

*This document relates to the Medical Innovation Bill
as introduced in the House of Lords on 15th May 2013*

HOW CAN AN ACT OF PARLIAMENT CURE CANCER?

*A Guide to the Medical
Innovation Bill [HL]*

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A

B I L L

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 to deter reckless departure from standard practice.
- (2) It is not negligent for a doctor to depart from the pre-existing range of accepted treatments for a condition (standard practice) if the decision to innovate is taken responsibly.
- (3) A responsible decision to innovate will, in particular, be based on consideration of—
 - (a) the reasons why the available research or other evidence is insufficient or unclear including, in particular, whether it is referable to the nature of the condition (as in, for example, a cancer that affects relatively few patients),
 - (b) the relative risks that are, or can reasonably be expected to be, associated with the treatment the doctor proposes to apply and other treatments,
 - (c) the relative likely success rates of the treatment the doctor proposes to apply and other treatments, in the doctor's reasonable judgment,
 - (d) the relative likely consequences of applying, or failing to apply, the treatment the doctor proposes to apply, and other treatments;
 - (e) opinions or requests expressed by or in relation to the patient, and
 - (f) any other matter that appears to the doctor to be reasonably necessary to be considered in order to reach a clinical judgment.

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- (4) A responsible decision to innovate must be made in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters; the process may include, in particular—
- (a) decision-making within a multi-disciplinary team;
 - (b) notification in advance to the doctor's responsible officer (within the meaning of Part 5A of the Medical Act 1983);
 - (c) explanation to the patient of the doctor's reasons for proposing to depart from standard practice, including discussion of any contrary opinions expressed by the doctor's colleagues.
- (5) Nothing in this section permits a doctor—
- (a) to provide treatment without consent that is otherwise required by law, or
 - (b) to administer treatment for the purposes of research or for any purpose other than the best interests of the patient.
- (6) In this section—
- (a) "doctor" means a person listed in the register of medical practitioners under section 2 of the Medical Act 1983, and
 - (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 Technical provision

- (1) This Act comes into force on Royal Assent.
- (2) This Act extends to the United Kingdom.
- (3) This Act may be cited as the Medical Innovation Act 2013.

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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 [] 2013. 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. The Bill gives a non-exhaustive list of criteria which a doctor will apply in determining whether to innovate and specifies some features of the process by which the decision should be reached. The Bill states that it is not negligent for a doctor to depart from standard practice where he or she does so by applying criteria, and following procedures, in accordance with the Bill.

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 the procedure set out in the clause.
6. That procedure has two components.
7. First, subsection (3) sets out a non-exhaustive list of criteria to be applied by a doctor in considering whether to depart from the pre-existing range of acceptable treatments for a condition: the factors to be considered include the reasons why there is insufficient research or other evidence to allow the doctor to make a purely evidence-based decision; the risks associated with the innovative treatment and standard treatments; the likely success rates of the innovative treatment and standard treatments; the likely consequences of each treatment; opinions or requests expressed by the patient; and other matters that the doctor considers need to be taken into account.

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8. Secondly, subsection (4) requires the doctor as well as applying the criteria necessary to enable him or her to form a judgement, to consider what process to adopt in order to ensure that a decision to innovate is made accountably, transparently and with full consideration of all relevant matters. The subsection sets out a non-exhaustive list of features that the process might include: the adoption of a decision to innovate following discussion within a multidisciplinary team; advance notification to the doctor's responsible officer; and discussion with the patient, including discussion of any dissenting opinions within the multidisciplinary team or outside.
9. Subsection (5) clarifies that the clause does not alter the position at law as to when consent is required and how that consent is to be obtained and formed. The subsection also 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.

Clause 2 – Technical Provision

10. Clause 2 makes provision to commence the Bill immediately upon Royal Assent and to apply the Bill's provisions throughout the United Kingdom.

SUMMARY

WHY DO WE NEED THIS BILL?

1. All cancer deaths are wasted lives.
2. Science learns nothing from these deaths.
Scientific knowledge does not advance by one centimetre.
3. Scientific discovery comes to a 'dead halt' at the bedside of the cancer victim.
4. Because current law requires that the deceased receive only the *standard procedure* - the endless repetition of a failed experiment.
5. Current law is a barrier to progress in curing cancer.
6. Under present law, any deviation by a doctor from *standard procedure* is likely to result in a verdict of guilt for medical negligence.
7. Current law defines medical negligence as deviation from standard procedure.
8. But as innovation is deviation, non-deviation is non-innovation.
9. This is why there is no cure for cancer.

SUMMARY

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?

1. The law may not have changed much, but society has. We are more informed, less deferential and more litigious.
2. The number of lawsuits filed against the NHS has doubled in four years. Last year's pay-out was £1.2bn. The Treasury provision for claims against the NHS has now reached £19bn.
3. So doctors are increasingly frightened of being sued, and even less likely to feel able to innovate.
4. "Risk-management" processes within the NHS and insurers' policies designed to stem the rise of litigation can only increase this anti-innovative pressure.
5. Growing fear of litigation leads to growing bias against innovation.
6. This is why there is no cure for cancer.

LEGAL MEMORANDUM

The purpose provision in clause 1(1) summarises the policy intentions of the Bill, and will clarify the legislative intent of the eventual Act for the courts and other readers.

The approach of the Bill aims to avoid intractable problems such as defining what amounts to an innovation, or what amounts to "responsible" innovation or "sufficient" evidence or research.

These judgments will remain a matter for doctors, subject to scrutiny of their regulatory bodies and, potentially, of the courts.

The Bill aims to codify the existing best-practice processes, as described by a range of senior medical consultees that are already followed in deciding to innovate in clinical management.

In legislative terms, the key operative provision is clause 1(2), which declares that it is not negligent to innovate if the decision is taken responsibly. Even this provision is arguably merely declaratory of the existing law - but sufficient doubt appears to exist as to a perceived legal presumption against innovation to make this provision necessary.

The expressions used in the Bill follow so far as possible the technical vocabulary of the medical profession as described by consultees.

THE STATUS QUO

Unfortunately, here is the status quo:

A woman is told her tests are 'normal', to come back in twelve months. Twelve months later, she is removed from her home.

The woman is cut and drilled until she loses half her body weight.

Wires and tubes are attached to her throat, nose, stomach, vagina.

Drugs are given to her which cause nausea, vomiting, diarrhoea and fatigue.

These procedures open the path for deadly infections to enter the woman's body.

Then, finally, they reduce her body's defences against infection.

The woman turns into a sparrow.

The woman is left for dead.

Soon after, the woman dies.

REASON FOR CHANGE IN LAW

The aim of the Bill is to improve the detection, diagnosis and treatment of cancer, in particular, 'hard-to-treat' women's gynaecological cancer.

The screening techniques for such a cancer are inadequate; no reliable early detection method is available, and even if it was, it would improve the overall survival statistics but not the date of death.

The treatment regimes, when belatedly provided - the drugs, the cycles of their administration, and the surgical procedures - are forty years old.

They open the path for fatal infections to enter the body, and reduce the body's defences against such infection. The woman is as likely to die from infection as from cancer.

They are also ineffective - cancer quickly develops 'resistance'.

"The process", as it is called, involves scenes which would not be permitted in a Hollywood horror movie.

Not surprisingly, the survival rate for such cancers is the same as it was forty years ago; i.e. nought; and the mortality rate is the same as it was forty years ago; i.e. 100%.

Current law in relation to medical negligence contributes to this failure. It defines medical negligence as *deviation from standard procedure*. But as innovation = deviation, then non-deviation = non-innovation.

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The result is that all cancer deaths are wasted lives. The deaths, and their attendant tragedies, have not advanced scientific knowledge by one centimetre.

Why?

Because all the deceased have received is the *standard procedure* - the endless repetition of a failed experiment.

DEFECT OF CURRENT LAW

The present pre-eminence in law of the *standard procedure* provides no inducement to progress. It outlaws initiative. The self-interest of medical practitioners, as defined, for example, in doctors' insurance policies, means that innovation (i.e. deviation) is a form of self-harm.

Under the present law, after establishing a duty of care, which is usually easily done in the case of a doctor/hospital and a patient, a plaintiff who alleges medical negligence must then demonstrate a breach of that duty. Breach of duty is analysed by examining whether the defendant has fallen below the standard of care deemed appropriate by the courts. Such carelessness has consistently been evaluated by the courts in medical malpractice actions as:

that which departs from the standard practised and accepted by a responsible body of medical persons skilled in the particular area of medicine in question. (Nelson-Jones and Barton, Medical Negligence Case Law 1990).

The courts will be concerned to decide as a matter of fact whether a practitioner has fallen below the ordinary skill of an ordinary practitioner exercising and professing to have the particular skill in issue (*Bolam v Friern Management Committee* (1957)).

In any such litigation, the courts will hear the expert opinion of medical witnesses on current modes of accepted practice. If it can be shown that there was no deviation from the relevant accepted medical standard of care, that no professional negligence by act or omission provided care which deviated from accepted standards of practice in the medical community, and that the performance of duties did not

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depart from the practice of those with similar training and experience, then no harm or injury to the patient was caused by malpractice, or resulted from negligent action or behaviour.

Breach of the current law means deviation from the *standard procedure*.

Under the present law, any medical practitioner accused of negligence has a cast iron defence in law, if it can be shown that he or she did not deviate from the standard procedure.

'Standard procedure' is clearly defined in the law as the practice which would be followed by a group of medical practitioners skilled in the particular area of medicine in question.

