

# Medical Innovation Bill [HL]

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## EXPLANATORY NOTES

Explanatory notes to the Bill, prepared by Lord Saatchi, the Member in charge of the Bill, are published separately as HL Bill 21 – EN.

# Medical Innovation Bill [HL]

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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 and to deter reckless departure from standard practice.
- (2) It is not negligent for a doctor to depart from the pre-existing range of accepted treatments for a condition (standard practice) if the decision to innovate is taken responsibly. 5
- (3) A responsible decision to innovate will, in particular, be based on consideration of—
  - (a) the reasons why the available research or other evidence is insufficient or unclear including, in particular, whether it is referable to the nature of the condition (as in, for example, a cancer that affects relatively few patients), 10
  - (b) the relative risks that are, or can reasonably be expected to be, associated with the treatment the doctor proposes to apply and other treatments, 15
  - (c) the relative likely success rates of the treatment the doctor proposes to apply and other treatments, in the doctor's reasonable judgement,
  - (d) the relative likely consequences of applying, or failing to apply, the treatment the doctor proposes to apply, and other treatments,
  - (e) opinions or requests expressed by or in relation to the patient, and 20
  - (f) any other matter that appears to the doctor to be reasonably necessary to be considered in order to reach a clinical judgement.
- (4) A responsible decision to innovate must be made in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters; the process may include, in particular— 25
  - (a) decision-making within a multi-disciplinary team;

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- (b) notification in advance to the doctor’s responsible officer (within the meaning of Part 5A of the Medical Act 1983);
    - (c) explanation to the patient of the doctor’s reasons for proposing to depart from standard practice, including discussion of any contrary opinions expressed by the doctor’s colleagues. 5
  - (5) Nothing in this section permits a doctor –
    - (a) to provide treatment without consent that is otherwise required by law, or
    - (b) to administer treatment for the purposes of research or for any purpose other than the best interests of the patient. 10
  - (6) In this section –
    - (a) “doctor” means a person listed in the register of medical practitioners under section 2 of the Medical Act 1983, and
    - (b) a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction). 15
- 2 Short title, commencement and extent**
- (1) This Act may be cited as the Medical Innovation Act 2013.
  - (2) This Act comes into force on the day on which it is passed.
  - (3) This Act extends to England and Wales, Scotland and Northern Ireland. 20

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To make provision about innovation in medical treatment.

*Lord Saatchi*

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