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Access to Medical Treatments (Innovation) Bill 2015-16

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Summary

On 24 June 2015 Chris Heaton-Harris presented the *Access to Medical Treatments (Innovation) Bill* (Bill 8 2015-16) having come second in the Private Members' Bill ballot.

The Bill aims to promote access to innovative medical treatments and contains two main provisions:

- to enable the creation of a database of innovative medical treatments; and
- to set out steps which doctors can take in advance of carrying out an innovative treatment, to show that they are acting responsibly (and therefore reduce the risk that they may be judged to have acted negligently for departing from established treatments).

The Bill received its Commons Second Reading on 16 October 2015. On 3 November 2015 the Commons agreed a Money resolution, on division, in relation to the additional expenditure required to set up a new database of innovative treatments. A number of amendments were tabled at the Committee stage on 16 December 2015 but these were either withdrawn or negatived on division. The Bill is due to have its Commons Report Stage on Friday 29 January 2016.

This Commons Library briefing provides information on the main provisions of the Bill and on the development of previous legislation on medical innovation (the Bill builds upon provisions in Lord Saatchi's *Medical Innovation Bill 2014-15*).

The Department of Health has prepared Explanatory Notes for the Bill, with the consent of Chris Heaton-Harris, which provide further detail on each part of the Bill, and about the impact of the Bill on existing law.

The Bill defines innovative medical treatment as treatment that involves a departure from the existing range of accepted medical treatments for a condition. The Bill would not apply to the use of treatments in research, rather it aims to support innovation in the treatment of individual patients while preserving the existing common law safeguards for patients.

The Government supports the objectives of the Bill, which are similar to those of the *Medical Innovation Bill* introduced by Lord Saatchi in the House of Lords (in the current session, and in previous sessions). The main difference between the two Bills is the addition of a separate clause in the Chris Heaton-Harris Bill enabling the establishment of a database of innovative treatment. The Bill extends to England and Wales, apart from the provisions relating to the database, which only apply in England.

1. The Bill

1.1 Introduction

Having come second in the Private Members Bill ballot for the 2015-16 session, Chris Heaton-Harris presented a Bill to make provision for access to innovative medical treatments. The *Access to Medical Treatments (Innovation) Bill* is due to have its Second Reading on 16 October 2015.

Clause 1 of the Bill sets out that the purpose of the Bill is to:

a. promote access to innovative medical treatments by providing for the establishment of a database of innovative medical treatments; and

b. encourage doctors to carry out innovative treatment by attempting to clarify when innovation is responsible, in order to reduce the risk that they will be judged to have acted negligently for departing from established treatments.

The rationale for the proposed measures is that promoting medical innovation could lead to the development of new cures and more effective treatments.

The Bill has similar aims to the *Medical Innovation Bill 2014-15* introduced by Lord Saatchi and further background on this Bill can be found in Section 3 of this briefing. The Government has said it supports the aims of promoting innovation; in June 2015 the *Telegraph* reported that the Government Life Sciences Minister, George Freeman, said he looked forward to working with Mr Heaton-Harris to help him shape the Bill.[1] While the intentions of Lord Saatchi's Bill attracted widespread support and a number of doctors, lawyers and medical researchers backed the Bill[2], there were also many high profile opponents of the Bill.

1.2 Database of innovative medical treatment

Clause 2 specifies that the Secretary of State may make regulations enabling the Health and Social Care Information Centre (HSCIC – see Box 1) to establish a database containing information about innovative medical treatments and their outcomes.[3] For the purpose of this database the Bill defines innovative medical treatment as treatment that "involves a departure from the existing range of accepted medical treatments" for a particular condition. The Clause also provides for the HSCIC to specify what information should be recorded, and how this should be accessed.

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1 *Telegraph,* 24 June 2015

2 Information on supporters of the Medical Innovation Bill can be found on the tumblr site for the Bill.

3 The regulations would subject to the negative resolution procedure.

Box 1: Health and Social Care Information Centre (HSCIC)

The Health and Social Care Information Centre (HSCIC) is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care. It was established in April 2013 under the *Health and Social Care Act 2012*, replacing the NHS Information Centre.

HSCIC has statutory functions relating to the establishment and maintenance of information systems as well as the collection, analysis, publication and dissemination of information; and functions relating to the quality of health and adult social care information. HSCIC currently collects Hospital Episode Statistics (HES) and other health and social care data at a national level and makes this information available to support health and care services.

