

**GUIDE TO**

**THE MEDICAL**

**INNOVATION BILL**

**2015 [*LORDS*]**

**As passed by the House of Lords and sent  
to the House of Commons on 26 January  
2015 [HC BILL 162]**

# CONTENTS

	<b>Page</b>
Medical Innovation Bill 2015 [LORDS]; [HC Bill 162]	3
Explanatory Notes	7
Q&A	10
Links and references	46
Appendix – Quotes	51

# **Medical Innovation Bill [HL]**

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## CONTENTS

1. Responsible innovation
2. Effect on existing law
3. Short title, commencement and extent

A  
**BILL**  
TO

Make provision about innovation in medical treatment.

BE 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.
- (2) It is not negligent for a doctor to depart from the existing range of accepted medical treatments for a condition if the decision to do so is taken responsibly.
- (3) For the purposes of taking a responsible decision to depart from the existing range of accepted medical treatments for a condition, the doctor must in particular—
  - (a) obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment,
  - (b) take full account of the views obtained under paragraph (a) (and do so in a way in which any responsible doctor would be expected to take account of such views),
  - (c) obtain any consents required by law to the carrying out of the proposed treatment,
  - (d) consider—
    - (i) any opinions or requests expressed by or in relation to the patient,
    - (ii) the risks and benefits that are, or can reasonably be expected to be, associated with the proposed treatment, the treatments that fall within the existing range of accepted medical treatments for the condition, and not carrying out any of those treatments, and

- (iii) any other matter that it is necessary for the doctor to consider in order to reach a clinical judgement,
  - (e) comply with any professional requirements as to registration of the treatment under the provisions of this Act with a scheme for capturing the results of innovative treatment (including positive and negative results and information about small-scale treatments and patients' experiences), and
  - (f) take such other steps as are necessary to secure that the decision is made in a way which is accountable and transparent.
- (4) For the purposes of subsection [\(3\)\(a\)](#), a doctor is appropriately qualified if he or she has appropriate expertise and experience in dealing with patients with the condition in question.
- (5) The steps that must be taken by virtue of subsection [\(3\)\(f\)](#) include the recording in the patient's notes of details relating to—
  - (a) the views obtained under subsection [\(3\)\(a\)](#),
  - (b) the doctor's decision to depart from the existing range of accepted medical treatments for the patient's condition, and
  - (c) the proposed treatment.
- (6) Nothing in this section—
  - (a) applies in relation to treatment carried out for the purposes of medical research;
  - (b) permits a doctor to carry out treatment for any purpose other than the best interests of the patient.
- (7) Nothing in this section applies in relation to treatment which is carried out solely for cosmetic purposes.
- (8) In this Act—
  - (a) "doctor" means a registered medical practitioner;
  - (b) a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction).

## **2. Effect on existing law**

(1) Nothing in section 1—

(a) affects any rule of the common law to the effect that a departure from the existing range of accepted medical treatments for a condition is not negligent if supported by a responsible body of medical opinion, or

(b) is to be read as limiting the circumstances in which any such rule of the common law may be relied on (including, for example, where emergency treatment is required).

(2) Accordingly—

(a) any decision by a doctor to depart from the existing range of accepted medical treatments for a condition in accordance with section 1 does not prejudice the doctor's ability, in relation to the departure, to rely on any rule of the common law referred to in subsection [\(1\)\(a\)](#);

(b) a departure from the existing range of accepted medical treatments for a condition is not negligent merely because the decision to depart from that range of treatments was taken otherwise than in accordance with section 1.

## **3. Short title, commencement and extent**

(1) This Act may be cited as the Medical Innovation Act 2015.

(2) Sections 1 and 2 come into force on such day or days as the Secretary of State may by regulations made by statutory instrument appoint.

(3) Regulations under subsection [\(2\)](#) may—

(a) appoint different days for different purposes;

(b) make transitional or saving provision.

(4) This section comes into force on the day on which this Act is passed.

(5) This Act extends only to England and Wales.

# **MEDICAL INNOVATION BILL [Lords]**

## **EXPLANATORY NOTES**

### **INTRODUCTION**

1. These Explanatory Notes relate to the Medical Innovation Bill [Lords] as brought from the House of Lords on 26th January 2015. They have been prepared by Michael Ellis MP in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.

2. The Notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill.

### **BACKGROUND AND SUMMARY**

3. The Bill is designed to codify existing best-practice in relation to decisions by medical practitioners to depart from standard practice and to administer innovative treatment, and to bring the test of whether innovation is negligent forward to the time of treatment in order to give clarity and certainty to patients and doctors. The existing common-law test of the support of a responsible body of medical opinion is expressly preserved. The fundamental proposition of the Bill is that it is not negligent for a doctor to depart from standard practice where the decision is taken responsibly, in consultation with relevant colleagues and by applying an accountable and transparent procedure that allows full consideration of all relevant matters. The process also includes provision for the recording of the results of innovative treatment.

