PARLIAMENTARY DEBATES

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OFFICIAL REPORT
GENERAL COMMITTEES

Public Bill Committee

ACCESS TO MEDICAL TREATMENTS (INNOVATION) BILL

Wednesday 16 December 2015

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STRICT ADHERENCE TO THIS ARRANGEMENT WILL GREATLY FACILITATE THE PROMPT PUBLICATION OF THE BOUND VOLUMES OF PROCEEDINGS IN GENERAL COMMITTEES

The Committee consisted of the following Members:

Chair: Mr Gary Streeter

Bardell, Hannah *(Livingston)* (SNP)
† Churchill, Jo *(Bury St Edmunds)* (Con)
† Davies, Byron *(Gower)* (Con)
† Davies, Chris *(Brecon and Radnorshire)* (Con)
† Davies, Dr James *(Vale of Clwyd)* (Con)
† Davies, Mims *(Eastleigh)* (Con)
† Freeman, George *(Parliamentary Under-Secretary of State for Life Sciences)*
Hayes, Helen *(Dulwich and West Norwood)* (Lab)
† Heaton-Harris, Chris *(Daventry)* (Con)
† Huq, Dr Rupa *(Ealing Central and Acton)* (Lab)
† Leslie, Chris *(Nottingham East)* (Lab/Co-op)
† Lumley, Karen *(Redditch)* (Con)
† Madders, Justin *(Ellesmere Port and Neston)* (Lab)
† Mak, Mr Alan *(Havant)* (Con)
† Thomas-Symonds, Nick *(Torfaen)* (Lab)
† Whitford, Dr Philippa *(Central Ayrshire)* (SNP)

Fergus Reid, Joanna Welham, *Committee Clerks*

† attended the Committee

Public Bill Committee

Wednesday 16 December 2015

[Mr Gary Streeter *in the Chair*]

Access to Medical Treatments (Innovation) Bill

2 pm

The Chair: Before we begin, I have a few preliminary announcements. Please switch all electronic devices to silent. Tea and coffee are not allowed during sittings. Hon. Members may remove their jackets if they so wish.

Today's proceedings are relatively rare; this is a private Member's Bill. Therefore, we will proceed in what used to be the time-honoured fashion—without a sittings motion and with our business governed by my selection of amendments and groupings and the decisions of the Committee.

In general, the choreography is like that in any other public Bill Committee. The Member with the lead amendment in a group kicks off. Then I propose the formal question. Then there is a debate on the whole group. Then the Member with the lead amendment responds and tells us whether they wish to withdraw the amendment or press it to a Division. We will deal with any votes requested on grouped amendments formally when we get to the lines of the Bill that they affect. That can be a little confusing, but I will seek to guide Members as we proceed. Then we move on to the next group or clause stand part debate as required.

There is no formal finishing time for this sitting—I was not looking forward to reading out those words. I hope that 4.30-ish will see us home, but we will see. Proceedings will be concluded either by us finishing our business and reporting the Bill or by a Member who has the floor—not intervening—moving the motion that the Committee do now adjourn. That is itself a debatable question, so there can be debate on that as well. If it looks like the Committee will not be able to complete its consideration of the Bill today, I will invite the Member in charge to move a sittings motion before any Adjournment.

Clause 1

Access to innovative medical treatments

Justin Madders (Ellesmere Port and Neston) (Lab): I beg to move amendment 1, in clause 1, page 1, line 3, leave out from first "to" to "for" in line 5 and insert "provide".

The Chair: With this it will be convenient to discuss the following:

Amendment 2, in clause 1, page 1, leave out lines 8 and 9.

Amendment 3, in clause 2, page 1, leave out line 17 and insert—

"(b) all of the positive and negative results of such treatments, and".

Amendment 4, in clause 2, page 1, line 17, at end insert—

"(c) patient experiences of such treatments.".

Justin Madders: It is always a pleasure to serve under your chairmanship, Mr Streeter. I congratulate the hon. Member for Daventry on successfully progressing his Bill to Committee. I have not been in this place long, but I am aware that many private Members' Bills fall well before this stage, so he deserves credit for clearing the hurdles placed in front of him so far. I also thank the hon. Gentleman for taking the time to meet me yesterday to discuss the Bill. I know from our conversation that he has put a huge amount of work into the Bill, and I am sure that even those who oppose it will have welcomed the opportunity that he has given to all the interested bodies to discuss it with him.

As I made clear during the debate on the money resolution, and as the shadow Secretary of State for Health, my hon. Friend the Member for Lewisham East (Heidi Alexander), set out in detail on Second Reading, Opposition Members believe that the Bill has been presented by the hon. Gentleman with the best of intentions, but we have serious reservations about some aspects of it. I will set those out in relation to our amendments 1 and 2, which we intend to press to a vote.

As I am sure the hon. Gentleman has been reminded on many occasions, the breadth of opposition to the Bill is extraordinary. It unites a huge number of professional bodies, royal colleges, charities and patients' bodies. That opposition has been particularly strong in relation to clause 3 onwards, and we share the concerns about those clauses.

Our first two amendments relate to the introductory comments in clause 1, which sets out the purpose of the Bill. Amendment 1 would remove the words

"promote access to innovative medical treatments by… providing"

in lines 3 to 5 on page 1 and insert instead in line 5 the word "provide". Amendment 2 would delete entirely lines 8 and 9. When combined together, and subject to what else is agreed today, those amendments would, we hope, remove entirely the provision in the Bill relating to what is described as "responsible innovation." In our view, that provision is at best unnecessary, possibly counterproductive and at worst potentially dangerous. It is unnecessary because to date no evidence has been provided to suggest that the threat of litigation acts as an inhibitor on doctors innovating. A number of bodies have spoken on that point, as indeed have hon. Members at previous stages of the Bill.

I will give a few examples. The British Medical Association 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 Academy of Medical Royal Colleges 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 Royal College of Surgeons said that

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

Even Sir Robert Francis, QC, said:

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

As the hon. Member for Daventry will know, many have also made the same point that the current law is not an impediment to innovation, so this part of the Bill

seeks to address a problem that we say simply does not exist. I am aware that some clinicians said in response to the Government consultation that that was a problem, but even the Minister conceded that very few saw it as the principal problem. If we are looking to break down barriers to innovation, a great many other factors mentioned in responses to that consultation could address the problem and are not set out in the Bill.

We also think that the Bill is counterproductive. Even were it accepted that there was a problem, the Bill could increase litigation and uncertainty among doctors. On that point, Earl Howe said in response to a similar provision in the Medical Innovation Bill that it may be that overall litigation claims increase slightly as the legislation is tested. This Bill adds an extra layer of complexity that the law does not warrant. I would be interested to know whether the Minister has any views on the potential for extra litigation arising from the Bill. As we know, the law on medical negligence has been developed over many years, and I am not persuaded that the perceived benefits of the Bill are worth upsetting the certainty and stability that the settled law has brought.

