BRIEFING ON THE MEDICAL INNOVATION BILL

1. Introduction

Action against Medical Accidents (AvMA) is the national charity for patient safety and justice. We have played a pivotal role in developing awareness and better practice in patient safety and access to justice for people who are affected by lapses in patient safety ('medical accidents'). Every day we advise and support people who have been harmed or who have lost a loved one. Whilst we recognize the Bill is based on good intentions, we believe that it is both unnecessary and could have the gravest unintended consequences. In summary, we believe:

- **The Bill proposes a solution to a problem which does not exist: current clinical negligence law is not an impediment to responsible innovation and there is little or no evidence to support the assertion that it is.**

- **The Bill will remove a layer of protection and redress for vulnerable patients who are harmed when their doctors act in a way which no other doctor would support.**

- **The Bill would encourage unsafe and unaccountable practice by doctors and lead to further tragedies and scandals such as that of Dr Ian Patterson. The Bill would affect all forms of medical treatment – not just exceptional circumstances such as when all evidence based treatment options have been exhausted.**

- **The Bill's provisions would have no positive impact on innovation: it will have no effect on funding, research programmes, clinical governance or professional and medical product regulation.**

2. A Solution Where No Problem Exists

2.1. The current law on medical negligence does not hinder responsible innovation. This view is shared by leading lawyers, defence organisations and doctors' organisations. For example, in answer to the Department of Health consultation question as to whether people have evidence of this, the NHS Litigation Authority says:

"We do not. However we are aware of innovation on the part of individual clinicians. For example various types of metal-on-metal hip replacement were invented by particular surgeons and the ideas were then sold to commercial companies for development. Also, we know of cases where drugs are used by NHS clinicians off-licence when doctors consider that their prescription will be beneficial to individual patients."

British Medical Association says:

"We are not aware of any evidence which shows that the possibility of litigation deters doctors from pursuing innovative treatments or that uncertainty exists over the circumstances in which a doctor can safely innovate without fear of litigation."

2.2. The law on medical negligence has been clear for over 50 years since Bolam-v-Friern Hospital Management Committee [1957] 1 WLR 582: a doctor is not negligent if he or she acts in accordance with a practice accepted as proper by a responsible body of medical men and women skilled in that art merely because there is a body of opinion that takes a contrary view. So, if 95% of doctors would not give a certain kind of cancer treatment but 5% would, and that 5% represents a reasonable body of opinion, then it is not negligent to give that treatment. Bolitho-v-City &Hackney HA [1998] AC 232 refined the test such that any conduct or decision to treat should be capable of withstanding rational analysis.

2.3. The law does not define medical negligence as deviation from standard procedure, as Lord Saatchi has claimed, but deviation from responsible or reasonable procedure. There is case law which demonstrates that medical negligence law does not hinder innovative treatment, even treatment previously untested on humans. In Simms-v-Simms [2003] 2WLR 1465 the court considered an application that two persons suffering from variant Creutzfeld Jakob disease should be given innovative treatment which was new and untested on humans. The court decided that the first question was whether the doctors would be acting in accordance with a responsible and competent body of relevant professional opinion as per Bolam, and the court held that there was a responsible body of professional opinion that supported the innovative treatment.

2.4. The *Bolam* test is no impediment to innovation, only to irresponsible or unreasonable conduct. Lord Diplock in the House of Lords in the leading case of Sidaway-v-Governors of Bethlem Royal Hospital [1985] AC 871 at 893, said as much:

"... *Members of the public ... would be badly served by the adoption of any legal principle that would confine the doctor to some long-established, well-tried method of treatment* [so as to avoid] *the risk of being held liable in negligence simply because he tried some more modern treatment... 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."*

Somewhat surprisingly Lord Saatchi quoted from this passage in his speech to the House of Lords in January 2013, apparently believing that Lord Diplock was condemning the Bolam test as a barrier to innovation rather than praising it as supporting innovation.

2.5. Properly considered the law already protects a doctor against an allegation of negligence if he innovates responsibly. The Medical Defence Union has publicly stated:

"The Secretary of State of Health in a written statement introducing the Medical Innovation (no.2) Bill stated that doctors wishing to depart from established procedures and carry out an innovative treatment may be fearful of doing so because of the possibility of an clinical negligence claim. We have seen no evidence to suggest that this is the case ... Our advice is that there should be no consequences providing there are appropriate safeguards in place, the patient full understands what is proposed and why the clinician believes it is in their best interests, and they give their fully informed consent... We are happy to reassure doctors that medical innovation should not leave them open to an increased threat of litigation."

3. Lack of Protection of Patients

3.1. The Bill provides a defence - doctors will not be negligent in relation to any treatment currently regarded at common law as negligent, if they take the decision to treat "responsibly". Whilst the purpose of the Bill is a laudable one - to promote responsible medical innovation - the intentional effect of the Bill is to deprive patients who are harmed[1] by doctors of a right of redress, even when the doctor has acted in a way that no other doctor would support. It is the rationale behind the Bill that doctors who would currently be regarded as negligent, should no longer be held liable.

3.2. AvMA is concerned that patients are afforded proper protection from irresponsible or negligent doctors. Regrettably the Bill does not provide adequate protection and could actually encourage unsafe practice and lead to further tragedies and scandals such as that involving Dr Ian Patterson, amongst others.

3.3. The provisions at clauses 1(3) and (4) do not "require" that the ultimate decision should be rational or reasonable. The decision is left to the individual doctor, provided they manage to obtain the patient's consent. Axiomatically, a decision may be "taken responsibly" even if it is a decision which would not be supported by any responsible body of medical opinion. So, it can be seen that a "responsible decision" under the Bill is not the same as a responsible decision under the common law. The Bill dilutes the protection currently afforded to patients.

