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PHARMACEUTICAL REPORT

Prepared at the request of:

SOLICITORS

for

The Court

In the case of

MT

Presented by

Dr Malcolm VandenBurg BSc MBBS MISMA FCP FFPM FRCP
Specialist in General Medicine
Consulting Pharmaceutical Physician
Author of Positive Under Pressure

Fellow, American College of Clinical Pharmacology, 1991
Fellow, Faculty of Pharmaceutical Medicine, 1993
Fellow, Royal College of Physicians, 1996

BSc Upper 2nd Class Hons. Physiology 1970 (Cardio-Respiratory and Neurology)
A registered Medical Practitioner since 1973
MBBS, St Bartholomew's Hospital, 1973
Membership of the Royal College of Physicians, 1976
Joint Committee on Higher Medical Training Certificate in General (Internal) Medicine. 1982
GMC Registration as Specialist in General Medicine. 2004

Law Society approved as Expert Witness, 2004
Registered: UK National Crime Operations Faculty, 2004
National Police Improvement Agency Expert Adviser Database 2009

Member Drug Information Association. 1984
Member American Academy of Pharmaceutical Physicians. 1993
Member International Stress Management Association. 1997

The Boden Memorial Award for Medicine, Haberdasher's Aske School, Elstree, 1967
Herbert Patterson Medal in Biochemistry, St Bartholomew's Hospital, 1969
BMA undergraduate Research Award, 1972
Elected member of European 500 Dynamic Entrepreneurs, 1995

PREVIOUSLY

Lecturer in General Medicine, London Hospital Medical School
Lecturer in Clinical Pharmacology, St Bartholomew's Hospital Medical School
Honorary Senior Registrar in General Medicine, The London Hospital
Director of Clinical Research, Merck Sharpe & Dohme
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Co-coordinator of Positive Under Pressure Workshops for healthcare professionals
Author of Expert Reports for Pharmaceutical Product Licences
and over 120 published articles on the effects of pharmaceutical medicines
30 papers and articles on stress
Editor in Chief: Dilemmas and Solutions in Global Drug Development – PJB Publications
Author: Good Clinical Practice for Investigators
Author: Standard Operating Procedures for Investigators

Medical Advisor to Release (the drug assistance charity) 1973 – 1978

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Throughout this report, where I quote from papers supplied, this will be entered in italics, whenever I am giving my opinion throughout the body of the report; this will be typed in bold.

1. I am instructed in this matter by solicitors for the defendant in letters dating from 19 June 2009 to 25 January 2010.
2. The case is subject to prior approval from Legal Services Commission and there have been three separate grants of authority to date, due to the complexity of the case and the five inches of medical records. There were finally at the end eight inches of records to review and further authority was requested.
3. I am told in their instructions of 7 July 2009 that '*My client has been charged with three offences of fraud by false representation. The circumstances of the offences being that she created false NHS patients in order to obtain further prescriptions for the painkiller - OxyNorm. There is also a schedule of similar offences to be taken into consideration. The TIC's are seven in number.*

   In addition to the fraud charges, my client faces a charge of possession of class A drug in relation to the possession of OxyNorm said to have been obtained fraudulently.

   I enclose a copy of the prosecution case papers. You will see from the summary that Miss T admitted to carrying out the relevant acts when she was interviewed.

   I also enclose a draft statement of Miss T, as yet, unsigned, which sets out her account of events. (**I have previously told the solicitors not to let me have sight of anything which I could not rely on and which they would subsequently claim privilege.**)

   Miss T asserts that she became addicted to the painkiller after being prescribed it four years ago following complications from a hysterectomy. (**It appears that the event was probably in February 2004 at which time she had a suspected pulmonary embolism.)**

   Our client has a caution for the same offence, in the same circumstances, committed in June 2008.

I should be grateful if you would prepare the report as you have outlined in your quote. You have indicated to Z that you would be able to prepare a report dealing with whether this drug would cause Miss T to act in the way she did and the effect of the dependency.'

4. The defendant has also been seen by Dr N whom has produced an independent psychiatric report and an addendum report for the court.

5. At one stage he indicated that the defendant was not fit to plead, but I am not clear of the status of his opinion at the present time or at any previous time. I clearly am not aware what it would be at any future time.

6. I have read all correspondence from solicitors.

7. I have in my possession:

- Copies of the prior authority letters from Legal Services Commission
- Charge sheet
- The summary on Directors Guidance Streamline Process.
- The Particulars of Other Offences (restricted)
- Witness Statements, unindexed and untabulated from:
    - Dr B
    - Dr Bo
    - Dr P
    - Dr A
    - Dr R
    - Nurse S
    - Ms W
- Exhibits printed out from a computerised system, from I believe [redacted], which is an out of hours medical service.
- Report to Crown Prosecutor for Charging Decision.
- List of Previous in the court/defence /probation print, noting the reprimands, warnings and cautions
- I have read the report by Dr N dated 23 September 2009 and addendum report 9 October 2009.

- I have read the statement of MT as supplied by the defendant's solicitors, being 3 1/3 pages, unindexed, unpaginated, undated and unsigned.
- I have read copies of notes as supplied by the [redacted] NHS Trust. (**These have been gone into in some detail but it is worth saying at their first mention that they are unindexed and unpaginated, not in date order, contain a number of duplicates, do not contain individual admissions completely, that there are admissions where nursing records are not available and also admissions, particularly the first admissions in 2003 and February 2004, which are completely absent. It is surprising to find records in such an indiscriminate order and I am not sure for the reason for this. We have made specific enquiries of the trust, and I am told by solicitors for the defendant that they have made further enquiries and that what has now been sent to them and forwarded to me are all they have on file. This clearly indicates that some notes have either been lost or destroyed, although how and why and whether it is carelessness or otherwise, is not clear**.)

8. I have also received notes from various GP practices, particularly the [redacted] & [redacted] Partnership which again are unindexed, unpaginated and unordered. They come from more than one surgery of the partnership and contain elements of computerised records, logs and hand written notes, as well as letters and summaries from other healthcare service providers. They clearly identify a Discharge Summary dated 19 March 2004 which is the first mention of OxyNorm. There are several other GP records in the bundle from different partnerships as listed later which have all been read.
9. I have also read summaries from [redacted] Hospital, again unluckily not indexed nor paginated. I have not gone into these in any detail as they have clearly been read by Dr N and are quoted in his report and are all subsequent to the alleged incidents.
10. I apologise to the Court, but of course at the time of my report there is not a Court Bundle which is superpaginated. Should one become available and I am called to Court, to realign my notes with the Court Bundle could require additional time for which Legal Services funding could be needed.

11. On Thursday 11 February 2010 I travelled to [redacted] to consult with MT the presence of the Paralegal, from the Solicitors. I consulted with MT for a period of two hours.

12. In view of the full psychiatric assessment prepared by Dr N, I did not repeat this exercise as he is clearly more experienced than me in psychiatric interviewing techniques and diagnosis and I rely on his findings where I believe his expertise is greater than mine.

13. I used the time to clarify the history as she remembered it, and to help me understand a number of issues which even the eight inches of evidence in front of me did not make clear.

14. We were accompanied at the interview by her partner.

15. I began my interview with her by explaining my role in the court process, that I was instructed by her solicitors, that my duty was to the court, and that if her solicitors chose not to call me as a witness, the other side may.

16. I told her I did not owe her a duty of care or confidentiality and that part of my review of the case would be to compare everything that she told me to other matters I have received. She was not aware or had sight of the extent of her medical records which were in my possession.

[B L A N K]

CHARGE SHEET

17. The charges relate to fraud and dishonesty to obtain OxyNorm on 13.12.2008, 16.12.2008 and 09.01.2009, and being in possession of OxyNorm between 12.12.2008 and 10.01.2009.

18. These dates are completely surprising as she was discharged from hospital on 20.12.2008, during which time she received OxyNorm in hospital and it even appears as a drug to be taken away from the hospital without being crossed out, although there are comments that this should not occur. There is also a second photocopied form which appears to show that it was crossed out and indeed there is a rapid escalation of her drug seeking behaviour immediately on discharge which would be compatible with her leaving hospital without any Oxycodone.

19. She also received OxyNorm while in hospital, which is to say the least, surprising. She even received OxyNorm after it had clearly been written in the notes that this may be unadvisable.

20. The key evidence relating to the charges comes from the witness statements previously mentioned and the admission is clear.