The Explanatory Notes to the Bill state that information about treatments will only be able to be disclosed where this is in accordance with the law, in particular the common law duty of confidentiality and the *Data Protection Act 1998*.[4]

The Explanatory Notes provide further background on this section of the Bill:

> "The Bill… provides a regulation-making power for the establishment of a database of innovative medical treatments by the Health and Social Care Information Centre ("the HSCIC"). It is intended that information relating to innovative medical treatments, and the outcomes of those treatments, carried out by doctors in England will be passed to the HSCIC through the use of coding in patient notes. The detailed design of the database would be consulted upon with professional bodies and organisations. It is envisaged that the patient's right to privacy would be respected and the data securely managed. The database would be searchable by other doctors to use as a knowledge base of innovation. Again it is intended that the exact detail of how the access to the database would be granted would be consulted upon with professional bodies and organisations. The database would support the Government's emphasis on increased transparency and sharing of innovation and learning."[5]

An amendment to provide for a data registry of medical innovations was introduced during the Lords stages of Lord Saatchi's *Medical Innovation Bill 2014-15*, which had similar aims to the *Access to Medical Treatments (Innovation) Bill* (see section 3).

1.3 Responsible innovation

Clause 3 sets out the steps which a doctor will need to take in order to show that he or she has acted responsibly under the Bill. They are intended to reflect the steps under the current common law which a responsible doctor could be expected to take when innovating.

Under the current law a doctor will not be negligent when departing from the existing range of medical treatments if he can show that his decision is supported by a responsible body of medical opinion. This is called the "Bolam" test [see Box 2].

4 DH, *Explanatory Notes*, 12 October 2015
5 *Ibid.*

Box 2: The Bolam test

The key precedent for judging whether a doctor has acted negligently was set out in a court judgement made in 1957, and known as the Bolam test.[6] This states that a doctor "is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical opinion". The Bolam test has been modified by subsequent judgements; notably in the case of *Bolitho v. City and Hackney Health Authority*,[7] where the House of Lords held that not only must a responsible body of medical opinion agree that the treatment was appropriate, but also that the treatment must have a *logical* basis.

The Bill seeks to offer clarity for doctors in advance of offering innovative treatment about the steps that they need to take to demonstrate that the decision to innovate was taken responsibly, rather than requiring doctors to wait for this to be determined by a court at a later date if their actions are challenged.[8]

Clause 3 also requires that:

- the views obtained by the innovating doctor in respect of the proposed treatment must be from "appropriately qualified doctors", with appropriate expertise and experience in dealing with patients with the condition in question;
- the decision-making process must include obtaining any consents required by law; the Explanatory Notes state that the Bill does not affect the legal requirement for a doctor to obtain a patient's informed consent to any treatment proposed;
- the decision-making process must include consideration of opinions or requests expressed by the patient or on behalf of the patient (for example, by family members in the case of a patient who is unable to communicate his or her own opinions);
- the decision-making process must include a risk-benefit analysis including comparison of the innovative medical treatment with the standard treatment for the condition, and with no treatment at all; and
- the doctor must take any other steps necessary to ensure that decisions to innovate are accountable and transparent.

The Explanatory Notes to the Bill state that **clause 4** expressly preserves the common law Bolam test [see Box 2, above], so that a doctor who chooses to innovate in reliance on that rather than on clause 3 of the Bill is able to do so. It also notes that clause 4:

- confirms that the availability of the Bolam test is not limited by clause 3; and
- provides that compliance with clause 3 will not protect a doctor from liability in negligence if the way in which the medical treatment was actually provided was negligent.[9]

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6 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582]

7 The *Times* Law Report, 27 November 1997 p.41

8 This was also the aim of Lord Saatchi's *Medical Innovation Bill* and the wording of clause 3(1) is broadly the same as Clause 1 of the *Medical Innovation Bill 2014-15*.

