Department of Health

Report on the consultation on the Medical Innovation Bill

Summary of responses and next steps

July 2014

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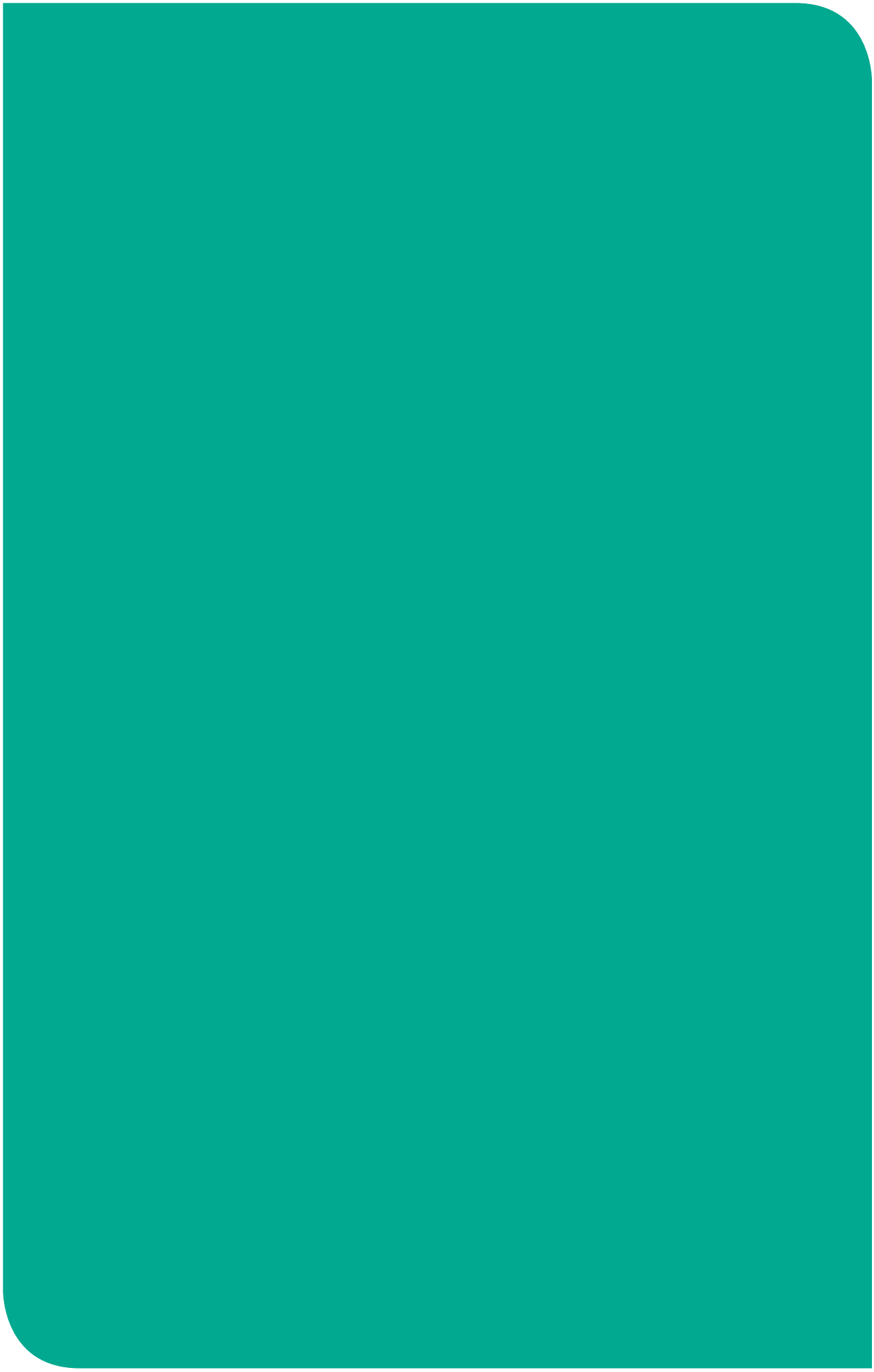
Prepared by the Department of Health



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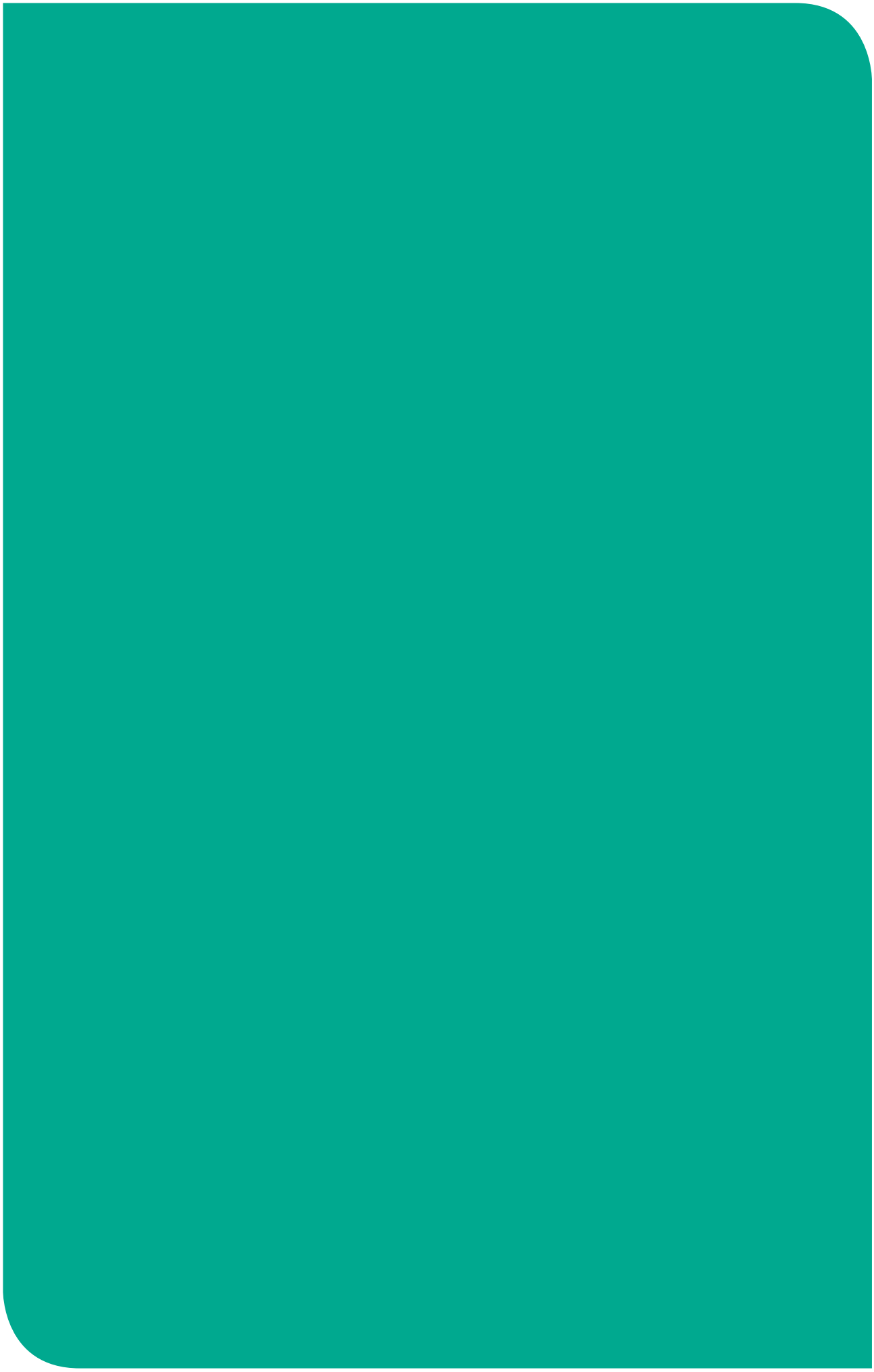