21. On or around the time as can be seen from the evidence, there were other attempts to get the medication, most of which appear to have, in many instances, been successful. (**Given that OxyNorm is a controlled Scheduled II drug, it is surprising that the patient was able to obtain the drug fraudulently given the checks a doctor should theoretically, morally and legally make before prescribing it**.)

22. It certainly was prescribed in instances where I would not, as a private physician, have deemed this to be appropriate, but I can make no comment of its normality or appropriateness in a NHS setting and defendant solicitors, prosecution and court may wish to take a view from a practising NHS General Practitioner. Within GP training and within publications from The Royal College of General Practitioner it is clear that a competent General Practitioner following all appropriate guidelines would not have prescribed in some of the circumstances alluded to, even in these circumstances where she is charged.

REVIEW OF MATERIAL REGARDING OXYCODONE

23. Considering the clinical effects of Oxycodone, the active ingredient of OxyNorm and OxyContin, I have relied on:

- The British National Formulary which is a publication on which doctors are instructed to rely, and is published by the Royal Pharmaceutical Society of Great Britain.
- The Summary of Product Characteristics, which is a document written by the manufacturer and approved by the MHRA (the Medicines and Healthcare products Regulatory Agency).
- The Patient Information leaflet, which is inserted into the original pack by the manufacturers to inform patients whom are prescribed the drug about the efficacy, precautions and side effects and other important information. It is drafted by the product licence holders and approved by the MHRA. It is a regulatory approved document.
- Martindale, which is published by the British Pharmaceutical Society and is the standard text to which all doctors should refer.
- Meyler's Side Effects of Drugs, 14th Edition published Elsevier 2000.
- Contact with the manufactures and my own database of the literature in relation to:
    - The addictive properties of Oxycodone
    - The effects both physical and psychological of withdrawal
    - The psychological drive of the addictive process
- I have relied on my own knowledge of standard text books and literature.
- In all matters I have searched the National Institute of Health Bethesda, Maryland, using their search engine PubMed, for appropriate research articles.

24. I have been in contact with the product licence holders for Oxycodone and Drugscope as well as the NTA, whom have indicated they will revert to me as to what should have been the practice in her area re Oxycodone addiction. To date they have not done so.

REVIEW OF ALL EVIDENCE

25. This report is structured in a slightly different way from that which solicitors and the court may be used to.

26. In my review of all evidence, I have structured as much as possible of it in a timeline sequence so that the interrelationship of the hospital records, the GP records, the charges and evidence against, as well as MT's recollection of events and her symptomatology can be followed sequentially.

27. Within this timeline sequence I identify the source by abbreviations as detailed below. I am doing this to the best of my ability as the papers I have received, particularly her medical records are the worst I have ever seen from both the hospital and the various GPs she has been involved with.

28. As identified by a doctor in one of her early admissions, in her hospital records there are multiple hospital records under the name MT and it would appear that these have never been aggregated, or even found, even though it was picked up at an early stage.

29. The notes are:

- Not in date order.
- Even for a given admission to hospital or within a given service at the hospital or within a given General Practice there is no particular order and they are not kept sequentially and papers relating to the same admission may be found throughout the bundle.
- There are clearly key pieces of evidence missing such as hospital records relating to her initial admissions in 2003 and 2004 for her hysterectomy and the removal of the ovarian cyst with its subsequent pulmonary embolism.
- Papers within the hospital records which the GP does not have, and papers within the GP records which the hospital does not have.
- There are a number of duplicates of papers scattered randomly throughout the pile, particularly key evidence such as the GP records relating to 2003/2004 which arrived separately from the other GP records

- Finally none of the records are filed, indexed or paginated and the totality is certainly not superpaginated. I did not take it upon myself to do this as if it does come to court, I am sure the bundle will be much more ordered and I will have to possibly have to re-reference my report, if so additional costs will be involved.
- There are even duplicate photocopies of the discharge form on 20.12.08 with different reductions. One showing the Oxycodone crossed out, the other not.

30. There is the additional problem, which is the fault of no one involved in the case, that as part of her mental health issues which include her addiction to Oxycodone and her depressive illness, MT has accessed many different local services.

31. I have identified these as the [redacted] at their two surgeries. All these surgeries, I believe, have used [redacted] as their out of hours service so they have separate records and I now know that MT is now registered at the [redacted] where she has not yet seen a doctor, but they are currently providing prescriptions.

32. As well as being known under the name MT, she has used the names ML and HP, when claiming medication for the fictionary patient JP and GL. She has clearly been seen by many doctors in many practices including those listed above and also there has been considerable contact with a practice in the [redacted] area when she lived there.

[B L A N K]

MEDICAL RECORDS

33. Medical records have arrived in many different bundles, all unindexed, unpaginated and not super paginated.

34. All the documents are out of order, come from many different practices and to make even harder, some are reduced in size and illegible.

35. No matter where the records come from, I have tried to put them in date order to give an overview of the case and provide a time line.

36. To help me identify where the information comes from, I have notated 'H' for anything in the two inch pile from [redacted] NHS Trust.

37. 'GP 1' for the three inches of loose papers which forms the majority of the data from the General Practitioner and 'GP2' for the small bundle of additional material covering the time May 2003 to June 2005 and 'GP3' for the most recent up to date GP records which are expected.

38. The bundle of 'GP 3' has not arrived. **(I have now seen the latest GP notes 'GP 3' and they do not affect the report in any way.)**

39. There is also one inch of medical records from [redacted] Hospital which will be annotated by 'P'. I have not to date summarised these, as it was done by Dr N.

40. The medical records are summarised in the Timeline.

[B L A N K]

GENERAL PRACTITIONER RECORDS GP1

41. There are computerised records from a GP in the [redacted] area (near [redacted]) from 09.11.06 to 17.01.07.
42. There are also computerised notes from Dr R of the [redacted] Health Centre, February 2008 through to January 2009.
43. These notes appear to fit in to the time when she is not at the [redacted] Practice and surprisingly do not overlap in the Oxycodone prescribing.
44. Oxycodone is clearly prescribed between April 2008 and end of January 2009 in varying doses, starting at 40mg per day up to maximum of 240mg a day.
45. There are two inches of notes reduced to quarter to one sixth in size which are very hard to read and contain copies of some of the things I have previously read. I do not think they add to the case.
46. There is evidence that at the time of the pulmonary embolism there was some suggestion that she had thick blood.
47. They contain letters to and from GPs regarding the removal of MT's ovarian cyst, possible pulmonary embolism, her Warfarin and her seven admissions to hospital with chest pain, many of which she leaves with both OxyContin and OxyNorm and relate to the period 2003/2004.
48. There are many [redacted] telephone contact forms subsequent to her pulmonary embolism advising her to take Tramadol, diazepam and OxyContin. It is not obvious whether she was seen by doctors or not. These occur throughout 2005 and 2006 when Tramadol is also prescribed.
49. Many are difficult to read, there are similar [redacted] forms for 2004 and some occasions OxyContin is given and some prior to 2004 when paracetamol is prescribed, as is Cocodamol and ibuprofen. Prior to 2004 opioids are not prescribed by [redacted], although there are frequent calls.
50. There are GP Patient Records from a computerised system from Dr [redacted]'s practice with medical logs throughout 2006 during which OxyContin is prescribed, including a signed contract for daily dispensing for OxyContin.

51. In September 2006 there a signed contract between Dr N1 and MT for the reduction of OxyContin reducing by one tablet every week and then reducing on a less frequent basis. This stepwise reduction is also too large.

52. There is another batch of records from Dr [redacted] surgery from 22.06.05 to 19.03.08 doctor mentioning similar dependence on OxyContin.

53. There are various other GP records prior to 12.5.03 showing prescriptions for antidepressants and Cocodamol, but no stronger analgesia and hand written notes prior to 1996 which I believe are of no relevance to the case.

[B L A N K]

[redacted] SURGERY NOTES

54. It appears that MT has used the [redacted] Surgery on many occasions between June 2005 and September 2009.

55. The printout I am using is from the 1 September 2009 and I therefore need updated records from that date. **(I have now seen the latest GP notes and they do not affect the report in any way.)**

56. Within these computerised records it appears to summarise data from December 1993 through to June 2005 and I am not sure of the origin of this data. The notes comprise the computerised records and copies of correspondence to and from other healthcare agencies throughout this period.

57. There appears to be a gap sequentially in these notes from 1 July 2008 to 17 February 2009 when I presume she was with another practice. This covers the dates of the index events.

58. She appears to have left the practice at the time when she was initially cautioned in 2008 and re-registered in February 2009 after all the index events.

