

MEDICAL INNOVATION BILL

SESSION 2014-15

BRIEFING NOTE

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FOREWORD

Session 2014-15 will be the third consecutive Session in which I have introduced my Medical Innovation Bill.

In the first Session there was no time to do more than have one debate in the Lords. In the second Session we achieved Government support for the Bill, as set out in the Written Ministerial Statement of 22nd November 2013.

This Session I hope that we will achieve Royal Assent, with your help.

My Bill is about ensuring that every patient knows that everything is being done that can reasonably be done to give him or her a chance of life. Patients demand that; and the health service must be empowered to deliver.

At present, when an innovative treatment is suggested, a red light flashes in front of the doctor's eyes: step away from the path of standard treatment and you risk litigation or disciplinary proceedings – do nothing, and you are safe. This light by no means stops all innovation but it reinforces a culture of fear and defensive medicine in the NHS, which is growing as a result of an increasingly risk-averse NHS. In turn, many doctors feel compelled to stick to the well-worn path of standardised treatment.

This is right when those standard treatments work. It is not acceptable in cases where standard treatments are known only to lead to the death of the patient. In these cases, a doctor and their patient are together entitled to try something new.

My Bill replaces the red light with an amber light, that says “proceed with caution”. This Bill will stop quacks more effectively than the law does at present; but it will give responsible doctors who want to innovate the ability to innovate responsibly, with clarity and certainty that the law will support them.

You can read more about how my Bill does that in this briefing note. Please read on; please become part of the debate about the Bill; and please help us all to empower patients and doctors as soon as possible. This Bill is urgent – because every life matters, and too many have been wasted.

Thank you,

Maurice Saatchi

WHAT DOES THE BILL DO?

The Bill has one main operative provision: it declares that it is not negligent for a doctor to innovate if he or she follows an accountable and transparent system when deciding whether and how to innovate.

In particular, if there is a Multi-Disciplinary Team in the doctor's hospital, that team must be involved in the decision. And a doctor must always inform his or her Responsible Officer of any proposed innovation, so that it can form part of the responsible officer's general oversight functions. Where there is no multi-disciplinary team, or where it does not include relevant expertise, a doctor will be able to find other ways of including enough relevant colleagues in the decision-making process to satisfy the requirements of an accountable and transparent system. If the doctor cannot do so, s/he will not be covered by the Bill.

The Bill includes mention of multi-disciplinary teams and responsible officers as specific components of an accountable and transparent system, but apart from that the medical profession will be left to determine best practice as to what an accountable and transparent system should be. Doctors are the right people to regulate their own best practice.

The stated purpose of the Bill (which the courts will consider if they are required to pronounce on the meaning and effect of the Bill) is to encourage responsible innovation and to discourage reckless innovation.

The Bill expressly preserves the existing common law (the *Bolam* and *Bolitho* test). That law says that innovation is not negligent if it is supported by a responsible body of medical opinion based on good science. The problem with the common law test is that it is applied after the event – in court, by marshalling opposing teams of doctors. The Bill allows doctors to be certain before they innovate that they have done it in a manner that will be supported and protected by the courts.

The Bill does not change the existing law that requires patients to consent to treatment. The purpose of the Bill is to empower patients to demand that every possible route should be tried to prolong their life and to improve its quality.

It will not allow anyone to be subjected to treatment without informed consent. Nor will it allow patients to be used as guinea pigs: the Bill expressly states that it is only about treatment that the doctor, supported by suitably qualified medical peers, is satisfied is in the patient's best interests.

More details about how the Bill will work and what it means can be found in the Explanatory Notes at Annex B and in the Frequently Asked Questions at Annex H.

WHO WANTS THE BILL?

Patients

Of the more than 18,000 responses to the Department for Health's Consultation in 2014 supporting the Bill, many thousand were from patients, determined that they should be empowered to ask that their doctors try everything, including innovative treatments where standard procedure holds out no realistic hope of life or quality of life. Illustrative patients' responses received are shown at Annex C.

Doctors

Many of those who responded to the consultation supporting the Bill are doctors, determined that the law should support responsible innovation and not deter it. Illustrative doctors' responses are shown at Annex D.

The Medical Profession

Some key organisations responded to the consultation supporting the Bill. Their responses are shown at Annex E.

The Government

The Secretary of State for Health wrote in November 2013:

“The Medical Innovation (No 2) Bill ... correctly identifies the threat of litigation as one such barrier. Their hope is that legislation to clarify when medical innovation is responsible will reduce the risks of clinical negligence claims. ... Their cause is a noble one, which has my wholehearted support. ... So the government commits today to carrying out a full consultation ... and ... will seek to legislate at the earliest opportunity, subject to the results of the consultation.”

The full text of the Written Ministerial Statement is at Annex F.

Senior Parliamentarians

Support for the Bill within the House of Lords has come from some of the most senior former judges in the country, [including the former Lord Chief Justice Lord Woolf, the former Lord Chancellor Lord Mackay of Clashfern and the former President of the Family Division Lady Butler-Sloss]. The Bill is also supported by some of the most distinguished medical peers including General Medical Council Member Professor Lord Kakkar.

WHO'S STILL TO BE CONVINCED?

Not every response to the Department for Health consultation supported the Bill. Some individuals and organisations expressed concerns. However, following the consultation, we believe that the concerns have been met and that this new, robust draft will find favour from many who harboured doubts.

The two most frequently expressed concerns were: (a) that there is insufficient evidence that the Bill is needed; and (b) that the Bill may encourage quackery.

As to the first, the consultation itself established the evidence-base for the Bill more effectively than ever before. As illustrated in Annexes C and D, thousands of patients and doctors have come forward to provide evidence that the law in its present form acts as a deterrent to responsible innovation.

As to the second, consultees raised many detailed concerns about the wording of the Bill, and how its details might appear to support quackery and to distract doctors from focusing on evidence-based medicine, which we all agree is the best form of medicine where evidence is available. Many of these details did not feature in my original Bill, but formed part of the draft attached to the Department's Consultation Paper.

To be clear, the new draft makes it an explicit requirement that the doctor wishing to offer an innovative treatment must consult with suitably qualified medical experts. In short, a doctor could not rely on the Bill without peer consensus.

The Bill for Session 2014-15 is set out in Annex A: it is the shortest of all the versions of the Bill so far, and it reduces the Bill to its essential message – innovate by following a responsible process with the support of a responsible body of medical opinion, and you can be confident that the law will support you; innovate in a reckless manner without the support of your colleagues, and the law will not protect you.

As a result of these changes, we hope that all or most of the individuals and organisations who expressed concerns about the Bill during the consultation process will now be reassured that their concerns have been met. We look forward to continuing the debate about the Bill during its passage through Parliament.

THE LAW BEFORE AND AFTER

The leading case in this area is still that of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582; in Mr Justice McNair's judgment in that case he said at page 258:

"The test is the standard of the ordinary skilled man exercising and professing to have that special skill. If a surgeon fails to measure up to that standard in any respect ..., he has been negligent ...".

The result of this is that a doctor deciding how to treat a particular case starts with the knowledge that as soon as he or she moves away from existing and established standards within the profession, there is an automatic and serious risk that he or she will be found guilty of negligence if the treatment is less successful than hoped.

As Lord Browne-Wilkinson said in the House of Lords in the case of *Bolitho v City and Hackney Health Authority* [1998] AC 232:

"The locus classicus of the test for the standard of care required of a doctor or any other person professing some skill or competence is the direction to the jury given by Mr Justice McNair in *Bolam v Friern Hospital Management Committee* ... I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art ... Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion which take a contrary view".

The *Bolam* test is sometimes turned around and becomes the proposition that it is very difficult to prove negligence if the doctor can show that he or she did what others would have done in the same position as a result of established practice.