### **COMMENTARY ON CLAUSES**

#### **Clause 1 – Responsible Innovation**

4. Subsection (1) sets out the purpose of the Act: to encourage responsible innovation.

5. Subsection (2) declares that it is not in itself negligent for a doctor to depart from standard practice where the decision to innovate if the decision is taken responsibly, as described in the later provisions of the Bill.
6. Subsections (3)(a) and (b) and (4) require the decision-making process to include consultation with appropriately qualified colleagues, who must have expertise and experience in dealing with patients with the relevant condition.
7. Subsection (3)(c) requires the decision-making process to include obtaining any consents required by law; the Bill does not affect legal requirements for doctors to obtain patients' informed consent to any treatment proposed.
8. Subsection (3)(d)(i) requires the decision-making process to include consideration of opinions or requests expressed by the patient or on behalf of the patient (for example, by family members in the case of a patient who is unable to communicate his or her own opinions). Opinions and requests are to be taken into consideration by the doctor in forming a professional judgment, but are not necessarily determinative.
9. Subsection (3)(d)(ii) requires the decision-making process to include a risk-benefit analysis.
10. Subsection (3)(d)(iii) requires the decision-making process to include consideration of any other matters that the doctor thinks necessary to consider in reaching a clinical judgment.
11. Subsection (3)(e) requires the doctor to comply with any professional requirements that may be in place to register the proposed innovative treatment with a data-capture scheme. The Bill does not establish a data-bank, but if one is established, and if the medical regulatory bodies require doctors to use it, then the Bill will make compliance with registration requirements compulsory for doctors relying on the provisions of the Bill in order to innovate. The provision includes reference to the registration of all data, including negative results and information about small-scale treatments and patients' experiences.
12. Subsections (3)(f) and (5) require the doctor to take any other steps necessary to ensure that decisions to innovate are accountable and transparent; that expressly includes a requirement to record in the



patient's notes details of the colleagues whose views were obtained, what those views were, and other details about the innovative treatment and the decision to provide it.

13. Subsection (6) clarifies that nothing in the clause allows a doctor to administer treatment to a patient for any purpose, including research, other than the best interests of that patient.

14. Subsection (7) excludes cosmetic surgery from the provisions of the Bill.

### **Clause 2 – Effect on existing law**

15. Clause 2 preserves the existing common law test in accordance with which the question whether a decision to innovate was negligent will be tested by the courts by reference to whether the decision would have been supported by a responsible body of medical opinion. The effect of the Bill is therefore not to replace the common law test, but to provide an alternative statutory route that in effect applies the responsible-body test at the time when the doctor decides whether to innovate.

### **Clause 3 – Short title, commencement and extent**

16. Clause 3(2) to (4) provide for the substantive provisions of the Bill to be commenced by order of the Secretary of State.

17. Clause 3(5) provides for the Bill to be part of the law of England and Wales, and not Scotland or Northern Ireland.

## **WHAT IS THE POINT OF THE BILL?**

Society has become more litigious.

An unintended consequence of existing law is to act as a deterrent to medical innovation.

## **WHAT DOES THE BILL ACTUALLY DO?**

The Bill is about giving greater clarity and certainty to patients and doctors at the point of treatment, and not forcing them to wait for the unpredictable outcome of possible litigation.

## **HOW DOES THE BILL ACHIEVE THIS AIM?**

The Bill draws a proper balance to remove barriers to innovation while at the same time taking into account the risk by doing so. It has found a balance between the dangers involved in innovations and the protection necessary in the interests of the patient.

The Bill achieves its aim – to encourage innovation – in a simple, safe and responsible way. Better still, it is modest and humble. It moves the Bolam “responsible persons” test from after the event to before the event.

The result is that doctors are not obliged to speculate in advance about what might happen in a subsequent trial, and they can move forward with confidence, safe in the support of a responsible body of medical persons—in other words, the Bolam test brought forward.

This crucial time change removes any uncertainty and ambivalence about what is or is not lawful medical innovation.

## WHAT IS THE LEGAL DEFINITION OF “INNOVATION”

The Former Lord Chancellor, Lord Mackay of Clashfern explains:

*“...the word ‘innovation’ is a straightforward word in the English language. ... if we want simplicity, we should go for perfectly clear English words. ‘Innovation’ is one of them. To define it other than that which is not the standard procedure, is to risk limiting it and it is for doctors to decide what is innovation and whether to apply the bill to their proposed procedure.”*

## **WHAT IS THE EVIDENCE THAT THIS BILL IS REQUIRED?**

The original premise of this Bill has been proved. It has exposed a fault line in the medical / legal profession.

Some say the law does not block innovation. Others say it does.

Some say there is no fear of litigation. Others say there is.

Some say they can innovate now. Others say they can't.

We have here proof of one thing beyond doubt – after all the words, blogs, letters, interviews, tweets and articles that have been written about the Medical Innovation Bill, there is one definite, irrefutable conclusion, as Lord Kakkar says:

*There is an ambiguity in the way that the current law may be interpreted*

And therefore uncertainty about what constitutes a safe path to lawful innovation. A lack of clarity demands a clarification.

## **HAS THERE BEEN ANY PUBLIC CONSULTATION?**

The Department of Health carried out a full Public Consultation in 2014.

18,000 responses were received by the Department and by the Bill team.

# WHY DO DOCTORS HAVE TO STICK TO THE STATUS QUO?

In 1957 Nathan and Barrowclough *Medical Negligence* (Butterworth) expressed the following view still applicable today concerning deviation from accepted modes of practice and the ethics of new treatment research and experimentation:

*Medical men cannot be permitted to experiment on patients: they ought not in general to resort to a new practice or remedy until its efficacy and safety had been sufficiently tested by experience (Slater v Baker and Stapleton) (1767). On the other hand the courts will not press this proposition to a point where it stifles initiative and discourages advances in techniques...a line must be drawn between the reckless experimentation with a new and comparatively untried remedy or technique, and the utilization of a new advance which carries with it wholly unforeseen dangers and difficulties’.*

The legal profession itself has acknowledged from time to time the tendency of this current law to inhibit medical progress.