59. There is a note of prescriptions issued in the last year which shows prescriptions of OxyContin up to 28.01. 08 with no OxyContin prescribed after that date, only Tramadol in March 2009.

60. There are regular OxyContin prescriptions throughout 2007 up to a maximum of 40mg per day, during which time the dose of OxyContin was reduced but in a large step-wise fashion (**I would have expected to have seen a reduction of OxyContin in smaller steps**.)

61. These records identify in summary fashion:

- ENT admission in 2005.
- Overdose of drugs in 2005.
- Seven admissions for atypical chest pains in 2004.
- Left ovarian cystectomy and pulmonary embolism on 24.02.04.
- Total abdominal hysterectomy on 19.05.03.
- Laparotomy in 2002.
- Appendicectomy in 2001.

- Large loop excision of transformation zone (**this is due to abnormalities in her cervical smear).**
- Dyskaryosis on cervical smear.
- Chlamydia cervicitis.

[B L A N K]

TIMELINE

62. The following key denotes the source of entries:

H	[redacted] NHS Trust
GP1	General Practitioner
GP2	Additional material covering May 2003 to June 2005
GP3	Recent up to date GP records
P	[redacted] Hospital
H[redacted]	Medical records from [redacted] surgery
EVE	Evidence Against

63. The completed Timeline is attached. It comprises data obtained from all the above sources, as well as my comments on some of the statements, notes and evidence. It is the only place I review the evidence against, as this has to be seen in the context of the entire case. (Please see attached reference 1.)

[B L A N K]

CLINICAL PHARMACOLOGY OF OXYCODONE

64. Throughout this case we talk about two preparations of Oxycodone, namely OxyNorm and OxyContin.

[B L A N K]

OXYNORM

65. OxyNorm is the trade name of a preparation of Oxycodone, containing 5mg, 10mg or 20 mg of Oxycodone hydrochloride.

66. It's therapeutic indication is '*For the treatment of moderate to severe pain in patients with cancer and post-operative pain. For the treatment of severe pain requiring the use of a strong opioid.'*

[B L A N K]

SUMMARY OF PRODUCT CHARACTERISTICS FOR OXYNORM

67. The Summary of Product Characteristics (SPC) for OxyNorm is a legal document drafted by the product licence holder and approved by a regulatory body. In the UK, this would be the MHRA - the Medicines and Healthcare Products Regulatory Agency. (Please see attached reference 2.)

68. The Summary of Product Characteristics notes '*In common with other strong opioids, the need for continued treatment should be assessed at regular intervals'*.

69. The dose should be given 4 to 6 hourly '*the dosage is dependent on the severity of the pain the patient's previous history of analgesic requirements.*

Increasing severity of pain will require an increased dosage of OxyNorm capsules. The correct dosage for any individual patient is that which controls the pain and is well tolerated throughout the dosing period. Patients should be titrated to pain relief unless unmanageable adverse drug reactions prevent this.

The usual starting dose for opioid naive patients or patients presenting with severe pain uncontrolled by weaker opioids is 5 mg, 4-6 hourly. The dose should then be carefully titrated, as frequently as once a day if necessary, to achieve pain relief. The majority of patients will not require a daily dose greater than 400 mg. However, a few patients may require higher doses.'

70. There is a specific section regarding its use in non malignant (cancer) pain:

'*Use in non-malignant pain:*

Opioids are not first line therapy for chronic non-malignant pain, nor are they recommended as the only treatment. Types of chronic pain which have been shown to be alleviated by strong opioids include chronic osteoarthritic pain and intervertebral disc disease. The need for continued treatment in non-malignant pain should be assessed at regular intervals.

Cessation of Therapy:

When a patient no longer requires therapy with Oxycodone, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.'

In section 4.4 under 'Special Warnings and Precautions for Use' it states that 'for appropriate patients who suffer with chronic non-malignant pain, opioids should be used

as part of a comprehensive treatment programme involving other medications and treatment modalities. A crucial part of the assessment of a patient with chronic non-malignant pain is the patient's addiction and substance abuse history. There is potential for development of psychological dependence (addiction) to opioid analgesics, including Oxycodone. OxyNorm capsules, like all opioids, should be used with particular care in patients with a history of alcohol and drug abuse.

If opioid treatment is considered appropriate for the patient, then the main aim of treatment is not to minimise the dose of opioid but rather to achieve a dose which provides adequate pain relief with a minimum of side effects. There must be frequent contact between physician and patient so that dosage adjustments can be made. It is strongly recommended that the physician defines treatment outcomes in accordance with pain management guidelines. The physician and patient can then agree to discontinue treatment if these objectives are not met. .....Oxycodone has an abuse profile similar to other strong opioids. Oxycodone may be sought and abused by people with latent or manifest addiction disorders.'

71. The undesirable effects are noted to be:

Commonly: ≥1% (at a frequency of greater than or equal to 1%) and

Uncommonly: <1% (greater or equal to 0.1% up to 1%).

72. Psychiatric disorders are noted as follows:

Common	**Uncommon**
Anxiety	Affect lability
Confusional state	Agitation
Insomnia	Depression
Nervousness	Drug dependence
Thinking disturbances	Euphoria
Abnormal dreams	Hallucinations
	Disorientation
	Mood altered
	Restlessness
	Dysphoria

73. Nervous system disorders are common:

Common	**Uncommon**
Headache	Amnesia
Dizziness	Hypertonia
Sedation	Tremor
Somnolence	Hypoaesthesia
	Hypotonia
	Paraesthesia
	Speech disorder
	Convulsions
	Muscle contractions involuntary
	Taste perversion
	Syncope

74. Under '*General Disorders'* it notes that drug tolerance may develop.

75. The Summary of Product Characteristics particularly notes '*tolerance*' and '*dependence'* and '*The patient may develop tolerance to the drug with chronic use and require progressively higher doses to maintain pain control. Prolonged use of OxyNorm capsules may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation of therapy. When a patient no longer requires therapy with Oxycodone, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. The opioid abstinence or withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhoea, or increased blood pressure, respiratory rate or heart rate.'*

[B L A N K]

PHARMACOKINETICS

76. OxyNorm is a normal tablet formulation and the elimination half-life is approximately three hours.

[B L A N K]

PATIENT INFORMATION LEAFLET FOR OXYNORM

77. The Patient Information Leaflet is a regulatory approved document which is written by the product licence holder and approved by the competent regulatory authority in European states. (Please see attached reference 3.)

78. The Patient Information Leaflet states that one should only take the capsules if they have been prescribed for you.

79. This also says you should tell your doctor if you have an addiction to alcohol or drugs as well as or taking other strong analgesics or pain killers and also warns of:

- Confusion
- Nervousness and anxiety
- Hallucinations
- Disorientation
- Mood change
- Depression
- Feelings of restlessness
- Excitement
- Agitation
- Tolerance or dependence (reliance) on the medicine
- Loss of memory

[B L A N K]

SUMMARY OF PRODUCT CHARACTERISTICS FOR OXYCONTIN TABLETS

80. OxyContin is a prolonged release formulation of Oxycodone and available in tablets 5mg to 80mg. The tablets should be taken 12 hourly as a prolonged duration of action due to its formulation. (Please see attached reference 4.)

81. The Summary of Product Characteristics notes that '*OxyContin is not intended for use as a prn analgesic'.*

82. The dose, like the immediate release tablets, should be titrated to the patient's pain.

83. They have exactly the same warning for use in non malignant pain and cessation of therapy as the immediate release tablets and have similar special warnings and precautions for use.

84. They have exactly the same warning regarding abuse as the immediate release tablets. In particular it states '*OxyContin has an abuse profile similar to other strong opioids. Oxycodone may be sought and abused by people with latent or manifest addiction disorders'.*

85. In section 4.8 under '*Undesirable Effects'* the adverse drug reactions for both psychiatric and central nervous system reactions are the same as stated in the Summary of Product Characteristics for OxyNorm.

86. The Summary of Product Characteristics notes Oxycodone has an elimination half life of approximately 3 hours and that '*The release of Oxycodone from OxyContin tablets is biphasic with an initial relatively fast release providing an early onset of analgesia followed by a more controlled release which determines the 12 hour duration of action. The mean apparent elimination half-life of OxyContin is 4.5 hours which leads to steady-state being achieved in about one day.'*

87. Oxycodone is metabolised to noroxycodone and oxymorphone and although the latter has some analgesic actions, it is not thought to contribute to the effects.

