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**HOUSE OF COMMONS  
OFFICIAL REPORT**

**PARLIAMENTARY  
DEBATES**

**(HANSARD)**

**Friday 16 October 2015**



# House of Commons

Friday 16 October 2015

The House met at half-past Nine o'clock

## PRAYERS

[MR SPEAKER *in the Chair*]

**Mr David Nuttall** (Bury North) (Con): I beg to move, That the House sit in private.

*Question put forthwith (Standing Order No. 163).*

*The House divided: Ayes 0, Noes 42.*

**Division No. 78]**

**[9.34 am**

## AYES

**Tellers for the Ayes:**  
**Mr David Nuttall and**  
**Philip Davies**

## NOES

Alexander, Heidi  
Bingham, Andrew  
Boles, Nick  
Bottomley, Sir Peter  
Brazier, Mr Julian  
Buck, Ms Karen  
Cairns, Alun  
Campbell, rh Mr Alan  
Carmichael, rh Mr Alistair  
Chope, Mr Christopher  
Coffey, Dr Thérèse  
Coyle, Neil  
Ellis, Michael  
Eustice, George  
Fitzpatrick, Jim  
Freeman, George  
Garnier, Mark  
Gauke, Mr David  
Goodwill, Mr Robert  
Hancock, rh Matthew  
Hayes, rh Mr John  
Heaton-Harris, Chris  
Hollingbery, George

Hollobone, Mr Philip  
Hopkins, Kris  
James, Margot  
Jenkin, Mr Bernard  
Jones, Mr Marcus  
Leadsom, Andrea  
Leigh, Sir Edward  
Morton, Wendy  
Pennycook, Matthew  
Penrose, John  
Raab, Mr Dominic  
Shapps, rh Grant  
Skinner, Mr Dennis  
Smith, Henry  
Smith, Julian  
Swire, rh Mr Hugo  
Timpson, Edward  
Tomlinson, Justin  
Wollaston, Dr Sarah

**Tellers for the Noes:**  
**Mr Steve Baker and**  
**Grahame M. Morris**

*Question accordingly negatived.*

# Access to Medical Treatments (Innovation) Bill

*Second Reading*

9.48 am

**Chris Heaton-Harris** (Daventry) (Con): I beg to move, That the Bill be now read a Second time.

Not a day goes by without those practising medicine in our national health service innovating. Talk to any doctor, and especially any surgeon—in fact any registered medical practitioner—and they will show how they have been innovative and, in being innovative, how they have helped those they are trying to treat. The levels of innovation are, without doubt, inspiring.

Let me give an example to demonstrate what I mean. An eminent surgeon was telling me only the other day of how he had helped a patient who came to him with a particular stomach tumour. At the time of surgery, he found this tumour to be so large that if he had continued with his original plan of removing it, it would probably have killed the patient. This surgeon had just a few nights before read about a drug called Glivec. Glivec creates a mutation called C-KIT, common in chronic leukaemia, where it is a succeeding treatment. Reports appeared indicating that the type of tumour this patient had carried had the same sort of mutation, so rather than trying to remove the tumour, a bypass operation was performed to overcome the obstruction and allow the patient to take the drug.

When the surgeon put his patient on this drug, the tablets were tolerated. The tumour disappeared. Years later that patient occasionally visits his surgeon to say thank you for being innovative and saving his life. In fact, as that surgeon will confirm, there is only one thing wrong with what happened that day. There was no way of recording the innovation on a database that could share it with other surgeons preparing for a similar operation and show how it had worked.

**Mr David Nuttall** (Bury North) (Con): Will my hon. Friend confirm that the doctor in that particular case would have had to obtain his patient's consent before proceeding with that innovative treatment?

**Chris Heaton-Harris:** I believe that the decision was taken while the patient was unconscious, but there would then have been a conversation, absolutely, because the doctor would have acted responsibly, as would any surgeon.

This was a life-saving decision, but there was no simple, quick way to tell anyone about it and, in so doing, perhaps save someone else's life. Earlier this year, when we in this place were getting excited and building up to some sort of election campaign, the House of Lords was passing Lord Saatchi's Medical Innovation Bill. It passed through all its stages in the other place and, as with many Bills, ideas were refined and concepts were introduced in Committee, on Report and on Third Reading. One of the new ideas that was introduced into the Bill is the central idea that I have plagiarised for my Bill—namely, the introduction of a database for innovative treatments conducted by registered medical practitioners.

**Dr Sarah Wollaston** (Totnes) (Con): Would my hon. Friend accept that such a database could be set up anyway, without this Bill, and that what is really needed if we are to record medical innovations is adequate funding? This does not require legislation.

**Chris Heaton-Harris:** I shall come to that point in a moment.

When this idea was introduced during the passage of Lord Saatchi's Bill, it was not a novel one. Several of the royal medical colleges, among others, had already called for such a database. The Academy of Royal Medical Colleges has recently stated that it believes that there should be

"an explicit requirement for the results of an innovation to be properly recorded with the outcomes made available to clinical colleagues for scrutiny and learning...The Academy believes that this is an essential requirement.

The Association of Medical Research Charities has said of data collection:

"This is a key aspect of innovation since new interventions require an evidence base to demonstrate safety and efficacy and to ensure effective uptake in practice."

**Sir Edward Leigh** (Gainsborough) (Con): I am not opposed to my hon. Friend's Bill, which he is presenting in a very effective way, but I want to ask him a question about scrutiny. Might not a bureaucratic procedure that required medical practitioners to put innovations on to a database prevent some of those innovations from being carried out in the first place because people would fear being called to account? Might that not hold people back?

**Chris Heaton-Harris:** I will continue, if my hon. Friend will allow me, because in the depths of my speech I shall come to that point and go into detail about how this will work. I am simply proposing to confer on the Secretary of State the power to establish this process, and I hope to be able to give my hon. Friend a detailed answer to his question in due course.

The Royal College of Surgeons has stated:

"The value of innovation is severely diminished if we cannot learn from it. Registration of the results of an innovative treatment, whether positive or negative, ensures that clinicians can consider the data to learn from mistakes or spread instances of good practice."

**Dr Wollaston:** My hon. Friend has quoted a number of organisations. Does he accept that all those organisations oppose the Bill? He needs to make that explicit to the House. It is not fair to quote the Royal College of Surgeons, for example, without making it clear that it has explicitly opposed this Bill.

**Chris Heaton-Harris:** I would like to think I am making the point that although we all recognise that we need to encourage innovation in the NHS, and there is tons of it going on, it is not captured in a way that is easily spread throughout the NHS. All the royal colleges I am citing, which do not like parts of this Bill, do accept the concept of spreading innovation, which is something I am trying to do through this Bill.

The Royal College of Psychiatrists has said that

"a register that is available to other doctors would allow sharing of knowledge about a potential innovation and this would be beneficial."

The Royal College of Physicians add to the list, by stating:

"Innovation relies on a culture of knowledge sharing and a collaborative environment that stimulates ongoing improvement."

The concept of innovation being spread is welcome throughout the medical community, and I hope to capture it in this Bill. A way of encouraging and recording innovation, and spreading knowledge about it throughout medicine, is widely recognised by most of the royal colleges as being a solidly good thing.

That is also recognised by individual doctors, patients and families. It seems that most people know and understand that there is a need for a culture change in knowledge-sharing and the reporting of success and failure. In researching for my Bill, I was told a story by a dad named Alex Smith, and it is as follows:

"Four years ago, my wife Donna and I were told by a paediatrician to take our son Harrison, who had been diagnosed with Duchenne Muscular Dystrophy, home, love him, give him a good life, there's nothing we can do, he's going to die.

How is it possible that our specialist doctors and GPs were, AND STILL to this day are, not willing to try something to help save our son's life?...every day something we all take for granted as simple as opening a jar is taken away from him, in the last month alone his ability to get off the floor unaided has almost left him and one day in the not-too-distant future his ability to breathe and his heart to beat will be taken away and we will lose him, way, way too soon."

Mr Smith believes:

"With a robust framework to allow our doctors to innovate safely and responsibly and share that data, the chance to save this generation could become a reality."

It therefore should come as no surprise that an idea that has been called for by so many worthy and excellent minds, including people such as Alex, Donna and Harrison, who are facing such horrendously difficult times, should be taken up by a legislator, especially given that for decades this simply has not happened.

**Wendy Morton** (Aldridge-Brownhills) (Con): I am no clinician, but I am a patient, like many of us here. In today's world, where we so often go on the internet to search for solutions, would it not make sense that when clinicians and the medical profession are seeking innovation, we do all we can not only to encourage them, but to share it, so that others in the medical profession have access to that information? That must, however, be done safely and in the correct manner.

**Chris Heaton-Harris:** I completely agree with my hon. Friend. The only surprise is that such a database of innovation does not already exist. Like generations of previous politicians, I therefore now rise to claim a fantastic idea, which so many cleverer minds than mine have conceived, as my own. Thus, the first half of my Bill seeks to confer a power on the Secretary of State for Health to create a database of medically innovative treatments. I strongly believe that the creation of such a database will help to share ideas and spread good practice.

**Heidi Alexander** (Lewisham East) (Lab): I asked the House of Commons Library whether the Secretary of State has this power already, and it suggested to me that section 254 of the Health and Social Care Act 2012 does give the Secretary of State the power to direct the Health and Social Care Information Centre to establish such a database. Does the hon. Gentleman accept that?

**Chris Heaton-Harris:** I am not sure I do. I would like to think that this Bill completely clarifies how this database can be set up and builds a foundation on

which the Secretary of State can do such a thing. My Bill does not build this database; all it does is confer on the Secretary of State the power, which the hon. Lady talks about, to build such a database. If the Secretary of State for Health chose to use the power, it would only be after detailed consultation. However, as we would all expect, when given the opportunity to take a private Member's Bill through into law, any Member of Parliament, myself included, would endeavour to consult widely on the matter in hand. Thus over the summer I have met pretty much everyone who has expressed an interest in this Bill—either for or against—to endeavour to allay any concerns about its content and direction of travel and to listen to what they have to say.

**Mr Nuttall:** Is it the case that the introduction of the database into this Bill is really in response to the concerns that were expressed in the other place when Lord Saatchi's Bill was being debated? There were concerns that, if his Bill was allowed to go through without the database, there would be difficulties? Is that not the case?

**Chris Heaton-Harris:** Absolutely, my hon. Friend is completely right.

The Minister will be pleased to hear that I have been working closely with some of the excellent officials in his Department to ensure that there is a little more detail in the Bill specifically to deal with some of the concerns that have been raised with me. First, after a great deal of thought and research, I suggest that the database is held by the Health and Social Care Information Centre. The HSCIC has experience of dealing with big data, and although a number of details would have to be worked out, it seems that it would be the obvious place in the existing health infrastructure to hold such a database.

How the database would work would be detailed outside my Bill by those best placed to do so. However, it is envisaged that a registered medical practitioner, having consulted with his or her patient, would flag up on the patient's notes that they were innovating. I recognise the pressure that medical practitioners are under, so I am determined that this database should not add much to their already heavy workload, and, hopefully, through this system it would not.

The Health and Social Care Information Centre already has in place a strong set of legal safeguards to protect privacy and confidentiality, which, again, makes it an ideal organisation to host the database. Clearly, privacy issues will be a core part of any consultation that takes place on the detail of the database.

Importantly, the Bill stipulates that outcomes, not just the process of innovation itself, will be on the database. Successes and failures would be recorded on an ongoing basis. There are a number of very, very good reasons for doing that. Of course sharing success is simple to explain. Sharing ideas is in itself a great idea. Letting others see that a treatment has been a success when that treatment might not be widely known is clearly helpful, perhaps even lifesaving. When we know that treatments can differ between NHS trusts and between individual surgeries, it seems clear that we should be encouraging a spread of the good innovation that comes from every individual medical practitioner, such as the surgeon I mentioned earlier and his use of the drug, Glivec.

We must also realise the potential of transparently sharing all outcomes of innovation—not just successes, but failures too. Critics of Lord Saatchi's Bill were rightly concerned about "quackology"—their term, not mine. There are some doctors who sell to desperately sick people treatments that do not work and that, in some cases, are dangerous. Having a database on which the whole of the registered medical practitioner community can see what an innovation is and then watch the results come in removes quackology from the database in a stroke.

I might well be on the lookout for someone who can cure my male-pattern baldness. Undoubtedly, it would require an innovative treatment; some would say a miracle cure. Currently, there are many treatments on offer to people such as myself. Many adverts will offer me an innovative cure, but there is no way of checking on the successes or failures of the treatments on offer.

**Andrew Bingham (High Peak) (Con):** My hon. Friend is making quite a powerful case. I do not wish to dwell on his receding hairline, but let me touch on the adverts that we all see for receding hairlines or whatever. Does he envisage an advert carrying a quality mark to say that the treatment is on the database with results that are proven, which would give it more credibility?

**Chris Heaton-Harris:** I am not particularly worried about what is going on up top, but what I would envisage is that if I wanted to get an extra bit of thatch put on I could go to my doctor, have a conversation with him and he would be able to look on the database and say, "There is nothing there. This is all pie in the sky, hokum pokum stuff and not worth going for." The database gives people a way of checking on the success or failure of the various treatments on offer, and if innovations such as this miracle cure for baldness are not there at all, there must be questions to be asked.

Perhaps some of the treatments on offer do work, but I doubt that the quacks out there would want their supposed innovations placed under the spotlight of transparency in both practice and outcome that the database would offer. There is another much more compelling reason for having a database that records the outcomes of medical innovation, be they successes or failures. It is impossible to learn, to move forward or to spread best practice if innovation is conducted in a silo and if no one else in the health community knows what is going on.

**Sir Edward Leigh:** My hon. Friend and I are fellow Conservatives and we have battled over the years to stop more and more bureaucratic burdens being put on professionals. Our ethos is that we should trust professionals and if they have a good treatment, they will want to test it in their own time and put it on the database. What worries me is that if we have this great bureaucratic mechanism with piles and piles of untested information poured into it, although it might discourage good doctors it will not necessarily discourage quack practitioners. Does he see my point? How does he meet this Conservative objection to the Bill?

**Chris Heaton-Harris:** There are many elements to this genuine concern. My hon. Friend was the Chairman of the Public Accounts Committee and I served on that

[Chris Heaton-Harris]

Committee for five years. We have seen plenty of IT action in the health service space that has not worked at all, but we have moved forward into a new era of big data and can now manipulate it sensibly and shrewdly. All that would be required from the medical practitioner would be a coding on the patient's notes that would go into the system electronically. All the work would be done behind the scenes to make that visible to the rest of the registered medical practitioner community. Hopefully, it will mean a very small amount of work in exchange for a huge amount of best practice being spread across the NHS.

I have been reading a truly great book by the author Matthew Syed, which is called "Black Box Thinking". Essentially, it makes the case for the database, for the recording of success and failure and for trying to encourage the reporting of failure so that lessons can be learned. To paraphrase, he basically says that it is rare for someone to come across "a eureka moment" without a huge amount of previous work. In fact, although most invention comes from innovation, most of it comes from innovation in tiny steps that occasionally build up to a large leap.

In a recent radio interview, the author said that healthcare needs a

"scientific mind-set that allows people to learn from their mistakes" and to be "brutally honest about failure". He said:

"For senior doctors, who have spent years in training and have reached the top of their profession, being open about mistakes can be almost traumatic. Society, as a whole, has a deeply contradictory attitude to failure."

He went on:

"Preventable medical error is one of the biggest killers in the UK—when doctors make mistakes they are worried about litigation so they are not open about mistakes and they are made again and again."

If preventable medical error was a disease, we would devote a whole medical specialty to dealing with it. Among the many causes of that disease would be fear and a culture of blame rather than learning that lead many doctors to conclude that the best option is not to be open about mistakes, which are then repeated again and again. As Matthew Syed says

"at a collective level...success can only happen when we admit our mistakes, learn from them, and create a climate where it is, in a certain sense, 'safe' to fail."

So the database would do several important things. It should increase transparency in innovation, creating an even clearer trail of evidence which not only improves patient safety but encourages further innovation. It would, hopefully, encourage a culture of information sharing, spreading good ideas and also learning from less successful ones. Additionally, I want registered medical practitioners to know and feel confident that they can use the database to innovate and to discover the innovations of others, and this is partly behind clause 3.

I want to provide clarity and give confidence to doctors about how they can demonstrate that they have acted responsibly when innovating, while using the database or not. The second part of my Bill, therefore, does one thing: essentially, it brings forward what the medical community knows as the Bolam test. Currently, the Bolam test is applied only when proceedings have gone to court. However, bringing it forward to an earlier stage would allow a responsible doctor to take a series

of steps to prove that they are being exactly that—responsible when providing treatment. This does not change common law. A doctor can continue to rely on the existing Bolam test before the court.

The Bill supplements the existing law; it does not replace it. The Bill will not stop a doctor being sued for clinical negligence. It simply allows a registered medical practitioner to demonstrate what their actions were and with whom they consulted. It gives a doctor that extra bit of confidence that they can prove that what they are doing is responsible and therefore not negligent. The Department of Health did a consultation on Lord Saatchi's Medical Innovation Bill that revealed that some doctors do find the threat of litigation to be a block to innovation, although this view is not universally or widely held.

However, given that that engagement has identified that some respondents feel constrained from innovating, there is a case for addressing this through legislation. This Bill is aimed at reassuring those doctors, even if that is just an underlying fear, and to encourage the culture change I described earlier.

As Dr John Hickey told me:

"As a registered medical practitioner, a former NHS Trust Chairman and with 30 years' experience in the field of legal medicine with the Medical Protection Society (the last five years as Chief Executive), I believe I am adequately qualified to comment on your Bill.

Over the last 30 years I have seen how doctors have increasingly practised defensive medicine both because of the fear of litigation and disciplinary action by their regulators; this defensiveness is not in patients' best interests.

I believe that your Bill, if approved by Parliament, would assist in meeting the concerns of clinicians treating such patients . . . I believe there are adequate safeguards in your Bill, particularly with respect to consent, to prevent the potential 'quackery' about which some of the critics of your Bill and Lord Saatchi's previous Bill have expressed concern."

I hope that my Bill is given the chance to fulfil the expectations of Dr Hickey, and many others who have contacted me to express their support for it.

I know that this Bill comes in the context of perhaps a new era in treatment, where patient choice is at the heart of decision making. Following on from the *Montgomery v Lanarkshire* ruling by the Supreme Court earlier in the year, I think it is fair to expect that all registered medical practitioners are now consulting their patients in a full and responsible manner and involving their patients in decisions about their ongoing treatment. So following these appropriate consultations a doctor might choose to innovate in the treatment of their patient and should feel confident to do so.

This Bill is not about research or about testing on patients. It is about harnessing the trust in the common law and the already well respected, tried and tested Bolam test. The Bill just provides clear steps to evidence Bolam, but before treatment takes place. It has always struck me as bizarre that although our national health service is constantly innovating, it rarely captures the innovative practice itself, let alone the results of that innovation. Out there right now in GP practices and in hospitals registered medical practitioners are innovating to help their patients. It is beyond belief that we fail to capture these innovations and allow others to understand and learn from them and then develop them to help others. That is the intention behind my Bill and I commend it to the House.

10.14 am

**Dr Sarah Wollaston** (Totnes) (Con): As with any book, we should not judge a Bill by its cover. All Members want to improve access to innovative medical treatments, but I sincerely believe that the Bill is not the right way forward. My hon. Friend the Member for Daventry (Chris Heaton-Harris) referred to a number of organisations, implying that they are in favour of the Bill, but he knows that the overwhelming majority of research and charitable organisations are ranged against it. It is opposed by the Association of Medical Research Charities, whose membership reads like an “A to Z” of expertise, including bodies such as Cancer Research UK, the Wellcome Trust—the list is very long, so I will not detain the House by reading it out. The Academy of Medical Sciences opposes the Bill, as does the Academy of Medical Royal Colleges, including all those he quoted in his speech.

The General Medical Council, the British Medical Association and the Patients Association oppose the Bill, and I direct my hon. Friend to their article in *The Guardian*. Action against Medical Accidents, and even the Association of the British Pharmaceutical Industry, oppose the Bill because of its unintended consequences. Legal experts, including Sir Robert Francis, firmly oppose the Bill. All those organisations oppose the Bill because it is unnecessary, it is unworkable, it would unravel important patient protections and, most importantly, it would have unintended and dangerous consequences for research.

I pay tribute to all the Bill’s sponsors and absolutely understand that they are motivated by very good intentions. I would love to sit down and work with them on how we genuinely improve access to innovative treatments. I hope they understand that I oppose the Bill because I sincerely believe that it is the wrong way forward.

The Secretary of State already has the power, as the hon. Member for Lewisham East (Heidi Alexander) pointed out, to set up a register of innovative treatments, so we simply do not need that provision. We also do not need the heavy hand of legislation. We do need a register, but it needs to be set up by the research bodies themselves and to be adequately funded. We absolutely need transparency. There is a danger that we will misunderstand the science.

**Mr Christopher Chope** (Christchurch) (Con): My hon. Friend refers to the power of the Secretary of State to set up a system. When does she expect that to happen, and what is causing the delay?

**Dr Wollaston:** My hon. Friend makes a good point. Principally, there are issues with funding and complexity. The Bill fails to recognise the science and the issues that a vast, sprawling database might cause. My hon. Friend the Member for Daventry referred to the desirability of the public being able to access a database and gave the example of male pattern baldness. There would be vast profits to be made by the quackery industry from male pattern baldness products. I envisage a vast, sprawling database of anecdotal treatments, and I am afraid it would act as free advertising for the quacks of this world. It is an invitation to quackery.

I started in medicine in the late ’80s and worked for a while in paediatrics. The prognosis for children with leukaemia was grim, but today most of the children diagnosed with the same conditions will survive and

thrive, not because of access to a vast, sprawling database of unconnected, anecdotal treatments but because of the meticulous progress of medical research, whereby with thousands of people we compare existing treatments with innovative treatments and find out which are genuinely the best. Any single anecdotal treatment might be effective in one single patient, but that does not tell us whether, when applied to a population, it is better or not.

Another problem with the Bill is the danger that it would undermine medical research. In effect, it would give private clinics the opportunity to offer anecdotal treatments as a way of bypassing clinical trials. When individuals, and particularly parents, are desperate because they have a dreadful diagnosis, they are at their most vulnerable to the claims of individuals who say, for example, “Look at the database and see how it worked for Mr Smith.” They might be lured into thinking that was the best way forward. Someone in a very vulnerable place might be lured into not taking part in a clinical trial by the siren call of an anecdotal treatment recorded on a publicly accessible database. I am afraid that the Bill would undermine research, and that is why the vast majority of bodies are very unhappy about it.

My hon. Friend should reflect on all the concerns that have been expressed about the Bill, and think about how science moves us forward. We progress not by a series of anecdotal treatments but through a solid research community.

We need greater access to clinical trials. The searchable database set up by the National Institute for Health Research is a welcome step forward, but it is rather clunky. Patients need to be able to see very clearly what trials are available and be able to take part in them. There is progress, people are surviving today with treatments based on clinical trials that may have taken place 10 years ago and many go on themselves to take part in clinical trials that will benefit future generations. It is absolutely vital that we continue to support this approach.

**Bob Stewart** (Beckenham) (Con): I thank my hon. Friend—a good friend—for giving way. Does she believe that there is no place for any sort of list whatsoever and that the system should be left as it is, or is she suggesting that a list could be made up? I understand all her inhibitions and worries about such a list, but should it be considered?

**Dr Wollaston:** As my hon. Friend the Member for Daventry pointed out, many of these bodies would like to have such a register, but they would also like to be able to guide how it should look and to have it within the existing research framework.

The Bill suggests that doctors are not already innovating, and that this is about fear of litigation. The original Bill was based on the premise that fear of litigation was stopping innovation. In fact, the position is very clear if we read what a number of bodies have said. My hon. Friend quoted some individual examples, but the vast majority of opinion from the medical community and the research community is that, genuinely, it is not fear of litigation that stops innovation. Every aspect of this Bill is based on a false premise, I am afraid. I do not want to detain the House by reading out all the various quotes on why the fear of litigation does not stop innovation, but he will know that that is the case.