Executive summary

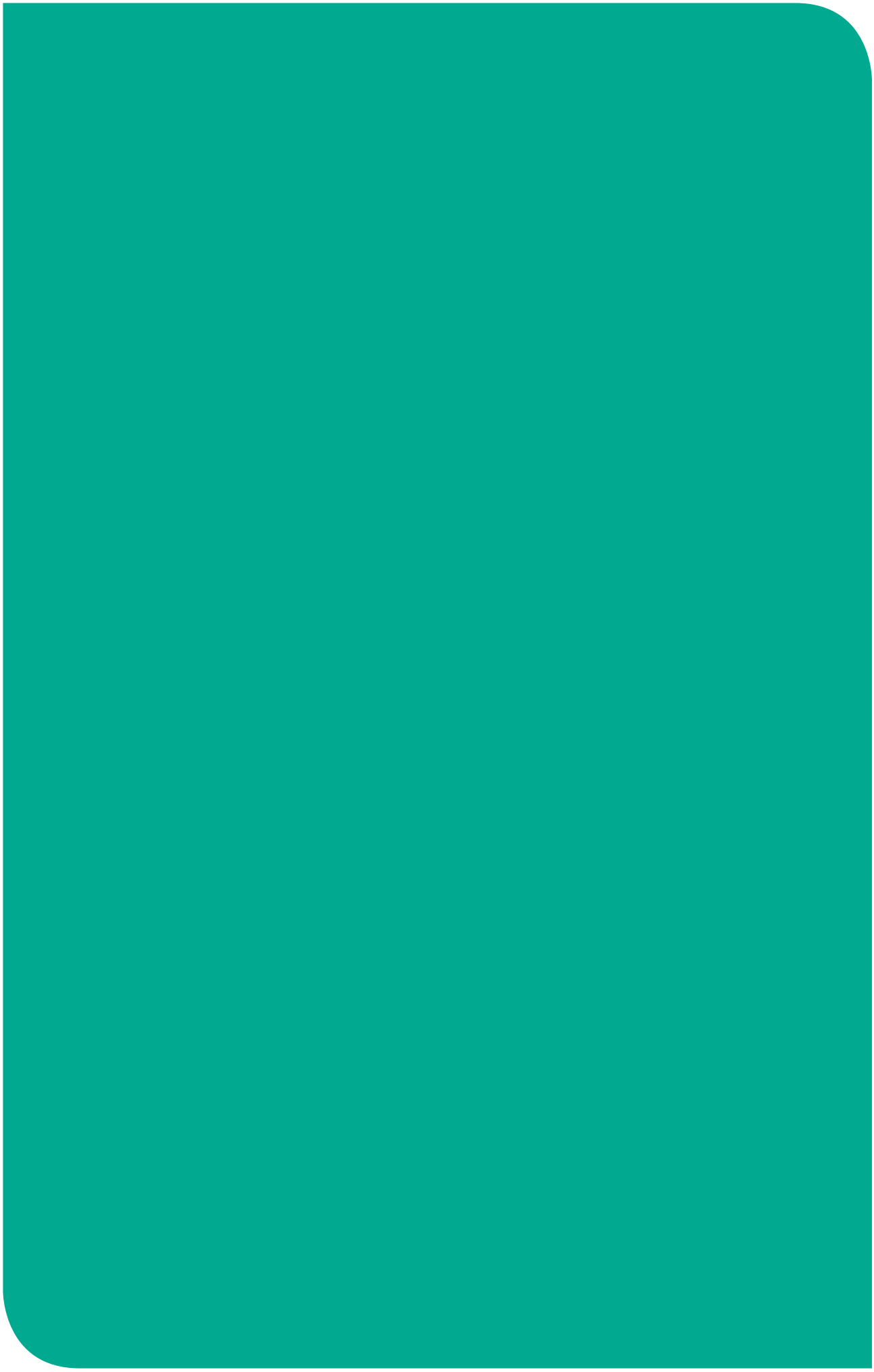
The Department of Health's consultation

In a statement to the House of Commons in November 2013, the Secretary of State for Health gave an undertaking to carry out a full consultation on the issues raised by the Medical Innovation Bill, which had been introduced as a private peer's Bill by Lord Saatchi and, in a slightly different version, as a private member's Bill by Michael Ellis MP.

A public consultation ran from February to April 2014 and attracted a high level of response, from doctors, lawyers, patients and the public. The bulk of this report provides a summary of those responses.

Next steps

Lord Saatchi has decided to introduce a new version of the Medical Innovation Bill as a private peers' Bill. The Government is pleased that Lord Saatchi has strengthened the oversight mechanisms in the Bill in response to criticisms expressed during consultation events. However, the Government has reservations about some provisions in the Bill and intends to work with Lord Saatchi to amend the Bill as it progresses.



Chapter 1: The Department of Health's consultation

1. The consultation paper[1] was published electronically on Thursday 27 February, when bodies listed in Annex D of the consultation paper were alerted to its existence, and a news story appeared on the Department of Health (DH) website. The consultation ran for eight weeks, to Friday 25 April 2014.

2. Four consultation events were held during the course of the consultation:

   - on 12 March 2014, at the Academy of Medical Royal Colleges in London;
   - on 18 March 2014, at the National Assembly for Wales in Cardiff;
   - on 2 April 2014, at DH's offices (Quarry House) in Leeds;
   - on 10 April 2014, at DH's offices (Skipton House) in London.

   The numbers attending each event ranged from 12 to 33. DH staff, and either Lord Saatchi (as the sponsor of the original private peer's Bill) or members of his team, were present at each event. The first event was held jointly with the Academy of Medical Royal Colleges and invitations were restricted to DH's strategic partners (particularly medical bodies). The other three events were open to the general public. They were promoted on the DH website (and those in Leeds and Cardiff were also promoted in the local media), although none was oversubscribed. The discussion at the events covered points similar to those made in the written responses.

3. At the fourth consultation event, Lord Saatchi explained that, to ensure the Bill gives protection from maverick clinicians, he is now attracted to the idea of requiring a doctor to take account of the views of the relevant multi-disciplinary team before carrying out an innovative treatment under the Bill. To alert those who had not been at that event to this development, the following update was published on the DH consultation website in the week of 14 April and sent to those who had already responded to the DH consultation mailbox:

[1] The consultation paper is still available at https://www.gov.uk/government/consultations/medical-innovation-proposals-to-make-clinical-negligence-law-clearer The draft Bill included in the consultation paper is available as a standalone document at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/285325/The_Medical_Innovation_Bill.pdf

The consultation so far (both events and written responses) has been extremely helpful in adding to our thinking. This has raised two additional issues that you might want to consider in your consultation response.