[B L A N K]

OTHER FORMULATIONS OF OXYCODONE

88. Oxycodone is also available as a liquid at a concentration of 5 mg per ml and 10mg per ml. and the Summary of Product Characteristics is similar.

89. Addiction specialists use the titrate ability of the liquid to use slow increments to decrease the total dosage given to patients.

[B L A N K]

BRITISH NATIONAL FORMULARY (BNF)

90. The British National Formulary for Oxycodone notes that it is indicated for '*moderate to severe pain in patients with cancer, postoperative pain, severe pain'* and refers you to the generality of side effects for opioid analgesics.

91. It lists both OxyNorm and OxyContin as available formulations. In the introduction to section on opioid analgesics it states '*Opioid analgesics are usually used to relieve moderate to severe pain particularly of visceral origin. Repeated administration may cause dependence and tolerance, but this is no deterrent in the control of pain in terminal illness, for guidelines see Prescribing in Palliative Care. Regular use of a potent opioid may be appropriate for certain cases of chronic non-malignant pain; treatment should be supervised by a specialist and the patient should be assessed at regular intervals'*. **(Please note that the prescribing should have been under the supervision of a specialist which it was not.)**

92. It goes on to state *'Repeated use of opioid analgesics is associated with the development of psychological and physical dependence; although this is rarely a problem with therapeutic use, caution is advised if prescribing for patients with a history of drug dependence. Avoid abrupt withdrawal after long-term treatment*.'

93. The side effects are similar to the Summary of Product Characteristics for Oxycodone, but particularly notes the central nervous system side effects. For Oxycodone it states specifically '*it is used primarily for control of pain in palliative care'*.

94. Also in the opioid analgesic section it notes that the other preparations that MT had received, namely Tramadol, Transtec patches (Buprenorphine), Fentanyl and Dihydrocodeine may all cause dependence, addiction and withdrawal syndromes.

95. For sake of brevity I do not cover fully in this report any of these drugs but attach their Summary of Product Characteristics. Please see attached reference numbers 5, 6 and 7).

[B L A N K]

MARTINDALE

96. Martindale, is published by the British Pharmaceutical Society and is the standard text to which all doctors should refer. (please see attached reference numbers 8.)

97. Oxycodone is noted to cause both dependence and have a problem with its withdrawal and also has similar adverse effects to opioid analgesics in general.

98. It notes under '*Abuse'* that '*Oxycodone hydrochloride modified-release tablets have been subject to abuse. The crushed tablets have been inhaled or injected by addicts and in some cases this has resulted in fatalities'*.

99. Martindale notes in the introduction to analgesics, under choice of analgesics it states '*More potent opioids such as morphine are mainly used in the treatment of severe acute non-malignant pain and cancer pain. Their use in chronic non-malignant pain is somewhat controversial because of fears of psychological dependence and respiratory depression. However, in practice such problems rarely occur and those fears should not prevent patients being given effective analgesic therapy. Opioids may also be of value in neuropathic pain in some patients. .....Occasionally other opioids may be useful ..... alternative opioid may be effective in patients who have inadequate pain control or intolerable adverse effects with morphine ..... Methadone (which also acts as an NMDA antagonist) or Oxycodone have a longer duration of action than morphine .....'*

100. It also notes the abuse addiction and withdrawal potential of Tramadol, Transtec (Buprenorphine) and Dihydrocodeine.

101. Martindale states in relation to opioid dependence and withdrawal '*Repeated use of opioids is associated with the development of psychological and physical dependence. Although this is less of a problem with legitimate therapeutic use, dependence may develop rapidly when opioids are regularly abused for their euphoriant effects. Drug dependence of the opioid type is characterised by an overwhelming need to keep taking the drug (or one with similar properties), by a physical requirement for the drug in order to avoid withdrawal symptoms, and by a tendency to increase the dose owing to the development of tolerance.* (**I ask the court to note the use of the word 'overwhelming'.)**

Abrupt withdrawal of opioids from persons physically dependent on them precipitates a withdrawal syndrome, the severity of which depends on the individual, the drug used, the size and frequency of the dose, and the duration of drug use. Withdrawal symptoms may also follow the use of an opioid antagonist such as naloxone or a mixed agonist and antagonist such as pentazocine in opioid-dependent persons. Neonatal abstinence syndrome may occur in the offspring of opioid-dependent mothers and these infants can suffer withdrawal symptoms at birth.

Opioid analgesics can be classified according to the receptors at which they act and withdrawal syndromes are characteristic for a receptor type. Cross-tolerance and cross-dependence can be expected between opioids acting at the same receptors.

Dependence associated with morphine and closely related μ-agonists appears to result in more severe withdrawal symptoms than that associated with κ-receptor agonists.

Onset and duration of withdrawal symptoms also vary according to the duration of action of the specific drug. With morphine and diamorphine withdrawal symptoms usually begin within a few hours, reach a peak within 36 to 72 hours, and then gradually subside; they develop more slowly with methadone. Withdrawal symptoms include yawning, mydriasis, lachrymation, rhinorrhoea, sneezing, muscle tremor, weakness, sweating, anxiety, irritability, disturbed sleep or insomnia, restlessness, anorexia, nausea, vomiting, loss of weight, diarrhoea, dehydration, leucocytosis, bone pain, abdominal and muscle cramps, gooseflesh, vasomotor disturbances, and increases in heart rate, respiratory rate, blood pressure, and temperature. Some physiological values may not return to normal for several months after the acute withdrawal syndrome.

Withdrawal symptoms may be terminated by a suitable dose of the original or a related opioid. Tolerance diminishes rapidly after withdrawal so that a previously tolerated dose may prove fatal.'

[B L A N K]

MHRA

102. In the UK, the medicines and Healthcare products Regulatory Agency (MHRA) has received the following reports for Oxycodone for the period 01/07/63 to 04/01/10 (earliest reaction date – 08/07/64):

- Nervous system disorders 114
- Psychiatric disorders 126

Out of a total of 686

Under General disorders:

- Drug withdrawal syndrome 11

Under Psychiatric Disorders:

- Confusion 22
- Drug abuse 1
- Agitation 14
- Akathisia 1
- Dyskinesis 4

Under Substance related disorders:

- Drug dependence 7
- Intentional drugs misuse 1

(Please see attached reference 9.)

103. I have been in contact with the MHRA who are to send me, under freedom of information, more information on the cases reported above.

[B L A N K]

REPORT OF DR N

104. This report details her psychiatric problems, as well as the fact that when reducing doses of Oxycodone, she suffered from agitation, could not sleep, had stomach cramps, sickness and diarrhoea, as well as no motivation. She felt as if he had flu-like symptoms, sweating with a runny nose and shivering.

105. He notes that she states she was '*not in her right state of mind when she did it* (**the alleged offences**) *and was preoccupied with overcoming her distressing withdrawal symptoms'.*

106. Dr N reviews her psychiatric notes. His report is a matter of record and concludes '*in my opinion it is likely that Ms T did not have the capacity to think clearly about the consequences of her actions at the material times as she was more concerned about the immediate relief of her symptoms'*.

107. Dr N further notes that at the time of the offences '*it could be argued that she was under a defect of reason arising from a disease of mind (opiate withdrawal syndrome)'.*

108. In his Addendum Report he notes that a custodial sentence is likely to have an adverse impact on her mental health and that she needs care and treatment in a community setting.

109. Both his reports are a matter of record.

[B L A N K]

STATEMENT OF DEFENDANT, MT

110. I have read the 3½ pages of the statement of MT which is undated and unsigned and I understand that privilege will not be claimed on this.
111. This statement is short and concise enough not to be précised by me and is a matter of record.
112. It in general tells the story of someone whom, as we know, was prescribed Oxycodone in hospital, became addicted to it, continued to receive it on prescription from GPs, the hospital and [redacted] and who then become dependent on it, has withdrawal problems and abuses the substance. MT admits the charges as to matter of fact.
113. It states on page 2, paragraph 1, that she suffered with manic depression, although she clearly has dual diagnosis of opioid dependence, withdrawal, and abuse, as well as a recurrent depressive illness which is sometimes accompanied by deluded thoughts. (**I have read no evidence that she in fact has manic depression**.)
114. She tells how she tried to come off the tablets with help, however, no specialised medical help was available. (**From her notes we know that the addiction unit at the [redacted] Hospital turned down her doctor's requests.**)
115. She notes '*the effect of the medication upon me was not just physical, but it also blotted out my feeling of depression. The drug would make me feel numb physically and emotionally'*.
116. She says that she used the drug as it '*made me numb emotionally and meant that I no longer felt suicidal'.*
117. She states she *'begged the doctors to provide her with counselling'*.
118. She states that in the end she decided to come off the drug herself and began this process in January 2009.
119. She notes that she rang '*50 organisations to try to get some help'*.
120. She notes that the reducing dose from her doctors was not enough for her needs.
121. She continues '*I was worried about the symptoms of withdrawal which were horrific. When I detoxified myself I spent two months in bed'*.