We face the danger of confusing the existing legal framework. Many have expressed their concern that we will end up with a sort of Heaton-Harris defence for

[Dr Wollaston]

those who have undertaken perhaps rather dangerous experimental treatments billed as innovation. My hon. Friend cited the case of the children who suffered from Duchenne muscular dystrophy, and that is very sad, but the Bill has an underlying assumption that all innovation is a good thing whereas the lesson of history is that it can be extremely dangerous and harmful. We need to be very careful about what we mean by innovation, and to accept that there are also very dangerous innovations. If, as a result of this well-intentioned Bill, we inadvertently end up with people being, in effect, experimented on by irresponsible doctors who are able to get off scot-free, we will have to come back to this place and amend it.

I would like to give my hon. Friend an example based on the case of somebody from my constituency who wrote to me to say that he was concerned that the Government were not doing enough with regard to experimental treatments. His specific example was a bogus treatment called GcMAF. The company promoting this entirely bogus treatment—it has a number of clinics in Europe and Guernsey—is very concerned that it cannot use it in this country because it is prevented from doing so by the current legislative environment. Well, jolly good. It puts out literature saying

“we state that if you have terminal stage 4...cancer, have not had chemotherapy, and you do the GcMAF protocol, you have an 80% chance of being cancer free in a year.”

That is the kind of claim that such doctors put out. In other words, the company is not only promoting its own product, but actively discouraging people from having a treatment that could help.

**Chris Heaton-Harris:** My hon. Friend is surely making the case for the database because successes and failures would have to be recorded. She would therefore be able to benchmark and see the evidence behind such a claim. A company cannot choose just to record successes on the database.

**Dr Wollaston:** I must say that I do not think my hon. Friend understands how this works. Companies will simply direct people to their successful treatments. Yes, they may have to record their failures as well, but it is only by comparing the results for bodies of patients having such treatments that people can see whether treatments are entirely bogus. This company cannot currently operate in the UK—quite rightly—and I am afraid that we would see this kind of bogus treatment.

My hon. Friend’s Bill would require doctors who want to undertake so-called innovative treatments to consult at least one other doctor. Seven doctors operate in the clinic concerned. We can see how, if a doctor is working in a clinic with others who are profiting from bogus treatments, it will be very easy for them to pop down the corridor and get one to agree that their bogus treatment is an absolutely fantastic treatment for cancer.

I am afraid that the Bill is based on a false premise, and such a randomly searchable database of unconnected treatments is very dangerous. In addition, if someone wants to start a trial of a new product but there are one or two examples on the database of the treatment not working, the Bill might inadvertently end up killing off a potentially useful treatment. Such things need to be established as part of a research trial. Databases that are randomly searchable by the public will be an absolute quacks charter.

**Chris Heaton-Harris:** My hon. Friend will know—in fact, we had a meeting about this just before the Bill was first drafted—that I do not tackle research in the Bill; it is specifically excluded. She will know that learning from failure is one of the most important things people can do. She will know that she is describing doctors not acting responsibly, but my Bill does nothing to change the current position: if a doctor acts irresponsibly, the full weight of medical negligence legislation will still come down on top of them. She is painting a picture that simply will not and could not exist if the Bill comes into force.

**Dr Wollaston:** I am afraid that I disagree. My hon. Friend’s Bill would not allow us to learn from failure. We learn from failure through medical research. He says that it will not undermine medical research, but I have read him a long list—I am happy to read it out again—of members from across the entire research community who are deeply concerned that it will undermine research for the reasons I have set out.

If someone was absolutely desperate—as in the very tragic case of the family my hon. Friend cited—and was persuaded not take part in a clinical trial by an unscrupulous doctor, why would they do so? They would mortgage their house to go to such a clinic if it persuaded them to do so, thinking that it was their best hope of a cure. The fact is that that hope is likely to be dashed. They are best off going to an established research community.

The Bill will undermine recruitment to clinical trials. Although my hon. Friend does not mention medical research, very vulnerable people will end up circumventing genuine medical research. He will set back the progress of science, and when that comes to pass we will have to come back to the House to amend the legislation. I very much regret that he has been persuaded to take up this Bill. He knows of the long list of members of the research community who are profoundly opposed to it, for the reasons I have set out.

I urge the Government to be very clear that they support medical research and that they want genuinely to move forward on that basis. My hon. Friend the Minister is right to be looking at the accelerated access review. Let us use that review to look genuinely at the barriers to research and to getting products rapidly into use for NHS patients.

I urge colleagues to read the briefings on their desks from the entire research and medical community, and robustly to reject the Bill.

10.30 am

**Heidi Alexander** (Lewisham East) (Lab): I congratulate the hon. Member for Daventry (Chris Heaton-Harris) on securing a place in the private Members’ Bills ballot and thank him for meeting me this week.

Sometimes in this place, we need to be careful what we wish for. The process of steering a private Member’s Bill through Parliament not only is time consuming, but can become very complicated. I suspect that, after the contribution of the hon. Member for Totnes (Dr Wollaston), the hon. Gentleman may be feeling that. I should probably be honest and warn him that my contribution may add to his headache.

The very fact that we are discussing the Bill means that we are having a vital debate about the critical issue of how we can improve patients’ access to innovative

and effective treatments. In putting his case for the Bill's Second Reading, the hon. Gentleman has demonstrated that he has the right intentions, but that is probably the best thing I can say.

Many people in this House will have been in the position of seeing someone they love dying too soon. In such situations, people want hope. I understand that. They want hope that there is a treatment or drug that offers a chance of survival or of extending life that little bit longer.

If I thought that this legislation would provide genuine, well-founded hope in a safe and sound manner, I would support it, but I am not convinced that it does. In truth, I am worried that it does the opposite. I am worried that unsafe treatments could be used on dying patients. I am worried that the Bill would muddy the waters for doctors who wish to innovate about the legal route to do so, that it would reduce participation in clinical trials and that it would reduce legal redress for patients with a genuine negligence claim.

In the few weeks that I have been in this job, I have approached the Bill with an open mind. I have met a range of experts, patient groups, royal colleges and charities. It is fair to say that they are overwhelmingly opposed to the Bill. I will put some of their concerns to the promoter of the Bill and to the Minister, who I understand is actively supporting it.

The first concern that has been put to me is that the Bill attempts to remedy a problem that does not exist. I will briefly quote a few of the experts in this area. The Academy of Medical Royal Colleges has said that

“the Bill rests on the false assumption that it is fear of litigation that is holding back innovation by doctors. There is simply no evidence that this is the case”.

The British Medical Association has said:

“We are not aware of any evidence to suggest that the threat of litigation inhibits innovation or that confusion exists amongst doctors over the circumstances under which they can deviate from standard practice.”

The Royal College of Surgeons has said that

“there is no evidence that doctors are deterred from innovating due to the threat of legal action.”

The Motor Neurone Disease Association has said that

“the Bill would not remedy the problem it is aimed at, for such a problem does not exist”.

Sir Robert Francis QC, who has done so much in recent years to make sure that the NHS is focused, rightly, on patient safety, has said:

“The law of negligence does not prevent responsible innovation and never has.”

I could quote many more people, but I have probably made my point. Why do the hon. Gentleman and the Minister think that all those experts are wrong and they are right? What evidence do they have that litigation, or the fear of litigation, is preventing new treatments or hampering doctors from innovating? Even if that were an issue, does the Bill provide a robust and safe mechanism to tackle it? I am not sure that it does, but I am willing to work with the hon. Gentleman and the Minister, and anyone else who is interested, to consider how we can work on a cross-party basis to address any potential barriers to innovation.

Before setting out why I do not believe that the Bill is the right approach, I will first deal with clause 2, which provides the Secretary of State with power to establish a

non-statutory database of innovative medical treatments. As the hon. Gentleman said, the clause was included as a result of concerns that were rightly raised in the other place by Lord Hunt when the previous incarnation of this Bill was debated. Lord Hunt's amendment to that Bill would have required the Secretary of State to establish a database, but such a requirement does not exist in this Bill. As currently drafted, the Bill gives the Secretary of State “power” to establish a database, but places no obligation on them to do so.

I also question whether clause 2 is needed at all. According to the House of Commons Library, section 254 of the Health and Social Care Act 2012 gives the Secretary of State power to direct the Health and Social Care Information Centre to establish a system for the collection or analysis of information. Will the Minister confirm whether the Secretary of State already has the power to establish a non-statutory database of innovative treatments without legislation?

The Bill gives no detail about how such a database might work, but is that not crucial? A database will be effective only if it is compulsory, regulated and quality controlled. For a database to work requires participants to be just as likely to register failure as success. Will there be a requirement to remove an innovation that is not effective from the database? Will the database be quality assessed or peer reviewed? Will it be used for marketing to patients? The Bill makes no reference to those crucial points.

I am concerned about the impact of the Bill on research, and particularly on participation in clinical trials. As the Minister will know, we are a world leader in clinical research, and we must be careful not to do anything that would put that status at risk. Last December the Minister said that he hoped that the forerunner to this Bill would develop into a form that

“the vast majority of medical opinion and respectable bodies in the medical field feel able to support”.—[*Official Report*, 9 December 2014; Vol. 589, c. 853.]

I am not sure we have got to that point.

Let me list some of the medical research charities opposed to the Bill: Alzheimer's Research UK, the British Heart Foundation, Cancer Research UK, the Motor Neurone Disease Association, Parkinson's UK, the Wellcome Trust. Is the Minister comfortable supporting a Bill that those experts say could have

“significant unintended consequences for medical research”?

**Bob Stewart:** I presume that one fundamental reason why such bodies are against the Bill is that they are concerned that people who are without much hope would pin everything on something that could largely be quackery. Those poor devils will be encouraged to think that there is hope for them, when actually they should come to terms with the truth of their situation.

**Heidi Alexander:** I think that is broadly the point, but it also goes back to what the hon. Member for Totnes said about the impact on participation in clinical research trials. It seems entirely possible to me that a doctor might choose to prescribe an innovative treatment, or a patient decide to take an innovative treatment, rather than enter a clinical trial. If a patient is faced with the choice of guaranteed access to a treatment or participation in a trial in which there is a 50-50 chance that they will not be part of the group receiving the innovative treatment,

[Heidi Alexander]

why would they choose to be part of the trial? I would be grateful for the Minister's comments on that. Does he not accept that the arrangements for clinical trials, including as they do monitoring and ongoing data collection, provide a much better mechanism for evaluating new treatments and advancing medical progress than a situation that could become more pervasive as a result of the Bill?

If the concerns I have set out so far are not enough, let me now turn to my main concern about the Bill, which, if passed, could undermine a patient's ability to hold doctors to account when things go wrong.

**Mr Dennis Skinner (Bolsover) (Lab):** It is on this very subject that I am interested. I have had treatment for cancer and a heart bypass and countless other things, which is why I am still here. I have had to give permission to countless doctors for them to take action. What I can see here is that the doctor's permission, which lists a lot of things they might or might not do, would also have to include a list of innovative treatments before I signed the document. It says on the document, say, that there is a 50% chance of having a stroke or a 5% chance that you might die. I remember saying to one of the doctors in Brompton hospital, after I had signed one for the fourth time, that I was down to even money. I would not even be even money if a list of innovative treatments was added to the ones I am already required to attend to. I cannot see, for the life of me, how the doctors could avoid having to put that on the document before a patient signed it. Believe me, it would frighten people to death.

**Heidi Alexander:** I am keen to find a way for doctors to innovate, but to do so using safe and effective treatments.

I was saying that the problem with the Bill is that it undermines a patient's ability to hold doctors to account when things go wrong. The hon. Member for Daventry claimed that this is not Lord Saatchi's Bill, but the wording of clause 3 is very similar to clause 1 of the previous Bill. Clause 3(2)(a) in today's Bill requires a doctor to

"obtain the views of one or more...doctors"—

which, in practice, could mean just one doctor—

"with a view to ascertaining whether the treatment would have the support of a reasonable body of medical opinion."

Will the hon. Gentleman confirm that that relies on someone's interpretation of a "reasonable body", as opposed to seeking a view from a responsible body directly? Does the Bill not boil down to one doctor who wishes to deviate from accepted medical treatments asking another doctor whether he or she thinks there is a reasonable body of medical opinion that would support such a treatment? As long as that second doctor perceives such an opinion to exist about support for the proposed treatment, this provides cover for the patient's doctor to proceed. I cannot say that I am particularly convinced by that.

**Chris Heaton-Harris:** To allay that concern, the Bill states that nothing in it would override existing common law. All it aims to do is bring forward the step of the Bolam test, so that the doctor himself or herself can make a judgment at that time on whether he or she is doing something correctly. It does not stop clinical negligence cases coming forward; it just helps to prove that the doctor might or might not be acting in the responsible way that he or she should be.

**Heidi Alexander:** The Bill would just confuse matters. The alternative approach outlined in the Bill would create uncertainty and undermine the mechanisms already in place to safeguard patients. Could this not lead to doctors being absolved from any liability for an experimental treatment if they follow the Bill's standards, making it much harder for patients to redress malpractice? Sir Robert Francis QC has said it would

"deprive patients of remedies when mistreated by those who have no acceptable justification for what they have done."

In conclusion, we are faced with deep and broad concerns, as expressed by patient groups, medical research charities and royal colleges, and I do not think we can ignore those voices. They include Action against Medical Accidents, which says the Bill is a threat to patient safety; the Association of Medical Research Charities, which says it

"may adversely impact on patients and medical research";

and the Royal College of Paediatrics and Child Health, the president of which simply says the Bill endangers the safety of infants and children. It would be irresponsible to support the Bill, which is why I will be opposing it, and I encourage other hon. Members to join me.

10.45 am

**Philip Davies (Shipley) (Con):** I start by welcoming you to the Chair, Madam Deputy Speaker. It is an absolute pleasure to speak for the first time under your chairmanship on a sitting Friday, and it will be a great pleasure to do so again in the Fridays to come. I hope you enjoy it as much as I do. I congratulate my hon. Friend the Member for Daventry (Chris Heaton-Harris) on bringing forward this interesting Bill, on which we have had a good debate already. It would also be remiss of me not to welcome the hon. Member for Lewisham East (Heidi Alexander) to her position under the new regime in the Labour party. I am sure she will do a splendid job, and I wish her every success in doing it.

I have been contacted by constituents about the Bill, both in opposition to and support of it. It seems to polarise opinion; people seem to be either very for it or very against it in a way that is not always the case with Bills. I want to outline some of the points brought to my attention, many of them by my constituents. I understand that the Bill aims to help doctors to develop safely and responsibly innovative treatments and cures for cancer and other diseases, and that the rationale behind it, as my hon. Friend seemed to confirm, is that the promotion of such medical innovation could lead to the development of new cures and more effective treatments for patients.

To that end, the Bill has two aims: to provide a regulation-making power to enable the creation of a database of innovative medical treatments and to enable doctors to access information on this database; and to provide an option for doctors who innovate to take steps in advance to show that they are acting responsibly, not negligently—which deals with some of the concerns already expressed. It specifically states that it would not apply to the use of treatments in research, thereby keeping that distinction, but rather would support innovation in the treatment of individual patients, while preserving the existing common law safeguards for patients. By bringing forward the legal test of negligence to the point of treatment, it allows doctors to remove the barrier of the fear of litigation when using innovative

techniques and working in a manner held as largely responsible. Those all strike me as worthy sentiments, and it is difficult to see why anyone would be against them in principle.

The Bill cannot be seen in isolation from its origin and progression in Parliament. As my hon. Friend made clear, the Bill stems from Lord Saatchi's Medical Innovation Bill, introduced in the last Parliament, which, it is important to mention, arose from Lord Saatchi's personal experience of losing his wife to a rare cancer. I think, therefore, that we can all appreciate, and should be mindful of, the Bill's intention, which was to try and prevent that from happening to other people. It aimed to provide a standard for the legal position surrounding innovation, hoping, in theory, to encourage doctors to use innovative techniques, confident that their good intentions would not be lost.

In taking up issues with the NHS on behalf of constituents, I have often seen its fear of litigation. That might apply if I take up a complaint about one of my local hospitals—I have very good local hospitals, but of course everybody makes mistakes and things do not always go according to plan. Sometimes responses from the NHS can be very defensive, not because it does not appreciate that something has gone wrong, but because it fears the consequences of admitting that something has gone wrong. We should always do what we can to try to help the NHS from that fear of litigation. Anything seeking to do that would be very worthwhile.

**Dr Wollaston:** That is an entirely separate issue. Admitting when a mistake has been made is entirely separate from the fear of litigation, which in some cases can be very reasonable. If a doctor is putting forward an entirely bogus treatment and pretending that it could be helpful when it could in fact be more harmful than existing treatments, that is an entirely separate issue. I hope my hon. Friend will not conflate the two.

**Philip Davies:** I am rather surprised, given my hon. Friend's background, that she has such little faith in doctors that she sees them wanting to peddle some bogus treatments. I was starting from the premise that the medical profession was far more responsible than that and would never seek to do that sort of thing. I certainly bow to my hon. Friend's greater knowledge of the medical profession, but as I say, I was starting from the basis that her profession was nobler than she seems to indicate.

**Dr Wollaston:** Of course the overwhelming majority of the profession does behave responsibly, but the whole point about having protections in law is to accept that some would not behave responsibly. My hon. Friend the Member for Daventry (Chris Heaton-Harris) referred to hair loss, for example, which is a field where vast profits are to be made, and I am afraid some doctors might be tempted to behave irresponsibly.

**Philip Davies:** I take my hon. Friend's point. She is an expert in her field in a way that I am not, and I certainly do not want to decry that. My perspective on the narrow point she raises, however, is slightly different. I would want to set the framework of the law for the overwhelming majority who are doing a good job. Let us try to find other ways to weed out those who are not doing so. Putting in place arrangements that apply to everybody in order to deal with the very small number of doctors

about whom my hon. Friend speaks is probably the wrong way of going about it. I am happy to have this conversation with her in a different setting; I do not want to deviate too far from the Bill in going into how many doctors are noble and how many are chancers. I do not know the answer to that; perhaps my hon. Friend does, but I am not getting into that today.

My hon. Friend the Member for Totnes (Dr Wollaston) made the point that the Bill is unnecessary—the shadow Minister made the same point—and that there is no need for a legal requirement for medical innovation to be made, particularly when the current common law Bolam test is appropriate. Although it may not be popular, however, I believe it important to give serious consideration to this part of the Bill.

The Medical Innovation Bill, although criticised, showed an appetite for more legal work in the area of medical innovation. After a commitment from the Secretary of State for Health, the Medical Innovation Bill was put to consultation in the last Parliament. Many organisations shared their views, some of which have already been mentioned. I shall highlight a couple of those views because they are relevant to today's Bill.

Cancer Research UK stated in its consultation response:

“There is clearly patient and clinician demand for more innovation to help treat people with cancer. We do sometimes see exceptional responses to treatments from individual patients, and therefore want to be in a position to innovate. Cancer Research UK is supportive of efforts to bring innovative treatments to patients faster and to improve the uptake of innovative treatments in the NHS. Any new legislation seeking to promote innovation should be drafted to ensure doctors have to establish there is sufficient intellectual underpinning and safety data about a treatment before proceeding. There should also be appropriate consultation with other doctors in the same or a related field to ensure patients receive the best care at all times.”

I understood from previous contributions to this debate that Cancer Research UK was against today's Bill, but it does not strike me from the response I have cited that it was opposed to it. It seems to me that it was looking for ways to bring about more innovation to help treat people with cancer. It seems to be open to the possibility that the Bill might be able to do that.

**Chris Heaton-Harris:** I fully admit that there are a number of critics of the Bill, but not so many critics of the central idea in the Bill. I welcome what the hon. Member for Lewisham East (Heidi Alexander) said about trying to work with those who are genuinely interested in spreading best practice and innovation across the NHS. If one of the Bill's core features is widely welcomed, even by some of the harshest critics of its later parts, I put it to the hon. Lady that it is surely worth taking the Bill forward into Committee to examine the provisions in greater detail, when we could debate it with expert witnesses and others.

**Philip Davies:** My hon. Friend makes a very good point. A Second Reading is, of course, a debate of a Bill in principle, so that we can establish whether people object to it in principle. I have been somewhat confused by the voices in opposition to the Bill because I cannot work out whether they consider the Bill to be dangerous or unnecessary because what it proposes is already being done. It seems difficult to argue that it could possibly be both. Either the Bill's provisions are already in place so there is nothing to be done, or the Bill is a terrible and dangerous thing.

**Dr Wollaston** *rose*—

**Philip Davies:** I cannot understand how it could be both, but perhaps my hon. Friend will explain that for me.

**Dr Wollaston:** On my hon. Friend's first point about Cancer Research UK, let me be absolutely clear that it is opposed to the Bill. On the second point, what these bodies are all saying is that the Bill is unnecessary, but that if it is put in place, it would be dangerous. That would be the consequence of the Bill, and people think there are other ways of moving forward to improve access to innovative treatments.

**Philip Davies:** I merely read out, word for word, Cancer Research UK's response to the consultation; I can do no more than quote its words. I will take my hon. Friend's point in that regard.

**Mr Chope:** If there is such widespread opposition to this Bill, why was it that the Saatchi Bill made such good progress in the other place during the last Parliament, when I understand it had the benign support of the Government?

**Philip Davies:** My hon. Friend often asks me questions that I cannot answer. He has now asked another that I am not in a position to answer. I often think it is a mistake to give way to him; he is far too clever for my liking. Again, he has stumbled across something that I cannot answer. He raises a very good point, so perhaps we shall leave it hanging there for others to have a crack at later in the debate.

The Academy of Medical Royal Colleges said that it applauds the intentions of the promoters of the Medical Innovation Bill:

"The stated purpose of the Bill is to encourage responsible innovation in medical treatment, and accordingly to deter innovation which is not responsible. Those are aims which medical Royal Colleges would wholeheartedly support and welcome."

That is an important point.

**Dr Wollaston:** The Academy of Medical Royal Colleges robustly rejects this Bill. Like me, it supports the intention of extending access to innovative medical treatments, but it is very clear that it opposes the Bill—and this House should oppose it, too.

**Philip Davies:** I am perfectly happy for people to put their own gloss on what others are saying. That is their right. If I may be allowed to do so, I am merely quoting, word for word, the responses that people made. If my hon. Friend is saying that the Academy of Medical Royal Colleges should not have written that, she should take that up with the organisation. I am merely quoting what it wrote, which I thought was quite clear.

**Dr Wollaston** *rose*—

**Philip Davies:** I want to make some progress, but I will give way again to my hon. Friend.

**Dr Wollaston:** I must take issue with my hon. Friend because he is quoting very selectively from the report. When he has finished speaking, I urge him to go online and have a look at the detailed briefing on the Bill from

the Academy of Medical Royal Colleges. It applauds the principle of improving access to medical treatment, but it is absolutely clear that it opposes the Bill.

**Philip Davies:** I do not deny that. If the Academy of Medical Royal Colleges wants to shy away from any part of what I have said, the academy probably should not have written it in the first place. I did not write it on the academy's behalf; the academy wrote it, and I have quoted it faithfully. People can make of it what they will, but what the academy said was that it

"applauds the intentions of the promoters of the Medical Innovation Bill...to encourage responsible innovation in medical treatment, and...to deter innovation which is not responsible. Those are aims which medical Royal Colleges would wholeheartedly support and welcome."

That is what the academy has said. I did not say it on the academy's behalf.

The Association of Medical Research Charities summarised its position as follows:

"We welcome the ambition of the Bill in seeking to address the important issue of encouraging medical innovation; innovation and its adoption can be low and slow in the NHS and there is much that can be done to improve this."

Genetic Alliance UK said:

"There is much more that could and should be done to address the barriers that currently inhibit the adoption and integration of research and innovation into the NHS."

The Royal College of Physicians said in its consultation document:

"The RCP strongly supports the aims of the Bill, and welcomes the debate and discussion around innovation that has occurred as part of the proposed Bill."

Others will have different perspectives and will want to make other points as part of the consultation, but it seems clear to me, at least, that—as my hon. Friend the Member for Daventry said in his intervention, and as has been said even by those whom my hon. Friend the Member for Totnes says oppose the Bill—there is clearly something in the Bill that deserves further scrutiny in Committee.

