Witness Name: Charles Hamilton Massey Statement No.: WITN3365001 Exhibits: WITN3365002-3365010 Dated: 17 July 2019

INFECTED BLOOD INQUIRY

EXHIBIT WITN3365007 OF MR CHARLES HAMILTON MASSEY

WITN3365007 (referred to as CM/6 in WITN3365001)

Exhibit WITN3365007 (referred to as CM/6 in WITN3365001)

GMC thresholds

https://www.gmc-uk.org/-/media/documents/dc4528-guidance-gmc-thresholds_pdf-48163325.pdf

Examples of the types of case where failure to meet standards may lead to action on registration

https://www.gmc-uk.org/-/media/documents/dc4596-ce-decision-guidance---annex-g---examples-of-failures-to-meet-standards-62041464.pdf

Guidance on conducting and deciding the outcome of single clinical incident provisional enquiries

https://www.gmc-uk.org/-/media/documents/dc11439-deciding-the-outcome-of-scipes_pdf-75558315.pdf

Making decisions at the end of an investigation https://www.gmc-uk.org/-/media/documents/dc4599-ce-decision-guidance---makingdecisions-on-cases-at-the-end-of-the-investigation-sta-58070536.pdf

Historical fitness to practise procedures

There have been many changes to the GMC's fitness to practise procedures over the period of time for which the Inquiry has requested information, that is, since 1970. We have set out an overview of key changes and processes below. The Inquiry may also find the Fifth report, chapter 15 onwards, of the Shipman Inquiry, chaired by Dame Janet Smith DBE, very useful as it sets out the historical fitness to practise processes of the GMC in some detail. At the time of that Inquiry, the GMC had already identified that significant reform of its fitness to practise procedures was needed, and was taking forward a major programme of reform which culminated in the General Medical Council (Fitness to Practise) Rules 2004. We have continued, and still continue, to reform and develop our processes. If there are particular areas of our procedures or time periods on which the Inquiry team require further information, then we would be happy to undertake further research in order to assist the Inquiry.

Overview

At its inception, the GMC had a limited disciplinary role whereby it could erase a doctor found guilty of 'infamous conduct in a professional respect'. Up until 1980, the GMC's fitness to practise remit extended only to issues of criminal conviction and conduct, although the term 'infamous conduct in a professional respect' was replaced by the Medical Act 1969 with 'serious professional misconduct'.

Determining whether or not conduct amounted to serious professional misconduct was a matter for the Professional Conduct Committee after considering the evidence in an individual case. 'The Blue Book', a guide provided by the GMC to all doctors from 1963 to 1995, described types of misconduct which had in the past been regarded as grounds for disciplinary proceedings but also said that these could not be considered exhaustive, stating: 'Any abuse by doctors of any of the privileges and the opportunities afforded to them, or any grave dereliction of professional duty or

serious breach of medical ethics, may give rise to a charge of serious professional misconduct.'

Following the recommendations of the Merrison committee – a committee chaired by Sir Alec Merrison to consider the structure and functions of the GMC – health procedures were introduced by the Medical Act 1978. These came into operation in 1980 and were designed to deal with doctors whose fitness to practise was impaired by ill health. It was not until July 1997, following provision in The Medical (Professional Performance) Act 1995, that performance procedures designed to deal with doctors whose professional performance was found to be seriously deficient, were brought into operation.

In November 2004, major changes were introduced to the GMC's fitness to practise procedures. Prior to this date, there were separate fitness to practise procedures to deal with the three different categories, that is, conduct, health and performance. All complaints to the GMC were considered first by a case manager who would decide whether a case should close or proceed into fitness to practise procedures. If they considered it should proceed, it was sent to a medical screener (or to a health screener if clearly about health). The medical screener would consider if an issue of fitness to practise was raised on the grounds of serious professional misconduct, health or seriously deficient performance. If they agreed, then the case would close. If however a fitness to practise issue was raised, the complaint would be transferred it to the appropriate procedural stream for further action.

Conduct procedures

Cases were first considered by the Preliminary Proceedings Committee. If they determined that a case should proceed, it went to the Professional Conduct Committee (PCC). Hearings before the PCC took place in public. If the PCC found serious professional misconduct, they could issue a reprimand, impose conditions, suspend or erase a doctor.

Health procedures

Cases entering the health procedures were first considered by a health screener. They would generally instruct a health assessment and depending on the outcome would determine whether the doctor's fitness to practise was seriously impaired. If so, they would invite the doctor to agree to appropriate restrictions on their practice. If they did not agree, the case would be likely referred to the Health Committee which could impose conditions or suspend the doctor from practise. The Health Committee sat in private.

Performance procedures

Performance cases were considered by medical screeners who could invite a doctor to agree to an assessment of their performance by an Assessment Panel made up of one lay and two medically qualified assessors, one from a similar speciality as the doctor being assessed. Following the assessment, a case coordinator would decide whether the doctor's performance was seriously deficient. If so, they could develop a set of requirements for the doctor to agree, for example, undertaking training or limiting their practice. These could subsequently be lifted following reassessment. If the doctor did not agree to or comply with the requirements or the case coordinator considered they were not appropriate, the case was referred to the Committee on Professional Performance (CPP) which could impose conditions or suspend a doctor. It could not erase them. The CPP usually sat in private.