122. She notes that during her admission to hospital for her hysterectomy that the hospital over prescribed the drug to her. (**We do not have these hospital admission records**.)

123. She states '*I was not worried about the possibility I would become addicted to the drug.'* (**We don't know what happened in hospital. We know from the hospital records that she was discharged from hospital after the hysterectomy without analgesia and it was during her admission for ovarian cystectomy with the subsequent pulmonary embolism that she first received OxyContin and was possibly discharged with it. She certainly received it as an outpatient in the weeks after discharge**.)

[B L A N K]

INTERVIEW WITH MT

124. I saw MT on 11 February 2010 at 12.30, in [redacted] in the presence of her partner, and a paralegal.
125. The interview lasted approximately two hours and was carried out in the relaxed atmosphere of her own lounge.
126. I gave her the usual warnings as detailed previously. I did not conduct a full psychiatric interview as this had been done by a Consultant Psychiatrist previously and I did not review all her records of the whole story with her as this would have taken far too long.
127. I used the opportunity to hear important aspects of her history in her own words.
128. She notes that while in hospital for both her hysterectomy and her removal of ovarian cyst, she was very ill. She tended to confuse the two admissions and we do not have the original records so we do not know the truth of the matter, however, from everything that has been read the difficulty with OxyContin occurred after the admission for ovarian cystectomy and pulmonary embolism.
129. She notes that during this admission she was very ill in hospital and was given OxyContin in increasing amounts. She does not remember being told that they were addictive.
130. She was in and out of hospital for about a year and on each admission would receive OxyContin. (**Records substantiate she was in hospital on about seven occasions**.)
131. During this time she says she was '*not really well'* and did '*not have a clear mind'*. Her partner interrupted '*she was like a zombie'*.
132. She believed that she received OxyContin when she left hospital after the pulmonary embolism. The records show that although this was a take home medication, it was crossed out.
133. MT did not remember and was very confused as to whether, when she left hospital after her cholecystostomy, she left with Oxycodone and stated she was *'very confused and it was hard to remember'*. (**As we know the discharge summary is very confusing.**)

134. She stated that she has never previously been an addictive personality, although had used and experimented with LSD and amphetamines during her early years. (**This is confirmed by the notes.**)
135. She states that she last had OxyContin on 13 January 2009 and came off this herself. '*I cold turkeyed for three months'* staying in bed with sickness, diarrhoea, body cramps and other symptoms.
136. She states that she tried to get a withdrawal on the NHS, rang at least 50 organisations but could not get help. (**Other than the refusal of the [redacted] Hospital to help withdrawal, we do not know the truth of this and I have asked solicitors if they can get further evidence.)**
137. She states if she gets pain now she takes '*just paracetamol or ibuprofen'*. She still takes antidepressants for her depression.
138. MT was keen to reaffirm that during her withdrawal she had panic attacks, anxiety and flu-like symptoms and since then has found it hard to leave the house.
139. On close questioning, she confirms she had used Tramadol occasionally when prescribed since January, although is not now actively seeking it.
140. She says she made up the name Mr P to try to obtain the Oxycodone and confirmed that no one from [redacted] had ever visited her to confirm his existence prior to prescribing Oxycodone.
141. She said she did it because she was desperate and very frightened of '*going cold turkey'*.
142. She thought that the doctors had reduced her drug intake in too greater steps which did not enable her to cope and precipitated withdrawal fears and withdrawal syndromes.
143. She denied ever having had letters from the Addiction Clinic which had been for an appointment requested by Dr [redacted].
144. She clarified to me that the practices she had been at were the [redacted] Partnership, the [redacted] Clinic with [redacted], and the [redacted] Partnership at both their surgeries [redacted] and [redacted].
145. She confirmed that at times she had been to all three at the same time and may have been registered with more than one at once.

146. She says the names HP and GL had all been made up and she had occasionally used her single name of ML.
147. When specifically questioned she did not mention the practice in [redacted] where we know she was registered for some time.
148. She was currently taking Escitalopram for her depression and Quitiapine for her psychotic thoughts and was currently seeing a clinical psychiatric nurse on a regular basis since her admission to [redacted].
149. She told me she was going to try to commit suicide in the morning, but her partner had talked her out of it. I recommended that the partner call her CPN or her key worker.
150. When asked to more fully describe how she felt when she was actively taking Oxycodone and during the time the dosage was being reduced by doctors she said that she was '*anxious, desperate and at her wits end'*. This particularly happened if she was getting low on tablets and she was not sure if she would get more. She was terrified of the thought of being without them. She would go cold and sweat and become very agitated during this time, become emotionally labile and very cross with her partner.
151. She could not stay in bed at all and in fact never went to bed, sleeping in the chair downstairs and pacing around the room.
152. She commented I got '*very restless legs'*. Her partner further commented '*it always looked like she was in body shock. Her legs kept moving and I had to lean on them to stop them.'*
153. When she was acutely withdrawing herself from them, she told me that she stayed in bed most of the time as she had no strength. It felt as if she had been '*hit on the head with an axe and had flu*'. She was '*very anxious, agitated and felt soul destroying and at her wits ends.'*
154. She had '*cramps, sickness and diarrhoea with cold sweats and could not eat and suffered weight loss'*. She also experienced nightmares.
155. When asked why she was fraudulent she said *'I didn't know what I was doing. I was desperate to pull something in'* (**meaning the Oxycodone**).
156. She told me that currently [redacted] Surgery would not see her as she was out of the area and that her psychiatrist had found her a new GP.

FORMAL DEPENDENCY DIAGNOSIS

157. DSM-IV is the diagnostic criteria of mental health illnesses published by the American Psychiatric Association and has worldwide recognition as a integrated listing of those conditions relating to mental health which may be diagnosed by clinicians as a recognisable entity and lists diagnostic criteria. It does have a cautionary note that inclusion in the criteria '*does not imply that the condition meets legal or other non-medical criteria for what constitutes mental disease, mental disorder or mental disability.'*

158. However, in practice it does indicate that psychiatrists consider those conditions listed as deviating from the normal psychological state and that patients who meet the diagnostic criteria would usefully be treated by psychiatrists and clinicians for their mental state.

159. The substance related disorders are divided into two groups; the substance use disorders namely substance dependence and substance abuse, and the substance induced disorders such as intoxication and withdrawal, as well as dementia, amnesia psychosis, mood disorders and anxiety disorders

160. Opioids are clearly indicated as being associated with dependence, abuse and withdrawal: (**MT clearly has all of these, except intoxication**).

'Table 1. Diagnoses associated with class of substances

	Dependence	***Abuse***	***Intoxication***	***Withdrawal***
Opioids	*X*	*X*	*X*	*X*

Note: X indicates that the category is recognised in DSM-IV.'

161. Criteria for substance dependence is defined:

'A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

(1) Tolerance, as defined by either of the following:

(a) A need for markedly increased amounts of the substance to achieve intoxication or desired effect

(b) Markedly diminished effect with continued use of the same amount of the substance

(2) Withdrawal, as manifested by either of the following:

(a) The characteristic withdrawal syndrome for the substance (refer to Criteria A and B of the criteria sets for Withdrawal from the specific substances).

(b) The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms

(3) The substance is often taken in larger amounts or over a longer period than was intended

(4) There is a persistent desire or unsuccessful efforts to cut down or control substance use

(5) A great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain-smoking), or recover from its efforts

(6) Important social, occupational, or recreational activities are given up or reduced because of substance use

(7) The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption).

Specify if:

With physiological dependence: evidence of tolerance or withdrawal (i.e. either Item 1 or 2 is present)

Without physiological dependence: no evidence of tolerance or withdrawal (i.e. neither Item 1 nor 2 is present)'

162. Criteria for substance withdrawal is defined as:

a) 'The development of a substance-specific syndrome due to the cessation of (or reduction in) substance use that has been heavy and prolonged.

b) The substance-specific syndrome causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

c) The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.'

