CHAPTER ONE

Introduction

Terms of Reference

1.1 In my First Report, I found that, over a period of more than 20 years, Shipman had secretly obtained very large quantities of diamorphine and had used it to kill many of his patients. It was apparent that the regulatory framework governing the use of controlled drugs had not operated as it should. The purpose of regulation is to ensure accountability for the use of controlled drugs so as to avoid their diversion to improper use and to detect such diversion if it occurs.

1.2 By its Terms of Reference, the Inquiry was required:

> **'... by reference to the case of Harold Shipman to enquire into the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring ... the use of controlled drugs; and**
>
> **... following those enquiries, to recommend what steps, if any, should be taken to protect patients in the future, and to report its findings to the Secretary of State for the Home Department and to the Secretary of State for Health'**.

1.3 I decided that it must have been the intention of Parliament that I should interpret the word **'monitoring'** widely so as to encompass an examination of the whole system of control, regulation and inspection by which the use of controlled drugs is governed. Only by looking at the system as a whole would it be possible for me to determine how patients could best be protected. I received evidence about the systems in operation in England, Scotland, Wales and Northern Ireland but my recommendations are confined to the system in England.

Controlled Drugs

1.4 Regulations controlling the prescribing, possession and supply of certain medicinal drugs have been in existence for more than 80 years. Before 1971, such drugs were described in the legislation as 'dangerous drugs'. They are now properly and usually called 'controlled drugs'. Controlled drugs (with one or two exceptions) have legitimate therapeutic applications but they also have a potential for abuse and dependence and carry a concomitant risk of diversion into the hands of persons other than those for whom they are prescribed. The controls imposed are designed to prevent the drugs from being misused; they cover such matters as the form of prescriptions, record keeping and storage. They are intended to prevent and detect the unlawful acquisition and diversion of controlled drugs (the kind of conduct of which Shipman was found guilty in Todmorden) but are not aimed at preventing or detecting the use of controlled drugs deliberately to kill.

1.5 Since 1973, all controlled drugs have been listed in one of the Schedules to the Misuse of Drugs Regulations (MDR) 1973–2001. The drugs attracting the highest level of control are

those that appear in Schedule 1 to the MDR 2001. They have no approved medicinal use. They include hallucinogenic drugs such as lysergide (LSD). The next highest level of control applies to drugs in Schedule 2 to the Regulations. Over 100 drugs are listed in this Schedule, which includes the major opiates such as diamorphine (commonly known as heroin), morphine and pethidine, as well as the major stimulants such as amphetamines. These have therapeutic properties but a very significant propensity for abuse and dependence. Schedule 3 includes most of the barbiturate drugs and a few minor stimulants. Barbiturates have sedative properties and physical and psychological dependence can result. Schedule 4 is divided into two parts. Part 1 comprises mainly the benzodiazepines. These drugs are widely prescribed for the relief of anxiety and insomnia. They are known to be addictive if taken over a long period. Part 2 comprises mainly the anabolic and androgenic steroids, which are liable to abuse, in particular by sportsmen and sportswomen. Schedule 5 includes certain preparations that contain a drug with a potential for abuse (usually a Schedule 2 drug) but in such form or strength that the risk of abuse is very small. For example, codeine is listed in Schedule 2 but tablets containing 15mg codeine phosphate fall within Schedule 5.

Pethidine and Diamorphine

1.6 The Inquiry's main focus has been on pethidine and diamorphine, the two drugs that Shipman obtained and used illicitly. Both drugs have a therapeutic use in the alleviation of pain. Both (but more particularly diamorphine) act as a respiratory depressant. Both are addictive. They give rise to a sense of euphoria and are, therefore, sometimes taken for non-therapeutic reasons.

1.7 In 1976, Shipman was convicted of criminal offences involving the diversion of pethidine for the purpose of self-administration. Those offences were committed during his brief period in general practice in Todmorden, West Yorkshire. While working there, Shipman killed at least one patient by the injection of an opioid (probably morphine or diamorphine), and it is possible that he killed several more in the same way. While working in Hyde, Greater Manchester, between 1977 and 1998, he killed at least 214 patients, by injecting them with lethal doses of diamorphine. Death was due to the respiratory depressant effect of the drug. When an overdose is given, respiration is slowed and eventually stops. The absence of oxygen supply to the brain leads to cardiac arrest and death.