1. To enhance the safeguards in the Bill we would be interested in views on whether the Medical Innovation Bill should only apply when the case has been discussed with clinical colleagues and their recommendations taken into account. The idea of this would be to give doctors greater confidence in advance that they had acted responsibly and thus not negligently.

2. Is the most appropriate approach for doing this (considering issues such as timeliness and the need to not add levels of bureaucracy) to use Multi-Disciplinary Teams (MDTs) to secure this input?

The level of response to the consultation

4. Responses could be submitted online at http://medicalinnovationbill.dh.gov.uk/ (where others could see and read them), or sent electronically or by post to DH. By the end of April 2014, comments from 70 people had been published online, and a further 100 responses to the consultation had been sent directly to DH.

5. In addition, Lord Saatchi's team created an on-line petition which collected over 16,000 signatures, supplemented in over 2,000 cases by additional comments, and an embeddable webform, which was hosted on various websites and collected over 2,000 responses. Lord Saatchi's team provided the comments that had been collected in these two ways to DH at the end of the consultation.

6. We are grateful to all who responded to the consultation. We welcome the fact that responses came both from organisations and from individual members of the public, and from a variety of backgrounds, including medical, legal, patient, research, science and industry.

Chapter 2: Summary of responses

7. This chapter provides a summary of the responses, concentrating on the main themes to emerge:

   - first of all it works through points made in the responses that came direct to DH, considering these under the headings of the nine questions posed in the consultation paper and on the consultation website.
   - then it considers the comments made by those who responded by the routes described in paragraph 5. Those responding by these routes may not have seen the consultation paper or the nine questions, and their comments generally focus on why they consider the Bill necessary, rather than on the detail of its contents.

   Where we quote from responses, we have aimed to correct typos, and to provide in square brackets our understanding of what any acronyms used stand for.

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

8. Some respondents stated that they had such evidence or experience. Some amplified these statements in fairly general terms. For example:

   BASO (a membership organisation for surgical oncologists) said "Yes – this may take place in clinical practice".

   A patient with relapsing remitting multiple sclerosis said "doctors are scared to suggest a treatment".

   The parent of a child with Duchenne muscular dystrophy said "I have found a certain reluctance to discuss medical innovations" for its treatment.

   A funder of clinical trials through a charitable trust said "Yes – direct discussion with clinicians on numerous occasions."

9. A small number of examples were provided identifying both the condition and a particular innovation (although none where a doctor described him- or herself personally as deterred). These were as follows:

   A doctor described the case of a relative who had not been offered allogeneic haematopoietic stem cell transplantation (HSCT), which he described as "currently the only curative treatment for myeloma", because offering the treatment would expose the consultant concerned to "disciplinary sanctions from her regulatory body for not following "standard and proper treatment" and the risk of a clinical negligence claim for not acting in accordance with the *Bolam* test.

A patient said "I have experience of trying to establish skype & VOIP [Voice over Internet Protocol] clinics with my transplant team. The surgeon wanted to engage but was told to do it off premises. The nursing team initially would not take part for fear of losing their licence. The clinic started from home and could only be set up in hospital after the IG [Information Governance] team had deemed it legally safe. By then the enthusiasm from the medical team had waned and everything had to be started from scratch. Both the patient and doctor wanted to engage in this way. Consent was obtained but still the trust and individuals feared litigation."

Another patient said "Yes – my daughter has MS [multiple sclerosis] and has been unable to obtain a prescription for Low Dose Naltrexone from her GP or consultant despite the fact that they support her taking it."

10. Some respondents "recognise[d] that the fear of litigation may influence behaviour of clinicians" (the Health Research Authority) or said "Fear of litigation could be one of a number of factors that act as barriers to innovation in the NHS" (the Institute of Cancer Research). Others argued that it is right that the possibility of litigation should discourage certain "innovations" – for example, one respondent said "Patients, after all, have a right to be protected from quackery".

11. Other respondents said they did not have experience or evidence to suggest that the possibility of litigation sometimes deters doctors from innovation. Some of these made clear that they did not expect to have such evidence or experience (for example, because they are not doctors).

12. However, many of the respondents who said "no" were medical bodies, including the Academy of Medical Royal Colleges and the Royal Colleges of Pathologists, of Physicians, of Physicians and Surgeons of Glasgow, of Radiologists, and of Surgeons of Edinburgh. It has been argued that "top doctors" are least likely, and the "rank and file" most likely, to be deterred from innovating by the fear of litigation, so it is worth noting that the British Medical Association and the two medical defence organisations that replied to the consultation also answered "no" to this question. The Medical Defence Union described the kind of queries it receives from its members about innovation, and noted that these focus on issues other than the 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 [General Medical Council] 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 already 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."

13. Other respondents also answered no to this question. These included:
    - medical research charities (including Cancer Research UK, Leukaemia & Lymphoma Research, the Motor Neurone Disease Association, the Muscular Dystrophy Campaign, Parkinson's UK, Prostate Cancer UK and Target Ovarian Cancer);
    - other bodies active in research and science (including the Academy of Medical Science, the Medical Research Council, the Wellcome Trust, and the British Pharmacological Society);
    - bodies primarily concerned with patients (including Action against Medical Accidents, Genetic Alliance UK and the Teenage Cancer Trust);
    - NHS England, the NHS Litigation Authority and the National Institute for Health and Care Excellence (NICE).
14. NICE (and an individual doctor) had reviewed published literature in search of evidence that the possibility of litigation deters innovation, but with little result.
15. Several respondents argued that there are greater barriers to innovation than the fear of litigation. Many argued that the NHS has become increasingly risk-averse and that there are cultural pressures not to innovate, partly because of the bureaucratic procedures that need to be followed (such as making an Individual Funding Request) where it is proposed to do something that is not standard. These pressures are not confined to the UK: for example, research by Macquarie University in Australia had found that "participants did not identify fear of litigation as a key barrier to innovation in surgery; rather they identified fear of bureaucratic processes as a potential barrier".
16. Several of those responding mentioned the status that various guidelines had acquired. NICE itself explained in its response:

    "We are always clear with practitioners that, while guidelines reflect the best evidence, they should not be rigidly followed with every patient regardless of different clinical conditions and individual circumstances"

    but some respondents argued that in practice NICE and other guidelines are given a different status. For example:

    The Royal College of Psychiatrists said "in the last few years management of risk has increased such that doctors may not be able to be as innovative as they wish. NICE demands a certain level of evidence, which may be lacking. By contrast, guidelines from the British Association for Psychopharmacology are built on a range of evidence, including clinical expertise. A likely unintended consequence of NICE is that some provider organisations appear to regard [NICE advice] 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. We suggest that fear of litigation is at the heart of this caution."

