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**B I L L**

TO

Make provision about innovation in medical treatment.

**B**E IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

**1 Responsible innovation**

- (1) The purpose of this Act is to encourage responsible innovation in medical treatment.
- (2) It is not negligent for a doctor to depart from the existing range of accepted medical treatments for a condition if the decision to do so is taken responsibly. 5
- (3) For the purposes of taking a responsible decision to depart from the existing range of accepted medical treatments for a condition, the doctor must in particular—
  - (a) obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment, 10
  - (b) take full account of the views obtained under paragraph (a) (and do so in a way in which any responsible doctor would be expected to take account of such views),
  - (c) obtain any consents required by law to the carrying out of the proposed treatment, 15
  - (d) consider—
    - (i) any opinions or requests expressed by or in relation to the patient,
    - (ii) the risks and benefits that are, or can reasonably be expected to be, associated with the proposed treatment, the treatments that fall within the existing range of accepted medical treatments for the condition, and not carrying out any of those treatments, and 20
    - (iii) any other matter that it is necessary for the doctor to consider in order to reach a clinical judgement,
  - (e) comply with any professional requirements as to registration of the treatment under the provisions of this Act with a scheme for capturing the results of innovative treatment (including positive and negative 25

- results and information about small-scale treatments and patients' experiences), and
- (f) take such other steps as are necessary to secure that the decision is made in a way which is accountable and transparent.
- (4) For the purposes of subsection (3)(a), a doctor is appropriately qualified if he or she has appropriate expertise and experience in dealing with patients with the condition in question. 5
- (5) The steps that must be taken by virtue of subsection (3)(f) include the recording in the patient's notes of details relating to –
- (a) the views obtained under subsection (3)(a), 10
- (b) the doctor's decision to depart from the existing range of accepted medical treatments for the patient's condition, and
- (c) the proposed treatment.
- (6) Nothing in this section –
- (a) applies in relation to treatment carried out for the purposes of medical research; 15
- (b) permits a doctor to carry out treatment for any purpose other than the best interests of the patient.
- (7) Nothing in this section applies in relation to treatment which is carried out solely for cosmetic purposes. 20
- (8) In this Act –
- (a) "doctor" means a registered medical practitioner;
- (b) a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction). 25
- 2 Effect on existing law**
- (1) Nothing in section 1 –
- (a) affects any rule of the common law to the effect that a departure from the existing range of accepted medical treatments for a condition is not negligent if supported by a responsible body of medical opinion, or 30
- (b) is to be read as limiting the circumstances in which any such rule of the common law may be relied on (including, for example, where emergency treatment is required).
- (2) Accordingly –
- (a) any decision by a doctor to depart from the existing range of accepted medical treatments for a condition in accordance with section 1 does not prejudice the doctor's ability, in relation to the departure, to rely on any rule of the common law referred to in subsection (1)(a); 35
- (b) a departure from the existing range of accepted medical treatments for a condition is not negligent merely because the decision to depart from that range of treatments was taken otherwise than in accordance with section 1. 40
- 3 Extent, commencement and short title**
- (1) This Act extends to England and Wales only.

- (2) Sections 1 and 2 come into force on such day or days as the Secretary of State may by regulations made by statutory instrument appoint.
- (3) Regulations under subsection (2) may –
  - (a) appoint different days for different purposes;
  - (b) make transitional or saving provision.
- (4) This section comes into force on the day on which this Act is passed.
- (5) This Act may be cited as the Medical Innovation Act 2015.

# Medical Innovation Bill [HL]

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To make provision about innovation in medical treatment.

*Lord Saatchi*

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