Vol. 809
No. 173

Thursday
14 January 2021

PARLIAMENTARY DEBATES
(HANSARD)

HOUSE OF LORDS
OFFICIAL REPORT

ORDER OF BUSINESS

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The following abbreviations are used to show a Member's party affiliation:

Abbreviation	Party/Group
CB	Cross Bench
Con	Conservative
DUP	Democratic Unionist Party
GP	Green Party
Ind Lab	Independent Labour
Ind LD	Independent Liberal Democrat
Ind SD	Independent Social Democrat
Ind UU	Independent Ulster Unionist
Lab	Labour
Lab Co-op	Labour and Co-operative Party
LD	Liberal Democrat
LD Ind	Liberal Democrat Independent
Non-afl	Non-affiliated
PC	Plaid Cymru
UKIP	UK Independence Party
UUP	Ulster Unionist Party

No party affiliation is given for Members serving the House in a formal capacity, the Lords spiritual, Members on leave of absence or Members who are otherwise disqualified from sitting in the House.

House of Lords

Thursday 14 January 2021

The House met in a hybrid proceeding.

Noon

Prayers—read by the Lord Bishop of Birmingham.

Arrangement of Business

Announcement

12.06 pm

The Deputy Speaker (The Earl of Kinnoull) (Non-Afl): My Lords, the Hybrid Sitting of the House will now begin. Some Members are here in the Chamber, others are participating remotely, but all Members will be treated equally. I ask all Members to respect social distancing. If the capacity of the Chamber is exceeded at any point, I will immediately adjourn the House.

Oral Questions will now commence. Please can those asking supplementary questions keep them to no longer than 30 seconds and confined to two points? I ask that Ministers' answers are also brief.

Constitution, Democracy and Human Rights Commission

Question

12.07 pm

Asked by ***Lord Young of Cookham***

To ask Her Majesty's Government when they plan to establish the Constitution, Democracy and Human Rights Commission.

The Minister of State, Cabinet Office (Lord True) (Con): My Lords, the Government remain absolutely committed to looking at the broader aspects of the constitution and the relationship between the Government, Parliament and the courts, as pledged in our manifesto. We are taking forward the work via a range of work-streams, some of which have already been announced, such as the Independent Review of Administrative Law. Others will be announced in due course.

Lord Young of Cookham (Con): My Lords, our manifesto said:

"In our first year we will set up a Constitution, Democracy & Rights Commission."

This was confirmed on 29 January last year, when the noble Earl, Lord Howe, said:

"We will set up the commission within this Government's first year. Further announcements will be made in due course."—[*Official Report*, 29/1/20; col. 1437.]

Since then, silence. But the Library tells me that the Government have established seven other independent reviews and one public inquiry. So, for the fourth time, I ask the Government for a debate in which they set out their emerging thoughts and your Lordships set out their priorities. We can then move forward on a broad basis of support that commands public confidence.

Lord True (Con): My Lords, as a very experienced Minister himself, my noble friend knows that debates are matters for the usual channels. He asked about progress with a constitutional review. I have indicated that the Government are determined to pursue this in a range of independent workstreams. That has begun in the first year with the Independent Review of Administrative Law.

Baroness Quin (Lab) [V]: I support the words of the noble Lord, Lord Young, and urge a cross-party and non-party approach to these issues; otherwise, what emerges from the Government's plans will lack credibility. Before we lurch into any more divisive or closely fought referendums, can we please try to have cross-party and wide agreement on when referendums should be used in our parliamentary democracy, perhaps by following some of the recommendations in the report of the House of Lords cross-party Constitution Committee published a few years ago?

Lord True (Con): My Lords, the Government are not seeking referendums, although I understand that another political party in the kingdom is. We will not go in that direction. I certainly agree that cross-party approaches are desirable. Another constitutional issue that we are addressing is fixed-term Parliaments, which the Government have put forward for pre-legislative scrutiny by a cross-party Joint Committee.

The Lord Bishop of Birmingham [V]: My Lords, I welcome the request from the noble Lord, Lord Young, and the call from the noble Baroness, Lady Quin, for a cross-party, independent approach to this. Were the commission to make a primary objective strengthening the union and a Parliament working for the whole United Kingdom, does the Minister agree that it should give serious consideration to the devolution of power in England away from Westminster, whether to regional mayors, assemblies or even an English assembly?

Lord True (Con): My Lords, those concepts are obviously extremely important and are no doubt the subject of continuing discussion in and across all parties. As the right reverend Prelate will know, regional assemblies were proposed by a previous Government and rejected by the electorate.

Lord Norton of Louth (Con) [V]: My Lords, given the sheer scale of the disparate constitutional reforms that have taken place in recent decades and that derive from no intellectually coherent approach to constitutional change, does my noble friend agree that we need a body that can stand back and make sense of where we are, that is grounded in an understanding of our constitution—qua constitution—and that does not rush in with knee-jerk reactions and ill-thought-through proposals for more change?

Lord True (Con): My Lords, I am not sure about the proposition of a body. I think that, ultimately, authority to determine must reside in Parliament and in part in your Lordships' House. I hope that we will have debates and discussion. I agree with my noble

[LORD TRUE]
friend that a lot of change was ill thought through, but I assure noble Lords that the Government intend to proceed cautiously and with independent advice.

Lord Tyler (LD) [V]: My Lords, does the Cabinet Office recognise that more piecemeal changes to the constitution and to electoral law, such as No. 10 taking back control of the Prorogation and Dissolution of Parliament, weakening controls on election spending and attacking the independence and integrity of the Electoral Commission, break the manifesto promise, which has been referred to, of a comprehensive constitution commission, set up to take evidence in the first 12 months of this Government?

Lord True (Con): No, my Lords. I do not accept the characterisation of my right honourable friend the Prime Minister by the noble Lord, Lord Tyler. I must say that the Liberal Democrat party has never been slow to come forward with radical changes to the constitution with very little consultation with others.

Lord Howell of Guildford (Con) [V]: My Lords, this is a big canvas but, given the enormous impact of the communications revolution and the ever more powerful media platforms' monopolies on trust in government, on parliamentary constitutional authority, on the unity of the UK itself and on our future national direction, can we be assured that the commission's remit when it is set up covers these fundamental issues, as many people are asking for, as well as more conventional areas of constitutional reform?

Lord True (Con): Aside from the question of whether it be under the ambit of a commission, I believe that my noble friend puts his finger on something that is profoundly important about the way in which the context of politics and government is changing. Without treading on anyone's feet, I would certainly be interested to hear your Lordships' opinion on that in a future debate.

Lord Carlile of Berriew (CB) [V]: Please could the noble Lord explain simply to a perplexed audience the relationship between Sir Peter Gross's review of the Human Rights Act, the review by the noble Lord, Lord Faulks, of administrative law and the constitution, democracy and human rights commission being discussed today?

Lord True (Con): My Lords, those are two separate workstreams as part of the constitutional reform consideration that we are undertaking. As my right honourable friend the Chancellor of the Duchy of Lancaster said, we are eating the elephant in chunks. The Fixed-term Parliaments Act review is another part, so there are already three strands and they each deserve careful and individual attention.

Baroness Hayter of Kentish Town (Lab): Assuming that the commission will go ahead—although I am not absolutely sure, from what the Minister said, that it will—then, following up on what my noble friend Lady Quin and the right reverend Prelate the Bishop of Birmingham said, it will have public support only if it is truly independent. Will the Government commit that the commission, when it is appointed, will be independent and non-partisan and ensure that its members are not beholden either to the Government or indeed to any other special interest?

Lord True (Con): My Lords, I have said that the Government are delivering the commitment in the manifesto to look at the broader aspects of the constitution in a range of separate workstreams. Obviously, this and others to be announced in due course will all reflect what the noble Baroness has said and what I have said—indeed, that is the case for those reviews that have been set up already and the cross-party Joint Committee that is looking at the FTPA.

Lord Wallace of Saltaire (LD) [V]: My Lords, I wish to repeat what the noble Lord, Lord Young, said in his opening question, which is that any constitutional reform needs to have broad-based support that inspires public confidence. How do the Conservative Party and its associated right-wing think tanks, eating the elephant in chunks and bending the conventions of the constitution in the way that it has in the last year, begin to deal with public alienation from politics and holding the union of Great Britain together?

Lord True (Con): I think that on reflection the noble Lord will think that he does a disservice to those serving on the Independent Review of Administrative Law, those reviewing under Sir Peter Gross the operation of the Human Rights Act and indeed Members of both Houses on the Joint Committee when he characterises them in that way.

Baroness D'Souza (CB) [V]: My Lords, the broad and radical mandate of the proposed commission would indeed be better managed in bite sizes, as the Minister has suggested. Do Her Majesty's Government have plans to expand the deliberative democracy initiatives that they have so far sponsored in Dudley, Cambridge and the Test Valley?

Lord True (Con): I am grateful for the noble Baroness's support for the approach that I have outlined. On her specific question, I cannot give a commitment on that at the Dispatch Box now, but I will repeat what I have said to the House: other workstreams on constitutional review will be announced in due course.

The Deputy Speaker (The Earl of Kinnoull) (Non-Afl): My Lords, the time allowed for this Question has now elapsed.

Foreign Policy: UK-EU Dialogue

Question

12.18 pm

Asked by ***Baroness Northover***

To ask Her Majesty's Government what formal arrangements they have put in place to enable regular dialogue between the United Kingdom and the European Union about foreign policy matters.

The Minister of State, Foreign, Commonwealth and Development Office (Lord Ahmad of Wimbledon) (Con): My Lords, we have agreed with the European Union that we shall co-operate on current and emerging global issues of common interest, including co-ordinating positions and maintaining dialogue in multilateral organisations. We do not need overly institutionalised formal arrangements or a treaty framework within the EU to continue to co-operate closely with allies on foreign policy matters, including EU member states. We shall continue to discuss shared foreign policy challenges and threats and we look forward to a future relationship based on constructive co-operation between sovereign and independent allies.

Baroness Northover (LD): The 2019 political declaration, which the Prime Minister said he supported, proposed a partnership between the UK and the EU on foreign policy, security and defence matters. Why then did the United Kingdom not take forward a formal arrangement despite EU willingness? Will the Government now do so? If not, how do they plan to protect and promote our interests in Hong Kong or on sanctions and other issues?

Lord Ahmad of Wimbledon (Con): My Lords, on the practical terms that the noble Baroness mentioned, she will be aware that we are working closely with EU partners and other allies on issues of sanctions and indeed issues relating to Hong Kong. The EU-UK Trade and Cooperation Agreement affirms our mutual commitment to democratic principles, the rule of law and human rights. As the noble Baroness will be aware, we are already working closely on many important issues—including issues of human rights, which are part of my portfolio—both bilaterally and through multilateral organisations.

Lord Browne of Ladyton (Lab) [V]: My Lords, an unstable and unruly world needs strong alliances between countries seeking international stability and co-operation rather than competition. The Biden Administration will expect the UK not to behave in a way that weakens the EU. As all but six members of the EU are members of NATO, we have already integrated sufficient elements of our defence. Does the Minister agree that formal arrangements of co-operation between us on security and foreign policy are inevitable? He certainly did so in October 2019, when he strongly supported deep co-operation as set out in the revised UK-EU political declaration.

Lord Ahmad of Wimbledon (Con): My Lords, as the noble Lord will know from his own experience as a Minister and as a Defence Secretary, and as he rightly articulated, NATO is the cornerstone of our relationship on the defence of Europe and the democratic values that we stand for. We remain committed to and at the centre of that NATO alliance, working with EU colleagues as well as other nations, most notably the United States. I reiterate our commitment to co-operation with our EU allies and others on important issues that currently confront the world.

Baroness Smith of Newnham (LD) [V]: My Lords, the Minister reiterates the Government's commitment to co-operation with the European Union, but now that we no longer have a seat at the table, what mechanisms is the FCDO putting in place to ensure that we have regular contact with our bilateral partners in the EU 27 and individual member states?

Lord Ahmad of Wimbledon (Con): My Lords, as I have already alluded to in my original Answer, formality of mechanisms is not a necessity for having close alliances, not least as demonstrated by our alliances with the United States, Canada and Australia in our meetings through the Five Eyes. We will continue to co-operate with our EU colleagues, as we have done on important statements on the JCPOA and on support for human rights issues around the world, including a recent statement in relation to Xinjiang.

Lord Lamont of Lerwick (Con) [V]: My Lords, is it not the case that, for the most part, the whole idea of a common EU foreign policy was always more of an aspiration or a myth than a reality, particularly when one looks at the divisions over EU policy towards Kosovo, Syria, Iraq and Russia, not to mention the shambles of EU policy towards Ukraine? Nevertheless, is it not possible and in our interest—without getting bogged down in the rather impractical bureaucracy of the common security and foreign policy—for there to be some formal mechanism for discussing policy with those with whom, after all, we share certain fundamental values as well as the same geographical space?

Lord Ahmad of Wimbledon (Con): My Lords, my noble friend speaks from insight and experience and I listen carefully to his suggestions. Let me assure him that we are already working closely with EU colleagues. As the new relationship evolves, I am sure that we will look at how we can further strengthen co-operation on the very issues that he has outlined for reasons of proximity. As my right honourable friend the Prime Minister said, we want to be the best ally and the closest friend of the EU.

