CHAPTER TWO

The Conduct of Phase Two, Stage Three of the Inquiry

Introduction

2.1 The Inquiry embarked upon the collection of evidence about all aspects of the regulation of controlled drugs. Apart from collecting the statutory materials, so as to trace the development of the legislation over the last 80 years, the Inquiry sought information from the Home Office (the Government Department with responsibility for controlled drugs) and from the Royal Pharmaceutical Society of Great Britain (RPSGB) (the pharmacists' regulatory body) about how the system of regulation is designed to work. The Inquiry also sought evidence from a large number of people and organisations about how the system works in practice. The Inquiry team examined in greater depth materials previously assembled relating to Shipman's methods of obtaining controlled drugs and sought evidence from those who had had dealings with him, in an attempt to discover why his illicit obtaining of drugs had not been detected earlier. The Inquiry looked closely at aspects of the systems of controlled drugs regulation in Northern Ireland and the Canadian province of British Columbia. Finally, the Inquiry consulted widely about ways in which the defects in the current system could be remedied.

The Collection of Evidence

2.2 Witness statements obtained from 67 witnesses and approximately 15,000 pages of documents were scanned into the Inquiry's image database in connection with Stage Three. Those statements and documents supplemented material from Phase One of the Inquiry (and some from Phase Two, Stage Four) that was relevant to the Stage Three issues. This material comes from the following sources.

Families

2.3 When providing their Inquiry witness statements for Phase One, the relatives of Shipman's patients were invited to give their suggestions for change, with a view to establishing additional safeguards for the future. Many provided considered views and positive suggestions as to how the procedures for regulating the use of controlled drugs might be improved. I have taken these suggestions into account. On the second day of the Stage Three hearings, I heard oral evidence from four relatives of patients of Shipman. Three of those patients were unlawfully killed by Shipman. All these witnesses had given careful thought to the issues under discussion and some brought to the Inquiry ideas from their own walks of life. I found their evidence thought provoking and helpful.

Local Pharmacies

2.4 In its attempt to identify all Shipman's sources of supply of controlled drugs, the Inquiry obtained and examined the controlled drugs registers (CDRs) from nine pharmacies in and around Hyde. Most contained no entries in Shipman's name and, from examination

of them, it seems likely that all the diamorphine Shipman used to kill his patients was dispensed from the pharmacy at 23 Market Street, Hyde.

23 Market Street

2.5 The pharmacy premises at 23 Market Street are close to Donneybrook House, where Shipman practised between 1977 and 1992, and adjacent to the surgery at 21 Market Street, where he practised from 1992 until his arrest in 1998. Witness statements were obtained from 11 members of the pharmacy staff, some qualified pharmacists and some not. They included the former owner, Mr Peter Rothman, the pharmacist manager, Mrs Ghislaine Brant, and a number of others, including locum staff. Six of those members of staff gave oral evidence. The witnesses were asked about the dispensing procedures at the pharmacy, with particular reference to controlled drugs. They were asked about the system of inspection by police chemist inspection officers (CIOs) and by the RPSGB. They were asked for their opinions of Shipman and whether they had noticed anything unusual about his prescribing and use of controlled drugs. Some of the staff also gave evidence in connection with an unusual sequence of dispensing of diamorphine that took place during 1993.

Nupharm Chemist

2.6 Five diamorphine ampoules that Shipman stole in July 1998 (after he had killed his last victim) had been dispensed at Nupharm Chemist, Clarendon Street, Hyde, which is owned by Mr Richard Aucott. I have referred to this episode in paragraph 1.30. Mr Aucott gave oral evidence to the Inquiry about the arrangements and procedures for the obtaining, storing and dispensing of controlled drugs (especially diamorphine) in his pharmacy. He also gave evidence about his experience of police chemist inspections and RPSGB inspections and commented on the appearance of the diamorphine CDR held at 23 Market Street.

