

The Legal Implications of the Administration of Placebo to Psychiatric Patients

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Introduction

This paper concerns a practice that is sometimes encountered in the treatment of patients with mental illness: the use of placebo for purportedly therapeutic purposes. It will consider the lawfulness of that practice under domestic law, and suggest that previous attempts to perform such an analysis may be flawed. It will argue that existing statutory restrictions may apply to – and prohibit – therapeutic placebo administration, and will conclude with a brief analysis of the possible impact upon such administration of the Human Rights Act 1998.

The word ‘placebo’ is here used in the sense of “a pill, medicine, procedure etc., prescribed more for the psychological benefit to the patient of being given a prescription than for any physiological effect”.¹ It does not describe the use of any similar substance in the testing of new drugs (nor, to acknowledge every facet of the formal definition, does it connote either vespers for the dead or an eighteenth century sycophant).

Furthermore, it is assumed that the use of placebo is founded upon a clinical assessment that such is the preferable course, for to deny a patient substantive medication that might carry a therapeutic benefit would be to invite litigation, primarily, though by no means exclusively, under the domestic tort of negligence.

Consent

The use of placebo for purportedly therapeutic purposes raises the question of patient consent, which is more fully considered in the Code of Practice to the Mental Health Act 1983.² There, ‘consent’ is defined as:

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are those of the author alone.

1 *New Shorter Oxford Dictionary* (1993)

2 *Chapter 15*

“ ... the voluntary and continuing permission of the patient to receive a particular treatment, based on an adequate knowledge of the purpose, nature, likely effects and risks of that treatment including the likelihood of its success and any alternatives to it”.³

Except where the common law or statute law otherwise allows, such consent is required from every patient who is to undergo medical treatment.⁴ It may, however, be dispensed with in the case of a patient who lacks capacity to make a decision about his or her medical treatment. Capacity is to be presumed, although this presumption may be rebutted in certain circumstances,⁵ and a person will not be incapable of giving or refusing consent merely because s/he has a mental disorder.

When considering the lawfulness of placebo use, it is necessary to distinguish between informal patients and those detained under the Mental Health Act 1983.

Placebo and informal patients

It is necessary to distinguish between those informal patients who possess, and those who lack, capacity to make a decision about their medical treatment.

Capable, informal patients

It is an established principle of English law that a patient who possesses capacity and is admitted to hospital otherwise than under compulsion may only be given medication to which s/he consents, and may decline to accept any and all forms of medical treatment without penalty.⁶ The process that is to be followed when seeking consent from a capable patient is set out in the Code of Practice.⁷

By definition, any consent of a capable patient is to medication other than the placebo that s/he is in fact receiving. S/he has consented to a course of treatment that s/he is not receiving and is receiving a course of medication to which s/he has not consented. Such treatment is not merely different from that consented to, it is in many ways its antithesis. It is therefore difficult to see any lawful basis for the administration of placebo to a capable, informal patient, whether or not s/he is suffering from mental disorder.

Incapable, informal patients

Patients who lack capacity to make a decision about medical treatment, and who are not detained under the Mental Health Act 1983, may be treated in their “best interests” under the common law doctrine of ‘necessity’.⁸ However, if it is to be lawful, any such treatment must be:⁹

3 *Code of Practice, paragraph 15.13*

4 *Ibid., paragraph 15.8. See also: Re T (Adult: Refusal of Medical Treatment) [1992] 4 All ER 649, CA; Re MB (Medical Treatment) [1997] 2 FLR 426, CA [below]*

5 *Re C (Adult: Refusal of Medical Treatment) [1994] 1 All ER 819; Re MB (Medical Treatment) [1997] 2 FLR 426, CA. See also: B v Croydon District Health Authority (1994) 22 BMLR 13. Code of Practice, paragraph 15.10 et seq*

6 *Re T (Adult: Refusal of Medical Treatment) [1992]*

4 *All ER 649, CA per Lord Donaldson, MR; Re MB (Medical Treatment) [1997] 2 FLR 426, CA per Butler-Sloss LJ*

7 *Paragraphs 15.14-15.17*

8 *F v West Berkshire Health Authority and another (Mental Health Act Commission Intervening) [1989] 2 All ER 545, HL; Re MB (Medical Treatment) [1997] [see note 6, above]. See also: R v Bournewood Community & Mental Health NHS Trust, ex parte L [1998] 3 WLR 107*

9 *Code of Practice, paragraph 15.21*

- necessary to save life or prevent a deterioration or ensure an improvement in the patient's physical or mental health; and
- in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular area.¹⁰

It is perhaps only in a minority of cases that the administration of a placebo to an incapable, informal mental patient will fulfil both of these criteria. In any case, the purpose of using placebo is surely to deceive a patient who has knowledge of the benefits of a particular form of medication – or who at least knows that it *has* benefits – into believing that s/he is receiving that medication. Such use therefore depends upon the existence of at least a basic measure of intellect, so that, to put it delicately, there will always be a proportion of incapable, informal mental patients to whom the administration of placebo would be futile.

