

COUNCIL FOR HEALTHCARE REGULATORY EXCELLENCE

SECTION 29 CASE MEETING OF COUNCIL MEMBERS

ON 12TH APRIL 2005

AT 11 THE STRAND, LONDON WC2

**RE: MRS GHISLAINE BRANT AND THE DECISION OF THE STATUTORY COMMITTEE
OF THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN ON 21ST MARCH
2005**

PRESENT: Peter North (Lay member, in the Chair)
Michael Copland Griffiths (Regulatory Member)
Sally Williams (Lay member)

IN ATTENDANCE: Julie Stone (Deputy Director)
Michael Andrews (Fitness to Practise Manager)
Briony Mills (Fitness to Practise Officer)
Christian Dingwall (Legal Adviser, Bevan Brittan)
Charles Atkins (Legal Adviser, Bevan Brittan)

Definition of the Statutory Committee's Decision

1 Mrs Brant is a 48 year old registered pharmacist. She appeared before the Statutory Committee (the Committee) of the Royal Pharmaceutical Society of Great Britain (the RPSGB) on 21, 22 and 24 February 2005 in relation to a charge of misconduct. The Committee gave their determination on 21st March 2005.

2 The Committee heard the case in accordance with the Pharmaceutical Society (Statutory Committee) Order of Council 1978 (the Rules). The heads of charge and findings against Mrs Brant were:

Head	Finding
'1. You first registered with the Society on 10 July 1978.	No finding made
'2. At the material times, you were a pharmacist employed at Battersby's Chemist, 23 Market Street, Hyde, Cheshire, SK14 2AD ("the pharmacy").	No finding made
'3. Between 22 February 1993 and 27 August 1993, on 13 or 14 occasions, you dispensed and/or were involved in dispensing prescriptions for a single 30mg ampoule of diamorphine in the names of 13 different patients.	No finding made
'4. On each occasion, the prescription was written by Dr Shipman	No finding made
'5. The dispensing of each of these ampoules was recorded in the Controlled Drugs Register ("CDR") at the pharmacy.	No finding made
'6. In respect of each of 4 patients namely the patients Mr F, Mrs A, Mrs P and Mr L, you did not make an entry in relation to the dispensing of 30mg single ampoules of diamorphine in the patients' Patient Medication Record held at the pharmacy.	No finding made
'7. One page of the drugs supplied CDR for diamorphine for the period between February and June 1993 shows 12 prescriptions in a row issued by Dr Shipman for a single 30mg ampoule of diamorphine.	No finding made
'8. Up until June 1993 you did not purchase supplies of 10mg ampoules of diamorphine for use at the pharmacy.	No finding made
'9. In early July you did purchase 5 x 10mg ampoules of diamorphine for use at the pharmacy	No finding made
'10. A competent pharmacist would have known that:	
i. A single 30mg ampoule of diamorphine is a most unusual amount of diamorphine to prescribe;	No finding made
ii. 30mg of diamorphine would be a lethal dose for someone not accustomed to the drug;	No finding made

- iii. 30mg ampoules are and at the relevant time were usually prescribed in ampoules of 5 as part of a course of treatment for cancer patients; No finding made
 - iv. Repeatedly to prescribe a single 30mg ampoule of diamorphine would be a very unusual occurrence. No finding made
- '11. It is, and would at the material time have been, within the knowledge of a competent pharmacist that (as provided in The British National Formulary No. 23 published in March 1992):
- i. Diamorphine is a powerful opioid analgesic No finding made
 - ii. That for acute pain the dose, by subcutaneous or intra-muscular injection, is 5mg repeated every 4 hours if necessary and up to 10mg for heavier well muscled patients; No finding made
 - iii. That for myocardial infarction the dose is 5mg followed by 2.5-5mg if necessary, by slow intravenous injection with a half dose for the elderly or infirm; No finding made
 - iv. That for acute pulmonary oedema the dose is 2.5 to 5mg by slow intravenous injection; No finding made
 - v. That the dose for chronic pain is 5-10mg orally (half of that quantity if administered intramuscularly, and about ¼ to 1/3 if subcutaneously) regularly every 4 hours to be increased according to needs. No finding made
- '12. By repeatedly dispensing single 30mg diamorphine ampoules between 22 February and 27 August 1993, on the prescription of one doctor, you failed to:
- i. Take any or any proper steps to satisfy yourself that an unnecessary and/or excessive dose was not being prescribed; and/or No finding made
 - ii. Appreciate that the fact that Dr Shipman repeatedly collected the single 30mg ampoules of diamorphine meant that there was a need to investigate this prescribing and collecting pattern further; and/or No finding made