Illustration of how the Bill would work in practice

Dr A is the consultant in charge of treating Patient B for a heart condition. At a meeting with Patient B, his wife mentions having seen mention in the press of a new kind of non-surgical treatment that is thought to be more effective than anything presently available and that might make surgery (with its attendant risks) unnecessary. Dr A agrees to investigate.

On investigation, Dr A finds that the new treatment has not been tested in clinical trials and is not the subject of any published medical research in relation to heart disease. But she recalls reading a paper on the use of a similar treatment for

cancer, based on which she thinks there are good reasons why it might be an effective treatment for heart disease in certain circumstances.

At present, Dr A may feel that the safest course is simply to report back to Patient B and his wife that the new treatment is not the subject of published research, and that she is therefore unable to advise anything other than the standard surgical procedure. She will be worried that if she applies the new non-surgical treatment and Patient B dies earlier than would be expected statistically with surgical intervention, disciplinary or legal proceedings may be taken against her, perhaps by another member of Patient B's family. She may be worried that should that happen, she would have to find a panel of experts "in favour" of the new treatment to oppose to a panel in favour of "standard treatment" produced by the claimant or complainant, with a necessarily uncertain outcome.

Under the Bill, if Dr A were instinctively impressed by the arguments in favour of the new treatment, she would be able to use the Bill as, in effect, statutory support describing a paradigm process for her decision. In particular—

She will ask herself why any research in relation to the cancer treatment has not been replicated for heart disease (for which a range of answers might be possible, perhaps based on timing or frequency of Patient B's exact condition).

She will also consider the risks of the treatment proposed, for which purpose she may be able to draw on adverse-reaction or other data in relation to the cancer treatment.

She will consider how urgent the surgical intervention is and whether delay pending investigation of the possible effects of the new treatment might make it impossible to carry out the surgery if it then became indicated.

She will consider the strength of Patient B's feelings and those expressed by his wife; and she will build into the process by which she usually obtains informed consent an appraisal of the media piece that they originally found, and an analysis of their hopes and expectations, from a medical perspective.

Dr A will then devise a system for the taking of her decision whether to apply the new treatment, based on the factors explored above. Depending on her position within a clinical team within a hospital, she will apply an appropriate process for consulting her seniors (if any). If she is the most senior and experienced doctor in her hospital, she may decide to hold minuted telephone consultations with one or more respected colleagues in other hospitals, noting their agreement or disagreement with her instinctive inclination towards or against administering the new treatment. Her hospital may have put in place a system for cascading proposals to other disciplines and expertise within the hospital, in which case she will comply with that procedure.

Dr A will be able to contact her insurers and explain to them that she proposes to depart from the standard treatment in Patient B's case; she will be able to explain that she is following the Bill's procedure, and she will be able to provide them with written records showing how the decision is being taken and the considerations on which it is based. She will not have to use any special form for those records, and she will be able to use the notes that, as a responsible clinician, she would have expected to take in any event. (As experience of operating under the Bill develops it is possible that a degree of standardisation of documentation might emerge; but there is no intention or expectation that it will be more lengthy or more demanding than that indicated by best practice at present.)

Finally, Dr A will return to Patient B and explain her decision. They will talk it through, and a signed copy of the audit trail will form an Annex to the informed consent form which Patient B will be asked to sign in the normal course of events before treatment (whether standard surgical intervention or the new form of treatment) is commenced. She will be confident that, should the treatment be challenged later in the light of Patient B's experience, she will be able to show the courts that her decision was based on the statutory codification of clinical best-practice; and that the courts will review her decision in the light of how and why it was taken, and not simply by examining opposed ranks of experts commissioned by the two sides after the event. (As experience of the Bill develops, she may also become confident that lawyers are less likely than at present to recommend litigation in a case where the statutory process has been rigorously followed.)

CONSULTATION RESPONSE ANALYSIS

Introduction:

The Secretary of State for Health initiated the consultation in his Parliamentary statement of 22 November 2013: <http://www.parliament.uk/documents/commons-vote-office/November-2013/22-Nov-2013/4.HEALTH-Medical-Innovation-Bill.pdf>

The Department of Health (DoH) ran the consultation which began on February 27th and closed on April 25th 2014.

Following several meetings with the DoH it was agreed we – the DoH and the Medical Innovation Team – would work together to ensure the public could respond to the consultation using a choice of channels. For example the DoH designed an online platform, hosted on their website, to gather responses. They also initiated discussions on doctor.net, encouraged respondents to email, write and attend a host of public meets hosted by the DoH together with the Medical Innovation Team. The questions placed on the DoH website was only one of many options which the DoH made available to respondents. This is standard DoH procedure.

As part of this, and with the support and agreement of the DoH, the Medical Innovation Bill team encouraged as many people to respond as possible in order to drive a robust data set on which to base a clear recommendation to the Secretary of State.

In conjunction with the DoH, the Bill team accordingly opened numerous response channels to stakeholders by running a media and social media publicity campaign, predominantly but not exclusively, with the Daily Telegraph as a media partner. (The Bill team did not pay the Telegraph, this was an editorial decision taken independently by the Telegraph).

With agreement from the DoH the Bill team designed an embeddable web form that enabled submissions, both positive and negative, to the consultation via the official DoH consultation email address. Submissions were sent directly and simultaneously to the DoH official email and the Saatchi Bill team database without any interference from the Bill team. The web form was embedded on our own website, The Telegraph online and was hosted on the websites of numerous patient groups, rare disease charities and supportive individuals.

We also ran a change.org petition enabling us to solicit responses from an even wider audience.

Analysis:

At the outset, the DoH team stated that a good response would be anything over 600 responses.

The total number of unique responses generated by the Medical Innovation Bill team official consultation channels was 18,535. Of those 18,502 were in favour of the Bill and only 33 against.

To this must be added 170 responses generated via DoH official consultation activity channels (detailed above).

The responses can be broadly divided into three categories.

1. The thousands of patients and relatives, individual doctors, institutions and other stakeholders who overwhelmingly support the Bill.
2. A minority, significant nonetheless, of individuals and institutions who support the principles of the original draft Bill, but do not feel those principles are met nor expressed adequately within the previous draft.
3. A smaller minority opposed to the Bill, comprising in part, but not exclusively, of medical negligence lawyers, individuals opposed to quackery and some institutions.

Why Patients Support the Bill

The support from patients is straightforward and centres around patients and relatives of patients, often with incurable diseases for which standard treatments are known not to work and for which there is a limited evidence base to develop new and effective treatments.

It is worth noting that the majority of cancer deaths (around 52 per cent) are a result of cancers outside the big four – that is, breast, bowel, lung and prostate. (Source: Cancer52.org). For such rare cancers, there is little research and consequently little evidence on which to base effective new treatments.

This is in part the case because it is difficult to recruit enough patients for trials and because there is no real market for any drugs that may be developed as a result of those trials.

Therefore the evidence base for many rarer diseases remains patchy and does not drive new, effective and innovative treatments.

Patients with rare diseases understand this very well. And while they agree that randomised trials driving new and robust evidence is the gold standard of medical science, randomised trials do not fit so well for the rare disease profile.

This is why they support the Bill – because they want their doctor to be secure and safe in trying new treatments on them, outside of the trial straitjacket, which may prolong or save their lives. They also wish for their lives – and deaths – to mean something. That is, they wish for their treatment to add to the sum total of medical knowledge. They wish in death to leave a legacy, rather as an organ donor does.

This is in stark contradiction to those specific cases where the standard treatment is known to lead only to the death of the patient – the meaningless repetition of a failed experiment which does not add to scientific knowledge and yet still leads to the certain death of the patient.

Why Doctors Support the Bill

Many doctors responded to the consultation. Broadly they supported the contention that there is a growing cultural lag on innovation within the NHS as a result, in part of increasing litigation against NHS trusts by patients. In the past financial year the total sum of monies paid out to litigants reached £1.2bn.