A patient said "Peer-reviewed medical literature shows that current treatment for Lyme disease does not always work. European guidelines state clearly that the optimum agent, dose and duration of treatment for Lyme neuroborreliosis are not known as there have been no good quality European trials. Yet doctors faced with a partially responding, or relapsing patient following treatment frequently say they are ruled by guidelines and cannot prescribe more. Because they have heard that some doctors have been reported to the GMC in the past for inappropriate diagnosis and treatment of Lyme disease they are clearly scared to use their clinical judgement. They do not know that there are genuine uncertainties in treatment and they do not know that the only doctor who was found to be acting outside his area of competence was one who failed on other counts. There are no UK guidelines for Lyme disease beyond very early disease and that is simply because there is little evidence on which to base treatment recommendations. There is a "Position Statement" by the British Infection Association but it is not, and was not intended to be, a set of guidelines. All doctors know is that they dare not step outside what they believe to be guidelines — totally unaware that there are no guidelines, just word of mouth and dire warnings about "inappropriate treatment". Such is the fear that doctors who have exercised their clinical judgement are unlikely to publish their case studies showing recovery following further treatment. So not only does this damage patient care, it stifles the advancement of knowledge in this area."

17. One legal firm that acts for claimants in clinical negligence cases (Kingsley Napley) offered an explanation of why patients may see the fear of litigation as a barrier when doctors do not:

"Blaming the external factor of the law may […] at times provide a convenient "hook" for a clinician to explain to a desperate patient or their family that the end of the road for rational treatment options has been reached."

18. A number of respondents argued that, in the absence of compelling evidence that the possibility of litigation deters doctors from innovating, it would be wrong (and ineffective) to try to solve any problem of "not enough innovation" by changing the law on clinical negligence, not least because doing so would remove a patient's right to compensation if harmed as the result of an innovative treatment that would be considered negligent under current law.

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?

19. This question was intended to ask whether there was a lack of clarity and certainty in terms of the legal position, but some respondents interpreted it more widely.

20. Of the respondents who answered yes to this question, some gave no further details. Some individual patients drew on their own experience, saying, for example:

"doctors seem unaware of the fact that they can prescribe innovative medicines and are afraid to do so"

"I have had a neurological illness for over 20 years […] There are things that can help, but to my doctors it is not always clear what they can prescribe"

Others answering yes did so from a professional perspective. For example, Ovarian Cancer Action and Professor Ahmed Ashour Ahmed argued that the advent of personalised medicine has changed the role of the large-scale clinical trial, while a respondent from Macquarie University Australia reported that research there:

"clearly indicated that there is confusion about when a surgical intervention is innovative. In particular, participants found it difficult to be clear about when an intervention is an acceptable variation from routine practice rather than an innovation."

The Institute of Cancer Research said "The regulation and funding arrangements governing innovation and access to new treatments in the NHS are highly complex, and there is a lack of clarity in a number of areas", while BASO referred to "the perception that national approval/guidelines are required even before the treatments can be considered for individual patients". More generally, an individual respondent noted that "decisions in medicine are often a fine balance".

21. Some respondents said they did not have such experience or evidence. These included, for example, the British Medical Association, the Medical Defence Union, the Medical Protection Society, the Royal Colleges of Physicians, of Pathologists, of Physicians and Surgeons of Glasgow, and of Surgeons of Edinburgh, the Academy of Medical Royal Colleges, NHS England, the NHS Litigation Authority and NICE.

22. Others accepted that individual doctors might lack clarity and certainty about the circumstances in which they can innovate, but thought this should be remedied, not by changing the current law (which might add to doctors' uncertainty), but by ensuring that doctors are better informed about what they can already do. Some noted that the General Medical Council and medical defence organisations already provide guidance for doctors. For example, the Academy of Medical Royal Colleges said:

"Individual doctors may or may not be clear […] However, the organisations to whom they are likely to turn for advice, particularly the medical defence organisations […] can certainly provide that clarity. 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."

23. Several respondents argued that the current state of the law serves both doctors and patients well. It does not constrain doctors unduly: there is no requirement to follow "standard practice", or even to have the backing of significant numbers of other doctors for a particular approach. Versions of this argument were advanced by medical, legal, patient, research and other interests. For example:

The Society of Clinical Injury Lawyers said "there is no difficulty with the legal tests […] the case law referred to (Bolam/Bolitho/Simms v Simms) provides a clear framework which has been operating successfully for many years."

The Association of Personal Injury Lawyers said: "We believe that it is precisely the *lack* of certainty and definition which protects doctors under the current law, and allows them

to innovate. If attempts are made to define the law and enshrine it in statute, it is more likely that something will be left out of the definition – eroding protection for the patient.

On the other hand, over-definition may also cause further problems for doctors trying to innovate. Doctors will be at risk of a clinical negligence claim against them if they are deemed by the patient not to have complied fully with list of factors contained within the statute."

Genetic Alliance UK said "We believe patients have the right to initiate clinical negligence litigation where a doctor has failed to follow agreed clinical guidelines or there is malpractice."

The Motor Neurone Disease Association said "We believe that the current legal position offers an appropriate balance between latitude for doctors and safeguards for patients – if anything, it is already tilted somewhat in favour of the former. Currently a doctor may proceed with a treatment if a responsible body of medical opinion – even if that is not a majority body of opinion, and the proposed treatment represents a departure from generally accepted practice – would support it. At the same time, if a patient's death is caused by reckless treatment for which only scant support among colleagues can be found, the doctor responsible will be found negligent: this is an important safeguard for patients".

24. Accordingly, several of these respondents argued that it is undesirable to change the law. Doing so would not give doctors a new clarity and certainty. Instead, they would need to consider in each particular case whether it is covered by the Bill or by existing case law. If they think it is covered by the Bill, they will need to consider the meaning of each of the requirements in the Bill and will need to recognise that clinical negligence claims might be brought that focus on whether they have met those requirements.

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.

25. Some respondents said yes. In many cases, these responses came from patients, their relatives or members of the public. The reasons given sometimes included a reference to the need to do something for patients who would otherwise be without hope. For example, one patient said:

"We must give some hope to those who we know are condemned to die."

and a doctor said the Bill:

"offers a sensible approach to improving medical treatments available and responding more individually to patients' needs especially those with rare life limiting conditions."

26. Others were not content with clause 1(3). Usually this was because of a concern that, by providing that a doctor is not negligent when acting without the support of a responsible body of medical opinion, an important protection for patients would be removed. For example, one patient said clause 1(3):

"is a fundamental failure in the Bill" which "would put patients at risk, and also do nothing to further medical innovation"

while a doctor said:

"This section would support any number of evidence-free interventions in any number of alternative or complementary medicine sectors, as well as those clinics and hospitals promising life-saving treatments and breakthroughs despite the absolute lack of trial evidence for their interventions."

27. Some respondents, such as the British Medical Association, drew a distinction between the two situations covered by clause 1(3):

- the situation envisaged in clause 1(3)(a) might well arise, where a doctor is not sure if a particular treatment would have support. In that case, the British Medical Association argued, the appropriate step is for the doctor to consult colleagues. The doctor can already do this, and there is no need to legislate.
- however, if the situation envisaged in clause 1(3)(b) arises, where a doctor thinks no responsible colleague would support the treatment, then the treatment should not be carried out, because the likelihood is that it will be either ineffective or positively harmful to the patient. It would therefore be wrong to legislate to permit a doctor to act in this circumstance.

A variant on this argument, advanced by a professor of medical law, was that the common law already provides a way of dealing with the situation where a doctor can find no colleague to support the proposed treatment:

"In the case of *Clark v MacLennan* [1983] 1 All ER 416 the court was faced with a scenario [where] a doctor [...] could find no others that might have done as he did. The judge suggested that while this would not necessarily demonstrate a breach of duty, the lack of professional support should essentially reverse the burden of proof, and it would be for the doctor to convince the court of why the conduct was reasonable rather than for the claimant to convince that it was not. Making this change would at the very least introduce safeguards for patients that are not currently included in the Bill."

