

Response of Robert Francis QC
to *Legislation to encourage medical innovation – A Consultation*

1. 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 the proposals represented in the Bill.

2. The distress and suffering that 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 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.

3. The proposal of this Bill proceeds from a fundamental misunderstanding of the effect of the current law of medical negligence. The advances made in medical science in the 57 years since the *Bolam* case have been truly remarkable. As yet no evidence has been produced which shows that innovative treatment has been significantly deterred by a fear of litigation related to the *Bolam* test. That judgment recognised explicitly the need not to impede responsible medical innovation. McNair J said

... 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. 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.

4. The *Bolam* test was designed to combine a requirement for a professional justification 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* 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."

5. While recognising the need to allow innovation, the protection of patients is ensured by a requirement that treatment should be capable of reasoned justification, as explained in *Bolitho*. A requirement that proposed treatment should be supported by some responsible professional opinion provides a degree of assurance that the risks and benefits have been appropriately balanced. This does not require a treatment to have been adopted already by others, merely that there is a level of professional support for it which has a logical basis. The judgment of Dame Butler-Sloss in *Simms* demonstrates the flexibility of the common law when faced with a challenge with regard to innovative treatment, and actually allowed for an untried treatment in spite of the refusal of a hospital trust to countenance it. She said:

*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".

6. Therefore it was not the law that stood in the way of innovative treatment in that case – it facilitated it by explicit reference to the *Bolam* test. Indeed the doctor wanting to provide the treatment was not deterred by the fear of litigation. He was inhibited by his employer for reasons which are unknown to me, but it is possible to speculate that the fear of the cost of treatment played a part.
7. 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
8. The scope of the Bill is uncertain and potentially far wider than the concerns expressed by Lord Saatchi. While the intention of the Bill is to encourage innovation in medical treatment [clause 1(1)] that term is not defined. In other statutes the term “medical treatment” includes nursing care and rehabilitation. It is possible to envisage a proposal to provide nursing care with less than the currently accepted staffing level through some supposedly more efficient working procedure. It is not difficult to imagine how such a freedom might be abused.
9. There is an alarming lack of accountability or scrutiny or other safeguard built into the Bill. It explicitly frees the doctor to offer treatment which has no support from responsible medical opinion, [Clause 1(3)]. This must mean that he is free to offer treatment that no other colleague agrees is a reasonable or in the patient’s interests, so long as he believes there are “plausible” reasons to suppose it “might be” effective [Clause 1(4)].
10. The Bill would allow an individual doctor to make a decision without consultation with professional colleagues. The “factors” that “may” be taken into account in determining whether an accountable and transparent process has taken place include involvement of a multi-disciplinary team and notice to a responsible officer “(if any)”. However a doctor working on his/her own may well not be part of a of multi-disciplinary team and may not have a responsible officer. He may argue that there would be no point discussing the issue with such colleagues because they would know nothing about it. In any event the decision to treat can only be found not to be “responsible” on process grounds, i.e. a process “which allows full consideration by the doctor of all relevant matters” . There appears to be no obligation that the doctor comes to a justifiable conclusion about them. In other words, given the lack of limitation on the scope of treatment which is the subject of the Bill, a form

of treatment which is considered on cogent grounds ineffective or dangerous by a body of experienced opinion, can be given and gain the benefit of the protection of this Bill, if in the opinion of the doctor, but not colleagues, a regulator or a court, there are “plausible” reasons why it might be effective. There does not appear to be anything to stop the Bill applying to treatment and practices believed to be dangerous to patients and which are not innovative, but which have been tried, tested, and found wanting.