9 DH, *Explanatory Notes*, 12 October 2015

1.4 Interpretation, extent and financial implications

Clause 5 confirms that nothing in the Bill applies to treatment carried out for the purposes of medical research (such as in the context of a clinical trial). The Explanatory Notes explain that this is because "research is subject to its own separate regulatory regime". Clause 5 also confirms that the Bill does not apply to treatment carried out "solely for cosmetic purposes". The Explanatory Notes state that this reflects the strong view, expressed in debates in the House of Lords on the *Medical Innovation Bill,* in favour of limiting the clinical negligence provisions to medical treatments that offer clinical benefits for patients.[10]

Clause 6 sets out that the Bill extends to England and Wales, apart from Clause 2, which provides for a database of innovative treatments, which would only apply in relation to innovative medical treatments carried out by doctors in England (see Box 4 on page 10 of this briefing for further background on the extent of medical innovation legislation).

The Explanatory Notes say that an impact assessment will be published in advance of Committee stage. They also confirm that a money resolution in the House of Commons will be required to authorise expenditure resulting from the establishment and operation of the database of innovative treatments.[11]

10 *Ibid.*
11 *Ibid.*

2. Debate on the Bill

During the Second Reading debate on 16 October 2015 Chris Heaton-Harris highlighted that innovation in the NHS is already widespread. He focussed on the provisions within his Bill to establish a database to capture this innovation and help others to learn from it.[12]

Dr Sarah Wollaston noted the broad range of medical royal colleges, charities and patient groups that opposed the Bill, on the basis it is unnecessary and may adversely impact on patients and medical research. The Shadow Health Secretary Heidi Alexander set out that while the Bill had been presented with the best of intentions the Opposition had serious concerns about unintended consequences, which could undermine safeguards on patient safety. She said that as a result Labour would vote against Second Reading.[13]

The Minister responding, the Life Sciences Minister George Freeman confirmed that the Government support the intentions behind the Bill. He said that while stakeholders concerns had to be addressed, the view of medical director of the NHS is that the Bill is safe for patients; and in the opinion of parliamentary counsel the Bill would not undermine the current law on clinical negligence:

> It has been asked in the House this morning and in the run-up to the debate whether the Bill is safe for patients. I again repeat that the Bill does not remove any of the current safeguards on patient safety. The test of responsibility in the Bill is intended to be the nearest possible equivalent to the Bolam test [see Box 2]. It simply seeks to provide clarity via a mechanism by which doctors can be sure they are complying with that test.[14]

The Minister also noted that while the medical royal colleges had concerns about the Bill there was more support, from some of these bodies, for the creation of a new database of innovative treatments.

The Bill received its Second Reading on division (Ayes 32, Noes 19). A Money Resolution was passed on 3 November 2015 (Ayes281, Noes 227), in relation to the additional expenditure required to set up a new database of innovative treatments. During the debate on the Money Resolution the Minister stated that the HSCIC had provided an indicative costing of between £5 million and £15 million for developing the database of innovative medicines that the Bill anticipates.[15] The SNP Health Spokesperson, Dr Philippa Whitford, also spoke against the Bill during this debate.[16]

Labour Members tabled a number of amendments at the Committee stage on 16 December 2015 but these were either withdrawn or negatived on division. The Labour shadow health minister, Justin Madders, introduced some amendments that would limit the purpose of the Bill to the establishment of a database of innovative treatments

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12 HC Deb 16 October 2015 c564
13 *Ibid.* c569
14 *Ibid.* c609
15 HC Deb 3 November 2015 c922
16 *Ibid.* c929-30

(Amendments 1 and 2) and to ensure that the information recorded is as comprehensive as possible (Amendments 3 and 4). Justin Madders withdrew Amendments 3 and 4, accepting Chris Heaton-Harris' offer to work on the issue before Report Stage. However, the Committee divided on Amendments 1 and 2. Justin Madders noted he was pressing these amendments to division as the widespread concern about the Bill from medical royal colleges and others meant there was a need to start again (the amendments were negatived: Ayes 5; Noes 9).[17]

Mr Madders commented that clause 2, that would provide for a new database, was unnecessary because the Secretary of State already has broad powers to instruct the HSCIC to establish information systems.[18] However he introduced two amendments that would amend this clause, to ensure certain bodies, such as the GMC, BMA, medical royal colleges and organisation involved in medical research, were consulted about the establishment of the proposed database. The Minister responded that the Government did not support the amendment as the list in the Opposition amendments was not exhaustive. He said he was happy to discuss other mechanisms to ensure that the parities listed in the amendment would be properly informed. Justin Madders confirmed he was also happy to discuss this with the Minister and he withdrew the amendments.