- iii. Take any steps to satisfy yourself that there was no abuse of diamorphine in relation to the prescribing: and/or No finding made
 - iv. Identify any discernable and/or unusual pattern in Dr Shipman's prescribing of diamorphine; and No finding made
 - v. Take any steps to report the clear and unusual pattern of prescribing either to your superintendent pharmacist or to the Home Office (either directly or through the Chemist Inspection Officer or to the Royal Pharmaceutical Society of Great Britain). No finding made
- '13. You failed to order into the pharmacy, supplies of 5mg or 10mg ampoules of diamorphine during the period of about March 1993 to about June 1993 when it was apparently your understanding that one reason for the prescribing pattern identified above was that Dr Shipman only required doses of 5 or 10mg of diamorphine and in fact was only prescribing 30mg ampoules because the smaller doses were not in stock at the pharmacy. No finding made
- '14. Once Dr Shipman had prescribed single 30mg ampoules on 4 occasions up until about the end of February 1993 you should have obtained appropriate lower dosages to treat one-off emergency cases. No finding made
- Accordingly, in summary, it is alleged against you that in the course of exercising your role of pharmacist between 22nd February 1993 and 27th August 1993 you:

SUMMARY

- a. Failed to exercise the professional judgment and/or the objectivity of a reasonably careful and competent pharmacist; No finding made
- b. Failed to exercise sufficient scrutiny of Dr Shipman's prescriptions for single 30mg doses of diamorphine; No finding made
- c. Did not act towards Dr Shipman in a way which was to the benefit and welfare of the public and patients; No finding made

- d. Failed to discharge your obligations as a pharmacist to patients; No finding made
- e. Did not in any way exercise sufficient control over the product supplied by means of enquiring, of the doctor or any other person into the repeated prescription by the same doctor of large amounts of a controlled drug, namely the 30mg ampoule of diamorphine. No finding made

3 In summary, it was the Society's case that Mrs Brant failed in her duty in not recognising that the repeated doses of 30mg of diamorphine gave rise to queries about its use that Mrs Brant should have raised with the doctor, and reported if not logically and adequately resolved, to her supervising chemist, the RPSGB Inspector or to the Chemist Inspection Officer, all of whom were available to her.

4 The Committee determined that it was appropriate to allow a submission on behalf of Mrs Brant of 'No Case to Answer' at the conclusion of the case presented on behalf of the RPSGB. In accepting the submission the Committee determined that on the basis of the complaint focused within the Notice of Inquiry, they were unable to discern a case requiring Mrs Brant's response even with the substance of the complaint taken against her at its highest and without regard to the credibility of witnesses. Accordingly, the Committee made no findings of fact and Mrs Brant was acquitted without having to present her case.

Documents

5 The following documents were before the meeting:-

- (1) Determination of the Committee given on 21st March 2005;
- (2) Transcript of hearing – 21st, 22nd and 24th February 2005;
- (3) Exhibits before the Committee;
- (4) Legal Report prepared by Bevan Brittan LLP dated 7th April 2005;
- (5) Summary of Evidence prepared by Bevan Brittan LLP dated 11th April 2005.

Conflicts of Interest

- 6 The members declared no conflicts of interest and none was apparent.

Jurisdiction

- 7 The members noted that the purpose of the meeting was to decide whether to exercise its statutory discretion to refer to the High Court under Section 29 of the NHS Reform and Health Care Professions Act 2002 (“the 2002 Act”) the Committee’s decision in respect of Mrs Brant.
- 8 It was agreed that the CHRE had the power to refer this case under Section 29 (4) (b) of the 2002 Act if they considered that the decision of the Committee was unduly lenient and it was desirable so to refer for the protection of members of the public.

Matters noted by the meeting

- 9 The Committee heard, on behalf of the RPSGB, factual witness evidence from Mr David Young, an inspector for the Society who had inspected the pharmacy where Mrs Brant worked at the relevant time, and expert evidence from Mr Robert Hallworth. They also considered parts of Mrs Brant’s case which had been admitted and accepted.
- 10 The members considered the evidence in the case in relation to each disputed head of charge.
- 11 In giving evidence to the Shipman Inquiry on 2nd June 2003, Mrs Brant accepted that, “It is pretty unusual for a single 30mg ampoule of diamorphine to be prescribed,” and that it would be a potentially lethal dose for someone not accustomed to the drug.
- 12 Mrs Brant was wholly unaware that the diamorphine that she dispensed was being used for any purpose other than *bona fide* treatment of patients.
- 13 At the time that Mrs Brant dispensed diamorphine to Dr Shipman, it did not occur to her that the pattern of prescribing was unusual.

