COMMENTS ON THE MEDICAL INNOVATION BILL[1]

SIR ROBERT FRANCIS QC

1. Summary

This paper is a personal reflection on the current version of the Medical Innovation Bill, the second reading of which is due to be debated on Friday 27 June. I am grateful to Professor Sir Ian Kennedy QC,[2] for reviewing this paper. He has authorised me to say that he supports the views expressed.

This Bill is, like its two or three predecessors, based on the fundamental misapprehension that the law of negligence inhibits genuine and responsible innovative treatment. Not only that, but for all its good intentions, it is actually dangerous for patients because it proposes "safeguards" which are illusory and which may give free rein to mavericks peddling dangerous remedies to vulnerable and desperate people. In short:

- The law of negligence does not prevent responsible innovation and never has.
- The Bill is not successfully limited in its effect to the sort of treatment Lord Saatchi has in mind and it abolishes the well

1 As proposed by Lord Saatchi [DG version 2 May 2014]

2 Sir Ian is the leading creator of the seminal work on the law in this area, *Principles of Medical Law*, [3rd edition, 2010, OUP Grubb, Laing, McHale] of which he remains the consulting editor. As well as being an internationally recognised authority in tis field, he chaired the Bristol Royal Infirmary Public Inquiry [report 2001], many recommendations of which are echoed in my own more recent report.§§§§§

established and understood principles of negligence in the clinical field across a very wide range of cases

- The safeguards which are proposed in substitution for this are in reality no safeguards at all, but bureaucratic hoops to be jumped through. Further some have no relevance in individual cases. Patients' safety and their rights to redress for injury caused by unacceptable and irresponsible practice should not be compromised so comprehensively to address a problem which is at worst a misunderstanding which could be cured by clear guidance.
- The Bill does nothing to address what may well be the real obstacles to some forms of innovation such as overzealous bureaucracy, scarcity of resources, ethical reservations and decision-making processes. The issues Lord Saatchi has so understandably raised need to be subjected to an evidence based review to identify the obstacles, and solutions to them, in order to produce guidance which could in itself answer any supposed difficulties arising out of the law of negligence.
- This is now the fourth attempt to present acceptable legislation, once previously by Lord Saatchi, one in the Commons and a draft Bill on which the Department of Health has issued a consultation paper and the outcome of which has not yet been made public. The evidence relied on by Lord Saatchi, in so far as it is quoted in his published briefing note, does not provide the convincing support claimed. The difficulties that have caused so many drafts to be produced suggest that if there is to be legislation a more considered and less rushed approach is called for if we are to be

satisfied that the patients who are intended to be benefit from this Bill, and patients generally, are not exposed to increased danger and risk.

2. **My background**

I offer this response in a personal capacity, but it is informed with my professional experience. This includes being the author of the two Mid-Staffordshire NHS Foundation Trust Inquiries, and over 30 years practice in the field of medical law. In that practice I accept instructions from patient claimants in negligence actions, as well as defendant doctors and healthcare providers. I have been involved in many inquiries into deficiencies in healthcare provision, and in many cases before the tribunals of professional regulators in the field. I am a past Chairman of the Professional Negligence Bar Association, and have the honour of being President of the Patients Association. I must emphasise that this response is not made on their behalf, but I am aware that the Association has made its own submission opposing a previous version of the Bill. I would like to believe therefore that I can speak not just from a lawyers' perspective but with the benefit of a record for supporting patient safety, well-being and choice. I have recently been appointed a Commissioner and non-executive director of the Care Quality Commission. I must make it clear that I do not make this statement in that capacity. I have no material interest in the outcome of this debate other than as a potential patient.

