

Responding organisation	Is law a barrier to innovation?	Concerns, if any?	What are barriers to innovation?	Comments, Suggestions, Recommendations
<i>Medical</i>	(comments added)			
BMA	<p>NO. 'The BMA is not aware of any evidence' 'We have no evidence to suggest that the threat of litigation is a barrier.. and we strongly question the necessity and desirability of introducing statute to clarify or change the law in this area' 'It is clear that treatment outside of standard practice can be provided ..and doctors are prepared to explore these options..under the law as it stands'</p>	<p>'unnecessary, risks removing important protections for patients and could encourage reckless practice, with attendant risks for patient safety'</p> <p>'possibility that a patient could be exposed to treatment which is of no clinical value and would have no redress under the Bill'</p> <p>Focus on negligence misguided, sends wrong message to pts. Risks diluting deterrent effect of law on best practice</p> <p>Inflexible</p> <p>'there are inherent disadvantages to attempting to codify best practice..and it is not clear in this instance that it is possible, desirable or necessary'</p>	<p>'funding, being allowed the time to undertake the necessary studies, and the various approvals processes.'</p> <p>'Practical barriers in the organisational, educational and economic context... include: workforce capacity, the quality of facilities available in different organisations and, crucially, the availability of funding for such treatments.'</p>	<p>'The BMA strongly believes that this Bill should not become law and.. does not believe that primary legislation which focuses on redefining clinical negligence is the best mechanism to promote or encourage responsible innovation'</p> <p>'The best mechanism.. is through well-regulated research and clinical trials' 'doctors should be confident in pursuing (untested or unlicensed treatment) where clinically indicated and in their best interests'</p> <p>'Alternative means through which a culture of innovation could be encouraged may include specific professional guidance, greater expansion of clinical ethics committees or similar support mechanisms, and the creation of registers of novel clinical experience.' Make register of clinical experience to capture/disseminate learning and encourage doctors, publically available.</p> <p>If hesitation exists, 'to provide information and guidance for doctors to improve their understanding and to encourage them to innovate responsibly within the law as it stands'</p>
RCP	<p>NO. ' The RCP does not have significant evidence (anecdotal or through case examples) from our members and fellows, nor we understand do two medical protection organisations, that litigation or potential litigation is a substantial or primary deterrent to clinicians' use of innovative treatment.'</p> <p>'departure from standard practice is not prevented in law'</p>	<p>'there could be unintended consequences of the Bill with the opposite effect to that intended.' 'encouraging experimentation without sufficient and appropriate peer review and evidence based decision-making, or potentially breaching professional guidelines and regulatory standards.'</p> <p>'Improvements that have been made in research regulation in recent years may be set back' and 'clinician involvement in and patient referral into larger NHS clinical trials .. could be put at risk'</p> <p>'proper consent from patients is crucial. Beyond this, it is also necessary to protect vulnerable patients who may have received a devastating diagnosis or have exhausted standard treatment options.'</p> <p>'a risk of exacerbating health inequalities'</p>	<p>- protracted processes involved in establishing clinical trials, timescales, investment</p> <p>- complex bureaucracy and delays in gaining approval and securing funding - time, money negotiation with multiple agencies</p> <p>- CCG/trust commissioning can prevent uptake of new and expensive treatments</p> <p>- 'personalised' medicine technologies may need a new approach to trials and testing of treatments</p> <p>- ethics committee consideration, broad large-scale randomised trials may take too long to benefit individual</p>	<p>RCP recommendations:</p> <ol style="list-style-type: none"> 1. Mandatory reporting- centrally recorded, reported and publicly accessible – clear strategy must be developed 2. Peer review – robust safeguards including peer and ethical review, assurances, active support for referral into larger clinical trials 3. Safeguards and promotion of innovation – support best practice checklist could be supplemented by guidance 4. Communication – clear strategy must exist 5. Removing existing barriers to innovation – or by improving and streamlining the funding and approval processes. <p>'The RCP encourages the government actively to support the extension of existing opportunities to promote the delivery of, and access to, innovative treatments, devices and technologies'</p> <p>'Support discussion with clinical colleagues .. feedback from colleagues in the multidisciplinary clinical team and ethics committee has been taken into account.'</p> <p>'Taking action to address funding and access barriers is.. possible without new primary legislation.'</p> <p>It is 'inaccurate to state that clinical trials are rarely conducted on children and that the Bill would somehow redress this'</p>