Baroness Deech (CB) [V]: My Lords, of course co-operation is a good thing, but now that we are free, we can diverge for the better and hope to persuade the EU to take a better path; for example, in relation to China. Only yesterday, we heard of the atrocities taking place there from the Conservative Party Human Rights Commission, but the EU has signed an investment agreement with China disregarding its crimes. Does the Minister agree that we must form an Anglo-American alliance and other alliances against Chinese atrocities and against buying Chinese-tainted goods and technology?

Lord Ahmad of Wimbledon (Con): My Lords, I agree with the noble Baroness's point about creating alliances against the human rights abuses that we have seen in places such as Xinjiang and the continued suppression of democratic movements within Hong Kong, but it is not just about further strengthening our alliances with the US; it is about building international alliances and co-operation. Let me assure the noble Baroness that we are doing just that.

Lord Collins of Highbury (Lab): My Lords, the Minister mentioned the JCPOA, and, of course, with the new US Administration, there is renewed optimism

[Lord Collins of Highbury]
that it could be revived. The Government have been working recently with France and Germany in relation to Iran's non-compliance. Could this E3 format be extended to other areas of mutual interest and concern?

Lord Ahmad of Wimbledon (Con): My Lords, the noble Lord makes a practical suggestion. I am sure that in time, as we see the strength of E3 co-operation and with the new Administration in the United States, there will be areas of further co-operation in this respect. We look forward to forging alliances with the E3 and with other European states, both bilaterally and within the context of the European Union, as well as with the new US Administration when it takes charge after President-elect Biden's inauguration.

Lord Campbell of Pittenweem (LD) [V]: My Lords, now that we are no longer members of the European Union, what influence will we have, for example, in preventing the creation of defence structures which would duplicate NATO?

Lord Ahmad of Wimbledon (Con): My Lords, we liaise closely not just on issues of defence but on other areas. The global human rights sanctions regime that we led on and that is now being taken forward by the European Union is a good practical example of that. We will continue to co-operate on defence and other matters with the EU to ensure non-duplication, as the noble Lord suggests.

Baroness Ritchie of Downpatrick (Non-Afl) [V]: My Lords, can the Minister detail the nature of future structured or unstructured engagement with the EU on foreign policy around the issues of security and human rights?

Lord Ahmad of Wimbledon (Con): My Lords, I have already alluded to that, but I assure the noble Baroness that we engage regularly. As a Minister responsible for human rights, I engage personally with the European Union human rights lead, Eamon Gilmore, and will continue to do so.

Baroness Helic (Con) [V]: My Lords, just before Christmas, and after 16 years, the United Kingdom left the EU-led military mission to Bosnia-Herzegovina. Separately, there are reports that the FCDO expects to cut expenditure on its western Balkans programme from the current £80 million to under £50 million or possibly even £35 million. Can my noble friend the Minister confirm that these reports of cuts are true and, if so, can I urge the Government to reconsider this step, which would have a damaging effect on our influence in the region and with our allies and risk being interpreted as yet further proof that the United Kingdom is turning its back on the EU and the western Balkans?

Lord Ahmad of Wimbledon (Con): My Lords, we continue to engage on the Balkans. On the specifics of my noble friend's question, I shall write to her.

Lord Bilimoria (CB) [V]: My Lords, the United Kingdom has one of the finest and largest diplomatic forces in the world, something of which we should be proud. Does the Minister agree that Britain has always been seen as a gateway to the EU and that now is an opportunity, with a new US Administration, for Britain to partner with the United States and the European Union on many areas, including security and foreign policy?

Lord Ahmad of Wimbledon (Con): My Lords, I totally agree with the noble Lord and I look forward to working with him on important priorities in terms both of trade and strengthening relationships, particularly in the Indo-Pacific region. Looking at the position of global Britain, it is worth reflecting that in under two years we have agreed 63 trade deals, which are valued at £885 billion. No country has done this; this is in less than two years. We still have trade deals being finalised with the United States and Australia to come. The picture for global Britain in terms of the facts on the ground is very positive. We look forward to strengthening our co-operation further with all partners across the world and working with your Lordships' House, with the experience it brings, on strengthening global Britain and its place on the world stage.

The Deputy Speaker (The Earl of Kinnoull) (Non-Afl): My Lords, the time allowed for this Question has now elapsed. We now come to the third Oral Question.

Construction Industry: Retention Payments

Question

12.29 pm

Asked by ***Lord Aberdare***

To ask Her Majesty's Government what steps they have taken since the publication on 26 February 2020 of the responses to their consultation on retention payments in the construction industry.

The Parliamentary Under-Secretary of State, Department for Business, Energy and Industrial Strategy (Lord Callanan) (Con): The Government, in conjunction with the Construction Leadership Council, are working to develop a sustainable strategy on retentions for the whole sector. During the current pandemic we have also provided guidance to the industry on responsible and fair contractual behaviour, including in relation to retentions. We are committed to improving payment practices and working with the construction industry to take this important matter forward.

Lord Aberdare (CB): My Lords, it is three years since the Government's consultation on retentions ended and, as we have been reminded today, three years since the collapse of Carillion, which led to small construction firms losing hundreds of millions of pounds in retentions. Retentions limit their ability to invest, grow, train staff, take on apprentices and, all too often, survive. The actions mentioned by the Minister are better than nothing but do not go nearly far enough. I have two questions. What are the Government doing now to prevent small construction firms, already under pressure from the pandemic, being crippled

because funds properly belonging to them are being used by larger clients to prop up their own cash flows? When will the Government introduce the legislation reform that is recognised as the only way of bringing proper ongoing relief to these small firms?

Lord Callanan (Con): I know that the noble Lord has been active for many years on this important issue. This has been a slower process than we might have liked, in part due to the complexity of the issues associated with the practice of cash retentions and the wide range of interested parties. While most in the construction industry favour or could accept change, unfortunately no consensus on a preferred solution has emerged from industry to date.

Lord McColl of Dulwich (Con) [V]: My Lords, what happened to the suggestion in the Murray review of 2017 that retention payments for subcontractors and vendors on major projects should be held in a designated trust account? As far as retention payments are concerned, will it help to develop the system of financial rewards for those who settle accounts earlier?

Lord Callanan (Con): That is indeed one of the policy suggestions we are looking at, but given the complexity of the policy issues, it is premature to commit to the introduction of a retention deposit scheme. We will continue to seek consensus and work with industry to find a way forward.

Baroness Wheatcroft (CB) [V]: Can the Minister estimate the construction payments retained by the public sector, specifying the extent of the payments to Carillion retained by the Government? Given that there were only 55 responses to a consultation that concluded in February 2018, why did it take two years to publish those findings on what he terms an "important matter"?

Lord Callanan (Con): I do not have figures for the public sector, but not withholding retentions is government policy—although I am aware that some departments and agencies do. Unfortunately, we do not have the power to instruct local authorities in this matter. If there are any figures available, I will of course let her have them.

Lord Stevenson of Balmacara (Lab) [V]: My Lords, I declare an interest as my wife is a construction lawyer. This issue was raised regularly by the late Lord O'Neill of Clackmannan, and I am sure I speak for the whole House when I say that we miss him. The consultation referred to by the noble Lord, Lord Aberdare, is highly critical of current practice. It also stresses that the pandemic raises major insolvency worries. Why do the Government not use their Covid-19 emergency powers either to introduce an RDS or to abolish retention payments and try out this new policy?

Lord Callanan (Con): I join with the noble Lord in paying tribute to the work of the late Lord O'Neill: as the president of the Specialist Engineering Contractors' Group, he was active on this issue for many years and instigated an inquiry on it in 2002. As I have said, given the complexity of the policy issues, there remains no consensus on the way forward, but we will continue to examine the issues, to work with industry and to seek a solution to this problem.

Lord German (LD): The last two paragraphs of the Government's responses paper lay out only two policy options: the retention deposit scheme or phasing out retentions completely. May I follow the noble Lord, Lord Aberdare, in pressing the Minister? He already has the responses and knows the two options before him. Can he tell us when the legislation will come forward to make this happen? It is much needed and will avoid late payments, non-payments and insolvencies.

Lord Callanan (Con): Those are two of the alternatives that have been suggested as a policy response. Changes in this area would require primary legislation, and there is always pressure on the Government's legislative timetable. We think that working with the industry to seek a consensus is a good way forward, but there is not yet a consensus: some notable companies are against a deposit retention scheme or the other policy option the noble Lord mentioned.

Baroness Donaghy (Lab) [V]: I would like to thank the Minister and the noble Lord, Lord Stevenson, for referring to Lord O'Neill. We miss him and I am sure the industry misses him.

This has been going on for decades. The large construction companies that owe money to subcontractors use it as working capital. Having a retention fund would stabilise the industry and prevent job losses and redundancies. What priority will the Government give to taking long overdue action?

Lord Callanan (Con): The noble Baroness is right: this has been going on for a long time and under many different Governments. The complexity of the issues is one reason why no action has been taken so far. As I said, we are committed to working with industry to find a consensus, and we are working with the Construction Leadership Council. We are committed to addressing the related issue of late payments, and we will try to find a consensus on a way forward.

Lord Kirkhope of Harrogate (Con) [V]: My Lords, although the consultation process was quite wide, only seven individuals contributed. Does my noble friend agree that, particularly at this time, any arbitrary or unfair retention of moneys due to individual tradesmen and women—whose skills we must retain in the construction industry—exerts a disproportionate pressure on them and the continuation of their specialist services? Is it not time to alleviate the pressures on these people in particular?

Lord Callanan (Con): I agree with my noble friend. We understand that the practice of cash retention can create problems for individuals and businesses in the construction supply chain, due to late payment or non-payment. We are committed to improving payment practices and working with the construction industry to try to take this matter forward.

Baroness Jones of Moulsecoomb (GP): My Lords, I understand the attraction of looking for consensus among all the players, but it is obvious that the current system is unjust and has a particular impact on smaller businesses, which need the money desperately. Why do the Government not just take a lead and govern as they should?

Lord Callanan (Con): At the risk of repeating myself, it would require primary legislation and there is pressure on the legislative timetable. There are a number of different options to take this forward. We are committed to ending the practice of late payment and we will work with industry to try to find a solution to this problem.

Lord Stunell (LD) [V]: The Minister's answers so far have been deeply disappointing. Of course there is no consensus within the industry, because there are winners and losers. The winners of the present system are the big companies; the losers are everybody else. The current retention system undermines trust and confidence, destroys capacity and deters long-term investment in training and skills. Having heard noble Lords today, will the Minister agree to come back to your Lordships' House before the end of this Session and say exactly how and when the Government plan to mitigate the damage caused by the current system? He cannot sit on his hands and say he is waiting for other people to come to their decisions first.

Lord Callanan (Con): We are not waiting for other people to come to their decisions. We are actively working with the Construction Leadership Council to try to find a solution to this problem.

Lord Bourne of Aberystwyth (Con) [V]: My Lords, this is clearly a serious problem. In the meantime, the building industry has committed to achieving zero cash retention by 2025. Can the Minister inform us how that process is being pursued? What success are we having?

Lord Callanan (Con): A lot of discussions are taking place between the Government, the Construction Leadership Council and different parts of the industry; we are actively exploring possible solutions and are committed to improving payment practices and working with the construction industry to take this forward. Of course, any solution has to work for the industry and its clients, and it has to be sustainable, addressing all of the issues: the need for surety and fair, prompt payment. As I said earlier, several policy options are being considered, including a possible retention deposit scheme and, of course, phasing out retentions completely. During the current pandemic, the Government, in conjunction with the Construction Leadership Council, have provided guidance to the industry on responsible and fair contractual behaviour, which, of course, includes retentions.

The Deputy Speaker (The Earl of Kinnoull) (Non-Afl): My Lords, all supplementary questions have now been asked, and we move to the fourth Oral Question.

Biodiversity: Impact of Neonicotinoids

Question

12.40 pm

Asked by ***Lord Randall of Uxbridge***

To ask Her Majesty's Government what assessment they made of the impact on biodiversity of the decision to grant authorisation to use a product containing a neonicotinoid to treat sugar beet in 2021.

The Minister of State, Department for the Environment, Food and Rural Affairs and Foreign, Commonwealth and Development Office (Lord Goldsmith of Richmond Park) (Con) [V]: The Government considered the impact on biodiversity and the environment posed by the use of the product Cruiser SB on the basis of expert scientific assessment. The Government concluded that, when mitigated by the strict conditions attached to the emergency authorisations, the impacts were outweighed by the benefits of use. The Government remain committed to tight controls on neonicotinoids and have no intention of lifting the restrictions that were put in place in 2018.

Lord Randall of Uxbridge (Con) [V]: I draw attention to my environmental interests, as laid down in the register. My noble friend cannot be unaware of the immense frustration, and even anger, felt by many at this decision. While I understand the plight of beet growers, can he acknowledge that there are no safeguards to prevent this dangerous substance entering watercourses? Even his own department acknowledges that this treatment is massively harmful to wildlife. Will my noble friend commit to publishing the NFU 2020 application and any detailed advice from the UK Expert Committee on Pesticides and English Nature, so that we can have full transparency to understand the decision-making process?