1.8 Despite the regulatory controls in place, Shipman's diversion of diamorphine went undetected for more than 20 years. When it eventually came to light, this was not because his unlawful acquisition of the drug had been detected (it had not) but because he had come under suspicion of murdering, and forging the will of, Mrs Kathleen Grundy. Although Shipman used diamorphine to kill patients, the same methods of obtaining the drug could have been used by persons wanting the drug for self-administration or to sell to others. Many of the problems identified in connection with pethidine and diamorphine also occur in relation to other controlled drugs. Where appropriate, therefore, the Inquiry has looked at the wider picture.

The Use of Pethidine in General Practice

1.9 Pethidine is a short-acting analgesic. In the 1960s and 1970s, it was widely used in general practice, in particular for the relief of pain in childbirth and the symptoms of pain

caused by renal stones. The usual dosage would be 50mg, administered intramuscularly. Nowadays, it has been superseded by other, more effective, modern analgesics, although it is still used occasionally in obstetric care and for the relief of severe short-term non-malignant pain.

The Use of Diamorphine in General Practice

1.10 Over the last 25 years or more, the most common use of diamorphine in general practice has been for the treatment of severe pain in cases of terminal cancer, when other treatment, such as oral morphine, is insufficient or when administration by mouth is difficult. If the terminal illness is prolonged, the amounts of diamorphine necessary for the relief of pain may become very large because the patient becomes habituated to the drug and the dosage has to be increased in order to achieve adequate pain relief.

1.11 Until the early 1990s, a general practitioner (GP) or a district nurse would administer the diamorphine by means of periodic injection. This did not always achieve adequate pain control, however, and repeated injection at the same site was prone to cause local soreness. Since the early 1990s (in Tameside, the change came in 1993), diamorphine has usually been administered to terminally ill patients by means of a syringe driver, a battery-operated device that administers a continuous flow of the drug to the patient and provides far better pain control than periodic injections. Whichever method is used, the GP will have to prescribe quite large quantities of diamorphine and supplies will have to be kept at the patient's home. It is now quite common for patients on a syringe driver to be on a daily dosage of 100mg diamorphine, and dosages of more than 2000mg a day are not unknown. One of Shipman's patients was in need of a daily dose of 2400mg by the time of his death. In such cases, diamorphine is prescribed in ampoules of 30mg, 100mg or even 500mg, although the use of the largest ampoules is relatively rare.

1.12 GPs also use diamorphine for the relief of acute pain, for example, the pain experienced during a heart attack or following serious traumatic injury. Much smaller doses are then required because the patient is not habituated to the drug. Usually, about 5mg will be sufficient and quite often less. Many GPs carry a few ampoules of diamorphine in their medical bags to meet such contingencies. The preferred sizes are 5mg or 10mg ampoules.

1.13 The respiratory depressant effect of diamorphine renders it dangerous in overdose and this effect is heightened if the patient is not in pain. For a patient who is not in pain and who is not habituated to diamorphine, an intravenous injection (by which the drug enters the nervous system very rapidly) of 20mg would be dangerous and possibly fatal. In a frail or elderly patient, it would almost certainly be fatal. I have formed the view that Shipman usually used about 30mg diamorphine to kill a patient.

Shipman's Use of Pethidine and Diamorphine

1.14 Shipman obtained his supplies of pethidine and diamorphine from community pharmacies. It was plainly necessary for the Inquiry to establish in as much detail as possible how Shipman had obtained the controlled drugs used to feed his own habit and

to kill his patients. Only then would it be possible to discover how he had exploited the loopholes in the system of regulation and control so as to avoid detection. I described Shipman's illicit methods of obtaining controlled drugs in some detail in the First Report. I will summarise them below and will refer to them again, where appropriate, later in this Report.

Todmorden

1.15 Very shortly after Shipman commenced practice at the Abraham Ormerod Medical Centre in Todmorden in March 1974, he began ordering large amounts of pethidine from the pharmacy of the local branch of Boots the Chemists (Boots). He presented 'requisitions' or 'signed orders' (terms which I shall use interchangeably), representing to the pharmacist that the supplies were for use in the practice. A requisition is simply a written request by a doctor for the supply of a specified quantity of a specified drug. The document need not be in the doctor's own handwriting although it has to carry the doctor's name, address and profession and must be signed by him/her. The purchase of a controlled drug in this way is a private transaction and the doctor or practice pays the ordinary commercial price of the drugs, although, if the drugs are later administered in the course of NHS treatment, the doctor can seek reimbursement of the cost of the drugs and an administration fee. If administered privately, the patient will pay the cost.