Placebo and detained patients

It is necessary to distinguish between those patients who have been receiving psychiatric medication for less than three months since being detained under the Mental Health Act 1983 and those receiving it for a longer period.

Medication in the first three months

If it is given “by or under the direction of the responsible medical officer”,¹¹ the consent of “a patient liable to be detained” under the Mental Health Act 1983¹² will not be required for “any medical treatment given to him for the mental disorder from which he is suffering”,¹³ provided less than three months have elapsed “since the first occasion in that period when medicine was administered to him by any means for this mental disorder”.¹⁴ Nevertheless, the Code of Practice states that:

“Even though the Act allows treatment to be given without consent during the first three months the RMO should ensure that the patient's valid consent is sought before any medication is administered ... If such consent is not forthcoming or is withdrawn during this period, the RMO must consider whether to proceed in the absence of consent, to give alternative treatment or no further treatment”.¹⁵

Although it is difficult to see how the RMO might obtain the patient's “valid consent” to a form of medication that may only be effectively administered to him by deceit, for a period of three months such consent is not necessary in law.

It is assumed that approval, if not the motivation, for the use of placebo will come from the RMO, and therefore that such might be said to be given by or under his/her direction. Therefore, the most relevant question in respect of a patient who is not yet subject to the ‘consent to treatment’ provisions will be whether the placebo is “medical treatment given to him [her]for the mental

10 Bolam v Friern Hospital Management Committee [1957] 1 WLR 582, at 587-8 [cf: Bolitho (administratrix of the estate of Bolitho (deceased)) v City and Hackney Health Authority [1997] 4 All ER 771, HL]

11 MHA 1983, section 64(1)

12 *Ibid.*, section 56(1)

13 *Ibid.*, section 63

14 *Ibid.*, section 58(1)(b)

15 Paragraph 16.11

disorder from which he [/she] is suffering". Given the wide definition that has been applied to the phrase "medical treatment",¹⁶ (which definition is discussed below,) and given also that the object of such treatment is clearly the patient's mental disorder, it seems likely that placebo *would* be deemed to fall within section 63 and, therefore, to be capable of administration to a patient without his/her consent for up to three months after his/her detention under the Mental Health Act.

Medication beyond three months

The 'consent to treatment' provisions that are contained in section 58 of the Mental Health Act 1983¹⁷ apply to the administration to a detained patient of "medical treatment for mental disorder" and state that, once three months have elapsed since first administration, such a patient may only be given "medicine" – clearly, medicine for mental disorder – if, being capable, s/he consents to receive it.¹⁸ If, though capable, s/he declines such consent, or if s/he is incapable, "medicine" may only be administered to him/her if an independent registered medical practitioner has certified in writing that, "having regard to the likelihood of its alleviating or preventing a deterioration of his [/her] condition, the treatment should be given".¹⁹

The reasons for prescribing a placebo are likely to vary from patient to patient, but in most cases it is likely that its use will be intended to alleviate or to prevent a deterioration of his/her psychiatric condition. However, this will only become a relevant consideration, and the consent to treatment provisions will only apply, if placebo is "medicine" and/or "medical treatment for mental disorder".

Placebo as 'medicine'

The most commonly expressed view upon the point is that placebo is not "medicine". The Mental Health Act Commission has suggested that:

"... as an inert substance, a placebo does not fall within the definition of 'medicine' and, therefore, falls outside the provisions of section 58".²⁰

If this were indeed so, the administration of placebo would be capable of being controlled only by the requirements of section 63, which, as has been demonstrated, it is likely to fulfil. However, this view may not reflect a complete understanding of the word "medicine".

The word has been authoritatively defined as, *inter alia*, "a substance or preparation used in the treatment of illness".²¹ Placebo is almost certainly "a substance or preparation"; but may it truly be said to be "used in the *treatment* of illness"?

This question is of more than lexicological significance for, as has been noted, the consent to treatment provisions will apply only where the psychiatric medication in question is being given to the patient as "medical treatment for mental disorder".²² Such use is not axiomatic: there are some medicines that are capable of being used in the treatment both of psychiatric and of non-psychiatric maladies.