The point was made by Lady Butler–Sloss, in her capacity as President of the Family Division of the High Court in the case of *Simms v Simms* [2002] FAM.83 where she said at paragraph 48:

*The Bolam test ought not 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.*

Despite occasional remarks from judges that the *Bolam* test should not be applied rigidly and should not be allowed to deter innovation, the reality remains that it is used not just as the starting point, but as



the end point, for most practical purposes in relation to medical negligence litigation.

To give a recent example, in the case of *Murray v NHS Lanarkshire Health Board* [2012] CSOH 123 Outer House, Court of Session, Lady Dorrian says at paragraph 7:

*There was some issue about the nature of the original discussion which led to conservative treatment being embarked upon, but since it is admitted that such treatment is standard practice I need not address the matter in detail.*

Statements such as this cannot but have a powerful deterrent effect on any doctor who is considering striking out along an innovative path.

The present pre-eminence in law of the *standard procedure* provides no inducement to progress.

In *Clark v McLennan* (1983), the significance of departing from an approved mode of practice was treated by the trial judge, Judge Pain, as having the effect of reversing the burden of proof so that once the plaintiff established a deviation the defendant had to disprove an inference of negligence.

In plain English:

*The practitioner who treads the well-worn path will usually be safer, as far as concerns legal liability, than the one who adopts a newly discovered method of treatment (Crawford v Board of Governors of Charing Cross Hospital) (1953).*

The point is that breach of the law means breach of the standard procedure – even if the doctor knows the standard procedure leads only to poor life quality followed by death.

The premise of the Bill is that a better balance has to be struck between therapeutic innovation and therapeutic conservatism. *In*

*Sidaway v Bethlem Royal Hospital Governors*, (1985), Lord Diplock warned of the dangers of so-called defensive medicine:

*Those members of the public who seek medical or surgical aid would be badly served by the adoption of any legal principle that would confine the doctor to some long-established, well-tried method of treatment only, although its past record of success might be small, if he wanted to be confident that he would not run the risk of being held liable in negligence simply because he tried some more modern treatment, and by some unavoidable mischance it failed to heal but did some harm to the patient. This would encourage “defensive medicine” with a vengeance*

As a result of this change in law, medical practitioners will be encouraged rather than discouraged to seek improvement on the *standard procedure*.

## HOW DOES THE BILL CHANGE THE LAW?

It does so by a simple time change – moving the Bolam ‘responsible persons’ test forward – from *after* the event to *before* the event.

The result is that doctors are not obliged to speculate in advance about what might happen in a subsequent trial, and can move forward with confidence safe in the support of a responsible body of medical persons; i.e. the Bolam test brought forward.

This crucial time change removes any uncertainty about what is or is not lawful medical innovation.

## **IS THE BILL NECESSARY? ISN'T THE LAW CLEAR NOW?**

Opponents of the Bill say it is unnecessary because the existing law is clear and they need “more than anecdotes to justify changing the law”<sup>1</sup>.

The 18,000 “anecdotal” responses to the Department for Health public consultation supporting the Bill are apparently not enough evidence for some that the Bill is necessary to make the law clearer.

Recent court cases demonstrate the complexity of law around medical negligence. The very recent case of *McGovern v Sharkey*<sup>2</sup> is a good example. This Note contains extracts from the judgment in this case; the judge’s articulation of the special legal principles to be applied in cases of clinical negligence demonstrate that whatever the law on this area may be, it is neither clear, nor simple nor certain.

The case also illustrates how the present law assumes that every claim will involve the claimant and the defendant each hiring two or more doctors to oppose each other in the witness box. One reason why the law is so uncertain is that it depends on how impressive the two sets of witnesses are at trial.

Which is why at present claimants may be advised to sue whether they have a good case or not, because there is always a chance that they will have a “surprise win”; and key opponents of the Bill –

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<sup>1</sup> “The law currently works and is fair and clear. I am afraid that I require more than a few anecdotes to justify changing the law.” – Suzanne White, Partner, Leigh Day & Co; <http://www.clinicalnegligencelaw.co.uk/2014/07/20/innovate-innovate-saatchi-bill/> – accessed 4.1.15.

<sup>2</sup> [2014] NIQB 117 - <http://www.bailii.org/nie/cases/NIHC/QB/2014/117.html>

notably Leigh Day & Co. – profit from running “no win no fee” cases relying on the uncertainty of the existing law<sup>3</sup>.

The Bill will preserve the existing common law for cases where it is necessary and sufficient. But it will also add a new statutory procedure by which doctors and patients can achieve clarity and certainty at the point of treatment. By following the process set out in the Bill, doctors can be confident that a decision to depart from standard practice will be upheld as responsible by the courts, the regulatory bodies and others.

That will improve certainty for doctors and patients, who can concentrate on exploring sensible avenues towards innovative treatments for rare conditions, and bringing hope to patients where it is reasonable and responsible to do so.

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<sup>3</sup> "Do you take cases on a “no win, no fee” basis? Does that mean I won't have to pay anything at all? Yes we do." - <http://www.leighday.co.uk/Illness-and-injury/Clinical-negligence/FAQs/Costs> - Accessed 4.1.15.