1.16 While obtaining pethidine on requisition, Shipman was also obtaining it by writing NHS prescriptions for the drug in the names of patients who did not need it. He would present a prescription at the pharmacy, saying that he was about to visit a patient and that he would deliver the drug in order to save the patient or carer the trouble of collecting it. He did this most often in the name of one particular elderly patient, who lived some way from Todmorden town centre, thereby adding verisimilitude to his story. In fact, Shipman kept the pethidine for himself. As a variant of this method, he also prescribed pethidine for patients who did have a need for the drug. In those cases, he would prescribe more than was necessary for the patient and would deliver only part of the whole amount, keeping the remainder for his own purposes.

1.17 Whether a pharmacist dispenses the controlled drug on a requisition or on a prescription, s/he must make an entry in a special book called the controlled drugs register (CDR). The CDR must be kept for at least two years after the date of the last entry in the book. A requisition must also be kept for at least two years. Prescription forms need be kept only if they are private (i.e. not NHS) prescriptions. Details of private prescriptions must also be entered into a private prescriptions book, unless those details have already been recorded in the CDR. NHS prescriptions are sent to the Prescription Pricing Authority for processing and payment. The CDR, requisitions, private prescriptions and the private prescriptions book should be inspected periodically by a specially designated police officer known as a chemist inspection officer (CIO). If the CIO detects any sign of unlawful conduct, s/he may call in an inspector from the Home Office Drugs Inspectorate (HODI) to assist in the investigation. Except when they receive such a request for assistance, Home Office inspectors usually concentrate on the licensing and inspection of businesses engaged in the manufacture or wholesale supply of controlled drugs.

1.18 In January 1975, a routine HODI inspection of records held by a pharmaceutical wholesaler in the North of England revealed that unusually large supplies of pethidine ampoules were being delivered to the pharmacy at the Todmorden branch of Boots. The CDR held at the pharmacy showed that large quantities were being both requisitioned and prescribed by Shipman. In July 1975, two inspectors from the HODI and an officer from the West Yorkshire Police (WYP) interviewed Shipman and examined the controlled drugs stocks and the CDR held at his practice premises. They found that there was no pethidine in stock and that the CDR was not being kept properly. Shipman had entered the practice's acquisitions of pethidine but not the amounts of the drug supplied or administered to patients from the practice stock. It was suspected that Shipman might be appropriating the pethidine but it was decided to take no action other than to warn him and other members of the practice of their duty to keep proper records in the CDR. Meanwhile, the police and the HODI arranged to keep a watch on Shipman's dealings with controlled drugs. Shipman continued to act as before and, only two months later, these activities came to light. Shipman's partners were told and he was dismissed from the practice. He admitted that he had been abusing pethidine. A consultant psychiatrist arranged for his admission to a private hospital for treatment and rehabilitation.

1.19 The HODI and the WYP were notified and Shipman's acquisition and prescribing of pethidine were investigated by reference to the entries in his name in the CDR. Shipman's improper use of NHS prescriptions was confirmed when the HODI inspectors and the WYP officer asked him about each prescription for pethidine. He told them that some patients had received small quantities of the drug and that others had received none. Shipman had kept most of it for himself.

1.20 The system of inspection (of the wholesaler's records followed by examination of the Boots CDR) had worked essentially as it should; it had drawn attention to the large quantities of controlled drugs that Shipman was requisitioning and prescribing. Once that abnormality had been noticed, both his requisitioning and his prescribing for individual patients came under suspicion. However, it is important to recognise that it is unlikely that Shipman's diversion of pethidine by improper prescribing alone would have been detected through the routine inspection of the wholesaler's records and pharmacy CDR. The volumes prescribed might have been explicable as supplies to terminally ill patients and the CDR would not have revealed that Shipman himself had been collecting the drugs. If he had not used requisitions as well, he might not have been detected.