16 *B v Croydon Health Authority* [1995] 1 All ER 683

17 MHA 1983, section 58(1)

18 *Ibid.*, section 58(3)(a)

19 MHA 1983, section 58(3)(b)

20 Eighth Biennial Report, 1997-1999, *The Stationery Office* (1999)

21 *New Shorter Oxford English Dictionary* (1993)

22 MHA 1983, section 58(1)

The Mental Health Act defines “medical treatment” so as to include “nursing ... habilitation and rehabilitation under medical supervision”,²³ and the latest edition of the Code of Practice expands this definition, applying it to “the broad range of activities aimed at alleviating, or preventing a deterioration of, the patient’s mental disorder”.²⁴ It is clear that the latter of these formulations derives from the judgment of the House of Lords in *F v West Berkshire Health Authority and another (Mental Health Act Commission Intervening)*.²⁵ Furthermore, in *B v Croydon Health Authority*,²⁶ Hoffman LJ held that “medical treatment” would include “a range of acts ancillary to the core treatment that the patient is receiving”, and that treatment would be ancillary to the core treatment if it was “concurrent with the core treatment or as a necessary prerequisite to such treatment”.²⁷

To elide these formulations and apply them to the circumstances envisaged in this paper: what is placebo if not “a substance or preparation which is ancillary – in other words, concurrent with or a necessary prerequisite of – a patient’s treatment”? Whilst placebo may not, perhaps, be a ‘prerequisite’ of a patient’s treatment, given that such treatment might simply consist of “nursing ... habilitation and rehabilitation under medical supervision”, its use is almost certainly ‘concurrent’ therewith.

It is therefore at least arguable that placebo used in the manner and for the purposes described above *would* fall within the definition of “medicine”, so as to bring it within the ‘consent to treatment’ provisions of MHA 1983, section 58(3).

Placebo and consent to treatment

If placebo is indeed “medicine”, so that its administration will fall within the consent to treatment provisions, several seemingly insuperable problems arise.

First, if treatment beyond three months is to proceed on the basis of the patient’s alleged consent, the RMO will have to certify on statutory Form 38 that the patient “is capable of understanding the nature, purpose and likely effects of” the specified treatment and that s/he “has consented to that treatment”.²⁸

Placebo depends for its effect upon a patient’s belief that it is another substance entirely – a drug that will help to alleviate his/her mental illness, or at least the symptoms that it produces. Therefore, unless it has been explained to the patient that his/her treatment will consist of a simple, inert placebo – a most unlikely, not to say self-defeating, course – the RMO will surely find it impossible to make the requisite certification on Form 38. Any more deceitful course – such as entering on the Form 38 the BNF classification of the drug that the placebo purports to be – might extract the patient’s acquiescence, but would end with the administration, not of *that* drug, but of “medicine” for which there was in fact no consent. Such administration would clearly fall foul of section 58(3)(a), and the Form 38 itself, being the certificate of a consent obtained by deception and therefore arguably vitiated, might well be susceptible to legal challenge. Without the legal authority of a valid Form 38, the continued administration of placebo/medicine to the patient might well amount to a trespass which would sound in damages.

23 *Ibid.*, section 145(1)

24 paragraph 15.4

25 (1989) [see note 8, above]

26 [1995] 1 All ER 683; followed in *Tameside & Glossop*

Acute Services NHS Trust v CH [1996] 1 FLR 762

27 *Ibid.*, at p 687

28 MHA 1983, section 58(3)(a); *Mental Health (Hospital, Guardianship and Consent to Treatment) Regulations* 1983, regulation 16(2)(b)

The position is no more propitious where a certificate is required in Form 39. In such circumstances, how might any SOAD certify, as section 58(3)(b) would require him/her to certify, either that the patient “has not consented” to a treatment the nature, purpose and likely effects of which have not, in fact, by definition been explained to him/her, or that “having regard to the likelihood of that treatment alleviating or preventing a deterioration of the patient’s condition it should be given”?²⁹

The Mental Health Act Commission’s revised *Advice to Second Opinion Appointed Doctors*³⁰ states:

“If asked, in error, to certify on Form 38 or Form 39 treatments that are not within the remit of section 58 (eg, behaviour therapy, Naso-Gastric Feeding, *placebos*, seclusion or restraint), the SOAD should decline. If, however, such treatments are relevant to the total plan when certifying *bona fide* section 58 treatments, they may be considered in the wider treatment plan and appropriate comments made in the case notes”.³¹

This advice is, of course, consistent with the Commission’s general stance on placebo use. However, it may be incorrect. As has been argued above, placebo may be capable of being regarded as a “medicine ... given for mental disorder” and, therefore, as falling within the ‘remit’ of section 58.