- 14** The members noted that it was accepted by Mr Young that he did consider it to be part of his job to observe and report on unusual prescribing practices of doctors.
- 15** It was noted by the Committee that if there had been patently obvious unusual prescribing practices, Mr Young (on behalf of the RPSGB), another qualified dispenser who saw the CDR at the time and the Chemist Inspection Officer (on behalf of the Police) should have picked up these irregularities. None of them did so and that it would be grossly unfair to single out Mrs Brant as culpable.
- 16** It was noted that the RPSGB's own expert, Mr Hallworth, accepted that although the pattern of prescribing looked unusual, in the opinion of some pharmacists it would not be necessary to challenge it. In his view such an opinion would be "perfectly reasonable".
- 17** The Committee appreciated the evidence of Mr Young and Mr Hallworth, but "taking that evidence at its highest" they could not see "what it is that is being alleged Mrs Brant did unprofessionally" to cause them to conclude that her name should be removed from the Register.
- 18** No evidence was led before the Committee that Mrs Brant wilfully or recklessly dispensed quantities of diamorphine that she knew or ought to have known were excessive. On the contrary the complaint against her was only that she failed to spot a pattern of prescriptions for relatively modest quantities of diamorphine.
- 19** It was noted that the Committee determined that it had the power to consider a submission of 'No Case to Answer'.
- 20** It was also noted that the Committee determined that they could not compel Mrs Brant to give evidence or call any on her own behalf.
- 21** It was noted that when considering the application of 'No Case to Answer' the Committee considered whether, on the basis of the complaint focused within the Notice of Inquiry, there was substance in the complaint against Mrs Brant taken at its highest without regard to the credibility of witnesses, which would allow them to conclude disciplinary action should be taken against her.

- 22** It appeared that Mrs Brant had kept her documentation longer than necessary and that that had assisted in the prosecution and subsequent conviction of Dr Shipman.
- 23** The members expressed some concern that the complaint had been brought against Mrs Brant when others had also failed to recognise the unusual prescribing practices, but they noted that Dame Janet Smith criticised Mrs Brant in the *Fourth Report of the Shipman Inquiry*. They further noted that the Committee had counselled that “there was a serious professional issue to be explored” such that in their view it was proper for the complaint to have been brought before them.
- 24** It was noted by the Committee and supported by the members that the premise on which inspectors operate on behalf of RPSGB must be that they “know best” and communicate on behalf of the Society not only what is required of a pharmacist under the Code of Ethics, but what they ought to be doing to match best practice.
- 25** Dame Janet Smith has made extensive recommendations in the *Fourth Report of the Shipman Inquiry* about various aspects of prescribing and dispensing controlled drugs.

Members’ consideration

- 26** The members considered the case did not raise the issue of public protection in terms of the extent to which Mrs Brant’s action could have caused direct or indirect harm to patients, the need to deter the same or similar conduct by practitioners and in terms of maintaining the reputation of the profession and public confidence in regulation. In particular:-
- (1) The unusual pattern of prescribing was an isolated one;
 - (2) The Society’s expert Mr Hallworth said that some people might have been of the opinion that there was no need to query the prescribing pattern and that would have been a perfectly reasonable opinion to hold;
 - (3) It was very unlikely that someone so careful with her records would find themselves in this position again; and
 - (4) Practice had changed in light of the Shipman case.

- 27** Where there are no public protection issues, the members would not usually go on to consider other aspects of the Committee's decision, but in light of the nature of the decision to acquit by the Committee, it was considered that it would be helpful to do so.
- 28** The members did not consider that there was evidence adduced on behalf of the RPSGB that was capable of supporting a finding of misconduct and accepted that the evidence given by Mr Young and Mr Hallworth had not supported the key disputed allegations contained within the Notice of Inquiry.
- 29** It therefore followed that the members did not consider that the Committee had been unduly lenient in finding that there was no evidence capable of supporting a finding of misconduct.
- 30** In reaching their decision the members agreed that the Committee did have the power to determine a submission of 'No Case to Answer' and that that there had been an appropriate application of the test when determining such an issue.
- 31** The members also considered that if there had been evidence capable of supporting a finding of misconduct, then the misconduct would not have been such as to render Mrs Brant unfit to be on the Register.

Conclusions

- 32** The meeting concluded that the case did not raise an issue of public protection such that the case should be referred to the High Court
- 33** Based on the matters noted by the meeting, they concluded that the decision to acquit was not unduly lenient
- 34** The section 29 criteria had not been fulfilled and the Council should therefore not refer the case to the High Court.

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Dated2005

(Peter North, Chair)

Time of commencement of meeting: 14.30

Time of conclusion of meeting: 15.15