1.21 Shipman was charged with eight offences of unlawful possession of pethidine, obtaining pethidine by deception, and forgery. In February 1976, he pleaded guilty and was fined and ordered to pay compensation and costs. A total of 74 similar offences were taken into consideration. His conviction was referred to the Home Office in London and to the General Medical Council (GMC). The Home Secretary had the power to restrict Shipman's right to possess, prescribe, supply or administer controlled drugs following his conviction but, as the result of a very recent change in Home Office policy, the case was not put before him for consideration of the exercise of that power. The GMC had the power to erase Shipman's name from the medical register (or to suspend its entry there) but decided only to issue a warning as to his future conduct. By early 1976, Shipman had found work in County Durham, in a position in which he had no need to prescribe or

administer any controlled drug and, so far as is known, he did not obtain any drug illicitly during that employment.

Hyde

1.22 In 1977, Shipman went to work as a GP at the Donneybrook practice in Hyde. When interviewed for the post, he told his partners about his previous abuse of pethidine and assured them that he did not intend to keep a personal stock of controlled drugs in future. He would not, therefore, need to keep a CDR. He was, however, free to prescribe controlled drugs for patients without keeping any record, other than making an entry in the patients' medical records. As is now well known, in 1978, Shipman did begin to obtain diamorphine illicitly and used it to kill patients. During the period of almost 15 years when Shipman worked at the Donneybrook practice, he killed 71 patients. After 1992, when he began working as a single-handed practitioner at 21 Market Street, Hyde, he killed 143 patients. I have concluded that he used an overdose of diamorphine in every case. There is no evidence that he self-administered any controlled drugs during this period.

Shipman's Methods of Obtaining Diamorphine in the Late 1970s and the 1980s

1.23 It has not been possible for the Inquiry to find out exactly how Shipman obtained his supplies of diamorphine during the late 1970s and the 1980s, as the relevant pharmacy records and prescription forms from that period have long since been destroyed. As I explained in the First Report, I think it most likely that he first obtained such supplies from cancer patients, after whose deaths there was a surplus. I think it highly unlikely that he reverted to the use of requisitions. He had been detected when doing that in 1975. From the evidence of the methods he used during the 1990s, I have inferred that, during the late 1970s and the 1980s, he used a variety of methods, essentially by over-prescribing for the needs of his cancer patients and retaining any supplies that were left over after the death. As I shall shortly describe, the fact that he had obtained diamorphine by those methods would not have been easily detected.

Shipman's Methods of Obtaining Diamorphine after 1990

1.24 Most of the controlled (and other) drugs prescribed by Shipman were dispensed from the pharmacy at 23 Market Street, next door to Shipman's surgery. From 1995, this was known as the Norwest Co-op Pharmacy. It had previously been known as Battersby's. The pharmacy CDR dating from 1991 was available to the Inquiry. Examination of this CDR has allowed the discovery of several of the methods Shipman had used to obtain diamorphine during the 1990s.

1.25 Shipman would sometimes prescribe diamorphine for a patient with cancer at a time when the patient had not yet developed a need for the drug; he would collect the drug from the pharmacy and keep it all for himself. Sometimes, for a cancer patient who had a genuine need of the drug and was receiving it regularly, he would prescribe more than was necessary, collect it from the pharmacy and keep part, or even the whole, of the consignment for himself. After a cancer patient had died, he would, if he had the chance, take any unused drugs for himself, although he would tell whoever was present that he was

doing so for the purpose of destroying them. On at least one occasion in the 1990s, he prescribed a large quantity of diamorphine for a patient who died on the same day; he collected the drugs and kept them for himself.

1.26 None of these methods of obtaining was likely to lead to detection. The patients were genuinely suffering from cancer. The prescriptions were all properly made out. Each dispensing would be recorded in the pharmacy CDR and the record would look entirely normal. The quantity of the drug prescribed might be large but this would be quite plausible in the case of a patient in the last stages of terminal illness. The pharmacist would have no way of knowing that, as was sometimes the case, a patient for whom Shipman collected drugs had died shortly before the drugs were dispensed. Nobody would realise that Shipman had kept all or part of a consignment. A patient or relative who received a package of drugs would not know that Shipman had removed some. Shipman could easily remove the outer packaging and the label on which the quantity might be written. No formal records have to be kept once the drugs leave the pharmacy. Nobody would realise that Shipman did not in fact destroy the leftover drugs he took; he was not under any duty to make a record of the drugs he took for destruction.