Placebo under MHA, section 63

As has been demonstrated, placebo use will only fall within the consent to treatment provisions if it constitutes “medicine” and “medical treatment for mental disorder”.³² If, contrary to the view expressed above, it is not medicine, the only lawful authority for the continued administration of placebo to a detained patient might be sought in section 63, on the basis that, having been given to him/her “by or under the direction of the responsible medical officer”, such also constituted “medical treatment given to him [her] for the mental disorder from which [s/he] is suffering”. As indicated above, it is likely that these conditions will be fulfilled.

However, such a course is not itself free from ethical difficulty, not least because the Code of Practice suggests that patient consent should even be sought for medication administered under section 63.³³ Nevertheless, such ethical difficulties are not within the scope of this paper.³⁴

Placebo use outside the Mental Health Act

Of course, if a placebo is not ‘medicine’, so as to bring it within section 58 of the Act, and if it is not “medical treatment given ... for mental disorder”, there is no statutory authority for – and there can be no statutory control upon – its use. In such circumstances, placebo might only lawfully be administered on the common law basis set out in Introduction to this paper.

29 *Ibid.*

30 *Mental Health Act Commission*, 21 April 1999

31 *Ibid.*, paragraph 42 [*emphasis added*]

32 *Mental Health Act 1983*, section 58(1) and (a)

33 *paragraph 16.38*

34 *See also: Mental Health Act Commission*, Eighth Biennial Report, 1997-1999, *The Stationery Office* (1999), paragraph 6.17

ECHR implications

The Human Rights Act 1998 ['HRA'] came fully into effect on 2 October 2000. Its purpose was to introduce into domestic law the European Convention on Human Rights ['ECHR'], and it requires, inter alia, that 'public authorities' such as NHS trusts and health authorities act compatibly with the ECHR. If the ECHR were to contain anything that might prohibit the use of placebo, it would be extremely hard to sustain such a practice.

Article 2 of the ECHR contains the "right to life", which the European Court has said "ranks as one of the most fundamental provisions in the Convention" and "enshrines one of the basic values of the democratic societies making up the Council of Europe".³⁵ It may be engaged even where death hasn't in fact occurred, provided it was a potential consequence of the act complained of.³⁶ Thus, a living mental patient to whom placebo has been administered might bring proceedings under the ECHR for damages in this regard.³⁷ However, if the placebo represented the only, or at least the best, treatment available for him/her, its administration would probably be considered more likely than any alternative to secure the right to life. Difficulties under Article 2 are only likely to be encountered by those administering placebo to mental patients where they have deliberately chosen to eschew a substantive treatment of proven efficacy. Those are not the circumstances upon which this paper is predicated.

Article 3 of the ECHR contains the "prohibition upon torture and upon inhuman or degrading treatment". Strasbourg has traditionally taken a very restrictive line in interpreting Article 3 in a medical context. So, for example, psychiatric treatment was held not to constitute a breach of Article 3 merely because it caused side effects that the patient found unpleasant.³⁸ Furthermore, the use of force-feeding, handcuffs, straps, a net and a belt were held not to amount to torture or to inhuman or degrading treatment because they were deemed "therapeutically necessary".³⁹ This last, of course, suggests that when considering Article 3 in medical cases, the European Court will apply something very similar to the existing domestic test for clinical negligence – the *Bolam* test – which was referred to above and, with neat circularity, concerned a claim for damages for injuries sustained during a course of ECT.⁴⁰

However, the ECHR is a "living instrument",⁴¹ and this has been particularly evident with Article 3, whose requirements are clearly in the process of changing. For example, the hurdle for 'torture' is being lowered, so that some things may now be inhuman or degrading that were not previously considered to be so.⁴² In any case, the European Court has already held that treatment may breach Article 3 where it is experimental and administered without the patient's consent.⁴³ In this context, treatment will be experimental where it has not yet become fully established, and there will be a lack of consent where the patient was not informed of that fact. In the instant situation, the patient will not be aware of – and, as I have already suggested, cannot therefore be said to have consented to – the use of placebo. If it can be shown not to be an 'established' treatment, therefore, such use may constitute a breach of Article 3.