## EXTRACT FROM JUDGMENT IN MCGOVERN V SHARKEY

[42] Disputes about questions of fact depend on the usual burden and standard of proof. However in relation to clinical or professional judgment the position is different. *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118 established that, in determining whether a defendant has fallen below the required standard of care, regard must be shown to responsible medical opinion, and to the fact that reasonable doctors may differ. A practitioner who acts in conformity with an accepted current practice is not negligent "merely because there is a body of opinion which would take a contrary view." In *Hunter v Hanley* 1955 SLT 231 at 217 it was stated that

"In the realm of diagnosis and treatment there is ample scope for genuine difference of opinion and one man clearly is not negligent merely because his conclusion differs from that of other professional men ... The true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care ... "

That test in *Hunter v Hanley*, was approved in *Maynard v West Midlands Regional Health Authority* [1985] 1 All ER 635 and Lord Scarman also stated "It is not enough to show that there is a body of competent professional opinion which considers that theirs was a wrong decision, if there also exists a body of professional opinion, equally competent, which supports the decision as reasonable in the circumstances. ... Differences of opinion and practice exist, and will always exist, in the medical as in other professions. There is seldom any one answer exclusive of all others to problems of professional judgment. A court may prefer one body of opinion to the other, but that is no basis for a conclusion of negligence.

... I have to say that a judge's 'preference' for one body of distinguished professional opinion to another also professionally distinguished is not sufficient to establish negligence in a practitioner whose actions have received the seal of approval of those whose opinions, truthfully expressed, honestly held, were not preferred. If this was the real reason for the judge's finding, he erred in law even though elsewhere in his judgment he stated the law correctly. For in the realm of diagnosis and treatment negligence is not established by preferring one respectable body of professional opinion to another. Failure to exercise the ordinary skill of a doctor (in the appropriate speciality, if he be a specialist) is necessary" (emphasis added).

[43] In *Bolitho (Administratrix of the Estate of Patrick Nigel Bolitho (deceased)) v City and Hackney Health Authority* [1997] 4 All ER 771 it was established that a doctor could be liable for negligence in respect of diagnosis and treatment despite a body of professional opinion sanctioning his conduct where it had not been demonstrated to the judge's satisfaction that the body of opinion relied on was reasonable or responsible. In the vast majority of cases the fact that distinguished experts in the field were of a particular opinion would demonstrate the reasonableness of that opinion. However, in a rare case, if it could be demonstrated that the professional opinion was not capable of withstanding logical analysis, the judge would be entitled to hold that the body of opinion was not reasonable or responsible. Accordingly the final arbiter as to whether there has been professional negligence is the court and not the medical profession. It is for the court to decide whether the requisite logical basis for a defendant's expert medical opinion is absent. The legal question is as to what features particularly characterise an expert medical opinion as one that is "illogical", "irresponsible", and "undefensible". It is clear that merely being a minority view of accepted medical practice does not, of itself, render that view "illogical" or "irrational" in the *Bolitho* sense. However it is suggested that a court would be more ready to find that the body of opinion was not capable of withstanding logical analysis if there was a dubious expert whose professional views existed at the fringe of medical consciousness, see *Khoo v. Gunapathy d/o Muniandy* [2002] 2 S.L.R. 414, at [63]. Another example would be "a residual adherence to out-of-date ideas" which "on examination do not really stand up to analysis" see *Hucks v. Cole* [1993] 4 Med. L.R. 393.

[44] It is however important to consider some limitations to the *Bolitho* test. A practice is illogical if there was a "clear precaution" which ought to have been, but was not taken. In this case the precaution that is suggested is that there ought to have been a diagnostic vitrectomy after one month given the risks of an unidentified tear of the retina and what is suggested was the lack of response to steroid treatment. However if there are risks attached to the precaution, in this case the risks associated with operating on an inflamed eye and the risk that the operation will not resolve the underlying problem, and one body of medical opinion considers that the risks ought to have been taken and the other does not then there is no "clear precaution" but rather a balancing of risks. In such circumstances both sets of expert opinion withstand logical analysis. For the plaintiff the expert opinion being that the risk of an adverse outcome, in that a tear was present in the retina, should have been prevented by taking the precaution of performing the vitrectomy. For the other body of expert opinion on behalf of the defendant, the precaution of performing a vitrectomy would have posed an unacceptable risk of operating upon an inflamed eye where given the diagnosis of ERD the operation would not have achieved a satisfactory outcome. This is merely a different weighing of risk rather than a determination that the defendant's expert

opinion is illogical. The precaution that is being suggested is not a "clear precaution" but rather a precaution which involves a balancing of risks and that is a matter of clinical judgment with a logical basis.

[45] Another feature of applying the Bolitho test is that it introduces a lack of symmetry as between the plaintiff and the defendant's expert evidence. The defendant's expert has only to persuade the court that his views are capable of withstanding logical analysis, but he does not have to satisfy the court that the views of the plaintiff's expert are not capable of withstanding logical analysis. However, the plaintiff's expert has to do both.

[46] If the case is one that involves clinical judgment to which the Bolam test applies, and if the medical practitioner does produce evidence that his practice was supported by a responsible body of medical opinion, then, in the words of Sedley L.J. in *Adams v. Rymney Valley DC* [2000] Lloyd's Rep. P.N. 777, at [41], "the judge or jury have to accept the opinion of a body of responsible practitioners, unless it is unreasonable [in the Bolitho sense]" (emphasis added).

Accordingly in an action involving clinical judgment there is a two-step procedure to determine the question of alleged medical negligence:

- (a) whether the medical practitioner acted in accordance with a practice accepted as proper for an ordinarily competent medical practitioner by a responsible body of medical opinion; and
- (b) if "yes", whether the practice survives Bolitho judicial scrutiny as being "responsible" or "logical".