<p>NICE</p>	<p>NO. 'NICE has not been made aware of any evidence that doctors are deterred from appropriate innovation by fear of litigation. We are aware, however, of many examples where doctors are successfully innovating under the existing law.'</p> <p>'A review of the published medical literature, searching all the main databases, identified no reports that doctors are deterred from innovative practice by fear of litigation.'</p> <p>'The current system provides safeguards for patients from inappropriate treatment, and protects doctors from the risk of litigation should patients consider they have been put at risk by inappropriate treatments.'</p>	<p>Lawful treatment currently – informed consent and overriding duty to act in best interests. Introducing change in law (without evidence that doctors are deterred by fear of litigation) 'may therefore pose a potential risk to patients of inappropriate experimentation.'</p> <p>'We are aware.. of the risks to which patients are exposed when they do not receive effective, evidence-based treatments. It is important that vulnerable patients are protected from this risk, while also being given the opportunity to try innovative new treatments. Careful consideration should therefore be given before introducing new legislation that might inadvertently increase the risk of harm to patients.'</p> <p>'effectively removing the Bolam test, takes away an important mechanism for protecting patients from poor medical care. The Bolam test has been important in many legal cases of poor practice, none of which relate to anything that could otherwise be described as 'appropriate innovation'.'</p> <p>'..a doctor is to be protected from a negligence claim as long as he can claim a genuine belief that there are plausible reasons for thinking that a treatment would be effective and has considered the factors set out .. even if his belief is unreasonable and his analysis of the relevant factors is of poor quality and below what would generally be expected of a clinician in his position.'</p> <p>'puts patients at risk' 'This is potentially very dangerous and provides no safeguards to the patient.'</p>	<ul style="list-style-type: none"> -funding - difficulties in facilitating development of clinical trials -data collection and availability -access to information to support innovation, data sharing 	<p>NICE recognises importance of innovation to identify and disseminate new treatments that improve outcomes for patients, and recommends encouragement within the existing legal framework.</p> <ul style="list-style-type: none"> -facilitating opportunities for research through formal trials, for example by better access to information and better funding -improved data collection about innovative treatments through expansion of registries and other ongoing data collection. - online portal, perhaps supported by an expert advice service, to provide doctors with information about potential new treatments and current evidence to underpin them -guidance could be developed in cases of particular uncertainty (GMC/clinical guidance) -guidance on mechanisms for innovation could be available 'through a number of routes, including GMC advice, Royal Colleges and through the NICE website.' - Development of an appropriate consent form by the GMC <p>The process set out.. 'is possible within the current legal framework'.</p> <p>'Support to facilitate innovation within the existing legal framework would be extremely welcome.'</p>
<p>GMC</p>	<p>---</p>	<ul style="list-style-type: none"> -'legislation which aims to clarify and encourage good practice in terms of when medical innovation is responsible could have the opposite effect as well as unintentionally weaken the principles which we regard as fundamental to safe, effective patient care.' -Would operate against GMC's 'Good Medical Practice' guidance. -Patients at risk of dangerous practice or exploitation of patients' lack of medical knowledge. 		<p>'Legislation is both unnecessary and undesirable.'</p> <p>' Good Medical Practice, our core guidance for all doctors, states that doctors must 'be satisfied that the drugs or treatment serve the patient's needs' and must 'provide effective treatments based on the best available evidence'.</p> <p>-Guidance on Consent already recognises and allows for innovation</p> <p>'We believe that much more can be done to promote responsible innovation in a way that may be more effective in achieving the stated aims of the draft Bill. For example</p>

		<p>-‘Could hinder responsible innovation’ ‘would involve substantially changing the role and remit of ROs. This would have resource and other implications for NHS and independent sector services, add unwelcome layers of bureaucracy, and require changes to the Medical Act which would be virtually impossible to draft in a meaningful way.’</p> <p>‘..seems to suggest that innovation is only present when a body of responsible colleagues may or do disagree with the opinion of the doctor who is proposing to perform a treatment that departs from accepted practice. We do not understand this to be the desired definition given the stated aims of the Bill.’</p> <p>‘the Bill would introduce new areas of uncertainty for doctors and others. ‘removes an important safeguard for patients by removing a key requirement of responsible practice. ‘does not provide a clear enough definition of medical innovation so as to define where the boundary lies between innovation and medical research.’</p>		<p>-coordinated effort by leading organisations, including the GMC, to raise the profile and importance of innovation;</p> <p>-encouraging medical students and doctors in training to participate in research and supporting those wishing to pursue clinical academic careers;</p> <p>-highlighting the resources available to support not just doctors but nurses scientists and others involved in seeking new solutions to important challenges in healthcare;</p> <p>-and supporting the emergence of centres of excellence to help achieve sustainable change and spread knowledge gained from innovation for the benefit of greater numbers of patients and their families.’</p>