Lord Goldsmith of Richmond Park (Con) [V]: I will certainly convey the noble Lord's request in relation to the NFU application, but I am afraid that is not a decision I can make here and now. The Government are committed, in the way that they were last month, last year and the year before, to the neonicotinoid restrictions that were put in place in 2018. This emergency authorisation has been approved for a very limited period for one specific crop, sugar beet, which does not flower and is grown only in the east of England. Tight controls are part of the conditions of the authorisation to minimise environmental and biodiversity impacts.

Lord Wigley (PC) [V]: My Lords, this initiative is for England only, of course, but it will certainly have a knock-on effect on Wales. Does the Minister accept that the neonicotinoids used on sugar beet will leach into the soil and water at the base of the crop, contaminating flowering weeds, with implications for other wildlife and pollinators and triggering further pesticide treatment? The Government contend that this will be avoided by ensuring that flowering crops will not be planted in fields previously supporting sugar beet—how will this be enforced?

Lord Goldsmith of Richmond Park (Con) [V]: If Cruiser SB were to be used by everyone who is covered by the emergency authorisation that has been provided, the amount used would be around 6% of the quantity applied in each of the years running up to the ban on neonicotinoids—so we are talking about very specific circumstances. The conditions include a reduced application rate, as well as a 22-month prohibition on any flowering crop being planted after a treated sugar beet crop. For oilseed rape, which, as you know, is particularly attractive to pollinating insects, the prohibition extends to 32 months. No one likes pesticides, but the conditions that Defra has applied will limit whatever potential negatives exist.

Viscount Ridley (Con) [V]: My Lords, I refer to my farming interests in the register. Given that the derogation for sugar beet was broadly supported by members of the UK Expert Committee on Pesticides at its meeting in November, will my noble friend confirm that this is in sharp contrast to the emergency derogation granted by Defra earlier in 2020 to spray copper hydroxide as a blight fungicide on organic potato crops, which was opposed by members of the UK Expert Committee on Pesticides because of environmental concerns over acute aquatic toxicity? Would he agree that the way to get both conventional and organic farmers to use less pesticide is to enable innovative breeding technologies?

Lord Goldsmith of Richmond Park (Con) [V]: The noble Lord makes an important point. The Government's goal and the purpose of our pesticides programme action plan is to minimise the use of pesticides. A big part of this is specified in our 25-year environment plan, which commits us to prioritising integrated pest management to maximise the use of non-chemical control techniques and to minimise the use of chemical pesticides. In plain English, that means increasing the use of nature-friendly methods with the potential to enhance biodiversity, including benefiting pollinators. This approach is laid out in the revised national action plan for the sustainable use of pesticides, which is currently out for consultation. I encourage the noble Lord to take part in it.

Lord Cameron of Dillington (CB) [V]: My Lords, I declare an interest as chair of the UK Centre for Ecology & Hydrology, whose scientists proved to Syngenta and the world that neonicotinoids did indeed reduce the overwintering and reproduction success of both honey bees and wild bees—and that a decline in pollinators could cost us billions of pounds. Bearing in mind that new breeding techniques could soon solve the issue of virus yellows in sugar beet, I ask the Minister: what are the limitations to this neonicotinoid authorisation, in relation to a sunset clause and whether there are any geographic boundaries drawn around it?

Lord Goldsmith of Richmond Park (Con) [V]: The authorisation that has been provided is for a specific and limited period of time, covering one season, and there are no plans to extend that emergency authorisation. The purpose of this authorisation was to allow time for the industry, as the noble Lord says, to develop alternatives; it is urgently seeking to do so now. As I said in my opening remarks, we have absolutely no intention—and indeed we will not—to go back on the restrictions and bans that were brought in in 2018, which have been translated into UK law.

The Deputy Speaker (The Earl of Kinnoull) (Non-Afl): The noble Lord, Lord Berkeley, has withdrawn, so I call the noble Baroness, Lady Parminter.

Baroness Parminter (LD) [V]: My Lords, how is this decision compliant with the Aarhus convention on environmental justice, given that the application documents and the chief scientist's advice to the Government are being kept secret, and that, while the NFU lobbied undercover, the public could not participate in the process?

Lord Goldsmith of Richmond Park (Con) [V]: The ability to consider this emergency authorisation comes from EU legislation. It is not a case of reducing our standards after leaving the EU, since 10 EU countries including Belgium, Denmark and Spain granted emergency authorisations for neonicotinoid seed treatments used on sugar beet in 2020, just as we have done this year. Our position on these pesticides remains exactly the same; there is no divergence. We supported restrictions in 2018 and this is a narrow emergency authorisation, which has been made on the merits of the case.

Lord Forsyth of Drumlean (Con) [V]: My Lords, I declare my interest as a rather poor amateur beekeeper, for environmental reasons. Give that the evidence is that neonics are highly toxic to bees—5,000 to 10,000 times more than DDT—the importance of pollinators, and that we know that the residue which is lethal to bees will lie on leaves for several days, is it really sensible to even consider opening the door to the use of this lethal material? I appreciate that there is no evidence that the bee colony collapse is entirely related to this material but, given the pressures on bee populations, is it not rather irresponsible to consider making a derogation even as limited as this?

Lord Goldsmith of Richmond Park (Con) [V]: Pollinators have an almost unimaginable and incalculable importance. They are an essential part of our environment; they play a crucial role in food production and have suffered huge decline. There have been some promising signs over the last two or three years. Nevertheless, the news for pollinators in this country is bad. We have a national pollinator strategy with a 10-year plan, which involves significant ramping up of our efforts to create habitat for pollinators, strengthening the monitoring and management of honey bee diseases and threats from invasive non-native species such as the Asian hornet. The decision we are discussing was assessed by the Health and Safety Executive, Defra scientists and the UK Expert Committee on Pesticides. They all considered that evidence, and the view was that the conditions placed were sufficient to remove the threat that noble Lords are concerned about.

Baroness Jones of Whitchurch (Lab) [V]: My Lords, I declare an interest through my involvement at Rothamsted. Can I follow up the question put to the

[Baroness Jones of Whitchurch]
Minister by the noble Lord, Lord Randall, which I do not think he fully answered? Given the direct negative consequences of this policy on bees, which as we know are already in serious decline in the UK, will the Government commit to publishing urgently the full scientific assessment by the UK Expert Committee on Pesticides of this policy change on our natural environment, so that there is transparency about how the decision was made?

Lord Goldsmith of Richmond Park (Con) [V]: I can commit to conveying that request to the department. I see no reason why the assessment should not be made public, but it is not for me to unilaterally make that decision here and now.

Lord Curry of Kirkharle (CB) [V]: I declare my interest as recorded on the register. I thank the Minister but can he confirm that standards of production, including constraints on pesticide use, will apply to imported crops, including sugar, so that UK producers are not disadvantaged?

Lord Goldsmith of Richmond Park (Con) [V]: The noble Lord makes an extremely important point. The Government are guided, as they pursue new free trade agreements and seek to expand our trading relationships around the world, by a commitment to ensuring that imports do not compromise or undermine the standards that we are proud to apply here in the United Kingdom, whether in environmental or animal welfare standards.

The Deputy Speaker (The Earl of Kinnoull) (Non-Afl): My Lords, the time allowed for this Question has now elapsed.

12.51 pm

Sitting suspended.

Free School Meals: Food Parcels

Private Notice Question

1 pm

Asked by ***Lord Watson of Invergowrie***

To ask Her Majesty's Government what steps they are taking to monitor the quality of food parcels currently being supplied to families in lieu of free school meals.

The Parliamentary Under-Secretary of State, Department for Education and Department for International Trade (Baroness Berridge) (Con) [V]: My Lords, the images circulating of poor-quality food parcels are unacceptable. My right honourable friend the Secretary of State for Education has met leading suppliers to insist on urgent action to ensure that parcels meet standards expected. We have guidance in place allowing schools to decide the best approach for supporting free school meal pupils; this can be through lunch parcels, locally arranged vouchers or the national voucher scheme, which will be up and running next week.

Lord Watson of Invergowrie (Lab) [V]: My Lords, it is a case of another week, another U-turn, this time resulting from the scandal of companies that supply free school meals parcels being exposed as profiteering. Perhaps the Minister will explain why the jointly prepared DfE guidance for the contents of food parcels, which is strikingly similar to the meagre items in parcels described as "disgraceful" by the Prime Minister, is still online. National food vouchers are to be reintroduced next week, two weeks after schools moved to remote learning. It seems that the Government's own lockdown took them by surprise. It will be at least a week from today before parents can actually use the vouchers, so why will the Government not put their trust in families and give them the money for free school meals? Children are going hungry now, and any decent Government would know that they cannot wait.

Baroness Berridge (Con) [V]: My Lords, the voucher scheme that the noble Lord outlines is one option that has been given to schools so that they can meet the needs of pupils who require food. It has been quite clear—my right honourable friend the Secretary of State and the Minister for Children and Families met the particular supplier and made it clear that those standards were not acceptable. We have given these options to schools so they can best meet the needs of their pupils, as they know them best. In fact, schools can re-register this week for the national voucher scheme, and vouchers will be redeemable as of Monday. We have left it to schools to choose the best means to deliver free school meals to their pupils.

Lord Storey (LD) [V]: My Lords, can the Minister confirm that the company providing these meals will not get compensated for the cancellation of the contract, thereby getting money for nothing on top of money for little food? Furthermore, does she agree with Marcus Rashford that now is the time for a full review of the free school meals system?

Baroness Berridge (Con) [V]: My Lords, as I have outlined, views were made clear about the quality of the food parcels. I make it clear that the department does not enter into contracts with any of these suppliers—it is done at local level. The standards that food needs to meet are outlined in statute, and the guidance is under that, so it is quite clear what should be provided. I must pay tribute to school staff and catering staff who are delivering meals to those free school meals pupils who are in school. Often the option of delivering food parcels to the door is the best way to meet the needs of a vulnerable child, particularly because it keeps the school in contact with them directly.

Lord Krebs (CB) [V]: My Lords, government figures show that more than 4 million children in the UK live in poverty, and many of them will be living with food insecurity. However, there are no official figures. Therefore, could the Minister tell us when the Government will publish their assessment of how many children in the

UK are living without enough healthy food, and could she tell us what policies they will implement to tackle the problem in both the short and the long term?

Baroness Berridge (Con) [V]: My Lords, the Government are awaiting the second part of the national food strategy, and we have said that we will respond with a White Paper within six weeks of that strategy being published. We have expanded the entitlement to free school meals; at the moment, 1.4 million children receive free school meals. We have given the undertaking that any family that moves from legacy benefits on to universal credit will have an entitlement to free school meals. So we are meeting the needs of children. In addition to that, there are the holiday activity clubs that we have expanded, as of the Easter holidays of this year. So we are looking to meet the needs of those in our society who need food.

Baroness Jenkin of Kennington (Con) [V]: My Lords, can my noble friend confirm how this affects food waste? Am I right in understanding that much of this food, which of course is designed for lunches only, had been ordered or bought well in advance?

Baroness Berridge (Con) [V]: My Lords, the noble Baroness is correct. One key reason why the Government gave schools the choice was that they were aware of the operation of their own school catering staff—but also, certain suppliers had already purchased food and they had already paid for it so, obviously, moving to a voucher system immediately could have resulted in food waste. Giving the flexibility to schools in terms of local vouchers enables them to use local suppliers and to support their local economy.

Lord Griffiths of Burry Port (Lab) [V]: My Lords, the Prime Minister has said that Marcus Rashford is doing a better job at holding the Government to account than the Official Opposition. Does that mean that the Prime Minister is now prepared to accept Mr Rashford's advice that a major review of free school meals and, indeed, child poverty, might be undertaken by them as a result of mistakes recently made? While on my feet, I point out that the Government add insult to injury by handing out these disgraceful bags, which would have been an insult to those receiving them. Whenever policies are directed towards those trapped in poverty, they should never forget the dignity of those receiving them and to treat them with respect.

Baroness Berridge (Con) [V]: My Lords, I join the Prime Minister in paying tribute to the work of Marcus Rashford, which was recognised in the latest honours that he was given. In relation to the flexibility that we have given to schools here, it is important to remember that schools know their children best; they know whether food parcels are best. Obviously, receipt of a food parcel can be vital if the parent at home at the moment is extremely clinically vulnerable, so a voucher perhaps would not be best. Schools generally do not want to deal in cash. Yet we have also seen the use of food parcels that are not necessarily synonymous with a lack of dignity in terms of the clinically vulnerable people in the first stage of the pandemic—and also businesses have sprung up during the pandemic using food that was potentially to supply restaurants and delivering it door to door. So although there needs to be sensitivity in each situation, it is not synonymous with a lack of dignity to offer actual food to people.

The Deputy Speaker (Lord Russell of Liverpool) (CB): I call the noble Lord, Lord Greaves. The noble Lord is muted.

Lord Greaves (LD) [V]: Well, I unmuted myself, as agreed, and somebody muted me again, so I have unmuted again. It needs sorting out.