[47] Questions of fact and the question as to whether there was negligence are not to be conflated. Questions such as whether in the event there was a right retinal tear or hole in December 2006 or whether there was inflammation in the right eye in 2007 or whether there was scleral thickening in the right eye are questions of fact to be determined on the balance of probabilities with the onus of proof being on the plaintiff. The question of clinical and professional judgment as to whether a responsible body of medical opinion would form the view, in say January 2007, that there was a right retinal tear or hole or that there was inflammation in the right eye or that there was scleral thickening in the right eye are all subject to the Bolam test as qualified in Bolitho. In some cases the determination of a question of fact may lead inexorably to a finding that the medical practitioner did not act in conformity with an accepted current practice. In others it may have no such impact. So for instance in this case if there was a factual finding, on the balance of probabilities, that on 26 December 2006 the first defendant was informed that the plaintiff had suffered a sudden and profound loss of vision in his right eye and that the plaintiff's right eye was not assessed or if the plaintiff was not advised to have his right eye assessed that day then inexorably that would lead to a finding that the first defendant had not acted in conformity with an accepted practice. Inexorably because no logical accepted current practice would do or advise anything other than immediate action. However if the factual finding was that the first defendant was informed that the plaintiff had some extremely modest effect on his vision in conjunction with a history that drops had not been taken then (though there was a dispute about this) it might be that to delay an examination until 4 January 2007 and to recommend that the plaintiff use his drops was in conformity with a logical accepted current practice.

## **IS THE BILL REALLY NECESSARY? AREN'T WE INNOVATING NOW?**

On this view, the recommended action is:

*Keep Up The Good Work*

If this view had a logo, it would be a shrug of the shoulders.

Not uncaring. Unable.

There is another view...

*One patient can change the world*

*Professor Alastair Buchan  
Dean of Medical Sciences, Oxford University*

To say that this Bill is necessary is not to say that there is no innovation. Just that we need more of it.



# **IS THE BILL NECESSARY? DO DOCTORS REALLY FEAR LITIGATION?**

The Royal College of Ophthalmologists expresses a common view:

*“Without unequivocal GMC and NICE support, ophthalmologists are understandably concerned that they may be assuming unacceptable personal liability by using an unlicensed drug when a licensed alternative exists”*

*“Consequently, patients may not be getting treatment when they need it and not getting the best results”*

## WHY DO WE NEED THIS BILL NOW?

The law of medical negligence hasn't changed for decades and medical innovations have still been made. So why is the Bill suddenly so urgent?

The law may not have changed much, but society has. We are more informed, less deferential and more litigious.

The number of lawsuits filed against the NHS has doubled in five years. Last year's pay-out was £1.2bn, also doubled in 5 years. The Treasury provision for claims against the NHS has now reached £26.1bn, up £3bn in one year.

So doctors are increasingly frightened of being sued, and even less likely to feel able to innovate.

“Risk-management” processes within the NHS and insurers' policies designed to stem the rise of litigation can only increase this anti-innovative pressure.

Growing concern about litigation leads to growing bias against innovation.

On 4<sup>th</sup> December 2014, The Parliamentary Under-Secretary of State, Department of Health (Earl Howe) said:

*As at 31 March 2014, the National Health Service Legislation Authority (NHS LA) estimates that it has potential liabilities of £26.1bn, of which £25.7bn relates to medical negligence. This is an increase of £3.1bn from 31 March 2013 which can mainly be attributed to a continual rise in clinical negligence claims over recent years. There are a number of factors driving this increase, including the rise in the number of patients cared for and in the complexity of their care; and the general rise in litigation across a number of sectors, including the NHS driven in part by “no win no fee” agreements.*

## **ISN'T THE BILL RECKLESS?**

The Secretary of State for Health asked Sir Bruce Keogh, the Medical Director of the NHS, to advise on adequate safeguards for patient safety.

He recommended five amendments to the Bill, which were carried in the House of Lords at Committee Stage during 18 months scrutiny of the Bill by some of Britain's leading doctors, scientists and judges.

## HASN'T THERE BEEN SOME FIERCE OPPOSITION TO THE BILL?

Be careful who your friends are...

The most vociferous critic of the Medical Innovation Bill has been the medical negligence law firm, Leigh Day, which specialises in law suits against the NHS.

This firm was recently denounced by the Secretary of State for Defence in the House of Commons for “*shameful conduct*” during the *Al Sweady* inquiry into allegations against the British Army.

The judge in that Inquiry denounced the firm for “*deliberate lies*” and “*reckless speculation*”.

The Bill also violently offends Dr Peedel, the Leader of the National Health Action Party, who says:

*“It’s time that people listened to the experts”*

This doctor sounds like Lady Ludlow in Elizabeth Gaskell’s novel, *Cranford*. She objected to the education of poor people on the grounds that:

*“it is becoming common for the lowest class to have some education ... the proper order of the world will be undone.”*

Dr Peedel may not have realised that the age of deference is over – not just in medicine but in politics and all walks of life.

The Bill would also be seen as pointless by Dr Richard Smith, now famous for his view that cancer research is:

*“A waste of money, because cancer is the best way to die”*

## **DOESN'T THE BMA OPPOSE THE BILL?**

It does, on grounds of “patient safety”.

It also opposes the 7 day NHS for the same reason.

It also opposed the creation of the NHS in 1946.

## WHY DOES HMG SUPPORT THE BILL?

The Regius Professor of Medicine at Oxford, Professor Sir John Bell says:

*There will be no cure for cancer until real doctors with real patients in real hospitals can attempt an innovation*

The Minister for Life Sciences, George Freeman, says:

*Who wants to be better for longer? One thing's for sure – I do. I think you do too. If any of us got that diagnosis, we'd want to know we had access to the latest drugs. The Saatchi Bill – helps make sure we do.*

The Secretary of State for Health says:

*We must create a climate where clinical pioneers have the freedom to make breakthroughs in treatment*

The Prime Minister says his vision of the NHS is:

*Every clinician a researcher, every willing patient a research patient*

## **HOW WILL WE KEEP TRACK OF INNOVATIONS?**

The House of Lords at Third Reading passed an Amendment by the Labour Front Bench and other Peers, including Lord Saatchi, to establish a Register of innovations which take place under the Bill.