163. Opioid withdrawal is specifically listed

a) 'Either of the following:

1) Cessation of (or reduction in) opioid use that has been heavy and prolonged (several weeks or longer)

2) Administration of an opioid antagonist after a period of opioid use

b) Three (or more) of the following, developing within minutes to several days after Criterion A:

(1) dysphoric mood

(2) nausea or vomiting

(3) muscle aches

(4) lacrimation or rhinorrhea

(5) pupillary dilation, piloerection, or sweating

(6) diarrhoea

(7) yawning

(8) fever

(9) insomnia

c) The symptoms in Criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

d) The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.'

164. Another diagnostic criteria published by the World Health Organisation is called The ICD-10 Classification of Mental and Behavioural Disorders, and this lists, in sections F10 to F19 disorders due to psychoactive substance use. The diagnostic criteria F11 being mental and behavioural disorders due to use of opioids. This also has criteria for a dependence syndrome and a withdrawal state.

165. Specifically the dependence syndrome clearly states that '*a cluster physiological, and cognitive phenomena in which the use of a substance or a class of substances takes on a much higher priority for a given individual than other behaviours that once had greater value. A central descriptive characteristic of the dependence syndrome is the desire (often strong, sometimes overpowering) to take psychoactive drugs (which may or may not have been medically prescribed), alcohol, or tobacco. There may be evidence that return to substance use after a period of abstinence leads to a more rapid reappearance of other features of the syndrome than occurs with nondependent individuals'.*

166. I ask the court to note that the characteristic may be often strong and sometimes overpowering. The diagnostic guidelines are similar to those for the DSM-IV. (please see attached reference 10.)

167. The withdrawal state is similarly attached. (Please see attached reference 11.)

168. What is absolutely clear is that MT fits into well accepted diagnostic criteria where the desire may sometimes be overpowering due to dependence or due to a withdrawal state where the feature of anxiety may be so great as to render the person incapable of rational thought and thus the ability to form intent. The most severe state is called akathesis which is psychomotor restlessness. Opioid withdrawal may last six months or longer.

169. The diagnostic criteria may be described as '*The disorder consists of severe muscle cramps and bone aches, profuse diarrhoea, abdominal cramps, rhinorrhea, lacrimation, piloerection or gooseflesh (from which comes the term 'cold turkey' for the abstinence syndrome), yawning, fever, papillary dilation, hypertension, tachycardia, and temperature dysregulation including hypothermia and hyperthermia. A person with opioid dependence seldom dies from opioid withdrawal, unless the person has a severe pre-existing physical illness such as cardiac disease. Residual symptoms – such as insomnia, bradycardia, temperature dysregulation, and a craving for opiates or opioids – may persist for months after withdrawal. At any time during the abstinence syndrome a single injection of morphine or heroin eliminates all the symptoms. Association features of opioid withdrawal include restlessness, irritability, depression, tremor, weakness, nausea and vomiting.'* (Please see attached reference 12.)

AKATHISIA

170. Akathisia is a recognised description of a mental state in which there is '*subjective complaints of restlessness with..... rocking from foot to foot or "walking on the spot" while standing, pacing to relieve the restlessness, or an inability to sit or stand still for at least several minutes. In its most severe form, the individual may be unable to maintain any position for more than a few seconds. The subjective complaints include a sense of inner restlessness, most often in the legs; but also mental inner restlessness and a compulsion to move one's legs; ..... Akathisia is associated with substance withdrawal and may be associated with dysphoria, irritability, aggression, or suicide attempts'*.

171. It is acknowledged that the symptoms may be due to substance withdrawal. The subjective distress is significant and may be associated with irritability, aggression and suicidal attempts.

172. It is also noted often as psychomotor agitation where there is excessive motor and cognitive over activity which is non-productive and in response to inattention it may be associated with dysmorphia which is an almost indescribable feeling of terror and doom. It is very difficult for patients to describe. Often it is noted by many that it may sometimes precipitate patients to act out in violent fits of rage and may harm themselves or others. It has been used as a defence often successful in patients whom have recently been prescribed serotonin reuptake inhibitors and act out of character.

173. Akathisia may be so severe that it may be mistaken for psychotic agitation.

174. It is a side effect of selective serration reuptake inhibitors such as Fluoxetine (Prozac).

175. It would not be unreasonable to presume patients with akathisia, due to opioid withdrawal, would not be in control of their thoughts, emotions or actions.

[B L A N K]

PRESCRIBING GUIDELINES FOR OPIOIDS AND PERSISTENT NON-CANCER PAIN

176. This is such a contentious issue that in both the UK and America there are extensive guidelines.

177. The balance for giving sufficient analgesia and the risk of dependence, abuse and withdrawal are so great that many bodies are so concerned, considerable effort is put into trying to guide clinicians.

178. In the UK the most appropriate guidelines are published as consensus statements by The Pain Society, The Royal College of Anaesthetists (**as anaesthetists usually run pain clinics**), The Royal College of General Practitioners and The Royal College of Psychiatrists.

179. The applicable guidelines at the time of the offences were published in March 2004, although they have been recently updated in January 2010.

180. To show the court the scope of the problem, the guidelines of March 2004 are attached. (Please see attached reference 13.)

181. In Section 1.10 of the Executive Summary, it states that '*Patients who are prescribed opioids for persistent non-cancer pain should be assessed regularly at intervals determined by clinical need. Initially it is expected that this assessment would be at least monthly. The assessment should include documented evaluation of: pain relief, physical, psychological and social function, sleep, side effects and signs of problem drug use (see sections 6 and 9). It is important to regularly discuss any concerns that patients have about their opioid use. Evidence of developing tolerance should prompt referral to a multidisciplinary pain management service or specialised addiction service. Evidence of problem drug use should initiate prompt consultation with and/or referral to a specialised addiction service.'* (**It would be my assertion that this was not fully practised in this case**.)

182. Although the diagnostic criteria DSM-IV and ICD-10 no longer use the word 'addiction', these guidelines do and say that '*addiction consists of the compulsive use of opioids to the detriment of the user's physical and/or psychological health and/or social function. Signs of compulsive use include preoccupation with obtaining and taking opioids, apparently impaired control over their use, and reports of craving. These signs of*

compulsive use are well established where opioids are taken not primarily for pain relief but for effects on mood and thinking. The use of opioids prescribed for pain relief probably only rarely results in addiction, although the exact risk is not known. Addiction can only be determined by observing these behaviours over time, not on a single event. Regular and frequent use and/or a high dose do not alone constitute addiction, although they do constitute a criterion for addiction in some diagnostic schedules that explicitly do not apply to the use of prescribed opioids for pain relief. What is more important is that the fear of addiction can lead to restrictions on prescribing or on taking opioids which thereby restrict pain relief. The term pseudoaddiction has been coined to describe behaviours such as drug hoarding, attempts to obtain extra supplies, and requests for early prescription or increased dose which may be mistaken as signs of addiction but are an attempt to obtain better pain relief. When pain is relieved these behaviours cease.' (**I ask the court to note the use of the word 'compulsive'**.)

183. In Section 7, on patient selection, it notes that '*opioids will only be considered after the use of other established therapies'* (**in this case once she is discharged from hospital receiving Oxycodone in 2004, the prescribing continues**).

184. The section also notes '*all patients should undergo a physical, psychological and social assessment before commencing opioids'* and this clearly did not happen. It particularly notes '*patients with persistent non-cancer pain may present with acute exacerbation of pain. Thorough assessment should take before long-term opioids are started in* response to this.' (**This does not appear to have happened**).

185. It continues '*Acute pain teams or other hospital services should not start long-term strong opioids without support from a multidisciplinary pain management service and liaison with the patient's primary care team. They must ensure that arrangements are in place to provide long-term supervision for the patient after discharge from hospital'.* (**Again I am not sure this appears to have happened, neither was to my mind the practical aspects of prescribing stated in section 8**.)

186. Section 9 is entitled '*Identification and Management of Problems'*. MT presents as a particularly difficult patient. In these terms she does have at least three conditions over the course of her care, necessitating strong analgesia the initial pulmonary

embolism, the gall stones, the cholecystitis and the ovarian cystectomy, notwithstanding the frequent attendances with chest pain after her pulmonary embolism, which in the end was clearly thought to be due to a non-serious pain such as the costoconderal syndrome which is pain at the junction of the bone and cartilage at the front of the rib cage.

187. Despite this clear diagnosis, Oxycodone continues to be prescribed by hospitals, so for completeness new 2010 guidelines are attached. (Please see attached reference 14.)