3. The need to balance the needs of desperate patients against the risks of proposed treatments

The distress and suffering undergone by patients for whom there is currently no known effective treatment demands our sympathy and understanding. It requires that every effort be made to find new treatment. Medical science has always been motivated by the desire to do just that. But the vulnerability of those who desperately seek new treatments should not be forgotten: those in the greatest medical need deserve protection from injury caused by unjustifiable practice, exploitation, the raising of false hopes, and outright deception. While not directly a case of claimed innovation, the MMR scandal shows the dangers to the public of unjustified and unjustifiable medical advice. The temptations to offer and to accept new treatments – or new ways of using existing treatments - without a balanced appraisal of the risks and benefits are great. Therefore to legalise the taking of a step which may result not only in disappointment but in some cases actual injury, while at the same time removing the right to compensation, is to do a disservice to patients rather than give them real hope.

4. The law of negligence does not prevent innovative treatment

The *Bolam* case has been the established principle by which the standard of care required by the law of negligence for 57 years. The advances made during that time in medical science have been truly remarkable. The patient stories quoted in Annex C of the Briefing note are moving testimony of the desperate need those with serious illnesses have for something new and more effective to treat them. None of them testify to any experience of have been denied treatment because an otherwise willing doctor was afraid of being sued for negligence. The doctors' stories in Annex D speak to the same wish and to a frustration

at being prevented from offering treatment they want to offer. None of them testify as to what it is that has prevented them. None in my view offer a description of what they had wanted to do which suggests they would have been exposed to liability in negligence. What may be evidenced is a frustration with conservatively minded colleagues, the lack of structure in which responsible proposals for innovation can be considered and approved, and a protest at the inadequacy of guidelines. The support for the Bill comes from a belief that removal of an imagined impediment in the law of negligence will solve everything.

5. The starting point of an examination of the merit of this Bill must be to look at what the law actually says. Starting with *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, the judgment recognised explicitly the need not to impede responsible medical innovation. McNair J said

… 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 exercising that particular art....

… a mere personal belief that a particular technique is best is no defence unless that belief is based on reasonable grounds.

So the starting point of the so-called *Bolam* test is that a personal belief that a technique is "best" *is* a defence if it is "*based on reasonable*

grounds". The judge went on to consider a way in which reasonable grounds could be shown:

… 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 the other way round a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view.

The judge was not saying that was the only way for a doctor to defend himself against an allegation of negligence, but he was saying that a doctor was not entitled to insist on doing what no other informed colleague would support as that would among other things stand in the way of progress:

At the same time, that does not mean that a medical man can obstinately and pig-headedly carry on with some old technique if it has been proved to be contrary to what is really substantially the whole of informed medical opinion. Otherwise you might get men today saying:
"I do not believe in anaesthetics. I do not believe in antiseptics. I am going to continue to do my surgery in the way it was done in the eighteenth century." That clearly would be wrong.

6. The *Bolam* test was designed to combine a requirement for a professional and rational assessment of the standard of medical treatment with the recognition that there will often be more than one reasonable approach to treatment. The law recognises that a significant

advantage of this approach is that it does not stand in the way of medical advances. In *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 Lord Diplock said:

"*The merit of the Bolam test is that the criterion of the duty of care owed by a doctor to his patient is whether he has acted in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion. There may be a number of different practices which satisfy this criterion at any particular time. These practices are likely to alter with advances in medical knowledge. Experience shows that, to the great benefit of human kind, they have done so, particularly in the recent past. That is why fatal diseases such as smallpox and tuberculosis have within living memory become virtually extinct in countries where modern medical care is generally available."*

7. It may be helpful to recall that the *Bolam* test, as defined in the judgment of McNair J, was the subject of common complaint from those seeking to assist injured patients make claims for compensation that it offered excessive protection to doctors. All, it was said, they had to do to mount a successful defence was to produce the evidence of an "expert" to say that he might not personally have acted as the defendant doctor had, but that he accepted that what had been done was reasonable practice. The contribution of *Bolitho v City and Hackney Health Authority* [1998] AC 232 was to confirm that such evidence would not provide a defence in the admittedly rare cases where the court found that the opinion was not justifiable as a matter of logic. After various references to a "responsible body of men" "a competent

reasonable body of medical opinion", and "respectable "body of medical opinion", Lord Browne-Wilkinson said this [my emphasis]:

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

The debacle around the MMR controversy provides an example of untenable and potentially dangerous opinions might beome defensible under this Bill.