Most significantly, we consider the clause to be potentially dangerous. That is not an attempt to cast aspersions on the hon. Member for Daventry, as I know he is genuinely trying to do his best, but we all know about roads paved with good intentions. To give an example, because "innovative treatments" is not defined in the Bill, it applies to all decisions to treat that are outside the range of accepted treatments. It therefore includes treatments that would currently be considered negligent, because negligent treatments are by definition outside the range of accepted treatments. That by itself is concerning.

The Bill requires the agreement of two doctors that a treatment decision would be supported by a responsible body of medical opinion, but it does not tell us how that agreement is to be reached. Is it a chat over a pint at the golf club? On any analysis, that is in no way comparable to a court finding on the basis of expert evidence that there was a responsible body of opinion that would have supported the treatment and that the treatment was rational and reasonable in all circumstances.

"Treatment" is defined in clause 5 to include "inaction". For example, a patient might suffer from complications after bowel surgery. The patient having a fever and abdominal pain, the surgeon decides not to return them to theatre, but to continue with treatment of antibiotics and monitoring. In fact, the patient has a bowel perforation caused by the surgery and sadly dies. Under the current law, the court would find that no responsible body of surgeons would have delayed taking the patient to surgery within 24 hours. Had the surgeon done so, the patient's perforated bowel could have been repaired and they would have survived. The court would find that the surgeon was negligent and that the negligence caused the patient's death. The patient's family would in those circumstances be compensated.

If the Bill becomes law, the surgeon might have a defence where there is none currently. Suppose he had consulted a colleague and asked whether he thought a responsible body of surgeons would not take the patient back to theatre, but would adopt a "wait and see" approach. If the colleague agrees, the surgeon could say that he had weighed up all the advantages and disadvantages, that he had the agreement of the patient to wait and see, rather than to go back to theatre, that he had gone through all the right steps under the Bill and that it was just that the decision was a bad one, which in fact no reasonable body of surgeons would condone. The Bill would give him a defence in such circumstances. If he had gone through the right steps under the Bill, by definition he could not be found negligent.

I am worried that the Bill will muddy the waters on the legal route for doctors who wish to innovate. I am worried that it will reduce patient participation in clinical trials. If patients are faced with the choice of guaranteed access to treatment or participation in a trial in which there is a 50:50 chance that they will not be part of the group receiving innovative treatment, why would they choose to be part of the trial? I am worried about the potential removal of legal redress for a patient with a genuine negligence claim. I am worried that unsafe treatments could be used on dying patients. Clause 1 should be amended to remove that provision from the Bill.

I will speak briefly to the other two amendments in the group. Amendment 3 replaces a paragraph that reads:

"the results of such treatments",

and is intended to make it clear that we expect negative as well as positive results to be reported to prevent unsuccessful innovations being repeated, which would cause unnecessary suffering.

Amendment 4 would ensure that the information recorded on the database is as comprehensive as possible. In order to be a comprehensive record of the treatment, patient experiences need to be included. It may well be that the hon. Member for Daventry intends the Bill to be fairly general in its description of the database at this stage, in which case he may say that it is not necessary to have this level of prescription in the Bill. However, we believe that these are important details that should be set out now and included at this stage.

The Parliamentary Under-Secretary of State for Life Sciences (George Freeman): It is a pleasure to serve under your chairmanship, Mr Streeter. As the hon. Member for Ellesmere Port and Neston has just said, this is one of those Bills that has aroused a lot of interest. We have a number of issues to deal with in Committee and outside this room in further conversations.

I know that we are discussing specific amendments, but let me say briefly that I agree with much of what the hon. Gentleman said. Everybody accepts that the ambition of the Bill is noble: to promote innovation. Everybody in the health system accepts that innovation has been the lifeblood of medicine and of the NHS, and of this country's leadership in medicine. The point of difference we need to focus on is the one he eloquently raised: identifying the barriers to adoption of innovation and the extent to which fear of negligence is one of them. If it is not, what is the barrier?

The hon. Gentleman made an important point about the risk of even well-intentioned attempts to clarify having an inadvertent effect of generating a festival for lawyers, to debate whether or not the Bill could potentially have any effects other than those that Parliament intended. I certainly agree with him that if that were to happen it would be unhelpful.

The point of the clause, as I understand it, is to clarify for those who fear that the existing protections on negligence create a burden of proof that is unclear in

[George Freeman]

law and thus create a de facto barrier to innovation, a clear process that in no way changes the current provisions of medical negligence law. I can confirm that one of my main preoccupations has been to ensure that we in no way inadvertently or deliberately change that protection. We have had counsel look at that very carefully, and we have been advised that this would in no way change the basis of medical negligence law.

The Bill simply seeks to create a procedure that would provide clinicians with comfort that by pursuing that they are simply pursuing what is currently best practice under existing medical negligence provisions. I take the hon. Gentleman's point that, if it creates any significant uncertainty and thus inadvertently creates confusion, it will have the opposite effect to that it was seeking, which is to clarify the process.

The hon. Gentleman touched on the importance of need, and I will return to that point later because it goes to the heart of where the Committee ought to help get the Bill. He also touched on safety. I want to address that profoundly, because my No. 1 concern as a Health Minister is patient safety. I join him in paying tribute to my hon. Friend the Member for Daventry for taking the wide interest of the House in the subject and seeking to come up with a measure that can satisfy all parties. He has done a magnificent job of moving us on.

As I have said on the record at the Dispatch Box on more than one occasion, if the Bill, despite its best intentions, undermined patient safety or significantly created the perception that patient safety had been undermined, that would be very damaging for the UK and for the NHS. As the Minster responsible for getting more medical and clinical research into the UK, I cherish this country's hard-won reputation for setting the highest standards in research medicine. I would be concerned if the Bill specifically, deliberately or inadvertently harmed that.

The chief medical officer has said that she supports the Bill. From a safety point of view, I take a lot of comfort from that. Sir Bruce Keogh has said that he is absolutely sure that the Bill is safe in terms of patient safety, which has been our No. 1 criterion. I think that it would be fair to say that although Sir Bruce Keogh says that the Bill is safe, he does not necessarily lie awake at night longing for it to be passed. He shares some of our concerns about the avoidable but none the less quite predictable outcome of the Bill having the opposite effect to the one intended. From a safety point of view, I am absolutely sure, as a Minister, that the Bill will in no way interfere with current medical negligence practice and that it is merely an attempt to clarify the existing protections available to patients and clinicians.

2.15 pm

The hon. Gentleman made an important point about the level of opposition to the Bill. Even if I as a Minister were happy that the Bill does not in any way damage patient safety and could well help with innovation, it would be a self-defeating measure that I would not support if the price of doing that was to trigger widespread confusion about and hostility towards what we are doing and the UK landscape. I made it clear at the beginning that the Bill would need to command widespread support, even if not everybody was satisfied with it.