In *Clark v McLennan* (1983), the significance of departing from an approved mode of practice was treated by the trial judge, Pain J, 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.

Generally speaking, deviation from accepted practice is likely to result in a finding of negligence if the practitioner cannot establish a cogent reason for adopting the practice he did (*Holland v Devitt and Moore Nautical College Ltd*) (1974), *Hoston v East Berkshire Health Authority* (1987), *Chin Keow v Government of Malaysia* (1967).

The further a practitioner moves from orthodox practice towards experimentation, the more likely the court is to impose a higher standard of care requiring the practitioner to justify his actions as reasonable (see the Canadian case of *Coughlin v Kuntz* (1987), cf *Zimmer v Ringrose* (1981), *Halushka v University of Saskatchewan* (1965).

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In *Maynard v West Midlands Regional Health Authority* (1984), the House of Lords affirmed the *Bolam* medical standard of care in cases of misdiagnosis. Lord Scarman quoted with approval the Lord President in *Hunter v Hanley* (1955) to the effect that to establish medical negligence in misdiagnosis a plaintiff had to prove a failure such that no doctor acting with ordinary skill and care would commit. The decision in *Maynard* to use a particular diagnosis procedure could not amount to negligence, when a competent body of professional opinion would have used the same technique.

In other words:

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).

This approach is adopted irrespective of whether the alleged lack of care concerns diagnosis and treatment, failure to furnish sufficient information in respect of various forms of treatment, negligent advice, or failure to establish proper communication between practitioners and between the patient and practitioner. Whether there has been a breach of the standard care is a matter of fact which requires careful analysis in each case.

But the point is that breach of the law means breach of the standard procedure.

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

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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*.

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 Courts can determine the difference between 'negligence' and 'recklessness' now, and the Bill will assist them in making a similar distinction between 'innovation' and 'recklessness'.

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The law as it stands does not strike a proper balance between reckless experimentation on the one hand, which puts patients' lives at risk, and complacent apathy which treads the well-worn path on which no liability can arise.

The defect of the present law becomes more apparent as the speed of technological change accelerates. It destroys inducements to progress. It encourages apathy. It discourages innovation.

The point of the Bill is to change the law in order to shift the balance towards innovation and away from complacency.

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Q & A

What does the Bill actually do?

The present emphasis of the law on medical negligence is for the parties to line up sets of opposing expert opinion and require the courts to choose between them. That inevitably makes it the safest course to adhere to existing established practices, irrespective of how long and how unsuccessfully they have been applied.

The Bill therefore shifts the focus of medical negligence from whether a decision is taken to depart from standard practice, towards consideration of how the decision is taken.

For the first time, the Bill will give statutory expression to what the range of medical consultees have described as proper practice and process for taking decisions to innovate.

The results are that—

- (a) a doctor who innovates irresponsibly without having gone through careful and structured consideration of all relevant criteria will be more easily exposed as negligent; and
- (b) a doctor who takes care to innovate responsibly and in accordance with best professional practice will have statutory support on which to rely in justifying his or her decision to insurers, to the GMC and other regulatory bodies and, if necessary, to the courts.

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*

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*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

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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.

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:

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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 Baroness Butler-Sloss, 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 Baroness 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.

Is the *Bolam* test still applied rigidly?

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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.

Isn't the real problem the culture? Can / should legislation be used to change culture and attitudes?

Unfortunately, the Government's well-intentioned efforts to weaken the dominance of the 'accepted mode of practice' by encouraging a culture-change towards innovation (as in NHS Chief Executive Sir David Nicholson's letter to NHS managers) 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.

An example of attitude change by Act of Parliament is found in 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.

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Despite its terms, the words "of itself" in the 2006 Act 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))

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

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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

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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.

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.

Is this just a “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. *(Text of section appended to this note.)*

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

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providing a safe place and system of work into a non-exhaustive list of components. (Text of section appended to this note.)

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Equality Act 2010

Section 20 Duty to make adjustments

(1) Where this Act imposes a duty to make reasonable adjustments on a person, this section, sections 21 and 22 and the applicable Schedule apply; and for those purposes, a person on whom the duty is imposed is referred to as A.

(2) The duty comprises the following three requirements.

(3) The first requirement is a requirement, where a provision, criterion or practice of A's puts a disabled person at a substantial disadvantage in relation to a relevant matter in comparison with persons who are not disabled, to take such steps as it is reasonable to have to take to avoid the disadvantage.

(4) The second requirement is a requirement, where a physical feature puts a disabled person at a substantial disadvantage in relation to a relevant matter in comparison with persons who are not disabled, to take such steps as it is reasonable to have to take to avoid the disadvantage.

(5) The third requirement is a requirement, where a disabled person would, but for the provision of an auxiliary aid, be put at a substantial disadvantage in relation to a relevant matter in comparison with persons who are not disabled, to take such steps as it is reasonable to have to take to provide the auxiliary aid.

(6) Where the first or third requirement relates to the provision of information, the steps which it is reasonable for A to have to take include steps for ensuring that in the circumstances concerned the information is provided in an accessible format.

(7) A person (A) who is subject to a duty to make reasonable adjustments is not (subject to express provision to the contrary) entitled to require a disabled person, in relation to whom A is required to comply with the duty, to pay to any extent A's costs of complying with the duty.

(8) A reference in section 21 or 22 or an applicable Schedule to the first, second or third requirement is to be construed in accordance with this section.

(9) In relation to the second requirement, a reference in this section or an applicable Schedule to avoiding a substantial

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disadvantage includes a reference to—

- (a) removing the physical feature in question,
- (b) altering it, or
- (c) providing a reasonable means of avoiding it.

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10) A reference in this section, section 21 or 22 or an applicable Schedule (apart from paragraphs 2 to 4 of Schedule 4) to a physical feature is a reference to—

(a) a feature arising from the design or construction of a building,

(b) a feature of an approach to, exit from or access to a building,

(c) a fixture or fitting, or furniture, furnishings, materials, equipment or other chattels, in or on premises, or

(d) any other physical element or quality.

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Health and Safety at Work etc. Act 1974

Section 2 General duties of employers to their employees.

(1) It shall be the duty of every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his employees.

(2) Without prejudice to the generality of an employer's duty under the preceding subsection, the matters to which that duty extends include in particular—

(a) the provision and maintenance of plant and systems of work that are, so far as is reasonably practicable, safe and without risks to health;

(b) arrangements for ensuring, so far as is reasonably practicable, safety and absence of risks to health in connection with the use, handling, storage and transport of articles and substances;

(c) the provision of such information, instruction, training and supervision as is necessary to ensure, so far as is reasonably practicable, the health and safety at work of his employees;

(d) so far as is reasonably practicable as regards any place of work under the employer's control, the maintenance of it in a condition that is safe and without risks to health and the provision and maintenance of means of access to and egress from it that are safe and without such risks;

(e) the provision and maintenance of a working environment for his employees that is, so far as is reasonably practicable, safe, without risks to health, and adequate as regards facilities and arrangements for their welfare at work.

(3) Except in such cases as may be prescribed, it shall be the duty of every employer to prepare and as often as may be appropriate revise a written statement of his general policy with respect to the health and safety at work of his employees and the organisation and arrangements for the time being in force for carrying out that policy, and to bring the statement and any revision of it to the notice of all of his employees.

(4) Regulations made by the Secretary of State may provide for the appointment in prescribed cases by recognised trade unions (within the meaning of the regulations) of safety representatives from amongst the employees, and those representatives shall represent the employees in consultations with the employers under subsection (6) below and shall have such other functions as may be prescribed.

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...

(6) It shall be the duty of every employer to consult any such representatives with a view to the making and maintenance of arrangements which will enable him and his employees to co-operate effectively in promoting and developing measures to ensure the health and safety at work of the employees, and in checking the effectiveness of such measures.

What is the origin of the "two doctors' authorisation" requirement?

The Bill's requirement for the approval of any proposed innovation by the hospital's Multi-Disciplinary Team (MDT) is a severe test - more severe than the "two doctors" authorization now required by law in order to carry out an abortion or sectioning in a mental health institution. However severe, it is better than the current position, in which the road ahead to any innovation is closed by law.

The Bill goes further in requiring that any dissent amongst the MDT is reported to the patient, before the patient is asked for consent - much more disclosure and transparency for patients and relatives than required by the present law.

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

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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).

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 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.

Aren't we making progress in cancer diagnosis and treatment?

You hear it said:

We are concentrating on "what is", not "what should be".

We do not have stars in our eyes looking for the Promised Land; nor our heads in the clouds searching for the end of the rainbow.

Our feet are firmly on the ground.

Research is being carried out in first class institutions, clinical trials are under way, money is being spent by pharmaceutical companies, data is being shared at global conferences.

Everyone is doing their best. The drugs available are harsh but help.

Screening tests are inadequate but as good as we have.

Day and night, as we sleep, devoted, dedicated professionals are hard at work.

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...

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One patient can change the world

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

Is scientific discovery blocked by law?

The striving for knowledge and the search for truth are the strongest motives of scientific discovery.

The boldness of our questions, and the integrity of our tests. That is what makes the man of science - subjecting our ever tentative answers to ever more rigorous tests.

All our marvellously imaginative and bold conjectures are carefully and soberly controlled by systematic tests. We try to overthrow them. Using all the weapons of our logical, mathematical, and technical armoury, we try to prove that our anticipations were false.