The Method of Obtaining Diamorphine Adopted by Shipman in 1993

1.27 For a period of about seven months in 1993, Shipman adopted a method of prescribing that was not related to cancer patients. I suspect that he was not, at that time, treating any patients who were suffering from cancer and, being in need of supplies of diamorphine, he adopted a different method of obtaining the drug. This entailed a course of conduct that might have led to his detection.

1.28 Between February and August 1993, Shipman wrote 14 prescriptions for a single 30mg ampoule of diamorphine. The prescriptions were in the names of 13 different patients, none of whom needed the drug. Indeed, some of them were already dead at the time he wrote the prescriptions. It is now known that he used each of those 30mg ampoules to kill a patient.

1.29 The dispensing of each of these 30mg ampoules was duly recorded in the CDR of the pharmacy at 23 Market Street. As it happens, between February and May 1993, the only entries on the 'drugs supplied' page of the CDR related to 12 prescriptions issued by Shipman. The record, which usually contained a variety of doctors' names and recorded the dispensing of differing quantities of various sizes of ampoules of diamorphine, had a most unusual appearance. Moreover, 30mg ampoules are usually dispensed as part of a consignment for the treatment of cancer pain. To prescribe a single 30mg ampoule is most unusual. That amount is not enough for the treatment of chronic pain; the patient will need more ampoules for use on subsequent days. On the other hand, 30mg is far too much for a single treatment for acute pain in an opioid-naïve patient. It follows that the appearance of the CDR was very unusual indeed. A copy of the relevant 'drugs supplied' pages appears at Appendix A. I shall have to consider whether the pharmacist who dispensed all but one of these single ampoules should have regarded this sequence as sufficiently unusual to require it to be drawn to the attention of the Greater Manchester Police CIO. I must also consider whether the CIO himself should have noticed the unusual sequence

of prescribing during an inspection and should have initiated an investigation of Shipman's prescribing practice. In the event, the sequence was not recognised as unusual and was not investigated. I shall describe the events of 1993 in greater detail in Chapter Eleven. Later in the year, Shipman gave up prescribing single ampoules; by November, he had access to supplies of diamorphine from a cancer patient. From that time on, he was never short of a source of supply from a cancer patient and, save for one fleeting moment, was never again in danger of being detected on account of his dealings with controlled drugs.

An Incident in 1998

1.30 The fleeting moment occurred in July 1998. Many of Shipman's cancer patients were cared for at home by district nurses. If a patient had been provided with a syringe driver, a district nurse would come in each morning to refill the syringe with a new supply of diamorphine, according to the dosage ordered by Shipman. Although they are not required by law to do so, district nurses keep a record of the supplies of medication received and administered, as well as a stock balance. Sometimes, Shipman would make an entry in the nurses' record. On one occasion after he had visited and had made an entry in the record, the stock balance did not tally with the stock. In fact, he had stolen five 10mg ampoules of diamorphine. The district nurse asked Shipman about the missing stock and he gave an account, which she eventually accepted. She did not report him. I shall discuss this episode in more detail in Chapter Eight. This incident has focussed attention on the value of the district nurses' records and has caused me to examine the feasibility of requiring records to be kept in respect of at least some types of controlled drug after they leave the pharmacy. It occurred only days before Shipman came under suspicion and after he had killed his last victim.

The Inquiry's Approach

1.31 The primary task in Stage Three of the Inquiry has been to investigate the ways in which the systems of control, regulation and inspection governing the use of controlled drugs failed to prevent or deter Shipman from obtaining controlled drugs unlawfully or to detect him when he did so. I have examined the systems in force during the whole period of Shipman's practice as a GP. They remain largely unchanged at the present time. In this Report, I suggest ways in which the loopholes Shipman exploited could be closed.

1.32 It has been said by some that, since Shipman could have used other, non-controlled drugs or substances (such as insulin or potassium) to kill his patients, it is inappropriate for the Inquiry to focus exclusively on controlled drugs. The Inquiry has done so primarily because it was required to do so by its Terms of Reference. The Terms of Reference are wide enough for me not to wish to extend them to other drugs without good reason. The fact that I have not considered in this Report how patients should best be protected from healthcare professionals who seek to harm them by the use of other drugs or substances does not mean to say that there should not be controls in place relating to such drugs. However, such controls are not a matter for this Stage of the Inquiry.