Nick Thomas-Symonds, introduced a number of amendments to promote the use of off-patent drugs (he had introduced a Private Members Bill with this aim, which failed to make it past Second Reading).[19] His amendments would support applications for licences for off-patent drugs for new indications; he said these were "in effect my Bill coming in via amendment to this Bill".[20] The Minister noted that while the Government did not support the amendments they supported their objective. The Minister said he was happy to ask the Government's Accelerated Access Review (AAR) to look specifically at the question of how to promote the use of off-label medicines (see section 5 of this briefing for more information on the AAR). He also offered to work with Mr Thomas-Symonds and Mr Heaton-Harris before Report Stage to see if this objective could be tackled through the Bill. Nick Thomas-Symonds accepted these assurances and withdrew his amendments.

George Freeman noted that the database provisions are the part of the Bill that the Government most strongly support. He also noted how proposals for a database had evolved:

> The database is not envisaged as it was in the predecessor Bill—if I may call it that—as a registry for recording ad hoc innovations by clinicians, but as a fundamental database to give all clinicians access to information on innovative medicines, including off-label uses of medicines and medicines that are either unlicensed but in use, as in the early access to medicines scheme, or in clinical trials, in which a patient might be eligible to enrol. (…)

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17 PBC Deb 16 December 2015 c14
18 Under s.254 of the *Health and Social Care Act 2012*
19 Further background on the Off-patent Drugs Bill can be found in the Commons Library briefing on this Bill (CPB07365, 5 November 2015).
20 PBC Deb 16 December 2015 c15

> I am pleased that my hon. Friend the Member for Daventry proposed the database for recording such treatments and for getting information on them out to clinicians. The measure is important in the promotion of innovation. Crucially, the measure would give doctors the ability to search the database for innovations, so the position is very different from that under the Bill introduced in the House of Lords last year, which proposed a database as a registry on which innovative doctors could log what they had done. The database proposed in this Bill is completely different, which is why I strongly support it.[21]

The Minister also outlined the Government's view of some of the benefits of the proposed database of innovative treatments:

> The database could result in better care and health outcomes for patients and a faster uptake of new treatments, and it could support our work to make Britain a world-leading centre for innovative medicines. The pace of progress in genomics and informatics is profoundly changing the way in which new drugs are developed, but our databases and systems information have not kept up, so that is among the things that are being considered under the accelerated access review. While the Secretary of State might already have the legal power to create a database, the Bill helpfully sets out that provision may be made to give instructions to HSCIC to create a specific database, which I would welcome. If the Bill does not, for whatever reason, reach the statute book, I would happily proceed towards establishing such a database, but it would be helpful if the provision were set out clearly in legislation.[22]

Chris Heaton-Harris accepted that clauses 3 and 4 of the Bill were the most controversial. These clauses seek to offer clarity for doctors by setting out the steps they need to take to demonstrate that a decision to innovate was taken responsibly, rather than requiring doctors to wait for this to be determined by a court at a later date if their actions are challenged. Mr Heaton-Harris stated that if they could not get these parts of the Bill right he would table amendments to delete them. He also said he looked forward to working with anybody to get these and the other provisions of the Bill "into the right place."[23]

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21 *Ibid.* c22
22 *Ibid.* c22
23 *Ibid.* c12 and c24

3. The Medical Innovation Bill [HL] introduced by Lord Saatchi

The *Medical Innovation Bill* was first introduced in the 2012-13 session by Lord Saatchi.[24] Lord Saatchi proposed the Bill after his wife, the writer Josephine Hart, died from a rare ovarian cancer in 2011. Lord Saatchi introduced the Bill again in the 2013-14 session[25], and Michael Ellis introduced a similar Bill, the *Medical Innovation (No. 2) Bill* in the Commons in the same session.