Clause 1(2)

28. Queries were also raised about earlier provisions in the draft Bill, particularly clause 1(2):

"It is not negligent for a doctor …"

- Some respondents thought this reference to a doctor too wide. They queried if it is intended that a doctor should be protected by the Bill if he offers an innovative treatment in an area of which he has no specialist knowledge, or at an early stage in his career, or regardless of the setting (general practice, district general hospital, teaching hospital …). Some suggested that use of the Bill should be restricted to specialist doctors and/or to specialist centres.

- Others questioned why the reference did not go wider, to include other healthcare staff, or the multi-disciplinary team and responsible officer (who might be involved under clause 1(7)) or the Trust employing the doctor (since that would normally be responsible for meeting the costs of any successful negligence claim).

"…to depart from the existing range of accepted medical treatments for a condition"

- Some thought this formulation unhelpful, on the basis that it might be seen as implying a presumption *against* innovation, when none currently exists, either in clinical negligence law or in medical practice. (The Royal College of Surgeons of Edinburgh noted that "the Declaration of Helsinki recognises that in the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician with informed consent from the patient must be free to use unproven or new measures if in the physician's judgement that offers hope of saving life, re-establishing health or alleviating suffering.")

Others, including the General Medical Council, had questions about the meaning of the terms. For example:

- How broadly is "medical treatment" (or "innovation" in clause 1(1)) to be interpreted? One of the medical defence organisations noted that some of the queries it receives about innovation are not about *medical* treatment as such but about the use of new information technology. Sir Robert Francis QC noted that in other statutes "medical treatment" is taken to include nursing care as well.
- What does "departure" mean? In particular:
  - what would determine whether a treatment is a minor variation on existing practice or a departure?
  - would the use of medicines for purposes for which they are not licensed count as a departure from the existing range of accepted treatments? (Some respondents noted that in some areas, for example, prescribing for children, "off-label" use is an accepted practice. Others were concerned the Bill might encourage "off-label" use of drugs where it should not do so: for example Bayer argued that "any legislation should explicitly state that an unlicensed medicine should only be prescribed when no available licensed alternative will meet a patient's individual need. The legal and regulatory framework around the use of unlicensed medicines and the GMC guidance should also be explicitly referenced in the guidance accompanying any legislation.")
  - would a departure from NICE guidelines count as a departure for the purposes of the Bill?

The Motor Neurone Disease Association noted that there is no requirement in the Bill for a "departure" to involve a new or an innovative treatment.

29. In addition to the suggestions already noted above for restricting the Bill only to certain doctors, or doctors in certain centres, other ways of restricting its scope of the Bill were proposed, for example, by limiting it to terminally ill patients, or to certain conditions, or

to patients for whom all other treatments had been exhausted, or to a combination of these. A reason put forward for this was that:

"The risk of adversely impacting a non-terminal patient's quality of life is too great to apply the Medical Innovation Bill beyond those in an end of life scenario" (a legal firm, Slater & Gordon).

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 clause 1(5)(a)-(c) include treatments offered as part of research studies?

30. Some respondents, including some individual patients, were content.

31. Others were not content, generally on the basis that it is wrong to allow the subjective opinion of a single doctor to determine if an action is negligent. This view was summed up by NICE:

"the Bill contains no requirement for the doctor's analysis of the factors, or the conclusions he draws from consideration of them, to be reasonable or of an appropriate standard"

and by an individual respondent, with a background in research and medical audit, who argued that, counter to the approach taken in the Bill:

"A decision is only responsible if a responsible body of fellow practitioners would support it. […] This must be the minimum basis for responsible decision-making".

Clause 1(4)

32. In relation to clause 1(4), particular concern was expressed about the reference to "the doctor's opinion that there are plausible reasons why the proposed treatment might be effective". Some suggested introducing a more objective requirement, for example, by requiring the doctor to have "reasonable grounds", which might need to be based on research or peer review.

Clause 1(5)

33. In relation to clause 1(5), some acknowledged that clause 1(5)(a)-(d) are reasonable factors to take into account, and some welcomed the creation of a statutory checklist. Some (such as BASO) argued that it is right to keep the provisions generic, so that the Bill would be relevant in a wide range of situations.

34. However, the General Medical Council argued that clause 1(5) provides a less clear description of good practice than the Mental Capacity Act 2006 and its supporting code, and case law on obtaining consent from patients who have capacity to take their own decisions. This could introduce new areas of uncertainty for doctors. On a similar point, the British Medical Association said "There are inherent disadvantages to attempting to codify best practice in this way and it is not clear in this instance that it is

possible, desirable or necessary." Its view was that "best practice should be described in professional guidance", which can be more nuanced, and which is easier to keep up to date, than primary legislation, and which the courts could be expected to look at in considering whether a doctor has acted negligently. NICE noted that the points listed in clause 1(4)-(5) "can be considered by doctors within the existing legal framework".

35. There were also concerns that some elements of clause 1(5) set an unfeasibly high standard. For example, in relation to (a)-(b), "It is impossible for doctors trying untested treatments to know what the relative risks or benefits of an intervention might be. If doctors knew these, then the intervention would either be accepted medical practice, or not" (an individual doctor). Moreover, "the volume and speed of accumulation of medical evidence is such that it is impossible for individual practitioners to keep up to date; such has been the rationale for bodies such as NICE […] As such, the ability of individual practitioners to independently critically appraise and apply evidence, without the support of their peers, must be viewed with great caution" (another individual doctor).

36. But there were also concerns that, in the case of a terminal and profoundly disabling illness such as motor neurone disease (MND), the provisions of clause 1(5) could signal that "anything goes". The Motor Neurone Disease Association argued:

"Under 1(5)(b), (c) and (d), doctor and patient together could quite reasonably come to the conclusion that the results of current treatments will be death, at best only slightly delayed, and that there is little to be lost by trying an experimental or unproven therapy, even if its effects also culminate in the patient's death. The doctor may seek the opinion of non-expert colleagues (indeed, according to the footnote in the consultation paper, the opinion of colleagues who are not even doctors), and as already noted may proceed even when there is essentially no feasible expectation of efficacy (on the basis that the outcome would be death either way). While the clause as drafted nominally includes an obligation (1(5)(c)) on the clinician to consider the possibility of adverse effects or undesirable side effects, by definition these will often not be apparent in relatively undeveloped treatments: more phase II/III trials of potential new MND drugs have been halted because of adverse effects or serious side effects than have ever succeeded in proving a new drug to be efficacious, despite the presence in all cases of "plausible reasons why the treatment might be effective". In short, these clauses appear to create 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."

37. Others (such as Professor Rogers of Macquarie University) thought that the Bill should provide more situation-specific support for doctors or (in the case of Cancer Research UK) asked for clear definitions of what is meant by terms such as "reasonable judgement" or "reasonably be expected".

38. NHS England thought the matters listed "reasonable in the context of responsible innovation, though not of equal weighting". However, it did not think the situation envisaged by clause 1(3) is a context of responsible innovation. Moreover, "in a publicly-funded system, consideration of the use of resources has to be part of the criteria for a "responsible decision" because it affects equity for others."