An idea acquires scientific status only when it is presented in falsifiable form: that is to say only when it has become possible to decide empirically between it and some rival theory.

That is *The Logic of Scientific Discovery*, as described by Karl Popper - refutation by application; severe tests to see if the theory:

can prove its mettle

This entire, magnificent scientific process comes to what we may perhaps call a 'dead halt' at the bedside of the cancer victim.

Put the case of the doctor in the hospital standing beside the patient.

Put the case that the doctor is considering an innovation.

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At that moment, a sign appears between the doctor and the patient.

It reads:



The sign is the law.

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The doctor must now ask himself:

Do I want to go ahead down this road? If I do, I will depart from the standard procedure? If I do, and anything goes wrong, there will be a trial. Expert witnesses will testify. I am likely to be found guilty of medical negligence. Should I put my livelihood, my family and my reputation at risk? Or should I stick to the well-worn path on which no liability can arise.

In this way, the current law obliges the doctor to follow the status quo, even though he/she knows it leads only to poor life quality followed by death.

This is how scientific discovery is blocked by law.

Why do we need a law change to encourage innovation?

Can't doctors innovate now if they have patient consent? Isn't the informed consent of the patient an 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.

Aren't mass clinical trials the route to innovation?

Our current method to overcome the uncertainty and doubt about cancer treatment is the Randomized Controlled Trial (RCT). A statistically representative sample of 10,000 of the afflicted will take part. The number of corroborative incidents will be noted. The participants will be followed for 10 years to see if they are cured, or if they die; or if they appear to be cured, but then die; or else, if they are neither cured nor die, whether they are later damaged in other ways.

Doctors are excluded from innovation. It has been removed from them and outsourced to the mass clinical trial. The requirements of statistical significance for clinical trials makes them unlikely to be relevant to relatively rare cancers.

How this concept of "mass average clinical trials" relates to the new era of genetic "personalised" "precision" medicine has yet to be explained.

Why change the law now?

There have been many medical discoveries under current law. Why should it be changed now?

The world has changed:

1. Patients are more informed.

They can follow the proceedings of medical conferences worldwide at the same time as their doctor

2. People are more litigious.

The NHS Litigation Authority recently had to be bailed out by the Government. The number of claims made against the NHS for clinical negligence show the taxpayer is liable for up to £15bn in such payouts.

3. Hospitals either are private companies, or are expected to behave like them.

Corporate Chief Financial Officers, on behalf of private shareholders, do not want lawsuits. For example, HCA (Hospital Corporation of America) which owns, amongst others, The London Clinic, The Harley Street Clinic, The Portland Hospital, The Wellington Hospital, The Princess Grace Hospital, the London Oncology Clinic and The Lister Hospital, is itself owned by a US Private Equity Company, Kohlberg Kravis Roberts (KKR).

Isn't this Bill the voice of the bereaved, driven to distraction by grief at the loss of the beloved?

Grief is not a good basis of law, but nor is it a disqualification from rational thought.

The motive for the Bill is no more original than what you often hear on news programs from the relatives of the deceased:

If one mother, child, father, brother, sister can be saved from a disease which is relentless, remorseless, merciless; and from treatments which are medieval, degrading and ineffective, that would be a blessing for us all

Doctors are decent and humane people striving by their own best lights to serve the community. This Bill is designed to help them.

The point is not grief.

The point is the law.

The Bill has the explicit support of a number of people and organisations of high repute who have no personal interest in it.

MEDICAL INNOVATION BILL

SUMMARY OF ADVICE OF CHRISTOPHER GIBSON QC

1. As a general proposition, a doctor who follows standard practice will be able to feel safe from the threat of litigation.
2. It follows that a doctor who chooses to innovate and to depart from standard practice faces an increased risk of litigation in the event of unforeseen consequences - but whether the risk will be significant will depend on all the circumstances.
3. Informed consent provides important protection for doctors and patients - but in the case of rare conditions and innovative treatments the clinician may not be able to give a sufficient explanation of the risks to found informed consent if the risks of the proposed treatment are not adequately known.
4. The use of a drug in a named-patient context brings no special protection from suit and places a particular responsibility on the clinician.
5. The fear of complaints to the employing and regulatory bodies may be more significant than the fear of litigation in relation to terminal conditions.
6. Risk-management within the NHS can be carried out entirely properly and responsibly; but there is also the potential to inhibit innovation.
7. The present approach of the courts to the resolution of medical negligence cases has the potential to inhibit innovation through the

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weight that it attaches to the use of standard procedures.

8. The Bill accurately expresses the existing law, and its application as a matter of best-practice, in articulating the balance of criteria that should be applied in deciding to innovate, and that determine whether innovation is negligent in a particular case.
9. The Bill does not change the substantive law on negligence; but it may influence how it is perceived and applied.
10. The Bill does not provide an inflexible or exhaustive list of matters to be considered in determining responsibly whether to innovate.
11. The framework of process provided by the Bill in relation to decisions to innovate also avoids inflexibility, but provides a clarity of approach together with the certainty and authority of statute.
12. The safeguards in the Bill should avoid unintended consequences in relation, in particular, to diluting the need for consent or the primacy of patients' best interests.
13. In so far as some doctors certainly do fear being sued and feel inhibited by that fear, the Bill would change perception of the way the law is applied; in time this should have a positive effect on stimulating innovation in medical treatment.

*Summary produced by Daniel Greenberg, Parliamentary Counsel,
Berwin Leighton Paisner LLP and Approved by Counsel*

THE MEDICAL INNOVATION BILL

A D V I C E

1. The Medical Innovation Bill is a private peer's Bill that was introduced into the House of Lords by Lord Saatchi. I understand that the second reading of the Bill is expected in early 2014. The premise behind the Bill is that the current state of the law, both in its effect and as it is perceived by medical practitioners, has a negative influence on doctors when the situation requires, or suggests, that a departure from standard procedures would be in the best interests of the patient. I have been asked to advise on a number of issues that arise in consideration of the Bill.
2. I am indebted to Mr Greenberg for the detailed and helpful instructions that I have received, and for the Guide to the Medical Innovation Bill which I understand has been prepared by Lord Saatchi. This contains detailed references to a number of authorities and I have found it extremely helpful.

The Background

3. The purpose of the Bill is general in that it is intended to encourage medical innovation by doctors in all areas, but the area with which Lord Saatchi is particularly concerned is that of cancer care.
4. Lord Saatchi has written and spoken eloquently about the tendency of doctors, when faced with a patient suffering from cancer, to give the standard and usual care with little or no hope that it will do any good. But because it is the standard care the doctor knows that he or she cannot be criticised. On the other hand the doctor who wishes to depart from the usual treatment, in

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the belief that some innovative treatment will or may help the patient, is faced with the situation that he or she will not be protected from criticism, and even possible legal action, in the event that the treatment goes wrong by having adopted a standard approach.

5. The belief is that the state of the law applicable to allegations of clinical negligence operates as a disincentive to innovative treatment that might effect significant advances, and it is obviously important to remove any such disincentive as long as there are proper safeguards to ensure that any innovative treatment is carried out responsibly, and appropriately, and in the patient's best interests and with the patient's consent and approval.
6. It is the experience of those of us who have practised in this field for a substantial period of time that the emphasis by the profession in arriving at the approval of treatments has changed. Many years ago the emphasis often seemed to be that a treatment would be said to be acceptable and appropriate if it was widely used, or if (though not widely used) it was used by some respectable practitioners. Sometimes the effect was that treatment could be defended (where the outcome was poor) more on the basis simply that others used it, than on the basis that evidence showed that it was appropriate.
7. In recent years the emphasis has changed with the result that treatment is considered appropriate (and therefore defensible) on the principle of evidence-based research and trials, and protocols and guidance issued by the National Institute for Health and Care Excellence (NICE) which was set up in 1999. Amongst other areas NICE issues guidelines in "the use of health technologies within the NHS" (such as the use of new and existing medicines, treatments and procedures),

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and "clinical practice" (guidance on the appropriate treatment and care of people with specific diseases and conditions).

8. It is considered that NICE has been effective in ensuring that similar standards of care are available to patients in different parts of the country, and that consistent guidance is given throughout the NHS, but the paradox of the gradual shift only to rely on evidence-based medicine is that it might serve as a barrier to innovation and change where the evidence to support the innovation or change is lacking. By definition, perhaps, innovative medicine is not going to be evidence-based.

**The Current State of the Law of Clinical Negligence
and Standard Treatment**

9. The proposition is this:
 - a) A doctor who follows standard practice, even when that amounts to doing nothing, will almost always be able to regard himself or herself as "safe" from the threat of litigation; but
 - b) A doctor who chooses to innovate, however responsibly and carefully, knows that the mere fact of innovation carries with it an increased risk of litigation in case of unforeseen undesirable outcomes, however small the risk and however important it may be in the interests of the patient to take it.

I have been asked to comment on the accuracy of this proposition.

10. There is no doubt that if a doctor follows standard practice - even where that standard practice is to do nothing other than to treat conservatively - he or she will almost always, if not always, be able to regard himself or herself as safe from the threat of litigation. I have no

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doubt that this is true as a general proposition - although there are points that can be made from the regulatory point of view as well as the Clinical Negligence aspect. Of course the clinician has to tell the patient what is happening, and the patient has to be given appropriate information and explanations about the treatment - even if it is doing nothing. Any failure in this regard might make the clinician open to criticism and complaint, possibly even a formal complaint to the GMC, even if the treatment itself cannot be criticised. But in such circumstances it is hard to see how there could be a claim in negligence.