While the reality is that the vast majority of cases do not relate to failed and negligent attempts to innovate (the lion's share of pay-outs relates to lifetime care for negligence in regards to childbirth), doctors have a fear of litigation which can act as a barrier to innovation.

Add to this the post-Shipman settlement and tighter and centralising influence of NICE, it is no wonder that in many cases, doctors will prefer to stick to the well-worn path of standard care – even when, in some cases, it is known to be largely ineffective.

In short, there is a culture of conservatism which stifles innovation. Doctors responding to the consultation wish to break free from the shackles of defensive medicine – carefully and appropriately and in the interests of their patients.

Concerns and answers

Concerns expressed were of two types. The first was that there was no evidence that a Bill of this nature was needed, and that innovation was happening already and innovation was already protected in law (under the Bolam-Bolitho test which allows a doctor to defend innovative treatment if a panel of experts in court also support that innovation).

However, evidence collected from the public consultation strongly suggests otherwise. Many doctors told us that they fear moving away from standard procedures. Whether this fear is well-founded or not, it is clear that there is uncertainty in the medical profession and this Bill will remedy this by offering clarity and protection in advance of any innovative treatment.

As Prof Mike Rawlins, President, Royal Society of Medicine and former chair of NICE, put it: “A number of legal authorities have pointed out that departing from what is regarded as “established practice” or “the standard of care” leaves a doctor open to an action for negligence. The Medical Innovation Bill attempts to rectify this situation.

“I believe that the use of the provisions in the draft Medical Innovation Bill offer benefits to patients – especially those with rarer diseases – as well as to the furtherance of medical science. ”

The evidence also suggests there is confusion in the medical profession as regards to the law. Many doctors fear moving away from standard procedures, others say the law protects them sufficiently already. The conclusion that can be drawn is that there is a distinct lack of understanding of the Bolam-Bolitho defence and the case law around medical negligence.

This being so, the Bill will clarify and simplify once and for all the law by statute. Crucially, doctors now face the possibility of trial for negligence if they innovate. The Medical Innovation Bill means that those that avail themselves of it are protected *in advance* of the innovative treatment. This means they can proceed with clarity and confidence.

Thus, the Bill removes the very fear – real or imagined – of a claim for medical negligence should an innovative treatment fail. It gives the doctor confidence to proceed in advance knowing that a claim will not be made.

This, in turn, will help change the culture of conservatism in medical science.

The second concern expressed centred on the fear that the Bill would expose patients to the maverick doctor acting alone.

The express intent of this Bill is to do the very opposite, by ensuring that no doctor can act alone but instead must consult a group of relevantly qualified medical experts and peers – as well as informing the [responsible officer](#).¹ Unless there is general consensus support for the proposed innovation, the doctor will not be able to rely on the Bill in order to proceed.

This rightly sets a much higher test than the Mental Health and Abortion Acts in regards to sign off for interventions such as sectioning a patient or undertaking an abortion.

The patient must also consent to the innovative treatment too.

However, the draft Bill that was opened to consultation lacked precision and clarity on this point. The new draft Bill is clear and explicit – there can be no protection under the Bill without following a clear and transparent process involving a panel of relevant experts and the responsible officer.

Although some legal professionals and bodies working in the field of medical negligence may remain unconvinced of the need for the Bill, overall, the consultation was effective. It produced a clear and overwhelming majority in favour of the Bill, it highlighted and crystallised concerns and has therefore facilitated a clear and robust redrafting which demonstrably meets those concerns while remaining true to the principles of the Bill, to encourage innovation and to deter reckless experimentation.

An ancillary but pertinent issue was also raised. Many also argued that for the Bill to work and to drive new treatments for hard to cure and currently fatal diseases, data from innovative treatments must be collected and be capable of being shared among patients and doctors.

The Bill team does not wish the Bill to be used as a guise for reckless experimentation and thus the Bill states that it may only be used in the best interests of the individual patient.

It is, however, in the interests of both the individual patient and others that evidence and data from innovative treatments should be collected centrally and made available to all. The Bill team is committed to working with Oxford University who have agreed to develop a method of data collection and sharing in relation to innovative treatments arising from the Bill.

Specially, following feedback from the consultation, we are committed to including an obligation on doctors that they must register innovative interventions in order to be protected by the Bill. We will do this as part of the statutory process during the Public Bill Committee Stage in the House of Commons

¹ <http://www.england.nhs.uk/revalidation/ro/>

THE PLAN FOR 2014-15

Parliamentary timetable 2014-15

The new Bill will be introduced into the House of Lords on 5th June - the day after State Opening of the new Session - and will be printed, together with Explanatory Notes, the following day.

The date for the Second Reading will be set by the Lords Business Managers following introduction, and it is hoped that it will occur before the Summer Recess. Subject to the progress of business and to the Bill finding favour in the Lords, it is hoped to take it through all its Lords stages before the Summer Recess and to have it reach the Commons when they return in the autumn.

The Bill will then have a Second Reading in the Commons in the autumn: that stage may take place with or without a debate, depending on circumstances. The Bill will then be sent to a Public Bill Committee for line-by-line scrutiny. In Committee it will be possible to make any necessary amendments to reflect points made in the Lords and Commons debates, and to adopt any amendments proposed by the Government.

It is hoped that the Bill will be out of Committee by early in 2015, following which its final Commons stages, and an opportunity for the Lords to consider any amendments proposed by the Commons, should leave comfortable room for Royal Assent before Parliament is dissolved for the May 2015 General Election

WHAT CAN YOU DO TO HELP?

This Bill would not have got as far as it has today without the support of doctors, patients, judges, journalists, bloggers and a wide range of interests. Your support will be the vital ingredient to ensure Royal Assent this Session. Here is how you can help.

Patients and family

- üü Email or tweet your MP – ask him or her to support the Medical Innovation Bill.
www.medicalinnovationbill.co.uk
- üü Sign the petition at <https://www.change.org/en-GB/petitions/support-the-medical-innovation-bill>

Doctors and lawyers

- üü Lobby your professional organisations to ensure that they support the Medical Innovation Bill.
- üü Write to your MP – ask him or her to support the Medical Innovation Bill.
www.medicalinnovationbill.co.uk
- üü Offer your time to contribute to a Parliamentary briefing on the Bill so that MPs and peers understand how it will work in practice.

CONTACT THE TEAM

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ANNEX A

DRAFT TEXT OF THE BILL

Draft of 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 (and accordingly to deter reckless irresponsible innovation).
- (2) It is not negligent for a doctor to decide to depart from the existing range of accepted treatments for a condition if the decision is taken in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters.
- (3) That process must include—
 - (a) consultation with appropriately qualified colleagues, including any relevant multi-disciplinary team;
 - (b) notification in advance to the doctor's responsible officer;
 - (c) consideration of any opinions or requests expressed by or on behalf of the patient;
 - (d) obtaining any consents required by law; and
 - (e) consideration of all matters that appear to the doctor to be reasonably necessary to be considered in order to reach a clinical judgment, including assessment and comparison of the actual or probable risks and consequences of different treatments.
- (4) Nothing in this section—
 - (a) permits a doctor to administer treatment for the purposes of research or for any purpose other than the best interests of the patient, or

- (b) abolishes any rule of the common law in accordance with which a decision to innovate is not negligent if supported by a responsible body of medical opinion.

(5) In this section—

- (a) “doctor” means a person listed in the register of medical practitioners under section 2 of the Medical Act 1983,
- (b) “responsible officer” has the same meaning as in Part 5A of that Act, and
- (c) a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction).

2 Technical provision

- (1) This Act comes into force on Royal Assent.
- (2) This Act extends only to England and Wales.
- (3) This Act may be cited as the Medical Innovation Act 2015.