I want to make two other comments. One is about need, and the extent to which fear of negligence is a barrier to innovation. As you may know, Mr Streeter, if I went on "Mastermind", one of my chosen subjects would be barriers to innovation in the late 20th and early 21st century NHS. I do not want to detain the Committee with—

Chris Leslie (Nottingham East) (Lab/Co-op): You've started, so you should finish.

George Freeman: As the hon. Gentleman says, I have started so I had better finish. Let me wrap up a lifetime's work by saying that there are many barriers to the uptake of innovation in the system. It is clear from pretty substantial anecdotal evidence from people on the frontline that latterly, the fear of unreasonable charges of negligent practice features in their consideration. Some institutions—partly for other reasons to do with tightening up commissioning processes and clarifying and rationalising—have given clinicians instructions such as, "We don't want you to do anything other than these things; by the way, if you did, you might put us in a difficult position and we'd have to make sure we could defend possible litigation claims." That is often used, anecdotally and apocryphally, to support a more general presumption about sticking to what we know works and what we have always done.

My hon. Friend the Member for Daventry is partly trying to tackle a culture that is rather difficult to prove and ill-evidenced, but that we none the less picked up in the consultation. In my 15-year career, clinicians said to me, "We used to have a culture that was a bit more conducive to innovation, but we're all now slightly treading on eggshells and worried about any attempt being misconstrued." I do not want to suggest that such fear is the No. 1 issue or the most important priority. This is a private Member's Bill. If I were introducing a Government Bill on access to innovative medicine, I would have measures on a number of other issues before that one, but I respect that there is a cultural fear that innovative practice is less encouraged, promoted and supported, which we picked up in the consultation.

That is one thing that I, as a Minister, am keen to tackle through our work at the Department of Health to sponsor the National Institute for Health Research. The Prime Minister and I have set out a strategic objective: every hospital a research hospital, and every patient a research patient. We do not mean that every patient should be experimented on; we mean that, in an intelligent health system, we should be learning from every moment that we treat patients in the NHS.

I do not think fear of litigation is the No. 1 barrier to innovation, but equally, in an open democracy, Members are free to promote legislation on their own account. I have supported the attempt of my hon. Friend the Member for Daventry to have a debate and find a way of accelerating the uptake of innovation because it is a noble purpose.

I hope that what I have said is helpful and clarifies where I think the barriers are and are not. The bigger barriers are siloed funding, strict and specific commissioning structures, organisational barriers between people who diagnose and people who treat and a lack of integrated funding—all the things we spend our time trying to tackle. It is important that the chief medical officer

supports the Bill and that Sir Bruce Keogh has said he is absolutely sure that it is safe; he has advised the Secretary of State and I to that effect.

The Bill was in some ways preceded by a different one: Lord Saatchi's Bill in the House of Lords, which generated a lot of attention and interest. This is a very different Bill. Lord Saatchi's Bill set out provisions for a registry, which came late in the process of Lords scrutiny of that Bill, with the thinking being, "Oh, we'd better keep a register of innovations that flow as a result of this Bill."

If I understand it correctly, my hon. Friend's purpose is different, and I support him strongly in it, because this is another passion of mine. It is not about creating conditions in which every medic is exhorted and encouraged to experiment and record that in a database—that is absolutely not the right approach or what the Bill seeks to do. Importantly, the wording of the preamble in the opening clause focuses the Bill on something quite different, which I support: the provision of information to clinicians on innovative medicines coming on stream that are either in research trials, which doctors might want to enrolling their patents in, or off-label uses of drugs. No clinician can be expected to keep in their head 24/7 information about all the innovative medicines out there or, indeed, unlicensed medicines that might be available through the early access to medicines scheme that I launched. That wording intends to clarify that the Bill is different from Lord Saatchi's Bill, with a focus on giving clinicians access to information about treatments that they consider their patient might be eligible for. For me, that is the best bit of the Bill, and I would strongly support the Committee in continuing to debate it.

The hon. Member for Torfaen proposed a Bill, which did not get a Second Reading, that sought to promote off-label use of medicines. A database for clinicians that gave them, at the click of a mouse, access on their desktop to information about innovative medicines that are available—or, indeed, about off-label, innovative uses of existing medicines—would be a powerful tool to help promote innovation.

Chris Leslie: I am focused on the amendments. Will the Minister give us his view on whether he supports amendments 1 to 4? That would help.

George Freeman: I do not. I am politely winding my way round to saying that. However, the reasons are important. It is not that I object to amendments at all—I hope the Bill will be heavily amended in Committee to reach that nirvana of all the parties—but, because the clause is important and helps to clarify the Bill's intention, I suggest that the amendments should not be pressed. However, we might work on a package of amendments on Report that tackle giving clinicians access to information about innovative medicines and the important points made by the hon. Gentleman.

Dr Philippa Whitford (Central Ayrshire) (SNP): My concern about the Bill is that it seems to create a parallel system for something that we already have. We already have clear structures around litigation, defence and informed consent, which the Bill seems to bypass. If a doctor finds one other doctor who agrees with them, they can do what they like to somebody—they can go out and clip their privet hedge and give it to them: they are at the end of life and desperate, so they will try anything. That is really concerning.

The database would create a second information system that is not just about people reporting something. Someone might go to it in desperation, read about privet hedges and try that. That creates a separate system from the research system that has been developed over many years.

When I was a young doctor—sadly that was quite a long time ago—there was a paternalistic approach, in which the patient did exactly what the doctor told them. The thing is, when people are at the end of life or suffering from something for which we do not have an easy treatment, they are incredibly vulnerable, so we have a duty to protect them.

Part of the problem with the Bill is that it would create separate systems. Why should a doctor go through the entire system of pre-clinical research phases 1, 2 and 3, getting permission and getting things passed when, whatever their idea is, they can talk some wee lady into it and give it to them without any cover? That is quite frightening and would undermine our trials process.

There are things that could be improved. I agree with the Minister that some institutions have become rigid and defensive, thinking, "We don't want you using that for anything else." Out of the Bill we could get, as the Minister said, a database that talks about research that is going on that we could collaborate in, and what the findings and trial results are. Busy, front-line clinicians are often unaware of trials. In Scotland, we have the Scottish Breast Cancer Trials Group so that we flag up trials to people. There could be merit in that, but the idea that putting on a database something that I do to a patient, just randomly, somehow gives it credence is actually quite frightening.

We have Bolam. We have a system and a definition of negligence and litigation. Creating these two parallels undermines the patient. How can they give informed consent if we are talking about something that has no work-up, no safety profile and no phase 1 trials? How do we ensure that we are not encouraging people to do that across the country? There are things that could be done with the Bill but, as it stands, I have grave concerns, as many other doctors do.