11. It is also possible to conceive of circumstances where there might be more than one approach to treatment even if there is only one approach that is considered standard practice. In such a situation the clinician could be open to criticism in the event that he or she did not consider with the patient the other possibilities. This sort of situation could be exactly the area with which we are concerned: the patient presents with a serious condition, and the standard treatment ensures the best chance of survival but carries a substantial risk of permanent disability. There is an alternative treatment that carries an increased risk of mortality, but improves the chance (if the patient survives) of reducing the consequential permanent disability.

12. It is always difficult to construct useful theoretical circumstances, but that which I have set out in the paragraph above might be possible in some instances of stroke, where there is a potential for the use of thrombolysis therapy. My view would be that in some circumstances the patient could complain if he or she was not offered the riskier treatment so that he or she could decide whether to take the increased risk of

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mortality in exchange for the chance of a better future outcome.

13. But the reality is that the initial proposition set out in 9(a) above is correct. Even in the sort of example I have tried to construct in paragraphs 11 and 12 above it is hard to imagine that the clinician could be at risk of facing a claim in negligence: the only area of criticism could be in not giving a full explanation of the possibilities to the patient; and on the basis that the patient has received the standard treatment it looks as if it would be inconceivable that it would be possible to prove that the patient would have been likely to have had a better outcome if a different and more risky treatment had been selected.
14. The end result is the same: if the clinician adopts standard treatment he or she will almost always be safe from the threat of litigation.
15. The other side of this coin is set out in the proposition at paragraph 9(b) above: if the clinician departs from standard practice and chooses to innovate, there will be an increased risk of litigation in the event of unforeseen undesirable consequences - however small the risk. I have been specifically asked because of the difficulty of quantification of such a risk not to try to assess what the increase might be.
16. In the context of this advice, where innovation is being treated as synonymous with departure from the standard treatment, I think that it has to be accepted that the doctor who innovates in the treatment of a patient runs an increased risk of litigation if there is an unforeseen and undesirable outcome. The risk may be small but it seems to me that it is self-evident that it will be greater where the clinician has departed from standard treatment.

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17. There are steps that a clinician has to take when departing from the standard: there has to be an explanation for the departure, and the patient has to understand the reason for that departure and any consequential risks, and give his or her consent. All of these elements should be noted by the clinician, and where the approach is reasonable, the explanation understood, and the patient consents, it is extremely unlikely that the clinician would face litigation.
18. But it is easy to see that the clinician might not be aware of all of the risks associated with the proposed innovative treatment - by reason of the very fact that it is non-standard. If it was subsequently felt that the clinician should have been aware of something that the patient was not warned about, there might be a criticism. The fact is that many doctors believe that the risk of being sued stifles innovation, and it seems to me that it must be the case that the departure from standard treatment involved with innovation must carry with it some increase in the risk of the clinician being sued.

The Issue of Informed Consent

19. There is on occasions a default response to questions of risk associated with innovative treatment that has been identified by the proposers of this Bill to the effect that it is all a matter of "informed consent". As long as the patient gives his or her informed consent, the response goes, the clinician will be safe from being sued in the event that the treatment causes unintended and undesirable consequences.
20. The counter-argument to this response is to this effect: where there are situations where the rarity of the condition that is being treated (such as rare cancers where it may be thought that there is the greatest need for innovation in the

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interests of the patients) is such that there is a lack of published research and a lack of experience of the effect of the treatment proposed, then the protection offered by informed consent is less secure for the clinician.

21. I have been asked to comment on the extent to which informed consent can protect a doctor in relation to an innovative approach to treatment.
22. It is generally believed that for a patient to give informed consent then he or she has to have been given an appropriate explanation of the different possible treatments and a reasonable explanation of the relevant risks and benefits of each possibility. If this has been done and a known risk eventuates then it is generally believed that the clinician should be immune from suit.
23. The situation that is being considered with the difficulty of treating rare diseases in an innovative way obviously gives rise to difficulties. I would, however, formulate it slightly differently from the formulation in my instructions. It is not that informed consent is not giving effective protection, it is more that this is a situation where it is not possible for the clinician to give the reasonable explanation of the relevant risks because they are not adequately known. I phrase it differently, but the effect is the same: the clinician is unable to secure protection from possible litigation by means of the informed consent of the patient, not because informed consent would not be effective, but because it is impossible to give the patient sufficient information about the possible consequences and risks of the treatment for the patient to give informed consent.
24. In considering this question the possibility arises that perhaps the clinician could say this:

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"Because of the explanation that I have given you I do not think that the standard treatment is likely to help you. There is a possible alternative that is new and largely untested, but I believe that it might help you. Because the treatment is largely untested in the context of your illness I cannot tell you what the risks are. You have to accept that it is risky, and that it might even kill you or cause you lasting damage". As long as such a warning was accurate, and it was not possible to set out the risks, and as long as it could be established that it was reasonable to offer the treatment with the hope that it might help the patient, I think that such a warning would be adequate if the patient consented. But the problem here is that it is very difficult to construct a theoretical situation to illustrate such a consent, and in the real world most clinicians will be reluctant to recommend or even offer a treatment if it is so untested that they cannot even set out all the risks associated with it.

Named Patient Drugs

25. The licensing of drugs for use in the UK is a complicated process. The Medicines and Healthcare Products Regulatory Agency (the MHRA) is the body in the UK whose role it is to license drugs for use by the public. In respect of drugs to be used in the EU drug companies can apply for a licence direct to the European Medical Agency. Some drugs can only be licensed through the European Agency. These include:

- 'High tech' biotechnology treatments, such as gene therapies;
- Medicines to treat HIV/AIDS, cancer, diabetes, and neurodegenerative diseases, such as multiple sclerosis and Alzheimer's disease ; and

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- So-called "orphan drugs" which are medicines that would not normally be commercially viable, because they have been developed for rare diseases, occurring in fewer than five in 10,000 people.
26. But in certain circumstances drugs can be used before they are officially licensed. A 1989 EU Council Directive laid out the framework for the supply of unregulated medicines in response to unsolicited requests for use by an individual patient "on his personal responsibility". The current legal basis for access to pre-launched medicines in the EU is Article 5 of Directive 2001/83/EC. This legislation offered the possibility of pre-launch use as an exception to the rule that medicines must be authorised before use, or used within the context of an approved clinical trial.
27. In 2004 Regulation 726/2004 set up the European Medicines Agency and set out a structure for the use of unlicensed drugs. Different countries are responsible for their own regulations and different terms are used, but the purpose is to grant access to drugs, before they have been approved or licensed, to patients who have exhausted all alternative treatment options and do not match clinical trial entry criteria. The principle is called "compassionate use", "expanded access" or, in the UK, "named patient" supply.
28. The MHRA website sets out in summary and simplified form the way that named patient supply is intended to work. The effect of its statement is as follows.
- Sometimes doctors find that a licensed medicine works well for a certain condition, age group, or at a dose for which it has not been licensed by the regulator. They prescribe it, based on their own and their*

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colleagues' experience, published studies, and findings presented at professional meetings. This is called 'off label' prescribing.

This is more likely to happen when there are either no alternatives, or where access to effective alternatives is restricted. Sometimes doctors will also ask the MHRA to import a medicine that has been licensed outside Europe if they think this might help a particular patient, on what is known as a named patient basis or 'unlicensed' use.

29. The possibility of the use of drugs in this way is sometimes said to provide a route to innovation that protects the doctor; but the question in the context of the Bill, and its purpose is whether:
- (a) Named patient usage brings with it no special protection from litigation in the event of undesirable and unintended effects; and
 - (b) The decision to recommend an unlicensed treatment brings with it an inevitable assumption of responsibility which might deter its use in cases where a doctor thought that it might be appropriate and beneficial.
30. It is many years since I was involved in a case involving the use of an unlicensed drug. The case was complicated, but in the end the shortest summary of the relevant issues in it was that the patient asserted that his life had been grievously affected by taking the drug, and that the risks had not been properly explained to him. The clinician said that he had given an appropriate explanation and the outcome could not have been predicted. The Claimant's expert said that the use of the drug amounted to unreasonable experimentation, and the Defendant's expert considered that it was a reasonable approach to use it.

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31. It could be said that my experience in that case shows the truth, or at least the potential truth of the proposition set out above. Of course one case provides no more than an anecdote in the context of the purpose of this Bill, and the purpose of the regime for named patient drug use is, in part, to encourage innovation, and the term "therapeutic innovation" is used in the text of Regulation 726/2004. But it is clear that the use of a drug in this context brings with it no special protection from suit - and it is probably the case that the reverse is true: the use of an unlicensed drug is going to be subject to great scrutiny in the event of unforeseen consequences. It might be thought in some circumstances to shift an evidential burden onto the clinician to justify its use. And it seems to me that it will inevitably be the case that by recommending the use of a drug in this context the clinician is accepting responsibility for the advice to use it. That does not, of course, mean that the clinician will always be at fault if there is an unexpected and adverse outcome, but where it is the case that the doctor has recommended the use of a drug where it has not (yet) gone through all of the testing that would be associated with a licensed drug, it must be inevitable that he or she will be more vulnerable than if the drug was licensed.
32. The proponents of the Bill are particularly concerned with rare and aggressive conditions. The example is given of ovarian cancer. The rarity of the condition and the way that it presents make the formulation of clinical trials to evaluate the effectiveness of different treatment very difficult. The clinician may be effectively presented with the choice of recommending standard treatment that provides some slight (and perhaps temporary) benefit against attempting to seek an innovation that might provide a much better outcome but cannot be sure even of the slight benefit afforded by the standard treatment.