**Heidi Alexander:** Will the hon. Gentleman clarify exactly what he is quoting from? Is he quoting from the consultation responses provided by those organisations, or from the most recent briefings that were provided before the debate? It is well known that opinion among a number of organisations has hardened against the Bill.

**Philip Davies:** I made it clear at the outset, but I am happy to make it clear again, that I am quoting from responses to the consultation. If those organisations want to shy away from any of those points, they are welcome to do so. As I have said, I am merely quoting what they said in response to consultation on Lord Saatchi's Bill when these issues were first introduced.

**Dr Wollaston:** The point is that we all support the aim of improving access to innovative treatments; we simply do not agree that the Bill is the right way forward. Because my hon. Friend has quoted all those bodies, may I quote back to him the conclusion of the medical royal colleges? They will of course issue consultation responses that will be nuanced in relation to various points, but what we should look at is their conclusion, which could not be clearer:

"In conclusion, Medical Royal Colleges do not believe that the Bill should be supported."

That is their position.

**Philip Davies:** I think that my hon. Friend is slightly in danger of arguing against herself. She began her intervention by saying that all those bodies supported the principle behind the Bill, and it seems to me that that is really an argument for supporting its Second Reading. What we are discussing now is whether or not we agree with the principle of the Bill, and my hon. Friend has just said that all those organisations support that principle. She may well wish to scupper the Bill on Third Reading, or amend it in Committee so that it is to her particular taste, but, as I see it, announcing that everyone supports the principle behind the Bill is a call to arms for people to support its Second Reading.

**Dr Wollaston** *rose*—

**Philip Davies:** I want to make some progress, but I will give way to my hon. Friend one final time.

**Dr Wollaston:** I thank my hon. Friend. He is being very generous. Can he not see, though, that supporting the principle of improving access to medical treatments is a completely different kettle of fish from supporting the mechanism whereby an individual Bill attempts to achieve that aim? In other words, it is perfectly consistent to say that one opposes the Bill robustly, as, indeed, did a long list of organisations and people, including research charities, medical royal colleges, Action against Medical Accidents and Sir Robert Francis. The list is huge. All those bodies state, robustly and clearly, that the Bill is not the mechanism to achieve those stated aims, and that is why the House should reject it.

**Philip Davies:** It is not for me to advise other Members how to pursue their own agendas. My hon. Friend is a wonderful exponent of ways of implementing her views, but my advice to her, for what it is worth—which she may think is not a great deal—is that if she wants to see more innovation in medicine, as she said at the beginning of her speech, but does not believe that the Bill is the right way forward, she should support its Second Reading and then seek to amend it in Committee so that it achieves the innovation that she would like to see. We shall then review the matter on Third Reading, and she can decide at that point whether the Committee stage has delivered to her what she feels would be a useful way of getting more innovation into the NHS. It seems to me bizarre that someone should stand up and say, “I want to get more innovation into the NHS”, and then block on Second Reading—and this is the principal point of the Bill—any attempt that might actually facilitate the introduction of improved innovation into the NHS. But that is just the way I see the matter; it is up to individual Members to pursue their agendas in the way that they see fit.

**Chris Heaton-Harris:** I believe that the Bill should go into Committee, because it is an evolution: it is a process that we are going through in trying to get the position right. The Royal College of Physicians says that it “generally welcomes” the first part of the Bill, which enables the Secretary of State for Health to establish a database of medical treatments. However, it issues plenty of caveats in respect of how the detail should run. Those should be discussed in Committee, and that is where I want the Bill to go.

**Philip Davies:** My hon. Friend has made a very fair point.

I now want to say something about the medical innovation database provision, which is one of the main differences between the Medical Innovation Bill and the Bill that we are discussing. Clause 2 provides for the Secretary of State to make regulations enabling the Health and Social Care Information Centre to establish a database containing information about innovative medical treatments and their outcomes. As a layman, I consider that to be a significant and fundamental part of the Bill. A central database recording all innovative treatments strikes me as a useful tool from which doctors can learn when tailoring medical treatments for their patients. Again, I speak as a layman, but I think that the creation of a system to enable that knowledge to be shared is a logical step towards medical innovation.

Having said that, I should add that the proposal is not without its worrying aspects. I wanted to raise them earlier, but the interventions from my hon. Friend the Member for Totnes delayed me. One of the main criticisms of clause 2 comes from the Royal College of Surgeons of Edinburgh, which states:

“The proposed database could only be effective if it is compulsory, regulated, has robust quality assurance and be journal-led, ethically framed and rigorously peer reviewed. It will also require an honest culture in which participants are just as likely to register failures as successes”.

The clause provides for the Health and Social Care Information Centre to specify what information should be recorded and how it should be assessed. More experienced people than me will be able to note what standards and specifics need to be recorded to make the database useful and usable. It is certainly not for me to make any suggestions. The database will also be designed in consultation with professional bodies and organisations.

The clause contains the important provision that the database will cover all individual patient innovations, not only those in respect of which doctors have chosen to rely on the steps in the Bill to demonstrate that they have acted responsibly. It is a significant inclusion, as it means that the database will include and cover all treatments and their outcomes—both positive and negative—that take place in England. That is my understanding of the clause, but if my hon. Friend the Member for Daventry wants to correct any misunderstandings, he is welcome to do so. Therefore, this national database not only spreads the knowledge of successful innovations, but also has the benefit of ensuring that innovative treatments that do not work, or perhaps have harmed patients, are not repeated by other clinicians. That should go some way towards reassuring those with concerns. It will also, therefore, create a standard practice that all innovative medical treatment should be recorded in this database, which can be a useful tool for other doctors to draw information from when they are doing their own innovation.

**Bob Stewart:** I came here to listen to my very good friend my hon. Friend the Member for Daventry (Chris Heaton-Harris) and to listen carefully to the debate. It seems to me that if Lord Saatchi’s Bill went into the sand and if this Bill does not make it into Committee and disappears, the one good thing that will come out of it is that the whole subject will be illuminated, and perhaps something good will come out of that. Therefore, the efforts of Lord Saatchi and my good friend the Member for Daventry will not be in vain. I hope very much that the medical authorities will look at this and think of it in that light.

**Philip Davies:** I take on board my hon. Friend's point. It seems to me that he was subtly saying he had come to listen to the speech of my hon. Friend the Member for Daventry rather than mine. I had hoped he had come to listen to my speech, but I am clearly mistaken.

**Bob Stewart:** I must intervene. I always come to listen to my hon. Friend the Member for Shipley (Philip Davies). I listen to him outside this hallowed hall and also inside it, and he is always well worth listening to.

**Philip Davies:** My hon. Friend is very kind, although it would have been rather better if he had not had to be prompted to say that. Nevertheless, I will take those comments in the spirit in which I know my good friend intended.

**Mr Chope:** My hon. Friend has not responded to the intervention of my hon. Friend the Member for Beckenham (Bob Stewart). Surely the point is that if we want to discuss this in more detail in Parliament, the ideal opportunity for that is in Committee when it can have detailed scrutiny.

**Philip Davies:** My hon. Friend makes a good point. I have not heard anything so far today to suggest that the Bill should not at least go into Committee for further scrutiny, and perhaps even for some improvement, if I may be so bold as to suggest that may be possible. I do not think I have heard anything today that suggests the Bill should be stopped in principle on Second Reading. I hope that my hon. Friend the Member for Totnes will appreciate, however, that I am also trying to be balanced in setting out some of the concerns that have been expressed, perhaps so they can be considered if we do get into Committee, which would be a useful exercise.

Another concern raised by some of my constituents is that the database may compromise patients' anonymity. Innovative medical treatments will be applied on a case-by-case basis with a specifically honed technique for one particular individual. The fear is that a degree of detail will be needed in the register, which would end up compromising a patient's anonymity. That is a valid concern, and protections would need to be put in place to ensure all information is stored securely within the database to protect anonymity. However, that may be at the cost of using innovative treatments. There may well be a tension between those two factors.

While the information stored in the database should only be accessible by doctors, it will need to remain confidential aside from access for medical purposes and, ultimately, it should be the patient's choice whether to use an innovative treatment that will be recorded for medical purposes. Furthermore, in an age when we want more doctors to spend more time with patients and not at their desks, we need to be careful to ensure that the register does not become overwhelming to the point where doctors are put off from using innovative techniques for the sake of the amount of paperwork and red tape that would accompany it. The Academy of Medical Royal Colleges said

"current experience in the NHS show that establishing an effective register for far more standard procedures is a complex task. Establishing and maintaining a register of innovations would be a costly and potentially burdensome and bureaucratic task."

My hon. Friend the Member for Totnes made that point. That is another factor that needs to be considered

when the database is created. Of course the database and the information gathered should be rigorously checked and regulated. However, that is not always easy when doctors are already busy.

Overall, I believe this clause, originating from an amendment to Lord Saatchi's Bill, is one of the key clauses. For rare diseases such as some cancers there is a lack of published evidence on which to rely when determining treatments to try. It is also widely regarded that some methods used to treat some types of cancers have remained similar for many years, with only slight modifications to the techniques. With this in mind, a database that allows knowledge to be stored and accessed at a doctor's level will be not only desirable but probably essential for allowing doctors to innovate responsibly. It will encourage a culture of knowledge sharing, which, importantly, will include both successes and failures. This is a vital part of the Bill, and indeed I do not see how the power to innovate can move forward without the inclusion of a database recording the results of these treatments. I therefore commend my hon. Friend the Member for Daventry on including this clause.

We need to look at what we consider to be a responsible innovative treatment. Clause 2(2) states that a treatment is regarded as

"innovative" if it involves a departure from the existing range of accepted medical treatments"

for a condition. We can therefore assume a wide scope to cover the cases that should be recorded in the new database.

However, concerns have been raised regarding the distinction between innovation and research. While clause 5(2) specifically states that this Bill does not apply to medical research, some medical organisations have raised concerns as to how this would work in reality. The Academy of Medical Royal Colleges states:

"We do not understand the distinction between 'individual patient innovation' and 'research'. The distinction seems false and potentially dangerous. As a college president stated 'Innovation without research isn't innovation, it's more often just advertising'."

Although the Bill uses the two in harmony, it is important to raise these points and for them to be considered in Committee.

One of the main differences that separates the two is that this legislation allows doctors more freedom to modify and specifically cater treatments towards the individual they are treating. That is very important and worthwhile. Although they will not be finding a brand new cure for cancer, it allows doctors to cater treatment plans more specifically to the patient's needs and wishes. Many patients will benefit from that, and often would prefer it.

We have discussed the Bolam test. By working from the current common law Bolam test, the Bill identifies the steps a doctor can take to show that they have acted responsibly before innovating. The common law Bolam test is defined as the test

"used to determine the standard of care owed by professionals to those whom they serve, e.g. the standards of care provided to patients by doctors."

Established from the case *Bolam v. Friern hospital management committee* in 1957, it shows that if a doctor acts in accordance with a responsible body of medical opinion, he or she will not be negligent. Subsequently this standard of care test was amended—the

Bolitho amendment—to include the requirement that the doctor should have behaved in a way that “withstands logical analysis” regardless of the body of medical opinion.

This determination of whether a professional’s actions or omissions withstand logical analysis is the responsibility of the court. The Bill, through clause 3, aims to reflect as closely as possible the steps under the current common law which a responsible doctor could be expected to satisfy when innovating. However, clause 3 has caused specific concern for many of my constituents and I would like to raise some of their concerns today.

Most groups and individuals from the medical profession seem to be satisfied with the current Bolam test as a standard for regarding medical innovation, with the Royal College of Surgeons regarding it as “adequate”, so there are concerns that, instead of clarifying the legal position, clause 3 will confuse the current mechanism for judging responsible innovation.

Subsection (2)(a) requires a doctor to

“obtain the views of one or more appropriately qualified doctors in relation to the proposed medical treatment, with a view to ascertaining whether the treatment would have the support of a responsible body of medical opinion”.

This implies that the innovating doctor need only rely on an interpretation of a responsible body, and need not gain the support from a responsible body itself. In practice this might not be a problem, however, as the Bill specifically states that those supporting views must be obtained from “appropriately qualified doctors”—that is, those with appropriate expertise and experience in dealing with patients with the condition in question. It may therefore be taken that the doctor is qualified in the relevant field, which would provide reassurance. It is this clause that many of my constituents are concerned about, however.

This brings me to another point that was raised by my hon. Friend the Member for Totnes. Some of my constituents fear that the database could be used as a tool by quacks, crooks and charlatans, giving them the flexibility to use devious experimental treatments. Indeed, that concern has been echoed by the Royal College of Surgeons, which claims, in reference to clause 3(2)(a):

“This sub-clause could also provide post-hoc justification for an unethical treatment from a doctor asserting s/he sought the view of one other doctor.”

We must be sure, therefore, that appropriate safeguards are in place to protect patients from such doctors. I do not think that many of them exist, but I do not know. My hon. Friend the Member for Totnes and I might have some disagreement about that. The important point is that there needs to be a safeguard, because it is inevitable that some such doctors will exist.

**Chris Heaton-Harris:** Those safeguards do exist. A doctor has to act responsibly, and if he does not do so, the full weight of the GMC and the law will come down upon him. That situation will not change at all as a result of my Bill.

**Philip Davies:** I take my hon. Friend’s point, and we should recognise the work of the General Medical Council in ensuring that high quality people are in the profession.

Much of the debate has rightly focused on the impact that the Bill would have on doctors and the medical profession, and on whether it would give them further

freedom to innovate or whether it could be misused. However, it seems to me as a layman that much of the focus should also be on the patient. Ultimately, it is the patients who will bear the consequences of this legislation. Many of my constituents, on both sides of the debate, have contacted me to offer opposing views on the effects the Bill would have on patient safety. Some are concerned that it would move the focus from determining whether a patient’s care had been negligent to whether the doctor’s decision had been responsible.

However, the Bill would provide another layer of protection for patients in that the assessment would be carried out before the innovative treatment took place. By following the steps of the common law test, the doctor would obtain the views and support of a responsible body of medical opinion before innovating, so that they could be confident in the knowledge that they had support and would thus not be found negligent. This would of course provide reassurance to the doctor administering the innovative treatment, but more importantly, it would also be in the patient’s interest. Patients could therefore be satisfied about the treatment plan they were undergoing. Any innovative treatment plan must, by definition, come with concerns, but at least the patient could be assured that the doctor had satisfied legal and sound tests to show that the proposed treatment was responsible.

The Bill also sets out that during their research enquiries, the doctor must act and record views in a responsible manner. Therefore, if an appropriately qualified doctor were to consult on the proposed innovative treatment and express reservations about it, the innovating doctor could not disregard those reservations without being found negligent. That is an important point that should not be forgotten. Presumably, the powers of the GMC could kick in at that point to deal with any parts of the medical profession that we might not be altogether pleased with. My hon. Friend the Member for Totnes should not discount the fact that this legislation could highlight some of those cases and bring to account certain people who are hidden from such exposure at the moment. The aim of these provisions is to preserve the existing safeguards of the common law for the patient while giving the innovating doctor the additional choice of taking steps to show that they have acted in a responsible manner prior to innovating, thus aiming to encourage most doctors to do so without fear of litigation.

It is also important to touch on the possibility of unintended consequences. On Fridays, we often debate Bills that have a worthy sentiment behind them—indeed, that applies to most of the Bills that we discuss on Fridays—but they often turn out to be accompanied by unintended consequences. Some of the potential unintended consequences of this Bill have been raised with me by my constituents. One such concern is that the Bill could inadvertently undermine the work of clinical trials or discourage patients from participating in clinical trials, instead leaving doctors to focus on individuals on a case-by-case basis.

Clinical trials, by definition, test methods that aim to be of general benefit in combating a disease collectively—that is, they aim to find a common solution that can work with all, or nearly all, patients. The concern is that if doctors are encouraged to use innovative treatments when treating their individual patients, this could harm the development of research and clinical trials, as they

[Philip Davies]

may bypass the need for a regular clinical trial, leaving innovation to develop on an individual level. That seems to be a reasonable point for my constituents to have raised.

Having said that, the proposal could provide an opportunity to enhance the work of clinical trials and research. I hope that my hon. Friend the Member for Daventry will look further in Committee at any unintended consequences, and determine what, if anything, needs to be done to the Bill to prevent any harm from being done to clinical trials. It could boost clinical trials, but there is the potential for both consequences, and we must ensure that it results in a good conclusion rather than a bad one.

If a doctor were to use an innovative treatment on a patient that seemed to be successful, and subsequently recorded it on the medical database, a larger-scale clinical trial could be established to determine whether the treatment provides an inclusive solution for the disease or is suitable only for that individual. I hope that such a complementary consequence will occur as a result of the Bill, and that the understandable concerns of my constituents will be unfounded. The Bill does not create the climate for innovative treatment to begin. Doctors already have the freedom to innovate in individual cases, and that has not yet caused any difficulties or concerns for researchers or clinical trials, so there is no reason why it should do so in the future.

When considering the unintended consequences, we must also consider the unintended positive consequences, such as the one highlighted by the Royal College of Surgeons. It has stated:

“We...believe the Bill could potentially help to prevent poor practice in the private sector where decisions to try unconventional treatments are, in some rare instances, taken without adequate evidence or support from a multi-disciplinary team (MDT decision-making is less common in the private sector).”

Passing the Bill, and setting a more robust legal framework, would automatically set a precedent in the medical community for the procedures that would be expected to be followed when using innovative treatments.

**Dr Wollaston** *rose*—

**Philip Davies:** I was doing so well! However, I appear once again to have incurred the wrath of my hon. Friend.

**Dr Wollaston:** Not the wrath; I just want to point out to my hon. Friend that he is quoting selectively from the Royal College of Surgeons, which robustly opposes the Bill.

**Philip Davies:** I am only quoting what the RCS has said. My hon. Friend might want to decry my statement, but the RCS's overall conclusion on the merits of the Bill is a different issue. I am merely pointing out that it has stated that this could be a consequence of the Bill. People can draw their own conclusions from that. I would like to think that I have tried to be as even-handed as possible by outlining the potential benefits of the Bill as well as the other potential consequences. I have quoted organisations that have raised concerns. I am trying to be even-handed, whether my hon. Friend likes it or not—I suspect that she does not—and that is what the Royal College of Surgeons has said.

**Dr Wollaston:** Let me read some conclusions:

“we believe this law is unnecessary and potentially dangerous. It will absolve doctors from any liability for an experimental treatment if they followed the Bill's low standards and will make it harder for patients to redress malpractice.”

That is the conclusion of the Royal College of Surgeons of Edinburgh and it is pretty clear.

**Philip Davies:** That may well be that body's conclusion as it stands, but my point is, as I have tried to make clear, that given that it can see there are potential benefits to the Bill, which I have expressed, in dealing with poor practice in the private sector, there is an argument for getting it into Committee to see whether we can make it a Bill that it wholeheartedly supports. That may or may not be possible, but it is certainly worth having a go, given that it has said clearly that the Bill has potential benefits.

Some medical organisations and groups have expressed their concern that the Bill will have an impact on the use of research clinical trials, but that should not be a sufficient reason to stop doctors using innovative treatments on an individual level. This should not be about one or the other—as I said, we should try to do both.

I was contacted, as I am sure many other Members were, by a concerned mother who is desperate for this Bill to pass so that it can benefit her young daughter, who suffers from a rare condition. As has been pointed out, the difficulty with rare diseases and conditions is that because they are so specific, research and clinical trials are not only costly, but very time-consuming. Many people suffering from these diseases do not have this time in finding a cure. The mother who contacted me explains that her daughter, Grace, is already awaiting the commencement of two clinical trials that may, in the long run, be able to help to treat her condition. Although she is appreciative of these movements, the mother explains that if, after the six-month or 12-month clinical trial, the drug is proven to be effective, her daughter will still not be able to have access to it for several years because of the lengthy approval system used by the National Institute for Health and Care Excellence. We should not forget that in a hurry. Although I do not doubt that the trial times and approval systems that new treatment methods must go through to be considered standard medical care are necessary in order to make sure they are safe, they are far too long for many people, given their particular illness.

**Bob Stewart:** Too late.

**Philip Davies:** Absolutely, this is too late for them. Therefore, patients may be willing to use innovative treatments, or even treatments that may be used elsewhere in the world but have not been approved in the UK, because in many cases they have nothing to lose. If that is the case, doctors should be allowed, and encouraged in many respects, to make informed choices on behalf of their patients.

During my research, I contacted NICE to ask for its opinion on the Bill, but it did not really have much of one. It responded by saying:

“NICE'S Chief Executive has met with Chris Heaton-Harris to discuss the Bill and will respond constructively to any further approaches for advice and comment”.

That was NICE's comment on the Bill, so I am not sure whether NICE supports it or opposes it—I could not

get anything further out of NICE. I hope it means that NICE will be happy to work with my hon. Friend the Member for Daventry to try to make the Bill a success, although it does not say that.

Why is this Bill necessary? As we have heard, one main criticism of the Bill has been that it is unnecessary: the status quo does not currently prevent or discourage doctors from innovating, and therefore this change will not encourage further responsible innovation. The Royal College of Surgeons of Edinburgh stated:

“As existing Clinical trial regulations provide a safe and patient centred framework for innovation, there is no evidence that doctors are being deterred from testing new drugs and treatments. None of the medical Royal Colleges, patient groups or research charities have evidence that litigation, or the fear of litigation, is preventing new treatments or hampering doctors from innovating. The overwhelming experiences of our members and fellows leads us to believe that an additional, parallel structure for innovation is unnecessary”.

I hope my hon. Friend the Member for Totnes is happy with my quoting from that passage and does not claim that it is a selective quote. I am trying to be even-handed in respect of the points that people are making.

That point made by the RCSEd is echoed by other medical groups, and these points are clearly valid, but my hon. Friend, too, should be even-handed in accepting that for every organisation suggesting there is no need for these changes, probably just as many organisations and doctors support the Bill. Let us take just one. Dr Max Pemberton was reported in *The Daily Telegraph* in 2012 as supporting the Medical Innovation Bill and writing:

“It is a tragic indictment of modern medicine that innovation is too often jettisoned in favour of the status quo—not because it is in the patient’s best interest, but because of the fear of being sued. This defensive medicine is at the heart of so much clinical practice now.”

Furthermore, in its consultation response to the Medical Innovation Bill, the NHS Health Research Authority stated:

“We recognise that the fear of litigation may influence behaviours of clinicians”.

That shows not that every doctor who does not use innovative methods takes that approach because of a fear of litigation, but instead that it may be a possible cause for some doctors. I am not advocating that every doctor in the NHS is concerned about the fear of litigation, because to do so would be absurd, but although litigation may not be a huge barrier to some innovative treatments within the NHS, to totally disregard it as a problem, as many critics have done, is not justifiable. There is clearly sufficient concern about litigation for it to need addressing.

**Heidi Alexander:** What assessment has the hon. Gentleman made of the survey by the Royal College of Physicians on the views of a range of clinicians about the barriers to innovative treatment? When asked, 70% said funding was the issue, 69% said that applying for funding requires too much effort and 69% said that their employer would not grant them the time they need to assess the benefits of carrying out that innovative treatment. If a fear of legal action is so serious, why does it not appear in those survey results?

**Philip Davies:** When the survey says that employers are not allowing people to carry out the innovation, the shadow Minister may have not appreciated why that

may be the case. One reason may be the fear of litigation. She should not take it that just because it was not mentioned expressly it is not one of the factors involved in why some employers do not want that innovation to be performed by their employees. She perhaps ought to have asked: why do the employers not want to give them the time to do it? She may well find that the fear of litigation is one of the reasons.