My Lords, there does not appear to be a major problem in Lancashire, because Lancashire County Council—and I congratulate it on this—set up a county-wide voucher scheme for schools when the schools closed again, after the first day. If Lancashire could do this on a county-wide basis, why could the Government not do it straightaway nationally?

Baroness Berridge (Con) [V]: My Lords, I applaud the example that the noble Lord has given, and I have outlined why it is important that these three options are open to schools. As I have said, schools can re-register this week for the national voucher system and reactivate their accounts, and vouchers will be redeemable and available from Monday. Also, of course, where there is a free school meal entitlement for those who also qualify for the breakfast club, that food should also be provided. This has been stood up as soon as we can. In the last phase of the pandemic we distributed more than £380 million through a national voucher scheme. Noble Lords made it clear that there were downsides to that, because it meant that the business was given only to supermarkets. So it is important that we use the food and do food parcels, local vouchers and national vouchers.

Lord Loomba (CB) [V]: My Lords, I commend the Government's decision to provide lunches to school-children. However, sadly, due to the carelessness of caterers, there has been a great deal of variation in the contents of the food parcels. What steps are the Government taking to tighten this up and be more specific, to stop this happening again? Alternatively, would they consider a voucher scheme again? That would go some way to alleviating this problem, as some schools still prefer to use their own caterers, which also helps save jobs.

Baroness Berridge (Con) [V]: I am grateful to the noble Lord for outlining the role that school caterers have at the moment. Some of them obviously want to be involved in the delivery of free school meals to qualifying children who are at home. It is clear that the standard of food that should be provided is based on a statutory requirement. The association of school food and caterers was part of putting that together. The provision of food should obviously be sensitive to dietary requirements and allergies, and to religious and cultural sensitivities, so that the food provided, whether in school or by way of delivery, is appropriate for the children.

Baroness Sanderson of Welton (Con): My Lords, this recent episode has, once again, highlighted the importance of an effective free school meals programme. Can my noble friend the Minister confirm whether the Government are considering the recommendation, outlined in the *National Food Strategy: Part One*, to expand eligibility for the free school meals scheme to include every child from a household where the parent or guardian is in receipt of universal credit?

Baroness Berridge (Con) [V]: My Lords, we are indeed considering the first part of the national food strategy. We expect part two to be with us, potentially, later this month and the Government have made a commitment to respond to it. We will be carefully considering that suggestion, but it must be borne in mind that there is a long taper for benefits with the universal credit system, rather than a cliff edge. There is data available that suggests that half the school population would then be eligible for free school meals, including some from households in receipt of income in excess of £40,000 a year. We need to consider carefully whether those suggestions are the best use of public funds.

Baroness Lister of Burtersett (Lab) [V]: My Lords, returning to my noble friend's Question, one parent described their treatment as "humiliating". They asked: "Why should you decide for us? Why not give us the money?" That, in the words of an academic expert, is the best way of ensuring that families are supported with dignity, respect and freedom of choice. Why not give parents the money? Do the Government not trust them?

Baroness Berridge (Con) [V]: My Lords, of course the Government trust parents. That is why we have given schools these options of how to deliver this. If there is any complaint about their treatment, parents should raise that with the school. There are also further avenues for them to make representations. However, as I have outlined, schools do not want to deal with distributing cash to parents, particularly during the pandemic. That is why a local or national voucher system is by far the best option for monetary support, rather than cash.

Baroness Bennett of Manor Castle (GP) [V]: My Lords, can the Minister confirm that the national voucher scheme will be operating through the same private company as last time? Can she also reassure me that its computer system will be adequate, and that school staff or parents will not find themselves having to log on at 3 am or 4 am as the only time it is possible to get into the system? Given that it is a for-profit company, what does the Minister consider a reasonable profit for it to be making on the scheme: 5%, 10% or more?

Baroness Berridge (Con) [V]: My Lords, I can assure noble Lords that, as I have outlined, from Monday e-codes will be issued that can be redeemed against supermarket vouchers. The department is closely monitoring the logistics of the scheme being set up. We anticipate thousands of schools wanting to access that portal as soon as they can, but we are monitoring this properly. In the emergency of the pandemic, we stood up a system that delivered vouchers worth £380 million last time.

Baroness Bakewell of Hardington Mandeville (LD) [V]: My Lords, I welcome the Government's decision to issue families with food vouchers, allowing them to choose the food to feed their children with a daily main meal. The quantity of food eaten by a six year-old girl is not the same as that eaten by a 14 year-old boy. Can the Minister reassure the House that the value of the vouchers will take account of the age of the child and the quantity of the food they require?

Baroness Berridge (Con) [V]: My Lords, the value of the voucher has actually been raised from the normal £11.50—a free school meal—to £15, recognising that schools and catering suppliers have economies of scale that a family would not have. I asked about this just this morning and, in terms of food supplied through a food parcel, we would expect schools to deliver appropriate food. A primary school food parcel would look very different from a secondary school one.

The Deputy Speaker (Lord Russell of Liverpool) (CB): My Lords, the time allowed for this Private Notice Question has elapsed.

Protocol on Northern Ireland: Disruption to Trade

Commons Urgent Question

The following Answer to an Urgent Question was given in the House of Commons on Wednesday 13 January.

"I am grateful for the chance to update the House on the operation of the Northern Ireland protocol. The protocol exists to recognise Northern Ireland's unique position as the only part of our United Kingdom to have a land border with the EU. It was designed to ensure that no customs infrastructure is needed between Northern Ireland and the Irish Republic, while protecting unfettered access for Northern Ireland's businesses to the rest of the UK market, and the gains of the peace process, and, of course, respecting Northern Ireland's position as an absolutely integral part of the United Kingdom.

As with any new trading arrangement, the protocol undoubtedly generates challenges as well as providing solutions. The Government are committed to addressing those challenges by providing pragmatic solutions to any problems that arise and to working with the Northern Ireland Executive in the interests of all the people of Northern Ireland.

UK Government Ministers are in daily contact with Ministers in the Executive, and with businesses in Northern Ireland and Great Britain, to ensure the effective operation of the protocol. Inevitably, the impact of Covid and the steps taken by the French Government at their border have affected retail businesses across the United Kingdom, but it is important to stress that freight volumes into Northern Ireland's ports are at normal levels for this time of year. There

have been no significant queues, and supermarkets are now generally reporting healthy deliveries of supplies into Northern Ireland.

None the less, the new processes that the protocol asks of businesses that are moving goods from Great Britain to Northern Ireland require the Government to do more. We are working with companies across Great Britain to help them understand the new requirements for moving goods, and the extensive government support includes the trader support service, to which more than 25,000 businesses are now signed up, yet we know that still more needs to be done.

That is why we are stepping up direct engagement with suppliers to ensure they have access to the real-time guidance they need, and we are also working closely with industry to address specific problems of moving mixed food loads from Great Britain to Northern Ireland through the process known as groupage. In the coming days, the Government will issue new guidance on the practical mitigations that have been developed with industry to enable this important practice to continue and to support hauliers and suppliers.

We also recognise that a number of hauliers have been affected by significant issues at Dublin Port. We welcome the easements that have been introduced by the Irish Government, but movements via Dublin are substantially lower than normal, so we have to intensify our engagement with the Irish authorities.

More broadly, the grace periods for supermarkets and their suppliers are now working well, but we are already planning for the streamlined replacements that will follow. A dedicated team within Defra, working with the Cabinet Office, is also in touch with the industry to promote readiness, supported by new specific government funding.

Ultimately, the future of the protocol is in the hands of Northern Ireland's people, and its renewal is a question of democratic consent. The responsibility of this Government is to ensure that it operates in an effective, legal and pragmatic way, and that is the spirit in which we approach its implementation."

1.17 pm

Baroness Smith of Basildon (Lab) [V]: My Lords, shoppers in Northern Ireland supermarkets were surprised to find competitors' products on the shelves. Of greater concern, some products have disappeared entirely, with the Government saying that

"the situation is likely to get worse before it gets better."

This is unacceptable. Michael Gove admitted yesterday that mistakes had been made, but that is not good enough and it fails to explain why the Government did not prepare for something that they had been warned about for more than a year. It is just shambolic. The protocol is not perfect, but it needs to be made to work. I have two questions for the Minister. Why did Ministers spend so much of last year denying the challenges, leaving it to business to make contingency plans? I also ask him to explain what urgent steps the Government are taking to get shelves stocked and trade moving today.

The Minister of State, Cabinet Office (Lord True) (Con): My Lords, it is important that we are clear about the overall picture. One must not overstate individual anecdotes into a systemic picture. I acknowledge that there have been issues—that was never denied—but, overall, goods are continuing to flow effectively. Supermarkets are able to move their lorries into Northern Ireland. There are some specific issues, as we have seen with individual suppliers, but it is holding up well overall. The UK Government will continue to work with supermarkets, retailers and suppliers to move in the longer run to end-to-end digital systems that enable goods to be moved in accordance with the protocol in the most streamlined way possible.

Baroness Ludford (LD) [V]: My Lords, the Government, led by the Prime Minister, put ideology over practicality and deception over honesty in the pursuit of Brexit. The claim made by the noble Lord, Lord True, in last Friday's debate that,

"the flow of goods under the Northern Ireland protocol is smooth overall"—[*Official Report*, 8/1/21; col. 442.]—

an answer he has just repeated—is contested by seven supermarket bosses. The Answer to this UQ is somewhat of an improvement on those rather complacent claims, but only when the Government are totally honest about the fact that there is a border within the UK can they start to resolve the practical difficulties of the protocol. When will that total honesty appear?

Lord True (Con): My Lords, the Government have been honest and have not been ideological. My right honourable friend the Prime Minister simply implemented the instructions of the British people—some noble Lords have not yet caught up with that. Goods are flowing effectively between Great Britain and Northern Ireland overall, with more than 1,000 trucks a day. I have acknowledged that there are certain difficulties and issues, but we must not overstate them and we are working pragmatically to address them.

Baroness Meyer (Con) [V]: Can the Minister reassure the House that nothing in the Northern Ireland protocol will prevent Northern Ireland businesses taking advantage of the UK's new trade agreements? Can he also confirm that its businesses will not suffer any harm resulting from possible tariff retaliation against the EU by states such as the US?

Lord True (Con): My Lords, I can confirm for my noble friend that Northern Ireland exporters will, as will those in the rest of the United Kingdom, be able to take full advantage of trade deals we strike with third countries. Certainly, we will not be participating in trade wars between third countries.

Lord Rooker (Lab) [V]: One of the key lessons I took when briefly a Minister in Northern Ireland was the vital importance of attention to detail. Is not the Prime Minister's lack of attention to detail the cause of chucking the Falklands to the Argentine, Gibraltar to Spain and Northern Ireland to the Republic? What is the Cabinet Office doing about the effect of Annexe 7 on the operation of Article 16 of the protocol?

Lord True (Con): My Lords, I do not agree with the noble Lord in his overall characterisation of the position. This Government are absolutely resolute that Northern

[LORD TRUE]
Ireland remains an integral part of the United Kingdom and will remain so as long as its people determine. As I have acknowledged to the House, certain practical issues have arisen; these are being addressed maturely and sensibly by the Government, suppliers and business, and I believe that that is the way we should proceed, without, at this stage, talking about Article 16.

Lord Caine (Con): My Lords, I welcome the Government's efforts to iron out what we all hope are teething troubles, and also the commitments made yesterday by the Prime Minister that they will do whatever is necessary to ensure that goods can move freely from Great Britain to Northern Ireland. Whatever one's view of the protocol, can my noble friend assure the House that it does not in any way change Northern Ireland's constitutional status, which, under the terms of the Acts of Union and the consent provisions of the Belfast agreement, remains a full and integral part of our United Kingdom?

Lord True (Con): Yes, my noble friend is right: the protocol and our implementation of it fully protects Northern Ireland's status as an integral part of our United Kingdom. That must remain the case. As I have said, there are teething problems and we have to address these, but if they ever become disproportionate, then that is the time, as my right honourable friend the Prime Minister said, when further action would have to be considered.

Lord Morrow (DUP) [V]: The Minister has acknowledged that there are problems and difficulties at the ports and elsewhere, and it is reported that some freight companies are losing tens of thousands of pounds per week because of the confusion that reigns there. We also have a problem with a Secretary of State who refuses to acknowledge that there is, in fact, a border at all. Will the Minister give his assessment today of the impact that the protocol and the sea border will have on the Northern Ireland economy? In light of the Prime Minister's comments yesterday, will he clarify the specific conditions in which the Government would act to invoke Article 16 of the protocol and restore unfettered market access for goods moving from Northern Ireland to the rest of the United Kingdom's internal market?

Lord True (Con): My Lords, I can certainly give the noble Lord the assurance that we will work extremely hard to overcome difficulties. As I just said in reply to my noble friend Lord Caine, the Prime Minister stated the position on the record in the House of Commons yesterday as far as Article 16 is concerned. Obviously, I stand by his words. As for movement of traffic, everybody should feel that they can and must send goods to every part of our kingdom normally. Flows of trucks into Belfast are now normal. There have been issues at Holyhead, but movements there are increasing and we hope to see that trend continue.

