Response form

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Are you responding as an individual or on behalf of an organisation? Organisation
If as an individual, are you responding as:
a) a doctor?
b) a patient?
c) a lawyer?
d) other?
If you are responding on behalf of an organisation, please give the name of the organisation and say who it represents: The Medical Defence Union is a mutual non-profit making organisation owned by our members who include over 50% of the UK's doctors. In return for payment of an annual subscription our medical members receive a wide range of medico-legal benefits including assistance with and indemnity for clinical negligence claims arising from their clinical practice. MDU members who work in NHS organisations are indemnified by their NHS employers which contribute to the NHSLA's clinical negligence scheme for trusts, but GPs and doctors in independent practice have to make their own indemnity arrangements. The MDU's benefits of membership also include a 24-hour telephone advice service which took over 30,000 calls from members seeking medico-legal advice during 2013.

The questions posed in the consultation paper are as follows:

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

The MDU does not have any experience or evidence to suggest that doctors are deterred from innovating by the fear of litigation.

Question 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?

We have no experience or evidence to suggest there is or that our members believe there is a lack of clarity or certainty about the circumstances in which they can innovate without fear of litigation. From time to time we provide medico-legal advice to members about innovation and examples of the areas we concentrate on are the need to provide detailed information when seeking consent and to ensure that the doctor complies with relevant GMC guidance, for example specific guidance on research.

We understand that most doctors who try innovative treatments or techniques do so in the context of research projects that have been carefully considered and approved by research ethics committees. In preparing this response we asked our (55) medico-legal advisers about their recent experience of questions about innovation from members through our 24-hour helpline. Questions about innovation are not common but we receive a few regularly each month. The questions members ask are generally about consent and the extent of information that patients need, as well as questions about GMC guidance, for example about the use of unlicensed medications. An interesting aspect of some recent calls is that they did not relate to innovation with drugs or surgical or other invasive procedures but covered aspects of practice such as moving away from face-to-face consultations and exploring use of computer consultations or apps, or setting up web-based discussion forums. The advice members seek is principally about ethical matters or other legal concerns such as compliance with data protection legislation.

Question 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.

We are concerned at the implications of clause 1(3) for patient safety. As drafted it would appear to allow a doctor to provide innovative treatment on the grounds that he or she alone believed it was appropriate without an evidence base and this could be in the face of strong opposition from one or more responsible bodies of opinion. Any proposed treatment should have the support of a responsible body of medical opinion, albeit even a small one. As the clause stands there is the potential that a vulnerable patient may be left unprotected in the hands of a practitioner who may advance reasons that sounded plausible, but the patient would have no way of

verifying the accuracy of what he or she is told.

We cannot suggest changes to 1(3) because we do not believe that what is envisaged in clause 1(3) and in other clauses within the Bill is consistent with the consent process as it is set out in the GMC's guidance. The Bill seems to concentrate on treatment whereas GMC guidance recognises the equal importance of the thoroughness of the decision-making process and communication with the patient. Paragraph 5(b) of the GMC's specific guidance on consent (pg 5) is particularly relevant. We believe that the Bill might be taken to sanction an approach to innovation that is inconsistent with the GMC's guidance on consent, and other GMC guidance.

Question 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?

Clauses 1(4)-(5) do not provide for the detailed analysis of information and the full and frank discussion with the patient based on that information that the GMC requires in its guidance on consent.

Further, 1(4)(a) relies on the doctor's opinion that there are plausible reasons. How would it be determined that the reasons were plausible other than by examining them in the context of medical science and therefore in the context of what some other doctors, even if very few and highly specialised, would consider plausible? The same applies to the doctor being required to consider other matters that he or she believes it would be appropriate to take into account. Again the test would presumably be what a responsible body of doctors considered it appropriate to take into account? If the standard applied to determining whether the doctor acted responsibly in making the decision would be the Bolam standard, this suggests that the current test that applies provides all the protection a doctor needs when considering innovation and that there is no need for a new law.

In response to the specific question about research studies in 1(5)(a)-(c), the GMC guidance in its consent booklet at paragraph 5(b) (referred to above) sets out clearly the types of information the doctor is required to provide, but not the detail. It does not mention clinical research specifically, because the GMC is not prescriptive about the types or sources of information a doctor needs to consider as that will depend on the circumstances of each case. As well as assessing and providing information the doctor considers appropriate, the GMC further expects the doctor to be able to answer the patient's questions and to provide other information the patient seeks in order to be in a position to make a decision about whether to undergo the treatment.

We are concerned that the clauses as drafted might cause doctors to think they had discharged their duty by complying only with the letter of this law, whereas they must also comply with the GMC requirements which are more detailed and more onerous.

Any new legal requirement must be consistent with existing GMC's requirements. This begs the question why it is considered necessary to set this out in new Bill as the GMC guidance is already clear. Introducing a new law may only add confusion.

Question 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?