In his speech to the Lords, Lord Saatchi summed up his Bill using the words of Professor Norman Williams, President of the Royal College of Surgeons:

“Protect the patient: nurture the innovator”.—[*Official Report, House of Lords, 27 June 2014; Vol. 754, c.1450.*]

Perhaps, therefore, this Bill is necessary in order to reassure doctors; society has become more and more litigious over the years. We even have a specifically assigned part of the NHS to deal with the cases of medical negligence claims—the NHS Litigation Authority. I am sure that if litigation was not an issue within the NHS, we would not need an NHS Litigation Authority, whose role is to manage and help resolve claims against the NHS. Despite resolving 96% of claims out of court, in order to keep legal costs low, the most recent information shows that in 2014-15 annual expenditure on NHS clinical negligence claims was £1.2 billion. For total liabilities, the figure is £28.6 billion, £16.1 billion of which is included to cover claims that have not yet been reported. These figures have increased year on year, showing that we live in a more litigious society. Between the financial years 2010-11 and 2013-14 the amount of new clinical claims rose year on year by 6%, 10.8% and 17.9% respectively. The amount has almost doubled since 2009-10, moving from 6,652 new clinical claims to 11,945 in 2013-14, and even non-clinical claims have risen from 4,074 to 4,802 in the same time. In stark contrast, the outstanding liabilities bill for 2013-14 was £26.1 billion, which was the equivalent to almost a quarter of the annual health budget for the same year. In July, the Triennial Review of the NHS Litigation Authority spoke of

“A significant challenge to the NHS LA in managing litigation on behalf of the NHS is the rising growth in clinical negligence claims.”

With a spending round forecast for 2015-16 of £1.4 billion, a 35% increase, and projections up to 2018-19 of £2.1 billion in spending on claims, it is clear that projections show that the litigation culture will continue to grow. An unintended consequence of this litigious culture is surely to act as a deterrent to medical innovation. We must therefore ensure that no doctor with the knowledge to help a patient should be deterred by fear of litigation.

It is also significant to point out that some of the most fearsome critics of this Bill have been medical negligence lawyers. However, we must be assured that they are not speaking out with vested interest—for example, how it might affect their business. In 2010-11, the NHS Litigation Authority reported total legal costs to be £257 million, £200 million of which was paid to claimant lawyers. That is a significant point to note and explains why they might be so opposed to this Bill.

**Dr Wollaston:** There tends to be an assumption in this debate that all innovation is a good thing. Some medical innovations turn out to be extremely dangerous and irresponsible. We need protections in law to protect patients from unscrupulous doctors. The reason Action

[Dr Wollaston]

against Medical Accidents and the Patients Association oppose this Bill is that they recognise that it will unravel some very important protections that are in place. We need to proceed with great caution.

**Philip Davies:** I do not think that anyone would disagree with my hon. Friend. Everybody is concerned about patient safety. I have stated at length some of the concerns that my constituents have raised about, for example, anonymity and safety. I hope that all those points will be considered by my hon. Friend to see whether anything further needs to be done in Committee. No one disagrees with that, but saying that we cannot have a Bill that does not protect patient safety is probably not the same as my perspective.

**Chris Heaton-Harris:** What my hon. Friend the Member for Totnes (Dr Wollaston) has to answer is what provision she would put in place to recognise failure of innovation. If this database is not the right way forward, what is?

**Philip Davies:** I do not propose to be the central hub of a three-way conversation involving my hon. Friends. I am sure that they are perfectly capable of sitting down in the Tea Room afterwards and going through this in some detail with each other, and they can leave me alone. They do not need me to speak on their behalf. We will leave the three-way conversation there, and I will press on.

Finally, I wish to raise the accelerated access review, which my hon. Friend the Member for Totnes mentioned. In 2014, an external review of the development, assessment and adoption of innovative medicines and medical technologies—the accelerated access review—was announced. This is expected to make recommendations to Government on speeding up access for NHS patients to cost-effective, innovative medicines, diagnostics and medical technologies. Some medical organisations have said that they wish to wait to see the recommendations of this review before implementing changes to rules around innovating treatments. I think that was the main thrust of the speech of my hon. Friend the Member for Totnes. The Royal College of Surgeons said:

“The Government’s consultation on the Accelerated Access Review recently closed and this is likely to prove a more productive route for identifying ways to encourage innovation.”

However, in an article earlier this year, my hon. Friend the Minister for Life Sciences—just to prove that I do read his articles—linked this Bill specifically to the Government’s accelerated access review. He stated:

“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.”

I look forward to the Minister’s comments in due course, but it seems to me that, rather than the accelerated access review being an alternative or something different from this Bill, the thinking is that these two things can go hand in hand with each other, and that one does not contradict the other.

Although the AAR is expected to report recommendations back to Government at the end of the year, its briefing specifically lists

“barriers that currently prevent the uptake of transformative healthcare within the NHS and the healthcare industry.”

Three areas are specifically mentioned: insufficient skills to adopt innovation; lack of leadership support for innovation; and lack of accountability for innovation. Those are just three points I have picked out from the list of areas identified for recommendations by the AAR. It seems that it is those issues that my hon. Friend’s Bill aims to target and it is therefore within the scope of what the AAR is trying to achieve.

In conclusion, this Bill attempts to provide leadership and support for innovation by setting a precedent that innovation should be encouraged and nurtured. It specifically pinpoints accountability by providing doctors with a test to satisfy prior to the beginning of any innovative treatment in such a way that satisfies doubts that the innovating is of a responsible nature. Finally, and most significantly, it sets a base for sufficient skills to adopt innovation by providing a database from which other doctors can work together and learn.

Ultimately, this Bill is not only for doctors; it must and should focus on the patients it affects. Although doubts are cast over whether the regulation to ensure innovating treatments are created responsibly, we must also consider the principle that responsibility can be satisfied before the innovating treatment is administered, thus reassuring the patient as well as the doctor. There is also a compelling argument that those patients who want innovative treatments—they may not be able to wait for lengthy research and approval systems—should be given the option to use innovative treatments. Those treatments should not be withheld because a doctor fears litigation. The patient should always be at the centre of what we do, and we should provide legislation that allows them to use the medical treatments of their choice that have that doctor approval.

I commend my hon. Friend for introducing this Bill, because he has hit on something that matters to a great deal of people. I have constituents on both sides of the argument. There are legitimate concerns, but I have heard nothing today that does not persuade me that this Bill should go forward from its Second Reading. I hope that some of the concerns that I have outlined today will be considered by my hon. Friend in Committee and that we end up with a Bill that is welcomed by those who support it and that deals with all the concerns that have been raised.

11.47 am

**Mr David Nuttall (Bury North) (Con):** As always, it is a great pleasure to follow my hon. Friend the Member for Shipley (Philip Davies), who has set out with his usual clarity the reasons why the Bill should receive the support of the House today. I too rise in support of the Bill.

I warmly congratulate my hon. Friend the Member for Daventry (Chris Heaton-Harris) on his success in coming second in the ballot for private Members’ Bills and on choosing such an important subject to bring before the House this morning. As we have seen, it is a Bill that is not without some controversy. Often, private Members’ Bills are technical and minor in nature and do not receive much public attention, but it is fair to say

that this one very much has. It brings before the House—I think that I am right in saying that it is the first time that these issues have been debated on the Floor of the House—the issues that were considered in the other place when the Lords debated the Medical Innovations Bill, which was piloted through all its stages by the noble Lord Saatchi in the previous Parliament. I note, incidentally, that the noble Lord reintroduced his Bill on 8 June. I hope that he does not fear for the possible success of this Bill; perhaps he is just hedging his bets. I certainly hope that this Bill will proceed safely through this House and arrive in the other place.

The Bill builds on the work of Lord Saatchi's Bill in that it deals, I think adequately, with some of the criticisms of it. The purpose of this Bill, as we have heard, is to promote the use by doctors of innovative medical treatments and it does that by allowing for the establishment of a database of such innovative medical treatments and by setting out the steps that doctors can take to demonstrate that they are acting responsibly in carrying out such treatments.

I have to admit at the outset that an impressive array of bodies have lined up either in outright opposition to the Bill or with at least some reservations about it. When I was considering the evidence, I had to take that into account. I had to decide whether in the light of that evidence I should simply go with the flow and decide that if all those people said that it is a bad thing, it must be a bad thing, or whether I should think about the other side of the coin. I did that, and on balance, I came down on the side of what I like to think of as my constituents' view. I believe that the Bill has the potential to improve the lives of my constituents if they are struck down by a rare disease that means that they require innovative medical treatment.

It is appropriate to try to deal with the concerns that have been raised by so many eminent bodies in the medical world. As we have heard, last year, many organisations responded to the consultation on Lord Saatchi's Bill. Like my hon. Friend the Member for Shipley, I shall try to deal with some of their concerns. The professional body for doctors, the British Medical Association, often described as the trade union for doctors, said in its consultation response to the Medical Innovation Bill:

“The BMA believes strongly in the value of innovation in medicine. Whilst the BMA would have concerns if the draft Medical Innovation Bill was to become law, if there was a need identified, we would support the exploration of other initiatives through which responsible, safe and effective innovation can be promoted to doctors.”

In its 2014 response to the consultation on that Bill, the AMRC, the Association of Medical Research Charities, a national organisation made up of 137 leading research and medical charities from across the UK that, incidentally, spends about £1.3 billion a year on research, welcomed the ambition of the Bill but was concerned about its unintended consequences. In February this year, it welcomed the idea proposed in the other place about the importance of collecting data. I am pleased to note that the Bill we are considering today appears to address that concern by establishing a database to collect the results of innovative medical treatment.

Without wanting to create confusion, I want to refer to another body that raised concerns, another AMRC—not the Association of Medical Research Charities this

time, but the Academy of Medical Royal Colleges, a body that comprises 20 medical royal colleges and faculties from across the UK and Ireland. It agrees with the idea that research and innovation are vital to the NHS, but does not support the Bill as a whole because, in its words, it is not clear what it is trying to achieve.

It is therefore a considerable challenge for my hon. Friend the Member for Daventry and those of us who support the Bill to demonstrate the need for it. To put it simply, I believe that it will provide access to innovative treatments to best meet a patient's desires and needs when other treatments might not achieve the best results. People might well ask why we need the Bill now. The law on medical negligence has not changed for decades and in those decades medical innovations have been made. The law might not have changed much, but society certainly has—it is more informed, less deferential and more litigious. The number of lawsuits filed against the NHS has doubled in five years and last year's pay out, which has also doubled in that time, was £1.2 billion. The Treasury provision for claims against the NHS has now reached £26 billion, so it is no surprise that doctors increasingly feel frightened of being sued and therefore, understandably, feel less likely to be able to innovate.

It is worth noting that back in 2013 the *Health Service Journal* stated:

“It is a popularly held view that the NHS is resistant to innovation. Despite several laws and policy directives and many successful examples of innovative approaches resulting over the years, the NHS is still seen to a late adopter of innovation—inventive but not creative.”

I believe that the Access to Medical Treatments (Innovation) Bill has the potential to counter that problem by putting innovation on a statutory footing.

NESTA, the independent charity in the UK that works to increase innovation in the UK, considered the whole question of innovation in the healthcare system in its 2014 report, “Which doctors take up promising ideas?” It highlighted the early adoption of drugs by general practitioners since 2010 to treat conditions such as diabetes, chronic constipation in women and deep vein thrombosis as well as to prevent stroke in patients with atrial fibrillation as an alternative to warfarin. The study also found that 86% of doctors found out about other innovative treatments from other doctors. It is a crucial component of this Bill that it places a responsibility on any doctor wishing to undertake innovative treatment to talk to another doctor about the proposed treatment.

NESTA'S report also recommended that there should be clear instructions on innovation to encourage early adoption, which is what I believe that the Bill aims to do, to provide reassurance, and to provide instructions to doctors to allow them to adopt life-saving treatments only when it would be in the best interests of their patients. The Bill would extend and encourage the idea sharing that is already going on between doctors and give them confidence in that process.

One of the key objections made by bodies such as the BMA was the “unproven threat” of litigation against doctors. In the summer, it was reported in the press that between 2010 and 2013 there was a 64% increase in the number of complaints to the UK medical regulator, the General Medical Council, and a 42% increase in the number of doctors struck off or suspended from the UK medical register. Let me make it clear that I believe that patient safety must be paramount. It is right that patients have

[Mr David Nuttall]

access to our world-class justice system if, sadly, things go wrong. It is, however, a curious observation to make that there is an “unproven threat” of litigation when the bill for legal fees paid out over clinical negligence claims in 2013-14 was £259 million, with many believing that there is an increasing culture of litigation.

The Royal College of Ophthalmologists expresses a common view:

“Without unequivocal GMC and NICE support, ophthalmologists are understandably concerned that they may be assuming unacceptable personal liability by using a unlicensed drug when a licensed alternative exists ... Consequently, patients may not be getting treatment when they need it and not getting the best results.”

Of course, the Bill must not be seen as a licence to experiment on patients, which is one of the more sensational claims I have seen about the Bill. I believe it clearly preserves the existing safeguards of the common law, which protect the patient while giving the doctor the option to take steps to demonstrate that the action they have taken has been taken responsibly before carrying out any innovative treatment.

As the guidance notes make clear, if another qualified doctor expresses reservations, those would have to be taken into account or, quite appropriately, the prescribing doctor could be found negligent. I do not believe that this Bill is simply a “get out of jail free” card for negligent doctors. It does not override the Bolam test, which was first set out in the leading 1957 case of *Bolam v. Friern Hospital Management Committee*. In that case Justice McNair said in his judgment that a doctor

“is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art”.

Therefore, a doctor would be negligent under the current law if they treat or manage a patient in a way in which no responsible body of doctors would have acted. That test was extended to include a requirement that they must also act in a logical manner, which is called the Bolitho test, established in the case of *Bolitho v. the City and Hackney Health Authority*.

I believe the Bill contains the appropriate reassurances that doctors cannot use it to run roughshod over the existing law. The necessary reassurance is contained in particular in clause 3(5), which explicitly states:

“Nothing in this section permits a doctor to carry out treatment for any purpose other than the best interests of the patient.”

To ram home that point clause 4(1) clearly states:

“(1) Nothing in section 3—

(a) affects any rule of the common law to the effect that a departure from the existing range of accepted medical treatments for a condition is not negligent if supported by a responsible body of medical opinion, or

(b) is to be read as limiting the circumstances in which any such rule of the common law may be relied on”.

I do not believe, therefore, that the Bill would limit redress in the event of negligence. A doctor would still be negligent if they acted in a way that was not in the best interests of their patient. However, the Bill would put into legislation a workable framework to allow responsible innovation where that would serve the best interests of the patient when a conventional treatment or lack of treatment might not meet the same goal.

I turn to the concerns of the Royal College of Surgeons, a professional membership organisation and a registered charity, which exists to advance surgical standards and improve patient care, with 20,000 members in the UK and abroad. That body has issued a parliamentary briefing on the Bill and one of its concerns is:

“The wording of the Bill confers the decision-making power on the doctor rather than the patient. There is a risk it misunderstands the doctor-patient relationship.”

The RCS may think there is such a risk, but having read the Bill and the guidance notes I fail to see that. As I have mentioned, the Bill clearly states the importance of the doctor acting only in the best interests of the patient and consideration being given to the patient’s views.

Clause 3(2) states:

“For the purposes of taking a responsible decision to depart from the existing range of accepted medical treatments for a condition, a doctor must in particular . . .

(c) obtain any consents required by law to the carrying out of the proposed treatment”.

The guidance notes for clause 3 clarify that that means that

“the Bill does not affect the legal requirement for a doctor to obtain a patient’s informed consent to any treatment proposed”.

It could not be clearer. The Bill does not affect that legal requirement for a doctor to obtain the informed consent of a patient. Indeed, only this year in the Supreme Court was the issue of consent and a patient’s understanding of treatment considered in the case of *Montgomery v. Lanarkshire Health Board*, when it was held that it would be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent on information from doctors. It was said that an adult of sound mind was entitled to decide which of the available treatments to undergo, and their consent must be obtained before treatment is undertaken. Doctors are under a duty to take reasonable care to ensure that their patients are aware of any material risks involved in proposed treatment, and of the reasonable alternatives available.

This seems to be in accordance with guidance from the General Medical Council which, as one would expect, provides lengthy guidance on the question of consent and outlines the steps a doctor should take to communicate in

“clear, simple and consistent language”

to a patient and to work on the presumption that patients have the capacity to make decisions about their own care.

The RCS is also concerned that

“the emphasis in the Bill is on proving the doctor’s decision was responsible. Courts are not asked to deal with whether a patient’s treatment has been negligent.”

I do not understand that comment. It seems to me that the courts would clearly be invited to deal with the question of negligence if something went wrong and the patient could establish that the necessary steps had not been taken by the doctor. I cannot see how the courts would not be asked to deal with whether a patient’s treatment had been negligent. As I hope I have demonstrated, the Bill makes it clear that it does not seek to override the law on negligence. The focus is all about providing a framework in which a doctor can act responsibly.

NESTA's 2014 report found that 73% of GPs surveyed said that they would be most likely to collaborate with other doctors when adopting innovations. Therefore, three out of four doctors—the vast majority—are already familiar with talking to their peers and working with them in a collaborative manner in this area. The requirement for consultation is simply what for them would be the natural course of action.

With people becoming ever more inclined to look for someone to blame when things do not turn out how they had hoped, and therefore with the threat of legal action increasing, it must be right that this House looks across the board at ways of making the vital work that our doctors do easier. I believe that allowing for responsible innovation as a means of treating patients who wish to receive such treatment is a positive way to help them.

A further concern from the BMA is that it believes doctors can already innovate as much as they need to. It states:

“The BMA has received anecdotal reports from members that funding requests for innovative treatment are submitted and approved, often on condition that the results will then be distributed, adding to the wider body of medical knowledge.”

I think that the very use of the word “anecdotal” suggests that we need a much greater degree of standardisation of approach. As far as I can see, that is precisely one of the problems that the Bill seeks to address: the fact that, at present, there is no standard basis for the recording of innovative medical treatments.

I am pleased to see that one of the changes in the Bill, compared with Lord Saatchi's Medical Innovation Bill, is the establishment and maintenance of a database, to be held and managed by the Health and Social Care Information Centre, because I believe that will provide an additional method of evidence-building for doctors. I note that the Royal College of Surgeons has suggested that a clinical society might instead manage the database, if it is limited to one area of medicine. Although that suggestion might warrant further examination, I have a couple of concerns about it.

First, taxpayers' money has gone into the establishment of the Health and Social Care Information Centre, which is an executive non-departmental body under the care of the Department of Health. It is the national provider of information, data and IT services for commissioners, analysts and clinicians in the health and social care sector, so it seems to me to be the ideal body to carry out that function. I have no doubt that taxpayers would expect it to carry out that work.

Secondly, I believe that there are considerable advantages in having a single database that doctors can consult, as the Bill proposes, rather than several. A database that shares innovative medical treatments would help improve the spread of best practice. The Government's competitiveness indicator report showed that medicines in the third year after launch were used in the United Kingdom at a level that was, on average, only one third of the average usage in the comparator countries, which included France, Germany and the United States. I believe that the creation of the database would go some way towards closing that gap.

The Academy of Medical Royal Colleges has expressed a concern that the database would be a substitute for research and might even sidestep clinical research. I take the view that the purpose of the database, which is

to be a collection of reports on individual innovative treatments outside conventional methods, would not have that consequence. The academy has also expressed concerns about the complexity of establishing a database and maintaining confidentiality. There is no doubt that the confidentiality of medical records is something that we must all take seriously. However, I do not believe that just because something is complex is grounds for us not doing it at all. I appreciate those concerns, given the roll-out of the care.data scheme, but the database proposed in the Bill would be very different. It would be much smaller in scope, in terms of the number of people it would relate to, than the care.data scheme, which has the records of virtually everyone, unless they have opted out.

The Royal College of Surgeons accepts the need for research to be made available, but it does not see the need for the database proposed in the Bill. It states:

“Surgeons in England have been the first in the world to publish their individual outcomes from surgery. We support this level of transparency in all areas of surgery including research and innovation. The College expects all researchers conducting trials, including those we directly support, to register the trial in a publicly accessible database. However, we do not see the need for a new database of innovative treatments in surgery. A number of audits in surgery already exist and it is unclear what different data this additional database would cover. It would be helpful for the Government to clarify what data it envisages collecting under this Bill”.

I am sure that the Minister will cover that in his remarks later today. I believe that most patients who benefit from a particularly innovative treatment, especially if they are the first to benefit, would have no objection to their treatment being recorded anonymously.

The Royal College of Surgeons also states:

“We believe the Secretary of State already has the power to establish a non-statutory database of innovative treatments without legislation.”

Well, if that is the case, there is nothing in the Bill for it to worry about. What is clear is that if the Secretary of State does have that power, he has not used it. Indeed, I believe that there is scope to strengthen the Bill, if it proceeds to its later stages, to clarify when the establishment of the database can be expected.

The NHS's 2011 publication “Innovation: Health and Wealth” lamented

“brilliant examples of pioneering work”

so often being “isolated examples”. As a principle of furthering innovation, therefore, surely gathering evidence in the database would be helpful to medical advancement. If treatments look like they are working, it must be right that the public and, of course, doctors know about it.

As with any new piece of legislation, we must be mindful of the cost to the public purse. That is one of the areas where I believe we still need more information at this stage. We do not yet have any real sense of what the financial implications would be, although I note that a full impact assessment is promised before the Bill goes to Committee. NHS England has forecast an annual cost increase for drugs in specialised services of 11%, rising from £2.4 billion in 2013-14 to £4.5 billion in 2019-20. I sincerely hope that the impact assessment will give some estimate of the impact that increased use of innovative treatments will have, for example on drug expenditure in the longer term.

[Mr David Nuttall]

I also believe that the impact assessment should consider what effect the Bill would have on the early access to medicines scheme, which was not in operation when the Medical Innovation Bill was first debated. The scheme allows patients to access medicines at an earlier stage in their development, following a risk-benefit assessment and subject to ongoing data collection.

A lot has been said about this Bill being potentially dangerous for patients. Yet doctors are currently prevented from carrying out reckless or dangerous treatments by the risk of proceedings being taken against them—either civil proceedings or, in the worst cases, criminal proceedings. Nothing in the Bill makes that risk any less likely. All the safeguards that are in place in law at the moment would simply remain in place.

**Chris Heaton-Harris:** I completely underline what my hon. Friend is saying. If a doctor is acting responsibly, they have nothing to fear; if they are acting irresponsibly, this Bill does not help them, and they will suffer the consequences of their actions.

**Mr Nuttall:** I am grateful that the sponsor of the Bill agrees with me on this, because it is the key point of the whole debate. Those who oppose the Bill have alleged that it will somehow put patients at risk. If that were the case, I would not be supporting it. I am supporting it because having read it carefully, and having considered all the evidence and all the views of all the professional bodies that are ranged against it, I have come to the conclusion that patients would have all the safeguards after the Bill has been passed that they do now.

The Bill has the potential to increase and improve the range of medical treatments available to my constituents.

**Philip Davies:** My hon. Friend is setting out a very good case. Does he accept, though, that the concerns of some of my constituents that I outlined are valid, and that in Committee we should look at ways in which they can be dealt with if necessary? We should not just accept the Bill in its current state; we should look to see whether we can improve it in Committee.

**Mr Nuttall:** I am grateful to my hon. Friend. The arguments are finely balanced. As he said, he has constituents who support the Bill and constituents who are against it. If the Bill receives its Second Reading, as I hope it will, the concerns of those who have reservations about it, and those who go further and are outright opposed to it, can be considered in detail in Committee and, if possible, reflected and taken into account by way of appropriate amendments at that stage or on Report.

**Chris Heaton-Harris:** I assure my hon. Friend and all other Members who have spoken, and everybody I have been in consultation with to get the Bill to this stage, that should it get through its Second Reading, I will continue to consult, to listen, to talk to and to take advice from all organisations with an interest to make sure that we take into account and deal with as many as possible of the concerns outlined by him, by other hon. Friends, and by Opposition Members.

**Mr Nuttall:** I hope that my hon. Friend's intervention will go some way towards satisfying the concerns of those who are opposed to the Bill.

From what we have heard, there seems to be a general acceptance of the principle in the Bill that there should be greater access to medical innovation. Even looking at the views of the various medical bodies—an impressive array, as I said—the best interpretation is that some are outright opposed and others are ambiguous. Either way, they all share the view that medical innovation is a good thing. It seems to me that the devil is in the detail. I hope that my hon. Friend's confirmation that if the Bill proceeds he will be generous in speaking to people and looking at all possible ways of dealing with their concerns will persuade the House to give it a Second Reading.

