MPS Briefing

Medical Innovation Bill: House of Lords, Committee Stage

October 2014

This Bill continues to generate significant debate about medical innovation which MPS welcomes. We support a responsible, innovative medical profession. Current law allows doctors acting responsibly to innovate and this Bill is therefore unnecessary. While some welcome amendments have been tabled ahead of Committee stage, we remain concerned that this Bill could inhibit responsible innovation, give false reassurance to some doctors, and damage the doctor/patient relationship.

The current draft of the Bill leaves a great deal open to interpretation and we do not believe that this Bill will achieve its stated objectives.

This Bill will confuse rather than clarify the law. The Bill recognises the value of existing law as it explicitly preserves the current Bolam-Bolitho tests for standards of care. Thus, a doctor acting responsibly with the support of a responsible body of peers and the informed consent of their patient would not be guilty of negligence under the current law. Improved education about the present law may be needed, but a new Bill is not.

Potential risks created by this Bill

- **Falsely reassuring some doctors.** We understand that the purpose of the Bill is to provide doctors with an assurance that before they innovate, if they follow the process outlined in the Bill, they will be supported and protected by the court. This is incorrect in law. For instance, the Bill fails to give an absolute definition of an appropriately qualified doctor. Whether the doctor consulted is in fact 'appropriately qualified' is open to the scrutiny of the courts. It would always be possible to challenge through the courts whether the provisions of this proposed legislation were complied with. Yet the Bill attempts to give a doctor reassurance ahead of any court decision. This is simply not possible.

- **Damage the doctor/patient relationship.** There are a number of potential barriers to responsible innovation, and funding is amongst the most significant. This Bill fails to recognise this and other barriers to innovation, yet could create a perception amongst some patients that innovative treatments are readily available and that every doctor has an understanding of all possible treatment routes. Neither is the case. It would be for the doctor to explain otherwise, and thus damage the doctor-patient relationship.

- **Unrealistic demands being placed on doctors.** This Bill could allow patients to force doctors to act in a way that is against their medical judgment. The sad reality of most cases where the Bill could apply is that there is seldom time to try all possible treatments, neither is there likely to be funding for these. Furthermore the use of one innovative treatment may in some circumstances preclude the use of another. It must also be stressed that not every possible route will be Bolam-Bolitho compliant. Despite this, the brief attached to the Bill [pg.4, para 6] claimed that it will "empower patients to demand that every possible route should be tried." It would be for the doctor to explain that they are unable to deliver what the Bill has led the patient to believe they are entitled to, thus again damaging the doctor/patient relationship.

- **Adding unnecessary bureaucracy to current good medical practice.** The Bill brings into question the significance of NICE guidelines. NICE guidelines have become the established method by which doctors gauge what procedures and/or drugs are standard. As there is no definition of innovation, this Bill could result in any procedure and/or use of drug that is not in NICE guidance having to go through this Bill's process, if that becomes the de facto definition of innovation. Currently, a slight departure from NICE guidance is done on the basis of a doctor's professional judgment, in line with the Bolam-Bolitho tests. Yet this Bill could require such decisions to be referred to colleagues as a matter of course, with more hurdles to treatment than there are at present.

For more information please contact Tom Reynolds, Public Affairs and Policy Officer: thomas.reynolds@mps.org.uk

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Amendments to be moved in Committee

- *Lord Winston, amendments to Clause 1, providing exclusions from the provisions of the Bill*

MPS welcomes Lord Winston's amendment for the exclusion of, amongst others, paediatric care from the provisions of the Bill. However, we believe exclusions should go much further. The provisions of the Bill should not apply in clinical geriatric treatment where the patient is unable to provide explicit consent, nor should it in psychotherapy treatment or intervention, and crucially not in primary care. The stated aim of the Bill is for it to be drawn upon when dealing with life threatening conditions, so we are concerned that it does not explicitly exclude primary care. It would be highly inappropriate for the scope of this Bill to extend to the primary care sector, because it is by no means certain that its decision making structures would pass the test for a 'responsible body.'

- *Lord Saatchi, Amendment 12, inserting a new clause – "Effect on existing law"*

Rather than clarify the existing law, we believe this to be an example of where the Bill confuses the law. In the guidance note on the amendment [pg.1,para 3], it states, "what the Bill does is to give doctors another option (in addition to the existing Bolam test)." This surely negates the need for the Bill, as it expressly preserves current common law. What is more concerning however, is that doctors pursuing innovative treatments under the provisions of this Bill, instead of the Bolam route, could be falsely reassured. With the Bolam-Bolitho tests, and even under this new Bill, innovative treatments are subject to the scrutiny of the courts. So not only does the Bill not add anything to current law, it confuses it, and creates new risks.

- *Lord Saatchi, Amendment 6, inserting new clause 1(4) – "… a doctor is appropriately qualified if he or she has appropriate expertise in dealing with patients with the condition in question."*

The amendment seeks to clarify when a doctor is appropriately qualified for the purposes of the Bill, but it fails to do so. This would be for the court to ultimately decide. Yet the Bill attempts to give a doctor reassurance ahead of a court decision which is not possible. This area of the Bill is open to interpretation, for instance, 'experience in dealing with patients with the condition in question' – a doctor in primary care may have experience in dealing with a patient with cancer, but not in treating them. A great deal more protection and clarity is needed. This is why we believe primary care should be explicitly excluded from the Bill.

Changes and considerations needed at Committee stage

- Further exclusions from the provisions of the Bill, including first and foremost primary care, alongside paediatric care and others.
- Greater clarity about when a doctor for the purposes of the provisions of this Bill is considered appropriately qualified, and the process by which that would be determined.
- Recognition of the established role of NICE guidance, and the risks posed by this Bill potentially becoming a de facto definition of innovative treatment.

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