The Deputy Speaker (Lord Russell of Liverpool) (CB): I apologise for leap-frogging over the next speaker, the noble Lord, Lord Lilley.

Lord Lilley (Con): Will my noble friend remind the House that the Northern Ireland protocol, as was made clear by our Attorney-General and the EU itself, is intrinsically temporary because the EU, under Article 50, was unable to enter into permanent trade agreements? This is why it could not even start negotiating a trade agreement with us until after we had left. However, as we resolve, by patches and devices, the structural problems that will grow because of the differences between EU legislation and our own, to avoid a barrier in the Irish Sea we will develop means that will enable us to apply the same mechanisms to avoid having a barrier or any infrastructure between Northern Ireland and the Republic when the Northern Ireland protocol fades away.

Lord True (Con): My Lords, we are addressing specific issues—for example, steel announcements and groupage announcements are imminent—and there will be what my noble friend calls "patches". Obviously, in the longer run the protocol's existence will be determined by the people of Northern Ireland.

Baroness Altmann (Con) [V]: My Lords, can my noble friend explain what will happen at the end of the three-month grace period if there is no rollover of the EU's decision not to apply its rules in full? Does he accept that this situation is already arising, when our standards have not yet diverged from those of the EU, and will accelerate after any divergence? I reiterate my apology to the people of Northern Ireland for the fact that the implications of Brexit were never fully and openly explained, although they must have been obvious right at the start.

Lord True (Con): My Lords, I am not following any further the comment that people did not understand where they were when decisions were taken on whether to leave. I believe that we should all leave that behind us. On the specific question, at the end of the grace period, as I said in an earlier reply, the UK will continue to work with supermarkets and retailers. We have a dedicated group of officials working on this. We are seeking new end-to-end digital systems that will enable goods to be moved in accordance with the protocol in the most streamlined way, and this will be backed by a major injection of UK government funding as part of a broader support package. However, it behoves all sides under this agreement, including the EU, to behave in a proportionate manner.

The Deputy Speaker (Lord Russell of Liverpool) (CB): My Lords, the time allowed for this Question has elapsed.

Elections: May 2021

Commons Urgent Question

The following Answer to an Urgent Question was given in the House of Commons on Wednesday 13 January.

"Safe and secure elections are the cornerstone of any democracy, and Parliament's decision, as set out in primary legislation, is that these polls should go ahead in May. Due to the pandemic, many of these elections have already been delayed by a year, but

voters have a right to be heard and to decide who governs them. During the pandemic, local authorities will have taken many serious decisions impacting directly on residents, on matters from council tax to road closures, and those are important issues on which elected representatives should be held to account.

Given the situation, however, we are, as the Prime Minister set out last week, keeping this position under review. Any change would require very careful consideration, including by this House, and would need to be based on robust evidence. There should be a high bar for any delay.

I remind the House that we have already seen polls go ahead despite coronavirus, in this country—for example, council elections in Edinburgh and Aberdeen—and internationally, with other countries holding general elections. Since the announcement of the postponement of the 2020 elections, we have been working towards holding them in a Covid-secure manner, and we will put in place a strong set of measures to support this. Voters have a choice as to how they participate in elections—at the polling station, by proxy or by post. We want to maintain that choice, but we recognise that the pandemic may change people's needs and preferences. We actively encourage anybody who is shielding or who would prefer not to attend a polling station to apply for an absent vote instead of going in person. We will bring forward additional measures to support absent voting, including extending the ability to appoint a proxy, so that anybody who might be affected by Covid-19 in the days before the poll is still able to make their voice heard. The Government this week set out our plan to roll out vaccines at pace, which will ensure that the most vulnerable are protected and provide a route map towards relaxing the restrictions when safe to do so.

We have worked closely with the Electoral Commission on the production of guidance to aid all involved. This guidance is based on the latest public health advice and will be updated as necessary ahead of the polls. We have been working across government to ensure that any activity required for participation in and the delivery of the polls is technically allowed under Covid regulations. I thank local government officials, who have stepped up to the mark enormously in dealing with new and challenging issues, in many cases since last March. That should be recognised. We are grateful to them for all the work they have done, and we will continue to work closely with them and all involved in elections to support them in delivering the elections successfully.

Finally, honourable and right honourable Members will know very well the importance of campaigning and providing information to voters. As well as the technical aspects of elections, voters rightly expect that campaigning activity should only be carried out safely. I can confirm that the Government have also worked with the parliamentary parties panel to ensure that we are aware of the views from political parties, and we will continue to do that. We recognise the importance of parliamentary scrutiny of this area. We will continue to keep the House updated on the preparations for the safe holding of these elections, which are an important upcoming moment in our shared civic life."

1.28 pm

Baroness Hayter of Kentish Town (Lab): My Lords, this May has a record number of polls, involving every elector in the country. If America can organise its massive ballot, surely we can also vote, especially since some of these elections are now a year overdue. I therefore ask the Government to assure the House that they will not run away from these votes. Will they also ensure that we use all the normal polling stations and not reduce their number, as I hear is happening in some places? That would not only produce dangerous crowds but would also disfranchise those who could not travel further to polling stations, particularly, of course, people with a disability.

The Minister of State, Cabinet Office (Lord True) (Con): My Lords, I certainly assure the noble Baroness that the Government believe that safe and secure elections are the cornerstone of any democracy. The law is that these elections should go ahead on this date. The Prime Minister said that all matters are always under review, as they are in a pandemic. People then seemed to ride away and say that that was an indication that they would be postponed, but, as the Minister for the Constitution said in the other place yesterday, a very high bar would have to be set to not proceed with these elections. As far as her comments about returning officers, they obviously look at polling stations, but I will take note of the points the noble Baroness made. Certainly, voting should be easy.

Lord Wallace of Saltaire (LD) [V]: I hope I can get the Minister to add that local democracy is absolutely part of the foundation to any effective constitutional democracy, which is one of the reasons why we have to be very careful about postponing these elections further. I thank the Minister for the Statement and I thank Bradford Council for the very extensive briefing it gave me this morning on the difficulties. Can the Minister assure us that, since elections are so fundamental to democracy, as such, any decision will be taken not by the Government alone but in full consultation with all other parties contesting the elections? Given the difficulty of campaigning under current circumstances, will the Government be prepared to consider providing, for example, two pieces of free post to every nominated candidate, to make sure that parties which have more easy access to funds do not get disproportionate benefits from being able to pay for post?

Lord True (Con): As the noble Lord knew I would, I thoroughly endorse the first remark he made. I believe local democracy is the cornerstone, and I wish that were more widely recognised. The Government will continue to engage with political parties to ensure that people are able to campaign safely and securely and to secure information. As far as his specific proposal is concerned, I will certainly make sure that that is fed into consideration.

Lord Hayward (Con): My Lords, I welcome the Government's response to the Urgent Question yesterday—both the commitment to having elections on 6 May and to minimising unnecessary face-to-face

[Lord Hayward]
campaigning. In that spirit, may I ask a question similar to one asked by the noble Lord, Lord Rennard, in a Written Question, a few weeks ago? Will the Government urgently introduce changes to the requirement for registered parties to seek large numbers of nomination signatures for each campaign? We already have election campaigns where signatures are not necessary, and I request that similar procedures are introduced for all elections on 6 May.

Lord True (Con): My Lords, I thank my noble friend for his remarks. There are no plans to change the number of signatures required for nomination in May 2021, or to allow nominations to be accepted by email. Although returning officers may allow parts of the nominations process to be carried out online, such as the arrangement of necessary documents, final nomination papers have to be delivered in person. The Government have considered these issues with the electoral sector and Public Health England, and they are of the view that the current process can be carried out in a Covid-secure way.

Lord Reid of Cardowan (Lab) [V]: My Lords, I suspect that we have another definite maybe from the Prime Minister, who says "We will go ahead". And yet, if the Government proceed with the elections in May in the normal fashion, in the midst of a pandemic, with half the electorate not yet vaccinated, unlike what the Minister said yesterday—

"the very idea that somebody would be forced to choose between their health and their vote is simply not an issue"—[*Official Report*, Commons, 13/1/21; col. 314.]

there will be precisely that issue. Can the Government give us a definite answer—for once—and get ahead of the curve and make a definite decision now whether they are to proceed or to put alternative arrangements in place in good time? Another late U-turn will cause great anger and great confusion.

Lord True (Con): I certainly agree with the noble Lord that clarity is important. The planning assumption in the law is that we are proceeding with these elections. I take the point that he makes about people who are shielding or unable to go to the polling station. That is why, under the current considerations, we are looking at, for example, enhanced arrangements for proxy voting for those affected by Covid. We believe, in concert with those authorities involved, that it would be possible to proceed safely.

Lord Young of Cookham (Con): Further to the question of the noble Lord, Lord Reid, it must be right to encourage as many people as possible to vote by post, as Covid will still be with us and many people will not have been vaccinated. When local authorities send out the council tax demand at the beginning of March, should they not include details of how to register for postal votes, and perhaps even include a form?

Lord True (Con): My Lords, characteristically, my noble friend makes an interesting and novel suggestion, which I will certainly ensure is passed on to those involved. But I repeat: we must have a high bar for even a short postponement of democracy, and any such decision would certainly never be taken lightly or rushed into. The Government will continue to work with the electoral community on the matter.

Lord Foulkes of Cumnock (Lab Co-op) [V]: My Lords, since health conditions are likely to be similar throughout the whole of the United Kingdom in May, and there are parliamentary elections planned for Wales and Scotland, what discussions are Her Majesty's Government having with the devolved Administrations to make sure that there is a uniform decision throughout the United Kingdom as far as elections are concerned?

Lord True (Con): As the noble Lord knows, there have been by-elections in Scotland. But it is for the Scottish and Welsh Governments to take decisions around polls which are within their competence. I can assure him that, in line with our approach elsewhere, all three Governments will try to co-ordinate our work, where possible. The UK Government continue to have regular discussions with counterparts in Scotland and Wales on delivering the polls in May.

Baroness Warsi (Con) [V]: My Lords, following on from the last question, in the interests of public health, what consideration has been given to holding the elections in May this year in England and Wales over a period of days, as opposed to on a single day, as is being proposed in Scotland?

Lord True (Con): My Lords, our belief is that the elections can go ahead in the normal way in a safe and secure manner—and that is our objective—with the kinds of safeguards to which I have referred for those shielding and others.

Lord Mann (Non-Afl) [V]: My local GP surgery is not allowed to give the Covid vaccine under NHS England guidelines because it has only one door in and the same door out. The building next to it is the local polling station, with exactly the same entrance and exit situation. Why have returning officers not been given the same guidance that GP practices have about which buildings are safe for polling using the NHS criteria?

Lord True (Con): My Lords, the electoral authorities are in contact with those in local government who are involved in delivering places for the vote, which ultimately is returning officers. They will take a number of factors into account in considering the safety of premises, and I am sure that they will secure safety.

Lord Dubs (Lab) [V]: My Lords, does the Minister agree that returning officers and political parties need the maximum notice to prepare for elections? The Minister used the expression "the planning assumption". That seems to be bureaucratic gobbledegook for saying "We have not quite made up our minds". Does the Minister agree that it is essential that we have a clear indication for local authorities and political parties as soon as possible, so we all know where we are in preparation for the campaign?

Lord True (Con): My Lords, I apologise for being guilty of bureaucratic gobbledegook. At the risk of repeating an earlier answer, the most unprecedented pandemic for generations is raging in this country. Occasionally, the Government are taken to task for not being cautious and advisory, but—I repeat—the Government's position is that the elections can go ahead in a safe and secure way; there would have to be a very high bar for that not to happen. But I accept the noble Lord's point that total clarity is always the ideal.

The Deputy Speaker (Lord Russell of Liverpool) (CB): My Lords, the time allowed for this Question has elapsed.

Financial Services and Markets Act 2000 (Regulated Activities) (Amendment) Order 2020

Motion to Approve

1.40 pm

Moved by ***Baroness Penn***

That the draft order laid before the House on 26 November 2020 be approved.

Relevant document: 37th Report from the Secondary Legislation Scrutiny Committee. Considered in Grand Committee on 6 January.

Motion agreed.

Arrangement of Business

Announcement

1.41 pm

The Deputy Speaker (Lord Russell of Liverpool) (CB): We come to day 2 of Report on the Medicines and Medical Devices Bill. I will call Members to speak in the order listed in the annexe to today's list. Interventions during speeches or "before the noble Lord sits down" are not permitted and uncalled speakers will not be heard. Other than the mover of an amendment or the Minister, Members may speak only once on each group. Short questions of elucidation after the Minister's response are permitted but discouraged. A Member wishing to ask such a question, including Members in the Chamber, must email the clerk. The groupings are binding and it is not possible to degroup an amendment for separate debate. A participant who might wish to press an amendment other than the lead amendment in a group to a Division must give notice either in the debate or by emailing the clerk. Leave should be given to withdraw amendments. When putting the question, I will collect voices in the Chamber only. If a Member taking part remotely wants their voice accounted for if the Question is put, they must make this clear when speaking on a group.