Research and innovation are crucial to the continued success of healthcare. The NHS faces increasing demands: a growing population with an increasing lifespan, which is a good thing; an increase in its own capability, fuelled by advances in knowledge, science and technology; and ever-increasing expectations from the public it serves. We should not shy away from new ideas that put the patient first and offer chances that they may not otherwise have. This Bill will increase the likelihood of life-saving solutions being found where they did not previously exist. It will mean more choice for patients—for my constituents. It will provide doctors with a mechanism to enable them to use innovative treatments giving them the best possible chance to do what they do best—help patients. I support the Bill and trust it will receive its Second Reading.

12.27 pm

**The Parliamentary Under-Secretary of State for Life Sciences (George Freeman):** It is a great pleasure, Madam Deputy Speaker, to serve under your stewardship today. I am usually to be found in my constituency on a Friday, unlike some colleagues who are more often here on Fridays, and it is a great pleasure to be able to debate private Members' business and respond to this very important debate on this very important subject.

I congratulate my hon. Friend the Member for Daventry (Chris Heaton-Harris), who has had a very busy summer trying to work with the huge number of people who have taken an interest in this Bill to try to get it to a place where it can command majority support. He has been tireless in that work. He will know from this debate that there is more to do, but I know he has the appetite for it. That is not least because he and many Members across the House often see from their constituency mailboxes, as well as from their own family experiences, the great pressure there is from patients, particularly those with a diagnosis for which there is no known treatment, for us in Government to do everything we can to accelerate access to the growing range of innovations. I am privileged to be the Minister responsible for the sector that is bringing those innovations to us.

I want to pay tribute to one or two other colleagues in this House and in the other place. The noble Lord Saatchi built up the original momentum and head of steam with his Bill in the other place during the previous Parliament. My hon. Friend has sought to develop that in his Bill, which is in many ways different but trying to achieve the same ends.

My hon. Friend the Member for Tewkesbury (Mr Robertson) has been a vocal supporter of the great campaigner Les Halpin, who was diagnosed with a terminal disease and launched the Empower: Access to

Medicine campaign. They have both been very vocal in supporting not only this Bill but the wider innovation agenda.

I also want to take this opportunity to pay tribute to the patients who suffer from terminal and untreated diseases, as well as their families, carers and loved ones. As the Minister for Life Sciences, it often falls to me to sign off very difficult decisions by NICE and NHS England. In the past six to nine months, I have met many people who are passionate about those of us in government and in Parliament doing everything we can to accelerate access to innovation. For all those reasons, this debate is timely and important.

An awful lot of points have been raised both this morning and in the months leading up to the Bill's Second Reading, and I will deal as substantially as I can with the issues to which the Bill has given rise. I want to say something about the wider context in which the Bill seeks to accelerate innovation, not least the things the Government are already doing. I want to say something about the problem and, indeed, the opportunity for the UK and for patients and the NHS. Some colleagues have hinted at the ambiguity in their minds about the problem the Bill seeks to solve, so I want to shed some light on what I think the problem is that we are trying to solve. Before one legislates, it is never a bad thing to be clear about the problem.

I then want to say something about the importance of public support for and patient trust in our clinical research and medical landscape. We lead the world in medical research: the NHS in the UK is globally recognised as a leader and we set the gold standard in ethical, regulatory and other aspects of clinical research. It is absolutely vital that the Bill reinforces and supports that, and does not in any way, with or without reason, alarm or undermine public trust and confidence in our NHS and our research infrastructure. To that end, I also want to look at some of the protections proposed by the Bill and the safeguards that are already in place, to address some of the key concerns raised, to highlight where the Bill is supported and to set out the Government's position.

I will start by addressing the context. Colleagues have touched on the UK's glorious history in medical innovation—from amputation in the 18th and 19th centuries to penicillin, bypass surgery, transplantation, the discovery of DNA and pioneering discoveries on genomics and digital health. Barely a month goes by without this country making another significant step forward in biomedical science. On any indicator, but particularly on the numbers of patents and learned papers, we punch well above our weight. We are the global leader on medical science and research per capita.

The Government place a very high priority on the promotion of medical innovation, not least because the context of our economy and the very urgent challenges faced by our health service demand that we significantly increase the pace at which we adopt innovation. The "Five Year Forward View" by the chief executive and the management team of NHS England, which landed on the Government's doormat a year ago, powerfully sets out the scale of that challenge.

By the end of this Parliament, demand for healthcare will be rising fast. There are 1 million more pensioners in 2015 than there were in 2010, and there will be 1 million more in 2020, while thousands of people are

now living to over 85. Those who heard the piece on Radio 4 this morning will know that we now have thousands of people living to over 100. Indeed, we have the oldest citizen of the globe in Britain: she is 114 today. Such a situation is a magnificent tribute to the extraordinary advances of our biomedical, life science and medical sector, but it of course creates added pressures on our health system because in the last decades of life our health demand rises exponentially.

The NHS has set out that, as a result of that rising demand and of the obesity and dementia epidemics in our society, health will require an extra £30 billion by the end of this Parliament. NHS England has stated that it can deal with £22 billion of that through the profound adoption of innovation to change care pathways—keeping people out of hospital, diagnosing earlier, treating smarter and embracing digital, genomic and a range of other technologies—but it has also stated that the NHS will need more money. I am delighted to be a Minister in a Government who immediately said we would put in the necessary money.

We will earn some of that money, not least through our leadership in the medical innovation and life sciences space. That is why the Prime Minister, the Chancellor and leading Ministers in the former coalition Government set out in 2011 the UK's groundbreaking life science strategy. The Prime Minister launched it in December 2011, and it is now my great privilege to be the Minister with responsibility for its implementation. At the heart of the strategy is the belief that by profoundly integrating our NHS healthcare delivery system with our research and innovation sector we can achieve a win-win-win situation: we can improve healthcare productivity by embracing new technologies; we can do so in a way that drives investment into the UK; and we can make this country as much a leading pioneer in the research, development and commercialisation of life and health science research in the 21st century as it was in the 20th century.

As the Minister for Life Sciences in the Department of Health in combination, for the first time, with the Department for Business, Innovation and Skills, my mission is clear: to accelerate the uptake of innovation in our health system and to unleash the power of our health system as a research engine. Essentially, the model is based on two cylinders of support. We have traditionally supported our life science and healthcare innovation sector through BIS, with a set of policies on investing in deep science, translational infrastructure and skills, but we have now decided that in the 21st century we must integrate that with our health service. The second cylinder is the health system, which is pumping in access to data on the genome or tissues and to our £1 billion a year clinical research infrastructure. Just as importantly—this brings us to the nub of the Bill—it is accelerating the uptake of innovation in our health service. That is my mission and that of the Department of Health's directorate of innovation, growth and technology, which the Government created at the same time as they set up my ministerial role.

Innovation is an urgent priority for this Government and, indeed, for all western Governments tackling the profound healthcare challenges caused by growing demand. That is why, during the past five years and during this Parliament, the NHS has made it such a priority. As other colleagues have mentioned, the essence of the

[George Freeman]

strategy is set out in the NHS report on “Innovation, Health and Wealth”, which captures the mission I have described and sets out a huge range of initiatives designed to drive the uptake of innovation across the system. You will be relieved to hear, Madam Deputy Speaker, that I will not list those initiatives, because there are a huge number of them, but I reassure the House that we are monitoring their delivery closely. We have launched the innovation scorecard, and through the digitisation of CCG scorecards, we will shortly build in an uptake of innovation metric, so that patients and users across the system can begin to see from heat maps which CCGs or parts of our NHS are the most innovative.

The fundamental challenge remains that to be a competitive life and health science research economy and to drive innovation into our health system in the way we need, we must take a more profound approach to tackle the challenges and barriers. That is why I launched the accelerated access review last year, which seeks to address three important questions at the heart of this agenda. There is a new landscape because the model for the development of drugs is undergoing a profound change. The 20th-century model is very silo-ed: there is deep research on a drug in universities; it is spun out to companies, if they are lucky; it is funded and acquired by a pharmaceutical company, if they are lucky; and there is a 15-year development pathway—the average drug takes more than \$2 billion and 15 years to develop—before it is brought back to the oh-so-patient patient waiting at the end of the chain. Our strategy recognises that that is too long and too expensive for patients, the industry and the NHS.

That problem is also an opportunity, because the profound advances in genomics and informatics mean that we are getting to a point where we no longer have to take that amount of time to de-risk the development pathway. In an era when a genomic biomarker can predict which patient will respond to a drug and which cohorts of patients will develop certain variations of a disease, we can dramatically accelerate the development of drugs and our ability to get innovations to patients in a way that hugely reduces the cost and the risk.

We are asking three questions at the heart of the accelerated access review, which a number of colleagues have asked about. First, what can we do to make it easier and quicker for innovators outside our health system to get clinical validation in the NHS? That would unleash not only the power of our £1 billion-a-year clinical research infrastructure, but the power of our NHS, which treats millions of patients every month, to act as an innovation platform, day in, day out.

Secondly, how do the new technologies of genomics and informatics change the way in which NICE and the regulators can assess, reimburse and work out the health economics in respect of innovations in the new landscape? When a drug comes to the system with a companion diagnostic and has an absolute guarantee of working in certain patients on the back of a genomic biomarker, it profoundly changes the way in which NICE is able to assess the drug. It unlocks the possibility of targeting drugs much more quickly at the right patients and changing the way in which we reimburse. We will be able to reimburse on the basis not of an average quality of life adjusted year, a notional price or a calculation of

the health economic benefit for the average patient, but of real value in our health economy for different patient groups who respond in different ways to different drugs. Just as NICE took the lead in the 20th-century model of health economics, I want it to lead in the 21st century and to embrace the new technologies.

Thirdly—and this goes to the heart of the space in which the Bill is positioned—what can we do, when we have a proven innovation, to reduce the barriers to rolling it out across the system? The NHS has a mixed track record on innovation. On the one hand, it has pioneered brilliantly, particularly in our specialist tertiary research centres, innovations that have changed global medicine, some of which I have listed. On the other hand, we have been poor at rolling out innovations in our own system across the breadth of the country. Improving that is a key ambition of the AAR.

The Bill comes in the context of our asking what we can do to incentivise the uptake of best practice across the NHS. I will say a little more about the difference between innovation and research in a moment. The Bill’s focus on supporting 21st-century medics to be more aware of what is available to them when prescribing and its insistence on their sovereignty and freedom in making clinical judgments as professionals are important and helpful.

The glorious history of medical innovation has relied on profound scientific breakthroughs, some of which I have listed, but it also contains a long-standing pattern of unpredictable and accidental innovations, many of which have been profound and have delivered substantial benefits to patients. The discovery of penicillin was an observational accident by an inquiring mind. More recently—you may well know about this, Madam Deputy Speaker—Viagra was developed as a heart treatment and the discovery of the benefit that it is now used for was completely accidental. The company in question discovered that none of the sachets of the drug that it had sent out to patients for the trial, some of which are normally returned at the end of the trial with a medical form, were returned. That was quite striking to the company and when it asked why they had not been returned, it discovered that the drug had a completely different benefit, which led to its being relicensed and becoming the popular drug that it is today. Again, that completely accidental discovery has benefited millions of patients. It is important to understand that accident and observation have always played a powerful role in our leadership of life sciences and research.

I will have a go at defining the problem and the opportunity that the Bill rightly tries to address. I do not for a minute pretend that it is simple, as has been highlighted in this debate. If the Bill goes into Committee, I suspect that this is something that the Committee will want to look at. I suggest that we should be looking at three or four issues. The first is the barriers to the uptake of innovation in our health system. There are a number of barriers and I will not delay the House with a long exposition of them all. Suffice it to say that they are in part organisational, in part financial and in part cultural.

The most profound barrier to the uptake of innovation is that innovating in our health system normally requires the permission of an awful lot of people—not always clinical permission, but purchasing permission and procurement permission. As the health service rightly

seeks to drive procurement efficiencies and control spending, we often inadvertently make it harder for people to innovate with treatments.

The biggest barrier in terms of substantial innovation in care pathways tends to be that the person who is asked to make the initial investment in a preventive treatment or any new treatment is often not the person on whose budget the benefits of improved treatment or outcomes will fall. The AAR is looking at that silo-ed budgeting and other organisational, financial and cultural barriers to the uptake of innovation in the system.

Procurement is an important factor. As part of Lord Carter's review of procurement in the NHS and the Department's efficiency drive, we are looking at how we can use the single purchaser advantage of the NHS to drive up procurement efficiencies and at how we can make it easier for front-line clinicians to innovate by making procurement decisions that drive efficiencies into their own local health economy, at whatever scale that is.

There is a barrier to innovation in respect of data. Information on innovative treatments and their benefits and on the improvements that different parts of the system are able to deliver is not always allowed to flow through our health system. Even today, there are huge differentials of efficiency and clinical outcome in different therapeutic areas that are not properly picked up or measured. That is part of what the programme of accountability and transparency that the Secretary of State and I are running through the CCG monitoring exercise and My NHS is intended to tackle.

Quite soon, we think that patients will want to click on My NHS and ask us the right questions, such as, "Why is my mother's clinical outcome in Norfolk three or four times better or worse than my mother-in-law's clinical prospects in London?" I do not for a minute seek to denigrate Norfolk's health service—it is doing magnificently well—but my point is that there are regional variations. We want the public and patients to be aware of them and to ask their CCGs, the Government and their health professionals why they are there and what can be done to tackle them.

There have been a number of questions today about the fear of litigation. The Government's consultation on the original Medical Innovation Bill highlighted some concerns about litigation. One difficulty is that much of the early reporting and discussion on that Bill created the impression that that was the problem that it sought to highlight. Of course, the picture is more subtle, difficult and complex than that, but it is worth highlighting that, as a number of colleagues have pointed out, the cost of clinical negligence claims to our health service is substantial. The latest figures that I have to hand state that in 2012-13, 10,000 claims were made and the payments totalled £1.2 billion. It is true that many of those claims related not to innovation, but to obstetrics and other standard procedures. However, the NHS is conscious of that bill and in most of our hospitals and other institutions, there is an acute awareness that we live in an ever more litigious society. Heaven forbid that we should ever become like America, where litigation is a daily routine in the health system, but we need to be aware of the risk. There is a legitimate fear among clinicians of doing anything that might trigger a reasonable or unreasonable claim for litigation.

**Dr Wollaston:** How much of the litigation cost is related to complaints about innovative treatments?

**George Freeman:** Most of the cases are a result of other contexts—as my hon. Friend will know, obstetrics is a big part of that—rather than innovation. I am happy to write to her with the actual figure as I do not have it to hand. My point is that the fear of litigation runs through the system.

I recently spoke to a senior paediatric consultant who is neutral about this Bill—he is neither a passionate advocate nor an opponent of it. He observed that over the past 20 or 30 years, a gradual conservatism has crept into clinical practice. When I asked what he thought drove that, he mentioned three things. First, ever tighter procurement control makes it harder to do things differently. Secondly, there is a subtly growing fear of negligence, and a lack of clear data information and guidance on what is available. Thirdly, many clinicians find it easier to stick to normal practice, and that is what the Bill seeks to tackle.

**Heidi Alexander:** The Minister and the hon. Member for Daventry (Chris Heaton-Harris) have referred to anecdotal remarks about fear of litigation being a barrier to medical innovation. Can the Minister set out his evidence that that is a widespread concern and genuinely prevents doctors from innovating and prescribing new treatments?

**George Freeman:** The hon. Lady makes an important point because it is difficult to quantify the impact of that fear. I have gone out of my way to make clear that I do not think that issue is a primary concern, and that the organisational, cultural and financial barriers are higher concerns. That is partly what is difficult about the Bill. It gives the impression that fear of litigation is the big problem, whereas anecdotally I hear from leading clinicians—who, as I said, are not particularly for or against the Bill—that it is one of a number of issues in a complex landscape.

I am conscious of the time, so I will turn to the critical importance of patient and public trust and confidence in our clinical research infrastructure and NHS. The UK leads in clinical trials and in regulation through NICE, the Medicines and Healthcare Products Regulatory Agency, and our ethical framework. I am delighted that over the past four or five years we have made substantial improvements in recruiting more patients into trials. In 2014-15 the National Institute for Health Research—the jewel in the crown of NHS research—had 4,934 studies running, and last year we recruited 52 global first patients into trials. That is a key indicator of our leadership in the most innovative areas of medicine.

The MHRA has approved more than 80 first-in-human studies, and the NHS is becoming a leader in the forefront of that model of research, just as it was in the earlier part of the 20th century. It is also important to consider our leadership in regulation, ethics and approval, not least because those are major exports for this country. Over the next few decades, rapidly emerging economies will be looking for a lead from NICE, MHRA and our clinical trials infrastructure, and it is crucial to have a strong patient voice, and to maintain and develop patient trust. Central to my mission is to bring forward such development and put a stronger patient voice at the heart of our research landscape.

[George Freeman]

Patient empowerment through technology and access to innovation are key themes of our mission and work, and medical research charities have a huge role to play. In this new research landscape in which genomic information, patient data, records and medical histories become such key assets for research, the question is who will control that information. I think that we should build a policy landscape on the notion that such information and assets ultimately belong to the patient, and that the sovereignty of their relationship with their clinician should remain sacrosanct.

To answer an earlier question from the hon. Member for Lewisham East (Heidi Alexander), there is nothing in the Government's plans to make such a database available to the public and drive the sort of quackery charter that I know the Chair of the Health Committee is worried about. We do not want to change the law that prevents pharmaceutical companies from talking to patients directly, and it is important that recruitment into clinical trials and access to innovation is done through patients and their clinicians.

Charities will have an increasingly important role. Cancer Research UK leads in much of this area, and many smaller charities are becoming strong advocates for their patients and collecting data. With the rise of apps and digital technologies, charities will soon create portals for patients to get involved in research communities, and work with industry and academics to drive and accelerate innovation.

**Dr Wollaston:** Does the Minister accept that all the bodies he has referred to, as well as the Association of Medical Research Charities, the Academy of Medical Sciences and the Academy of Medical Royal Colleges, have expressed concern that the Bill could undermine recruitment to clinical trials? That is an important point and I hope that the Minister will accept that it is a genuine concern.

**George Freeman:** I was addressing that point to make it clear that I and the Government take strongly the need to ensure that the Bill does not undermine patient support in any way. I have heard some of those concerns, and if the Bill goes to Committee it is important to address them. It is also crucial to protect and support the sovereignty of clinicians to look after their patients, and to do as much as possible to try to liberate them from the burden of unnecessary bureaucracy and excessive targets. We must remind clinicians that they have freedoms in law and a vocational mission to do whatever they think is best for their patients.

On safeguards and protections let me make three important points about the Bill. I have taken advice from counsel, and I will respond to a number of questions raised by colleagues. As currently drafted the Bill provides no change to existing protections on medical negligence, and that is important. It sets out the power to create a database, and a mechanism to make clear to clinicians how they can demonstrate compliance with existing legal protection—the Bolam test has been referred to—and allow innovations to be recorded for the benefit of other clinicians and their patients. Importantly for the Government, that does not change existing protections on medical negligence, and it is crucial to understand that. Secondly, the Bill does not change our gold standard

regulatory and ethical framework for clinical research. The Bill is not about research; it is about reinforcing freedoms for clinicians and how they prescribe. I will return to the detail of that in a minute.

**Heidi Alexander:** The Minister says that the Bill does not change the law on medical negligence but sets up an alternative pathway or framework. Does he accept that that could confuse matters?

**George Freeman:** That is an important question. The Bill does not change the legal framework on negligence; it merely seeks to clarify matters for those doctors who understand that they have the freedom to innovate but fear that current understanding in law about the test is not clear enough. It sets out an agreed, statutorily approved procedure to reassure doctors that if they follow that procedure, they will be covered by existing negligence and liability protection that the Bill does not change in any way. The hon. Lady's second point is about whether people understand that, and whether there is a risk of the Bill inadvertently triggering fear. That is an important point, and it behoves everyone to ensure that we discuss it in the right way.

I have been shocked by some—not all—of the briefings, one of which referred to this being a “concentration camp” or a “Mengele” charter. Such unhelpful language triggers unhelpful media interest and will alarm patients completely unnecessarily. All the provisions in the Bill reinforce and endorse existing safeguards on the use of data and regulatory protection.

Time is short, but I want address the concerns that have been raised by hon. Members across the House. My hon. Friend the Member for Daventry gave a powerful speech and my hon. Friend the Member for Totnes (Dr Wollaston) made a number of interventions. There were contributions from my hon. Friends the Members for Beckenham (Bob Stewart), for Gainsborough (Sir Edward Leigh), for Bury North (Mr Nuttall) for Shipley (Philip Davies) and for Aldridge-Brownhills (Wendy Morton), and the hon. Members for Lewisham East and for Bolsover (Mr Skinner). I would like to take the opportunity to welcome the shadow Secretary of State to her post. I value hugely her offer to work on the Bill in a cross-party spirit and to deal with the issues raised. If the Bill goes to Committee, that will be an important offer. I am certainly happy to take it up and see, in a cross-party spirit, whether we can help to ensure that it does not trigger the doubts that she and other hon. Members have expressed concern about.

I want to address the specific concerns raised by my hon. Friend the Member for Totnes. She is a very distinguished Chairman of the Health Committee, as well as a doctor. For those reasons, they merit proper scrutiny and attention. I apologise to her if I am unable to deal with all of her concerns, but I will try to address them all.

The first concern is that the Bill is based on a false premise, which is that doctors are afraid to innovate because of fear of litigation. I reaffirm that the Department of Health's consultation on the previous Medical Innovation Bill revealed that some doctors do find the threat of litigation to be a block to innovation, although that was not a universal view and I do not want to suggest in any way that it is the principal barrier. This Bill is aimed at reassuring those doctors who feel unable to innovate due to concerns about litigation. It sets out a series of

steps that doctors can choose to take when innovating, to give them confidence that they have acted responsibly. I read the Bill again this morning and I am happy to highlight some of the key protections in it.

**Dr Wollaston:** Will the Minister clarify that the vast majority of medical bodies feel that it is not a barrier to innovation, and that there are some important points where we need to protect patients from irresponsible innovation? We have to accept that there is a risk inherent in going down a route that would make that possible.

**George Freeman:** My hon. Friend makes an important point about public trust, and patient safety and confidence. I do not want to detain the House by reading the relevant provisions in the Bill. I think my hon. Friend has tried, during the summer, to draft a Bill that deals with a number of those concerns. She makes the important point that if the Bill is inadvertently undermining public trust and confidence, that is in itself a problem. That is partly a function of how people discuss it and it is regrettable that the Bill has generated the level of antagonism it has, but she makes an important point that we should look at those specific measures and ensure we tackle the issues and concerns that leading doctors have raised.

**Dr Wollaston:** My initial point was whether the Minister would accept that the overwhelming number of respondents felt that fear of litigation was not the barrier?

**George Freeman:** I made the point earlier that the barriers to access of innovation are much broader than the fear of litigation, and I am happy to reinforce that.

**Mr Steve Baker (Wycombe) (Con):** The Minister will know that in the treatment of wet AMD Lucentis costs £700 an injection and Avastin £60. Does he think the Bill could help clinicians use Avastin to treat wet AMD, thereby saving the NHS, I understand, some £84 million?

**George Freeman:** My hon. Friend is quick to leap on to a very important point. The answer is no, because in law we have an important provision to protect people who invest billions of pounds in developing new innovations. Clinicians are free to use alternative off-label drugs where there is evidence they work, but not on the basis of cost. We have a presumption in law that where a drug is licensed or on patent for a particular indication, which is the protection for the company that has invested to bring the drug to market, we allow an alternative to be used only where there is clinical evidence, not on cost grounds. The price falls dramatically when drugs come off patent and the generics industry picks them up. There is price protection for a short period of patent life to create the incentive for people to make the extraordinary investments up front. We then get the benefit of cheap drugs through the generics sector.

**Mr Baker:** The Minister raises a critical point. I am concerned that cost grounds do matter and that some people might be going without early treatment for wet AMD, because they cannot, for a range of reasons, access Avastin. My concern is that people might be going untreated for wet AMD at a point when the relevant drug, Avastin, might help them more than Lucentis at a later stage.

