MEDICAL LEGISLATION **Michael D Rawlins**

"Saatchi bill" will encourage innovation in treatment

The Medical Innovation Bill currently under consultation aims to make it easier for doctors to try untested interventions

Many doctors, myself included, will have occasionally tried, when all other treatment options have failed, to treat patients with novel interventions. They may do so when there is no recognised form of effective treatment; or when existing ones have not produced the desired effect. The legal basis for such recourse, at least for pharmaceuticals, has been the so called "named patient" provisions of Section 9 of the Medicines Act 1968,[1] which permits any doctor to be able "to sell, procure or supply a medicinal product to a patient under his or her care."

Although my own experience of novel interventions has been disappointing, some such interventions have led to important advances. Indeed, these observations are arguably a form of "n of 1" trial.

However, confidence in using the Medicines Act's named patient provisions has become eroded. Several legal authorities have pointed out that departing from what is regarded as "established practice" or "the standard of care" leaves a doctor open to legal action for negligence. The definition of "the standard of care" traditionally follows the Bolam principle,[2] as amended by the Bolitho decision,[3] but was forcefully criticised by Elizabeth Butler-Schloss in her capacity as president of the High Court's Family Division: "The Bolam test ought not to be allowed to inhibit medical progress. And it is clear that if one waited for the Bolam test to be complied with to its fullest extent, no innovative work such as the use of penicillin or performing heart transplant surgery would ever be attempted."[4]

The Medical Innovation Bill attempts to rectify this situation. It proposes legislation stating that it would not be negligent for a doctor to depart from the existing range of accepted medical treatments for a condition, in carefully defined circumstances. These circumstances—allowing for responsible innovation—are laid out in later sections of the bill. They include a plausible basis for the use of the proposed treatment and an assessment of the risks that could be reasonably expected to be associated with it. The bill also proposes that, before a doctor embarks on such a treatment, he or she should have discussed it with the patient, the multidisciplinary team responsible for the patient's care, and the institution's responsible officer. The bill emphasises that its provisions are solely concerned with the patient's best interests.

Originally introduced into the House of Lords in May 2013 as a private member's bill by Maurice Saatchi, it has become known colloquially as "the Saatchi bill." The Department of Health for England is currently consulting on a draft version.[5] I was originally sceptical about the need for the bill but have been persuaded otherwise, for three reasons. Firstly, it is clear from the comments of Butler-Schloss and other legal authorities consulted by Saatchi that there are serious legal impediments in civil law to using therapeutic interventions that do not represent the current standard of care. Secondly, although Saatchi's original bill was confined to patients with malignant disease, this restriction has, rightly in my view, been removed in the current draft. After all, many other miserable conditions have no, or very limited, remedies. Thirdly, originally I did not believe that his suggestion for approval by a multidisciplinary team alone provided sufficient safeguard; the inclusion now of agreement by a doctor's responsible officer reassures me.

I believe that the use of the provisions in the draft Medical Innovation Bill will benefit patients, especially those with rarer diseases, and the furtherance of medical science. However, it has important consequences for the medical professions when (as I hope) it becomes law:

- Just because a particular intervention seems to have been effective in an individual patient it cannot be assumed that the results are generalisable. Further research in the form of one or more randomised controlled trials, or case series, will be needed to establish its effectiveness. To take a recent example, a case report describing the apparently successful treatment of generalised juvenile pustular psoriasis with etanercept requires confirmation before it can be regarded as the current standard of care.[6]
- There may be occasions when responsible officers wish to seek other advice before approving the use of an intervention in accordance with the provisions of the bill. This advice will often need to be given rapidly, especially when a patient has a life threatening illness. The Academy of Medical Sciences, or some of the specialist associations such as the British Pharmacological Society, could have an important role here in offering a speedy advice service.
- If the bill's intentions are to be fulfilled, NHS hospital trusts, and their responsible officers, will need to look on proposals sympathetically. Anecdotal evidence indicates that too many trusts are fearful of departing from the prevailing standard of care because of the possibility of litigation. The bill should provide them with adequate reassurance.
- It is essential that the results of using the bill's provisions for individual patients are placed in the public domain, whether or not they have succeeded. This would allow others not only to learn from such experiences but—especially in the case of interventions that seem to have been successful—to undertake formal research.

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Consultation on the Medical Innovation Bill is open until 25 April at http://bit.ly/1kodLTN.

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References are in the version on bmj.com.
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