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33. These are terribly difficult situations. The clinician wants to do the best for the patient, but may be reluctant to risk forgoing a temporary benefit for an uncertain outcome; and every doctor starts from the proposition that his or her job is to "do no harm", and will want to make sure that he or she has behaved in a way that cannot be criticised. The patient may be desperate in the knowledge that the conventional treatment, although it may provide some relief, will do nothing for the poor prognosis; and the patient may be suffering great pain and taking large doses of powerful drugs with consequences for his or her awareness and judgment in taking decisions. And the family may be anxious to prolong the life of the patient, or to reduce the patient's suffering, or to take any risk in the hope of long-term survival. A family with many members might encompass all of the inconsistent aims referred to.
34. It seems to me that some doctors might thrive on such an environment and rise to the challenge of treating each patient individually and inventively within the confines of what is safe and possible; but it seems to me also to be beyond doubt that it is inevitable that some doctors will be intimidated by such circumstances and will tend towards standard treatment, and therefore ensure that they are not going to be criticised.
35. I would only add this in this context. If a doctor is faced with a patient who is going to die with the standard treatment, then if he or she understands the process of clinical negligence claims (which many, of course, do not) he or she will probably not greatly fear being sued. If a patient is going to die and consents to an innovative treatment that is unsuccessful, it is hard realistically to see how a negligence claim could then be brought. In my view the clinician is more likely to fear a complaint about his or her

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conduct to the employing Trust, or to the GMC. In the end, though, the effect is the same: the clinician fears criticism, and perhaps proceedings of some sort, where the innovation has not had the effect hoped for and has perhaps had an unforeseen adverse result.

36. Lord Saatchi and the supporters of the Bill consider that the factors that I have set out above, together with the recent sharp increase in the level of negligence claims against the NHS, have combined to have a deterrent effect on medical innovation. The argument is that doctors fear innovation for the reasons set out and the NHS managers are concerned more and more with "Risk Management" to bring down the number of negligence claims. And "Risk Management" is inevitably going to be at odds with innovation.
37. I do not know if any work has been done with the NHSLA figures to show what percentage of claims could be said to be associated with innovative treatment, and I do not know what such work would show if it was possible. Some risk management measures are entirely responsible and would not in any circumstances prevent or discourage responsible innovation. I have seen many "Serious Untoward Incident" reports (and differently named reports into bad and unexpected outcomes) that are of the highest quality and carried out by senior clinicians who have entirely understood the pressures facing the doctors involved. Many of these reports exonerate the clinicians. But there are other types of risk management that are less benign.
38. I have attended seminars and conferences attended by individuals involved in risk management as well as doctors and lawyers. I have been involved in discussions and heard questions asked that I found surprising. I have no doubt that there are some risk managers working in the NHS who would

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consider that any innovation by doctors makes their job more difficult. I cannot say what the effect of such people is on the work done by doctors in their hospitals, but it is certain that their attitude does not encourage innovation.

The Bolam Test and the Current State of the Law

39. Lord Saatchi's briefing note on the Bill refers in some detail to the cases and the conclusion to be drawn that a doctor who follows standard practice will be safe from being sued - with the inevitable conclusion that this is a clear deterrent against innovative developments.

40. The summary starts with the case of the unfortunate Mr Bolam, who broke his hips when he fell off a bed while he was undergoing ECT and had not been properly restrained. This case¹ has come to define the approach to what constitutes "reasonable skill and care", or the approach to defining what is a departure from that standard. The formulation of the principle was contained in the judge's direction to the jury (which took 40 minutes to dismiss the negligence claim, and find for the Defendant):

"...where you get a situation which involves the use of some special skill or competence, then the test as to whether there has been negligence or not is not the test of the man on the top of a Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man

¹ **Bolam v. Friern Hospital Management Committee** [1957] 1 WLR 582.

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exercising that particular art ... he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art ... Putting it another 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 who would take a contrary view."

41. But it is not quite right to say (as the briefing note does at page 16) that this means that a doctor will have a cast iron defence if he or she has followed a practice that would be followed by a group of medical practitioners skilled in that area of medicine. It is probably right to say that for many years this was considered to be the effect of the Bolam Case and the early cases approving it. Lord Saatchi refers to the case of **Bolitho** in his note, and this was an important case in modifying the Bolam test.

42. In the Bolitho² Case the House of Lords, amongst other things, defined the basis on which the Court could reject the evidence of the support of a group of practitioners for a criticised course of treatment or management. The formulation of the right of the Court to reject the medical expert evidence on the question of negligence is set out by Lord Browne-Wilkinson at page 241:

"The court is not bound to hold that a defendant doctor escapes liability for negligent treatment or diagnosis just because he leads evidence from a number of medical experts who are genuinely of opinion that the defendant's treatment or diagnosis accorded with sound medical practice. In the Bolam case itself, McNair J. [1957] 1 W.L.R. 583,

² **Bolitho v. City and Hackney Health Authority** [1998] AC 232

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587 stated that the defendant had to have acted in accordance with the practice accepted as proper by a "responsible body of medical men." Later, at p. 588, he referred to "a standard of practice recognised as proper by a competent reasonable body of opinion." Again, in the passage which I have cited from Maynard's case [1984] 1 W.L.R. 634, 639, Lord Scarman refers to a "respectable" body of professional opinion. The use of these adjectives - responsible, reasonable and respectable - all show that the court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis".

And then he says at page 243:

"These decisions demonstrate that in cases of diagnosis and treatment there are cases where, **despite a body of professional opinion sanctioning the defendant's conduct**, the defendant can properly be held liable for negligence (I am not here considering questions of disclosure of risk). In my judgment that is because, in some cases, it cannot be demonstrated to the judge's satisfaction that the body of opinion relied upon is reasonable or responsible."

43. This is considered by practitioners to be an important modification of the Bolam principle. It leaves open the possibility of establishing that a practice that is sanctioned by some respectable practitioners is irrational, and should still be considered to be negligent.

44. But it is also right to say that this is an approach rarely attempted by Claimants, and even more rarely is it thought likely to be successful. In general terms I have no doubt that it is right to say that, except in the rarest of circumstances, the doctor who follows a standard

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approach will be immune from suit or criticism. And it is also right to point out, as Lord Saatchi has by his reference to the statement of Baroness Butler-Sloss in the cases of *Simms v. Simms*,³ that it has been acknowledged that this principle has the potential to stifle innovation.

The Purpose and Effect of the Bill

45. As set out in my instructions the intended effect of the Bill is:

- (a) To codify the present state of the law in so far as it supports responsible innovation and penalises irresponsible innovation;
- (b) To provide an authoritative statement of established best practice;
- (c) To provide greater clarity as to the difference between responsible and irresponsible innovation;
- (d) To encourage (as a result of that greater clarity) the increased use of responsible innovation in medical practice; and
- (e) To make it easier for the courts and others to detect and deter irresponsible, reckless innovation.

46. I have been sent two versions of the Bill. The later version, published in May of 2013, provides as follows in Section 1:

1 Responsible Innovation

(1) The purpose of this Act is to encourage responsible innovation in medical treatment and to deter reckless departure from standard practice.

(2) It is not negligent for a doctor to depart from the pre-existing range of accepted treatments for a condition (standard practice)

³ **Simms v. Simms** [2002] Fam. 83

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if the decision to innovate is taken responsibly.

- (3) *A responsible decision to innovate will, in particular, be based on consideration of—*
- (a) *the reasons why the available research or other evidence is insufficient or unclear including, in particular, whether it is referable to the nature of the condition (as in, for example, a cancer that affects relatively few patients),*
 - (b) *the relative risks that are, or can reasonably be expected to be, associated with the treatment the doctor proposes to apply and other treatments,*
 - (c) *the relative likely success rates of the treatment the doctor proposes to apply and other treatments, in the doctor's reasonable judgement,*
 - (d) *the relative likely consequences of applying, or failing to apply, the treatment the doctor proposes to apply, and other treatments,*
 - (e) *opinions or requests expressed by or in relation to the patient, and*
 - (f) *any other matter that appears to the doctor to be reasonably necessary to be considered in order to reach a clinical judgement.*
- (4) *A responsible decision to innovate must be made in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters; the process may include, in particular—*
- (a) *decision-making within a multi-disciplinary team;*
 - (b) *notification in advance to the doctor's responsible officer (within the meaning of Part 5A of the Medical Act 1983);*

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- (c) explanation to the patient of the doctor's reasons for proposing to depart from standard practice, including discussion of any contrary opinions expressed by the doctor's colleagues.
- (5) Nothing in this section permits a doctor—
- (a) to provide treatment without consent that is otherwise required by law, or
 - (b) to administer treatment for the purposes of research or for any purpose other than the best interests of the patient.
- (6) In this section—
- (a) "doctor" means a person listed in the register of medical practitioners under section 2 of the Medical Act 1983, and
 - (b) a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction).

47. I have considered this formulation with care. It seems to me that there is nothing in this draft that effects a substantive change in the law. By definition the Bill is not concerned with standard treatment that conforms to standard practice: I have considered how a Court would consider treatment that was intended to be innovative and which departed from standard procedure, and it seems to me that this is an effective definition of how the task would be approached. I believe that it succeeds in the aim of setting out a framework and defining an approach that does not change the existing law.