**George Freeman:** My hon. Friend makes an important point. The NICE clinical guidance to NHS England, after carrying out a health technology appraisal, is binding. NHS England has a duty to implement it across the system. There is an issue about how quickly different parts of the NHS implement guidance and how quickly innovative drugs are rolled out. Another Bill going through the House will be looking at what can be done to support the use of off-label drugs. My position on that is that the most profound barrier to the adoption of off-label drugs is in fact information for clinicians on the clinical benefits of an off-label indication. It is the clinical evidence that provides the basis on which they are perfectly free at the moment to use alternative drugs.

Let me address the other points raised by my hon. Friend the Member for Totnes, the Chairman of the Select Committee. She expressed concern that the Bill would undermine research and clinical trials. That is an important point. I stress that the Bill, as drafted, does not cover clinical trials, which are regulated by the MHRA and the HRA from a scientific, safety and ethical viewpoint. Rightly, the Bill does not stray into that regulatory environment. I confirm that we would be concerned if it did. It does not relate to formal clinical research, only to clinicians' duties to their care of individual patients. If the database is got right, we think it could contribute to the sum of healthcare knowledge by collecting information on innovations and their success or not.

My hon. Friend said that she fears the Bill would do more harm than good. I merely point out that the chief medical officer for England supported the final version of the Medical Innovation Bill, which ran out of time in the House of Lords at the end of the previous Parliament. The national clinical director for NHS England confirmed that he had no concerns about patients' safety with regard to that Bill. Hon. Members may debate whether the Bill is needed, but it is really important to understand that we are clear that the Bill in no way damages patient safety. The test of responsibility under the Bill is intended to reflect absolutely the requirement of the Bolam test, which has been the gold standard for decades. I highlight that a doctor has to obtain any consents required by law when taking a decision to part from the existing range of medical treatments. The Bill expressly provides that a doctor must have regard in particular to the requirements of patient safety. Under both existing common law and the Bill, the doctor would need to show that they had acted responsibly. There is absolutely no escape for a negligent doctor under the Bill. The Bill seeks to give doctors access to the database as a source of learning—doctors, not patients. We hope that if the database has got right it could help to drive both innovation and information through the system.

My hon. Friend set out some concerns about safeguards for patients. I reiterate that the Government are clear that the negligence provisions in the Bill do not provide any immunity to irresponsible doctors. It would be irresponsible for anyone to suggest that they do. I want to make that point very clearly from the Dispatch Box and to reassure her that in our view the Bill does not remove any of the current safeguards in place to protect patients' safety. Our view is that the Bill does not apply a weaker test to a doctor's decision to innovate than the existing law on clinical negligence.

[George Freeman]

My hon. Friend raised points about the rigour of the database, which I will come on to in a moment. A number of other concerns have been raised. I want to run quickly through, in two batches, the concerns about the database and about negligence and legal protections. Colleagues have asked whether there is really a need for legislation for a database. I confirm that the Bill gives power to the Secretary of State to confer functions on the Health and Social Care Information Centre in relation to the establishment of a database. Legislation enables provision to be made for the disclosure of information from the databases, ensuring that the HSCIC has the necessary powers to disclose information and that appropriate safeguards are in place. Were the Bill to become law, we would obviously consult on regulations setting out the detail of how the database would be constructed.

**Heidi Alexander:** Does that power not exist under section 254 of the Health and Social Care Act 2012?

**George Freeman:** The hon. Lady might be surprised to know I do not have that section right in front of me, but I will happily come back to her. The Bill would allow a database to be created for specific purposes. It is not for me to judge the merits of the wording of different private Members' Bills, but this would not be the first such Bill to command the authority of the House and then to be rewritten to put into effect the ambitions it sets out. I think, however, that the Bill goes a lot further than the existing powers in requiring us to consider a database with specific functions linked to providing a mechanism of statutory protections for clinicians under existing law. We understand what it is trying to achieve, although it is complex in that it does not change the legal protections but merely sets out a particular runway in which clinicians can have confidence.

Questions have been asked about how the database will work. As I have said, if the Bill becomes law, we will want to consult on regulations, but it is intended to be principally for the use of medical practitioners, not patients. We would not support the Bill if it were to be a database—my hon. Friend the Chair of the Select Committee expressed concern about that point—providing support for companies, quacks and unregulated providers to contact patients directly and to validate illegitimate innovations. It is for clinicians to record the innovations that they, in their professional judgment, have decided to adopt. We would envisage the database being used to flag a treatment as innovative, meaning it would be coded and picked up by the HSCIC, allowing us to form a national database.

Questions have been asked about who would submit information to the database. As with all data provisions, patient confidentiality will absolutely be protected. I would envisage the detail of who could access information, and in what circumstances, being a source of substantial discussion, if and when we came to pass regulations. I stress, however, that it would not be used by patients. We could not support that.

Questions have also been asked about who would determine which groups could get information. It is designed for clinicians, the HSCIC and regulators. At the moment, a doctor passing information to the HSCIC

is bound by the common law duty of confidentiality and their professional obligations. The HSCIC would need to be satisfied that any disclosure was in accordance with the law, including the Data Protection Act 1998.

Hon. Members asked about funding. The exact level of grant in aid required would be subject to additional scoping by the HSCIC, and if the House decided to proceed, we would need to come back with the details. Hon. Members also asked whether the treatments in the database would be flagged with some kitemark or advert. The Government would oppose this being used as a marketing tool. Such flagging by means of kitemarks, being regulated differently, would not be appropriate. We want a database focused on helping doctors to see what other clinicians have decided is an appropriate treatment. We would see the database not as a process of quality assurance, but as a way for doctors to learn from and see transparently what other doctors have decided is an appropriate treatment.

I turn quickly to the negligence and regulatory questions. Colleagues have asked whether the negligence provisions provide another way for doctors to carry out research, circumventing the usual safeguards. The answer is an emphatic no. The Bill would apply not to research, but only to individual treatment decisions, as clarified in clause 5(2). Research is highly regulated—rightly so—by the Health Research Authority and the MHRA. Research studies cannot go ahead without ethical approval overseen by the HRA, and research that involves clinical trials and the investigation of medicinal products must be thus authorised. The Bill is concerned with innovations in individual treatments by clinicians. The results of an innovation might trigger further research—I think my hon. Friend the Member for Daventry envisages the database triggering questions such as, “Well, if one or two clinicians think this is an appropriate innovation, shouldn't we look at whether it might be more widely applicable?”—but that would then take it into the more formal jurisdiction of a research application.

Hon. Members asked whether the Bill would relate to clinical trials. It is important to note that it does not cover clinical trials, which are regulated by the MHRA and the HRA. We would not want the Bill to stray into that territory and risk undermining that international gold mark of UK clinical trials infrastructure. It has been asked whether innovation is just the same as research. I strongly believe they are not the same thing, although they are often confused. They are closely related, but they are not the same thing. Research is highly regulated; innovation is the application of different ways of practising medicine, which clinicians have always done. That is partly what makes it hard to regulate and why the Bill has raised the questions it has.

Hon. Members asked whether patients would be asked for their consent before being given an innovative treatment. Yes, patients would have to give their consent. There is no change to the law of consent, which requires patients to provide informed and voluntary consent to any treatment offered. Colleagues have also asked whether the Government support the Bill in the light of the concerns raised by the medical profession about its impact on patient safety. I will confirm the Government's position in a moment, but we believe it is an important and timely debate for the reasons I have set out, and we support the intentions behind the Bill. My hon. Friend has engaged with those who have raised concerns, and if

the Bill goes to Committee, issues raised today would need to be tackled, but in the view of the Government and parliamentary counsel it does 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. It simply seeks to provide clarity via a mechanism by which doctors can be sure they are complying with that test.

**Heidi Alexander:** As I understand it, the current test requires a doctor to seek the advice and medical opinion of a responsible body, while the arrangements in the Bill require them to seek someone else's view on whether such a responsible body holds an opinion about the safety of treatment. I think those two things are slightly different. Does the Minister share that concern?

**George Freeman:** The hon. Lady raises an interesting point. I am just looking at clause 3(2):

“For the purposes of taking a responsible decision to depart from the existing range of accepted medical treatments for a condition, a doctor must in particular—

(a) obtain the views of one or more appropriately qualified doctors in relation to the proposed medical treatment, with a view to ascertaining whether the treatment would have the support of a responsible body of medical opinion,

(b) take full account of the views obtained... (and do so in a way in which any responsible doctor would be expected to take account of...),

(c) obtain any consents required by law”,  
including

(d)(i) any opinions or requests expressed by or in relation to the patient,

(ii) the risks and benefits”

and to

(e) take such other steps as are necessary to secure that the decision is made in a way that is accountable and transparent.”

Let me repeat that we would not even countenance supporting the Bill if its intention were in any way to change the basic test of clinical professionalism to which every clinician is subject. They remain subject to all the professional safeguards of the GMC and other regulatory bodies and clinical negligence law. The Bill merely seeks to put in place one particular mechanism on which doctors can rely to be clear that the innovation they propose is in accordance with the law. There is a danger of thinking of that if this Bill ever became law, it would be the last and final word on the area of medical innovation. It would absolutely not be; it is a small contribution to a vast canon of common law and practice that—importantly for the Government—does not change.

Counsel's advice to us has been very clear that the negligence provisions provide no immunity to irresponsible doctors. Under both existing common law and this Bill's provisions, doctors will need to show that they have acted responsibly. There will be no escape for a negligent doctor.

Members have asked whether the Bill will allow doctors to prescribe untested medicines. It is important to make it clear that the Bill does not change existing medicines legislation, which permits the use of unlicensed medicines

—tested or untested—prescribed by physicians on their own responsibility, subject to all their own professional tests, regulatory conditions and the law. This will be based on what they believe, in their own professional clinical judgment, is right for their patients. If there is an unmet medical need, there is clearly more scope for clinicians to innovate.

Finally, I was asked whether the Bill will prevent patients from making a claim if they receive negligent treatment. No. I want to be clear that this Bill in no way changes patients' rights to claim for negligent treatment. We are completely committed to ensuring that patients are safe and protected. On the occasions when, regrettably, things go wrong and treatment has been given negligently, it is absolutely right that patients are entitled to seek compensation. It is essential that any new legislation or any amendments to the Bill do not put patients at risk in any way. If a doctor carries out a procedure negligently, they would not be protected by this Bill, as is made clear in clause 4(3).

In conclusion, let me highlight that although substantial concerns have been raised—my hon. Friend the Member for Totnes has expressed some of them this morning—it is true to say that there has been support for the Bill. The “Empower: Access to Medicine” campaign has said:

“This new Bill provides a real opportunity to renew the focus on patients' rights to try innovative medicines within a reasonable risk framework. Empower: Access to Medicine has long advocated appropriate access, for some patients, to certain medicines earlier in the clinical trials process. Chris Heaton-Harris' new Bill provides a real opportunity to make that ambition a reality.”

It is particularly supportive of the accelerated access review that I am running. A number of colleagues have suggested that we look at the Bill in the context of those recommendations that will shortly arrive on my desk.

The Royal College of Physicians has said that it

“generally welcomes the first part of the Bill to enable the secretary of state... to establish a database of medical treatments. However, the RCP strongly recommends that the medical and research communities should lead in developing the database.”

If the Bill became law, it is very important for that to happen. I understand that the RCP has particular concerns about the second half of the Bill.

Let me also highlight what was said in the extensive discussion of the Medical Innovation Bill, which was launched in the other place. The chief medical officer, Dame Sally Davies, said that she was

“confident that, with the amendments made in Committee stage, the Bill is safe for patients and has the potential to encourage responsible innovation.”

She was referring to the provisions in the second half of the Bill. Sir Bruce Keogh, clinical director of NHS England said, in connection with the same provisions in the former Bill:

“Encouraging innovation in medicine and protecting patients are both of vital importance. This is why I am pleased that amendments have been devised to address concerns about patient safety.”

Sir Michael Rawlins, president of the Royal Society of Medicine said that the Medical Innovation Bill would

“allow responsible innovation in treatment... I believe that the use of the provisions in the draft Medical Innovation Bill will benefit patients, especially those with rarer diseases, and the furtherance of medical science.”

[George Freeman]

I appreciate that there are real issues of contention and debate, but I wanted to highlight the views of eminent people on both sides of the debate, of which the House should be cognisant.

I was particularly struck by the comments of the hon. Member for Lewisham East. At the end of the last Parliament, her predecessor as shadow Health Secretary said, interestingly, that he was “disappointed” that the Liberal Democrats had withdrawn their support for the Bill. He said that

“there should at least have been some cross-party talks about this”,

and I was glad to hear the hon. Lady echo that view this morning. He went on to say:

“The Bill was heavily amended and extra safeguards put in, and I worry a little bit that those who are opposed to it don’t realise that it is actually quite a different Bill now.”

He said that for parents whose children suffered from untreatable diseases and had no hope, the Bill was “about opening up hope”, and added:

“It is often parents who struggle to get their voice heard”.

In the other place, although some peers had concerns about the Bill, a number of others supported it. I have a list in front of me, which shows that the numbers were equal on both sides. It also shows that some pretty eminent peers supported the Bill: Lord Kakkar, Lord Patel, Lord Ribeiro, Lord Mackay, Lord Woolf, Baroness Gardner, Lord O’Donnell, Baroness Butler-Sloss and Lord Blencathra. Those are all eminent people in their fields. I am not suggesting for a minute that there is not a debate, but I think it is a genuine debate, which is, after all, what the House is here to provide.

The Government support the intention of the Bill to promote innovation, to reinforce existing medical negligence law, to promote the dissemination of information on innovations, to protect and reinforce the sovereignty and the freedom of clinicians to vary and innovate treatment in their interests of their patients, and to promote the use of identification and data on innovation as critical to 21st-century healthcare. We are—and I am—very concerned to ensure that the Bill promotes, rather than undermines, patients’ and doctors’ trust in the legal and regulatory framework for innovation, to ensure that it fits into the wider landscape and framework for innovation that I—along with various bodies—am putting in place, and to ensure that it reflects and supports the growing discussion about research medicine and innovation.

The House has many and varied ways of improving the lot of our citizens, and private Members’ Bills are one important way. As you well know, Madam Deputy Speaker, we Ministers are normally sceptical about the virtues of private Members’ Bills, and jealously guard our, and the Government’s, unique monopoly on legislative virtue and competence; but I believe that when a Bill—such as this Bill—seeks to do something that we support, even if the mechanics proposed may not yet be perfect, there is a strong argument for it to proceed to a Committee stage and be subjected to detailed scrutiny. I hope that the Bill is given such a hearing in Committee. The hon. Member for Lewisham East has signalled her willingness to work on a cross-party basis to try to get the Bill into a shape that will address the concerns that have been expressed, and I was delighted to hear my hon. Friend the Member for Totnes make a similar offer.

**Heidi Alexander:** I am slightly worried that the Minister is ascribing to me words that I have not used. I have indicated a willingness to work on a cross-party basis to address the barriers to innovation, but, as the Minister will have heard me say in my speech, I have very serious reservations about the Bill, and I intend to oppose it today.

**George Freeman:** I am grateful to the hon. Lady for clarifying that.

**Dr Wollaston:** Perhaps the Minister will give me an opportunity to clarify my position as well. I shall robustly oppose the Bill’s Second Reading. As the Minister has said, we all support the principles and aims of the Bill, but many of us robustly reject the motion that this is the way in which to achieve them.

The Minister has quoted two bodies who he says support the Bill, one of which disagrees with half of it. Does he accept that the Association of Medical Research Charities, the Academy of Medical Sciences, the Academy of Medical Royal Colleges, the British Medical Association, the General Medical Council, the Patients Association, Action against Medical Accidents, and even the Association of the British Pharmaceutical Industry—as well as legal experts such as Sir Robert Francis—all oppose the Bill? It reads like an A to Z of opposition. All those bodies would work with the Government if the Bill were given a Second Reading, but they robustly reject the motion that this is the right way in which to achieve its aims. Does the Minister accept that list, and does he accept that, according to the vast majority of opinion, this is the wrong way forward?

**George Freeman:** I well accept that views on the merits of this Bill are divided, not least for the reasons I have highlighted in my speech. Some of the commentary on it, referring to it as the Mengele Bill for example, has played a very damaging part in misrepresenting—*[Interruption.]* I can show the hon. Member for Lewisham East the briefing after the debate if she would be interested.

It is important that colleagues decide for themselves whether to vote for this Bill. My own view, and the Government’s view, is that it is seeking to address a matter of public policy that we share in terms of promoting access to innovation. The measures in the Bill may not be quite perfect; it would not be the first Bill to be in that situation, and I dare say many of our proudest legislative breakthroughs going right back to the 18th and 19th centuries started in a format that possibly did not command unanimous support. I would have thought it is worth us debating this further in Committee, but I reiterate that if we cannot get a Bill into a position where it clearly has, and reinforces, public and clinician support from our world-leading expertise in research medicine and clinical practice, and if it any way undermines patient trust and confidence, it would be retrograde.

I think this Bill is trying to do something laudable, however; I think my hon. Friend the Member for Daventry is trying to do something laudable. This is a complex field, and the Government are trying to put in place the right measures, and I thank him for raising it—and I thank you, Madam Deputy Speaker, for allowing me to respond in full.

1.31 pm

**Chris Heaton-Harris:** Even though there has been some negativity, this has been a very positive debate. I have enjoyed trying to work with various colleagues and all the royal colleges—the list of organisations, actually, that my hon. Friend the Member for Totnes (Dr Wollaston) read out—and I hope that if the Bill has its Second Reading, I can continue to try and work with them, because I think the aspiration and concept behind the Bill, of spreading best practice and innovation quickly throughout our national health service, has widespread support. If this Bill is not the right mechanism, as I said earlier I am very willing to work in Committee to amend and change and to get to the point where I would like to think I could allay any concerns. So I thank everybody for their contributions, give them that assurance, and commend this Bill to the House.

*Question put,* That the Bill be now read a Second time.

*The House divided:* Ayes 32, Noes 19.

**Division No. 79]**

**[1.32 pm**

**AYES**

Bingham, Andrew  
Boles, Nick  
Brazier, Mr Julian  
Cairns, Alun  
Chope, Mr Christopher  
Cleverly, James  
Davies, Philip  
Ellwood, Mr Tobias  
Eustice, George  
Freeman, George  
Garnier, Mark  
Gauke, Mr David  
Goodwill, Mr Robert  
Hayes, rh Mr John  
Heaton-Harris, Chris  
Hollingbery, George  
Hollobone, Mr Philip  
Hopkins, Kris

James, Margot  
Jenkin, Mr Bernard  
Jenrick, Robert  
Jones, Mr Marcus  
Leadsom, Andrea  
Morton, Wendy  
Penrose, John  
Raab, Mr Dominic  
Shapps, rh Grant  
Smith, Henry  
Smith, Julian  
Swire, rh Mr Hugo  
Timpson, Edward  
Vaizey, Mr Edward

**Tellers for the Ayes:**

**Mr Steve Baker and  
Mr David Nuttall**

**NOES**

Abrahams, Debbie  
Alexander, Heidi  
Allen, Mr Graham  
Bottomley, Sir Peter  
Brown, Lyn  
Buck, Ms Karen  
Coyle, Neil  
Cryer, John  
Fitzpatrick, Jim  
Gardiner, Barry  
Hayes, Helen

Huq, Dr Rupa  
Marris, Rob  
Pearce, Teresa  
Pennycook, Matthew  
Pound, Stephen  
Reed, Mr Steve  
Skinner, Mr Dennis  
Wollaston, Dr Sarah

**Tellers for the Noes:**

**Mr Alan Campbell and  
Grahame M. Morris**

*Question accordingly agreed to.*

*Bill read a Second time.*

## Homes (Fitness for Human Habitation) Bill

1.47 pm

**Ms Karen Buck** (Westminster North) (Lab): I beg to move, That the Bill be now read a Second time.

When I announced that I was introducing this Bill, there was some surprise that homes could be let that were not fit for human habitation, but, extraordinarily, that is the case in 2015. As long ago as 1885, when the Housing of the Working Classes Act was passed, Parliament first decided that residential rented accommodation should be fit for human habitation. That concept continued in subsequent housing, landlord and tenant statutes, culminating in the Landlord and Tenant Act 1985. In theory, section 8 of that Act places a statutory duty on landlords, covering issues such as damp, mould and infestation. Failure to meet that statutory duty could result in a civil action by the renter for an injunction or compensation. The great weakness of those provisions is that they tie the repairing obligation to rent limits.

**Dr Rupa Huq** (Ealing Central and Acton) (Lab): I congratulate my hon. Friend on introducing this important Bill. She mentioned damp, mould and infestation. After this debate, I will be holding my surgery where the majority of cases will be to do with those things as well as collapsed ceilings and so on. Does she agree that these things are brought more closely to our attention now? People show us pictures of them on their mobile phones. Also, the logical extension is the phenomenon of beds in sheds. The London borough of Ealing has the dubious distinction of being a leading geographical location in that regard.

**Ms Buck:** I am very aware of what my hon. Friend describes. Technology is bringing to the attention of representatives conditions of which many of us were previously unaware.

The extraordinary thing about the Landlord and Tenant Act is that it is based on rent limits that were last updated in 1957. The provisions were of course originally intended to give redress in regard to accommodation rented by the working class, hence the limits. The law as it stands applies only when the annual rent is less than £80 in London and £52 elsewhere in the country. If any hon. Members can find a property where the annual rent is less than £80, I am sure that millions of people across the country would be delighted to know where it is.

At the moment, the weekly average rent in London is £362, which gives an indication of just how far out of line the rent limits are. Many of Britain's near 9 million renters are well served by their landlords, but for the significant minority who are not there is a long overdue need to strengthen the law, to give improved redress to tenants living in very poor conditions and to correct this bizarre legal anomaly.

The Bill lifts the rent cap above which tenants do not enjoy the legal right to live in a home fit for human habitation. It will enable tenants to bring civil proceedings in the county court when the property is in such a poor condition that it contains a housing health and safety rating system category 1 hazard under the Housing Act 2004 or is otherwise unfit for habitation. The tenant could enforce improvements to the property to make it fit for habitation and seek compensation for the period

[*Ms Buck*]

for which the property was unfit. That brings the law on conditions in substandard properties into line with that on disrepair and complements the duties that lie with increasingly hard-pressed local authority environmental health departments. In so doing, it enacts the recommendations of a Law Commission report that itself dates back nearly 20 years that was subsequently reinforced by decisions by the Court of Appeal.

I am extremely grateful for the support I have had in drawing up the Bill, particularly from the Housing Law Practitioners Association, specifically Giles Peaker and Justin Bates. I am also appreciative of the support of Generation Rent, Shelter, Stephen Battersby, the former president of the Chartered Institute of Environmental Health, and the Communication Workers Union, as well as Adam Johnstone in my office. There have been many constructive comments and much support, including very constructive comments and help from the Residential Landlords Association and the National Landlords Association.

Why is a change in the law necessary after all this time? Quite simply, renting is on the rise, dramatically so, especially in the private rented sector. As I have said, many landlords maintain their properties well and fulfil their obligations, yet the fact remains that standards in the private rented sector are poorer than those in owner-occupation.

**Catherine West** (Hornsey and Wood Green) (Lab): I congratulate my hon. Friend on securing the debate, which is of such importance to so many in London and the south-east in particular. Is she aware that in Finsbury Park, which was quite affordable once upon a time, one now needs an average income of £70,000 per household to rent a three-bed home? What does she think of that?

**Ms Buck:** My hon. Friend brings to the attention of the House the extraordinary situation with rents, particularly, although not exclusively, in London. There was a report in today's papers about the scale of rent rises in the private rented sector affecting the whole country. Given the extraordinary rents that many private tenants are paying it is even more the case that the conditions to which they are entitled should be of a decent standard. Unfortunately, a significant minority of renters are not well served.