General Practitioners from Hyde

2.7 During the course of Phase One, it became clear to me that Shipman was able to divert controlled drugs during the whole of his career by purporting to collect them from a pharmacy on behalf of patients. I wanted to discover whether it was normal practice for a doctor to collect drugs on behalf of a patient. Accordingly, enquiry was made of 13 doctors who had been identified from the CDR held at 23 Market Street as having prescribed diamorphine or obtained it on requisition. Ten of those doctors responded, mostly by letter.

2.8 In Phase One of the Inquiry, 11 general practitioners who had at various times worked at the Donneybrook practice provided details of their arrangements (and of their knowledge, if any, of Shipman's arrangements) for keeping controlled drugs. In statements made either for Phase One or for Stage Four of Phase Two, some of those doctors also explained what Shipman had said, when interviewed for the position at the Donneybrook practice, about his intention not to keep a personal stock of controlled drugs in future.

Practice Staff

2.9 Members of the practice staff from Donneybrook House and 21 Market Street made statements concerning their knowledge of Shipman's arrangements for the use and storage of controlled drugs.

District Nurses

2.10 I have explained that, nowadays, many terminally ill patients are cared for at home, with the assistance of district nurses, who are responsible for the administration of a supply of diamorphine by means of a syringe driver. Much of the diamorphine obtained by Shipman was diverted from supplies prescribed for such patients. Witness statements were provided by four district nurses from the Tameside area, three of whom gave oral evidence. Mrs Diane Nuttall, Directorate Manager of the Community Care Directorate, Tameside and Glossop Primary Care Trust, also gave evidence. These witnesses explained their working arrangements, focussing upon the administration of diamorphine to terminally ill patients. They gave evidence about their experience of Shipman in general and they were also asked specifically about the cases of several patients whose diamorphine was diverted by him.

2.11 A demonstration of the operation of a syringe driver was provided by Mrs Carla Hartley, a Macmillan nurse and clinical nurse specialist.

Care Homes in Hyde

2.12 Some of the patients killed by Shipman lived in what are now known as 'care homes' or 'care homes with nursing'. Special requirements exist in respect of the keeping of controlled drugs for patients who live in such accommodation, and the Inquiry obtained statements from three persons occupying nursing or managerial positions in such homes.

The Royal College of Nursing

2.13 Mr Ian Hargreaves was, until 30th April 2003, Regional Director of the Royal College of Nursing. He retired on that date, although he has continued to represent the College during the remainder of the Inquiry. He gave evidence about nurses and their dealings with controlled drugs, about the special arrangements that apply for midwives (especially in the community) and about issues of diversion in general. He made some suggestions for improvement of the current systems. He outlined the procedures that apply in a hospital setting.

Expert Evidence

Mrs Kay Roberts

2.14 At an early stage, it became apparent that the Inquiry would need assistance in the form of evidence from an independent pharmacist with knowledge of the law and procedures relating to controlled drugs, together with personal experience of how they work in practice. Mrs Kay Roberts filled that role and was of great assistance to me. She is a former

Area Pharmacy Specialist in Drug Misuse, employed by the Greater Glasgow Primary Care NHS Trust. She is the Lead Pharmacist for the Royal College of General Practitioners (RCGP) National Drug Misuse Training Programme and, since 1999, has been a pharmacist member of the Advisory Council on the Misuse of Drugs. She also serves on the Scottish Advisory Committee on the Misuse of Drugs. Mrs Roberts qualified in pharmacy in 1961 and, during her distinguished career, has occupied hospital, community and administrative posts.

2.15 Mrs Roberts gave evidence on three days. She provided an invaluable explanation of the law applying to controlled drugs and community pharmacy and of the evolution of the relevant law. She provided an insight into the practical workings of a community pharmacy, in particular the procedures relating to controlled drugs. She also helped me to evaluate the unusual features of the sequence of dispensing of single 30mg ampoules of diamorphine that took place in 1993.

Professor Richard Baker

2.16 Professor Richard Baker is Director of the Clinical Governance Research and Development Unit at the University of Leicester. He has made important contributions at several stages of the Inquiry process. In the course of the Stage Three hearings, he gave oral evidence explaining the findings of a survey carried out by himself and colleagues from the University of Leicester, dealing with the quality and efficacy of local controlled drugs procedures. His evidence provided a useful insight into the arrangements for storing and dealing with controlled drugs by doctors, as well as by pharmacists.