ANNEX B

DRAFT

These Notes refer to the Medical Innovation Bill [HL] as introduced in the House of Lords on 5 June 2014 [HL Bill]

MEDICAL INNOVATION BILL [HL]

EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes relate to the Medical Innovation Bill [HL] as introduced in the House of Lords on 5 June 2014. They have been prepared by Lord Saatchi 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. It allows the test of whether innovation is negligent to be applied at the time when the doctor is deciding whether to innovate. The existing common-law test of the support of a responsible body of medical opinion is expressly preserved. The Bill states that it is not negligent for a doctor to depart from standard practice where he or she does so by applying an accountable and transparent procedure that allows full consideration of all relevant matters.

COMMENTARY ON CLAUSES

Clause 1 – Responsible Innovation

4. Subsection (1) sets out the purpose of the Act: to encourage responsible innovation and to deter irresponsible 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 is taken in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters.
6. Subsection (3) requires the process to include consultation with appropriately qualified colleagues, including a multi-disciplinary team if there is one. It also requires the doctor's responsible officer to be notified. The process must involve considering the patient's wishes and obtaining the informed consent required by

law; it must also include substantive consideration of all relevant factors, including a risk-assessment.

7. Subsection (4)(a) 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.
8. Subsection (4)(b) 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 clause 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 2 – Technical Provision

9. Clause 2 makes provision to commence the Bill immediately upon Royal Assent and to apply the Bill's provisions to England and Wales only.

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LEGAL ANALYSIS

Introduction

1. This legal analysis is produced by the Bill Team's Parliamentary Counsel to assist in understanding the Bill. It should be read in conjunction with the Bill and the Explanatory Notes published with it.

Clause 1(1) – the purpose clause

The purpose of this Act is to encourage responsible innovation in medical treatment (and accordingly to deter reckless irresponsible innovation).

2. Purposes clauses are increasingly common in legislation. There has been much discussion about their use over the years¹ but there is consensus among modern judicial and other commentators that they can be helpful where appropriate; and the courts have shown willingness to have regard to them in applying or construing Acts.
3. In this case the purpose clause will enable the courts and other readers to set the provisions of the Bill in the context of a desire for responsible innovation: so that the provisions of the Bill will be applied and interpreted in a manner likely to provide encouragement to doctors who wish to innovate responsibly. Whether that encouragement is effective or significant will be tested by reference to the law as it was without the Bill.
4. The parenthetical words in the purpose clause are designed to encourage the courts to use the standards set by the Bill to determine what is irresponsible innovation, and to make it harder for a maverick doctor acting unilaterally and without a consensus of support to argue that he or she has behaved in a non-negligent manner.

Clause 1(2) – the central proposition – responsible innovation is not negligent per se

It is not negligent for a doctor to decide to depart from the existing range of accepted treatments for a condition if the decision is taken in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters.

¹ For an overview see *Craies on Legislation*, D Greenberg, 10th Edition, 2012, paras.8.1.20 – 8.1.21.2.
Medical Innovation Bill briefing note. Session 2014 – 2015.

5. The policy at which the Bill is aimed is to remove the perception which appears to be held by some doctors and others, that a decision to depart from standard treatment for a condition is presumed to be negligent treatment unless the opposite is shown, and that it is therefore always safest to follow standard treatment even if it is known to be ineffective.
6. Clause 1(2) therefore states that a decision to innovate is not *per se* negligent, and that what matters is why and how that decision was taken.
7. The subsection establishes the general proposition that the process by which a decision is taken will not be negligent if it is accountable, transparent and allows full consideration of all relevant matters.
8. The concepts of “accountable” and “transparent” are left to be determined by the reader (including, but not limited to, the courts). They are non-technical words which will fall to be given a natural meaning in the context of medical practice. They are glossed in an expressly non-exhaustive way by subsection (3).
9. In essence, transparency will require the compilation and maintenance of an audit-trail showing how different components of the decision-process were conducted, including details of consultations and other discussions. There is no reason why that should impose a procedural or bureaucratic burden that exceeds existing good clinical practice.
10. (In extreme emergency situations where there is no time to put any process into place at all, the Bill will not apply and the doctor will rely on his or her judgment and the application of the existing common law *Bolam* test; but there will be emergency situations where a serviceable modified form of procedure can still be deployed.)
11. The essence of accountability is that the doctor should be able to show that there is some person or group to whom he or she has to account, on some appropriate basis, for professional decisions in general, and that the decision to innovate is part of that process. This might mean that a doctor who operates outside the NHS and who operates without clear oversight arrangements might feel unable to rely with certainty on the Bill, in which case he or she would have to rely on the existing common-law *Bolam* test and be satisfied that their conduct was defensible by reference to it.
12. The subsection also requires the process used to allow for full consideration of all relevant matters. The Bill does not attempt to specify what those matters might be. The policy of the Bill is to leave substantive regulation of doctors to the existing medical regulatory bodies and to the medical profession as a whole.

Clause 1(3)(a) – mandatory consultation

That process must include—

(a) consultation with appropriately qualified colleagues, including any relevant multi-disciplinary team

13. Clause 1(3)(a) provides that a doctor will not be able to rely on the Bill for validation and protection of a decision to innovate unless he or she has

consulted appropriately qualified colleagues, including the Multi-Disciplinary Team if there is one.

14. This is a duty to consult – it does not give colleagues a veto. But a legal duty to consult sets a high threshold². In particular, it requires full communication, allowance of proper time to respond, and through and open-minded consideration of any responses received.
15. A doctor who does not receive consensus support from colleagues consulted under the Bill is unlikely to feel confident in relying on the protection of clause 1(2) – and that is precisely the policy of the Bill.
16. The Bill does not give any particular set of colleagues an express veto because it is not possible to be dogmatic about whose support and concerns will be most relevant in a particular case. For example, although the Multi-Disciplinary Team is always to be involved in any decision to innovate, so that the broadest range of cross-discipline expertise can be brought to bear, in some cases the doctor will feel that the MDT lacks significant experience or expertise in the context and that he or she needs to seek also, and attach particular importance to, the opinions of others with specialist clinical knowledge.
17. (As described above, in extreme emergency situations where there is no time to consult anyone at all, any process into place at all, the Bill will not apply and the doctor will rely on his or her judgment and the application of the existing common law *Bolam* test.)

Clause 1(3)(b) – mandatory notification of the responsible officer

That process must include— ...

(b) notification in advance to the doctor's responsible officer

18. The post of responsible officer is provided for by Part 5A of the Medical Act 1983, as inserted by the Health and Social Care Act 2008. The Government's Explanatory Notes to the 2008 Act explain that the intended purpose for the responsible officer system is to ensure that they have responsibilities which can "include the evaluation of the fitness to practise of medical practitioners ... and a duty to co-operate with the GMC in connection with its responsibilities ... It is intended that this co-operation will include making recommendations to the GMC (with whom the final decision rests) on relicensing of medical practitioners based on individuals' records."

². "The common law duty of consultation is well-established: consultation must be undertaken at a time when proposals are still at a formative stage; it must include sufficient reasons for particular proposals to allow those consulted to give intelligent consideration and an intelligent response; adequate time must be given for this purpose; and the product of consultation must be conscientiously taken into account when the ultimate decision is taken: *R v Brent London Borough Council*, ex parte Gunning (1985) 84 LGR 168 ; *R v North and East Devon Health Authority*, ex parte Coughlan [2001] QB 213, [108]." (*R. (on the application of Compton) v Wiltshire Primary Care Trust* [2009] EWHC 1824 (Admin) at para.104.); "The essence of consultation is the communication of a genuine invitation, extended with a receptive mind, to give advice ... without communication and the consequent opportunity of responding, there can be no consultation." (*Agricultural, Horticultural and Forestry Industry Training Board v Aylesbury Mushrooms* [1972] 1 W.L.R. 190 per Donaldson J.).