Later on Lord Browne-Wilkinson said:

… it would be wrong to allow such assessment to deteriorate into seeking to persuade the judge to prefer one of two views both of which are capable of being logically supported. It is only where a judge can be satisfied that the body of expert opinion ***cannot be logically supported at all*** *that such opinion will not provide the benchmark by reference to which the defendant's conduct falls to be assessed.*

8. To absolve a doctor from compliance with the *Bolam* standard of care is to absolve him or her from having to offer a justification that others, including a judge, would find logical or justifiable in the circumstances.

In other words a doctor would be protected by forming an opinion that treatment was in the best interests of the patient however irresponsible or unreasonable that opinion might be. The *Bolam/Bolitho* test does not require a formal body of supportive opinion for a doctor to have a defence. It requires the doctor only to avoid acting as no responsible and competent medical practitioner would have done in the circumstances. That does not mean that a doctor has to produce in court evidence that a treatment or approach to treatment has been used before. What the court does have to assess is whether what he did was responsible and reasonable. (The Bill would remove the ability of a judge to make that assessment.) One way of doing that is to produce evidence from an appropriate expert that what was done was reasonable practice in the circumstances, even in cases where there is no precedent for the treatment.

9. Contrary to the interpretation offered by the briefing papers the judgment of Dame Elizabeth Butler-Sloss, President, as she then was, in *Simms v* Simms [2003] Fam 83, demonstrates that the *Bolam* test does *not* prevent innovative treatment, but actually allowed for an untried treatment in spite of the refusal of a hospital trust to countenance it. She felt able to declare that the proposed innovative treatment was in the best interests of the child whom the Court had a duty to protect, on the basis of the opinion of the doctor proposing to offer the treatment, because it was a "responsible" and a "carefully thought out" opinion. Were the law to be otherwise I suggest there would have been no pioneering heart transplants. Dame Elizabeth said this [emphasis supplied]:

To the question: "Is there a responsible body of medical opinion which would support the PPS treatment within the United Kingdom?" the answer in one sense is unclear. This is untried treatment and there is so far no validation of the experimental work done in Japan. The Bolam test ought not to be allowed to inhibit medical progress. And it is clear that if one waited for the Bolam test to be complied with to its fullest extent, no innovative work such as the use of penicillin or performing heart transplant surgery would ever be attempted: see Lord Diplock in Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] AC 871, 893. I do, however, have evidence from responsible medical opinion which does not reject the research. Mr T is a very experienced and clearly very responsible neurosurgeon. He has carefully thought through at considerable length in his two reports, the research, its implications, the uncertainties, the risks and the doubts about the benefits to these two patients. He has come to the conclusion that "it is in the best interests of [JS and JA] to be treated and I would personally be prepared to carry out that treatment".

The learned judge was not saying that such treatment was negligent under the *Bolam* principles, but was permissible under them because the treatment was supported by a "responsible opinion". When the judgment is read in full it is clear that it was not fear on the part of the doctor about being sued that was the problem but the reluctance of his employing hospital to permit him to provide the treatment. That reluctance seems to have much more to do with difficulties in persuading an ethics committee to support the proposal and, almost

certainly, anxieties about resources. Anyone interested in the background to that case should approach the solicitor in that case, Mr David Body of Irwin Mitchell. It is certainly not his view that the problem in the case was the *Bolam* test. It is relevant in this context to note that the existing law already recognises that saving life and limb justifies taking risks beyond what might be expected in less important contexts: see Watt v Hertfordshire CC [1954] 1 WLR 835

10. So it is clear that responsible medical innovation is supported by a proper understanding of the Bolam test, not inhibited by it. If there is misunderstanding then it should be corrected by guidance, not by legislation which exposes vulnerable patients to unjustified risks and deprives them of remedies when mistreated by those who have no acceptable justification for what they have done. Clearly this is not the intention of this proposal, but on analysis it is suggested that the Bill gives rise to more dangers and difficulties than it has any chance of solving. Thus the Bill is unnecessary .