RCR	<p>NO. ‘we ‘have no evidence that doctors are deterred from innovation by fear of litigation.’</p>	<p>There is concern that the intent of the Bill is to allow ‘greater flexibility for those in independent practice’ ‘This could have perverse effects as there might be fewer checks and balances to ensure that innovation is appropriate, safe and potentially effective.’</p> <p>‘we are very concerned that there could be serious unintended consequences of the proposed legislation.’</p> <p>It ‘risks exposing vulnerable and desperate patients to false hope, futile and potentially harmful (and expensive) treatments.’</p>	<p>‘Securing funding is one of the biggest obstacles to innovation at present.’</p>	<p>‘If the doctor considers that the proposed treatment would not ...satisfy the Bolam test if challenged in court, then the overwhelming likelihood is that the treatment will not be of value and there is a significant risk that it may be harmful.’ ‘If the decision to offer an innovative treatment has been made within a multi-disciplinary team.. then it is highly likely that it would satisfy the Bolam test if challenged in court, therefore making this Bill unnecessary.’</p> <p>‘We do not believe this legislation is needed. We do not feel that doctors are constrained as regards innovation and we believe that the current structures provide the appropriate checks and balances.’</p> <p>-‘An improved system of registration of innovative treatments, together with recording of outcome data, would be extremely valuable and would support responsible innovation.’</p> <p>-‘Securing funding’</p>
Wellcome Trust/MRC /AMS	<p>NO. ‘No substantial recorded evidence has been raised with us to suggest that doctors are being deterred from the use of innovative treatments or</p>	<p>‘significant concerns’</p> <p>‘patients could be at risk of receiving treatments for which the evidence base is not well established, including treatments which could prove ineffective or even harmful.’</p> <p>‘may discourage patients and their clinicians from participating in clinical trials if they are</p>	<p>‘We believe that some of the biggest barriers to innovation are at the structural and organisational level, rather than at the level of the individual. Such barriers include the cost of innovative products and budgetary constraints, bureaucracy,</p>	<p>-‘We believe the best way to assess the efficacy and safety of treatments is through full and robust research studies with appropriate collection of data and other evidence, on a rigorous statistical basis and with appropriate ethical approval(s)’</p> <p>-Measures to ‘increase access to innovative medicines where these are based on robust regulatory mechanisms and appropriate</p>

	<p>procedures owing to fear of litigation’</p>	<p>aware that treatments can be provided without the necessity to do so.’</p> <p>‘may shift the emphasis from the importance of prescribing treatments based on scientific evidence..’</p> <p>Lack of data collection may ‘lead to some practitioners continuing to provide untested and ineffective (or potentially harmful) treatments to numerous patients.’</p> <p>‘may undermine the importance of fostering a culture where outcomes are recorded, and practices are examined and compared continuously.’</p> <p>‘may add an additional hurdle to the already lengthy task of setting up and carrying out clinical trials and other studies, and dissuade practitioners from performing such studies.... might discourage patients from participating in clinical trials if they are aware that treatments can be provided without the necessity to do so.’</p> <p>‘This may unintentionally authorise uncontrolled experimentation and mean that an appropriately informed research evidence base can never be accumulated on novel interventions.’ Would make decisions about adopting treatment very difficult if not impossible.</p> <p>-ROs not equipped, ‘not aware of existing institutions .. that are appropriately constituted and resourced to offer such support’</p> <p>- ‘Finally, we would like to raise concerns about the possibility of undue pressures placed on individual doctors to test unproven treatments by manufacturers. We believe it would be important to raise awareness of the safeguards that already exist to ensure that this does not take place.’</p>	<p>and the lack of financial incentives, clinical engagement and training for the development, adoption and diffusion of innovative approaches and treatments. The above all need to be addressed if we wish to support innovation and we welcome ongoing efforts by NHS England and the National Institute for Health Research in this area.’