The Chartered Institute of Housing's 2014 housing review calculated that 33% of all private rented housing in England—one third—would fail the Government's decent homes standard for social housing compared with 15% of the social rented sector. According to the Government's English housing survey, just under three quarters of a million homes, or 16.5% of private rented sector homes, failed to meet the minimum standard of the housing safety rating system. A quarter of a million properties in the private rented sector are estimated to have a category 1 hazard and, according to a major report by Shelter backed up by a YouGov survey, 61% of tenants were found to have experienced mould, damp, leaking roofs or windows, electrical hazards, animal infestations or a gas leak in the past 12 months.

Only this morning in *City A.M.* Hannah Williams wrote:

"As someone who runs a website that enables tenants to review properties they've rented, I see reports every single day of mould, damp and infestations that sound so Dickensian I can hardly believe they come out of 21st Century Britain."

Some 10% of tenants report that their health has been affected adversely in the past year because their landlord has not dealt with repairs and poor conditions in their property, and 9% of private renting parents said that their children's health had been affected.

The key issue addressed by the Bill is that, because of the rent limits, tenants are currently denied the same redress in respect of substandard conditions as they enjoy in respect of disrepair. The most obvious example relates to condensation and consequential mould. There is no obligation on the landlord as this issue is not one of repair. Causes can be lack of ventilation or extractor fans, inadequate though not necessarily defective windows, and so on. The structure in some cases may be sound, but design defects mean that the property is not fit for habitation. Suppose a property was built with no damp proof course and now suffers with damp. The existing disrepair laws do not help in such a case. Disrepair requires a change of state, but in this example there is no change. The Bill fixes that problem by shifting the focus on to the condition of the property, not simply the causes.

I have one of the largest private rented sectors anywhere in the country and I rely heavily on my local environmental health department to provide assistance in seeking redress for tenants who live in substandard accommodation. I shall return to the role of environmental health officers. Despite having a good and responsive environmental health department, I shall give some examples from my own caseload of the kind of conditions that I hope the Bill will redress.

A mother writes to me:

"For years my daughter has had damp in her home to the point where the walls were black. Many times surveyors come out but the situation is not resolved. This year workmen were sent out to deal with the damp and thought the problem was solved, but two months ago another surveyor had to come out to look at the property, inspected it and found that there was damp again.

My daughter has to live with the damp, ruining her health, numerous times reporting it and nothing done because she's vulnerable, and although I as a mother try and look after her affairs I cannot be with her 24/7 as I work. My daughter suffers with poor health. She suffers from depression, self-harm, high blood pressure and alcohol problems. She has counselling and suffered from abuse. I know that is part of her problem. I know that if my daughter was to get out of the flat it would help her situation immensely, but her landlord is not doing what they should be doing, and that is addressing the situation with the damp."

Another parent writes:

"My main concern is with the damp, mould and condensation as my son keeps on getting ill every 1 or 2 weeks. He has chronic asthma. I've had to throw away furniture that was only a year old as mould was growing on the back of it. Mould has grown in the microwave, the cooker, affecting my plates and cups, and under the sink where I have to store my pots and pans. Mould has grown on my shoes in the cupboard and on my son's clothes and my clothes. It grew on his buggy seat and I cannot remove it."

A third constituent writes:

"I have tried everything I can to stop and prevent the mould and damp from returning to my property, from covering the walls, constantly airing the property by opening the windows and doors in all weather, having the heating on and off at different times as advised, to constantly moving the furniture around so all the walls get enough air. Whatever I am asked to do I have done. The walls have had several treatments and redecorating simply covers over the problem. It's not fair that I've had to live like this for so long. It's 15 months I have lived in these awful conditions."

There are many other cases, and that is in only one local authority.

Last year, the Building Research Establishment, working with the Chartered Institute of Environmental Health, published two important pieces of work looking at the costs to health of substandard housing. In respect of health, it found that remedial action to tackle category 1 hazards would save the NHS £1.4 billion. In addition to the consequences for physical and mental health that so many of my constituents and renters across the country report, problems relating to damp and condensation cause financial distress to tenants, who often have to spend excessive amounts of their income on trying to heat their homes when damp and condensation make it difficult for them to do so and plague their property with excess cold.

The Bill would effectively enable tenants to enforce the kind of improvements that previously only local authorities could take steps to deal with via the Housing Act 2004 and the housing health and safety rating system. It would ensure that they have potential redress in respect of substandard conditions, as currently exist in respect of repairs. It would allow a tenant to secure an injunction to ensure that remedial works are carried out. The Law Commission's 1996 report, which I referred to earlier, supported that change in principle, backed by the Court of Appeal, which remarked on the case of *Issa v. Hackney London Borough Council* in 1997 that the unsatisfactory state of the law currently means that tenants are

“wholly without remedy in the civil courts against their landlords, however grievously their health may have suffered because they are living in damp, unfit conditions.”

Why can environmental health officers not deal with these problems? In my view, environmental health officers are the unsung heroes of the modern welfare state. I draw very heavily upon Westminster's environmental health officers, and I am proud to say that they do an excellent job—I spend a lot of time fighting Westminster City Council on almost every front, and quite rightly so, but when its officers do a good job I am delighted to say so—but across the country performance is highly variable.

The housing health and safety rating system, which was introduced by the 2004 Act and has been in force since 2006, allows local authorities' environmental health departments to inspect and identify hazards. Where they identify a category 1 hazard—the most serious type—they are required to take action, but they can also choose to take action with regard to less serious hazards, and there is a risk assessment approach to property standards. However, the remedy available depends entirely on the choice that local authorities make on their enforcement strategy and, of course, the resources available to them. Overall, local authorities have not used their powers as often, or met their duties as well, as they might, too often acting only after receiving complaints from tenants, rather than proactively.

Despite the duty set out in section 3 of the 2004 Act, the removal of the Department for Communities and Local Government's capital for private sector renewal and lack of funds for gathering the necessary information mean that few local authorities have a coherent strategy for the private rented sector and can take proactive action. Indeed, the most common way of dealing with hazards that are found when environmental health officers go into a property is informally. It is not clear what that is, but it is extremely hard to monitor and get a national

picture for how effective it is. In the case of category 1 hazards, that would also be a breach of their statutory duty.

A piece of research I carried out with Stephen Battersby, from the Chartered Institute of Environmental Health, found enormous variations in practice and a high reliance on informal action. In 2010, just 3,744 improvement notices were issued, or an average of just 18 in each local authority, and that was up by just two per authority since 2007.

**Catherine West:** Is my hon. Friend aware that there are now nearly 4 million people living in the private rented sector? This is no longer just a small proportion of our country's population, which makes tackling the issue so much more important.

**Ms Buck:** Indeed, I am. Of course, it is in the context of the rapid growth of the private rented sector, where the worst conditions are undoubtedly to be found, that the lack of progress in taking action against landlords who have substandard properties is so alarming. That is why I am drawing attention to how modest the increase has been in the number of enforcement notices since 2007, at a time when so many more people have entered the private rented sector. For the 86,227 referrals to local authorities in 2007, there were just 3,744 notices. Prohibition orders were even rarer, with an average of just 2.7 per authority, or 531 from all the authorities that responded to my survey. The survey found that fewer than one in 10 dwellings with category 1 hazards are dealt with in any year.

That effectively means that we can no longer rely on the source of support and redress that we relied upon for so many years. The rent limits have effectively meant that the Landlord and Tenant Act protection has fallen out of use. We are therefore unable to rely on the work being done by environmental health officers. In the financial context in which we are now operating, with the cuts that we have seen in local authorities, I cannot see any likelihood of an improvement in the situation in the foreseeable future. Therefore, we cannot rely entirely on environmental health departments—we have to draw on a new power that individual tenants can take to enforce for themselves action against landlords where the conditions of the property are unfit for human habitation.

The National Landlords Association and the Residential Landlords Association, quite rightly, wanted me to reassure them that steps would be taken to protect landlords against unreasonable action by tenants. Of course, there are cases where tenants can act in an unreasonable manner, and the Bill protects the position of landlords in two ways. In new section 8(4) of clause 1, we prevent liability arising where the unfitness is caused by the tenant's behaviour or as a result of natural disaster, and make it clear that the landlord is not obliged to maintain property that belongs to the tenant. In new subsection (4)(d), we provide that a landlord cannot be required to carry out works that would put him or her in breach of any other legal obligation such as works contrary to building regulations. A landlord cannot be liable under this provision where the works would necessitate consent being obtained from a superior landlord or where that superior landlord has refused to give such consent. I am confident that within the terms of the Bill we are able to protect landlords against any unreasonable action.

[Ms Buck]

Where councils are unable or unwilling to enforce existing provisions against bad or rogue landlords, the Bill enables tenants to take up the opportunity of enforcement. It strengthens existing provisions for enforcement. It does not introduce any new standards or new obligations on landlords. The requirement for properties to be free of category 1 hazards is already in the Housing Act 2004. There is no liability on the landlord for issues that are due to the tenant's conduct or breach of tenancy agreement. The Bill would work in a very similar way to section 11 of the Landlord and Tenant Act in terms of procedure, evidence and so forth. This is a familiar and well-established process.

As the Law Commission report said way back in 1996, predicting what the objections to the Bill might be, first, the proposals, if implemented, would be prospective and not retrospective, and the implied obligation of fitness would apply only to tenancies granted after the coming into force of the Act; and secondly, following on from this, the basic requirement that rented residential property should be fit for human habitation is not an unreasonable one to impose on private sector landlords in the unregulated financial environment that has applied to lettings made by them since the Housing Act 1988. That reinforces what my hon. Friend the Member for Hornsey and Wood Green (Catherine West) said about the upward trend of private rents in recent years.

Given that the Law Commission and Court of Appeal have implored Parliament to remedy this problem, and that Wales seems about to do so in the Renting Homes (Wales) Bill, I very much hope that this Bill can make progress. In the light of the rapid growth of the rented sector and the appalling conditions in which hundreds of thousands of tenants are forced to live, damaging their health and their income, and with no satisfactory redress under the present system, it is time for the law to come into the 21st century. I commend the Bill to the House.

2.8 pm

**Philip Davies** (Shipley) (Con): I congratulate the hon. Member for Westminster North (Ms Buck) on bringing forward her Bill and giving it a good airing. Unfortunately, we do not have a great deal of time left, so I am not sure we will be able to do it justice, but I certainly commend her for it.

First, I should draw the House's attention to my entry in the Register of Members' Financial Interests. As I have said in previous debates on this subject, I am both a landlord—although an accidental landlord, I might add—and a tenant, and therefore in the unusual position of being able to see both sides of the argument and having an interest on both sides of the argument.

The private rented sector has been a topical issue for many years, not least recently, and there have always been arguments for more regulation of the industry. Indeed, landlords appear to be an easy target for the left. As this Bill is again directly targeted at landlords, it is worth considering exactly who these landlords are. The DCLG's private landlords survey of 2010 found that more than three quarters—78%—of all landlords owned only a single dwelling for rent, comprising 40% of the total private rented housing stock, while 95% had fewer than five dwellings in their property portfolio,

accounting for 61% of the total stock. A large majority—81%—of private individual landlords owned just one dwelling, of whom 97% had fewer than five properties in their portfolio. Only 3% of private individual landlords owned five or more dwellings, and they accounted for almost a quarter of all dwellings owned by private individual landlords.

Basically, nearly four in five landlords only rent out one property. When we talk about additional regulations and burdens, it is always worth pointing out that the vast majority of those affected are individuals with just one property, not great conglomerations or massive corporations renting out huge numbers of properties. I sometimes think that Labour Members want us to believe such a caricature.

**Mr David Nuttall** (Bury North) (Con): As someone in the category of accidental landlords who rents out only one property, will my hon. Friend confirm that the vast majority of such landlords—many of them may have inherited the property—are law-abiding landlords who ensure that their properties are kept to a very high standard?

**Philip Davies:** My hon. Friend is absolutely right. There is no doubt that the overwhelming majority of landlords—I put myself in this category—want to do the right thing, would never dream of renting out a property that was not in a fit state to be rented out and want to comply with every regulation that is introduced. As someone in that situation, I can however tell him that it is very difficult to keep tabs on all the things expected of a landlord. It is very difficult for a landlord—an accidental landlord or one who has not set out to earn money from being a landlord—to keep tabs on every dot of the i and cross of the t that hon. Members seem to want to impose on landlords, as though they had nothing to do but wade through legislation generated by this House.

**Catherine West:** Does the hon. Gentleman agree that as there are some excellent landlords and paragons of virtue, including in my constituency, we should ensure that the very small number who are not good landlords are kept under much closer scrutiny and are held much more closely to account by local authorities? Will he join those of us who care about housing in approaching the Minister for more funding for local authorities on that matter?

**Philip Davies:** The hon. Lady wants me to cover rather a lot of ground, if she does not mind me saying so. If we get into the funding of local authorities and funding formulas, I am sure that you might start to raise an eyebrow or two at my going off piste, Madam Deputy Speaker.

**Madam Deputy Speaker (Mrs Eleanor Laing):** Order. For the avoidance of doubt, let me say that the hon. Gentleman is absolutely right that I would raise several eyebrows. As I am sure the hon. Member for Hornsey and Wood Green (Catherine West) who has intervened to ask all those questions will appreciate, I will make sure that we deal only with what is in the Bill. There is more than enough in the Bill to keep us going.

**Philip Davies:** I am very grateful to you for that guidance, Madam Deputy Speaker. My new year's resolution was to try to stick to the subject on Fridays.

As I have not always achieved that, I thought I would make a special effort this term to stick to the point, and I am rather pleased that you have supported my first attempt to do so.

On the part of the intervention by the hon. Member for Hornsey and Wood Green (Catherine West) that is most relevant to the Bill, I accept her premise that it is important for everybody to be in a home that comes up to a certain standard. I am not aware of anybody who would disagree with that proposition. The issue is whether the Bill is necessary to achieve that. If I am allowed to make a bit more progress—time is pressing—I would like to set out my contention that the Bill is not necessary to achieve what she would like, which is exactly the same as what I would like. I cannot speak for the Minister, but I would like to think that he agrees—I am pretty certain he does—with the proposition that all housing should be fit for human habitation. We do not object to that principle.

The starting point for the Bill, as the hon. Member for Westminster North said, was the 1996 Law Commission report, “Landlord and tenant: responsibility for state and condition of property”. The explanatory notes to the Bill confirm that it is adapted from the Law Commission’s draft Bill, which was included in the report. The report was 230 pages long and covered many issues.

I cannot resist pointing out that we are nearly 20 years on from when the report was produced. I hope it has not escaped everybody’s attention that since 1996, we have had 13 years of Labour Government. They had plenty of opportunity to put the draft Bill into legislation if it was a matter of great importance, as the hon. Member for Westminster North claims.

**Helen Hayes** (Dulwich and West Norwood) (Lab): Does the hon. Gentleman agree that the growth in the number of people who live in the private rented sector—40% of people in the London Borough of Lambeth now live in the private rented sector—gives rise to the need for additional protections for tenants against irresponsible landlords? Responsible landlords have nothing to fear from the Bill, but that additional protection is urgently needed.

**Philip Davies:** I think that the hon. Lady is going down a rather dangerous line of argument, if she does not mind my saying so. She seems to be saying that as long as only a few people are affected, it does not matter what the condition of houses in the private rented sector is, but now that a lot of people live in the sector, all of a sudden it does matter. I would argue that the standard and condition of the housing matters regardless of how many people live in the private rented sector. It does not matter whether it is 40%, 20%, 5% or 2%—we should make sure that all accommodation is fit for human habitation. I do not accept her premise that this has only become an important issue because there are so many people in the private rented sector.

**Helen Hayes:** Will the hon. Gentleman give way?

**Philip Davies:** I will give way in a second, if the hon. Lady is patient.

Anybody who was living in the private rented sector between 1997 and 2010 would have thought that this was an important issue, but for some reason the Labour Government, which I presume the hon. Lady supported,

did not think that there was any necessity to introduce this legislation. I am happy for her to explain why that might have been the case.

**Helen Hayes:** The hon. Gentleman is being very generous with his time. By the extension of his argument, it should not matter whether a landlord is a small landlord with only one property or a large private sector landlord with many properties—the same rules and regulations should apply to all, and all tenants deserve the same level of protection.

**Philip Davies:** I do not think anybody has disagreed with that proposition, either. I certainly have not said that there should be different rules for different sized landlords, and I do not agree with that view.

I was merely making the point—I will reiterate it because I obviously made a dog’s dinner of explaining it clearly the first time around—that it is unnecessary for the House to keep passing legislation that affects landlords because there is already lots of legislation that makes it perfectly clear that homes should be fit for human habitation. When this House adds more and more regulations, it does not achieve anything for tenants because there are already rules and regulations in place. All it does is pass on a huge burden to landlords who have to work out whether they are complying with the law today compared with what it was yesterday. Good landlords who want to do the right thing find it difficult to keep up with all that. We had lots of legislation that affected landlords during the last Labour Government and the coalition Government, much of which was very challenging for landlords.

My contention is that we should make the law for landlords reasonable and sensible, and then leave it at that and let them get on with it, rather than introducing a law and then 10 minutes later introducing another law that does exactly the same thing but that sends out the message that this is so important that we can send a press release to our local paper saying that we really care about tenants, even though the law already applies. This legislation does not achieve anything; it just causes a lot of grief for many people who did not deserve it in the first place. I reiterate that if the Law Commission report was so important, the Labour party had plenty of opportunity to implement it, but it did not bother to do so.

The 1996 Law Commission report states:

“This is the third occasion on which the Commission has considered possible reforms to the law on repairing liability in leases. The recommendations in the first of our two previous reports, *Civil Liability of Vendors and Lessors for Defective Premises*, were enacted in part by section 4 of the *Defective Premises Act 1972*. Our second report, *Obligations of Landlords and Tenants*, has not been implemented.”

Its point was that the previous report had not been implemented, yet now we are moving on to another one.

Understanding what is meant by “fitness for human habitation” is crucial to this debate. The Law Commission report stated:

“When the implied term of fitness for human habitation was first introduced in 1885, the term ‘fit for human habitation’ was not defined. The meaning of those words was therefore a matter for judicial decision alone, at least in the context of the implied term. It was only in the *Housing Act 1936* that an attempt was made at some form of statutory definition.

[Philip Davies]

Before the introduction of statutory criteria for determining whether or not a property was fit for human habitation, the issue was treated as one of fact to be determined according to the standard of the 'ordinary, reasonable, man'. A property might be unfit for human habitation not just because of structural defects or internal physical conditions, but because of 'external causes, such as want of ventilation, noxious effluvia, etc'. In the earlier decisions, the standard was held to be satisfied quite readily. It was 'a humble standard' and it 'only required that the place must be decently fit for human beings to live in.'

**Ms Buck:** The Bill is based around category 1 hazards in the housing health and safety rating system, as set out in the Housing Act 2004. That is the basis on which enforcement will be carried out, and the point is to give a power of enforcement to tenants when local authorities cannot and do not act. I can see no relevance to the points raised by the hon. Gentleman.

**Philip Davies:** If there was no relevance to my points, I am sure that you would be the first to tell me, Madam Deputy Speaker. I am not entirely sure when the hon. Member for Westminster North became judge and jury for what is relevant to a debate, but as you made clear, Madam Deputy Speaker, there is plenty to go at in the Bill. I am trying to be as comprehensive as possible in explaining why the Bill is unnecessary.

I will therefore repeat—well, I will not repeat anything, Madam Deputy Speaker, as you would not want me to, but I will continue from where I left off. The report states that at the time:

“Unfit for human habitation’ was ‘a very strong expression, and vastly different from ‘not up to modern or model requirements’”. Those were two very different principles and definitions.

“Nor did it equate to ‘good and tenantable repair’. Some decisions were remarkably harsh. A plague of rats was thought by the divisional court not to make a house unfit, though the correctness of this decision must be open to serious doubt.”

**Mr Steve Reed (Croydon North) (Lab):** The low standard of repairs is fundamental when we are talking about the state of some of these properties. I presume the hon. Gentleman agrees that there should be more direct accountability back to tenants to allow them more power to force change where that is required in their properties.

**Philip Davies:** I would contend that plenty of legislation already allows tenants to ensure that their house is properly repaired by landlords—indeed, some of that legislation was introduced in the previous Parliament.

**Mr Reed:** Would the hon. Gentleman like to come with me to visit some of my constituents in Croydon North who are completely exasperated by landlords who refuse to do even the most basic repairs on properties that people are living in with their children? I would be happy to take him around and show him how wrong he is.

**Philip Davies:** I do not want to get sidetracked, but local authorities have much of the power to ensure that landlords maintain their houses to a proper standard. I know that the hon. Gentleman was leader of a local authority. Perhaps he should look to see what he and that local authority did to ensure that private landlords in his area were of a sufficient standard. He had the powers to do that.

**Mr Reed** rose—

**Philip Davies:** I will not give way again because time is pressing and I do not want to embarrass the hon. Gentleman further about his record as leader of Croydon Council—[*Interruption.*] It was Lambeth Council. I apologise to the hon. Gentleman, although I am sure the same principles apply.

It has to be said that a rather broader view came to be taken, under the influence of Lord Atkin, on what was considered fitness for human habitation. In his opinion:

“If the state of repair of a house is such that by ordinary use damage may naturally be caused to the occupier, whether in respect of personal injury to life and limb, or injury to health, then the house is not in all respects reasonably fit for human habitation.”

That definition was approved by the House of Lords in the case of *Summers v. Salford Corporation*. In that case, a defective sash cord on the only window in the bedroom of a small house was held, in the circumstances, to make the property not reasonably fit for human habitation. Lord Atkin equated the requirement of reasonable fitness for human habitation with habitable repair, which had been defined earlier.

There was an attempt to come up with a specific definition in the Housing Act 1936. It is clear from the definition relating to sanitary defects that this approach was derived from the regulations made under the housing Act of 1925. There have, therefore, clearly been developments in the definition. The Bill proposes to change that definition once again, despite the fact that for all the previous stages of the definition there was not the other legislation in place that is in force now. We did not have all the legislation that came into being in the '70s, '80s and '90s. None of that was in place, yet even then there was a narrow, if evolving, definition of homes fit for human habitation. There is even more legislation in place to protect the rights of landlords now, yet the hon. Lady wants to change the definition once again.

The report also gives the history of the fitness for human habitation provisions. That is key to understanding why they originally came into being, as they are the subject of the changes proposed in the Bill. I would, if time had allowed, have gone through the origins of the legislation and the definition, because if we are trying to fiddle with a definition, it is very important to know why it was introduced in the first place. I will not test your patience by doing that, Madam Deputy Speaker, because time is precious.

The hon. Lady argued that the Bill will merely do as the law originally intended on human habitation, but I do not accept that. Yes, the Bill seeks to address the original rent limits which exist to trigger the fitness for human habitation provisions in the Landlord and Tenant Act 1985, but it does so in such a way that includes nearly all properties, not just those with a certain level of rent. That was certainly not the intention when this was first introduced. It also extends the list of matters in the fitness for human habitation list and ignores the fact completely that there has been so much other legislation covering landlords since. The Bill covers nearly all properties, not just those in a certain rent band. The only exemptions appear to be those—the hon. Lady can correct me if I am wrong—contained in section 14 of the 1985 Act, which states:

“Section 11...does not apply to a new lease granted to an existing tenant, or to a former tenant still in possession, if the

previous lease was not a lease to which section 11 applied... Section 11 does not apply to a lease granted on or after 3rd October 1980 to—a local authority... a new town corporation, an urban development corporation, the Development Board for Rural Wales, a co-operative housing association, or an educational institution”—

or housing action trust.

The hon. Member for Croydon North (Mr Reed) made a point about the terrible state of repair of houses in the private rented sector. I will make no comment on the back of it—people can draw their own conclusions—but of all the people who have come to me in my surgeries to complain about the standard of their housing, I think I can count on one hand the number who come to me in a year to complain about the standard of housing in the private rented sector. However, the numbers who come to see me about the standard of their housing in the social rented sector by their social housing provider is huge. I get no end of complaints about social housing. People can draw their own conclusions from that fact.

**Mr Christopher Chope** (Christchurch) (Con): Would my hon. Friend therefore join me in bringing forward a private Member's Bill directed specifically at social landlords?