11. The scope of the Bill is ill-defined and in reality will cover much treatment that is not genuinely innovative

Clause 1(1) is presumably intended to inform construction of the meaning of the rest of the Bill. In my view it does not succeed in that and does not limit the scope of the exemption which follows. It does not define what is meant by "innovation". Clause 1(2) appears to cover the treatment of any condition in respect of which there is an existing range of accepted treatments. If those treatments were generally

accepted as being satisfactory to deal with the problem faced by the patient, a different treatment might be innovative but also unnecessary. Treatment rejected by all responsible medical opinion because it was thought to be useless, ineffective, or dangerous when compared with an existing treatment would qualify for the exemption in clause 1(2). For example, a dangerous form of cosmetic improvement would potentially be covered.

All treatments are experiential. Often doctors and nurses will quite rightly explore the edges of conventional treatment - they do so every day (combining drugs when treating Parkinson's disease or MS, varying doses, carrying out an operation in a slightly different way). We expect them to do so. We want them to do so. Some would say that they have a duty to do so if by doing so they may benefit the patient. But, we also require that they practise within the four corners of known medical-scientific experience and understanding.

12. Clause 1(1) refers to "responsible" innovation, but the scope of clause 1(2) is not limited to "responsible" treatment. There is no requirement that the decision to depart from accepted practice is "responsible" in the sense of being "reasonable" or capable of rational justification. Of course, were such a limitation to be introduced into the Bill, the necessary importation of the *Bolitho* principle would confirm that the Bill was unnecessary.

Innovation means something more than merely new. It must be based on existing science, knowledge and practice, have been tested where possible, and have some demonstrable prospect of success. The risk to be taken by the patient (and it is the patient who takes the risk)

should be proportionate to the consequence of not proceeding and it must have been demonstrated that no existing treatment will benefit the patient.

13. The Bill is limited to the position of doctors. Many forms of treatment require the involvement of other professionals such as nurses, or ancillary staff. Are they and the organisations who are vicariously liable for their acts and omissions to be judged in accordance with different standards to the doctor? Is the Bill intended to give further protection from suit to pharmaceutical companies?

14. The Bill is limited to potential liability for the decision to use a particular treatment, not to negligence in the performance of it. So a doctor who decides, after following the statutory process not to sterilise his instruments might be exempt from liability, whereas one who merely forgets to do so may not. In both cases the doctor has provided objectively inexcusable treatment but only in one does the patient have a remedy. It would be naïve to believe that both doctors and lawyers will fail to be concerned about this.

15. The Bill introduces in clause 1(1) a concept which has long vexed lawyers, namely recklessness. Legal experience has shown that recklessness as a concept requires the most sophisticated legal analysis to define in different contexts. Its presence here will only encourage lawyers to seek to establish that offering a treatment without knowledge of or caring about the risks might be reckless. Who is to

judge "irresponsibility" and by what test if not the test of Bolam/Bolitho?

16. Clause 1(2) tries to exempt from liability for negligence doctors who depart from an existing range of accepted treatments. It says nothing about cases where there are no accepted treatments, nor offers any clue as to the identity of those whose acceptance is referred to.

17. **The Bill removes protection for patients and a right to redress without any adequate safeguards. It merely requires a loosely defined process to be followed without regard to the outcome of the process.**

Clause 1(2) requires a decision to be taken "in accordance with a process…" The clause removes for the first time the ability of a Court – or any tribunal – objectively to review and criticise a doctor's treatment – even if is irrational and unreasonable. Clause 1(3)(a) requires the doctor to consult "appropriately qualified colleagues", but remarkably it does not make it a condition that they agree with or support the doctor's proposal. Thus apparently a doctor is to be exempted from liability by going through the motions of consulting a colleague, even if wholly unreasonably but honestly he rejects the colleagues' contrary advice.