</p>	<p>evidence review; we welcome the Medicines and Healthcare products Regulatory Agency’s recent announcement of the Early Access to Medicines Scheme to provide a rapid approval mechanism for innovative medicines when there is a clear unmet medical need and before phase III trials, as well as the European Medicines Agency’s decision to provide ‘adaptive licensing’ through its pilot project. These two recent initiatives, together with widespread information on the provisions of the ‘named patient’ prescribing system, should provide a stronger basis for innovation.’</p> <p>-‘We also support work aimed at streamlining the governance of clinical trials. We welcome the new Health Research Authority Assessment and Approval process, which should reduce the delays and duplications in obtaining research permissions and consolidate the NHS research governance pathway.’</p> <p>-Appropriate collection and sharing of results locally and centrally, however noting that ‘success of treatment in one patient will not, and should not, provide an evidence base for service improvement for patient benefit as it cannot be generalised’</p> <p>-‘important to establish how commissioners would allocate resources for activities outlined in the Bill and how the process described in the Bill takes account of weighing up the value or opportunity cost of treatments.’</p>
<p>BPS</p>	<p>NO. ‘We have not received any anecdotal evidence from our members that anxiety around the possibility of litigation is a</p>	<p>-could create..’a situation in which doctors, and employers, are unclear about the boundary between the Bolam test and this Bill and therefore what provisions are required for</p>		<p>‘Situations.. could be handled via a Clinical Ethics Committee which would allow a multi-disciplinary team to consider the merits of an innovative treatment and advise individual doctors. This recourse</p>

	barrier to innovative treatments. ‘	<p>a decision that does not expose that doctor or employer to a negligence claim.</p> <p>‘it is not realistic to expect an accurate assessment of the possible benefits and harms of innovative interventions as described by the Bill. Despite mechanistic arguments, or the benefits seen in individual cases and case series, many interventions do have unpredictable adverse effects.’</p>		<p>could be a useful means for doctors to ensure responsible decision-making’</p> <p>-Dissemination of information on outcomes essential.</p> <p>‘There is ‘a need to remain mindful of patient safety and the importance of safeguards. Our members are not convinced of the need for legislation’</p>
RCPsych	Organisations may use NICE recommendation as protocol, not guidance through fear of litigation.	<p>‘.. ‘doctor’ means ANY registered doctor, specialist or not, and therefore the way is open for any doctor who might be wholly unqualified ..’</p> <p>‘if a doctor was thinking about doing something unorthodox, a multi-disciplinary team (MDT) with a range of expertise which is likely to include non-medical and non-nursing staff may not necessarily be aware of all the knowledge and also be risk-averse. Would it not be better to ask other medical colleagues in the field rather than the MDT? It is important for the MDT to understand why the approach is being taken, however it would not be appropriate to have one member with insufficient knowledge blocking the innovation.’</p>	<p>‘management of risk has increased such that doctors may not be able to be as innovative as they wish.’</p> <p>‘A likely unintended consequence of NICE is that some provider organisations appear to regard them as a protocol, with the result that if NICE does not recommend a treatment or approach, a doctor will find it hard if not impossible to deliver it. ‘</p> <p>‘introducing a licensed treatment may also incur significant ‘paperwork’ to gain approval to use and this can take many months.’</p>	<p>‘ ‘Relative risk’ carries very specific scientific meaning with respect to the background comparator in a statistical test. An alternative should be used, clearly specifying what is meant by ‘risk’ and ‘relative’ to what.</p> <p>Recommendation:</p> <p>-Publicly registering clinical trials/outcomes worldwide. A register that is available to other doctors would allow sharing of knowledge about a potential innovation and this would be beneficial</p> <p>- Research should be covered by research protocols and regulatory approvals (e.g. from Research Ethics Committees, the Medicines and Healthcare Regulatory Agency [MHRA], the Research and Development Consultative Committee).</p>
