MEDICAL INNOVATION BILL

MYTH vs REALITY

A Q&A briefing from the Association of Personal Injury Lawyers (APIL)
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MYTH: ***Doctors don't innovate because they are afraid of being sued***

REALITY: As far as APIL is aware there is no evidence to suggest a doctor has ever been sued as a result of trying an innovative treatment, and plenty of evidence that doctors are prepared to break new ground when treating patients. For example, the life expectancy of people who are HIV positive has improved rapidly over the past 20 years due to modern treatments which help to control the condition. And this year, Non-Hodgkin's lymphoma sufferer Ian Brooks from Bolton trialled a new drug which eradicated 70 tumours from all over his body. He is in remission and the drug, Brentuximab Vedotin, is now routinely available through the Cancer Drugs Fund for NHS patients with the same rare condition.

The fact is doctors need only fear being sued if they have been negligent. In fact, doctors should already be fully aware that trying something new to help a patient is not the same as being negligent. If doctors do not understand what is expected of them by the law, they should seek guidance from their professional bodies.

MYTH: ***The Medical Innovation Bill removes confusion***

REALITY: The Bill will actually generate confusion. The current legal test for negligence, set out in *Bolam v Friern Hospital Management Committee* has applied for almost 60 years. It is not credible to suggest that a legal standard for negligence which has been in use for almost six decades, along with the case law which accompanies it, is not enough guidance for doctors. The current 'Bolam test' provides that a doctor will not be considered negligent where he has 'acted in accordance with a practice accepted as proper by a responsible body of medical men'. Under the Medical Innovation Bill, doctors would be faced with the uncertainty as to whether the treatment they apply is governed by the Bill, or the Bolam test. Doctors could be falsely reassured that they are protected by the Bill because they consulted with their "appropriately qualified colleagues" and notified their responsible officer.

If a doctor consults with other doctors who are competent in the relevant field and agree that to undertake the innovative treatment is responsible and the correct thing to do, then it would satisfy the Bolam test in court if the patient were to suffer harm. Doctors know this and understand this. The fact that no doctor appears to have been subject to a negligence claim solely for trying an innovative treatment shows that the current system works well.

MYTH: ***Fear of litigation is the reason there is no cure for cancer***

REALITY: Cancer survival in the UK has doubled in the last 40 years.[1] The Medical Innovation Bill will not provide the cure for cancer. It is also important to understand that the Bill applies to other medical treatments.

The British Medical Association (BMA)[2] states that there are other barriers to innovation in medicine such as a lack of funding and allocation of time for medics to undertake the necessary studies. The BMA is also one of many respondents to the consultation on the Bill who agree that there is no evidence that the threat of litigation is a barrier to the provision of innovative treatments.

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[1] *Cancer Research UK http://www.cancerresearchuk.org/cancer-info/cancerstats/keyfacts/Allcancerscombined/*

[2] *Legislation to encourage medical innovation – BMA response page 2*

There are plenty of ways to further promote innovation in medicine, such as increased funding, and the creation of a 'register of experience' so that doctors can see how other patients have fared in similar circumstances, a suggestion supported by organisations including the BMA and the NHS Litigation Authority. Oxford University said that it will maintain a public register of innovations which take place under the Bill. APIL supports this idea, although this could happen now without the need for legislation.

MYTH: ***Any deviation by a doctor from standard procedure is likely to result in a verdict of guilt for medical negligence - M. Saatchi***

REALITY: This is a highly misleading and damaging statement. Any doctor who satisfies the criteria of the Bolam test will not be found 'guilty' of negligence. It is important to understand that negligence does not mean that something has simply gone wrong, or that a mistake or wrong decision has been made - it means providing a standard of care the medical profession itself considers unacceptable.

Trialling an innovative treatment which does not work is completely different from being negligent in the care of a patient and causing harm. A verdict of guilt for medical negligence may arise following the latter only and only if that negligence has been proven.

If a doctor deviates from standard procedure, and other doctors agree that it was a reasonable and responsible action to take, then he would meet the requirements of the Bolam test. The Bolam test protects both patients and doctors, as doctors can take whether their actions would pass the Bolam test into consideration when making decisions. They have been doing this for nearly 60 years, during which time there have been some incredible advances in medicine - cancer survival rates have increased dramatically, paralysed people have been able to move again, and vaccinations keep life-threatening diseases at bay.

MYTH: ***'obtaining views' means 'agreement'***

REALITY: The Medical Innovation Bill provides that as part of the process of deciding whether to try an innovative treatment, a doctor must 'obtain the views of one or more appropriately qualified doctors'. Lord Saatchi has been quoted as saying, however, that the Bill will allow doctors to use innovative treatments "so long as they have the agreement of the patient… and of a panel of medical specialists". But 'agreement' and 'obtaining views' are two very different things.

The requirement to 'obtain views' is a half-hearted safeguard, because it does not produce a veto. If the other doctors do not agree with the innovative treatment, the doctor who wants to use it can go ahead with the treatment and still be protected by the Bill. The Bill would effectively allow a doctor to run an idea past another doctor out on the golf course but still not require him to agree to the proposed course of action. Also, clause two of the Bill as amended by Lord Saatchi still puts the decision to undertake medical treatment in the hands of the doctor himself. The bottom line is that without the Bill, doctors would continue to ensure that other medics agree that a treatment is a reasonable course of action to take. Again, there is no apparent evidence that innovation has resulted in a finding of medical negligence. The Bolam test works.

MYTH: ***Lawyers benefit from the current system, which is why they oppose it***

REALITY: It is not only lawyers who oppose this Bill. Many other organisations and individuals agree that the Bill is unnecessary and are concerned that safeguards could be removed, including the Medical Protection Society, British Medical Association, and Cancer Research UK. APIL supports responsible innovation and the advancement of medical science, but not at the expense of patient protection.

MYTH: 20,000 respondents to a Government consultation support the Medical Innovation Bill

REALITY: In fact, a response to a freedom of information request from the Department of Health makes it quite clear that the "thousands" refer to Lord Saatchi's own petition asking for support for the Bill, rather than formal and considered consultation responses. The petition asked that people support a call for the Government to 'do whatever is needed to remove the barriers that prevent innovation which can save and improve lives.' It did not go into any detail about the Bill or what would change for patients and stated that the barriers for removal which prevent innovation are in the current law – something with which many well-informed medical and legal firms and organisations disagreed in their responses to the consultation. It should come as no surprise that, faced with a possible cure for cancer and in all probability in possession of little knowledge about the legal system, people have been keen to sign the petition.

MYTH: ***Dying people have nothing to lose***

REALITY: The Medical Innovation Bill will apply to people who are not dying as well as those who have no other options left in standard medicine. For example, doctors may try new treatments on asthma patients who are not terminally ill but looking for a more effective treatment to keep their condition under control. Equally, someone with a debilitating and life-shortening disease such as motor neurone disease may be persuaded to undertake an innovative treatment which causes unnecessary additional harm and suffering, with ultimately the same outcome.

While people who are facing their own mortality might be willing to try any options which are presented to them, the Bill could leave already vulnerable people exposed to harmful treatments. There are doctors who are seeking to be the ones to 'break new ground', most of whom are responsible and dedicated to their patients. But patients must be protected from the inevitable mavericks in the system.

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