This legislation was subject to a Department of Health consultation in February 2014 following a commitment to do this by the Secretary of State for Health in November 2013 (see Box 3). Lord Saatchi introduced a new version of the Bill in the 2014-15 session, on 5 June 2014, taking account of some of the consultation responses. The 2014-15 Bill completed its Lords stages before having its First reading in the House of Commons on 26 January 2015. After the Bill failed to progress to Second Reading in the Commons Lord Saatchi introduced the Bill again at the start of the current session.[26]

Like the Bill introduced by Chris Heaton-Harris, the various versions of the *Medical Innovation Bill* introduced by Lord Saatchi have all aimed to encourage doctors to use innovative treatments and to provide clarification on the legal situation surrounding the use of new treatments. The Bill's proponents argue that one barrier to doctors using innovative treatments is their concern that they may be liable for claims of clinical negligence for doing so. Lord Saatchi has explained that the aim of his legislation is to "bring forward" the Bolam test (see Box 2, above) to the point of treatment, so that doctors can be reassured in advance that they are innovating in a manner that the law will regard and uphold as responsible:

> "[Doctors] would not have to wait or speculate about the possibility of litigation or disciplinary proceedings before finding out whether their action is considered reasonable. By giving certainty we help doctors to innovate with confidence. We help the thousands of patients who wish to benefit from innovative treatment and do not wish the doctor to be scared off or institutionally discouraged by the mere possibility of later litigation."[27]

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24 *Medical Innovation Bill 2012-13*
25 *Medical Innovation Bill 2013-14*
26 Lord Saatchi reintroduced the *Medical Innovation Bill 2015-16* in the House of Lords on Monday 8 June 2015.
27 HL Committee Stage Deb, 24 Oct 2014 c863

Box 3: Responses to the Department of Health consultation

In February 2014 the Department for Health asked for views on whether clarifying the law would encourage doctors to develop innovative treatments in a responsible way (see: *Legislation to encourage medical innovation: A consultation*).

The consultation responses received raised a number of important questions about barriers to innovation (see: *Report on the consultation on the Medical Innovation Bill: summary of responses and next steps*, 30 July 2014).

In particular, the responses highlighted a lack of agreement about the extent to which litigation, or a fear of this, was in fact a major barrier to innovation; many respondents raised other issues that they considered to be more important, such as lack of funding for new treatments, bureaucratic barriers, or some doctors' lack of awareness about their existing discretion to innovate.

Supporters of legislative change generally emphasised the value of innovation as a way of finding better treatments, particularly for rare diseases and life limiting conditions where existing treatments offer little chance 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.

Many of those opposed to legislative change made it clear that they supported innovation but that the proposed legislation was unnecessary or counter-productive, and would not benefit doctors, patients or research. Others highlighted a risk of limiting a patient's right to compensation if harmed as the result of an innovative treatment that would be considered negligent under current law.

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 responses noted the practical challenges of creating such a resource and keeping it up to date and accessible while also preserving patient confidentiality.

The original consultation document (*Legislation to encourage medical innovation: A consultation*, February 2014) also provides information about the current precedents and case law relating to medical negligence.

Lord Saatchi introduced a number of additional safeguards in the *Medical Innovation Bill 2014-15,* introduced in June 2014, based on early responses to the consultation. A package of amendments, devised with advice from Sir Bruce Keogh, the medical director of NHS England, was also accepted during the Lords Committee stage on 24 October 2014. These changes sought to provide greater protection for patients against negligent treatment, and ensure that doctors act responsibly when innovating in accordance with the Bill. The "Keogh amendments" included a requirement that, for the purpose of innovating under the Bill, a doctor must "obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment".[28] These amendments also required a doctor "to take full account of those views

[28] This replaced the requirement to consult "with appropriately qualified colleagues" under the 2014-15 Bill as introduced in June 2014. A further "Keogh amendment" specified that an "appropriately qualified doctor" must have "appropriate expertise and experience in dealing with patients with the condition in question".

in a way that a responsible doctor would be expected to do". Lord Saatchi, who introduced the Keogh amendments said the changes provided "a critical safeguard in ensuring that there is expert peer review of the doctor's proposal and that the doctor acts responsibly in taking account of that view."[29]

A number of further amendments were made to the 2014-15 Bill during the Lords Third Reading and Report Stages. One of the key changes at Report was an amendment to introduce a requirement to record the results of innovative treatment, including information on both positive and negative outcomes.[30] This amendment was supported by the Royal College of Physicians[31] and a number of Peers during the debates on the 2014-15 *Medical Innovation Bill*.[32] Whilst the Government agreed with the spirit of this amendment, it resisted it on the basis that it raised a number of complex issues in relation to the establishment and enforcement of a data registry which would need to be resolved through further dialogue with the medical community.[33]

The *Report on the consultation on the Medical Innovation Bill: summary of responses and next steps* (July 2014) noted that clinicians from Oxford University had offered to host an online repository of innovative treatments and that NHS England is working with them to explore if this is feasible.