The Chair: Before I call the Bill's promoter, I have allowed quite a lot of latitude but it is important in Committee to focus specifically on the amendments that we are deliberating, which the hon. Lady did without referring to them. That is the way forward and that is our system.

Chris Heaton-Harris (Daventry) (Con): It is a pleasure to serve under your chairmanship yet again, Mr Streeter. I hope you will be as gentle with me this time as you were last time.

The Chair: Unlikely.

Chris Heaton-Harris: It was worth a try. I welcome the speeches that we have just heard and I certainly welcome the engagement that I have had with the shadow spokesman and a whole range of people across the House on my Bill. I thank the Minister for his engaged

[Chris Heaton-Harris]

help and that of his officials, who have been unbelievably helpful behind the scenes and have set me right on a whole host of issues as I have been through the process—a process that has been very enjoyable but that I never intend to undertake again.

In talking about amendments 1 and 2, we probably just had the stand part debate for clauses 3 and 4. I am sure there will be a better debate at that point but, essentially, that is the major area of controversy in the Bill. I know that the hon. Member for Central Ayrshire has some concerns about the database. She has been unbelievably constructive in her approach to the Bill and I know that we can sit down and get to a point where her concerns are listened to and taken on board. I am very happy to work with her on amendments for Report, if she has any then, to get the Bill to that position.

On the amendments, the Minister said—I will not repeat all the Minister's words because they were wise, and wise words need to be heard only once by any parliamentary Committee—and parliamentary counsel gave me the same advice, that the Bill does not change medical negligence law. In fact, that is stated in the Bill. However, is there an actual need for it?

The Minister set out what happened in the consultation, as to whether there was a need and whether doctors were concerned about litigation. I want to put a couple of things on the record to show that I have not just made up the concern based on a casual hearing of what the Minister said about the consultation. On Second Reading, I read out a quote from Dr John Hickey. I will read it out again because I am not sure that many people heard it at the time. He said:

"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."

He was actually the chairman of my local NHS trust and I have a great deal of respect for him.

We all received a host of briefings; I know Committee members have enjoyed the briefings on the Bill they have received over the past few days. I apologise for any extra work I might have created.

2.30 pm

The BMA briefing is very powerful:

"*Provisions on negligence and 'responsible innovation' in clause 3 are counterproductive*: we are not aware of any evidence to suggest that the threat of litigation inhibits doctors to innovate, or that confusion exists amongst doctors over the circumstances under which they can deviate from standard practice."

In a moment we will discuss the amendments tabled by the hon. Member for Torfaen, whom I greatly respect and with whom I hope we can work to reach a place on off-patent drugs and the database, as the Minister said. The BMA also issued a briefing note for the hon. Gentleman's Bill on off-patent drugs that fell on Second Reading. In that briefing, the BMA notes two barriers to the use of off-patent drugs in a new indication. The first is:

"*Clinicians' confidence in prescribing:* clinicians take on a personal and professional liability if they prescribe an off-patent drug in a new indication therefore requires adequate reassurance."

In other words, they are asking for reassurance that what they are doing is not going to get them sued. The briefing goes on to say:

"The guidance also indicates a greater level of responsibility for the doctor prescribing off-label and therefore potential greater risk of liability which would be a disincentive for a doctor prescribing off-label drugs."

The BMA might well be against my Bill but it is well aware of some of the thoughts and processes that I have tried to identify. They are not made-up concerns; they happen on a daily basis throughout the NHS. I have spent so much time trying to get the Bill to the right place because, having identified a problem, I want to find a solution that works and does not create other trouble elsewhere.

I know from all the briefings I have read and the meetings I have had that I am still not yet in that place. However, I say to the hon. Member for Ellesmere Port and Neston, just as I made an offer to the hon. Member for Central Ayrshire, that I really want to get these parts of the Bill right. If I cannot, I will happily table amendments myself to delete them.

However, I think they have a purpose. I would like to have another go, working with others, to try to get them to the place that deals with the specific problem that I have identified; that does not change the common law and gives doctors the assurance they require. Therefore, I ask the hon. Member for Ellesmere Port and Neston, taking in the Minister's words, not to press the amendments, and work with me, the Minister and other interested people to see what we can do. If we cannot get anywhere, he has my assurance that I will table amendments to delete those parts of the Bill at a later stage. I cannot be much clearer than that on how I go forward.

I would like to talk briefly about amendments 3 and 4. There are positive and negatives. When I have talked about results that would include everything, I am not sure that the hon. Member for Ellesmere Port and Neston needs much more assurance on that. I believe that the current structure and wording of the Bill cover the hon. Gentleman's amendments. I am willing to consider them if he wants to push them again on Report.

I am trying to offer—not an olive branch, because there is no need for that—and to emphasise the constructive nature in which we can get the Bill to where it needs to be, so that we have a real understanding that it does what it says on the tin, that it is the Ronseal Bill for medical innovations, and that the database does what it is meant to do.

On amendment 4, which refers to patient experiences of such treatments, when the hon. Member for Ellesmere Port and Neston and I had our conversation, I said I thought it was not required. The Bill is wide enough to cover patient experience in the databases, including information about treatments and results. Actually, the purpose of the Bill is to confer a power on the Secretary of State to consult widely on covering all such matters

when he decides to act on that conferred power, so I do not think that the amendment is required at this stage. If the hon. Gentleman feels the need to press the amendment or to re-table it on Report, I will willingly work with him to get the words correct, so that he is satisfied with the wording and its purpose. For now, I ask him to withdraw his amendment.

Justin Madders: On amendments 3 and 4, I am happy to work with the hon. Gentleman and, if necessary, table an amendment on Report. I take what he says about this being a conferring Bill, but I think it was important for us to place on record our views about the importance of patient experience. We can have further conversations on that, and if we consider it necessary we will re-table those amendments. However, we will press amendments 1 and 2 to a vote.

I appreciate what the Minister said about the need to focus on innovation barriers. There is something in what he said about it being a cultural issue—there is no doubt about that. I do not think, however, that a piece of legislation of this nature is the right way to tackle that cultural issue. As I said in my opening comments, the Bill carries the risk of unintended consequences. We can all work together to try to tackle some of the barriers, but the Bill is not the way to do it.

Of course, the Minister has had the benefit of legal advice that I have not had on the impact on existing medical negligence law, but I am sure all members of the Committee have seen the representations from Nigel Poole QC, who is the leading authority on clinical negligence in this country. His view is that the Bill does make changes. We cannot get into a debate about who is right or wrong about that, but I focus on what the Minister said about how, even if the Bill only changes the perception of patient safety, that is important in itself. That alone is reason for us to pause and look again at the Bill, and that is why I will press amendments 1 and 2 to a vote.

Chris Leslie: To be absolutely clear on the effect of the amendments, as I read them, amendments 1 and 2 would delete the provisions about access to innovative treatment, but would retain the creation of the database. Have I got it right?