This Register was considered essential by all sides of the House, both to advance scientific progress through the dissemination of knowledge to the global medical community; and to provide full public transparency and disclosure necessary for patient safety.

HMG is committed to the creation of such a Register.

A number of individuals and organisations said that doubts that they had about the utility of the Bill are removed by the emergence from it of this new and exciting initiative in data collection and sharing. One of the reasons for the Bill is that for “rare” conditions (the majority of cancer deaths) there is a lack of published evidence on which to rely when determining what treatments to try. Randomized trials cannot be run and results cannot be published with only a handful of precisely similar cases arising in a given year.

This database will be a significant development in the field of medical practice.

Once the regulatory requirements are put in place, it will be compulsory for doctors relying on the Bill to register their innovation, and it will quickly become effectively compulsory for all doctors when innovating to comply with regulatory best practice as to registration and as to recording their results. Hospital protocols will ensure that doctors are required to keep the developing database fully up-to-date. In its turn, it will then inform both future innovation decisions and, perhaps even more importantly, decisions as to the

undertaking of new research projects, including fully randomized trials.

As the Secretary of State for Health says:

*“Improved accountability is the only way to avoid untold human tragedy”*



## **ISN'T THE PROBLEM THE CULTURE? CAN/SHOULD LEGISLATION BE USED TO CHANGE CULTURE AND ATTITUDES?**

Any efforts to weaken the dominance of the 'accepted mode of practice' by encouraging a culture-change towards innovation are unlikely to succeed in the current judicial climate.

Such a risk-benefit culture, under present law, can only be met by persuading the courts that the opinion of the defence experts is not as a matter of fact one held by a responsible body of opinion or alternatively that it is not a proper and responsible one to hold.

## ISN'T THIS BILL A SLIPPERY SLOPE?

By releasing doctors from the requirement to conform with standard procedure, won't this Bill encourage recklessness?

All agree that optimal care is evidence-based care. Therefore, *evidence-based medicine is standard procedure* for the protection of patients.

But cancer is the least *evidence-based* disease of all. There is great uncertainty: either the evidence does not exist, or, if it does, it is not clear what it means.

Therefore, innovation is more appropriate in cancer treatment, and the consequences of not innovating are greater – poor life quality followed by death. But the present law leaves much uncertainty about what is *best practice* in innovation. Present law makes the status quo the only safe option, and gives clinicians no confidence about how to pursue *responsible innovation*.

By codifying proper practice in innovation, the Bill does more to discourage irresponsible innovation than the existing law. Patients' lives are put at risk as much by failure to innovate as by irresponsible innovation. This Bill aims to safeguard patients against both. A doctor who innovates recklessly or irresponsibly will be judged by reference to the criteria and processes set out in the Bill and it will be easier than at present to demonstrate that he or she has failed to comply with best practice.

By applying the same process, the doctor who is presently deterred from innovating by the fear of litigation will know that if he or she rigorously applies the criteria and processes set out in the Bill, in accordance with General Medical Council guidance, then he or she is taking a robust and defensible approach that ought to withstand future challenge.

The present state of the law exposes patients to harmful inaction as a result of the uncertainties of litigation, as well as to irresponsible innovation, in the absence of clear statutory criteria to determine how decisions to innovate should be taken.

## **HOW DOES THE BILL PROTECT PATIENTS AGAINST RECKLESSNESS?**

The Bill strengthens the ability of the medical profession to prevent irresponsible innovation and to control the manner in which responsible decisions to innovate are taken.

At present, there is no “gold-standard” of “best practice” by which to determine whether decisions to innovate have been taken responsibly or not. Neither the profession, nor the regulatory bodies nor the courts have a standard set of criteria and tests to apply in judging whether or not decisions to innovate were taken appropriately.

This may deter doctors from deciding to innovate, since they cannot be sure by reference to which standards and processes the decision will be tested should it come to be challenged later. But it may also encourage irresponsible innovation by doctors who can argue that in making a unilateral decision they were applying an appropriate clinical judgement, there being no statutory formulation of best practice against which to test their assertion.

The Bill, therefore, gives statutory force to the best practice of the medical profession as expressed in a consensus of opinion taken from a wide range of respected medical practitioners throughout the United Kingdom.

While the criteria and processes as set out in the Bill are necessarily and expressly not exhaustive, they set the common denominator for decisions to innovate. They set out the basic criteria to be considered, along with any others that are necessary or appropriate in the circumstances of a case. And they also give statutory examples of the kinds of process that should be applied in forming a decision to innovate.

This all gives the courts a clear statutory yardstick by which to measure whether a decision was taken appropriately and responsibly or not, and it thereby for the first time introduces an effective deterrent against the kind of irresponsible innovation that will not stand up to scrutiny by reference to the Bill's new statutory criteria.

# **WHAT ARE THE *WHO* EBOLA GUIDELINES ON THE ETHICS OF DEPARTURE FROM STANDARD PRACTICE?**

The same as the Bill.

<http://www.telegraph.co.uk/news/health/11054104/If-it-works-for-Ebola-it-can-work-for-cancer.html>

## **ISN'T THE REAL PROBLEM FUNDING?**

Doesn't the Bill fail to address the main pressure against innovation; i.e. funding?