19. The Bill makes it an express condition precedent of its protection for innovation that the doctor has given advance notice to his or her responsible officer.
20. In accordance with the policy that it is for the medical profession to determine its methods of self-regulation, the Bill leaves it to individual responsible officers, in accordance with their hospital and local procedures, to determine what methods of control to apply in relation to notifications under the Bill.
21. A doctor who is concerned that in the ordinary course of events his or her responsible officer may not have the time to consider a routine notification with particular care, will be able to request whatever level of additional scrutiny is given to the notification in a particular case to give the doctor the confidence that the notification and its results will form part of the transparent and accountable procedure required by subsection (2).

Clause 1(3)(c) – patients’ opinions and requests

That process must include— ...

(c) consideration of any opinions or requests expressed by or on behalf of the patient

22. A key part of the policy of the Bill is patient empowerment: that patients must feel able to ask their doctor to consider a possible innovative form of treatment, knowing that their request will be taken seriously and that the doctor will not be able to dismiss it on the grounds that it is necessarily safer for everybody (including the doctor) to rely on standard procedure.
23. The Bill makes the patients’ opinions and requests central to the process and requires the doctor to include their consideration in the process for deciding whether to innovate.
24. That does not mean that a doctor necessarily has to accede to a request to innovate; the Bill expressly requires the doctor to treat the patient only in what the doctor believes are the patient’s best interests (clause 1(4)(a)). Where a patient passionately believes in the possible efficacy of a new treatment which the doctor considers likely to be either ineffective or harmful, the doctor will refuse the request and will explain why.
25. Equally, a doctor will not be able to insist on innovating against a patient’s request or opinion: the Bill does not alter the law on informed consent and requires the innovation process to include the process by which informed consent is obtained – subsection (3)(d).
26. What will be possible, however, is for a doctor to take into account the strength of a patient’s desire to try an innovative treatment when balancing the potential efficacy of the treatment against its risks.
27. The reference to opinions or requests expressed on behalf of the patient deals with the case where the patient is unable to communicate direct. Doctors already have principles that they apply in determining how much weight to give to expressions by family and friends of opinions on behalf of the patient.

Clause 1(3)(d) – requirement for consent

That process must include— ...

(d) obtaining any consents required by law

28. The Bill does not alter the law on informed consent and requires the innovation process to include the process by which informed consent is obtained.

Clause 1(3)(e) - substantive factors to be considered

That process must include— ...

(e) consideration of all matters that appear to the doctor to be reasonably necessary to be considered in order to reach a clinical judgment, including assessment and comparison of the actual or probable risks and consequences of different treatments.

29. The Bill leaves it to the medical profession to determine what substantive factors require to be considered when determining the appropriate treatment for a patient.
30. So clause 1(3)(e) does not attempt to prescribe what factors a doctor should consider; but it requires the doctor to ensure that the process followed in determining whether to innovate allows all the appropriate substantive matters to be considered.
31. The provision mentions risk-assessment and risk-comparison as examples of the factors for which the process must make allowance: these are singled out because of their inevitable relevance to a decision whether or not to depart from standard practice. Where the standard practice is relatively effective it will require more to persuade a doctor to depart from it for the purposes of attracting what may be marginal benefits of an innovation. Similarly, in a context where risk of harm from side-effects is set against a probable non-terminal outcome of the patient's condition, the doctor will require more in the way of evidence or outcome to support a decision to innovate. Equally, where the condition is such that the condition as treated by standard methods is expected to result in imminent death, relatively marginal prospects of success with an innovative treatment might be thought to justify departure from standard practice. The balancing exercise will be carried out by the doctor in his or her clinical judgment, with the aid of the consultation and other processes already referred to.

Clause 1(4)(a) – no experimentation on patients

Nothing in this section—

(a) permits a doctor to administer treatment for the purposes of research or for any purpose other than the best interests of the patient

32. The policy of the Bill is to support innovative treatment where the doctor is satisfied that it is likely to be in the best interests of the individual patient receiving treatment.

33. This provision clarifies that a decision to experiment on a patient, not for their own good but for the possible benefit of others in the future, will never be protected by the Bill.
34. The law on the undertaking of clinical research trials is set out elsewhere, and by this provision the Bill expressly leaves that law untouched.
35. A number of commentators on the Bill have suggested that data acquired from the use of innovative treatments in reliance on the Bill should be shared with the medical community so as to inform future decisions (including the decision to run a formal clinical research trial). This provision would not prevent that. But it prevents the acquisition of useful information from being used as the justification for subjecting a patient to treatment which is not likely to be in their own medical interests.

Clause 1(4)(b) – preservation of Bolam

Nothing in this section— ...

(b) abolishes any rule of the common law in accordance with which a decision to innovate is not negligent if supported by a responsible body of medical opinion.

36. Some commentators on earlier drafts of the Bill were worried that it would be construed as replacing the existing law of medical negligence in its entirety. Although other commentators were satisfied that it did not, the opportunity has been taken in this draft to avoid the possibility of confusion.
37. Clause 1(4)(b) therefore expressly preserves the existing common law rule that looks at whether a decision is supported by a responsible body of medical opinion³.

Clause 1(5)(a) – “doctor”

“doctor” means a person listed in the register of medical practitioners under section 2 of the Medical Act 1983

38. The protection provided by the Bill is only in relation to registered doctors, whose professional standards and behaviour are regulated by the General Medical Council and other components of professional self-regulation.
39. The Bill will not protect anyone who while not a registered medical practitioner purports to offer any kind of medical treatment or healing.

³ Bolam v Friern Hospital Management Committee [1957] 1 WLR 582 per Mr Justice McNair at page 258: “The test is the standard of the ordinary skilled man exercising and professing to have that special skill. If a surgeon fails to measure up to that standard in any respect ..., he has been negligent ...”; per Lord Browne-Wilkinson in *Bolitho v City and Hackney Health Authority* [1998] AC 232: “The locus classicus of the test for the standard of care required of a doctor or any other person professing some skill or competence is the direction to the jury given by Mr Justice McNair in *Bolam v Friern Hospital Management Committee* ... I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art ... Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion which take a contrary view”.

Clause 1(5)(b) – “responsible officer”

“responsible officer” has the same meaning as in Part 5A of [the Medical Act 1983]

40. The post of responsible officer is provided for by Part 5A of the Medical Act 1983, as inserted by the Health and Social Care Act 2008.

41. The Government’s Explanatory Notes to the 2008 Act explain that the intended purpose for the responsible officer system is to ensure that they have responsibilities which can “include the evaluation of the fitness to practise of medical practitioners ... and a duty to co-operate with the GMC in connection with its responsibilities ... It is intended that this co-operation will include making recommendations to the GMC (with whom the final decision rests) on relicensing of medical practitioners based on individuals’ records.”

Clause 1(5)(c) – “treatment”

a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction).

42. This provision is included for two reasons.

43. In policy discussions senior doctors explained that treatment can be thought to be confined to the application of particular surgical procedures or the prescription of medicines, whereas it can include components which consist of neither. The term “management” is understood to be used in the profession to be capable of including the broadest possible aspects of the process.

44. A decision to do nothing may be as innovative as a decision to do something, and may require equal protection. Where the standard practice is to treat a condition with surgical intervention, a doctor who believes that in the circumstances of his or her patient the risks of surgery outweigh the likely benefits, that inaction is a form of treatment that requires to be protected by the Bill in accordance with the same safeguards that apply to active treatment.

Clause 2(1) – short title

This Act may be cited as the Medical Innovation Act 2014.

45. This provision gives the Bill its short title and has no other effect.

46. If the Bill is given Royal Assent in 2015, the title will be changed editorially to refer to the correct year.

Clause 2(2) – commencement

This Act comes into force on the day on which it is passed.

47. This provision ensures that the Act comes into immediate effect. It will not need to be brought into force by a commencement order made by the Government.