Professor Henry McQuay

2.17 Professor Henry McQuay, Professor of Pain Relief at the University of Oxford and Honorary Consultant at the Oxford Pain Relief Unit, provided a written statement for Stage Three, setting out the various therapeutic uses of controlled drugs, in particular diamorphine.

The Home Office

2.18 The Home Office Drugs Branch is responsible for administering the statutory systems of control applicable to the production and distribution of controlled drugs, although routine community pharmacy inspections are carried out, not by the Home Office, but by the police. The Home Office Drugs Inspectorate (HODI) is responsible for investigating the suspected breach of certain controlled drugs regulations. Mr Alan Macfarlane, Chief Inspector of the HODI, gave oral evidence. He explained how the systems currently operate and, by reference to a large quantity of documentation supplied by the Home Office and various police forces, explained the history and purpose of the systems, from the inception of police pharmacy inspections in the early twentieth century to the present day.

2.19 The Inquiry obtained evidence about the investigation into the offences of which Shipman was convicted in 1976. A senior inspector from the Northern Regional Office of the HODI, who had been involved in the investigation, gave oral evidence. An inspector from the

Northern Regional Office provided a statement about his involvement in that investigation. In all, four HODI inspectors gave evidence about the way in which the Inspectorate operates.

2.20 The Inquiry also collected evidence about the procedures within the Home Office by which decisions were made to seek or not to seek directions under section 12 of the Misuse of Drugs Act 1971 (MDA 1971). The Home Secretary has the power to restrict the right of a doctor convicted of controlled drugs offences to prescribe, possess, supply or administer controlled drugs. In 1976, the Head of Division E4 of the Home Office (the Division that included the HODI) was Sir Geoffrey de Deney. It was he who decided that no direction should be sought from the Home Secretary in Shipman's case. Sir Geoffrey attended the Inquiry to give evidence about the policy governing directions that was in place at that time and to explain why no direction was sought. A witness statement was also obtained from a legal assistant at the Home Office. Twenty two case files relating to section 12 directions (or equivalent directions under the previous legislation) against doctors, dentists and pharmacists, spanning the period from 1969 to 1993, were also obtained.

The Royal Pharmaceutical Society of Great Britain

2.21 The RPSGB employs a number of full-time inspectors who carry out periodic inspections of all community pharmacies. One of the issues I had to consider was whether RPSGB inspections of the pharmacy at 23 Market Street and, in particular, inspections of the CDR held there, should have alerted the authorities to Shipman's acquisitions of diamorphine. For this reason, the Inquiry obtained witness statements from five past and present RPSGB inspectors, four of whom gave oral evidence.

2.22 I also heard oral evidence from Mr Stephen Lutener. Mr Lutener qualified as a pharmacist and then worked for Boots the Chemists for approximately seven years before joining the RPSGB as an inspector in 1987. He was appointed Head of the Ethics Division in 1991 and thereafter occupied a number of senior posts. When he gave evidence in June 2003, and at the time of his departure from the RPSGB in October 2003, his job title was Head of Professional Conduct. Mr Lutener's evidence covered many aspects of the work of the RPSGB and I found it invaluable.

Greater Manchester Police

2.23 It was also necessary for me to consider why the routine inspection of the CDR kept at 23 Market Street by the CIOs of the Greater Manchester Police (GMP) did not lead to the detection of Shipman's activities. I wished to know whether the failure to detect the diversion arose from individual or systemic failings (or both). I wished to compare the performance of the CIO responsible for inspection of the CDR with that of his fellow GMP CIOs. I also needed to compare the performance of the GMP CIOs with that of CIOs employed by other forces over the relevant period.