AoMRC	NO. ‘We have not seen any evidence that suggests litigation or the possibility of litigation is deterring clinicians from innovative practice’	<p>‘Bill will not actually deter innovation which is irresponsible and may indeed have the opposite effect’</p> <p>‘inadvertently undermine the undertaking of proper taking of clinical trials’</p> <p>‘informed consent... becomes much more difficult when there is little evidence to support innovation’.</p> <p>‘could easily lead to innovation that is not responsible or in the best interests of patients..’</p> <p>‘opportunity cost. If doctors devote time, drugs or operating time to patients where there is no consensus on likely benefits, those doctors, drugs and operating theatres will not be</p>	<p>-access to funding</p> <p>-complex, bureaucratic arrangements for agreeing trials and research</p> <p>Re: clarity for doctors: ‘The issue is probably less about the complexity of the legal position and more about the level of awareness. It has to be said, therefore, that it seems unlikely that passing a further piece of legislation with its own set of rules will in itself ensure that individual doctors are any clearer than they would have been before.’</p>	<p>‘legislation is effective through <i>prohibition</i> rather than <i>promotion</i>. Legal sanction or financial penalty drives compliance rather than promotes behaviour change. Therefore we are not convinced that legislation is going to be effective in promoting the culture change required to encourage medical innovation.’ ‘medical Royal Colleges do not believe that this proposed legislation is necessary and, indeed, may have unintended adverse consequences’</p> <p>‘there are various ways to encourage and promote innovation. These include:</p> <p>-Removing or streamlining the very considerable bureaucratic barriers involved in establishing and approving proper clinical trials and research</p> <p>-Supporting an innovative culture within NHS organisations which gives the clinicians the time and space for innovation</p> <p>- Ensuring the funding for effective clinical trials</p>

		<p>available to those who might more clearly benefit from them’</p> <p>‘Promoting innovation that unequivocally does not have the support of responsible medical opinion would seem to be entirely flawed, is unlikely to be of value and gives a real risk of inappropriate innovation that may be harmful.’</p>		<p>-Devoting real attention and effort to spread and adoption of innovation</p> <p>-An ‘explicit requirement for the results of an innovation to be properly recorded with the outcomes made available to clinical colleagues for scrutiny and learning. Without recording and dissemination a new treatment or procedure practised by an individual clinician becomes an experiment rather than an innovation.’</p>
NHS HRA	<p>‘ The existing legal framework allows for innovation in the NHS’</p> <p>‘claims in relation to research are a very minor proportion of those handled by the NHSLA... in the 15 year period to 2010, litigation associated with clinical research accounted for 0.01% of the all the NHSLA’s payments. The HRA therefore considers that innovation, and studies to resolve uncertainty, in a research setting protects against litigation.’</p>		An absence of published data	<p>‘ we strongly hold the view that good quality research should remain the gold standard and that this principle should not be undermined.’</p> <p>-‘would propose that it is a requirement for all such innovations to publish results, both where it is reported that intervention was successful and, as importantly, where it was not.’</p> <p>‘the HRA is of the view that the current legal framework provides for innovation in the NHS and that good quality research is, and should remain, the gold standard for the NHS where there is uncertainty. We accept though that there will be occasions when there is no remaining treatment option and a research trial is not available to an individual patient and the HRA fully supports that clinicians should be able to use innovation without fear of litigation.’</p>
RCS	<p>‘ there is little evidence that doctors are deterred from innovation because of the threat of litigation’</p>	<p>‘we do not believe the wording of the Bill achieves (its) aims’.</p> <p>‘we have a concern that it could protect doctors deviating in a harmful way from standard practice. For example, the Bill says it is aimed at circumstances where, in a doctor’s opinion, ‘the proposed treatment does not or would not’ have the support of ‘a responsible body of medical opinion’, or where such support is unclear. Similarly, clause 5(e) suggests doctors only need to take into account the opinions of those individuals who the doctor believes it is appropriate to take into account.’</p>	<p>The College continues to advocate for:</p> <ul style="list-style-type: none"> - CECs not in all Trusts to support doctors on ethical issues including one-off innovations -(reduction in) research bureaucracy; -encouragement of NHS staff and patients to participate in research -funding 	<p>‘We would like to see the following principles adhered to by those redrafting the legislation:</p> <ul style="list-style-type: none"> -The Bill should aim to protect the patient while nurturing the innovator. This means that a doctor should not be allowed to simply disregard a body of clinical opinion or colleagues in their multi-disciplinary team; -It should avoid setting out additional legal criteria that could expand the scope of legally defined medical negligence; -It should allow flexibility in both elective and emergency situations; -The Government should provide assurance that any new legislation will not undermine protections provided through current case law -Improving implementation and monitoring of uptake of innovations, including the monitoring of compliance with NICE approved medicines and devices; -Increased funding for surgical research and innovation.’ <p>-‘We also believe there is merit in medical specialty associations setting up an Innovation Oversight Panel composed of individuals</p>

				with experience of the trials and tribulations involved in surgical innovation.'