There is no requirement that the doctor's decision should be reasonable in the circumstances, capable of logical justification, or be based on a view of the risks and benefits of the proposed course of action that any other person would accept to be reasonable.

18. There is likely to be scope for lawyerly argument about whether the colleagues consulted are "appropriately qualified" or whether any multi-disciplinary team is "relevant". It is not specified who is to judge appropriateness or relevance. If it is to be open to the court after the event to assess this then the Bolam test is likely to be applied in any event. Otherwise the matter will be left entirely to the honest judgment of the doctor with no requirement that he come to a responsible, reasonable or justifiable decision even about the process, let alone its outcome.

19. It is not clear what a "responsible officer" is meant to do with the notification required by Clause 1(3)(b). I am not confident that all registered medical practitioners have or will have a responsible officer in any event. The clause gives no powers to the responsible officer to intervene. It does not require his or her approval. Such officers will have duties no doubt to refer breaches of conduct to the General Medical Council, but that body will surely decide that compliance with legislation cannot be a breach of its codes of conduct. If in the alternative it remains open to professional regulators to seek sanctions, the basis of this will be quite uncertain and likely to be a far more powerful inhibition on innovation than any supposed effect of the *Bolam* test.

20. Clause 1(3)(c) does not require the opinions or requests of the patient to be solicited.

21. Clause 1(3)(d) requires the doctor to obtain any consent required by law. A doctor is required by the common law to warn the patients of such risks as a responsible body of medical opinion would adopt in the circumstances of the case. As much is required by *Sidaway v Board of Governors of Bethlem Royal Hospital* [1985] AC 871. In other words the Bill proposes leaving the *Bolam* test to apply to the consent taking process while removing it from the actual provision of treatment. It may be difficult for practitioners and lawyers to resolve that apparent contradiction. Applying *Sidaway* I would consider that the Bill – as a minimum – makes it mandatory for a doctor to advise the patient that he is about to act in a way which is not supported by a responsible body of medical opinion and that the risks are not ones which any responsible body of medical opinion would support.

22. Clause 1(3)(e) applies an entirely subjective test to the assessment of what is reasonable in the case for the doctor to consider, apparently to the exclusion of what might be considered reasonable by colleagues or the courts. Therefore if a doctor comes to a view about what is reasonable that all other doctor and the court would consider unreasonable, or perverse, nothing can be done to stop him or her proceeding with a clear mistaken view. This is to take self-regulation to its extreme: the only limit placed is the doctor's own assessment of his own proposed treatment.

23. Clause 1(4)(a): it seems odd that the Bill is not intended to apply to cases where treatment is primarily offered to a patient because it is

believed to be in his/her best interests, but may have a secondary research purpose.

24. **The Bill does not address any other potential obstructions to innovation**

It is clear from the patients' stories quoted that they yearn for more energy and imagination to be put into finding effective treatments for conditions for which there is currently no cure and little relief. There is an expressed desire for a codification of the law and procedures. The doctors refer to the lack of support from colleagues which suggests to me a need for better means of seeking supportive opinion. It can be inferred that there are concerns about over-regulation, the lack of structure for prescribing drugs "off label". To this one could add the potentially obstructive effect of ethics committees, the unknown attitudes of professional and systems regulators, the reluctance of institutions, whether they be providers, commissioners, or insurers to fund treatments of unknown effect. NICE clinical guidance is informed not only by the evidence base with regard to effectiveness and safety but also value for money. Treatments not recommended by NICE are difficult to find support for. None of these issues, and there are bound to be many others, are addressed by this Bill. In order to fulfil the aspiration of Lord Saatchi, and indeed Professor Norman Williams, President of the Royal College of Surgeons of England when he says "Protect the patient, Nurture the innovator", a much more considered approach is required than this Bill. What patients need is comprehensive guidance which addresses not only how to allow doctors

to undertake innovative treatment but how patients – often at their most vulnerable and desperate – are to be protected.