Commissioning Bodies take the view that they will only pay for treatment if it is known to be effective. Therefore, innovation is not attractive to funders, whose aim is to drive down the cost of care.

In this way, aren't funding decisions anti-innovative, and clinicians' desire to innovate frustrated?

Agreed.

The Bill does not affect UK GDP, the % of GDP devoted to healthcare, or the % of health expenditure allocated to innovation.

## **DOES THE BILL OBLIGE THE DOCTOR TO 'INNOVATE'?**

No.

The Bill does not require any doctor to do anything.

If the doctor is confident that any proposed innovation will be supported in a subsequent trial, the doctor can continue to rely on the existing common law “Bolam Test”.

The Bill has no impact on the existing common law.

But if the doctor has any uncertainty about how to legally depart from standard procedure, he/she can only be protected by this Bill provided he follows its statutory stringent procedures and safeguards.



## **DOES THE BILL HAVE FINANCIAL IMPLICATIONS?**

Nothing in the Bill requires individual doctors, or an NHS trust, or any other medical body, to incur expenditure that they would not otherwise incur.

It is true that in some instances the encouragement of innovation may indirectly lead to an increased expenditure within NHS bodies, where a new process or treatment costs more than the process or treatment that would be applied in accordance with existing standard practice.

It would be wrong, however, to assume that this will always be the case: a new treatment for a condition could well involve the use of a drug or process already commonplace for other conditions, and which may well be cheaper than the standard treatment for that condition. Equally, it is important to recognise that the Bill supports any kind of innovation, which could amount to a calculated decision not to act at all: as, for example, in the case of a decision that invasive surgery to remove a tumour is more likely to lead to its spreading than to leave it alone.

There is therefore no reason to assume that the Bill will lead to increased costs for the NHS overall. The question of how much should be allocated to particular NHS budgets, and how decisions on allocation within those budgets should be made, is entirely unaffected by the provisions of the Bill.

## **CAN'T DOCTORS INNOVATE NOW IF THEY HAVE PATIENT CONSENT?**

Doesn't the informed consent of the patient provide immunity from prosecution?

That is a misunderstanding of current law. It does not provide immunity from prosecution for negligence.

It is for the clinical judgement of the doctor to take responsibility, not the patient.

Some doctors believe:

*You can innovate with consent*

Other doctors think:

*No deviation is allowed, with or without consent*

Conclusion: the problem with current law is uncertainty.

This Bill corrects that problem.

## ISN'T CANCER SCIENCE ADVANCING?

Cancer is the No.1 cause of the untimely death of British citizens. 165,000 this year. 165,000 last year. And 165,000 next year. It would take a fleet of the biggest JCBs to dig the mass grave for all these people.

All these cancer deaths are wasted lives. Scientific knowledge does not advance by 1cm as a result of all these deaths, because the current law requires that the deceased receive only the standard procedure—the endless repetition of a failed experiment. In this way, the current law is a barrier to scientific progress. It defines medical negligence as deviation from standard procedure. Any deviation from standard procedure by a doctor could currently result in a verdict of guilt for medical negligence.

However, as innovation is deviation, non-deviation is non-innovation.

Sticking to the status quo does not meet Professor Popper's *Logic of Scientific Discovery* - refutation by application. No application. No refutation. No science.

This is at least one reason why there is no cure for cancer.

The latest scientific view on current state of cancer diagnosis and treatment comes from America's distinguished Johns Hopkins University. It says:

*Cancer is just bad luck*

Cancer has not yet found its Newton.

## **WHO IS THIS BILL AGAINST?**

The Bill is not a criticism of anyone, for anything.

Everyone is doing everything by their own best lights to serve the community.

It is against an attitude of mind, a culture driven by fear of litigation, in which the only safe route is the well-worn path of the status quo.

## AREN'T CLINICAL TRIALS THE ROUTE TO INNOVATION?

Perhaps, but so few patients are involved in clinical trials of new treatments. 94.4% of cancer patients receive only the standard procedure.

The House of Lords Library reported on this subject on 11<sup>th</sup> November 2014:

*“We do not hold completely accurate data for these questions.*

*I am afraid that it has not been possible to obtain statistics from readily available published sources on the number of cancer patients diagnosed in the last three years who have been admitted into clinical trials.*

*Cancer Research UK publish collections of statistics on their website, but these focus on incidence, mortality, survival, types of cancer, causes of cancer, and characteristics of people diagnosed with cancer (such as gender, ethnicity or socioeconomic group). I could not find any statistics amongst their collection giving detailed breakdowns of participants in clinical research.*

*In the UK, for the equivalent type of trials which are the NCRI CSG portfolio interventional trials, the number recruited annually is around **5.6% of the UK cancer incidence.***

*Recent changes to the NHS including changes to treatment commissioning, and the funding of some cancer drugs through a different system (the National Cancer Drugs Fund), together with financial pressures on NHS England and the high cost of many new cancer drugs, together mean that the funding of treatment for trial patients is increasingly under pressure.*

*I understand that this information doesn't exactly answer your questions but I hope it is helpful in some way. The National Cancer Registration Service would like to collect more systematically information on trials in the future and this is an area of work we are currently exploring."*

**Sir Austin Bradford Hill, the forefather of the randomised controlled trial said:**

*"Any belief that the controlled trial is the only way [to study therapeutic efficacy would mean not that the pendulum had swung too far, but that it had come right off its hook."*

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## APPENDIX - QUOTES

*“It is a tragic indictment of modern medicine that innovation is too often jettisoned in favour of the status quo for fear of legal action. Defensive medicine is at the heart of so much clinical practice today, but the Bill – if accepted into law – would deftly excise this, leading the way for doctors to feel free to strive for medical advancement.”*

Dr Max Pemberton writing in the Daily Telegraph.