Legal & defence				
MDU	<p>NO. 'The MDU does not have any experience or evidence to suggest that doctors are deterred from innovating by the 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'</p> <p>'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.'</p>	<p>-Concerned at the implications ..for patient safety</p> <p>-Allows doctor to provide treatment s/he alone believes in without '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. .. 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.'</p> <p>-concerned that ' might cause doctors to think they had discharged their duty by complying only with the letter of this law ' rather than GMC guidance</p> <p>-Bill seems to apply to registered not only licensed practitioners</p> <p>-Onerous responsibility on ROs, outside their roles</p> <p>- '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....'</p>	<p>'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.</p> <p>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.</p> <p>The advice members seek is principally about ethical matters or other legal concerns such as compliance with data protection legislation. '</p>	<p>'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.'</p> <p>'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.'</p> <p>'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. '</p>
MPS	<p>NO. – 'refusing treatment to a patient purely because of the fear of litigation might in itself amount to a fitness to practise issue.'</p> <p>'Despite many years of experience in the clinical negligence claims environment we have no evidence that the fear of litigation is holding back innovation in medicine.'</p>	<p>-Lack of appropriate safeguards</p> <p>-no objective test of responsible or plausible – arguably removes Bolam/Bolitho objectivity, no clear definition of MDT, Dr 'should consider 'opinions expressed by colleagues whose opinions appear to the doctor to be appropriate to take into account.'</p> <p>'We believe that it increases risk... The consultation admits that 'it has not been possible to identify the likelihood and scale of these risks'. It is important that thorough</p>	<p>Potential barriers:</p> <p>-Fear of regulator sanctions</p> <p>-medical training may or may not encourage innovation</p> <p>- bureaucracy and complex arrangements for agreeing research and trials may be a barrier to innovation</p>	<p>Suggested solutions to potential barriers:</p> <ol style="list-style-type: none"> 1.Create greater awareness about the existing legal position 2.Build an innovative culture in medical training institutions and employers 3.Registering and awareness raising of medical innovations <p>-'If there is a lack of awareness of the implications of current law this can be solved through education and training; not new law.'</p>

		<p>analysis is undertaken before there is any change in law.’</p> <ul style="list-style-type: none"> -Could be used a ‘tool for patients to force the hand of doctors’ -May lead to a ‘shortcut for consent’ - ‘There is a risk that patients will misunderstand and overestimate what this Bill would do’ -‘A barrier to responsible innovation’ in a way that bypasses the tried and tested clinical trials process. -Doctors are currently protected undertaking responsible innovation. A doctor would not be able to rely solely on this Bill to defend fitness to practise allegations at the GMC 	<ul style="list-style-type: none"> - willingness or ability of the NHS to pay for innovative but unproven treatments -claims directed at NHS Trust not individual may have an impact 	
<p>Robert Francis QC</p>	<p>NO. ‘The proposal of this Bill proceeds from a fundamental misunderstanding of the effect of the current law’ ‘no evidence has been produced which shows that innovative treatment has been significantly deterred by a fear of litigation related to the <i>Bolam</i> test.’</p>	<ul style="list-style-type: none"> -Protection of patients is maintained under current law – a treatment should be capable of reasoned justification (Bolitho). Logical basis for some support is required. Bill removes this. -Scope is uncertain -‘Alarming lack of accountability or scrutiny or other safeguard’ -‘It explicitly frees the doctor to offer treatment which has no support from responsible medical opinion’ -Doctor will be left in doubt about what is considered ‘reasonable’, and laborious judicial reconsideration will ensue -Does not protect patients from inducement into treatment that will benefit manufacturers -Effectively passes risk entirely to patient and lifts it from the promoter of the treatment -Increases risk to vulnerable patients of mavericks and those with commercial interests -Does not relieve the conscientious doctor from a laborious consideration of what is reasonable, responsible, appropriate under a multiplicity of headings -‘there is likely to be protracted and complex litigation about the meaning of this Bill’ 	<p>Employer inhibited doctor in <i>Simms</i> - possibly linked to cost of treatment</p>	<p>‘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.’ ‘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’</p> <p>‘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.’</p>