11. There is no obligation to consult “colleagues” which, as the consultation paper points out, do not even have to include medical colleagues. The obligation is only to have regard to opinions expressed, which the doctor considers appropriate to take into account. Therefore the judgement about what is “appropriate” is left exclusively to the one professional.
12. The Bill fails to achieve its claimed purpose of reducing the uncertainties to which the innovative doctor is said to be exposed by the *Bolam* test. Most, but not all, the factors referred to in clause 1(5) require the doctor to exercise a “reasonable” judgment. This will leave the doctor in doubt about what a court might consider reasonable. Laborious judicial reconsideration of reasonableness in the context of a defence to an allegation of negligence can be predicted. The courts may be tempted to test reasonableness by something close to the *Bolam* test.
13. While the Bill excludes “treatment for the purposes of research” from its ambit, it is far from clear that it protects patients from being induced to accept treatment which is untested but the experience of which will benefit the manufacturers. The learning from the use of innovative treatment will often benefit inventors as well as patients, but this Bill effectively passes the risk entirely to the patient and lifts it from the promoter of the treatment.
14. The requirement for an “accountable, transparent” process could, it is suggested, be fulfilled by the doctor making a full record of his thought process. It requires nothing of its content.
15. In short the Bill does not effectively limit itself to genuine innovation. It increases the risk to vulnerable patients of mavericks with irrational or unjustifiable grounds for proposing a treatment and those with commercial interests in promoting dubious treatments. It does not relieve the conscientious doctor from a laborious consideration of what may be thought to be “responsible” “reasonable” or “appropriate” under a multiplicity of headings. Above all patients, for whom this Bill is intended to be a benefit, are to be left without a remedy when injured by treatment which many doctors would consider unacceptable, and at the mercy of the judgments made by individual practitioners who have no professional support or oversight.

16. Responses to the consultation questions

Q 1 – Do you have experience or evidence to suggest that the possibility of litigation sometimes deters doctors from innovation?

No

Q 2 – Do you have experience or evidence to suggest that there is currently a lack of clarity and certainty about the circumstances in which a doctor can safely innovate without fear of litigation?

No

Q 3: Do you agree with the circumstances in which the Bill applies, as outlined in clause 1(3)? If not, please identify any changes you suggest, and give your reasons for them.

No. Please see the observations made above. As currently it is suggested that the scope of the Bill ranges far wider than a [misconceived] protection for genuine innovation.

Q 4: Do you have any comments on the matters listed in clause 1(4)-(5) on which the doctor's decision must be based for it to be responsible? Are there any that should be removed, or changed, or added, and if so why? For example, should the Bill explicitly indicate that the other treatments mentioned in 1(5) (a)-(c) include treatments offered as part of research studies?

Please see the observations above.

Q 5: Do you have any comments on the process set out in clause 1(6)-(7)? Are there any provisions that should be removed, changed or added – and if so, why?

Please see above. While it is right that the process for deciding to offer what could be very dangerous treatment should be accountable, transparent and allow the doctor consider fully all relevant matters, the process can presumably be created entirely by the doctor himself, in spite of his/personal interest in the outcome. There is no specification of what form accountability should take, to whom the accountability is owed and who may bring the doctor to account for it. There is no specification of what is meant by transparency. Is it intended that the process should be transparent to the patient only, an employer, a professional association, a regulator, or the public? As observed above a requirement for process that allows for full consideration of relevant matters does not require the doctor to come to a tenable conclusion.

Q 6: If the draft Bill becomes law, do you have any views on the best way to communicate its existence to doctors?

It is not communication of the existence of the law which matters so much as the communication of guidelines with regard to the professional requirements that are relevant to any proposal to offer innovative treatment.

Q7: To reinforce the Bill, are there other things that need to happen to encourage responsible innovation?

No comment.

Q 8: Do you have any comments and suggestions for inclusion in the draft impact assessment and equality analysis?

The assessment suggests there will be a reduction in medical negligence claims. On the contrary there is likely to be protracted and complex litigation about the meaning of this Bill.

The assessment suggests that the Bill mitigates the risk of inappropriate use of the Bill by the requirements within it. The observations above suggest why this may not be the case.

Neither the assessment nor the Bill itself addresses the very real issues it raises with regard to the treatment of those incapable of making decisions for themselves or are particularly vulnerable, other than a reference to the requirement for consent. There is no special protection offered with regard to the vulnerable patient, and no guidance offered about the interrelationship between the Bill and the Mental Capacity Act 2005.

Q 9: Overall, should the draft Bill become law?

No. Please see the comments above. To the extent that the law of clinical negligence requires change to protect patients against [over] defensive medicine it is suggested that the issue needs to be looked at with regard to all treatment, not just innovative treatment.

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