The final version of the 2014-15 Bill, as brought from the Lords, together with explanatory notes, is available here. The provisions relating to responsible innovation in the final version of the *Medical Innovation Bill 2014-15*, as amended, are broadly the same as those in the *Medical Innovation Bill 2015-16* and the *Access to Medical Treatment (Innovation) Bill 2015-16*.

Box 4: Does medical innovation legislation extend to Wales?

Although health policy is largely devolved the UK Government's position on the *Medical Innovation Bill 2014-15* and the *Access to Medical Treatments (Innovation) Bill 2015-16* is that it would apply to Wales as well as England. It held that the provisions in the Bill (apart from those providing for a database of medical innovation) relate to clinical negligence and the common law of tort, which are non-devolved matters, as opposed to subjects under the "health and health services" heading, which are devolved under Schedule 7 of the G*overnment of Wales Act*. However, the Welsh Government took the view that the *Medical Innovation Bill's* provisions did relate to the latter, and, noting its "grave concerns" about Lord Saatchi's Bill, requested that the provisions within this Bill should not apply to Wales (see: Written Statement from Mark Drakeford, Minister for Health and Social Services, *Response from the UK Government to the Legislative Consent Motion vote on the Medical Innovation Bill*, 31 March 2015)

29 HL Committee Stage Deb, 24 Oct 2014 c863
30 Amendment 5, introduced by Lord Hunt of King's Heath, HL Deb 12 December 2014, c2059.
31 In April 2014 the Royal College of Physicians briefing on the Medical Innovation Bill called for a database for the mandatory reporting of innovative treatments.
32 Links to other Bill documents and the text of debates at each stage of the 2014-15 Bill can be found here.
33 DH, *Explanatory Notes* to the A*ccess to Medical Treatments (Innovation) Bill 2015-16*, 12 October 2015

4. Reaction to the Bill and Lord Saatchi's Medical Innovation Bill

The intentions of Chris Heaton-Harris' Bill, and Lord Saatchi's *Medical Innovation Bill,* have attracted widespread support, not least from the Health Secretary, Jeremy Hunt and there are a number of senior doctors, lawyers and medical researchers who back legislation to encourage medical innovation. However, there were also many high profile opponents of the legislation. The Association of Medical Research Charities' (AMRC) briefing on Lord Saatchi's Bill in February 2015 raised concerns about the rationale behind the Bill, and about the potential unintended negative consequences of the Bill for patients and for medical innovation. However, the AMRC welcomed the inclusion of the amendment to introduce a requirement to record the results of innovative treatment.[34] The Academy of Medical Royal Colleges and the BMA also said they were unconvinced that Lord Saatchi's Bill would achieve its worthwhile intentions and noted the risk of unintended consequences.[35]

On 9 December 2014 the chair of the Health Select Committee, Dr Sarah Wollaston, introduced an Adjournment debate on patient safety and medical innovation. She used the debate to outline her opposition to Lord Saatchi's *Medical Innovation Bill*, stating that it is "fundamentally flawed in its premise, it is unnecessary, it removes essential protections for patients, and it increases the risks of their exposure to maverick doctors. I believe it will undermine not only patient safety but medical innovation and so will have precisely the opposite effect to that intended."[36] Dr Wollaston listed the royal colleges, professional bodies, patient groups, research organisations and charities that were opposed to the legislation. She also referred to concerns raised by patient safety expert Sir Robert Francis QC, and a letter from 100 cancer specialists who opposed the Bill, which was published in *The Times* on 13 November 2014.[37]

The Life Sciences Minister, George Freeman, responded that the Government was supportive of the Bill's aims but that it was important that the Bill should also have the "very strong support of our most senior lawyers and medics". The Minister closed his remarks by reading out some supportive comments the Bill has received from the Chief Medical Officer, Dame Sally Davies, the Medical Director of NHS England, Sir Bruce Keogh, and the President of the Royal Society of Medicine, Sir Michael Rawlins. The Minister also noted a letter to *The*

34 Association of Medical Research Charities joint briefing (27 February 2015)
35 Academy of Medical Royal colleges statement (January 2015) and the BMA briefing for Peers ahead of Third Reading in the Lords (January 2015)
36 HC Deb, 9 December 2014, c841
37 *The Times,* 13 November 2014

Telegraph in June 2014 from 40 leading medical professionals who supported the Bill.[38]

There has been a great deal of social media comment, both for and against the legislation. There is a tumblr site supporting both the Saatchi and Heaton-Harris Bills and a twitter account (although the most recent updates are from March 2015). There is also a "Stop the Saatchi Bill" website. Press coverage has also been mixed although the *Telegraph* has generally been the most supportive of the Saatchi Bill.