Medicines and Medical Devices Bill

Report (2nd Day)

1.42 pm

Relevant documents: 19th and 33rd Reports from the Delegated Powers Committee, 10th Report from the Constitution Committee

Amendment 16

Moved by ***Baroness Thornton***

16: After Clause 6, insert the following new Clause—

"Strategy for tackling vaccination disinformation

(1) Within one month of the day on which this Act is passed, the Secretary of State must prepare and publish a strategy outlining plans to prevent the promotion of disinformation related to human vaccines.

(2) The overarching objective of the strategy must be safeguarding public health.

(3) The strategy must be laid before Parliament.

(4) In formulating the strategy under subsection (1), the Secretary of State must include proposals to—

(a) build public trust and encourage uptake of vaccines;

(b) require social media companies to promptly remove disinformation related to vaccines that has been reported to them by an appropriate authority, employees or other social media users, including financial and criminal penalties if they fail to act; and

(c) prohibit social media users or companies from directly profiting from vaccine disinformation through advertising revenue."

Member's explanatory statement

This amendment requires the Secretary of State to publish a strategy for tackling anti-vaccination disinformation within one month of the Bill passing.

Baroness Thornton (Lab) [V]: My Lords, this amendment requires the Secretary of State to publish a strategy for tackling anti-vax disinformation within one month of the Bill passing, to safeguard public health. The strategy should include proposals to build public trust and encourage uptake of vaccines, require social media platforms and companies to promptly remove anti-vax disinformation, and prevent profiting from vaccine disinformation through advertising revenue. The context to this amendment is the problem that lies designed to erode trust in vaccines and persuade people not to protect themselves and their families are being broadcast to millions of people online every day.

Covid-19 has been a "growth opportunity" for anti-vaxxers, according to research by the Centre for Countering Digital Hate, which estimates that the largest English-language social media accounts promoting vaccine scepticism have increased their followers by nearly a fifth over the past year. Intelligence assessments suggest that while the majority of anti-vax propaganda seen by UK internet users comes from within Britain, a small proportion of it is being amplified or initiated by hostile states, notably Russia.

Whereas the normal vaccine debate is largely limited to the parents of young children and teenagers, the Covid-19 pandemic is a rare instance where the entirety of a society has to choose whether they wish to be vaccinated. The spread of disinformation online presents a "real and present danger" to vaccination efforts. This is why action must urgently be taken to tackle anti-vax campaigns and build public confidence to save lives.

Disinformation is distinct from legitimate scientific questions and scrutiny, although valid concerns can be and often are manipulated. Disinformation encompasses the full spectrum of—

Baroness Penn (Con): My Lords, we appear to have lost the connection to the noble Baroness, Lady Thornton, so I suggest that we adjourn for five minutes.

1.45 pm

Sitting suspended.

1.50 pm

Baroness Thornton (Lab) [V]: My Lords, I think I am back now. I apologise: I have no idea what happened then, but the trusty old iPad is coming in useful. I think that when I lost my link I was talking about media companies, so I will pick up with that.

Despite the Government's and social media companies' announcement last week of new measures to tackle the issue, dedicated anti-vaccine groups with hundreds of thousands of members on social media are still churning out disinformation—100,000 Facebook users and 180,000 on TikTok. Although the Government have talked about online harms for a long time, it is unlikely that that legislation will have Royal Assent in time to help with this.

Finally, the situation was made clear in the Question in the House yesterday from my noble friend Lady Lawrence about the BAME community and the vaccine being rolled out. She said:

"I have heard messages from the black community about their mistrust of and lack of confidence in the vaccine. I ask Her Majesty's Government: what proportion of those taking part in the vaccine trials were black, Asian or from ethnic minorities before the rollout?"—[*Official Report*, 13/1/21; col. 725.]

That was amplified by the noble Baroness, Lady Warsi, who made the point that, although BAME communities were initially less likely to accept a Covid vaccine than white communities, when they had the opportunity to discuss their concerns with healthcare professionals, they were more likely than white communities to be persuaded to have the vaccine. Is the noble Lord familiar with that polling, and will he follow it up? I beg to move.

Baroness Altmann (Con) [V]: My Lords, first, I apologise to the House because this is the first time I have spoken on this Bill, so I will not detain the House long. However, I support the aims of the amendment. This is something I have felt strongly about for some years.

Tackling anti-vax disinformation can be life-saving, and continuing to promote anti-vax messaging can be so damaging to public health as well as individual health. As the noble Baroness, Lady Thornton, rightly said in her excellent introduction—I am grateful to her for tabling the amendment—the online anti-vax messaging problem is growing. It is not just from a tiny minority in any one country; there could be systemic efforts to damage public health in our country and others. Given that those minority views can be spread, potentially to the severe detriment of the public and those who perhaps tend to support those views, believe them or be convinced by them, I should be very grateful if my noble friend would explain to the House the Government's position. What do they believe they can do to combat the anti-vax messaging, not least as we are in the middle of this dreadful pandemic, for which the way out seems to me and many others to be to vaccinate as much of the population as we can, as soon as we can, to enhance their protection? Therefore, this is a very important and live issue, given the dreadful consequences that the pandemic is having not only on health through the virus itself, but on other aspects of public health and the country's wider ability to support our beloved NHS.

Baroness Masham of Ilton (CB) [V]: My Lords, I am speaking on the telephone, as something went wrong with my iPad.

I support Amendment 16, which is tackles anti-vaccination disinformation. For some years, this has created a problem. For example, there has been an epidemic of measles in many countries because many people, including the growing number of vegans, mistrust vaccines. Clear messages should go out about the benefits of vaccines and how they work. Some vaccines are very complicated and difficult to develop, but they are desperately needed for diseases such as HIV, TB and malaria.

Regarding these important coronavirus vaccines, I hope that the Government will be very careful that disinformation is not going out to the public about the Pfizer vaccine. Many health workers and elderly vulnerable people have had one dose, and the second dose should be given in three weeks' time. People have signed up to that, as there are written instructions to do so, but the Government are trying to delay the second dose by up to three months, which is not recommended by Pfizer-BioNTech or the regulator.

There is a risk that with only one dose, people may become carriers and the virus may become resistant to the vaccine. The Doctors' Association is not happy about the Government's idea of a three-month delay. More careful monitoring and research is needed, but these mixed messages are extremely unhelpful. I hope that the Government will realise that people need to trust the information they receive.

Baroness Cumberlege (Con) [V]: My Lords, I congratulate the noble Baroness, Lady Thornton, on her comprehensive introduction, expressing the urgency of the situation, which was also stressed by the noble Baroness, Lady Masham, in another interesting contribution for which I thank her. This is a difficult and hugely important issue, and it needs serious consideration on two counts. We have to look beyond the present situation with anti-vaccine campaigners and decide very carefully what is information and how we should combat damaging information being spread. Secondly, how do we reserve the right of the individual to use social media to express their personal views?

I spent six years on the Press Council, dealing with complaints. It was taxing, but today the print media is regulated to a greater extent. Even then, accountability for what should be published and what should not lay with not only the journalist who had written the article but with the editor and, in some newspapers, the owner.

2 pm

However, social media is not regulated. A Private Member's Bill by the noble Lord, Lord McNally, was introduced and had its First Reading exactly a year

ago today, 14 January 2020. It never received a Second Reading or reached further stages in either the Lords or Commons. He was prescient. Perhaps if we had enacted that Bill we would be in a better place than we are today.

Not all is lost, however. As I understand it, a government Bill is to be introduced in the next Session of Parliament. There is an ongoing debate as to whether there should be pre-legislative scrutiny. I hope that there will be. The Government have also produced their response to the consultation carried out on the dilemmas we face. They clearly understand how difficult it is to get this right.

Social media has democratised communication, and that is a good thing. News and opinions are not the sole province of those who are well educated or articulate but are for any individual who wishes to express views or opinions. Some are, of course, deeply harmful—for example, children who are bullied by others and so on. Some are simply irritating. Others express views of great value. What do we do about social media?

It was interesting that the noble Baroness, Lady Masham, raised the issue of measles. I was a Health Minister and responsible for infectious diseases. When I left that post in 1997, there were no cases of home-grown measles. That was before Andrew Wakefield started his anti-vax campaign, which was hugely damaging. Today, not only do we have many cases of measles but in 2019 there were 810 cases. We also have had deaths.

I therefore share the sentiments of the noble Baroness, Lady Thornton, but we are into the debate we had on Tuesday. This is about benefits versus risks and whether we should uphold the freedom of the press in all its different forms, or whether it should be controlled. That needs a lot of thought. We need legislation and that will take time. The problem is urgent and I accept that but, much as I would like to support the amendment, it is difficult to find a quick solution. The risk of agreeing to it in the Bill is that we are in danger of doing more harm than good because this is a big issue that needs a lot of clever minds and thought in deciding how we go forward.

We should not rush on this. We have to get it right. However, I am disappointed, not only not to be able to support the noble Baroness, Lady Thornton, because she has been so generous in supporting my amendments, but because this subject is truly difficult. We need to concentrate minds and the amendment is a way to do that. It is a good initiative but we have to be careful to ensure that the Government give their proposed Bill priority, which they say they will do in the next Session. We should do all we can to ensure that that happens.

Baroness Bennett of Manor Castle (GP) [V]: My Lords, it is a great pleasure to follow the noble Baroness, Lady Cumberlege, and I join her and other speakers in thanking the noble Baroness, Lady Thornton, for tabling the amendment, which I think is largely intended to start a debate and get some focus on this terribly important issue.

My approach to the whole issue of disinformation about harmful content on the internet is slightly different from those of some of the other speakers. We need to take the same approach as we do with the vaccine, which is to think about vaccination being better than treatment—prevention being better than cure. Ensuring good public communication, information and education about Covid and many other issues is the best possible way in which to take on misinformation, rather than after the fact—after the infection—and then trying to treat it. As soon as one starts trying to combat such messages, it is difficult to avoid repeating them. As any communications professional will tell you, you are then trapped in a difficult cycle of raising the issue up the agenda and raising it up the hashtags.

When we are talking about problems on the internet more generally, we need much broader education on media literacy and critical thinking throughout our education system. That will not help us in the immediate future but, when we are talking about Covid, we can think about the nature of the Government's communications and public information campaigns that will, in effect, inoculate people against the disinformation so prevalent in cyberspace. We need calm, factual, often quite detailed information that will educate the public about what is going on.

It is telling that we have seen a great deal of hunger among the public for briefings involving senior scientific officers and advisers. Some of them now have their own fan clubs and T-shirts. There is a real hunger for that kind of quality of information with clear scientific facts. That needs to come from all levels of the Government, including the politicians, not just the technical people. Let us trust the public with more information, data and facts, and with more of the difficulties and uncertainties, than we do now.

If one looks at the messaging in countries such as New Zealand and Germany, one can see that the level of detail and facts, and the quality of the information, given to their publics is much better than ours. Nearly every time there is a major government announcement or bit of advice, I see good technical people, senior professors and consultants on social media screaming in frustration about the quality of the presentation, data and messaging. I am talking not just about the shape of the graphs being wrong or whatever; we need to get the whole of government communications much better. That is the best way in which to tackle all these issues.

We all, even those of us with a scientific background, have learned a great deal more about IgG versus IgM versus IgA antibodies. A huge amount of information is out there, as is a hunger among people to find it. We must make sure that the good sources are there. That is the best way to tackle this problem when it comes to Covid and, indeed, much more broadly.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, this is an interesting debate and I am grateful to my noble friend Lady Thornton. We know that there is a problem with vaccine uptake, which is linked to anti-vaccine sentiment—though not necessarily always.

Looking back over the past few months, I note that there was in November a survey by Savanta ComRes on behalf of ITV News that found that almost 70% of people in the UK would like to receive a vaccination. More recently, in December, the Royal Society for Public Health published a poll showing that 76% of

[Lord Hunt of Kings Heath]
people would take the vaccine but, significantly, that only 57% of people from BAME backgrounds would do so. There was also a lower response among lower-income groups.

No doubt the Minister will give us figures, but my understanding is that the initial results on vaccine uptake are encouraging. However, we cannot be complacent in the face of the pernicious anti-vaccine sentiment around. Even before the pandemic, vaccine hesitancy was described by the WHO as one of the top 10 threats to global health.

We are interested in what the Government are doing. Last month, we debated this issue and the noble Baroness, Lady Evans, the Leader of the House, referred to the work of a central government unit on it. I should like to hear from the Minister about what is happening. We clearly need strong pro-vaccination campaigns, and the majority of people who may be described as vaccine hesitant are not necessarily anti-vaccine. Most people who are hesitant can be persuaded by good public health messages.

However, as my noble friend and other noble Lords have said, there has been a huge amount of misinformation across social media in the past few months. This is obviously cited by survey respondents as an area of concern when it comes to levels of trust in those delivering public health messages. As Scientists for Labour pointed out, since the recovery from the false findings around the MMR vaccine and autism from Mr Andrew Wakefield, the UK overall now ought to be in a good place when it comes to routine vaccine uptake. For example, the HPV vaccine has a consistent uptake of between 80% and 85%, which is an excellent return for a vaccine that is not part of early childhood schedules.