Clause 2(3) – extent

This Act extends only to England and Wales.

48. This provision makes the Bill part of the law of England and Wales (which share a single jurisdiction).
49. The law of medical negligence is not devolved to the National Assembly for Wales, and it is therefore not necessary for the National Assembly to pass a Legislative Consent Motion allowing this Bill to be made by the Westminster Parliament for the whole of England and Wales.
50. Should the legal jurisdictions operating in Scotland and Northern Ireland wish in due course to make similar provision, they will pass their own legislation that reflects their local legal and medical arrangements.

ANNEX D

Patients' stories submitted as part of the consultation

Jane

"I have secondary breast mets in my bones and brain. Current medications are working to suppress the cancer but I am sure there will come a time when licensed drugs stop being effective and I would like the opportunity to be given medications that my consultant feels will extend and provide me with a good quality of life."

Katherine de Retuerto

"I work at a University and see, first hand, the amazing breakthroughs our scientists are having in cancer research. I have lost several people close to me to the disease and in the future, I would like the treatments I know are being explored and discussed, to be available to the people I care about and others faced with a terrifying diagnosis and only very limited, and all incredibly destructive, options for treatment."

Kerry Rosenfeld

"My son is dying from Duchenne Muscular Dystrophy it is a cruel and relentless illness that needs access to anything potentially helpful at whatever point it seems useful as time is not in our side. My baby is only 12 and yet he's lived the best years of his life already. We don't want to lose a son and our other 3 children don't want to lose their brother! I would rather he was clinically significant to the cure than just dead! Risky is not risky when you have nothing to lose"

Lizzie Perdeaux

"The current culture of defensive medicine - while completely understandable as doctors need to protect their livelihoods - is harming patients by halting medical progress. Although great strides have been made in some areas, survival rates for some cancers (e.g. ovarian and pancreatic) and many rare diseases have not improved at all. Rare diseases affect 1 in 17 of the UK population and are often severe, chronic and debilitating. Most affect children, and most have no standard treatment or cure. Based on current rates of drug development, it would take more than 1000 years to develop treatments for all rare diseases. Innovation is sorely needed to get therapies to these patients faster. The Saatchi Bill will encourage doctors to help this group of patients who are in desperate need of innovative therapies by legally protecting those doctors who will use this opportunity to innovate responsibly and in their patients' best interests. To not support the Bill is to ignore the plight of millions of adults and children currently living with incurable diseases."

Julia Brooks

"Because the Bill will codify the existing law allowing medical doctors, clinicians & surgeons who follow the required transparent and accountable procedure, to safely provide innovative treatments, with consent, for patients."

Leven Beverley

“My son is part of the Manchester hospital team which has trialled an HIV drug in the treatment of cervical cancer. Even at stage 1 the results have been phenomenal. Bureaucracy should not be the decider of whether a woman lives or dies.”

Lorraine Doyne

“I lost my 19 year old daughter last year 16 months after she was diagnosed with a rare cancer. Any information from hospital was very limited and we often felt dismissed with questions on research we had done ourselves and put forward. My daughter wanted the chance to fight, but she was denied the chance of treatment. Young adults in the age group of 16-24 tend to get the rarest cancers and within this group there is less chance of being offered a clinical trial. As with my beautiful daughter, symptoms so often dismissed in this age group by doctors, until delayed late diagnosis.”

Teresa Rose

“I have Hashimotos Thyroiditis and am on Levothyroxine which I am resistant to, I would like the option to try Natural Dessicated Thyroid extract, and this is normal practice in Europe, the U.S.A and Australia but NOT in the U.K. I feel this medication could potentially improve my quality of life and lift me from years of suffering with pain and depression.”

ANNEX E

Doctors' stories submitted as part of the consultation

Mr Ali Majeed, Consultant General Surgeon, Sheffield

"I believe it is time for fresh ideas and approaches to be applied to the problem....If blue-sky thinking and radical new approaches are to be encouraged and developed, there need to be mechanisms whereby small but dedicated outfits can obtain the support they need."

Dr Angus Dalglish, Professor of Oncology, St George's Hospital, London

"I totally agree with you that here in the UK such creativity, which has given many patients years of non-toxic life and, on some occasions, completely reversed the cancer, is looked upon as maverick and potentially dangerous, as opposed to contributing to the nation's health."

Dr. Shabbir Ahmed

"We as doctors are required to stick to guidelines. We are not allowed in most instants to think laterally. This is holding up progress in my view..."

Regius Professor of Medicine at Oxford, Professor Sir John Bell

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

Dr Brian Blood

"As a former cardiac physiologist I understand that future treatments and cures lie in the unknown, otherwise they would be being used now. The only route to the unknown is to deviate from current treatments in the search for a greater understanding of disease. If a properly informed patient is prepared to agree to such treatment he or she should be able to work with their doctor and independent medical assessors to explore such alternatives."

Dr Chris Govender, Kilmarnock, Scotland

"My 5 year old son Brandon has Duchenne. Brandon's story like all other boys with Duchenne resembles that of Harrison's. Being a doctor myself I understand how close our boys are to receiving effective treatment. If this bill becomes law it will bring quality of life and save thousands of boys from this horrible disease. Thank you very much for your help."

Dr Stephen N Connolly

"As a contributing member of the discovery group which developed the anti-migraine drug rizatriptan I am familiar with the difficulty inherent in bringing new therapies into being. Under proper scrutiny, the repurposing of existing drugs is a sensible and logical approach in respect of difficult to treat conditions like cancer in an era when drug development is in decline and massively expensive."

Dr Charlie Chan

"As a cancer surgeon, I have regularly seen people, both young and old, suffering from advanced, terminal cancer. ...The scientific world has advanced enormously since the Bolam case. We must now remove the fear of litigation from doctors, so that they can consider responsible innovation with suitable patients. ...This Bill does

indeed have proper safeguards to prevent maverick practice. This is a once in a generation opportunity to change the culture from one of defensive conservatism to innovative co-operation in a new altruistic culture.”

Dr Sudha S Sundar

“As a practicing gynaecological cancer surgeon and an academic, in daily practice I encounter patients who are terminally ill and have exhausted treatment options. As a researcher I am also very aware of safe drugs that have evidence of activity against cancer - e.g. metformin - a commonly used very safe anti-diabetic drug. I find it frustrating that I cannot prescribe these for patients and that there is no structure outside of expensive randomised trials where these drugs can be prescribed and results quickly disseminated...”

Stephen Kennedy, Professor of Reproductive Medicine

“In my experience, patients want to be certain that their doctor has done everything possible to help them, within the bounds of what is reasonable and scientifically plausible. That is our duty of care as medical practitioners. This bill, therefore, liberates us to explore with our patients how best to provide the best possible care, particularly when there is a lack of knowledge or ignorance about which is the best treatment to offer.”

ANNEX F

Former Lord Chief Justice, Lord Woolf

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

President, Royal Society of Medicine, Michael D Rawlins

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

“The Bill emphasises that its provisions are solely concerned with the patient’s best interests.....”

“Anecdotal evidence suggests 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.....”

“I believe that the use of the provisions in the draft Medical Innovation Bill offer benefits to patients – especially those with rarer diseases – as well as to the furtherance of medical science”

*The President of the Royal College of Surgeons, Professor Norman Williams said:
“Protect the patient. Nurture the innovator.”*

President of BASO, The Association for Cancer Surgery, Professor Riccardo A. Audisio

“Frequently, physicians are led to believe that medical innovations which are not highlighted in the latest clinical guidelines are to be disregarded with no further discussion. There are instances where innovations with proven efficacy have not been implemented into routine clinical practice and these constitute an excellent example of how the Medical Innovation Bill could benefit patients. There are other instances, with respect to rare medical conditions where robust clinical evidence is not achievable and decisions should be taken in the best interest of patients. In this respect, the Medical Innovation Bill could also assist individual patients. We firmly believe that Lord Saatchi’s Bill could create a more flexible and patient- centered therapeutic approach of benefit to patients.”