1.33 Nor is it a matter for this Inquiry to consider whether society is right to seek to control the use of addictive drugs and to treat their unauthorised possession or sale as a criminal

offence. There are those who believe that the taking of controlled drugs should be decriminalised and that such a measure would reduce many of the undesirable effects of illicit trafficking. I shall say nothing about those issues. The Inquiry has sought only to find ways of improving the systems that are designed to achieve the objectives of the current legislation.

The Scope and Extent of Diversion

1.34 Diversion of controlled drugs occurs in many ways. It was inevitable that, when looking into the shortcomings of the system that Shipman exploited, I should learn about other abuses related to controlled drugs of which he was not guilty, so far as is known. For example, I have heard evidence that some doctors sell controlled drugs or prescriptions for them. Some prescribe controlled drugs on private prescription for patients whom they scarcely know, turning a blind eye to the fact that the patient is a drug addict who is selling part of his/her supplies in order to finance his/her next prescription. So far as I know, Shipman did not do those things. I have also come across inappropriate prescribing. For example, I have heard about doctors who prescribe controlled drugs for themselves or their families. Such prescribing is not unlawful if done in good faith for proper therapeutic reasons but it can be a cover for the illicit prescribing of a drug for the feeding of an addiction. Shipman did not do that either, so far as is known. However, such practices pose a risk to patient safety and are contrary to the public interest. It seems to me that it would be wrong if I were to decline to consider ways of reducing or detecting those practices just because they happen to fall outside the ambit of Shipman's criminality.

1.35 The Department of Health (DoH), the Home Office and many others who gave evidence to the Inquiry accept that the true extent of diversion of controlled drugs is not known. Dr Jim Smith, Chief Pharmaceutical Officer for England at the DoH, told the Inquiry that the development of palliative care over the last 30 years has resulted in a vast increase in the quantities of controlled drugs being supplied to cancer patients. He said that this increase had brought with it problems of diversion that could not be ignored. A report entitled 'Audit of Controlled Drugs Prescribing in England for the Financial Year 2002/03' published by the Prescribing Support Unit (PSU) of the DoH in October 2003 (the PSU Report) records that the number of Schedule 2 and Schedule 3 controlled drugs prescribed is increasing at an annual rate of 8%. No fewer than 2.7 million prescriptions for Schedule 2 and Schedule 3 controlled drugs were issued during 2002/03. As the volume of controlled drugs dispensed increases, so must the size of the problem of diversion. According to an internal Home Office memorandum from 1997, **'... the number of individual transactions of controlled drugs in Great Britain is in the order of 200,000 every day, with an opportunity for diversion in every one of them'**.

1.36 One of the HODI inspectors told the Inquiry that more than 50% of the benzodiazepine drugs that found their way onto 'the street' had been dispensed on prescription. Mrs Kay Roberts, Lead Pharmacist for the Royal College of General Practitioners National Drug Misuse Training Programme and pharmacist member of the Advisory Council on the Misuse of Drugs, confirmed that a 'street market' exists for these drugs, which are, as I have said, widely prescribed. Several other witnesses said much the same thing.

1.37 Mrs Roberts also spoke of anecdotal evidence of children selling methylphenidate hydrochloride (Ritalin), which had been prescribed (apparently lawfully) for their treatment. Her evidence about the problem was supported by that of Detective Constable Neville Hanley, the CIO for the WYP. The PSU Report describes a rapid increase in the amount of Ritalin prescribed, with nearly 17 million tablets dispensed in 2002/03.

1.38 Several witnesses told me that there is little actual evidence of diversion of diamorphine onto 'the street'. While I accept that there may be little actual evidence of it, it does not necessarily follow that no such diversion is taking place. First, Shipman diverted diamorphine for over 20 years without detection. Although he was using it to kill, he could equally well have been selling it to dealers or addicts. I also heard about other doctors whose diversion of diamorphine continued for several years before it was detected. Some doctors who divert the drug will never be detected. Second, police efforts are understandably focussed on the large volumes of heroin that are unlawfully imported, rather than on the more moderate quantities of pharmaceutical diamorphine that might emanate from an individual community pharmacy. Dr Smith said that, although he had 'no feel whatsoever' for the scale of diversion by professionals, he had heard anecdotes about it and accepted that it was probably significant. In his view, it must be taken seriously.