2.24 Detective Chief Superintendent (DCS) Peter Stelfox, the officer in charge of GMP Crime Investigation, gave oral evidence to the Inquiry, providing the perspective of a senior GMP

officer. Witness statements were obtained from 11 past and present GMP CIOs, seven of whom (including Detective Constable (DC) Michael Beard, Chairman of the National Association of Chemist Inspection Officers (NACIO)) attended to give oral evidence. Their evidence shed valuable light on the various methods of diverting controlled drugs used by healthcare professionals. A witness statement was also obtained from a retired detective superintendent who had been in charge of the GMP Force Drugs Unit from 1993 until 2001 and who had prepared an internal report on GMP inspection of community pharmacists. DCS Bernard Postles, former Commander of the Investigative Support Branch, Crime Operations Department, GMP, also provided a witness statement.

Other Police Forces

2.25 The Inquiry obtained some general information from all 43 police forces in England and Wales about their CIO arrangements. More detailed information was obtained from 14 forces in England and Wales, from the Police Service of Northern Ireland and from six Scottish police forces. Senior officers from two forces gave oral evidence, as did four past and present CIOs from other forces. DC Diane Cooper, a trainer involved in the CIO training course at the West Yorkshire Police Training Centre, also gave oral evidence. DC Duncan White, a CIO and Secretary of the NACIO, provided a witness statement. He also attended the Inquiry's seminars. Further material was provided by the Association of Chief Police Officers.

The Department of Health

2.26 The last witness to give evidence before the Inquiry in Stage Three was Dr Jim Smith, Chief Pharmaceutical Officer for England at the Department of Health (DoH). Dr Smith, who also attended the Inquiry seminars, described the role of the DoH with regard to controlled drugs from 1974 to the present day, as well as explaining guidance and directions issued by the DoH on the MDA 1971 and the Misuse of Drugs Regulations 1973–2001. He also dealt with a number of issues related to diversion of controlled drugs into the community. The DoH provided a large quantity of written material for consideration.

Documents from Other Sources

2.27 Statements, correspondence and other material was received from a large number of other organisations. These included Government Departments and Agencies, among them the Department for the Environment, Food and Rural Affairs and the Medicines and Healthcare Products Regulatory Agency. Professional bodies supplying such material included the British Medical Association, the RCGP, the General Medical Council, the Medical Defence Union and the Dispensing Doctors' Association. The Nursing and Midwifery Council, the Association of Nurse Prescribing and the Royal College of Midwives also provided material, as did Macmillan Cancer Relief, Marie Curie Cancer Care and numerous individual hospices. The National Pharmaceutical Association, the British Association of Pharmaceutical Wholesalers and the Association of the British Pharmaceutical Industry provided further material.

2.28 In considering the systems in other jurisdictions, the Inquiry received material from Northern Ireland, Canada, the United States of America and Australia.

Evidence Relevant to Both Stages Three and Four

2.29 The Inquiry received some evidence that was relevant to both Stage Three and Stage Four. For example, evidence relating to the monitoring of prescribing by primary care trusts, relying on data provided by the Prescription Pricing Authority (PPA), was given during Stage Four but was relevant also to Stage Three. The evidence of Mr Michael Siswick, Director of Human Resources for the PPA, was particularly helpful.

Before the Oral Hearings

The Arrangements for the Distribution of Evidence

2.30 The arrangements for the distribution of evidence were the same for Stage Three as for Phase One and the earlier Stages of Phase Two. They are described at paragraphs 3.17 and 3.18 of my First Report. As in Phase One, all the evidence available to the Inquiry was released into the public domain via the Inquiry website, except where material had to be withheld in order to protect the identity of certain individuals unconnected with the enquiries into Shipman's activities.

The Public Meeting

2.31 On Monday, 17th March 2003, the Inquiry held a Public Meeting, at which I explained the arrangements for Stage Three.

Representation

2.32 Before and after the Public Meeting, I granted leave to various individuals and organisations to be represented before the Inquiry during the Stage Three hearings and, for some, recommended funding for that representation at public expense. A list of participants in Stage Three and their representation can be seen at Appendix B of this Report.