The Secretary of State for Health

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

ANNEX G

WRITTEN MINISTERIAL STATEMENT
DEPARTMENT OF HEALTH
Medical Innovation (No 2) Bill
Friday 22 November 2013

The Secretary of State for Health (Jeremy Hunt): Medical innovation has been vital to the dramatic rise in life expectancy of the last century. This country has a proud heritage of medical innovation from Alexander Fleming and the discovery of penicillin to Sir Peter Mansfield's enabling of magnetic resonance imaging.

The government should do whatever is needed to remove barriers that prevent innovation which can save and improve lives. We must create a climate where clinical pioneers have the freedom to make breakthroughs in treatment.

The Medical Innovation (No 2) Bill, sponsored by my honourable friend the Member for Northampton North (Michael Ellis), and the comparable Bill introduced by my noble friend Lord Saatchi in the other place, correctly identify the threat of litigation as one such barrier. Their hope is that legislation to clarify when medical innovation is responsible will reduce the risks of clinical negligence claims. Their argument is that with this threat diminished, doctors will be confident to innovate appropriately and responsibly. This innovation could lead to major breakthroughs, such as a cure for cancer.

Their cause is a noble one, which has my wholehearted support. Lord Saatchi, in particular, is a great example of a parliamentarian motivated by conscience. It is precisely because this issue is so important, because it affects us all, that we need a full and open consultation. A consultation that gets the views of patients on the right balance between innovation and safeguards. A consultation that hears from clinicians on the problems they face in innovating and how to overcome them. We are grateful to the hon Member and the noble Lord for their own work to understand and address these issues.

So the government commits today to carrying out a full consultation, working with Lord Saatchi and the hon Member for Northampton North. This will draw on the wide engagement and discussions that they have already carried out with the public, patients and the legal and medical professions. Such a consultation will enable an open debate on medical innovation, as well as highlighting its vital importance. The government expects to launch this consultation in January 2014 and to respond by May 2014.

My second commitment is that the government will seek to legislate at the earliest opportunity, subject to the results of the consultation.

We all owe a debt to the hon Member and Lord Saatchi for the great effort they have already expended on this issue. The government will work closely with them to bring this to a satisfactory conclusion.

ANNEX H

FREQUENTLY ASKED QUESTIONS

1 Why is the Bill urgent?

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

ØØ Medical litigation is growing at an enormous rate.

ØØ The number of clinical claims against NHS Trusts has nearly doubled in the last 5 years.

ØØ The cost of clinical claims to the NHS has more than doubled in that time, and now exceeds £1 billion a year.

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

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

Legal clinical claims against NHS trusts²

<i>Year</i>	<i>Claims</i>	<i>Cost £m</i>
2011/12	9,143	1,095.3
2010/11	8,655	729.1
2009/10	6,652	651.1
2008/09	6,088	614.3
2007/08	5,470	456.3
2006/07	5,426	424.4
2005/06	5,697	384.4
2004/05	5,609	329.4

² Source – National Health Service Litigation Authority Report and Accounts:

2011-12; 2010-2011; 2010.

2 Medical product liability

1. Product liability is the principle that manufacturers of products are liable when a defect causes harm.
2. Proposed developments in EU law may leave doctors classified as the manufacturer of medical products, or as bearing deflected liability from the manufacturer.
3. The risk is particularly high in the innovative use of off-license drugs, in-house adaptations and personalised medicine.
4. Liability arises under the Consumer Protection Act 1987 which in part implements the EU Product Liability Directive.
5. Liability under the Act extends to pharmaceutical products and medical devices, and goods used in medical practice.

3 Why is legislation needed at all?

Politicians, medical regulators, and leaders in the medical and legal professions and industries agree that doctors should and can innovate responsibly. To that extent, the Bill codifies what is agreed to be best practice. So why is legislation needed at all?

1. There is still a perceptible legal bias against innovation, in so far as “standard practice” is seen as an unassailable defence.

“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.” – Murray v NHS Lanarkshire Health Board [2012] CSOH 123 Outer House, Court of Session, Lady Dorrian at [7].

2. There is still a perceptible industry bias against innovation, in so far as it is seen as not within the normal clinical options for doctors outside research.

“It was Mrs Hill's belief at this time that Mr Noordeen was not entitled to implant magnetic rods in patients. She appears to have believed, mistakenly, that because the magnetic rods were so new, they could only be used on patients as part of a study.” – Noordeen v Hill [2012] EWHC 2847, Males J at [14].

3. There is a real problem with irresponsible innovation – legislative principles of best practice will support the suppression of bad practice.

There is a real tension, recognised by senior professionals:

“Lord Saatchi, has highlighted the push and pull of the dilemma of innovation in medicine. We have a push from research councils to innovate; we have a push in academic medicine ... to innovate ...; and we have a push from industry to come up with developments. However, we have a pull, which is a risk-averse system that is frightened of taking the decision to go with something that looks as if it might be high-risk or to go with the unknown. It is that tension between the push and pull that I think we are caught in the middle of today.” – Baroness Findlay of Llandaff, Professor of Palliative Care, HL Deb 16.i.13 c.768.

The aim of the Bill is to resolve or to ease that tension, by providing legislative support for responsible innovation, and clear statutory principles to deter reckless innovation.

The Bill gives statutory authority to, and therefore strengthens, best clinical practice.

4 Will the General Medical Council have a role under the Bill?

The basic policy of the existing practice of the courts in relying upon medical standard practice is to recognise that the medical profession must effectively regulate itself, and that it is only doctors who are capable of expressing reliable judgements about how clinical decisions should be taken.

One of the purposes of the Bill, therefore, is to ensure that the courts continue to have regard to the opinions and practices of the medical profession: but this is no longer to be expressed by each side having to amass a group of experts whom the courts are required to weigh against each other.

The Bill requires a transparent and accountable process to be used. It recognises that this leaves a considerable area of flexibility, within which it is not possible to be prescriptive. Hard-letter legislation is not the place to give advice, or to finesse the finer details of clinical practice. As is the case under existing law, the courts must use their judgement in determining those finer shades at the parameters.

However, both the courts and the medical profession can gain considerable assistance from the regulatory bodies within the profession, including the General Medical Council. Rather than requiring the GMC to express its view only through disciplinary action taken in cases where things are alleged to have gone wrong, the Bill allows the GMC to be proactive and to express its views on how the Bill should be applied, and what processes and criteria should be used to give the necessary flexibility and adaptability, by issuing guidance.

The Bill does not impose a duty on the GMC to give guidance. It will be open to the GMC to decide whether to give guidance and, if so, in respect of what features of the Bill, and whether and how often to revise and reissue it.

5 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.

In particular, clause 3, which requires the government and other public bodies with responsibility in the medical field to have regard to the desirability of supporting responsible innovation, does not impose any obligation to spend additional money.

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.

6 How does the bill prevent quackery?

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.

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.

7 What is the origin of the “two doctors’ authorisation” requirement?

Section 2 (3) of the Mental Health Act 1983 which deals with compulsory admission of mental patients to hospital for assessment provides that: “An application for admission for assessment shall be founded on the written recommendations in the prescribed form of two registered medical practitioners, including in each case a statement that in the opinion of the practitioner the conditions set out in subsection (2) above are complied with.”

Section 3 of the Mental Health Act 1983 which deals with compulsory admission of mental patients for treatment provides: “An application for admission for treatment shall be founded on the written recommendations in the prescribed form of two registered medical practitioners, ...”.

Section 7(3) of the Mental Health Act 1983 which deals with applications for guardianship of mental patients provides: “A guardianship application shall be founded on the written recommendations in the prescribed form of two registered medical practitioners, ...”.