35 *McCann v United Kingdom* (1995) 21 EHRR 97

36 *X v United Kingdom* (1978) 14 DR 31

37 HRA 1998, section 7(1)(a)

38 *Grare v France* (1993) 15 EHRR CD100

39 *Herczegfalvy v Austria* (1993) 15 EHRR 437

40 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 (see note 10, above)

41 *Tyrer v United Kingdom* (1993) 15 EHRR 437

42 *Selmouni v France*, *The Times*, August 24, 1999

43 *X v Denmark*, 32 DR 282

Article 5 of the ECHR contains the “right to liberty and security”, which those detained against their will have customarily used to challenge the *fact* of their detention. However, it has also been successfully invoked by a mentally ill offender to challenge the failure to transfer him from prison to a psychiatric hospital.⁴⁴ Generally, it is now felt that if the *conditions* in which a patient is kept are having an “anti-therapeutic” effect upon him/her, they may constitute a breach of Article 5. There will have to be some relationship between the justification for detaining a person – that s/he is suffering from an “unsound mind” – and the place in which that detention is effected. If this doctrine is capable of being expanded to cover the regime – and in particular, the *treatment* regime – to which a patient is subject, it may render the use of placebo unlawful under the ECHR, at least where such has proved *counter*-therapeutic. It is also possible that placebo use that has not yet proved counter-therapeutic but which has merely been neutral in its effect, neither ameliorating nor exacerbating the patient’s illness, will bring about a breach of Article 5, at least where the patient is detained under MHA 1983. In *Bouamar v Belgium*, the European Court held that detention – in this case, the detention of a child for educational purposes, which is ordinarily permitted under Article 5(1)(d) – would breach the ECHR where it had come to amount to the “fruitless repetition” of placements in institutions with inadequate educational facilities.⁴⁵ This would offend against the implicit prohibition in Article 5 upon ‘arbitrary detention’. The continued detention of a mental patient solely so that s/he might receive ‘treatment’ which may not in fact be such, and which is in any case proving ineffective, may also be said to infringe the *Bouamar* reading of Article 5.

Any prediction about the impact of the ECHR upon domestic law – including those contained in this paper – should be viewed with caution. Few of those made in the months before the coming of the HRA have proved correct. In fact, any prudent prediction must have several caveats: first, and as has been explained, the ECHR is intended to change with the times and is clearly doing so; in any case, the HRA adopts an arm’s length approach to the ECHR, and only requires domestic courts to “take into account” its jurisprudence;⁴⁶ and finally, and as perhaps too few commentators acknowledged prior to 2 October 2000, the existing Strasbourg jurisprudence will have to be passed through the filter of the English courts, which are hardly renowned for their radicalism.

It is certainly true that the Court of Appeal has declared the burden of proof in MHRT proceedings – which at the moment falls squarely upon the patient – to be incompatible with Article 5.⁴⁷ However, such a finding had long been predicted.⁴⁸ Generally, the domestic judiciary has adopted a restrictive approach to the ECHR and to its application to mental health law.⁴⁹

44 *Aerts v Belgium*, *Judgment of European Court* 30 July 1998

45 *Bouamar v Belgium* (1988) 11 EHRR 1

46 HRA 1998, section 2(1)

47 *R v Mental Health Review Tribunal, North & East London Region and Secretary of State for Health*, ex parte H, *Court of Appeal*, 28 March 2001

48 *See, for example, Hewitt, D in Community Care*, 2-8 December 1999, p21

49 *R v Secretary of State for Health, ex parte Lally*, *The Times*, October 26, 2000; *R v Mental Health Review Tribunal, ex parte Secretary of State for the Home Department (M, W and FO Intervening)*, *The Times*, February 20, 2001

Conclusion

There are few authoritative data about the administration of purportedly therapeutic placebo to mental patients in British hospitals. Nevertheless, anecdotal evidence suggests that, although uncommon, such a practice is by no means unknown. It is therefore desirable that its implications are set out clearly and unequivocally.

There can be no lawful basis for the use of placebo upon a capable patient who is not compulsorily detained in hospital. Such a course in respect of an incapable, 'informal' patient may be justifiable under the common law doctrine of 'necessity', but is unlikely in practice to have very much appeal.

With patients who are subject to the Mental Health Act 1983, the use of therapeutic placebo may be lawful in strict terms for three months after detention. Thereafter, however, the position may be more complex – and the lawful administration of placebo more difficult – than has been previously supposed.

It is at least strongly arguable that placebo use falls within the 'consent to treatment' provisions of the Mental Health Act 1983. Though previous analyses have suggested otherwise, they have been founded upon an incomplete understanding of the word 'medicine'. The nature of placebo is such that the statutory provisions, with their requirement that patient consent at least be sought, simply cannot be fulfilled. Thus, there may be no authority under domestic law for the purportedly therapeutic administration of placebo to many detained mental patients.

The ECHR contains several provisions that may in some circumstances be interpreted so as to prohibit therapeutic placebo use. However, although it would be imprudent to discount the Convention as a force for change, the experience of the months since its introduction into domestic law suggests that it will not be permitted to have such an effect.