Justin Madders: Yes, my hon. Friend is absolutely correct. That is why we spent some time talking about those issues. They are really at the heart of the concerns.

George Freeman: Before the hon. Gentleman decides how he wants to proceed, I wanted to welcome the commitment my hon. Friend the Member for Daventry made to withdraw if we cannot reach agreement and to second my offer to sit down and work with members of the Committee and others to see whether we can get a package of amendments. I am rather less worried about other bits of the Bill from a Government point of view, but this bit is in many ways the best bit of the Bill. This is a very different Bill from the original Saatchi Bill, in that it focuses—perhaps not strongly enough for the hon. Gentleman—on getting information to clinicians on the innovative medicines that are out there. Funnily enough, it is the bit of the Bill I would most like us to keep. I reiterate that I am happy to work with members of the Committee, and to get officials to help us try to get the Bill into a better place, if that helps us to avoid an unnecessary Division.

Justin Madders: I am afraid that I do not have the confidence that we will be able to get the Bill to a place where we can agree. The widespread concern among all the royal colleges says to me that we need to start again, and that is why I will press the amendment to a vote.

Question put, That the amendment be made.

The Committee divided: Ayes 5, Noes 9.

Division No. 1]

AYES

Churchill, Jo	Freeman, George
Davies, Byron	Heaton-Harris, Chris
Davies, Chris	Lumley, Karen
Davies, Dr James	Mak, Mr Alan
Davies, Mims	

NOES

Huq, Dr Rupa	Thomas-Symonds, Nick
Leslie, Chris	
Madders, Justin	Whitford, Dr Philippa

Question accordingly negatived.

Nick Thomas-Symonds (Torfaen) (Lab): I beg to move amendment 7, in clause 1, page 1, line 3, after "treatments" insert,

", including access to off-patent drugs in new indications,"

The Chair: With this it will be convenient to discuss the following:

Amendment 8, in clause 1, page 1, line 9, at end insert—

"(c) providing for the establishment of an arm's length body to provide assistance to those seeking regulatory approval for off-patent drugs in new indications."

Amendment 9, in clause 2, page 1, line 29, after "involves" insert—

"(a) the use of off-patent drugs in new indications where there is strong evidence for their effectiveness; and

(b) a departure from the existing range of accepted medical treatments for the condition".

New clause 1—*Licenses for off-patent drugs*—

'( ) The Secretary of State, or a body nominated by the Secretary of State, has a duty to seek licences for off-patent drugs in new indications where—

(a) there is no commercial incentive for a profit-making body to do so,

(b) there is robust evidence of its effectiveness in the new indication, and

(c) the drug meets NICE's prioritisation criteria for Technology Appraisals."

New clause 2—*Appraisals for off-patent drugs*—

'( ) The Secretary of State has a duty to direct NICE technology appraisals or a suitable alternative, for off-patent drugs in new indications where—

(a) there is no commercial incentive for a profit-making body to do so,

(b) there is robust evidence of its effectiveness in the new indication, and

(c) the drug meets NICE's prioritisation criteria for Technology Appraisals."

Nick Thomas-Symonds: It is a pleasure to serve under your chairmanship, Mr Streeter. I join in congratulating the hon. Member for Daventry, who cares a great deal about policy on this matter and is promoting this Bill with the best of intentions. I also congratulate him on his Bill surmounting the hurdles and reaching Committee stage.

Before I come to the amendments, I think it would assist to explain the background, because that will make them explicable in the context of the Bill. I was also drawn in the ballot for private Member's Bills. The Second Reading of my Off-patent Drugs Bill took place on 6 November. I will quote from *Hansard* what I said that day to explain the purpose of that Bill.

"The Bill is a UK-wide Bill that creates a duty on the Government to make cheap drugs available when pharmaceutical companies have no incentive to do so. There is a problem: if a drug is shown to be useful for a new purpose after its original patent has expired, there is no financial incentive for a pharmaceutical company to sponsor that off-patent treatment through the processes that are normally used to license it, and to ensure its adoption on the NHS. Such off-patent treatments are usually available at low cost, but the current system is not set up to make them routinely available when they have been repurposed. Put simply, without a licence to act as a kitemark of safety, and a cost-effectiveness appraisal to give the NHS a mandate to provide it, there are multiple disincentives to treatments being prescribed, meaning that they are not routinely made available." —[*Official Report*, 6 November 2015; Vol. 601, c. 1289.]

The Under-Secretary of State for Life Sciences has already spoken about barriers.

My Bill received a great deal of support, not just across parties but outside the House, including from 12 medical research charities, the umbrella body for the NHS clinical commissioning groups in England and the BMA. More than 10,000 members of the public wrote in support to their MPs in addition to the more than 20,000 who wrote to Jonathan Evans, the then Conservative Member for Cardiff North, in support of the same Bill the year before. Four medical royal colleges backed it and 40 eminent physicians wrote to *The Daily Telegraph* in support of the Bill.

In addition, the all-party parliamentary group on off-patent drugs, which I chair, held an evidence session on 15 October this year during which Pan Pantziarka, a repurposing specialist, spoke in favour of the mechanism that my Bill would have provided to deal with the problem. He said that the obtaining of a licence created "a whole cascade" of other events, including the updating of the British National Formulary, the updating of guidance and the fact that clinical commissioning groups would take further note of that treatment.

The amendments in this group, including new clause 1 and new clause 2, are in effect my Bill coming in via amendment to this Bill. New clause 1 would place a duty on the Secretary of State to seek licences for off-patent drugs in new indications, and new clause 2 relates to direction of NICE technology appraisals. The Minister has concerns about those aspects of my Bill, so with the amendments I have attempted to provide a series of options for discussion, but they are what I would call the strong version of what is essentially my Bill. The Minister takes a different view, but I remain of the view that they represent a better way of dealing with this matter. Otherwise, of course, I would not have promoted my Bill in the first place.

2.45 pm

Amendment 7 would insert

"access to off-patent drugs in new indications"

into clause 1, which sets out the Bill's purpose. Amendment 8, which is a middle way—perhaps even a third way—would provide

"for the establishment of an arm's length body to provide assistance to those seeking regulatory approval for off-patent drugs in new indications."

That of course falls short of placing a duty on the Secretary of State, about which the Minister has concerns, but it goes beyond simply dealing with the matter on an information basis. Amendment 9 would incorporate off-patent drugs into the database, and I know that the Minister is passionate about the information issue.

My intention in tabling the amendments is constructive. I am keen to see whether a solution to the problem can be found, with both the hon. Member for Daventry and the Minister. The Second Reading of the Off-patent Drugs Bill on 6 November created some controversy when it was talked out by the Minister on duty, and the public's reaction has indicated that something needs to be done about off-patent drugs. I am willing to listen to what the Minister has to say and want to be as constructive as I can, but we need action on this matter.