<p>Kingsley Napley LLP</p>	<p>NO.</p> <p>'In our experience, doctors are not deterred from innovation by the possibility of litigation. Current case law provides protection to doctors for any treatment they give which would be supported by a responsible body of medical opinion.'</p> <p>'We cannot think of any claims in which we have represented successful claimants that would be unsuccessful if brought once this bill became legislation. Therefore, we do not think that this bill will reduce the number or cost of clinical negligence claims. On the contrary, we have identified the potential for satellite litigation which would increase legal costs.'</p>	<p>'if this bill becomes law there will be confusion and lack of certainty which will mean that doctors are less inclined to innovate.'</p> <p>'this legislation will open the door to satellite litigation.'</p> <p>'Arguably, concerns about satellite litigation would add to the confusion and discourage doctors from offering innovative treatment, or prevent it being sanctioned.'</p> <p>-Creates a 'mavericks charter which would allow doctors to freely experiment on vulnerable patients provided that the patient consents. Arguably, a desperate patient will consent to any treatment on offer.'</p> <p>- 'vague and ill thought-out'</p> <p>- 'The MDT will reflect the prevailing culture of an organisation.' MDT not objective or appropriate safeguard. 'MDTs are already overstretched and under resourced.' with very busy patient lists.</p> <p>-Use of MDT as gatekeeper keeps knowledge at local level, stifles innovation</p> <p>- 'serious danger that the better informed patient will be able to demand innovative treatment, or threaten satellite litigation which, because of limited time and financial resources will lead to them securing treatment. Less informed patients will be left with fewer opportunities to undergo innovative treatment.</p>	<p>There is 'a possibility that funding for innovative treatment will not be made available by NHS commissioners.'</p>	<p>'The AllTrials campaign highlights the need for the results of clinical trials to be shared and published, regardless of whether the results are positive or negative. Both NICE and the NHS Health Research Authority are signatories to this petition, but the consultation does not address how positive and negative experiences of innovation will be reported'</p>
<p>NHSLA</p>	<p>NO. <i>[Do you have experience or evidence to suggest that the possibility of litigation sometimes deters doctors from innovation?]</i>: '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</p>	<p>- Bill suggests responsible innovation could occur even where the proposed treatment "does not or would not have" support from a responsible body of medical opinion...There is no reference to research or to peer review.'</p> <p>- 'the phrase 'plausible reasons' is not defined and appears to place too great an emphasis on a subjective judgment by the doctor in question'</p> <p>-subjective standards – the opinion of others does not have to be taken into account</p> <p>-concerns that wording allows for relatives/others to discuss patient's care</p>		<p>-Research and peer review are essential</p> <p>'Our broad view is that existing case law caters appropriately for cases of innovative treatment'</p> <p>Recommend:</p> <p>- central registration of all innovative treatments;</p> <p>-a duty on clinicians to report upon the outcome of such treatments</p>

	NHS clinicians off-licence when doctors consider that their prescription will be beneficial for individual patients.'	-'in the short term there is likely to be litigation on the meaning of individual words and phrases in the Act, should the Bill be passed'		
<i>Charities / patients</i>				
AMRC Association of Medical Research Charities	NO. ' we are not aware that fear of litigation is a barrier to innovation' 'Some of our member charities have consulted clinicians with whom they have close links and have not been able to identify any notable fear of litigation among those doctors.'	- unintended harmful consequences	'Our vision for research in the NHS.. identified the major barriers as an NHS culture that does not see research as integral to improving care, a workforce lacking research and analysis skills required for innovative thinking, leadership at all levels that values research, inflexible and unresponsive regulation, a medicines pricing system that does not encourage the adoption of innovation, and a lack of sharing of best practice and dissemination of research findings.' Barriers outside the NHS include ' a regulatory system that can make it time-consuming and expensive to setup clinical trials, a licensing system that is not equipped or flexible enough to deal efficiently with the most novel and innovative treatments, and a science budget that is being eroded by inflation, thus reducing the UK's capacity for fundamental research on which innovation and medical progress is based.'	'A systemic approach is required to tackle.. (the existing barriers) and truly and effectively encourage medical innovation for the benefit of patients.' -A 'possible greater operational role for Academic Health Science Networks'- 'AHSNs may be able to provide a valuable source of oversight and advice on clinical innovation in their area.'