1.39 The PSU Report dealt only with the prescribing of controlled drugs within the NHS and not with private prescribing. The authors acknowledged that this was an important limitation, as a significant proportion of private prescribing is for controlled drugs. This is a cause for concern because private prescribing is not monitored to the same extent as NHS prescribing. As a result, the scale of private prescribing of controlled drugs is unknown.

1.40 Although, therefore, the scale of the problem of diversion of controlled drugs is not known, there is a recognised risk that any healthcare professional with access to controlled drugs (and this must include pharmacists and nurses), might divert such drugs to improper use. If the public interest requires that the risk of such diversion should be reduced so far as is possible, consistent with the needs of patients, the current regime must be strengthened. It appears to me that, where controlled drugs are concerned, it is unwise to rely on a system that depends wholly on trusting those professionals who have access to them. Everyone's actions should be subject to some degree of supervision, control and audit. I recognise that it may well be impossible to prevent a doctor or other healthcare professional from obtaining illicit supplies of controlled drugs if s/he is determined to do so. However, the system could be a great deal more effective than it is at present. In my view, much could be done to deter such misconduct and to improve the chances of detection if it occurs.

Patient Safety in General

1.41 My examination of the systems of regulating controlled drugs has also led, sometimes unintentionally, to a discussion of issues and problems of wider application. For example, I heard evidence about the frequency with which doctors make prescribing errors, which can have serious or even fatal effects, especially when a controlled drug is involved. This evidence led to a discussion about the need for a pharmacist to check very carefully the appropriateness and dosage of a controlled drug prescription. It was suggested that

pharmacists should have access to patients' medical records so as to be aware of the condition for which the drug had been prescribed. Such a measure would permit the pharmacist to make a more satisfactory check and would contribute to patient safety. The pharmacists' point was that this would be a sensible measure not only in relation to controlled drugs but also with many medicines that are available only on prescription. Thus, at times in this Report, I find myself expressing a view on issues that are not directly related to Shipman and are not even limited to the regulation of controlled drugs. However, I have not strayed into these wider issues unless led there by evidence relating to the regulation of controlled drugs. There is nothing in this Report that is not linked to the final section of my Terms of Reference, which requires me to make recommendations for the safety of patients in future.

Striking the Balance

1.42 In this country, medical practitioners are given an almost unfettered freedom to prescribe any medicinal drug for the treatment of organic disease. They are free to prescribe or administer very powerful drugs such as diamorphine, which (as I have said) are readily susceptible to misuse and which can easily have fatal consequences if used carelessly or in bad faith. All doctors are also entitled to prescribe some types of controlled drugs for the purpose of treating drug dependence. Although the range of drugs is more limited, it includes the prescription of such drugs as methadone, which can also be dangerous. Many Western countries do not allow the use of such drugs as diamorphine even for the treatment of organic disease. They consider that the risks of abuse outweigh the advantage to patients and that other, less dangerous, drugs can adequately meet patients' therapeutic needs. At an early stage of the Inquiry, I was persuaded that such drugs as diamorphine are of very great benefit to patients, provided that they are properly used. I therefore decided that any recommendations I would make would not seek to limit the availability of controlled drugs for legitimate patient needs but would focus on ensuring that they were safely and lawfully used. At times, during the evidence and in discussion, it was urged that some ideas or proposals for change would be unacceptable because they might interfere with patients' access to drugs. I cannot accept that there must be no regulation that might affect the ease with which a patient has access to a controlled drug. In my view, the proper balance must be struck between the degree of regulation necessary to control abuse and the right of patients to have access to the drugs they need.

1.43 It might be possible to devise an elaborate system of regulation and inspection of the use of controlled drugs that would effectively deter abuse and would detect it whenever it occurred. However, the cost of such a system in terms of financial and human resources would be very great. I have not recommended such a system. Instead, I have sought to recognise the abuses and to recommend ways in which they may be countered without placing too great a strain on limited resources.