48. I have also considered the task that has been undertaken in this formulation of defining best practice in the context of therapeutic innovation. It also seems to me that this is an effective

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approach to this task as well. I am aware that a great deal of expertise and thought has gone into this: I think that an excellent balance has been struck by not including too many considerations and steps that might be taken while still setting out an effective definition. The only tentative comment that I would make on the drafting is in respect of (4)(c). It seems to me that it might be thought that the words "expressed by the doctor's colleagues" are too restrictive, and that it would be better simply to provide for the discussion of contrary views.

49. But this is not a substantive criticism: it seems to me that the formulation does effectively emphasise the importance of best practice, and points the practitioner in the direction of implementing best practice.

50. I would expect the Courts to be conservative in the implementation of a clause in this form; and I would expect most legal practitioners similarly to regard it as providing a framework to consider best practice in different circumstances without effecting any significant change in the law. I do not think that I can say that no lawyer will come up with a surprising interpretation - but the important thing is the approach of the Courts. I would expect, as I have said, a conservative approach, and as soon as the Court of Appeal considers it for the first time I would expect the scope for surprising interpretations effectively to be removed.

51. I note the words of Professor Findlay, Baroness Findlay of Landaff, in a debate on the policy of the Bill in the House of Lords in January 2013 that have been set out in my instructions. It is eloquently put: there are the drivers of research councils, academic research and the drug industry, and the brakes of a risk-averse system, and perhaps in certain circumstances managers

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reluctant to embark on the unknown, or the high risk.

52. The intention of the Bill in sub-clause (1) (the purpose clause) is to express the balance which is or should already be recognised in the best practice relating to innovation. It seems to me that the clause cannot be criticised: I have asked myself whether the use of the word "reckless" to define undesirable departure from standard practice might be too extreme. I have considered whether it might be better to use the term "inappropriate". This may benefit from further consideration and I am sure that it has been considered by others, but I do not consider that the use of the term "reckless" detracts from the effect of this clause. In my view it effectively sets out the balance that is intended.
53. Clause 1(2) of the Bill provides that: *It is not negligent for a doctor to depart from the pre-existing range of accepted treatments for a condition (standard practice) if the decision to innovate is taken responsibly.* The purpose of this clause is that it is the basis for the propositions set out in the two following clauses: accordingly it has to be right if the Bill is to be declaratory of the existing law.
54. Again, I have considered the drafting with care. It seems to me that it is possible to say that, without further definition, departure from "standard practice" is not necessarily "innovation". It might conceivably be the case that there was a departure from standard practice in treatment of a patient that was explained only in part by innovation. But again this is not a substantive criticism of the clause. In my view the clause does set out the existing law: if the departure from standard practice is a responsible one, the treatment is responsible. And if the treatment is responsible then it is not

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negligent. I do not doubt that the Clause accurately sets out the existing law.

55. Clause 1(3) then sets out the particular considerations to be taken into account for a responsible decision to innovate. I have been instructed that the intention in the drafting of this section is as follows. That it:

- (a) does not purport to prescribe an inflexible or exhaustive list of factors to be considered;
- (b) leaves doctors free to give such weight to such factors in individual cases as appears right to them in the exercise of their clinical judgment; and
- (c) provides the courts with a non-exhaustive list that they can use both in confirming that a decision has been taken in a responsible way and also in establishing, in an appropriate context, that a particular decision has been taken in a reckless or otherwise irresponsible way.

56. I have, as before, considered the wording of this section with care. It clearly does not purport to provide an inflexible or exhaustive list of matters to be considered: it seems to me that the words "in particular" make this clear. This could be slightly expanded in the drafting, which might include a reference to something like ". . . all the circumstances, including but not limited to consideration of" But it seems to me that the existing economical draft has the same effect.

57. It also seems to me that the formula of listing considerations that has been adopted appropriately leaves open to the clinician the job of balancing the factors and giving each such weight as seems right in all of the circumstances. In (b), (c) and (d) there is express reference to "relative" considerations, and in my view the thrust and effect of the clause is to leave the doctor to

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consider the weight of the factors in the individual case.

58. If a claim against a doctor arising out of innovation is to be considered by the Courts it will be in the context that a claim has been brought alleging that the treatment was negligent by reason, at least in part, of a departure from standard practice; there will be a defence perhaps denying that it was such a departure, but also alleging that the departure was reasonable and responsible, and there will be a statement from the clinician justifying what was done. There will also be experts' reports considering the merits of the case from both sides.
59. The Bill would provide a framework for all of these elements (and not just the consideration by the Court): the claim would address the issue of negligence by reference to the matters set out in the Bill, as would the defence, and the clinician involved would do so in his or her statement. The experts would approach their task in the same way; and finally the Court would be in the position of being able to embark on the same consideration after evaluating the approach of both sides. The circumstances of the case might necessitate consideration of other matters that are not specifically referred to in the Bill, but it would still provide a starting point for the framework of the decision.
60. Statutory guidance should always provide clarity and authority: the intention in a situation like this is that it provides clarity in a way that a succession of decided cases does not. There is a trade-off between flexibility and clarity where the statute does not attempt to set out an exhaustive definition. This is a case where the statutory framework is deliberately neither inflexible nor exhaustive - this means that it is not definitively codified. But it seems to me,

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nevertheless, that because of the way that it is drafted it certainly provides clarity of approach and the authority of statute.

The Unpredictability of a Dispute between Experts

61. Lawyers who practise in the field of Clinical Negligence are accustomed to hearing the view that doctors will defend their own, and that the Defence will always be able to line up experts to counter what the Claimant says. This is usually a misapprehension both of the job done by doctors as expert witnesses, and the way that allegations of negligence are determined. As a matter of fact the way that allegations are decided, or should be decided, particularly after the case of **Bolitho** that I have referred to above, is not to count the experts on both sides, or to see whether somebody respectable for the Defence will defend the management or treatment that is being criticised. The task to be undertaken is (after finding any disputed facts) to evaluate the criticism that is being made by the Claimant, and to consider the defence of the treatment that is criticised. This is not a crude undertaking of simply seeing if the case is being defended by a respectable expert, but it can be (and usually should be) an exercise in careful analysis and evaluation of the merits of arguments being put.

62. In rejecting the proposition that a Defendant could always escape a finding of negligence if he could show that experts genuinely believed that the treatment accorded with sound medical practice (see above) Lord Browne-Wilkinson in the case of **Bolitho** in the House of Lords said this:

In particular in cases involving, as they so often do, the weighing of risks against benefits, the judge before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that, in forming their views, the experts

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have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter.

This is the exercise that the Court is supposed to do: the Court goes beyond considering simply whether or not the treatment is defended by respectable clinicians by evaluating the defence and looking at the analysis of the risks and benefits.

63. I have no doubt that the Bill would change the perception of the way that the task of evaluating negligence is undertaken; and it seems to me that it also has to be said that sometimes the impression is given that Courts are perhaps more reluctant than they should be to analyse the logic of an expert's position. In this regard, by concentrating on analysis and the way that a decision in respect of treatment was made, I believe that the Bill would have a beneficial effect both in affecting the perception of those concerned with such cases, and to some extent in concentrating the minds of judges. It would go some way to ensuring that the decision-making process is based on a cumulative analysis of the work that was done by the clinician, both as to the consideration of the prospects of success of the different possible treatments, and the way that the clinician took the decision to depart from the standard approach.

64. I have considered the wording of the non-exclusive list in Clause 1(4). In particular I have noted the reference to advance notification to the doctor's responsible officer. It seems to me that this provision is interesting and important: on my first acquaintance with this Bill I consider that this clause sets the bar appropriately high with this list. It seems to me to be an effective provision. But I have to point out that this

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consideration would depend in part on suggestions by clinicians with an interest in medicine in the sort of difficult areas in which it is envisaged that this Bill will be most effective. I would be most interested to see the results of any consultation or less formal enquiries as to the view of doctors in this regard.

65. My instructions expressly acknowledge that the idea of encouraging innovation in medicine can alarm those who may feel that it is a first step on the way to legitimising experimentation on patients with interesting illnesses. Clause 1(5) has been included to make it clear that there is no intention to change the law as to the need for consent to any treatment, and also that its relevance is to the treatment only of patients in their best interests and not to assist in experimentation or clinical research.
66. This part of the Bill (in common with the rest of it) is clearly and accurately drafted. It seems to me that it makes quite clear that there is no relaxation in the requirement for consent, and that any treatment to which the Bill applies has to be in the best interests of the patient - and therefore not for the purpose of research.
67. I understand that it was thought necessary expressly to include in the definition of treatment the concept of "inaction". This is on the basis that increasingly in the field of cancer there is a view that some traditional surgical interventions can cause the spread of the disease - and that innovative treatment might be NOT to carry out surgery.
68. In my experience the concept of doing nothing by way of intervention is frequently referred to as conservative management. It may be that this definition is not strictly necessary, but I have no doubt that it means what it is intended to

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mean, and its purpose may be more in drawing attention to the consideration behind the clause rather than in its strict legal effect.