George Freeman: I thank and pay tribute to the hon. Member for Torfaen for his persistence and patience in working with all parties on this matter. Similar to the Bill we are discussing, his Bill touched on an ambition shared by colleagues across the House to promote greater off-label use of medicines. I have encouraged him and my hon. Friend the Member for Daventry has welcomed his commitment to try to work through this Bill to see whether we might be able to tackle some of the same objectives, which is an ambition I strongly support.

In this Bill, my hon. Friend the Member for Daventry has repositioned a much stronger focus on the database being a registry not for capturing innovations that medics might or might not think are reasonable to record, but for the provision of information to clinicians on licensed, unlicensed and off-label uses for innovative medicines that are currently being developed. That represents a powerful opportunity for us to strike a blow for getting clinicians access to drugs that are in development, in trials or in an early access to medicine scheme and to off-label drugs currently in use of which clinicians might be unaware.

I dream of the day when a clinician can talk to a patient, click on their electronic medical records to see their history, click on available treatments for patients of that profile and see, at the click of a mouse, what clinicians around the country are doing, including the numbers. That could then be used to help intelligent prescribing, using their best clinical judgment and their knowledge of the patient. There is an interesting opportunity for us to do something here.

Let me turn to the amendments. Amendment 7 seeks to make it explicit in the Bill that "treatments" includes access to off-patent drugs. I actually support that ambition. Lawyers at the Department of Health will tell me that it is otiose—a legal term meaning that it is not strictly necessary—but, as a pure democrat, I think that it would be helpful if we could find a way to make it clear that that is specifically what we want to achieve. I can list the reasons why a lawyer might say it is not a good

use of legislation because it is already covered by the existing definition, which it is. I think it would be helpful to send a message that we explicitly want the database to promote off-label use. As the Minister responsible, I would happily take instruction in whatever mechanism from the House to go away and come back with a proposal on it.

Amendment 8 seeks to provide for the establishment of an arm's length body to assist those seeking regulatory approval for off-patent drugs in a new indication. As the hon. Member for Torfaen is aware, we have talked about that at length. Although I understand the thinking behind it, I do not accept it. For those colleagues who have not been following this debate closely, the thinking is broadly that because an off-label indication does not have an applicant company with a patent and a commercial interest, there is nobody to promote its case, and to put together the data package, lobby for it and advocate for it through the system, and to ask NICE to look at it. Word has got round that, because of that absence of a commercial interest, those uses are not being properly looked into, and that if it had a licence clinicians would use those off-label indications.

I understand it, but I think that the logic is profoundly flawed for two or three reasons. First, the evidence is that even where off-label indications are well evidenced and even recommended by NICE, in which case there is clearly no barrier, uptake is patchy and in some places slow. That is not because of the absence of recommendations and data. In the example of the use of Tamoxifen as a preventative treatment for cancer, in fact, patients and clinicians decide not to use it, in many cases because of the side effects or because women prefer to have surgery. It is not due to the lack of a licence; it is because it is an off-label use and has different impacts on different patients, and patients always want to reserve the right. It is the same with the use of bisphosphonates. There are off-label treatments that are well evidenced and well supported and recommended by NICE. It is not about the absence of a licence.

Most profoundly, I worry that if we expected all off-label uses to have a licence we would inadvertently create a situation in which those off-label uses that did not have a licence would suddenly become questionable. I totally understand that is not the intention of the hon. Member for Torfaen. We might actually undermine our objective and end up in a situation in which we have to license every single off-label use in order to keep it legitimate, which would be the complete opposite of what my hon. Friend the Member for Daventry wants to achieve. I will come later to why the Secretary of State and I do not want to become the licensors of medicines.

Dr Whitford: I accept the Minister's point about Tamoxifen. There are certainly other reasons why patients do not take it. As we move into an era of more and more non-medical prescribers—nurses and professions allied to medicine—those people are going to be a lot less comfortable prescribing unlicensed drugs that are not in the "British National Formulary". Those people are made to sign a liability form and they are simply not going to do that. We are moving patients out into the community. The idea that they will come to a specialist every eight weeks for a prescription is not practical.

George Freeman: The hon. Lady makes an excellent point, with the benefit of her front-line experience. It goes to the heart of why this Bill and that of the hon. Member for Torfaen mesh together. As she says, there are now clinicians on the frontline, nurses and others, making decisions and they need guidance. My only point of dispute is that a licence is a very heavy-handed form of guidance. I want to signal that I am actively and enthusiastically looking at ways of ensuring that front-line clinicians get the right guidance without creating a structure that requires the Department and Ministers to become the licensors of every off-label use. That is not least through the accelerated access review, about which I will be specific in a minute.

Nick Thomas-Symonds: That has been the difference between myself and the Minister in this debate for a number of months. The aim surely has to be to get consistency both across different medical sectors and prescribers in terms of off-label use. The big problem, as the Minister is aware, has been inconsistency.

There is an argument, and the Under-Secretary of State for Life Sciences made the point, about licences being heavy-handed. However, there would at least be consistency. We must find a way through that provides such consistency.

George Freeman: The hon. Gentleman makes a good point, up to a point, because one needs to preserve clinical freedoms and clinicians need to be free to make the right decision for their patient. However, I appreciate that the point he is making, principally, is that we do not want pockets of enlightened use of off-label drugs, perhaps because a group of clinicians has access to the information or works in a research hospital, for example. We want patients to have access across the whole system. That is why the ambition to use, and the possibility of using, the database in the Bill could be powerful.

Amendment 8 seeks to provide for the establishment of an arm's length body to assist those seeking regulatory approval for off-patent drugs in a new indication. The Government do not support the amendment. As I have said, we support the objective, but we do not support that mechanism. The Medicines and Healthcare Products Regulatory Agency, for which I am responsible, already provides advice to people who want to apply for marketing authorisations.

We have no plans to fund an additional arm's length body, and I do not believe that it would be helpful. However, I am happy to ask the accelerated access review team to look specifically at the question of how we could promote the use of off-label medicines, and to give recommendations to that effect, and, if that is not possible in the next few weeks, as the team finalises its recommendations, to take action as a review and come back on that specifically.

I would happily sit down with the hon. Member for Torfaen and the promoter of the Bill to see whether we can agree a form of words. I am signalling my willingness to amend the Bill to make the ambition very clear, but I cannot accept the amendment. I do not want to go back to the Secretary of State tonight and tell him, "Great news, Secretary of State! You and I have now become the licensors of off-label medicines and will be putting together regulatory and litigation packages. We are going to set up a pre-clinical office." It is not what he and I are here for, mainly because we are here to drive and protect patient safety.

[George Freeman]

It is for others to bring forward drugs and for us to regulate them. It would be a profound and fundamental conflict of interest if we were to take that on. Off-label use of medicines is widespread in the system today, particularly in paediatrics, without the need for licences. I do not accept that licensing is the right mechanism, but I happily accept that we should put into the Bill the fundamental objective of promoting off-label use.