**Philip Davies:** Again, I do not want to deviate. I was merely asking whether the Bill addressed the right problem. It seems to me that there are many other problems with many other housing providers that are not being addressed. Labour Members seem to think that social housing landlords can get away with anything and do not need regulating. All they ever want to do is clamp down on private landlords, even though the problem does not seem to exist to the extent they believe—

2.30 pm

*The debate stood adjourned (Standing Order No. 11(2)).*

*Ordered,* That the debate be resumed on Friday 29 January.

## Business without Debate

### HEALTH AND SAFETY EXECUTIVE (POWERS) BILL

*Motion made,* That the Bill be now read a Second time.

**Hon. Members:** Object.

*Bill to be read a Second time on Friday 4 December*

### CONSTITUTIONAL CONVENTION (NO. 2) BILL

*Motion made,* That the Bill be now read a Second time.

**Hon. Members:** Object.

*Bill to be read a Second time on Friday 4 December.*

## Child Food Poverty

*Motion made, and Question proposed,* That this House do now adjourn.—(*Margot James.*)

2.31 pm

**Ruth Smeeth** (Stoke-on-Trent North) (Lab): I thank my colleagues who have kindly stayed behind on a Friday afternoon for this important debate.

I wish to speak on an issue that is close to my heart and of great consequence for my constituents and many thousands of children and families across our country—the hidden horror of holiday hunger in the United Kingdom. It is not uncommon to have disagreements across the House—each of us has come to this place with strong beliefs and a mandate to pursue them—but there is one thing on which I hope we can all agree. It is a simple question the answer to which serves as a barometer of our progress towards creating a fair society: are our children going hungry? It might be easy to ask, but the answer is hard to bear. In the 21st century in a civilised society such as ours, there are certain social and health issues that should have been confined to the history books, such as rickets, malnutrition, and starvation, but, unbelievably, in communities across the country, health and education professionals are seeing the impact of these things daily.

In my constituency, in Stoke-on-Trent North and in Kidsgrove, 31% of children are living in poverty. One third of our children are born into families living hand to mouth, struggling to make ends meet, pay the bills and feed the kids. The Government's new index of multiple deprivation makes clear the scale of the problem. Stoke-on-Trent is ranked as the 13th most deprived authority out of 326. In one secondary school in my constituency, 52% of pupils qualify for free school meals.

Even these statistics do not do justice to the terrible reality of poverty in my city and our country today. The situation is bad enough during term time. Stories have reached me of children fainting in school on a Monday morning because they have not eaten since the Friday before. Others are surviving on little more than a packet of crisps a day. For these children, their school meal can often be the only hot meal they get. It has long been understood by all parties in the House that many families struggle to afford to pay for school meals during term time. In fact, free school meals were first introduced in 1906 and remain an established part of our education system over a century later.

But lunch is just one meal, and many schools have gone even further in their attempts to ensure our children are well fed, with breakfast and after school clubs becoming more and more common. Teachers recognise the clear link between hunger and concentration in the classroom, and who with a heart could ignore a hungry child in front of them? These projects make a huge difference and ensure that our most vulnerable children are receiving the nutrition they need during term time. Last week, the Prime Minister said we needed to do more to nurture the educational attainment of our young people. He was speaking of the dangers of truancy to our children's aspiration, and he had a point, but if our children are not coming to school well fed and ready to learn, their presence alone will not be enough to bridge this divide in outcomes.

[Ruth Smeeth]

The issue is even worse when our children are not at school. What happens to our kids when school is out and the holidays loom? How can we expect them to achieve their potential when they are returning to school in September malnourished? Let us not be in any doubt—that is exactly what is happening at present.

The statistics are stark. A recent report by Kellogg's on isolation and hunger in the school holidays found that a third of parents skipped a meal so their kids could eat during the school holidays. Six out of 10 parents with household incomes of less than £25,000 said they were not always able to afford to buy food outside term time. For households with incomes of less than £15,000, that figure rises to a staggering 73%. We must never forget that behind each of these statistics is a child, a parent and a family.

The impact of holiday hunger can be seen elsewhere, too, as in the increase in food bank usage during the school holidays. In 2014, the Trussell Trust saw food bank usage in August increase by 21% compared with the same time in June, before the holidays began. These problems are exacerbated by the hidden costs of school holidays. Lone parents are particularly hard hit, with a 2014 survey indicating that 29% had reduced their working hours to look after their children during the school holidays, and 22% had taken unpaid leave.

The trends are getting only worse. Disgracefully, child poverty is set to rise, not fall, in the next five years. The Institute for Fiscal Studies predicts that 3.5 million children, which is one in four—let me repeat that: one in four of our children—will be living in absolute poverty by the end of this Parliament.

This crisis is not just a tragedy in its own right, as it is having a major impact on educational attainment, which threatens critically to undermine social mobility in our country. Teachers say that if a child arrives at school hungry, they will lose one hour of learning time a day. If a child arrives at school hungry just once a week, they will lose over eight weeks of learning over their primary school life—70% of a full school term because they are hungry.

It should come as no surprise to hear that if a child comes to school hungry and malnourished, they are never going to achieve their full potential. Concentration, behaviour, the ability to learn—all these are affected if a child is not receiving the sustenance needed to get through the day.

To be candid, not enough research is available about the impact on attainment for limited periods of malnutrition—a situation we very much need to rectify. We do know, however, that for those suffering from severe malnutrition, a lack of concentration is the least of their worries. Organisations such as Save the Children have produced comprehensive reports detailing how long-term malnutrition causes devastating and irreversible damage to children globally. I would like to take this opportunity to extrapolate the findings to this situation.

A lack of nutritious food, combined with illness and infection, leads to a condition known as “stunting” in which children's bodies and brains do not develop properly. Stunting has a real and demonstrable impact on a child's mental development, which in turn affects relative IQ and the ability to learn. The link between childhood

malnutrition and future attainment has also been identified. Stunted children are predicted to earn on average 20% less than their healthy counterparts.

We cannot start to narrow the gap in pupil attainment until we recognise the gulf in opportunity between our poorest students and the rest. Nor can we expect teachers, even great teachers, to keep a child's development on track without dealing with these structural inequalities. We cannot pretend that inspiration can overcome starvation.

The repercussions of holiday hunger resonate far beyond the classroom. There is increasing evidence that many students backslide academically during school holidays. A 2014 report by *The Times Educational Supplement* reported that 77% of primary school leaders and 60% of secondary school leaders had concerns about summer learning loss among their pupils. This regression is far more pronounced in our poorest and most vulnerable communities—and that, too, should come as no surprise because the issues are not solely related to food, but touch on wider social inequalities.

For parents struggling to put food on the table during the school holidays, finding the money to provide their children with the programmes and activities that occupy their more privileged counterparts is an impossible dream. For these kids—the kids I see in my constituency, week in, week out—the summer holiday is not some childhood idyll of splash pools and camping trips. It is not a chance to explore or create. It is boredom, hunger and isolation. That is why I am asking the Government to work with us and begin taking positive steps to tackle the problem of holiday hunger in our country.

We need to do that holistically, and thankfully we do not need to start from scratch. Up and down the country, we have seen examples of local, community-focused projects that are attempting to provide children with the nutrition they need outside term time. In my constituency, several schools run summer programmes funded through the pupil premium, but they are sadly limited to two of the seven weeks. In other parts of the United Kingdom, we see projects such as the one run by the M32 group in Stretford, an out-of-school club that fed an average of 100 kids a day over four weeks this summer, and the summer play scheme set up by Kirklees Neighbourhood Housing, which worked with other agencies to provide activities for young people. The provision of healthy meals was the cornerstone of that scheme.

In Stoke-on-Trent, we have schools and community groups that are willing and able to work with me, and with the Government, to ensure that our kids are being fed during the school holidays. The local food bank is seeking to make links with the Cinnamon Network's MakeLunch project, which provides lunches for children who otherwise would not have them during the school holidays. The will is there; what is lacking is the financial support to get local pilot schemes off the ground so that they can start to tackle the problem.

What amazes me is that we have ignored this issue for so long while other countries have recognised that they have a basic responsibility to feed their communities. In the United States, not only is holiday hunger nationally recognised as a serious issue, but the measures to alleviate it are federally funded. It is time for the UK Government to step up, acknowledge the scale of the problem, and work with stakeholders to develop a framework for ending child food poverty, in term and out.

In recent days, the Government have been quick to dismiss these issues as having somehow been brought about by the families themselves, or as the inevitable consequence of “tough decisions”. Far from making tough choices, however, the Government are taking the easy option in this regard, and it is the most vulnerable who bear the brunt. Ignorance or looking the other way is not an excuse. It is easy to stand here, in the middle of a palace, and denounce the poor as feckless. It is easy to pontificate, from a position of comfort and security, about the failings of those at the bottom. It is easy—all too easy—to say that if people cannot afford to eat, it must be because they are not working hard enough or not spending their money wisely enough, or even that they should not have had kids in the first place. We know better than that. We know that the majority of children living in poverty today are in working households. We know that 43% of children in poverty are living with two parents, one of whom is employed. We know that a Government who talk of making work pay are stripping tax credits from those who need them most.

**Matthew Pennycook** (Greenwich and Woolwich) (Lab): My hon. Friend is making a powerful and compelling speech. More than 10,000 children in my constituency face steep reductions in their tax credit support next year. Does my hon. Friend agree that in the light of the impending withdrawal of that support, the measures that she recommends are more important and urgent than ever?

**Ruth Smeeth:** I could not agree more. In my own constituency, 10,800 young students will be affected by the cuts.

**Stephen Pound** (Ealing North) (Lab): My hon. Friend is making an intensely powerful and very timely speech. The London borough of Ealing, like many other boroughs, set up summer play schemes, which were initially intended to provide entertainment, amusement and healthy exercise for young people during the summer holidays. Now we have to provide hot food, but when our budget is cut by £96 million over the next four years, we may not be able to sustain that. Will my hon. Friend please urge the Minister—whom I know to be a decent, humane man—to recognise the impact of local government cuts on these essential services?

**Ruth Smeeth:** I could not agree more with my hon. Friend. We have yet to see the impact of wider cuts on local government, but I cannot imagine that it will make the present position better.

Following the proposed tax credit changes, a single parent with two kids who works 16 hours a week on the minimum wage will be £460 a year worse off. A couple with two kids, when one parent is earning the national average, will be down two grand a year.

We know that what is really holding children back in constituencies like mine and those of my hon. Friends is not a lack of will, or talent, or perseverance; it is a lack of opportunity, a lack of support, and a lack of hope for a better future. That is the challenge that our children face. It is a challenge that could be met if only the helping hand of Government is extended to them, and that is what I am asking the Government to do today. I am asking them to begin to take concrete steps to

address the issue of child food poverty in school holidays. So I ask the Minister to meet the holiday hunger taskforce as a matter of urgency to discuss the detail of this issue, to free up innovation funding for local trials beginning in the worst affected areas, and to develop best practice in holiday provision, and, of course, I offer Stoke-on-Trent North and Kidsgrove as the perfect constituency for an initial pilot. Finally, I ask the Minister to support further research into the impact of holiday hunger here in the UK, particularly on learning loss among vulnerable students.

This issue is simply too important to be a party political football, but it is also an immediate challenge to our very definition of responsible and caring Government, so we need actions, not words. Let us meet to get something done so our children are well fed, well educated and able to fulfil their potential.

2.45 pm

**The Minister for Children and Families (Edward Timpson):** I congratulate the hon. Member for Stoke-on-Trent North (Ruth Smeeth) and Kidsgrove on securing this debate. We have not met, but we are quite close neighbours and it is good to have another representative from our area speaking so passionately about an extremely important subject, which she rightly emphasised should exercise all our minds. We should be working as closely together as we possibly can to come up with the right solutions to all the problems society can throw at us, such as those she raises in this debate.

I think we can all agree that no child should go hungry. Like the hon. Lady, I have seen, both in my personal and professional life before politics, what can happen to children when that takes place, so I am in no doubt about the need for good nutrition and the vital role it plays in children’s development and health.

The Government want to give every child, regardless of background, the very best start in life. That approach is at the heart of our reforms to school meals. We have made real progress towards ensuring that all children are eating good, healthy food, which in turn will help them to concentrate in the classroom and support the healthy lifestyle we want to see.

The hon. Lady rightly pointed out that there is some developing research in this area, but considering how long this has been discussed—over many decades—there is still a paucity of research and that will need to be addressed so we can better understand the potential links between nutrition and educational attainment. I want to start by setting out the work being done by my Department to tackle this issue and we will then talk a little more widely about Government action in this area.

We published the school food plan, developed by independent food experts drawing on the views of teachers, cooks, caterers, nutritionists, parents, charities and volunteers. This has led to a practical action plan that is increasing the quality and take-up of school meals—which has been a long-standing problem—developing a whole-school food culture and exciting children about good food and cooking so that they can lead healthy lives.

As part of that plan, we have revised the school food standards so that they are easier for schools to understand and implement. They allow school cooks more creative freedom to adapt to the preferences of the children at

[Edward Timpson]

their school, source seasonal or local food, take advantage of price fluctuations, or create dishes that suit their particular talents. Importantly, parents will more easily be able to know if the food served to their children meets the standards. Most crucially, they restrict unhealthy foods to ensure our children eat well.

I took the time to read the Kellogg's report and it was interesting. One point it made is that although more money is being spent on food, the nutritional value is going down by virtue of the poor choices being made by parents for their children. We also need to tackle that, so children are eating nutritious meals.

**Catherine West** (Hornsey and Wood Green) (Lab): I thank the Minister for giving way; that is a convention not always observed in these debates. What is his view on the growing numbers of machines selling junk food? The name escapes me—

**Ruth Smeeth:** Vending machines.

**Catherine West:** Thank you. The number of vending machines in schools and hospitals seems to be growing. What is the Minister's view on that?

**Edward Timpson:** We have set out in the school food plan a clear objective to make as much home-grown nutritious food available to children as possible. I am not going to gainsay the position of other Ministers in the Department of Health and elsewhere who have responsibility for these areas, but we need to look carefully at the proliferation of vending machines to ensure that there is no exploitation going on and that they are not undermining the overall principle that we have set out in the school food plan and the school food standards.

We have also reformed the national curriculum to include new content on food, nutrition and healthy eating and on how to cook a whole repertoire of dishes. For the first time, learning about food is statutory for every pupil up to the age of 14. The school fruit and vegetable scheme provides a daily piece of fruit or a vegetable on school days to key stage 1 children—typically aged four to six—in primary schools and nurseries attached to eligible primary schools in England. We have also extended the right to free meals during term time to include disadvantaged students in further education as well as children from low income families in schools.

More widely, our ambition for disadvantaged pupils to be successful during their school years and to achieve the highest possible levels of educational attainment is at the centre of our education reform programme. That is why we are committed to raising the bar among disadvantaged pupils as part of pushing up standards for everyone, so that no pupil is left behind. This is built on the knowledge of how important educational attainment is for improving their life chances.

The Wolf report, which was commissioned by the last Government, showed that English and maths skills were vital for labour market entry and continued to have a significant impact on career progression and pay. That is why we are committed to ensuring that more poor pupils achieve excellent grades at GCSE, attend the very best universities or go on to an apprenticeship that will lead to their gaining skilled employment, so

that every child, regardless of their background, has an education that allows them to realise their full potential. Our reforms are working. More young people have got into work in the last year in this country than in the rest of the EU put together, and there are more than 1 million more pupils in England in good or outstanding schools than there were in 2010, with the attainment gap narrowing in the process.

As I said earlier, it is not just the Department for Education that has a vested interest in ensuring that all children, irrespective of their background, are protected from or lifted out of a childhood spent in poverty, including food poverty. That is why this Government want to work to eliminate child poverty, as did the last Labour Government, and to improve the life chances of every child. Our new approach, set out in the Welfare Reform and Work Bill, will incentivise the Government to focus on tackling the root causes of child poverty, not just the symptoms. Our new statutory life chances measures will drive continued clear action on work and education. This will make the biggest difference to disadvantaged children, now and in the future.

In reaching for that goal, we know that work is the best route out of poverty. Research shows us that around 75% of poor children living in families where both parents move into full employment leave poverty altogether. Economic growth and employment offer the best route to giving people a better future and to reducing poverty. As we have seen in the past year, we now have the fastest growth of any major advanced economy.

**Ruth Smeeth:** Thank you very much for giving way, Minister. I am grateful for your time and your commitment to this issue, now and previously. One of my concerns is that you have not talked about what happens during the school holidays. The Kellogg's report is obviously incredibly important, but this is about the impact of malnutrition during the school holidays on children's attainment when they come back to school. I agree with you that, traditionally, employment would be—

**Madam Deputy Speaker (Mrs Eleanor Laing):** Order. I allowed the hon. Lady to get away with it three times, but on the fourth time I have to tell her that she should use the word "you" only to address the Chair. If she means the Minister, she should refer to "the Minister" or "the hon. Gentleman".

**Ruth Smeeth:** I apologise. I am still claiming new status.

Will the Minister please give us some clarification on what action we can now take to draw a line in the sand and work together to tackle the specific issue of holiday hunger?

**Edward Timpson:** The hon. Lady is right to challenge me to move on to that aspect of this debate, and I intend to do so, once I have set out the underlying principles that the Government have in order to tackle poverty at its source by bearing down on its root causes. They help us to start to pull together exactly how we should respond to any of the issues she has raised on what happens in the school holidays for some children.

Employment is up by more than 2 million since the 2010 election, and the number of children growing up in workless households is at a record low—it has decreased

by 480,000 since 2010. Household incomes will be higher in 2015 than in 2010. In the summer Budget, the Government announced that a new national living wage of £7.20 an hour will be introduced, giving full-time low-paid workers an extra £20 a week when it is introduced in April. The hon. Lady rightly reminds us, however, that times are still tough for many families, and it would be wrong to deny that some deep-rooted problems leading to children being in food poverty need to be tackled. As the all-party group on hunger and food poverty has found, the reasons behind demands for emergency food assistance are complex and frequently overlapping. We need to understand better how we start to unravel that, so we can address it in the best way possible. The work of civil society and faith groups to support vulnerable people has been immensely impressive, and I would like to take this opportunity to recognise the valuable contribution of all those involved.

Perhaps the greatest frustration for all of us is that as a country we have enough food to feed us all—there is enough food to go around—and so it is wrong that anyone should go hungry at the same time as surplus food is going to waste. Food waste must be tackled—that has to be part of the solution—and surplus food must be redistributed. That is why the Government have taken action to ensure that more surplus food is redistributed to people before being put to any other use. The Waste and Resources Action Programme has published research, guiding principles and good practice case studies to help industry take action. Building further on that work, the Secretary of State for Environment, Food and Rural Affairs and the Minister for Civil Society have brought together key players from retail, food manufacturing and redistribution organisations to agree new actions to further increase levels of food redistribution, so that people who need it can access it. A working group is driving that forward—to waste less and redistribute more.

**Matthew Pennycook** *rose*—

**Edward Timpson:** I am sorry, but I am short of time and I have to keep going.

We are also taking action to help families with their food costs specifically, for example, through the Department of Health's Healthy Start scheme, which provides nutritional support for pregnant women, new mothers and low income families throughout the UK. Healthy Start is helping half a million families buy milk, fruit and fresh and frozen vegetables. The hon. Lady also highlighted a number of other schemes going on up and down the country, and I have taken time to look at those. The National Housing

Consortium, in particular, has been helping lead many of those initiatives. I welcome that work that is going on, and I would be happy to ensure that the Minister responsible has a chance to consider them as well, together with the other requests that the hon. Lady made towards the end of her speech, so that we can see this as a joint venture to tackle what we know to be a real part of pervading societal problems for far too long. Although I believe the work the Government are doing to tackle the root causes of poverty will help alleviate many of those issues, we still need to look carefully at how it affects different communities in different parts of the country, so that we can be more creative and innovative about how we respond to it, so that as few children as possible ever find themselves in that position in the future—we hope none will.

The Government have put in place a long-term plan for economic growth, to raise living standards for all, and that plan is working; we were the fastest-growing major advanced economy in 2014, wages are rising at the fastest rate in a decade, employment has risen by 2 million since 2010 and the number of children in workless families has fallen to a record low.

In schools, we have introduced measures that will ensure that children are offered more nutritious and appetising meals, which will improve their health and development. We know that we have 1 million more children being taught in good and outstanding schools, and we have raised the bar for achieving for all children no matter what their background is, so that their performance will match and exceed that of their peers in the highest-performing countries across the world, giving them the best possible chance of securing rewarding further education and employment.

We should never dilute our determination to tackle child poverty in all its forms. I have set out a range of actions in this short debate. The Government are taking action to reduce poverty and to give children, wherever they live, a better and healthier future. As we see changes in our society, we need to ensure that we do not shy away from problems, complex as some of them may be, and that we are open about them. As someone who has seen what happens when things go horribly wrong and children have ended up in need, I am as determined as the hon. Lady to ensure that we as politicians lead on this issue and that many more children do not suffer the consequences of our doing nothing.

*Question put and agreed to.*

3 pm

*House adjourned.*



# Petition

Friday 16 October 2015

## OBSERVATIONS

### EDUCATION

#### Ending violence against children

*The petition of residents of the UK,*

Declares that the petitioners support Unicef's campaign to end violence against children; further that the petitioners note that not all children have the opportunity to speak and therefore need people to speak for them; and further that Minehead Middle School recently held a campaign day on this subject and 200 pupils signed postcards calling for action.

The petitioners therefore request that the House of Commons urges the Government to support Unicef's campaign and to commit to working to end violence against children now.

And the petitioners remain, etc.—[Presented by Mr Ian Liddell-Grainger, *Official Report*, 7 July 2015; Vol. 598, c. 292.]

[P001531]

*Observations from the Secretary of State for Education:*

It is a fundamental right that children and young people are protected from abuse and neglect.

We applaud the petitioners' support for UNICEF's campaign to end violence against children. The campaign covers a broad range of child abuse and neglect, including physical, sexual and emotional abuse, in addition to violence.

We are also pleased that 200 pupils at Minehead Middle School signed postcards calling for action following a campaign day on this issue in June. This action shows clearly that they are against what is happening to children

all around the world. Raising awareness of global issues like this is an important part of encouraging children to become active, responsible citizens who allow their voices to be heard.

The petitioners may be interested to note that at a parliamentary reception earlier this year, many parliamentarians offered support for UNICEF's campaign. We also published updated statutory guidance on how services should work together and take action to protect children from abuse and neglect, working together to safeguard children, in March 2015.

The petitioners may also wish to note that tackling child abuse and neglect is already at the heart of the Government's agenda. In July, the Prime Minister announced a ministerial taskforce, chaired by the Secretary of State for Education, to take forward work on child protection.

The Government are committed to doing all that they can to reform the system of child protection in England to better protect children and young people against all forms of abuse and neglect; child sexual abuse has been prioritised as a national threat and there are major reforms aimed at driving improvements in the social care response to abuse by improving the quality of front-line social work practice.

In September, in New York, along with other UN member states, we adopted the sustainable development goals (SDGs). These are a new, universal set of goals and targets, that UN member states will be expected to use to frame their agendas and political policies over the next 15 years. Under goal five—achieve gender equality and empower all women and girls—there is a target on eliminating all forms of violence against women and girls in public and private spheres, including trafficking and sexual and other types of exploitation. Under goal 16—promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels—there is a target to end abuse, exploitation, trafficking, and all forms of violence against and torture of children.

The SDGs will become applicable from January 2016. The deadline for achieving the SDGs is 2030.



# PETITION

Friday 16 October 2015

	<i>Col. No.</i>
<b>EDUCATION</b> .....	5P
Ending violence against children .....	5P

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**CONTENTS**

**Friday 16 October 2015**

**Access to Medical Treatments (Innovation) Bill [Col. 558]**

*Motion for Second Reading—(Chris Heaton-Harris)—on a Division, agreed to  
Read a Second time*

**Homes (Fitness for Human Habitation) Bill [Col. 614]**

*Motion for Second Reading—(Ms Buck)*

**Child Food Poverty [Col. 626]**

*Debate on motion for Adjournment*

**Petition [Col. 5P]**

*Observations*

**Written Answers to Questions [The written answers can now be found at <http://www.parliament.uk/writtenanswers>]**

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