39. There were also some queries about clause 1(5)(d). For example, the NHS Litigation Authority noted:

"Such opinions could, for example, be those of relatives but in the case of a patient who has capacity, the patient must have the final decision in terms of consent."

40. There were particular concerns about clause 1(5)(e), for two main reasons:

- It allows the individual doctor to decide which colleagues' opinions to take into account: "an innovating practitioner – subconsciously or intentionally – [might] seek the opinion of those who already share their enthusiasm for the innovation". A suggestion was made (by Professor Rogers) that this provision should be replaced with a requirement to consider "opinions expressed by colleagues whose opinions would be deemed appropriate by a responsible body of medical practitioners".
- There is no requirement in the consultation draft of the Bill for the colleagues to be doctors. Some wanted a clearer requirement to involve doctors with relevant expertise. On the other hand, the Academy for Healthcare Science said that it "is particularly important in an era when interventions are becoming more technological" that the doctor involve "healthcare scientists and the many other clinical professionals who are involved in the selection, planning and delivery of treatment approaches". The Academy noted in particular that "The devising, planning and assessment of a regime of radiotherapy is the explicit responsibility of Healthcare Scientists within the multi-professional team".

Research

41. Those who commented on the specific research question generally agreed that the doctor should consider research treatments as well as "standard" treatments. As one respondent said:

"Think of the sadness of discovering too late that the research demonstrates that it would have saved the patient's life."

The Medical Defence Union emphasized that the doctor should comply fully with the General Medical Council's guidance on consent, not merely with any provision in the Bill about considering research.

42. The Institute of Cancer Research, amongst others, wanted the Bill to include "an explicit acknowledgement" that "clinical trials are the most appropriate vehicle for innovation in the NHS", while GSK (the healthcare company) said:

"A provision should be added to the Bill to clarify that if a treatment is currently undergoing clinical trials it should not be considered as an "innovation" or "proposed treatment" for the purposes of the Bill as it would undermine the ability to recruit appropriate patients. For example, the Bill could state that a treatment would not be considered an "innovation" under this bill if there is already an on-going trial as listed in the UK Clinical Trial Gateway and the doctor should enrol the patient in the trial if possible."

43. There were some suggestions that the provision at clause 1(8)(b) needed redrafting, to make clearer what the Bill does, and does not, mean for research.

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?

44. Some respondents were content, or at any rate (without necessarily committing themselves to the view that legislation is needed) accepted that these provisions aim to reflect best practice.

45. Some were fundamentally not content, on the basis that clause 1(6)-(7) focuses on a process, not on whether it leads to a tenable conclusion. For example, NICE said:

"We do not consider that transparency alone is sufficient protection. It places too great an onus on the patient to object and to identify themselves deficiencies in the doctor's reasoning."

Clause 1(6)

46. Others had more detailed comments. In relation to clause 1(6), no respondent argued that the process should not be "accountable" or "transparent", though some asked how it would be decided what these terms mean in a specific case. Some argued that it is unrealistic to require the decision-making process to allow "full consideration … of all relevant matters".

Clause 1(7)

47. Some respondents thought clause 1(7) too weak. As a minimum, some suggested replacing "The factors that may be taken into account" with "The factors that will be taken into account". Others wanted one or more of the factors that followed to be made mandatory.

Clause 1(7)(a)

48. In particular, clause 1(7)(a) prompted many comments on the issue of informed consent. For example:

- some respondents emphasised that informed consent is essential, and/or argued that a "higher standard" of informed consent should be required in the case of innovative treatment than in that of normal practice, particularly as patients may be desperate and feel under pressure to consent to innovative but possibly dangerous treatments as a last resort;
- others argued that informed consent is not achievable in the situation envisaged by the Bill, where even the doctor does not know what the outcome will be;
- others were concerned that desperate patients might consent to anything.

One suggestion (from a lawyer) for dealing with the concern about informed consent was that a provision might be added to the Bill, either to the effect that "in advising the patient whether to undergo the treatment the consultant must draw the patient's

attention to and advise the patient and the patient's GP on any publications or statements of medical opinion of which he is or ought reasonably to be aware that conflicts with the advice given to the patient" or requiring the patient to be advised by a second consultant not recommended by the first".

49. Some comments relating to clause 1(7)(a) emphasised the patient empowerment agenda. Others were concerned that the Bill might raise patients' expectations and lead them to think they have a right to whatever treatment they want: this could lead to new tensions in the doctor-patient relationship, and might create pressure for new procedures for referring patients for a second opinion where the first doctor they consult does not want to carry out an innovative treatment.

Clause 1(7)(b)

50. Many respondents agreed that it is right to involve the doctor's colleagues in the decision to carry out an innovative treatment.

51. Some thought the multi-disciplinary team (MDT) well-equipped to carry out this role, and welcomed the extra suggestions made part way through the consultation process on this basis. Others had concerns or queries, for example on the basis that:

    – MDTs do not necessarily include people with appropriate qualifications. Some are already under-resourced and over-stretched, without taking on this additional role. They are not consistent throughout the NHS. Some MDTs might be risk-averse, or unduly dominated by the doctor proposing to carry out the innovative treatment. In any case MDTS are not found in all settings. There might therefore be a case for involving other bodies, such as clinical ethics committees.

    – The term MDT is not defined in the consultation draft of the Bill, so a doctor might rely on a team that is too small to have sufficient expertise, or construct a team specifically to produce the result the doctor wanted. NICE suggested that a definition might be along the lines that the MDT should include at least two doctors and two non-medical specialists who, taken together, have the range of expertise and experience necessary for making sound recommendations in relation to the care of the patient.

    – It is not clear what role the MDT would play: would it advise or authorise the doctor? Would the doctor be required merely to "take full account of" its recommendations or to "follow" them?

    – The Bill might need to include an additional requirement for the doctor to provide full documentation to the MDT.

52. Others argued that the law already allows doctors to discuss a proposal for innovative treatment with colleagues before carrying it out; so the Bill is unnecessary.

Clause 1(7)(c)

53. Comments on the reference in clause 1(7)(c) to notifying "the responsible officer (if any)" included the following:
    - merely "notifying" the responsible officer (possibly without providing full details) did not amount to a worthwhile safeguard. There should instead be a requirement to obtain the responsible officer's approval;
    - on the other hand, the responsible officer's role is currently focused on doctors' revalidation, and would need to change significantly if the responsible officer is to take on a role relating to innovation. It might not be practical to do so, since the responsible officer might not have the specialist knowledge to form a view on the proposed innovation and might be responsible officer for a large number of doctors;
    - clarification is needed of who will fulfil the responsible officer role in the private sector or for self-employed doctors.

Other points on clause 1(7)

54. It was suggested that clause 1(7) might also include a reference to:
    - the policy of the doctor's employers on the procedure to be adopted when proposing innovative treatments (NHS Litigation Authority);
    - relevant advisory bodies in the local governance structure, such as the Medicines Management Committee (Royal College of Psychiatrists);
    - a declaration by the innovating doctor of "any links they have with third parties such as pharmaceutical companies" (Royal College of Surgeons of Edinburgh).

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

55. Most of those who responded to this question suggested communications with doctors should be through their professional bodies or defence organisations.