Conclusion

69. The basic premise behind this Bill is that the fear of being sued (or perhaps of facing other proceedings for misconduct) acts as a deterrent to Doctors adopting reasonable but innovative, and non-standard treatments. This, in turn, leads to the stalling of necessary developments in treatments for rare and lethal diseases.
70. If the premise is right it will mean that the problem is effectively hidden from the Clinical Negligence lawyer because the clinicians will have avoided being sued by not departing from standard treatments and not trying innovative techniques. In my practice I have seen very little to demonstrate that innovation is stifled by the risk of being sued, but the case that I have referred to above in which an unlicensed drug was involved in fact illustrated the possibility of many of the points which are under consideration here. Further, I know from talking to doctors that they say that they do fear being sued, and that they believe that the risk of suit inhibits therapeutic innovation. And further, everybody knows that various cancers stubbornly resist cures and qualitative advances in treatment.
71. I have had almost no cases in practice that have demonstrated to me that the current state of the law inhibits innovation, but this is not necessarily surprising. I believe that the analysis contained in my instructions, and on which the Bill is based, is correct. The state of the law may mean that there is a genuine risk to the doctor associated with innovation, and (just as importantly) doctors may genuinely believe that there is a risk.

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72. My own belief is that if the right case was before the Courts one could expect a statement of principle that was in accordance with the formulation of this Bill - that is the same as saying that I consider that the Bill does reflect the current state of the law. Lawyers spend their careers waiting for the perfect case to establish a principle: it is almost axiomatic that it never comes. But the establishing of a principle usually only affects the rights of people involved in a dispute. In this area the principle may be affecting the development of medical science, and in that event legislation can and should bring the wait for the perfect case to an end.
73. In truth I do not know whether this Bill, if enacted into law, would stimulate innovation and lead to significant advances in medical science; but I do believe that in certain areas it would diminish the emphasis on the desirability of treating in accordance with standard practice, and would encourage practitioners to believe that they were not at risk if they tried to innovate in a responsible way for the benefit of their patients. In time this should have a positive effect on stimulating innovation in medical treatment.

Outer Temple Chambers,
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Christopher Gibson QC

14th August 2013

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MEDICAL INNOVATION BILL

LEADING COUNSEL'S ADVICE

BIOGRAPHICAL DETAILS OF CHRISTOPHER GIBSON QC

Christopher Gibson was called to the Bar in 1976 and was appointed Queen's Counsel in 1995.

He practices from Outer Temple Chambers, The Outer Temple, 222 Strand, London WC2R 1BA.

Christopher's practice is in clinical negligence and personal injury, with a specialisation in high value negligence and injury cases. His experience includes cases involving injuries of maximum severity including, in particular, cases of cerebral palsy involving birth injuries to children where allegations are made in respect of the obstetric and neonatal management.

Christopher sits as a legally qualified chair of the Fitness to Practise Committee of the General Pharmaceutical Council.

For further information, including case summaries, see:

<http://www.outertemple.com/barristers/100/index.html>.

MEDICAL INNOVATION BILL [HL]

INSTRUCTIONS TO COUNSEL TO ADVISE IN WRITING

INTRODUCTION

1. Counsel has herewith—

- (a) a copy of the Medical Innovation Bill as introduced into the House of Lords earlier this Session;
- (b) a copy of the Explanatory Notes prepared by Lord Saatchi's Bill team to accompany the Bill;
- (c) a copy of the slightly longer Bill introduced in the last Session;
- (d) a copy of the Explanatory Notes that accompanied that Bill; and
- (e) Lord Saatchi's Guide to the Bill.

2. The Medical Innovation Bill is a private peer's Bill introduced into the House of Lords last Session and this Session by Lord Saatchi. Second Reading of the Bill in the Lords is not expected until early 2014.

3. It is expected that a Bill in identical terms will shortly be introduced in the House of Commons through a private Members' procedure. Substantive proceedings on the Bill in the House of Commons are likely to be relatively short. The Bill team's aim for this Session is to achieve at least a Committee Stage in the House of Commons, but this depends in practice upon the Government and private Members being prepared to allow the Bill to

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proceed to that extent without substantive debate.

4. Counsel is asked to advise on matters relating to the Bill as set out in the instructions below.

THE LAW AS A CONSTRAINT ON INNOVATION

5. The underlying thesis of the Bill is that the fear of litigation places a significant constraint on doctors when deciding to depart from standard procedure and to innovate.

6. In particular, the policy underpinning the Bill rests on the assumption that the state of the law on medical negligence presently operates as an implicit disincentive to innovation.

7. It is **not** Lord Saatchi's position that innovation is impossible under current conditions, or that it is not presently best practice within the profession to innovate when appropriate and in accordance with an appropriate procedure.

8. It is, however, Lord Saatchi's contention that the approach of the courts to claims for medical negligence creates an implicit disincentive to innovation, simply because—

- (a) a doctor who follows standard practice, even when that amounts to doing nothing, will almost always be able to regard himself or herself as "safe" from the threat of litigation, but

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(b) a doctor who chooses to innovate, however responsibly and carefully, knows that the mere fact of innovation carries with it an increased risk of litigation in case of unforeseen undesirable outcomes, however small the risk and however important it may be in the interests of the patient to take it.

9. Counsel is invited to comment on the accuracy of the propositions in paragraph 8(a) and (b).

10. The Bill team is not aware of any method of quantifying objectively the increase in risk specified in paragraph 8(b). A certain amount of anecdotal evidence has suggested that in particular areas of medicine - notably in the area of rare cancers - it is enough to exercise a significant influence on treatment-patterns. The size of the risk is not, however, considered by Lord Saatchi to be essential to the desirability of the Bill or the importance of enacting it. **Counsel is not, therefore, specifically instructed to quantify the risk specified in paragraph 8(b), but any observations that arise from Counsel's experience will be welcomed.**

11. The primary method by which a doctor protects himself or herself when recommending particular courses of treatment to a patient is by obtaining informed consent. In discussion of the Bill it is sometimes suggested that the possibility of obtaining informed consent is a complete answer to the problem identified above. The understanding of the Bill team is that informed consent can only give partial or limited protection from litigation if a course of treatment has unintended and undesirable consequences, particularly where it was not possible to predict and quantify the risk accurately in

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advance. The Bill team believes that this limitation is a particular constraint in relation to conditions - such as rare cancers - where there has been limited opportunity for published research or for obtaining a clear picture of the likely effects of particular treatments. The result is that in the Bill team's view, the more that innovation may be thought necessary because of the lack of effective standard treatment underpinned by published evidence, the less informed consent is likely to be an effective protection where a doctor decides to recommend an innovative treatment. **Counsel is asked to comment on the extent to which informed consent can protect the doctor in relation to a decision to innovate.**

12. As Counsel knows, it is already possible for doctors to obtain drugs which have not been licensed for general use in the United Kingdom on a "named-patient" basis. In discussion of the Bill the availability of named-patient usage is sometimes referred to as a method by which the freedom to innovate is presently protected. It is the understanding of the Bill team that-

(a) named-patient usage brings with it no special protection from litigation in the event of undesirable and unintended effects; and

(b) the decision to recommend an unlicensed treatment brings with it an inevitable assumption of responsibility which might deter its use in cases where a doctor thought that it might be appropriate and beneficial.

13. **Counsel is asked to confirm the accuracy of the propositions in paragraph 12(a) and (b).**

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14. The problem described above is thought by the Bill team to be particularly acute in the case of relatively rare conditions such as ovarian cancer, where the nature and incidence of the condition makes it relatively difficult to mount effective clinical trials of new treatments and approaches to management. The proposition is that a doctor who applies the treatment that has been standard in relation to the condition for the last forty years, which is thought in practice to amount to little or nothing, will be able to feel safe from actions for negligence on the grounds that he or she has followed the professional standard approach. By contrast, a doctor who wishes to innovate will be departing from standard practice and will therefore be exposing himself or herself to a risk of litigation should the treatment be less successful than hoped or have unpredicted side effects. While a doctor will of course rely on such evidence as is available, in the case of rare conditions that evidence will be sparse or non-existent. A doctor will also, of course, do as much as possible to protect himself or herself against litigation, and in accordance with good practice in any event, by obtaining fully informed consent of the patient; there is thought, however, to be an inevitable risk that in the case of a relatively rare and particularly severe disease it will be particularly difficult after the event to show that consent was truly informed, particularly where patients may later be said to have been desperate in the face of little or no prospect of success using standard treatment. **Counsel is invited to offer any observations that occur to him about this statement of the application of the general principles discussed above to the circumstances described in this paragraph.**

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15. Lord Saatchi's Guide to the Bill explains why it is thought that the issues discussed above are likely to present an increasing barrier to innovation. In particular, the Guide notes the rate of acceleration in litigation in respect of the number of claims brought against the National Health Service in the last few years, and the spiralling cost of meeting those claims. The National Health Service Litigation Authority Report and Accounts for the years from 2010 to 2012 record an enormous increase since 2004 in the number of claims for clinical medical negligence brought against NHS trusts and in the sums paid out in response to those claims. The Reports describe the implementation of what are described as "risk-management" measures in relation to that increase of litigation. Lord Saatchi's view is that the risk-management process established by the NHS authorities and by insurers can only increase the constraining influence of potential litigation on innovation in medical treatment as discussed above, and give a particular urgency to the passage of the Bill. **Any comments that Counsel may be able to offer in relation to that view will be welcomed.**

16. **Counsel is also invited to offer any other observations that occur to him in relation to the present state of the law, particularly in respect of the matters discussed in pages 15 to 18 and 22 to 26 of Lord Saatchi's Guide to the Bill.**

THE EFFECT OF THE BILL

17. As stated above, it is common ground that the law makes provision for innovation and that best-practice within the profession already

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emphasises the importance of innovating responsibly.

