













wellcome trust

Joint statement on the Medical Innovation Bill House of Lords Report Stage – 12 December 2014

We welcome the progress that has been made in the House of Lords to amend the Medical Innovation Bill, particularly to strengthen safeguards for patients. We also welcome the discussion around medical innovation that has been prompted by the Bill.

However, we still have significant concerns over whether the Bill as drafted achieves the aim of encouraging innovation, and over the necessity and practicality of further legislation as a means of doing so. The Bill does not tackle other significant barriers to medical innovation that need to be addressed (highlighted in our previous briefing dated 24 October), and may have unintended consequences that will harm innovation.

Our primary outstanding concerns include:

- It is essential that provision is made for collecting and sharing data in order to
 ensure that information of both beneficial and harmful effects of treatment is
 captured for the benefit of subsequent patients. We were pleased to hear the
 commitments made on the floor of the House during the Committee debate to
 address the issue of collecting data, a point which remains of fundamental
 importance and must be followed through;
- The Bill may discourage patients and their clinicians from participating in clinical trials by encouraging the provision of novel treatments on an ad hoc basis. Without properly controlled studies, it is not possible to develop the evidence of efficacy necessary to support wider adoption of new treatments in the NHS
- While we welcome provisions in the most recent amendments to clarify the Bill's
 intersection with common law, we feel that the Bill still risks introducing a degree of
 ambiguity to the law governing clinical negligence, potentially placing doctors at
 risk of further litigation. We would welcome further clarification of how the Bill will
 work in practice without conflicting with existing law or regulation, particularly in
 relation to research.

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