports, are designed to extend and improve the existing framework of protective systems. In this Report, I have suggested improvements to clinical governance systems; in particular I have stressed the need for the proper investigation of complaints and the need for a system of monitoring mortality statistics. I have recommended ways in which the protective role of PCTs can be enhanced, for example by providing them with improved information about the doctors on or seeking admission to their lists. I have made recommendations that will provide patients with more information about their doctors and will enable them to exercise some, albeit limited, degree of choice. I have made recommendations designed to ensure that the GMC's FTP procedures work effectively for the protection of patients and are also fair to doctors. Finally, I have suggested a way in which revalidation could be made to comply with the requirements of the 1983 Act and to fulfil the high aspirations of those who have sought to promote it.

27.317 To some extent, these recommendations are bound to give rise to tension and conflict between the interests of those affected by them. However, I am confident that there is a large body of opinion both within and outside the medical profession that will recognise the need for all those involved to work together and to pull in the same direction. In making these recommendations, I have striven to achieve three things: first, that, if ever there were to be another potential Shipman, he would be detected very quickly; second, that the prospects of detecting all forms of aberrant behaviour or substandard performance in doctors should be enhanced; and, third, that the good quality of care provided by the large majority of doctors should have scope and opportunity for continued improvement.