We have explained above that the Bill would need to be consistent with the GMC's requirements on consent to treatment. Clause 1(7)(a) is consistent with GMC requirements as well as the law on consent, which already apply to all doctors, irrespective of whether the treatment they are providing is innovative.

If a multi-disciplinary team supports the proposed innovation as at clause 1(7)(b), it is very likely the Bolam test would be met and there would be no need for a new law.

We are concerned at the suggestion in clause 1(7)(c) that a responsible officer (RO) might be brought into the decision-making process. Such a role was not envisaged for ROs and it would be an onerous additional requirement to make of them even if it were consistent with their roles as set out in the regulations. The clause suggests that ROs might be put in a position to make a clinical judgement which they may not have the skills and competence to make, and one which does not accord with their other responsibilities for clinical governance that do not extend to making clinical decisions in respect of the doctors for whom they are responsible. Responsible officers may be responsible for hundreds of doctors and many of them will be from a wide range of medical specialties where the RO has no experience, skills or competence. Even assuming ROs had time to do so, it is hard to see how they could be expected to form a view on a doctor's proposal for innovation in a specialty with which they are unfamiliar and what it would add to the process for an RO to be expected to undertake such a role. What would be the position of a doctor where the RO refused to become involved, or where an RO took a view that disagreed with the doctor's proposal for innovation? While a doctor might be expected to seek views from peers and/or a multi-disciplinary team or to submit a proposal to a research ethics committee, we cannot see how an RO would provide any additional safeguards. Indeed we believe clause 1(7)(c) might land ROs with a considerable additional burden of work that they are too busy to undertake, that is outside their expertise, and that would bring with it responsibilities that are not within the regulations nor reflected in their job descriptions.

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

If the Bill became law it would be straightforward to communicate its existence to doctors through the usual channels. It would be less straightforward, however, to communicate to doctors precisely what effect it might have on their practice and how it might change their existing ethical and legal responsibilities towards patients. We

believe there is considerable potential for confusion and that such confusion could have the opposite effect to what is intended. We believe new legislation could impede innovation because doctors would have an additional process to undertake while they worked out how and what effect the Bill had on any innovation they were proposing.

Question 7: To reinforce the Bill, are there other things that need to happen to encourage responsible innovation?

The law currently considers innovation is responsible if it is in the patient's best interests and can be supported by a responsible body of medical opinion and the patient has been fully informed and given consent. We do not think anything else needs to happen to encourage responsible innovation.

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

It is suggested in the impact assessment that an increasingly litigious culture may be putting pressure on doctors to practise defensive medicine. The MDU is not aware of any evidence that doctors in the UK are practising defensive medicine. Further there are a number of reasons for the increase in litigation but innovation is not one of them. The principal reason is that recent changes to the law governing claims costs resulted in a flood of claims brought by English solicitors seeking to notify claims under the old procedure, which benefits them financially. The existence of bodies such as the Oxford Centre for Accelerating Medical Innovations (CAMI) and (CASMI), the Centre for the Advancement of Sustainable Medical Innovation, that draw upon world leading expertise to research and promote sustainable biomedical innovation, suggest that doctors are not deterred from innovating by fear of litigation.

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

No. The draft Bill should not become law. The current legal and ethical requirements upon doctors already provide adequate safeguards for patients and for doctors.

We also welcome any other comments you wish to make.

<u>Clause 1(1)</u>

We believe that 'medical innovation' should be defined more clearly and that the Bill

must specify the aspects of clinical practice that it applies to. We understand the intention is for 'medical innovation' to refer to innovation related to treatment with drugs or other clinical procedures or interventions. However, it is clear from our members' requests for advice that some of them understand the term to have a far wider definition. In our response to question 2 we have referred to some of the other ways in which the medical profession innovates, but there will be very many other ways in which this Bill would have an impact, without necessarily intending to do so. One of our main concerns about the Bill is that we believe it has the potential to cause considerable confusion among doctors who might be uncertain about their legal and ethical obligations in circumstances where there is no evidence to suggest there is a problem now. It would be unfortunate if the current broad definition of medical innovation extended such confusion to innovative aspects of medical practice that the Bill is not intended to apply to.

Clause 1(8)(b)

One of the phrases in this clause may lead to considerable confusion. We assume the intention of this clause is to exclude research studies from the protections provided in this Bill on the grounds that there are already protections available for doctors and patients who take part in research studies. However, one reading of the phrase could be that doctors are not permitted to carry out treatment for research at all. The fact that research is mentioned in the same clause that acknowledges that treatment must always have consent and that it must be in a patient's best interests may lead to confusion. All doctors know patients must give consent and that treatment must always be in their best interests and it may seem to them that the same force applies to their not being permitted to carry out treatment for research. This is the opposite of the intention of the phrase and its intention needs to be clarified.

Clause 2(1)(a)

We believe the definition should be licensed medical practitioners. The GMC has two categories of doctors on the register and only doctors who are licensed are able to practise medicine. If the Bill also applied to doctors who were only 'registered medical practitioners', this might suggest to them that they were allowed to practise, which they are not.