Nick Thomas-Symonds: The Minister is entirely right on paediatrics. There is also quite widespread off-label use in anaesthetics, but of course that shows the problem, because there is pretty consistent use in those two areas but not in other medical specialisms, which is of course the point.

George Freeman: It is a point well made by the hon. Gentleman.

It could be argued that strictly speaking the wording of the Bill makes amendment 9 unnecessary, but I have quite a lot of sympathy with it, in the spirit of my response to amendment 7. Again, I wanted to offer the possibility of sitting down with the hon. Gentleman and officials to see whether we could reach a wording to bring before hon. Members to capture the ambition of giving effect to greater off-label use.

Currently, all innovative treatment falls within the scope of the Bill, including not only innovative medicines but the innovative use of existing medicines. However, given the level of interest in and the particular challenge with off-label drugs—the subject elicits particular interest, not least with some patient groups—it could be powerful to make that more explicit.

With regard to new clause 1, I reiterate that, as the licensing authority for the United Kingdom, the Secretary of State cannot become a routine applicant for licences. Neither would it be appropriate for the Government to take on responsibility for bringing medicines to market, which is a requirement of marketing authorisation holders. If my right hon. Friend the Secretary of State was responsible for nominating a body to undertake the role, that would still place him in far too close a proximity to the state of being a licence applicant, and would conflict with his responsibility to oversee and ensure the quality of the system. I encourage the hon. Gentleman not to press the new clause, but I am very open to seeing whether we can put a package together on Report.

The Secretary of State already has the power—a power he delegates to me, for this purpose—to direct NICE to carry out a technology appraisal where appropriate, but new clause 2 would turn that freedom into a binding obligation for NICE to carry out an appraisal where the use of an off-patent drug might be better addressed by a different NICE product. I understand the ambition behind the new clause, and I am happy to work on the wording of the Bill, but that mechanism is too restrictive and too binding. It would put the Secretary of State and me in a difficult situation.

3 pm

NICE clinical guidelines often cover off-patent drugs, and NICE evidence summaries have been developed specifically to cover off-label uses. NICE technology appraisals are often not the most appropriate type of mechanism for off-patent drugs. I am happy to pick up the action and talk to NICE and the accelerated access review about whether we can make specific provisions, to ensure that we have the right mechanisms for NICE to promote off-label use in a much less expensive and bureaucratic way.

I hope that I have given the hon. Gentleman enough reassurance and explained the rationale. I strongly support his intentions and will happily talk to him about amendments we might table, but I cannot accept the mechanism proposed.

Chris Heaton-Harris: I will be brief. I have listened to the debate. The hon. Member for Torfaen put his case strongly, and there is a constructive and helpful offer on the table from the Minister. I simply ask the hon. Gentleman to withdraw his amendment and to take up the offer to return to this on Report, having worked on something with the Minister, the team from the Department of Health and me. Hopefully we can then get to a good place on the off-label use of drugs.

The Chair: Our timing is good. We might have a Division downstairs shortly, so we have plenty of time for Mr Thomas-Symonds to respond.

Nick Thomas-Symonds: I am grateful to both the hon. Member for Daventry and the Minister for Life Sciences for their reassurances. Having spent 11 years as a lawyer, I know that while certain things may be otiose, the more explicit one can be in a Bill such as this, the better it is and the more reassurance that is given. That is important.

It is important that off-patent drugs are on the face of the Bill; I do not think the Minister has any objection to that, from what I heard. His reassurance about specifically asking the accelerated access review to look at the matter is much appreciated. On new clause 2, if the role of NICE technology appraisals could be made explicit in the Bill, that would be extremely helpful.

I am very willing to take up the Minister's offer to sit down and look at this issue with me and to work constructively. On the basis of the reassurances I have been given, I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Amendment proposed: 2, in clause 1, page 1, leave out lines 8 and 9—*(Justin Madders.)*

Question put, That the amendment be made.

The Committee divided: Ayes 5, Noes 9.

Division No. 2]

AYES

Huq, Dr Rupa	Thomas-Symonds, Nick
Leslie, Chris	
Madders, Justin	Whitford, Dr Philippa

NOES

Churchill, Jo	Freeman, George
Davies, Byron	Heaton-Harris, Chris
Davies, Chris	Lumley, Karen
Davies, Dr James	Mak, Mr Alan
Davies, Mims	

Question accordingly negatived.

3.4 pm

Sitting suspended for a Division in the House.

3.15 pm

On resuming—

Clause 1 ordered to stand part of the Bill.

Clause 2

DATABASE OF INNOVATIVE TREATMENTS

Justin Madders: I beg to move amendment 5, in clause 2, page 2, line 20, at end insert—

'(b) the General Medical Council,

(c) the British Medical Association,

(d) the Association of Medical Research Charities,

(e) the Royal Colleges,

(f) the Academy of Medical Sciences,

(g) the Medical Research Council,

(h) the National Institute for Health and Care Excellence, and

(i) the Medicines and Health Products Regulatory Agency.'

The Chair: With this it will be convenient to discuss amendment 6, in clause 2, page 2, line 20, at end insert—

'(6A) Regulations under subsection (1) may not be made unless the Secretary of State is satisfied that the regulations have the approval in principle of—

(a) the HSCIC,

(b) the General Medical Council,

(c) the British Medical Association,

(d) the Association of Medical Research Charities,

(e) the Royal Colleges,

(f) the Academy of Medical Sciences,

(g) the Medical Research Council,

(h) the National Institute for Health and Care Excellence, and

(i) the Medicines and Health Products Regulatory Agency.'

Justin Madders: I will be briefer on these amendments.

The clause deals with the creation of the database, which we consider unnecessary, because the Secretary of State already has the relevant power under section 254 of the Health and Social Care Act 2012. Even if there is a difference of opinion and the clause remains in the Bill, we want to broaden the number of bodies that the Secretary of State must consult. We think the list in the amendment is comprehensive, whereas, as the Bill stands, to make regulations under clause 2, the Secretary of State need consult only the Health and Social Care Information Centre. The explanatory notes to the Bill state:

"The detailed design of the database would be consulted upon with professional bodies and organisations",

from which we take some comfort, but we feel that it is better to be clear in the Bill about the wider range of bodies to be consulted.

Amendment 6 would insert a proposed new subsection (6A) requiring the Secretary of State to seek approval for regulations from the bodies on the same list, in essence, as in amendment 5, but with the addition of the HSCIC. It is about having approval in principle, as well as the details and mechanics of the database.

We are not making a complicated point, but we are putting on record our wish for a broader selection of groups to be consulted.