3.4. Proponents of the Bill have claimed that the Bill requires that a "senior panel of doctors" approves the decision to treat.[2] That is not so. The Bill merely provides that in determining whether a decision has been taken openly, the court may take into account whether the decision has been made within a multi-disciplinary team. So there is no requirement. Further, multi-disciplinary team" is not defined so it may or may not include senior doctors. It may not even include other doctors at all. A doctor, nurse and nutritionist might constitute a multi-disciplinary team (even if the nurse and nutritionist were employed by the doctor).

3.5. AvMA is concerned that patients who agree to treatment which is beyond the bounds of what is considered acceptable by all responsible bodies of medical opinion, are precisely those who require particular protection. The desperate patient who will try anything to be "cured" of for a short extension to their life, may be the most vulnerable to

[1] A patient is entitled to redress for negligence only if they have suffered harm as a result of the alleged negligence.

[2] Dominic Nutt in Daily Telegraph, March 2014 (Dominic Nutt is Director of Communications for the Saatchi Cancer Initiative, not that that is apparent from the article).

exploitation. A doctor selling vitamin X from his private practice may very well be able to show that he took his decision to treat "responsibly" whilst providing treatment which no other doctor would support.

3.6. There is a danger that an individual doctor's decision with regard to 'innovative' treatments could be affected by other influences. For example, there could be a financial interest / conflict of interest for the doctor themselves to be motivated to put forward a particular treatment. The pharmaceutical industry and others may certainly try to influence doctors to exercise their freedom that this Bill would provide to step outside the normal systems designed to protect the safety of patients, to push their particular product.

3.7. Media coverage and statements by supporters of the Bill give the impression that the Bill is designed specifically to open doors to 'innovative treatment' for those with life threatening conditions for which all evidence based treatment options have been exhausted. This is not the case. The Bill would apply equally to any form of medical treatment where the doctor convinces their patient that it would be in their best interests to receive it. This could include, for example, cosmetic treatment.

4. <u>The Bill Will Have No Positive Effect On Innovation</u>

4.1. The law of clinical negligence is not the sole, or even the primary, restriction on the freedom of doctors to try new treatments.

4.2. Most obviously, substantial funding is required to research, develop and instigate new treatments. Often, whether as a result of determinations by NICE or otherwise, funding is not available for doctors to allow access to new treatments to all patients.

4.3. All doctors are regulated by the General Medical Council. Most will be subject to employment contracts which stipulate adherence to protocols or ethics committee guidance and directives. The Medicines and Healthcare Products Regulatory Agency regulates the provision of new medicines and medical devices. The Bill has nothing to say about these controls on the freedom of doctors to innovate.

4.4. The Bill is directed to individual doctor/patient relationships. The notion that a "cure for cancer" will arise from such relationships when "freed" from the shadow of the threat of litigation, is tendentious. The Bill has nothing to say about funding, laboratory research, drug development, professional regulation, the MHPRA or the requirements for large scale and peer reviewed studies.

4.5. In a Ministerial Statement from November 2013, the Secretary of State said:

> The Bill's sponsors *"correctly identify the threat of litigation as one such barrier* [to innovation]*. Their hope is that legislation to clarify when medical innovation is responsible will reduce the risks of clinical negligence claims. Their argument is that with this threat diminished, doctors will be confident to innovate appropriately and responsibly. This innovation could lead to major breakthroughs, such as a cure for cancer. Their cause is a noble one, which has my wholehearted support."*
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> Cancer Research UK has recently run a campaign highlighting ten myths about cancer, one of which is that there is a miracle cure for cancer. That the Secretary of State for Health should talk of individual doctors finding "a cure" for cancer is surprising.

4.6. If doctors are truly prevented from innovating responsibly by the threat of litigation, then perhaps the most effective way of solving that problem is by providing more education of doctors as to the law of negligence. The removal of a right of redress to patients harmed by doctors who act in a way no responsible body of medical opinion would support might not be the best way to promote responsible innovation.

5. Claims of support for the Bill

5.1 Supporters of the Bill and the media have made much of claimed popular support of the Bill. This is based on responses to the campaign website promoting the Bill. It is hardly surprising that the vast majority such responses would be in support of the Bill. This is particularly so bearing in mind the emotive publicity that the campaign has generated and the misleading impression that has been given that this Bill specifically deals with the exceptional circumstances of people facing death when evidence based treatment options have been exhausted; and that there are safeguards requiring approval of the proposed treatment by independent doctors.

5.2 In an extraordinary move, the Department of Health granted the campaign for the "Saatchi Bill" to act as a conduit for responses to the formal consultation. No corresponding arrangement was made for organisations opposing the Bill to act as a conduit for responses to the formal consultation. At the time of writing the Department of Health had still not published the findings of its formal consultation and its analysis. It is likely to be skewed in numerical terms by responses received from the "Saatchi Bill" campaign website. This arrangement is akin to allowing a campaign group in favour of fox hunting being allowed to be a conduit for responses to a formal consultation on whether or not fox hunting should be banned, without having a corresponding arrangement for campaigners against fox hunting.

5.3 We would encourage all those considering the arguments for and against the Bill to look at the responses from a wide range of well informed and respected organisations representing patients, health professionals, and regulators. These are overwhelmingly contrary to the Bill's main arguments and include: the British Medical Association; the NHS Litigation Authority; the Medical Defence Union; the Medical Protection Society; the Academy of Medical Royal Colleges (and several individual colleges); the General Medical Council; Cancer Research UK; Action against Medical Accidents (AvMA); the Patients Association.

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