18. The policy intent of the Bill is therefore to codify what is already recognised as best practice within the medical profession and to give reassurance to doctors that if they innovate responsibly they will be protected from exposure to liability for negligence. At the same time, the Bill wishes to make it clearer that doctors who choose to innovate without applying appropriate criteria and procedures will expose themselves to liability.

19. Specifically, the intended effect of the Bill, therefore, is—

(a) to codify the present state of the law in so far as it supports responsible innovation and penalises irresponsible innovation;

(b) to provide an authoritative statement of established best-practice;

(c) to provide greater clarity as to the difference between responsible and irresponsible innovation;

(d) to encourage (as a result of that greater clarity) the increased use of responsible innovation in medical practice; and

(e) to make it easier for the courts and others to detect and deter irresponsible, reckless innovation.

20. To that extent the Bill is in part a declaratory measure, and in part a clarifying measure.

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21. The Bill team have identified comparisons with sections 1 and 2 of the Compensation Act 2006, of which Counsel will be aware and which were designed to correct perceived imbalances in the law of negligence and to increase clarity, rather than to effect fundamental change of the existing balance struck by the courts.
22. In the same way, the Bill is not intended to change the fundamental proposition of the present law, according to which doctors are permitted to innovate, but only if they do so in accordance with proper clinical practice.
- 23. Counsel is asked to confirm that the form of clause 1 of the Bill is apt to avoid changing the law while strengthening perception of, and reliance on, best practice as described above.**
- 24. Counsel is further asked to offer observations on the likely attitude of the legal profession and the courts to the implementation of clause 1 of the Bill.**
25. In a debate on the policy underlying Lord Saatchi's Bill in the House of Lords on 16th January 2013 Baroness Findlay of Llandaff, a Professor of Palliative Care, said: "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." The

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need for an appropriate balance to be struck between these two opposing considerations is expressed in the purpose clause in clause 1(1) of the Bill, which expresses the equal policy aims of encouraging responsible innovation and deterring irresponsible innovation. **Counsel is asked to comment on the aptness of the purpose clause for expressing the balance which is already recognised in best-practice and which, as described above, the Bill aims to support and strengthen.**

26. Clause 1(2) of the Bill expresses a proposition that adds nothing to the existing law (or to what would intuitively be the position). Its importance is that it serves as a foundation to the propositions in subsections (3) and (4). **Counsel is asked to confirm that in itself subsection (2) represents an accurate statement of the present law.**

27. Clause 1(3) is designed to provide clarity in relation to the kinds of consideration that doctors should take into account when determining whether or not to innovate. Again, the list of factors in clause 1(3) is not intended to include anything that would not already be relevant and appropriate to be considered as the law stands. The purpose of the subsection is to give statutory authority to a non-exhaustive check-list of factors so as to make it easier for a doctor in deciding whether or not to innovate both to satisfy himself or herself, and to be able to demonstrate to others, that the clinical judgment has been taken in accordance with best and lawful professional practice. **Counsel is asked to confirm that clause 1(3)–**

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(a) does not purport to prescribe an inflexible or exhaustive list of factors to be considered;

(b) leaves doctors free to give such weight to such factors in individual cases as appears right to them in the exercise of their clinical judgment; and

(c) provides the courts with a non-exhaustive list that they can use both in confirming that a decision has been taken in a responsible way and also in establishing, in an appropriate context, that a particular decision has been taken in a reckless or otherwise irresponsible way.

28. Counsel is further asked to comment on whether clause 1(3) reflects the general thrust of the existing law and by codifying it supplies additional clarity and statutory authority.

29. Counsel is invited to offer any other thoughts on the likely effect of clause 1(3) that occur to him.

30. Clause 1(4) is designed to provide clarity in relation to the kinds of processes that doctors should apply when determining whether or not to innovate. Again, the list of factors in clause 1(4) is not intended to include anything that would not already be appropriate as the law stands. The purpose of the subsection is to give statutory authority to a non-exhaustive check-list of processes factors so as to make it easier for a doctor in deciding whether or not to innovate both to satisfy himself or herself, and to be able to demonstrate to others, that the clinical judgment has been taken in accordance with an

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appropriate procedure. Counsel is asked to confirm that clause 1(4)–

(a) does not purport to prescribe an inflexible or exhaustive list of processes to be followed;

(b) leaves doctors free to adopt whatever appears to them to be the most appropriate procedure in individual cases; and

(c) provides the courts with a non-exhaustive list that they can use both in confirming that a decision has been taken in accordance with an appropriate procedure and also in establishing, in an appropriate context, that a particular decision has not been taken in accordance with an appropriate procedure.

31. Counsel is further asked to comment on whether clause 1(4) reflects the general thrust of the existing law and by codifying it supplies additional clarity and statutory authority.

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32. As illustrated by and discussed in a number of cases referred to in Lord Saatchi's Guide to the Bill, the keynote of medical negligence today is often the lining up of opposing groups of witnesses to give evidence that the decisions taken were, or were not, those which the witnesses would themselves have counselled or taken. This inevitably leads to an unpredictability for doctors, since so much depends on the future attitudes of witnesses whose identities and opinions cannot be ascertained in advance of the doctor taking the decisions which may later be the subject of litigation. A key feature of the Bill is therefore to inject a degree of certainty, or at least standardisation, into the process; so that by following specified procedures, or other procedures of similar purpose and authority, a doctor can show that a decision was taken in accordance with a procedure allowing for the participation of those best-placed to judge the needs and circumstances of the individual patient at the time. It is hoped that if the Bill changes, rather than codifying, any one aspect of the law of medical negligence, it is by enabling the courts to focus less on a simple balance of two opposing sets of opinions presented to it after the event, and more on forming a view as to whether an appropriate and responsible procedure was followed at the time when the decision was made. **Counsel is asked to express an opinion as to whether clause 1(4) is capable of having a beneficial effect on litigation of the kind described in this paragraph; and he is invited to offer any other observations on the point that occur to him.**

33. Counsel is further invited to offer any other thoughts on the likely effect of clause

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1(4) that occur to him (including the aptness of the non-exhaustive list in paragraphs (a) to (c)).

34. Counsel is further invited to offer any thoughts that occur to him on the distinction between substance and process reflected in clause 1(3) and 1(4).

35. The concept of encouraging innovation sometimes rings alarm bells with people who fear that the purpose or effect of the Bill will be to encourage, excuse or protect "quackery" or other forms of irresponsible behaviour. As clause 1(1) of the Bill states, the aims of the Bill are as much about protecting patients from recklessness as about making it easier for doctors to innovate with confidence as appropriate. Concerns in this area normally centre on the prospect of patients being made the object of experimentation, with or without their notional consent. For this reason, clause 1(5)(a) expressly rebuts any suggestion that the Bill might be thought to be altering the law about when consent is required, and what consent is required; and clause 1(5)(b) makes it expressly clear that the Bill concerns only decisions about treatment for a particular patient, not participation in clinical research. **Counsel is asked to confirm the effect of clause 1(5)(a) and (b) as described in this paragraph.**

36. Clause 1(6)(b) defines treatment as including management and, in particular, inaction. This is particularly relevant to cases where the standard practice is interventionist and a particular doctor believes that the patient's interests will be served best by non-intervention. There is, for example, as Counsel will be aware, a

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growing school of thought that surgical intervention in relation to some instances of breast cancer is likely to encourage spread of the cancer and thereby do more harm than good. The purpose of clause 1(6)(b) is to include non-intervention in the range of possible innovative decisions addressed by the Bill. **Counsel is asked to confirm the effect of clause 1(6)(b) as described in this paragraph, and to offer any observations that occur to him.**

37. In so far as not included in matters raised expressly above, Counsel is asked to consider the likely effects of the Bill if enacted on the theory and practice of the law of medical negligence.

CONCLUSION

38. Overall, Lord Saatchi's understanding is that the situation can be summarised by the following syllogism:

- (a) current law defines medical negligence as deviation from standard procedure;
- (b) under present law, there is uncertainty and ambiguity about whether any deviation by a doctor from standard procedure is likely to result in liability for medical negligence; and
- (c) current law is therefore a barrier to progress in curing cancer.

39. Having regard to the matters discussed above, Counsel is asked whether he agrees with Lord Saatchi's assessment that there is uncertainty and ambiguity in the present law, and that only legislation can resolve that problem.

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**40. Counsel is asked to advise in writing on
this point, and on the other matters specified
in these instructions.**

Daniel Greenberg
Parliamentary Counsel
Berwin Leighton Paisner LLP
3rd July 2013

CONCLUSION

What is the benefit of the Bill?

a) For the Government?

It fits into their innovation agenda. The Health Minister in the House of Commons is himself a doctor. The Health Minister in the House of Lords is also the Minister for Medical Innovation. The Secretary of State's priority is a culture of more innovation to improve the UK's cancer survival statistics.

b) For Doctors?

It helps doctors to feel safe because they can justify their desire to innovate by reference to a strict list of criteria. It brings certainty to the process, by codifying into law the key features of existing best practice

c) For Medical Insurers?

Clarity about the merit of claims against their clients

d) For Patients?

It will discourage any tendency to apathy and complacency; and encourage responsible innovation in diagnosis and treatment. It will expose quackery more effectively than the present law.

There has been revolutionary technological change in many fields but not in the treatment of cancer, which is restricted by present law to conformity with consensus. The Bill, by codifying existing best practice into law, will safely shift the balance of *standard procedure* away from the status quo and towards innovation.

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