Section 1(1) of the Abortion Act 1967 which deals with medical termination of pregnancy provides: “Subject to the provisions of this section, a person shall not be guilty of an offence under the law relating to abortion when a pregnancy is terminated by registered medical practitioner if two registered medical practitioners are of the opinion, formed in good faith – (a) that the pregnancy has not exceeded its 24th week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman or any existing children of her family...”.

Similar provisions are found elsewhere in legislation: see, for example, Armed Forces Act 2006, section 166 (fitness to stand trial); Bail Act 1976 section 3 (incidents of bail in criminal proceedings); Criminal Appeal Act 1968 section 14 (substitution of findings of unfitness to plead); Criminal Procedure (insanity) Act 1964 section 4 (finding of unfitness to plead).

8 Examples of useful “box-ticking” exercise in legislation

In so far as the Bill purports to be giving statutory effect to what is already best practice, it may be attacked as an unnecessarily prescriptive box-ticking exercise.

There are numerous examples in legislation of issues that are essentially questions of common sense or good practice being codified through box-ticking exercises that give statutory guidance as to, and support of, best practice, while leaving enough flexibility to reflect particular circumstances.

Section 20 of the Equality Act 2010 deals with the duty to make adjustments where a disabled person is placed at a substantial disadvantage in comparison to non-disabled people. By breaking down the concept of reasonable adjustments into a series of considerations, the section gives a degree of consistency to what is inevitably a context-specific issue.

The Adoption and Children Act 2002 contains a number of examples of “box-ticking”: for example, section 61(5) (disclosing protected information about adults) says:

“In deciding whether it is appropriate to proceed with the application or disclose the information, the agency must consider—

- (a) the welfare of the adopted person,
- (b) any views obtained under subsection (3),
- (c) any prescribed matters,

and all the other circumstances of the case.”

The Health and Safety at Work etc Act 1974 also contains a number of examples of “box-ticking”; for example, section 2 breaks down the basic principle of providing a safe place and system of work into a non-exhaustive list of components.

9 Can / should legislation be used to change culture and attitudes?

The Compensation Act 2006 section 2 provides:

“An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty.”

Prior to the enactment of the 2006 Act, insurance companies routinely instructed people involved in accidents not to offer any expression of regret, for fear that as a matter of law that would be construed as an admission of liability.

In fact, of course, the courts are perfectly capable of distinguishing between an expression of ordinary human politeness and concern and an intention to admit legal liability. But the perception that an apology would be seized upon in litigation made people feel that the only safe course was to make no comment, and that any kind of apology was inherently dangerous as a matter of law.

Despite its terms the 2006 Act has not changed the law: the words “of itself” are key to preserving the courts’ ability to consider in the circumstances of each apology whether it in fact should or should not be taken as an admission of liability.

But the perception and presumption have been shifted, so as to enable a change of culture, under which people can feel safe in behaving with normal courtesy and showing normal human concern.

Section 2 was added at the Report Stage of the Compensation Bill in the House of Lords. Introducing the new clause Lord Hunt of Wirral said as follows:

“So we must ask ourselves, regardless of whether we believe that there is a compensation culture, whether there are not now in place perverse incentives that actively discourage people from doing the decent thing. ... There is no doubt that, by taking the heat out of situations where there has been an injury and encouraging basic human civility, we can do a great deal to improve the way society responds to such incidents.” (Hansard, HL Vol.679, col.657 (March 7, 2006).)

10 Why are survival rates better in France and USA if law is essentially the same there?

Comparison of survival rates is dangerous because it is rarely comparing like with like. In particular, the stage at which a diagnosis is recorded varies, and obviously affects the “survival” period.

The concern underlying the Bill is not based on a comparison of survival rates in terms of months or even years, but on the lack of progress over a period of decades towards finding treatments that provide real cure rather than prolonging death by a variable but short period.

11 Is the *Bolam* test still applied rigidly?

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.”

Once again doctors are being given the clear message that to do little or nothing will be the reliably safest course of action, provided everybody agrees in doing little or nothing. Statements such as this cannot but have a powerful deterrent effect on any doctor who is considering striking out along an innovative path.

12 Are the judges generally happy with the existing law?

The legal profession itself has acknowledged from time to time the dangers of the *Bolam* test and in particular its tendency 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 remarks like those of Lady Butler-Sloss in *Simms*, however, the mere fact that the Bolam test is the undoubted starting point in cases of medical negligence, must of necessity create a predisposition or bias against innovation. It is true that a courageous doctor who is determined to take a novel and creative approach to a particular patient will be able to draw some comfort from the words of Lady Butler-Sloss and other judges in *Simms* and a handful of other cases. It is equally true, however, that both the doctor, and perhaps more importantly his or her professional indemnity insurers, will be aware from the start that by departing from established practice – including where that amounts to the absence of effective treatment, they are exposing themselves to risks that the courts may, but equally may not in their particular case, protect them from.

13 Why does the fear of litigation create an inherent bias against innovation?

The leading case in this area is still that of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582; in Mr Justice McNair's judgment in that case he said at page 258:

"The test is the standard of the ordinary skilled man exercising and professing to have that special skill. If a surgeon fails to measure up to that standard in any respect ..., he has been negligent ...".

The result of this is that a doctor deciding how to treat a particular case starts with the knowledge that as soon as he or she moves away from existing and established standards within the profession, there is an automatic and serious risk that he or she will be found guilty of negligence if the treatment is less successful than hoped.

As Lord Browne-Wilkinson said in the House of Lords in the case of *Bolitho v City and Hackney Health Authority* [1998] AC 232:

"The locus classicus of the test for the standard of care required of a doctor or any other person professing some skill or competence is the direction to the jury given by Mr Justice McNair in *Bolam v Friern Hospital Management Committee* ... I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art ... Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion which take a contrary view".

The *Bolam* test is sometimes turned around and becomes the proposition that it is very difficult to prove negligence if the doctor can show that he or she did what others would have done in the same position as a result of established practice. In the House of Lords' decision in *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634 Lord Scarman said:

"The present case may be classified as one of clinical judgment A case which is based on an allegation that a fully considered decision of two consultants in the field of their special skill was negligent clearly presents certain difficulties of proof. It is not enough to show that there is a body of competent professional opinion which considers that there was a wrong decision, if there also exists a body of professional opinion, equally competent, which supports the decision as reasonable in the circumstances."

That passage illustrates starkly how in the law of medical negligence the normal process is for the parties to line up bodies of established opinion and invite the courts to compare and contrast them. It is therefore true to say that where there are divergent standard practices, a doctor can be reasonably confident in following whichever of them appears to be the more appropriate for the case which the doctor is confronting. By the same token, however, where there is only one established practice, even if it is the same course of treatment that has been applied unchanged for 40 years without any particular history of success, it will be impossible for a doctor to depart from it with confidence that he or she will not be exposed to litigation.

In particular, Lord Scarman's phrase "a body of professional opinion, equally competent" sets the bar almost impossibly high when it comes to establishing a case for innovation, which by definition means departing from the existing body of professional opinion.

In *Bolitho* itself, a two-year-old child was admitted to hospital suffering from respiratory difficulties; the doctor failed to attend on a number of occasions; and the child died. The doctor was held not to have been negligent simply because it was established that, had the doctor attended, "a decision by the doctor not to intubate would have been in accordance with a body of responsible professional opinion" and causation had therefore not been proved. So powerful, therefore, is the concept of reliance on an established body of professional opinion, that a doctor can quite literally sit on his or her hands and not even trouble to attend upon the patient, if satisfied that he or she would have a body of opinion to rely upon in deciding to take no action were he or she to attend. It is not surprising, therefore, that doctors feel safer in reaching for the medical journals, and in failing to treat wherever there is not an established consensus behind a particular line of treatment, rather than thinking creatively and in the patient's best interests on each occasion.