56. Some emphasised that although those bodies might serve as conduits for information, it was for Government and its agencies (including NHS bodies) to take responsibility for the content of the information and any questions about it.

57. The Medical Defence Union argued that communicating the effect of the new legislation would not be straightforward.

58. A legal respondent noted that organisations would need time to prepare information for doctors on the effect of the legislation. He therefore supported the suggestion in the consultation paper that the legislation should not come into effect at Royal Assent.

59. Some emphasised that if the Bill becomes law, it is as important to communicate its existence to patients as well as to doctors.

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

Reporting and publishing information about innovations

60. A theme that emerged repeatedly from responses was that information about innovations and their outcomes – both successful and otherwise – should be published in a form accessible both to doctors and to patients. Some thought this should be a requirement in the Bill itself; others did not specify this. Some recognised the practical challenges of creating such a resource and keeping it up to date and accessible while also preserving patient confidentiality.

61. Clinicians from Oxford University have offered to host a online repository of innovative treatments and NHS England is working with them to explore if this is feasible.

Steps in relation to the Bill

62. Steps suggested specifically in relation to the Bill included empowering patients and patient groups to use the legislation to encourage doctors to innovate.

Steps to be taken independently of the Bill

63. Many respondents suggested steps that could be taken independently of the Bill, in some cases within the existing legal framework. Some made clear that they saw these steps as of higher priority than progressing the Bill.

64. The main steps suggested included:

- continuing with initiatives that are already under way, such as NHS England's work on *Innovation, Health and Wealth*, the work of the National Institute for Health Research, the Health Research Authority's Assessment and Approval process, the Association of Medical Research Charities' report *Our vision for research in the NHS*, and the Medicines and Healthcare products Regulatory Agency's Early Access to Medicines scheme;
- specifically in relation to research, increasing the capacity and capability of the NHS to conduct research; increasing public participation in research; accelerating patient benefit from research; and using the evidence from research and innovation;
- specifically in relation to medicines, reducing the bureaucracy involved in licensing medicines; making new medicines – and off-label use of drugs for rare diseases – more affordable on the NHS; reviewing the barriers to licensing off-patent drugs for new indications.

65. There were also suggestions that the General Medical Council might work with others to raise the profile of innovation (a suggestion from the General Medical Council itself) or clarify the situation for doctors, for example by developing an appropriate consent form, or guidance in particular areas, such as end of life care (a suggestion from NICE).

66. Some healthcare companies suggested changes to the NICE appraisal process, and the provision of funding to enable the NHS to buy innovative devices in order to evaluate them where their producers did not have the resources for this.

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

Effect on doctors

67. Some thought the Bill would have an adverse effect on doctors because it would:
    - result in more clinical negligence litigation, at least in the short term, as the meaning of various terms used in the legislation is tested;
    - increase bureaucracy;
    - put the doctor-patient relationship under pressure, if the Bill raised unrealistic expectations in patients about what treatment they could receive.

Effect on patients

68. The Royal College of Surgeons thought the Bill might benefit patients by improving practice in the private sector, where decisions to try unconventional treatment are, in some rare instances, taken without adequate evidence or support from peers.

69. Others thought the Bill would have an adverse effect on patients, because it would:
    - increase the promotion of untested treatments, both by pharmaceutical companies and by bogus practitioners;
    - risk harm and suffering to patients, by exposing them to false hope and to futile and possibly damaging treatments. Vulnerable and desperate patients might be in a position where it is particularly difficult to give informed consent;
    - remove the right of redress from patients who suffer because of action that would currently count as clinical negligence but that would not do so if the Bill becomes law. Genetic Alliance UK suggested that, if the Bill went ahead, no-fault compensation should be introduced to protect patients.

Effect on innovation and research

70. Views were divided over whether the Bill would result in more innovation. Some thought it would not, because one-off experiments would not increase medical knowledge. The Academy of Medical Science, the Medical Research Council and the Wellcome Trust in their joint response argued the Bill might undermine the work of Academic Health Science Networks. Some also thought the Bill might discourage both doctors and patients from participating in research and clinical trials, which in the long run might produce more benefits than a one-off innovation.

Costs to the NHS

71. One respondent argued the Bill would neither increase nor reduce NHS costs. Others thought it would increase costs, as the NHS would meet, for example, the costs of "innovations" carried out by GPs seeking to increase their income.

No impact?

72. Some suggested that the Bill might have little impact on innovation, as it does not tackle NHS funding or commissioning or remove the possibility of professional misconduct action by the General Medical Council.

Equality analysis

73. Some respondents were concerned that patients with some characteristics, or in some parts of the country, might be more likely to access innovative treatments under the Bill than others. For example, Parkinson's UK thought it might increase the "postcode lottery", while the Patients Association said:

"It is well known that black and minority ethnic groups and others such as those with learning difficulties and mental health problems, are less likely to engage with the NHS.

In addition, many older patients do not feel able to speak up when their care is below standard. Every attempt must be made to support them in making their voices heard. Similarly, people with cognitive difficulties such as those with dementia may also need to be engaged proactively. It is also important that we avoid a postcode lottery. Many of the callers to our Helpline are people who are very vulnerable due to their age or their condition and special effort must be made to ensure that people in such circumstances are not sidelined and subject to differential treatment."

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

74. There was support for the Bill in some responses (including some that supported the Bill but with modifications or alongside other action). Where reasons for support were given, respondents generally emphasised the value of innovation as a way of finding better treatments, particularly for rare diseases or conditions where existing treatments offer little hope of success; they saw the Bill as offering patients hope and potentially saving lives. There were also references to enabling doctors to "use their clinical judgement" in a way that the current culture discourages.

75. Other responses said the Bill should not become law. Many of those not supporting the Bill made clear that they support innovation. Their reasons for not supporting the Bill tended to be one or more of the following:

i) The draft Bill is not necessary. It is based on a misunderstanding of how the current law already permits innovation while protecting the interests of both patients and doctors.

ii) The draft Bill would not benefit doctors. They would need to understand new legislation, the meaning of which is not clear. They might come under increased pressure from patients desperate to "try anything".

iii) The draft Bill would not benefit patients, because it removes safeguards that protect them from quacks and entitle them to compensation if they suffer from actions that would currently be classed as negligent.

iv) The draft Bill would not benefit research. It might encourage doctors and their patients to take short cuts, rather than to participate in clinical trials. In the case of rare diseases, it might significantly reduce the number of people capable of taking part in clinical trials. Little could be learnt from the result in one case: "the end result will be trading robust, valid and actionable clinical trial data for anecdote".

76. Other responses (for example, that from NICE) did not say explicitly if the Bill should go ahead or not, but argued that the consultation paper made only a weak case for legislation.

Responses routed through Lord Saatchi's team

77. Over 18,000 people signed the online petition created by Lord Saatchi's team.[2] The text of the petition (given in full in the box below) made clear that those responding in this way saw support for the Bill as a way "to make innovative treatments a reality for all patients", with "doctors … able to prescribe, with their [patients'] consent, safe and effective innovative treatments."