AvMA	NO. – Not aware of any case where there has been an unreasonable finding of clinical negligence as a result of innovative medical treatment.	-Bill is both unnecessary and may have serious unintended consequences should it become law' –removes access to justice for patients -contains completely inadequate safeguards -individual doctor has absolute discretion 'In effect this would be a license for individual doctors to carry out the treatment they want to, provided they are able to persuade the patient that this is the best or only course of action which might (in their individual opinion) help them..patients can easily be led into accepting proposed treatment from a doctor which in fact is not clinically appropriate.' -deprives patients/next of kin if they die of compensation for negligent treatment		-Training and education if problem is perceived by doctors -'We do not think that the Bill is needed at all and in fact may have serious unintended consequences' -'The Bill should not become law.'

		<p>-‘likely to harm attempts to improve patient safety and lead to more patients actually being harmed because of inappropriate treatment’ -would ‘lead to patients’ and families’ hopes being unrealistically raised and then dashed.’</p>		
MND Assoc	<p>NO. ‘the Bill would not remedy the problem it is aimed at, for such a problem does not exist: uncertainty around the law or fear of litigation do not, as far as we can see, dissuade doctors from trying new treatments.’ ‘We have no evidence to suggest that that the possibility of litigation, or a lack of clarity and certainty about the circumstances in which a doctor may innovate without fear of litigation, has ever deterred a doctor from deploying an innovative treatment in respect of MND.’</p>	<p>‘ We fear that the provisions.. could .. open the door to the exploitation of people with MND.’ ‘Faced with superficially plausible claims by the promoter of an unproven or experimental treatment, a doctor inexperienced in MND could easily err and come to the view that the treatment might be beneficial, particularly if encouraged by a patient who is understandably anxious to explore every last option, however slight its chances may be, to overcome the devastating effects of MND ‘These clauses together appear to give a signal to doctors that ‘anything goes’ when faced with a terminal and profoundly disabling illness’ - creates ‘a charter for irresponsible treatment and experimentation, and the exploitation of potentially vulnerable patients faced with a devastating diagnosis and feeling – rationally or not – that they have nothing to lose’ -reduces quality of medical advice available to patients and redress in event of harm - ‘The Bill poses a risk to legitimate research’</p>	<p>- ‘personnel lack research skills, leaders do not appreciate the value of research, and research is not recognised as a route to providing high quality care.’ -treatment options simply do not exist- scientific progress -many barriers do exist, not related to litigation</p>	<p>-‘this Bill offers no prospect of benefit but poses a genuine risk of causing harm, and we advise the Government not to proceed with it.’ -‘we believe that the current legal position offers an appropriate balance between latitude for doctors and safeguards for patients’ -‘the quality of life that a person ..can achieve with appropriate care and support should not be gambled with lightly’</p>
CR-UK	<p>NO. ‘ We have been unable to find evidence that fear of medical litigation is currently a barrier to innovation in cancer. ‘We have been unable to find evidence that cases have been brought, or led to compensation, based on a competent doctor attempting to use an innovative treatment with the consent of a patient. ‘</p>	<p>-..‘the Bill would apply in circumstances where the medical treatment may not have the support of a responsible body of medical opinion’ -lacks clarity in what is reasonable</p>		<p>-Data publication ‘would help ensure the body of evidence for newer treatments was being added to, for the benefit of future patients.’ -The ‘most important mechanism for encouraging responsible innovation in the UK is to continue to build a thriving clinical research environment.’ ‘There are a number of other mechanisms already in place that should be evaluated which, if further strengthened, could lead to significant improvements in medical innovation. These include: -MHRA Early Access Scheme -Adaptive Licensing -Cancer Drugs Fund -Commissioning Through Evaluation -Better use of data within the NHS’</p>