We do not have too much in the way of well-organised anti-vaccine groups, unlike the USA or, indeed, even the Republic of Ireland, so the likelihood is that the UK population will show less hesitancy about recently introduced vaccines compared with other countries. But the level of misinformation out there is high and we have to learn lessons from other recent vaccine scares. Clearly the Government have a huge challenge in making sure that the uptake of the vaccine is as high as possible—which is why I welcome this debate and the amendment, and very much look forward to the Minister's response.

Lord Naseby (Con) [V]: My Lords, I declare an interest in that I am married to a retired general practitioner.

I congratulate the noble Baroness on her proposed new clause. Whether the detail is correct is another matter, but the principle that she is promoting is absolutely right. I make my observations as someone who, before he came into politics, was a senior director in the fifth-largest advertising agency in the world. I was actually handling the UK Government's COI account—that is, the general one for specific purposes.

I have four observations. First, all misinformation must be refuted immediately, wherever it occurs—whether it is in the main media or other media. That is not just social media; it includes radio, TV, print, posters, et cetera. Secondly, every medical professional body must make it unequivocally clear that disinformation must be refuted. Thirdly, I suggest that all medical outlets should provide a clear statement, in poster format, for hospitals, surgeries, clinics and pharmacies. Fourthly, consideration should be given to how best to communicate with schools, universities and colleges.

In conclusion, we must all remember the terrible harm that was done to the MMR—measles, mumps and rubella—programme, largely by one pioneering rogue doctor. Against that background, I plead with the Minister to ensure that we have a robust new clause and a plan, worked on now so that it can be communicated instantly, if possible.

Baroness Jolly (LD) [V]: My Lords, I support this amendment to require

"the Secretary of State to publish a strategy for tackling antivaccination disinformation within one month of the Bill passing."

The noble Baroness, Lady Thornton, has picked a fascinating, current topic, and the noble Baroness, Lady Bennett of Manor Castle, posed some pointed questions about the quality and effectiveness of the messages. I look forward to the Minister summing up on these points.

Misinformation is not new. I remember websites being used many years ago to persuade parents to ensure that their children had their childhood vaccinations at the appropriate time, and it is paramount that the Government take a robust stance against anti-vaccination disinformation. Research from Oxford University suggests that 12% of the UK population is "strongly hesitant" about taking the vaccine, with a further 16% unsure. Together, that makes 28%, a very significant proportion of the population—over a quarter. We are putting all our efforts into stopping the spread of this virus. This means that if the 28% avoid vaccination, they will run the real and severe risk of catching the virus; not only that, we will run the risk of catching it from them, so undoing all the benefits of the programme.

2.15 pm

When I was doing my research, I was astounded by the volume of anti-vax propaganda undermining public trust. Social media of course carries a large amount of the extreme views. While not the majority, the minority is not insignificant, and with the Government putting their efforts into the rollout of the vaccine as their strategy for exiting the crisis, strong action is needed to counter the threat of anti-vax disinformation. The Government were quick to adopt our mobile phones as a tool to fight the virus. Are they as willing to counter this misinformation via those phones that have the Covid-19 app installed? In summing up, will the Minister tell us whether there is a plan to do this?

The Parliamentary Under-Secretary of State, Department of Health and Social Care (Lord Bethell) (Con): My Lords, what a helpful and instructive debate, and I thank all noble Lords who were involved.

In December 2020, we witnessed a landmark moment in our battle against Covid: the launch of an effective and safe vaccination programme, which has yielded great results. Thankfully, confidence in vaccines remains

very high across the UK. None the less, some citizens have questions and there is a prevalence of misinformation. It is therefore absolutely and entirely right that we should answer those questions in the spirit of constructive dialogue, which is exactly what we seek to do.

I completely share the aspiration of the noble Baroness, Lady Bennett, for Covid to be an inflection point in a business model moving away from late-stage acute medicine toward prevention. Vaccines play an absolutely critical role in that, and this could be a profound legacy of this awful disease.

Despite all this, I completely recognise that we have also seen a range of baseless and sometimes absurd narratives being shared, particularly through social media platforms. It is completely unacceptable that a minority of people seek to exploit legitimate questions about vaccines and spread dangerous lies about vaccines for their own malicious reasons and profit.

Noble Lords will agree that it is vital that both misinformation and disinformation about vaccines are tackled. Before I address the Government's response on how we will handle these two challenges, I pay tribute to the cross-party alignment on this issue and the spirit in which the noble Baroness, Lady Thornton, moved her amendment. Noble Lords from all sides of the House have shown a strong commitment to tackling anti-vax conspiracies and I express profound thanks for this tremendous collective effort, of which we can all be proud.

Throughout this pandemic, we have remained committed to transparency around the vaccine and to ensuring that people have access to accurate information about the virus and vaccines. DHSC is leading extensive cross-government communications activity, providing advice and information to anyone who has questions about the vaccine.

I do not think it would be helpful for me to run through our efforts in this area in detail, but I reassure noble Lords that we have worked, and continue to work, extremely hard to rebut false information online. In March 2020, we stood up the Counter Disinformation Unit, bringing together cross-government monitoring and analysis capabilities to tackle misinformation and disinformation. The Government have worked tirelessly to act wherever false and harmful content appears on social media platforms, either by flagging the content to the platforms or through direct rebuttal on social media via our Rapid Response Unit.

We are particularly committed to dialogue with and the protection of communities that might be particularly susceptible to disinformation and which, coincidentally, are particularly vulnerable to the virus. I thank all those involved in those efforts, including ministerial colleagues and noble Lords. I note the reference by the noble Baroness, Lady Thornton, to my noble friend Lady Warsi's optimistic update in this area.

I turn to the point the noble Baroness's amendment makes about requiring social media platforms to remove and demonetise anti-vaccination content. My noble friend Lady Cumberlege's points on this are extremely valid. The Government have already secured commitments from platforms such as Facebook, Twitter and Google to the principle that no company should profit from or promote anti-vaccine misinformation and disinformation, and to respond to that content much more swiftly. We are holding platforms to these commitments and have set a series of policy forums in motion, bringing together platforms, academia and civil society organisations to better develop responses to online misinformation and disinformation. These forums are chaired by my ministerial colleagues in DCMS, to whom I give thanks. I attend them and can report back that they have a constructive and thorough approach.

I understand the concern that noble Lords have about anti-vaccination content and the harm it causes. I stress that the Government are totally committed to working with the platforms and other key stakeholders to combat that content and to build public trust in our vaccination programme. I point noble Lords to the continued high rates of Covid-19 vaccine uptake that we see, which have been achieved in part by our effective approach to tackling vaccine misinformation and disinformation. We are not complacent; we are on the case. Therefore, for that reason, I hope that the noble Baroness, Lady Thornton, sees the Government's efforts in this area and feels able to withdraw her amendment.

Baroness Thornton (Lab) [V]: I thank the Minister for that comprehensive answer. I particularly thank what I can describe only as a bouquet of Baronesses—the noble Baronesses, Lady Altmann, Lady Bennett, Lady Masham and Lady Cumberlege—for their support. I say to the noble Baroness, Lady Cumberlege, fear not: if I had intended to have a Division on this I would have given her pre-warning, do not worry. I also thank my noble friend Lord Hunt for his pertinent questions and the noble Lord, Lord Naseby, for his four action points, which were instructive and useful.

This has been a useful debate that has been worth having, because we have so few opportunities to knock around issues that we all agree on and really want to support the Government to get right. That is why I tabled the amendment. I am very happy with the response to it and I beg leave to withdraw the amendment.

Amendment 16 withdrawn.

The Deputy Speaker (Lord Faulkner of Worcester) (Lab): We now come to the group beginning with Amendment 17. I remind noble Lords that Members other than the mover and the Minister may speak only once and that short questions of elucidation are discouraged. Anyone wishing to press this or anything else in the group to a Division must make that clear in debate.

Clause 7: Disclosure of information in accordance with international agreements

Amendment 17

Moved by ***Lord Bethell***

17: Clause 7, page 4, line 36, after "a" insert "relevant"

Member's explanatory statement

This amendment and the amendment in the Minister's name to add a definition of "relevant person" to Clause 7 restrict the persons to whom information may be disclosed in reliance on Clause 7(2).

Lord Bethell (Con): My Lords, in moving Amendment 17 I will speak also to Amendments 19, 22, 23, 25, 35, 37, 38, 55, 56 and 58 to 62. All amendments in the group deal with the sharing of information outside the UK where this is required to give effect to an international agreement or arrangement.

I have listened to the concerns raised by noble Lords as to further safeguards that could be provided in relation to Clauses 7, 12 and 37(5), and the amendments made in Grand Committee. I am enormously grateful to noble Lords who have met and spoken to me and my team over the weeks between Grand Committee and Christmas. Their further explanations and collaborative spirit have been enormously valuable. I can say confidently that this collaboration has definitely improved the drafting of the Bill.

It is worth saying first that the Bill introduces powers for international information sharing only where it is pursuant to international agreements or arrangements concerning the regulation of human medicines, medical devices or veterinary medicines. As such, we are starting from a place where it is in the public interest for data to be shared to support the safety of human medicines, medical devices and veterinary medicines in the UK and globally.

As I explained in earlier debates, information sharing with other regulators plays an absolutely critical role in the work of the MHRA and the VMD to protect patient safety and to support international collaboration. For example, in medical device safety investigations, international information sharing allows for better signal detection and gathering of evidence to support the safety of medical devices available on the UK market. It is worth saying that failure to share that data has been one of the contributing factors to many patient safety issues. However, it is right that we ensure that when the MHRA and the VMD share information they do so with the appropriate persons. These amendments will ensure that.

Nevertheless, I have heard the concerns about the use of the term "persons" and whether this may be subject to broad interpretation. Noble Lords will agree that including in the Bill an exhaustive list of named organisations we share data with is not practical. Therefore, we have amended Clauses 7, 12 and 37 to include a definition of "relevant person". These amendments clarify the types of persons outside the UK that information may be shared with. In short, they make it clear that these clauses do not offer a "blank cheque".

We also heard concerns from noble Lords in Committee about the sharing of patient-identifiable information internationally. Clauses 7 and 37 already include safeguards to protect personal and commercially sensitive information, and there are additional safeguards in data protection legislation. However, we are keen to provide additional reassurance. That is why we have tabled further amendments that ensure that patient-identifiable information can be shared only if patients have provided consent.

In the vast majority of cases patient information is anonymised before being shared. These amendments account for the rare instances where it is necessary to share patient-identifiable data internationally to support our commitment to uphold patient safety; for example, in sharing patients' concerns with an international regulator about a clinical trial they are taking part in in another country.

Finally, Amendments 22, 37 and 59 seek to clarify that the information-sharing powers in the Bill do not limit the circumstances in which information can be shared under any other enactment or rule of law. Such housekeeping amendments can be found as standard in many Acts and will ensure that the powers in the Bill cannot be construed as replacing existing statutory, prerogative or common laws of disclosure, which is not the intention. In introducing these amendments we seek simply to remove any potential confusion over what the powers in the Bill are intended to deliver.

I say again that I am enormously grateful to all noble Lords for their constructive challenge and thoughtful contributions on this subject. International information sharing is fundamental to the effective functioning of the MHRA and the VMD, but it is of vital importance that data is shared with care and that the appropriate safeguards are in place. I believe that our amendments deliver this balance. I beg to move.

Lord Patel (CB) [V]: My Lords, before I address the amendment from the noble Baroness, Lady Thornton, I reciprocate by thanking the Minister enormously for the many meetings he and his colleagues have had with all of us who are trying better to understand what the Government are trying to do with the Bill, particularly with these amendments. I agree that there are times, including in clinical trials—I have done this—when there is a need to share information with people involved in trials not only in the United Kingdom but overseas. I will come back to that in a minute.

2.30 pm

I will start by saying that I support the amendments tabled by the noble Baroness, Lady Thornton, which address the broadly drafted government amendments that were introduced in Committee. Those amendments allow information held in connection with medicines and medical devices to be shared with relevant persons outside the UK, to give effect to international agreements in relation to the regulation of medicines and medical devices.

The original wording of these clauses was worrying due to the use of vague terms. It was not clear, for example, whether any information held by the relevant authority could cover all information contained in patient records relating to medicines and medical devices, including any information in medical records relating to the use of medicines for patients. As highlighted in Committee debates, there was also no definition of

"persons outside the United Kingdom",

which left it open to broad interpretation, placing no limits on the category of persons to whom information may be disclosed.

The purposes of information disclosure are also broad, relating to the fulfilment of the requirements of any potential international agreement concerning the regulation of medicines and medical devices. In fact, a letter which the Minister sent to us all explaining these amendments in Committee argued that any such

information disclosure would be related to the purposes of promoting public safety. There was and still is no mention of public safety in the purposes of information disclosure in the Government's amendments, although I accept that, in presenting his amendments, the Minister did mention it in his introductory remarks.

The purposes are left to be determined by any international agreement, and thus this power is exceptionally broad. The Government's own amendments to these clauses are welcome. They narrow the powers slightly by providing a definition of "relevant persons" to whom such information may be disclosed, and add new subsections requiring that no patient information be disclosed without consent. However, it is not clear to me what mechanism or form of consent is required.