> Dear Jeremy Hunt, Department of Health,
>
> I know that you support the Medical Innovation Bill – but I'm urging you to make it law. To make innovative treatments a reality for all patients. I want boys like Harrison,[3] patients all across the UK and the millions more who will be diagnosed in the years to come to have a chance at life. 1 in 17 of us will be diagnosed with a rare disease. And 53% of all cancers diagnosed are rare. That's millions of people across the UK who want, and need their doctors, surgeons and clinicians to be able to prescribe, with their consent, safe and effective innovative treatments. I want my voice to count in this public consultation. I want the Medical Innovation Bill. You said: 'The Government should do whatever is needed to remove the barriers that prevent innovation which can save and improve lives.' Make that promise a reality.
>
> Sincerely,

78. Nearly 2,400 of those who signed the petition also made comments which were passed to DH by Lord Saatchi's team.

79. In addition, the webform created by Lord Saatchi's team logged over 2,000 comments. Most of the comments logged begin "YES I would like this Bill to become law", but a small number say "NO the Bill should not become law." In some cases, further comments were provided to explain the respondent's stance. Where those answering "NO" gave reasons, they generally argued that the current law already allows innovation with proper safeguards, or expressed concern that the Bill would be a quacks' charter.

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2 http://www.change.org/en-GB/petitions/jeremy-hunt-department-of-health-33-days-to-change-medical-history/responses/new?response=31b6abb653b6

3 Harrison was mentioned at an event organised by Lord Saatchi as a child with Duchenne Muscular Dystrophy.

80. The majority of the comments made by those who signed the petition, or who said "YES I would like this Bill to become law", referred to:

- personal experience of disease (including, in particular, cancer and Duchenne muscular dystrophy);
- the need to find cures for incurable conditions and to give hope to those affected by allowing them to try all the options, including "alternative" therapies; and/or
- a view that the Bill would improve the situation.

A small number referred in general terms to the possibility of litigation being a barrier to innovation, while some described specific examples of cases where innovation had not been pursued.

The consultation process

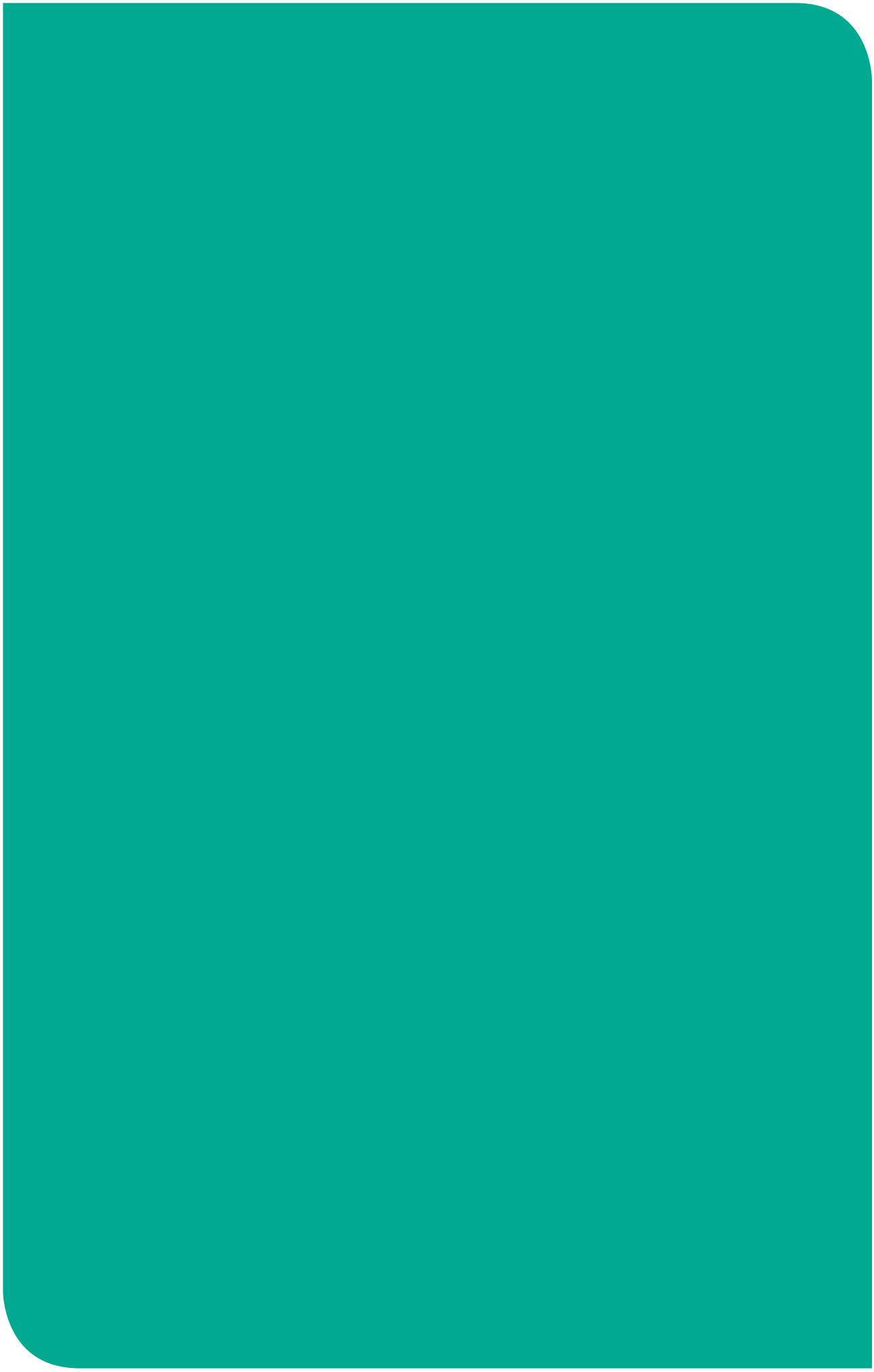
81. Three main criticisms of the consultation process were made in the responses:

i) It was misleading to include figures showing the growth in clinical negligence claims in the NHS without making clear what proportion of this, if any, was attributable to innovation.

On this point, the consultation paper did make clear that it was seeking evidence that the fear of clinical negligence litigation was deterring innovation, not arguing that this was the case without evidence.

ii) It was evident, for example at the fourth consultation event, that the drafting of the Bill under consideration had changed during the consultation process, but a new draft was not made available to all with an interest.

iii) Some of the statements made by supporters of the Bill (although not by DH) during the consultation period were misleading but received much publicity.



Chapter 3: Next Steps

82. As a result of this open consultation, Lord Saatchi decided to change his draft Bill. The new Bill is available at http://medicalinnovationbill.co.uk/the-new-bill/

83. The Government is pleased that Lord Saatchi has strengthened the oversight mechanisms in his Bill in response to criticism. However, the Government has reservations about some provisions in the Bill and intends to work with Lord Saatchi to amend the Bill as it progresses. The amendments would seek to:

- build in extra safeguards for patients to ensure that doctors must be acting responsibly under the Bill;
- ensure that the Bill does nothing to deter good and responsible innovation under the current law;
- ensure that the Bill does not place an undue bureaucratic burden on the NHS;
- build in safeguards to ensure that the Bill doesn't expose doctors to a risk of additional liabilities.

84. There is a fine balance to be struck between ensuring patient safety and putting in bureaucracy that could actually stifle innovation, which is clearly not the goal of Lord Saatchi. The Government hopes that Lord Saatchi will be open to amending the Bill in a way that achieves this. The next step is for Parliament to scrutinise the Bill in detail.

Department
of Health

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