In advance of the Second Reading of the *Access to Medical Treatment (Innovation) Bill* on 16 October the Association of Medical Research Charities, the Medical Research Council and the Royal College of Surgeons issued briefings confirming their concerns about the Bill.[39]

38 HC Deb, 9 December 2014, c853-4

39 Royal College of Surgeons (England), Medical Research Council and AMRC briefing on the Access to Medical Treatments (Innovation) Bill, 16 October 2015

5. Medical innovation and the Accelerated Access Review

In an article about the *Access to Medical Treatments (Innovation) Bill* in the *Telegraph*[40], the Life Sciences Minister George Freeman, linked the private members' legislation to the Government's Accelerated Access Review:

> "The Medical Innovation Bill highlighted some of the important issues and obstacles to the adoption of innovation in the NHS. The growing pressure from patients and medical charities for faster access to innovation, and the potential of the NHS as a world beating research 'engine' in 21st century life and health science creates an opportunity for the UK to deliver benefits for patients, NHS and economy.
>
> This is the aim of my Accelerated Access Review of NHS adoption of medical innovation. I look forward to working with Chris Heaton-Harris to help him shape a Bill to help unlock this exciting opportunity."[41]

George Freeman announced an external review of the development, assessment and adoption of innovative medicines and medical technologies in November 2014.[42] What is now known as the Accelerated Access Review (AAR) is expected to make recommendations to Government by the end of this year, on speeding up access for NHS patients to cost-effective, innovative medicines, diagnostics and medical technologies. It will focus on new types of products such as medicines based on a stratified approach, new diagnostics, and digital health technologies.[43]

In March 2015 the AAR announced the appointment of a Chair of the Review, Sir Hugh Taylor, the Head of the Advisory board, Professor Sir John Bell, and its Terms of Reference. The AAR has also set out its plans to engage with patients, charities, researchers and think tanks, industry, the NHS and government and regulatory organisations to develop its recommendations.

In June 2015 the AAR set out the main themes and questions it will be looking at. These are:

- establishing need, priorities and principles for innovation – how can we find a transparent way for innovators to make sure that innovation is based on patient need, and that industry, the NHS, research charities and academia collaborate to understand and respond to patient need?
- new development pathways – how can we make sure that the existing safety and efficacy process is more efficient and simple, while maintaining safeguards for patients, and that

40 *Telegraph*, 24 June 2015
41 *Ibid.*
42 House of Commons Written Statement, Innovative medicines and med-tech review, 20 November 2014
43 Gov.uk website on Accelerated Access Review

there is a clear, and quicker way to have access to particularly innovative products?

- affordable national funding models to drive innovation – how can we integrate and speed up national reimbursement processes, and fund clinically and cost-effective innovation across the pathway?
- local adoption and diffusion – how can we speed up how clinically and cost effective innovative products are commissioned by the local NHS, and get to patients?

The AAR will also include a review of the first year of the Early Access to Medicines Scheme (EAMS). The EAMS aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. The Government launched the EAMS on 14 March 2014 and seven "Promising Innovative Medicine" (PIM) designations, and the first early access Scientific Opinion, were awarded in the first year of the EAMS. More Information about the scheme is provided on the MHRA website.

On 18 June 2015 the *Independent* published a letter from the Chair of the BMA and the Presidents of a number of the medical Royal Colleges stating that the AAR strengthened their view that Lord Saatchi's Medical Innovation Bill was not necessary:

> Supported by medical organisations, the Innovative Medicines and Medical Technology Review, chaired by Sir Hugh Taylor, has just started its work investigating how innovation can be promoted in the NHS. It is therefore not necessary for the Bill to progress at this time. Medical organisations do not believe the Bill is necessary and this view is strengthened with the work of the Review.[44]

The AAR published an initial report in October 2015 and is expected to produce a final report and recommendations in April 2016.[45]

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44 Letter to the Independent, 18 June 2015

45 Gov.uk website, press release on AAR progress, 24 September 2015

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