188. It should be noted that many of the other drugs prescribed for MT, namely Buprenorphine and Tramadol to name but two, are categorised as strong opioids.

[B L A N K]

ADVICE TO GENERAL PRACTITIONERS

189. Not only do many learned societies contribute to the Pain Management Guidelines previously reviewed, but some produce their own advice to General Practitioners. *'InnovAiT is a journal for Associates in Training (AiTs) of the Royal College of General Practitioners that promoted excellence in primary care and quality education. Rotating through the whole new curriculum for the nMRCGP on a three year cycle, InnovAiT supports and assists the learning and development of AiTs as they progress through training'*.

190. This, in 2008, published an article by Bollan and Simon entitled '*Controlled Drugs: Regulations and Prescribing as a Guide'* for GPs.

191. This notes under '*prescribing for medicinal purposes that 'prescribers have a duty to prescribe responsibly to prevent patients receiving legitimate prescriptions from developing dependency to their prescribed drugs. They also have a duty to prevent patients who abuse drugs from obtaining those drugs on prescription by deception*.' ([redacted] **clearly fell far short of these guidelines**.)

192. It has a specific section on temporary residents as new patients '*drug misusers may obtain supplies of drugs on prescription by visiting more than one doctor under several names, fabricating stories and forging prescriptions. To avoid being an unwitting source for addicts, be suspicious if a temporary resident or new patient requests a prescription for any controlled drug. If you decide to prescribe, only provide a small amount of the drug unless the patient can provide evidence that they have an ongoing condition requiring treatment with that drug. Where possible, check the patient's story out with their usual or previous GP before prescribing. If you suspect a drug misuser is going around surgeries with intent to obtain supplies, contact your PCT so that they can issue a warning to other practices'.* (**Which [redacted] and other GPs ought to have noted and taken account of.**)

193. Once the doctors had noted MT' addiction, it could be argued that they should have prescribed no more as the only remit of non registered doctors is to treat organic pain which by this time everybody was aware she did not have.

194. The BNF clearly advised GP only to prescribe it under the care and advise of the specialist.

THE LITERATURE, OXYCODONE ADDICTION, OPIOIDS AND NON-CANCER PAIN

195. There are many papers published on individual legal cases and the prescribing of Oxycodone by doctors leading to addiction and the use of OxyContin as a drug of addiction. Most of these come from the US and I attach a bibliography of some possible useful papers, all of which are available on request. (Please see attached reference 15.)
196. Of particular note is how patients abuse OxyContin. 78% of subjects report that they have not been prescribed it in the US and this is clearly not the case in the UK where controls are much better.
197. In the US where it is often known as *'hillbilly heroin',* there are far more problems of it as a true drug of abuse, whereas in the UK, according to the manufacturers and Drugscope, there is little evidence of such abuse in this country.
198. In particular it is not mentioned in the UK national statistics, nor does the British crime survey measure prevalence and it is not featured in Drugscope's street surveys of abused drugs, although it is in the US.
199. The American guidelines are far more practically oriented, but not reviewed in depth as you would not expect a UK physician to be aware of them. In particular they recommend the use of instruments prior to prescription of opioids and also contain sample agreements prior to prescription
200. There is considerable move in the US for the drug only to be prescribed by specialists, as does the BNF.

[B L A N K]

TREATMENT OF OPIOID DEPENDENCE

201. It is clear that MT has not engaged with drug addiction or specialist pain units or consultants, which is possibly the reason she has not been offered planned withdrawal and detoxification, which may be effected slowly or rapidly. It is not clear as to whether specific Oxycodone withdrawal services are available in her locality or who would be responsible for its safe withdrawal.

202. There are many methods available, one is to replace the drug of dependence with methadone and then slowly withdraw this, or there may be inpatient acute withdrawal in a specialised unit. The liquid may be used to reduce the Oxycodone intake by increments as small as 1mg a week. Withdrawal should include complete physiological support and is best accomplished in conjunction with patients attending appropriate 12-step fellowships.

203. Although it is clear that people have tried to get MT to attend Chronic Pain Clinics, I have not seen a body of evidence which suggest she has been referred to or treated specifically for her addiction.

204. If MT had been street heroin user she would have easily found her way to a clinic that would legally prescribe methadone for her or even now participated in the heroin addiction study where intravenous heroin is prescribed, which has been shown to reduce all the crimes associated with heroin addiction.

205. These services do not appear to have been available to her for Oxycodone addiction.

[B L A N K]

OPINION

206. This is one of the most difficult cases I have ever had to write in view of the complexity of the notes I have had to read, the way they have been presented to me as mentioned before and the propensity of MT to change her name, address and phone number, register with at least four practices and continually use [redacted].

207. In particular, MT told me when I saw her that other than the four surgeries mentioned and the doctors locally, she had not used other doctors, however, she also told me she had not used other names and she told me she had not shopped on the internet.

208. In reviewing all the medical records, and I believe I have read almost every page sent, I have found, perhaps not surprisingly, references to additional surgeries such as the one in [redacted], references to her telling doctors she shopped on the internet.

209. She also says that she is completely off Oxycodone and is now off painkillers. However, as those who read my summary will note, there appears to be some suggestion that she has subsequent to Oxycodone, been hunting Tramadol.

210. Notwithstanding MT's behaviour mode, which in my belief is all part of her mental health status and illness, including depression and addiction, as well as dependence, abuse and withdrawal, it does appear that despite the best intentions, doctors have colluded in her addictions both in hospital and in general practice, as it is my belief that all these doctors have acted in her best interest, although possibly misguidedly, I have not mentioned any specifically by name as being remiss.

211. What is however astonishing is the behaviour of [redacted], whom as well as continuing to issue painkillers to MT, possibly in part due to her changing persona, but not entirely, allowed over the course of time, particularly the time period related to her charges, to allow a phone call which was extensively about a fictitious patient with cancer in the name of Mr [redacted], issue prescriptions for a Schedule II drug without not only seeing the patient, but not even interviewing firsthand the caller.

212. It is beyond belief that when a drug is listed as Schedule II for good reason, it is well known to produce addictions and for patients to actively hunt the medicine, that they did do this.

213. This has to be, at best, not in compliance with good medical practice, and at worst, may be seen by many to be clinically negligent.

214. The medical notes I have read stretching back over a long period of time do not show MT as having an addictive personality per se. Despite the fact that her mother was known to be an alcoholic, MT's use of alcohol and illegal drugs was in no way evidenced through any of the substantial records I have seen until her admission to hospital for her ovarian cystectomy and her subsequent pulmonary embolism.

215. We are lucky enough to have many assessments of her before this time which clearly shows that for a very short period she experiments with two illegal drugs, namely LSD and amphetamines, but it is not clearly a consistent pattern in either her drug history or in her usage of medical services.

216. Her use of alcohol is always recorded as limited all the way through her medical records.

217. One of the things that is not helpful is the absence of medical records relating to the period of late 2003 and 2004 of her inpatient admissions, when it appears Oxycodone was used and was given as discharge medication to be continued by the GP. This is formally stated on her discharge summaries and discharge letters.

218. From this stage it appears she is both physically dependant and psychologically dependant, is subject to withdrawal reactions both physical and mental. The descriptions that are read in the notes are suggestive of the typical physical reactions with agitation, and the much fuller description that she gave to me unprompted when I interviewed her showed decisive and definite withdrawal during the time when her drug dosage was going up and down and she was restricted and at the time when she allegedly cold-turkeyed in February and she describes a desperate physical and mental state.

219. The description from her partner and her own when taken together, would be diagnostic of the mental and physical condition known as akathisia in which psychomotor restlessness and agitation are present at which time it is generally accepted that the patient's drives are not under their conscious control and there have been many cases

of criminal and even homicidal behaviour during this state which have resulted in mitigating circumstance at worst and acquittal at best.

220. During the state of akathisia the mind is in such a state that it is driven beyond anyone's ability to control it and the only thought on her mind, as she described, was to do anything to get medication. The state should not be minimised in any way. It should also be noted as previously highlighted in the report that various authorities describe the dependence as compulsive and overwhelming.

221. In terms of her treatment by her doctors, the main GP appears to be caring and concerned of her state and I will particularly mention Dr [redacted] at the [redacted] Surgery and Dr R at the [redacted] Surgery. However despite their caring and professional manner at all times, including their concerns for her health wise and indeed personally, they both appear to be as one would expect out of their depth in knowing what exactly to do. Additionally, other doctors change her from Oxycodone to various patches which are not entirely effective at facilitating dependence and do not prevent withdrawal.