*“..As yet there is no formally established quality assurance framework for proactive evaluation of innovative therapy in respect of its applicability, or suitability, prior to delivery. The existing pathways tend to be post hoc review through litigation, regulatory or disciplinary processes, or local procedures such as root cause analysis, serious incident review, or clinical audit. These ‘after the event’ mechanisms are unsatisfactory, since they are usually predicated on some form of adverse outcome. “*

Jo Samanta, Principal Lecturer at Leicester De Montfort Law School, specializing in medical ethics.

*“The Bill seeks to support doctors who endeavour to act in the best interest of their patients without the fear from litigation. It deters from irresponsible experimentation but encourages a much needed attitude change of innovation in the provision of care to cancer patients.”*

Professor Ahmed Ashour Ahmed, Professor of  
Gynaecological Oncology, Consultant  
Gynaecological Oncology Surgeon and Scientist,  
University of Oxford

*“At the moment, the doctor’s hands are tied – by concerns about professional reputation and potential negligence claims. That needs to change.”*

*“It is nonsense to suggest that the culture of litigation that now exists does not have a dampening effect on doctors. It is something that hangs over them”*

The Former Lord Chief Justice, former Master of the Rolls, Lord Woolf

*“We all believe in evidence-based medicine. But in cancer there either is no evidence, or if there is, it is not clear what it means”*

Professor Stephen Kennedy, Nuffield Department of  
Obstetrics & Gynaecology, University of Oxford



*“In our case the risk of doing nothing is not nothing, the risk of doing nothing is fatal. Fatal every single time. You never survive this. What we are not willing to do is assume the risk of doing nothing”*

Alex Smith runs Harrisons Fund, a charity that funds research into Duchenne Muscular Dystrophy – a 100% fatal condition with no cure.

*‘There will never be enough trials for the less common diseases. So when patients are in a situation with “nowhere else to go”, they need to be able to try treatments that might work, based upon the best judgment of their medical advisors. We need to allow them to try such new drugs that may be applicable and collect that experience to inform the next generation of trials. The Saatchi Bill would do this, by protecting individual doctors who try new, licensed but untrials treatments, on patients who have consented to such treatment outside of a formal trial.’*

Professor David Walker – Professor of Pediatric  
Oncology Faculty of Medicine Health Sciences,  
University of Nottingham.

*“This doesn’t mean that doctors would have free rein to experiment on a patient – they would still be bound by professional guidance and their duty of care would remain to their patient. Nor would it mean that the Bill would become a substitute for proper clinical trials.*

*“But what it does mean is that, in cases where the evidence is shaky, wanting or not yet clear, the Bill would set out a code by which doctors could try alternatives. It would provide a legal framework by which doctors, in discussion with their patients, could try off-label drugs or a device, treatment or intervention that might have some clinical data supporting it, but has yet to be fully proven.”*

Dr Max Pemberton, The Daily Telegraph

*“I received a briefing from the BMA which said that there was no evidence to support such things. Of course there was no evidence; that is the whole point. We have to find ways to generate evidence. I strongly support the Bill.*

Lord Gus O’Donnell – former Cabinet Secretary

*“There have been major advances in some areas, but in others it has been agonisingly slow, and we are still left with treatments that are extremely blunt instruments. Take, for example, bone cancer. Treatment frequently involves amputation and extremely toxic chemotherapy. Lord Saatchi’s Bill draws attention to the need to innovate when the prognosis of an individual patient is poor.”*

Professor Andy Hall, Associate Dean of  
Translational Research at Newcastle University

*“Once Chloe only had six months left to live, how could any radical potential new treatment have been defined as too risky or too dangerous. These words risky, dangerous, are utterly meaningless in this context. What if doctors tried something different, something new, something promising? Chloe might well have died anyway, and I accept that, but surely what she would have left behind would have been more clinically valuable for other children, for other teenagers.”*

Debbie Binner, mother and campaigner who lost her 18-year-old daughter to Ewings Sarcoma.

*“Much of this problem has been driven by ‘no win, no fee’ lawyers. They have been increasing fees to cover those cases they lose as well as adding on extra costs, known as ‘success fees’ when they win. In many cases these far outweigh any settlement paid to the claimant. For example, in one of the worst cases costs spiralled to almost £93,000 whilst the claimant only got £2,000.”*

Steve Barclay MP, as member of the Public  
Accounts Committee

*Protect the patient. Nurture the innovator.*

Professor Norman Williams, President of the Royal  
College of Surgeons



*“...this is a vitally important Bill to drive forward the practicalities of innovation in clinical practice. I hope that it will also drive forward a positive culture of putting innovation at the heart of all clinical thinking.”*

Lord Kakkar, Professor of Surgery at University College in London and a member of the General Medical Council

*“Departing from what is regarded as established practice or the standard of care leaves a doctor open to an action for negligence”*

*“The Saatchi Bill will allow responsible innovation.”*

Sir Michael Rawlins, Chair of Medicines and Healthcare Products Regulatory Agency; Founder Chairman of the National Institute for Health and Clinical Excellence (NICE) and President of the Royal Society of Medicine.

*An extensive risk management programme...most healthcare organisations are regularly assessed against the NHSLA Risk Management Standard.*

The NHS Litigation Authority, which has been formed to deal with the tidal wave of medical litigation, on doctors' awareness of the risk of lawsuits.