The Committees referred to above were made up of GMC members. As numbers of fitness to practise cases increased however, the GMC began to appoint non GMC members, or associates, onto its committees in 2000. By mid-2004, panels of the various committees were made up entirely of associates except in exceptional circumstances. After introduction of the new fitness to practise procedures in 2004, GMC members became ineligible to sit on the panels.

Fitness to practise reforms - 2004 onwards

The new procedures brought in by the 2004 Fitness to practise rules were designed to unify the different procedures, enabling cases to be dealt with more flexibly and coherently, for example where health, conduct and performance issues arose in the same case. A unified Fitness to practise panel replaced the different committees. The different methods of gathering evidence, for example health and performance assessments, expert reports on clinical practice, were available to all types of case. The result was a more streamlined and efficient fitness to practise procedure.

The reforms also introduced greater separation between the investigation and adjudication stages of the fitness to practise process. At the end of the investigation stage, case examiners applied a test of whether there was a realistic prospect of establishing that a doctor's fitness to practise was impaired to a degree justifying action on registration. This test remains to this day. However, until May 2008, fitness to practise panels applied the criminal standard of proof to their assessment of evidence. That changed on 31 May 2008, when the civil standard of proof was adopted, namely that on the balance of probabilities the allegations were proved. Since that date therefore, the assessment of a realistic prospect of finding impairment has been considered on that basis. 2008 also saw case law which established that in assessing whether or not a doctor is impaired, it is the current risk to patient safety or public confidence that must be taken into account.

A further major programme of fitness to practise reform began in 2010. This led to the establishment of the Medical Practitioners Tribunal Service in 2012 to provide a clear separation between the GMC's investigation function and the separation of hearings. Other key changes include the introduction of the Employer Liaison Service to support timely and consistent referrals from employers; the introduction of the Patient Liaison Service both to help complainants understand our role and processes and to ensure that we fully understand their concerns; and the introduction of provisional enquiries to improve the information we can gather at the triage stage.

Timeline of FtP and consent guidance changes

1975

The Merrison Report recommended that the GMC should have new powers to provide guidance on medical ethics

1980

- FtP Health procedures come into operation (introduced by Medical Act 1978)
- The GMC is given legal power to give advice to the medical profession on standards of conduct, performance and medical ethics

1988

 'HIV and AIDS: The Ethical Considerations' guidance is published in response to the handling of HIV and AIDS

1992

GMC guidance, 'Transplantation of organs from live donors' makes clear there is a need for doctors to ensure that patient consent to a donation is freely given and fully informed

1995

'Good Medical Practice' is first published replacing the 'Blue Book', Professional Conduct and Discipline: Fitness to Practise

1997

- Performance procedures are introduced following provision in The Medical (Professional Performance) Act 1995
- 'Serious Communicable Diseases' (SCD) guidance is published to replace 'HIV and AIDS: The Ethical Considerations'

1998

The second edition of 'Good Medical Practice' is published and reflects the evolution of how consent is discussed with patients Seeking Patients' consent: The ethical considerations' is published

2002

- s35A¹ power gained by the GMC to require disclosure of information from a practitioner (except the practitioner in question) or any other person for the purpose of carrying out a fitness to practise investigation (e.g. an employer or healthcare Trust). And, s35B¹ our duty to disclose documents/information to employers and those with a public interest argument.
- Making a complaint as a member of the public becomes easier, before 2002 a sworn affidavit was needed

2003

The Council for Health Regulatory Excellence (CHRE) gained s29² power of appeal against FtP panel decisions (CHRE was the predecessor of the Professional Standards Authority (PSA) who oversee the nine health and care professional regulators including the GMC)

2004

- New FtP changes come into effect: Rule 4 (5), the 5 Year Rule³
- FtP rules are introduced to unify the three different processes (conduct, performance and health)

2006

- FtP Sanctions Guidance is first introduced (changes made in 2012 and 2013)
- The 'Serious Communicable Diseases' guidance is withdrawn

¹ Referenced sections relate to the GMC's governing legislation, the Medical Act 1983 (as amended).

² Section 29 of the National Health Service Reform and Health Care Professions act 2002 (as amended).

³Rule 4 (5) known as the 'five year rule,' means that if five or more years has elapsed since the most recent event giving rise to the allegation, then enquiry will not proceed to a full investigation, '*unless the Registrar deems that it is in the public interest and exceptional circumstances.'*

2008

- The FtP burden of proof changes from the criminal standard (beyond reasonable doubt) to the civil standard (on the balance of probabilities the allegation is more likely to be proven than not)
- Consent guidance is updated, 'Consent: patients and doctors making decisions together' (current guidance)

2010

 A major programme of reform began leading to the establishment of the Medical Practitioners Tribunal Service (MPTS)

2012

- The MPTS is operationally separate from the GMC FtP function
- Revalidation is introduced
- The Employer Liaison Service is established
- The Regional Liaison Service is established

2015

- The Patient Liaison Service is fully rolled out having been piloted from 2012
- MPTS Sanctions guidance introduced

2018

- The Emerging concerns protocol is signed
- The 'Patient Voice' project introduced a new policy and process to ensure timely communication with families or those close to the care of the patient in cases where the patient would lack a voice in our processes.

The consent guidance review is started with the intention of publishing in late 2019.