222. They have tended to issue warnings, but then relent and re-prescribe or increase the dose, tell her they will never give her more medication and then do, and move the dose of Oxycodone prescribed up and down, certainly not at a whim or in a random fashion, but in response to what they are being told.

223. When it is decided to reduce her medication and they issue daily or weekly scripts, it would be my concern that the stepwise reductions are in too great an interval and appear, as expected to precipitate withdrawal reactions and cravings and they both realise that they are in some difficulty and both refer MT to Community Drug Services.

224. We are told by MT and her partner that the NHS services were not interested in helping her withdraw and that they approached 50 different service providers and help centres for help. (**I do not know the truth of this, although they say that they never received the appointment set up by Dr [redacted] and I am not sure that there is evidence that there was any follow-up after Dr R's referral.**)

225. When MT was referred to the Drug Services at the [redacted] Hospital they refused to treat her as they are not funded for therapeutic addicts and they recommend a much slower reduction in opioid use than any of her GPs ever attempted. Their

recommendations are a slow linear reduction and nowhere near as drastic as had been tried.

226. The scope of the problem of Oxycodone as a prescribed drug of abuse is much greater in the US than in the UK and in particular is precipitated by the different healthcare systems.

227. Oxycodone has not yet reached the level of common street drug in the UK and indeed it has not reached the radar of Drugscope who do an annual survey of street drugs. Despite this difference, I would have expected any competent GP to be aware of the joint guidelines of the dangers of prescription use of Oxycodone which are clearly delineated in the Multipartite Guidelines issued by the British Pain Society.

228. The 2004 guidelines were current over the period of concern and the 2010 Guidelines have just come out.

229. Additionally, Napp Pharmaceutical who manufacture the various preparations of Oxycodone, are very concerned about the issue and actively partake in the communication of the message of safe use and the dangers associated with their drug.

230. The warnings in the Summary of Product Characteristics are clearly appropriate and an aide to good prescribing and indeed if different Oxycodone is used according to the Summary of Product Characteristics as written by Napp and approved by the MHRA and doctors follow the Multipartite Guidelines, Oxycodone may be used safely and effectively and be a benefit to a number of people.

231. Not all doctors who have seen MT have prescribed in a way that they are aware of the Summary of Product Characteristics and the Guidelines, although I am sure that they found MT to be a difficult patient to treat and she certainly did not help herself by her behaviours and her frequent aliases and her non attendance at clinics

232. Certainly in mitigation, possibly in defence, MT suffers from an iatrogenic (**doctor induced**) addiction and was prescribed it frequently by hospitals, regular GPs, A & E Departments, locum GPs and [redacted], all of whom probably tried to act in what they saw as the patient's best interests, but clearly collectively fell below the standard one would hope for.

233. The alarm bell went off for many doctors who made intrinsic notes of the dangers and possible addictions, although these never seem to be coordinated or followed up entirely, even in the same practice or the same health institute.

234. This case of Oxycodone addiction does not follow the typical pattern and criteria and although fraud has been committed and aliases used, and Mr [redacted] invented, I would contend that during the time the offences were happening, there was an acute exacerbation of the chronic problem in that she was prescribed it while in hospital for her cholecystitis and probably even left hospital with the medicine, although due to the quality of the notes there would be some doubt about this. It certainly is written up and not crossed out as a take home medication. In support of the fact that it may not have been dispensed to her is the enhanced seeking ability at the time of discharge which would be completely understandable if she was sent home only on Fentanyl patches and without Oxycodone. This would have been far too rapid a reduction.

235. The difficulty of prescribing adequate analgesia to known addicts is very difficult in view of her gall stones and her probable cholecystitis she would have needed strong opioid analgesia, but this would have been fraught with difficulty.

236. It continued to be prescribed in hospital as well as probably taken away, despite at least three doctors noting that this should not happen.

237. All MT's medication appears to have been prescribed although there is one reference to her buying some on the internet.

238. It does not appear that altering doctor's prescriptions played any part in her fraud, although there is one reference to this in one place. She has told people she has rheumatoid arthritis when no obvious opinion exists that she does.

239. There certainly appears to be no diversion to friends, family or the illegal market, and there was no systematic, consistent or planned doctor shopping in an organised way.

240. All the prescriptions appear to have originated form practitioners local to [redacted] and [redacted] apart from one reference to [redacted]. She certainly was not travelling around England in a planned collection.

241. Thus in her favour, is the iatrogenic nature of the addition, the repeated prescription by hospitals, A & E departments and GPs even after the addiction was known, the non-

following by most GPs of the Napp Summary of Product Characteristics for the various preparations, the lack of documented knowledge, if indeed there was knowledge of the Multipartite Guidelines for opioids in non cancer pain and the lack of written fraud and lack of diversion. The GP and [redacted] prescribing was not in line with current teaching of The Royal College of General Practitioners.

242. The most complete medical defence to the charges would be the akathisic state that she undoubtedly got into when well-meaning doctors reduced the dose in too big a step. The court should again note the many authorities who describe the dependence and need for drugs, as compulsive and overwhelming.

243. Of most concern is the prescription by [redacted] of a Schedule II opioid analgesic to patients who were never visited at all.

244. Oxycodone is in UK law defined as a Class A drug and a Schedule II drug and as such is subject to the full controlled drug requirement regarding prescriptions of custody and the need to keep records.

245. It is in my opinion that the combination of the overpowering drive of her addiction and the withdrawal state of akathisia would allow for MT to be thought of as having an abnormality of mind which would substantially impair her mental responsibility for acts and omissions (**as may be a defence in the Homicide Act**) and that similarly the state of mind would have been induced by a disease, namely her opioid dependence and her injury which would be her opioid withdrawal.

246. The judicial view of a disease of the mind could be used in defence or mitigation. It is my understanding that the defence has to show that such a disease would have occurred on the balance of probabilities and indeed in this case I am sure this is the situation.

247. The definition of abnormality of mind given in Regina v Byrne, 1960, '*.....means a state of mind so different from that or ordinary human beings that the reasonable man would term it abnormal. It appears to us to be wide enough to cover the mind's activities in all its aspects, not only the perception of physical acts and matters, and the ability to form a rational judgement whether an act is right of wrong, but also the ability to exercise will power to control physical acts in accordance with that rational*

judgement. The expression 'mental responsibility for his acts', points to a consideration of the extent to which the accused's mind is answerable for his physical acts, which must include a consideration of the extent of his ability to exercise will power to control his physical acts'. Again I think MT, due to her akathisia, her dependence, and her withdrawal symptoms would meet this.

248. There is also often in judicial reviews mention of the fact that the condition is a lesser defence if it is self-induced. It is clear to me that MT's addiction is not self-induced and is clearly a result of prescribing, intermittent dosage alterations, inappropriate prescribing by doctors. She clearly did not have an addictive personality, nor were there any signs of addiction prior to her hospitalised prescriptions.

249. It is also clear that guidelines were not followed regarding her opioid prescriptions and that her withdrawal symptoms were not voluntarily induced, but were due to acute reductions in the prescriptions.

250. I would have thought that MT' mind was outside of her conscious control as does Dr N. She would not have been in any state to rationally form an intent. I do not believe a custodial sentence would be appropriate in any way and possibly a more appropriate action would be to drop the charges against MT and concentrate on her medical care and [redacted] and all doctors in the community using this as a case study to improve their well meaning services.

[B L A N K]

STATEMENT OF TRUTH

Declaration

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and that the opinions I have expressed represent my true and complete professional opinion.

I believe that the facts I have stated in this report are true and that the opinions I have expressed are correct.

I understand that my primary duty is to the Court both in preparing reports and in giving oral evidence.

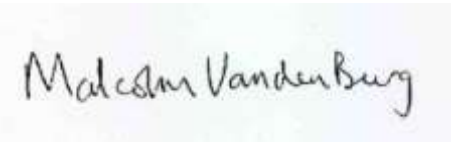
I have set out in my report what I understand from those instructing me to be the issues in respect of which my opinion as an expert is required.

I have endeavoured in preparing this report to be accurate and complete. I have included all matters, which I regard as relevant to the opinions I have expressed.

I have drawn to the attention of the Court all facts of which I am aware which might affect my opinion.

At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if for any reason I subsequently consider that the report requires correction or qualification.

This report is the evidence that I am prepared to give under oath subject to any correction or qualification I may make before swearing or affirming to its correctness.



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