An admittedly unscientific survey of members of these chambers with extensive clinical negligence experience finds no evidence of cases having been brought for negligence in the provision of innovative treatment except in the context of alleged failures to obtain properly informed consent. On the contrary my colleagues have not infrequent experience of hearing experts justify innovative paediatric or neonatal treatments on the basis of being reasonable and responsible in accordance with *Bolam*.

25. **The number of attempts at this Bill suggest it is not the right answer**

Each time objection has been raised to the Bill and its contents a different version is forthcoming While there is much to be said for a responsive process in legislation, the deficiencies all versions show indicate that it would be quite wrong to rush legislation through. It is also surprising that a new Bill has been proposed so soon after the last consultation period ended when there has been no adequate time for the DoH to complete a review of the responses received or for consideration of the DH response when published. Considered scrutiny is required, together calm assessment of the evidence of what are the real problems in practice.

26. Summary

In summary the new version of this Bill suffers from the same deficiencies as its predecessors:

a. It purports to address a problem of law which in reality does not exist.

b. It proposes requirements which are bureaucratic and ineffective.

c. It does not succeed in limiting its scope to treatment that would be generally accepted as innovative.

d. It frees a doctor from any duty to be reasonable or rational in a decision to offer a treatment so long as he goes through the motions of a process. It is therefore a threat to patient safety in relation to a particularly vulnerable group. In reality the claimed safeguards are no safeguards at all.

The Bill would apparently free a doctor from any constraint to act in a logical, responsible or reasonable manner, so long as he/she follows a process the outcome of which he/she is free to reject. If this is right the Bill exempts a wide range of mavericks from liability, and deprives patients of a remedy when injured by them. The Bill does not promote responsible innovation; on the contrary it permits irresponsible and unsafe practice which is justified by little more than an honest – even if ill informed – belief on the part of the doctor in the effectiveness of what he/she offers. It substitutes for fears of litigation, misinformed if they exist, a realistic prospect of having to engage with lawyers and a threat of litigation based on whether the provisions of this legislation

have been complied with. To the extent that it does not it may be worth recalling the wise words of the judge in In Hepworth v Kerr [1995] 6 Med LR 139. There the defendant anaesthetist had adopted a new technique which had never been attempted routinely and had no scientific validation, which resulted in the patient suffering a spinal stroke. In the judge's view the procedure had taken patients "to the very edge of existence". It had been argued that, as a matter of public policy, the courts should be slower to impute negligence to the medical profession than to others. The judge responded to this argument by saying:

I can think of only one thing more disastrous than the escalation of defensive medicine and that is the engendering of a belief in the medical profession that certain acts or omissions which would otherwise be classed as negligence can, in a sense, be exonerated."

This Bill introduces a level of complexity and process driven rigidity to an area calling out for responsible flexibility to meet new circumstances as they arise, as well as an increased risk of provoking litigation over the meaning of the legislation.

27. In conclusion I should emphasise I am not opposed to effective steps being taken to promote the use of innovative treatment in the circumstances of cases such as *Simms v Simms*, the case much referred to by the Saatchi team. While that case shows that judges will not interpret *Bolam* in such a way as to prevent such treatment, there can be forces at work which hinder its provision. In particular it seems likely that healthcare provider organisations may be reluctant to authorise

such treatment for financial reasons, or through organisational inertia, or through ethical reservations. None of these factors are addressed by the Bill. If there is a problem of perception or of organisation which can be removed, then what is required is guidance, based on a review of what actually has happened in practice. To do otherwise is not only to put patients at risk, but will not solve the very problem that so many clearly want to se addressed.

23 June 2014 SIR ROBERT FRANCIS QC

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