Salmon Letters

2.33 Before the Stage Three hearings began, the Solicitor to the Inquiry, Mr Henry Palin, sent letters (known as 'Salmon letters') to those persons and organisations whose conduct might become the subject of criticism by the Inquiry. The potential criticisms were clearly identified in those letters. In the event that any further potential criticisms came to light at or after the hearings, these were the subject of further Salmon letters. Recipients of Salmon letters were given the opportunity to respond to the potential criticisms in writing, as well as in the course of their oral evidence at the hearings.

Permission to Broadcast

2.34 I had given permission for the Stages One and Two hearings to be broadcast in accordance with a protocol prepared by the Inquiry and designed to ensure that Inquiry

material would not be misused. Those arrangements caused no difficulties during Stages One and Two and I received no representations suggesting that they should be discontinued. I therefore gave permission to recognised organisations to broadcast during Stage Three, provided that they complied with a slightly amended protocol, clarifying the broadcasters' duties in respect of websites. During Stage Three, I received and granted one application from a witness that her evidence should not be broadcast.

The Oral Hearings

2.35 The oral hearings were held in the Council Chamber at Manchester Town Hall. The Stage Three hearings took place between Monday, 19th May and Wednesday, 2nd July 2003, and on Friday, 18th July 2003.

2.36 The arrangements for the oral hearings, and for the publication of evidence, were the same as for the Phase One hearings. They are described at paragraphs 3.28 to 3.36 of my First Report.

2.37 Volunteers from Tameside Victim and Witness Support attended to assist family witnesses at the start of the Stage Three hearings, but were not required during the remainder of these hearings. I remain most grateful to Tameside Victim and Witness Support for all the assistance they have given during the course of the Inquiry.

2.38 In general, witnesses who gave oral evidence during the Stage Three hearings were called by Counsel to the Inquiry. However, in the interests of fairness, those witnesses who had received Salmon letters were given the opportunity of making an opening statement of their evidence in response to questions by their own counsel or solicitor, before being questioned by Counsel to the Inquiry. In the event, none of the recipients of Salmon letters chose to avail themselves of this opportunity.

Submissions

2.39 Following the conclusion of the Stage Three hearings, representatives of a number of the individuals and organisations represented made written submissions. Counsel to the Inquiry also produced written submissions. I offered an opportunity to all representatives to make representations that I should hear oral submissions, but received no such representations.

The Inquiry's Consultations

The Discussion Paper

2.40 On 1st July 2003, before the end of the Stage Three hearings, the Inquiry published a Discussion Paper entitled 'The Use and Monitoring of Controlled Drugs in the Community'. The purpose of the Discussion Paper was to provide a focus for both written responses and oral discussion at a series of seminars held in January 2004. The Inquiry received written responses from 126 individuals and organisations. The views expressed in those responses were considered and discussed at the seminars.

The Seminars

2.41 Seminars were held in the Council Chamber at Manchester Town Hall on Monday, 12th, Wednesday, 14th and Friday, 16th January 2004. There were 16 participants, some representing organisations involved in the day-to-day operation of controlled drugs procedures, some being individuals with a particular interest in or knowledge of controlled drugs. The first day of the seminars was devoted to presentations about the systems of monitoring and inspection of controlled drugs in two other jurisdictions, Northern Ireland and the province of British Columbia, Canada.

2.42 On the second and third days, there was an exchange of views about the various issues raised in the Discussion Paper. The proceedings were led by Senior Counsel to the Inquiry. Participants in the seminars had submitted written responses to the Inquiry's Discussion Paper in advance and expanded on those responses during the course of the seminars. Persons attending the seminars as observers were able to raise points through Counsel for the consideration of seminar participants. After the seminars, the Inquiry received a number of further responses, both from participants who wished to confirm or revise views previously expressed and from people who had attended the seminars, or who had become aware of the discussions that had taken place and wanted to contribute their own opinions.

2.43 I found the seminars, and indeed the whole consultation process undertaken by the Inquiry, extremely valuable in clarifying my thoughts and helping me to formulate my recommendations for the future. A summary of the seminar discussions will be found in Chapter Fourteen.