George Freeman: I will be brief. Following our earlier conversation about the database provisions, I emphasise that they are the part of the Bill that the Government most strongly support. The database is not envisaged as it was in the predecessor Bill—if I may call it that—as a registry for recording ad hoc innovations by clinicians, but as a fundamental database to give all clinicians access to information on innovative medicines, including off-label uses of medicines and medicines that are either unlicensed but in use, as in the early access to medicines scheme, or in clinical trials, in which a patient might be eligible to enrol. The clause gives the Secretary of State the power to make regulations conferring functions on the HSCIC, the body that develops and puts into place databases such as the one we are discussing, in connection with the establishment, maintenance and operation of the database for innovative medical treatments.

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

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

The Government do not support amendment 5 because it is not exhaustive. Although it represents a helpful list of consultees, such a provision would need to include many more organisations. While I understand the intention behind the amendment, restricting the process would not be helpful, but I would be happy to write to members of the Committee about our approach. I undertake to write to all the relevant organisations and to ensure that they are consulted, but I am old enough and ugly enough to know that well-intentioned lists of statutory consultees can quickly become out of date. They can create weird anomalies whereby parties that really have nothing to say are statutory consultees, yet those who have a lot to say are not. I am happy to discuss what other steps we can take to ensure that those who, rightly, need to be informed about the Bill and the mechanisms it proposes are properly informed.

[George Freeman]

The Government do not support amendment 6 for the same reason—because the list is not exhaustive—but I will be happy to put in a place an alternative mechanism to ensure that those parties listed the amendment and others are properly informed. I would not want to put in law a list of consultees that we might well need to amend quite quickly. I, for one, do not want to find myself back in Committee considering a statutory instrument to amend a list of statutory consultees established by a well-intentioned proposal, so I hope that the hon. Member for Ellesmere Port and Neston will withdraw the amendment.

Chris Heaton-Harris: Obviously, I agree with the Minister, and I have discussed the matter with the shadow Minister. I know from my consultation on the Bill with stakeholders that we would need longer lists than those in the amendments. I hope that the hon. Member for Ellesmere Port and Neston will agree to the Minister's generous offer and therefore withdraw the amendment.

Justin Madders: Our debate has shown that a well-intentioned proposal might have unintended consequences, so I accept what the Minister and the hon. Member for Daventry say about the need for comprehensive lists. I think that the lists in the amendments are pretty comprehensive, but I accept that other bodies might emerge or feel that they should be included. I am happy to work with the hon. Gentlemen to ensure that we reflect the intention behind the amendments, yet do not create additional work a few years down the line because we have to amend the legislation. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Clause 2 ordered to stand part of the Bill.

Clauses 3 to 5 ordered to stand part of the Bill.

Clause 6

EXTENT, COMMENCEMENT AND SHORT TITLE

Question proposed, That the clause stand part of the Bill.

George Freeman: On a point of order, Mr Streeter. This may be a point of order, although I stand to be corrected.

The Chair: If you want to say something nice about the Committee, let us do that after clause 6.

George Freeman: I just wanted to repeat the offer I made earlier. Although we are skittling through these clauses, let me say, in the spirit of co-operation between all Members, that, if Members felt it appropriate, I would happily convene a round table before Report and Third Reading. There is obviously a bit of work to be done between the hon. Member for Torfaen and my hon. Friend the Member for Daventry. I will happily put my office at the disposal of that work and convene a meeting to try to prepare some amendments that might be tabled on Report. If you think it appropriate, Mr Streeter, we could circulate them among the members of this Committee, and, if it were possible to say, "These amendment are in the spirit of the Committee deliberations and are agreed"—albeit possibly not unanimously—I happily suggest that as something we might do.

The Chair: That is a very fine offer and I am sure the Committee is grateful to the Minister, whom I thank for his point of order. We were, however, considering the Question that clause 6 stand part of the Bill.

Question put and agreed to.

Clause 6 accordingly ordered to stand part of the Bill.

Question proposed, That the Chair do report the Bill to the House.

The Chair: This debate is an opportunity for Mr Heaton-Harris to say something nice about the Chair.

Chris Heaton-Harris: Thank you, Mr Streeter. What a wise Chairman you are—one of the best Committee Chairmen ever.

I thank all members of the Committee for their forbearance, especially those who have distinct issues with parts of the Bill. The offers I made are real, and, if I cannot get the controversial parts in clauses 3 and 4 into the right place quickly, I intend to table amendments to delete them, as I said to the hon. Member for Torfaen, so that there is absolute clarity. I look forward to working with anybody who wants to work with me on getting all the other provisions in the Bill into the right place.

I thank you very much, Mr Streeter, and would like to wish a very merry Christmas to every member of the Committee and staff, especially the departmental staff. There is a gentleman called Mr Peter Knight who helped convene a workshop last week for me to explain to interested organisations what the database could look like and how the consultation on it might proceed, which shed a lot of light on this issue and clarified things.

George Freeman: I would like briefly to add my thanks to you, Mr Streeter, for chairing the Committee.

We have had a constructive discussion with all parties represented on the Committee, with some front-line advice from clinicians. I thank my hon. Friend the Member for Daventry for his clear offer. I pay tribute to him for the clarity of that offer. The Government are concerned that this Bill, with the noblest of intentions, is still not in a place where it has widespread support from all parties. A Bill that elicits concerns and opposition from both industry and charities, patient groups, lawyers and the General Medical Council is a Bill whose nobility of purpose is not yet reflected in unanimity of support.

I am grateful to my hon. Friend, and I know that he is keen to get the Bill to a point where it can be distinguished from a predecessor Bill that generated a lot of heat and some opposition. I genuinely believe he is trying to get to that point, particularly on the database provisions. I urge him to keep his foot to the pedal, particularly on the negligence provisions, on which we have a bit more work to do. I repeat that if a well-intentioned Bill has the inadvertent effect of undermining patient and public trust in the world-class status of our research medicine and clinical trials, it will be self-defeating and I would find it impossible to support. However, we have a chance to avoid that.

I thank you for your excellent chairmanship of the Committee, Mr Streeter, and add my thanks to the officials sitting on both sides of you, who have guided

us through this process. I hope we can get to a point where we can go back to the House on Report and say that this Committee has managed to rescue a noble cause and, with the help of my hon. Friend the Member for Daventry, put forward a proposal we can all support.

Justin Madders: May I start by thanking you, Mr Streeter, for your chairmanship of the Committee? I hope that this is the first of many times we will meet in such a situation. I also thank the Minister and the hon. Member for Daventry for the open way in which they took on board our concerns. I, along with my hon. Friend the Member for Torfaen, will be pleased to accept any offers to help get the Bill into a shape where it has the support of not only Members of all parties, but, most importantly, the greater medical community. The hon. Member for Daventry is a beacon of optimism in that respect, given the level of concern that remains, but we shall try. The Minister is right that we do not want to put into law something about which there is such widespread concern, but we shall see where we get to on Report.

Question put and agreed to.

Bill accordingly to be reported, without amendment.

3.31 pm

Committee rose.