Some may well remember that the care.data scandal evolved from the lack of a requirement for opt-in consent to the use of medical and healthcare data. The amendment tabled by the noble Baroness, Lady Thornton, addresses this issue by requiring that consent be "opt-in" in these situations. This is a sensible addition to ensure greater safeguards for patients. It is also worth highlighting that patient information is defined in government Amendment 22, in a new subsection relating to

"physical and mental … diagnosis … care or treatment",

and information that

"identifies the individual or enables the individual to be identified (whether by itself or in combination with other information)".

This means that information pertaining to patients can be shared where it has been rendered non-identifiable. This is in line with current data protection principles.

The amendment tabled by the noble Baroness, Lady Thornton, strengthens this protection further, through the addition of the word "could", so that any information which might lead to reidentification is also captured in this definition. These protections are necessary as aggregate data can reveal patterns which may allow for reidentification, especially for small patient clusters, such as in rare diseases and conditions, and even in cancers, and where patients with common diseases are stratified for particular medicines.

Regardless of the need for consent to disclose patient data, consent is not required where data has been anonymised. Decisions on the use of public health data represent a substantive area of policy that should be subject to scrutiny and debate, and not relegated to the discretion of the Government alone. Data can be of high commercial value, so this power would essentially be used to allow the sharing of such data with interested parties as part of their trade deals. It has "international agreements" within the meaning of this clause, and the Minister may wish to comment on whether trade deals are included in international agreements.

This comes back to the issue of scrutiny at the heart of the Bill. It may be that information sharing and disclosure is necessary to allow smooth functioning and support internationally on pharmacovigilance and medical device monitoring, but there is an issue that patient/NHS data could also be bought as part of commercial interests in trade deals which the operation of information disclosure clauses may still allow for. The clauses as they stand, and as the Government now intend to amend them, still potentially allow for sharing of anonymised data with commercial partners for undefined—and therefore unknown—purposes, to be settled as part of an international agreement or trade deal that would probably not be scrutinised by Parliament.

While it may be conceded that international agreements may require the sharing of information to allow for proper international co-operation for pharmacovigilance and monitoring of safety, as the Minister himself mentioned, in their current form the government amendments may allow sharing for broader purposes that we are currently unable to scrutinise. The amendment tabled by the noble Baroness, Lady Thornton, requiring that any information disclosure to relevant persons outside the UK be permissible only to aid pharmacovigilance and device safety, and for purposes that are in the public interest, represents an acceptable compromise in narrowing the purposes for which information can be shared. The public interest principle at least requires consideration by the Government of substantial ethical issues in sharing information, yet it still allows significant flexibility when contemplating future agreements post Brexit.

There can surely be no objection to this minimal protection being required when contemplating the broad power being taken by the Government in decisions on the international sharing of valuable public data.

Lord Clement-Jones (LD) [V]: My Lords, it is a pleasure to follow the noble Lord, Lord Patel. I support and will speak to Amendments 18, 36 and 57, which have been so well introduced and explained by him, and which I have signed, and will speak to my own Amendment 20.

We have had discussions on this Bill and the Trade Bill about health data and trade issues. The two Bills are intimately connected, and this amendment is very complementary to Amendment 11, passed on Report of the Trade Bill on 7 December. There was no debate or discussion about the new Clauses 7 and 12 and the new subsection in Clause 37 when they were introduced in Grand Committee. On both counts it is therefore vital that we get to grips with them today. I welcome the Minister's new amendments, which he has spoken to and which take us a step further in terms of patient consent, definition of information and relevant persons. But I have signed, and these Benches support, the additional amendments to those clauses and subsection put forward by the noble Baroness, Lady Thornton, to ensure that we further tighten these provisions. Specifically, we want to tie this to international co-operation on pharmacovigilance or in monitoring the performance and safety of medical devices, and a public interest test put around the disclosure of health data, for all the reasons put forward by the noble Lord, Lord Patel.

As I said when the House debated these issues on Report of the Trade Bill and later passed the amendment, NHS data is a precious commodity, especially given the many transactions between technology, telecoms and pharma companies concerned with NHS data. I cited a recent report in which EY estimated that the value of NHS data could be around £10 billion a year in the benefit delivered, and the fact that the Department of Health and Social Care is preparing to publish its national health and care data strategy shortly, in which it is expected to prioritise the

"safe, effective and ethical use of data-driven technologies, such as artificial intelligence, to deliver fairer health outcomes."

[Lord Clement-Jones]

I mentioned too that, while acknowledging that the UK is a leading player in the fields of life sciences and biosciences, health professionals have strongly argued that free trade deals risk compromising the safe storage and processing of NHS data in much the way that the noble Lord, Lord Patel, has mentioned.

Through the amendment to the Trade Bill from the noble Baroness, Lady Thornton, and likewise this amendment, the objective is to ensure that it is the NHS, not US big tech companies and drug giants, that reaps the benefit of all this data. This is especially important given what the Ada Lovelace Institute called in its report, *The Data Will See You Now*, the "datafication" of health, which, it says, has profound consequences for who can access data about health, how we practically and legally define health data, and our relationship with our own well-being and the healthcare system. Health information can now be inferred from non-health data, and data about health can be used for purposes beyond healthcare. Harnessing the value of healthcare data must therefore be allied with ensuring that adequate protections are put in place in trade agreements, if that value is not to be given or traded away.

At the time, I raised questions about the provisions of the UK-Japan trade agreement, and there is no doubt that these questions will linger unless an amendment of this kind, to both this Bill and the Trade Bill, goes forward.

There have been many shortcomings in the sharing of data between various parts of the health service, care sector and Civil Service. The development of the Covid-19 app and the way that the Government have procured contracts for data management with the private sector have not improved public trust in their approach to data use. That is why clear safeguards are needed to ensure that, in trade deals and international agreements, our publicly held data is safe from exploitation where it is not for public benefit.

On Tuesday, the Minister heavily emphasised the public interest test that he wanted to see applied to the sharing and use of Clause 3 information. The data covered by Clauses 7, 12 and 37 is even more important. He used the same language today and in correspondence, so I hope he can accept these amendments. As the noble Lord, Lord Patel, has said, we also want to see the aspect of patient consent clarified.

I turn briefly to Amendment 20. I welcome the Minister's Amendment 19, but Amendment 20 is designed to get the Minister to further clarify what is meant by "consent" in Clause 7. Informed consent is very much a familiar concept in healthcare, especially in treatment and trials, and, indeed, that is effectively the definition on the NHS website. It depends on capacity, explanation, understanding and it being voluntary. That is why my amendment would insert the word "informed", to make it abundantly clear that, at the very least, that is what is intended here. I look forward to the Minister's reply.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, it is a great pleasure to follow the noble Lord, Lord Clement-Jones, and I welcome the opportunity to debate this important group of amendments. I welcome the government amendments, but feel that my noble friend Lady Thornton's amendment is very important, as indeed are some of the others in this group.

I have always been strongly in favour of using patient information. It is a rich source of data for scientists to pursue in the search for medical advances. We all benefit, and I am sure that the great majority of the public see this and are agreeable to information being shared. But we must have appropriate safeguards, and that is why the government amendments to restrict the persons to whom information may be disclosed, and the addition of a definition of patient information and the need for individual patient consent, are all very welcome.

My understanding, however, is that information pertaining to patients can be shared where it has been rendered non-identifiable. As the University of Birmingham has commented, this may be in line with current data protection principles but there is still a danger of a care.data-type problem, in that the provisions might allow the Government to share with "relevant persons"—as they are now called—outside the UK information they hold on patient data through NHS bodies without consent when anonymised. The noble Lord, Lord Patel, referred to some of the issues with care.data. The stricter definition of patient information may address some of the concerns that the definition of patient data—being restricted to identifiable data—left anonymised data open for use or barter as part of international agreements. Part of this broader concern is that aggregate data can reveal patterns that may allow for re-identification, especially for small patient clusters in respect of rare diseases and conditions.

2.45 pm

The points that the noble Lord, Lord Clement-Jones, made about the interrelationship between this Bill and the Trade Bill are therefore hugely important. We know that data can be of high commercial value, and the power could in essence be used to allow the sharing of such data to interested parties as part of trade deals and international agreements, which certainly has implications for concerns about consent.

I just say to the Minister that the NHS has form in giving away data to American companies without enough care being taken over the conditions under which the data can be used, and certainly without adequate resource compensation. This makes it all the more important to ensure that we beef up the safeguards. The amendments from my noble friend Lady Thornton and those from the noble Lords, Lord Clement-Jones and Lord Patel, all deserve support for seeking to do that.

Lord Freyberg (CB): My Lords, I was privileged to speak at some length about the provisions of this Bill in Grand Committee, and I thank those who supported the amendments in my name, which concerned the role of cutting-edge, data-driven medical devices. The Minister has since reassured me of his intention to further explore their implications in the course of a consultation exercise about their definition and regulation over the coming year. Like the noble Lord, Lord Patel, I want to put on record my gratitude for the way that he has facilitated these discussions.

The amendments that I rise to support today seek to protect patient information, including what is properly "special category data" in the Data Protection Act 2018, which is crucial in the development of new pharmaceutical products and medical devices.

Of course, it goes without saying that efforts to facilitate the flow of data in the context of the ongoing health emergency are vitally important. These are extraordinary circumstances in which we find ourselves. Today, however, we must take steps with an eye to the long term; steps that will introduce legal provisions to prevent a situation that might give rise to undue concern or restrict scrutiny of matters pertaining to patient safety in the future, both at home and overseas.

I am certain that the Minister is well aware of public sentiment concerning privacy and data protection, which are, of course, not limited to the healthcare domain. Maintaining the trustworthiness of organisations that function as stewards of the nation's healthcare data is paramount, and a carefully considered approach to patient safety is needed to preserve that trustworthiness, as the Government move to improve upon and forge new international arrangements.

The Minister's amendments make it mandatory for consent to be provided where patient information is being shared with territories outside the United Kingdom. The noble Baroness, Lady Thornton, has tabled clarifying amendments to ensure that the purpose for which patient information is being shared is limited to patient safety and its scrutiny. For these reasons, I support Amendments 18, 36 and 57, to which I have added my name.

Lord Lansley (Con) [V]: My Lords, I am very glad to follow the noble Lord, Lord Freyberg, who has made some very cogent points, both in that speech and when we discussed these clauses in Grand Committee.

I want to make two points. The first is about the structure of Amendment 18. I am not entirely sure that I understand why pharmacovigilance has been singled out in the amendment as a reason why disclosure should be made, as distinct from, for example, public health co-operation or the pursuit of research. Indeed, the Minister referred to the sharing of information in relation to international clinical trials as a very good example. If one were to legislate in this form, it would be inevitable that the reference to pharmacovigilance would be regarded as having additional weight, and the absence of reference to other purposes for which information would be shared would be regarded as less important. I am not sure that that would be at all helpful to have in statute.

My other point is in relation to Clause 7(5). Government Amendment 22 refers to and introduces a provision that assists in understanding the relationship between this legislation and other enactments concerning the disclosure of information. Clause 7(5) states:

> "Nothing in this section authorises a disclosure of information which … contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this section)".

Noble Lords may recall the Trade Bill and, in particular, the debate we had on the Trade (Disclosure of Information) Act just before Christmas and new year. We passed legislation the purpose of which was, among other things, to ensure that we clarified the relationship between that enactment and others that authorise disclosures of information or, in some circumstances, prohibit such disclosures. The particular basis for the structure of that Bill was to clarify a situation where there is a statutory gateway and other enactments that put constraints on the disclosure of information.

In subsection (5) it is clear that if someone is considering a disclosure that might contravene the data protection legislation, that legislation must be considered alongside the powers in this legislation. That enables them to satisfy the test in the Christian Institute and others v The Lord Advocate 2016 Supreme Court decision, as referred to in my noble friend Lord Grimstone's letter to us about the Trade Bill. In the Trade Bill, though, as is the case in this Bill, we have reference both to the data protection legislation and to the Investigatory Powers Act. In the Trade Bill, amendments were introduced on Report to ensure that the saving reference—that is, when determining whether a disclosure would contravene the legislation, it takes into account the powers in this section—was applied to both the data protection legislation and the Investigatory Powers Act. However, in this legislation—Clause 7(5)(b)—the saving reference is applied to the data protection legislation but not to the Investigatory Powers Act.

My question, which I am sorry I have not had an opportunity to give the Minister notice of, as I have started working through these issues only very recently, is this. Having dealt with this matter on the Trade Bill, I would have thought that both these subsections should have the saving reference that allows the question of the contravention of those Acts to be considered, including reference to the powers in this Bill. I wonder if he would agree.

Baroness McIntosh of Pickering (Con) [V]: My Lords, I am delighted to follow my noble friend, who speaks with such great authority both as a former Secretary of State for Health and as someone who has followed the Trade Bill and the Trade (Disclosure of Information) Act so closely.

At the risk of dancing on the head of a pin, the amendments in this group are quite close, and the Minister set out every reason why we should support his Amendment 17. He said that information would be shared only in the circumstances where there is perceived to be a public need. The amendments and explanatory statement of the noble Baroness, Lady Thornton, refine that by saying that, in the context of giving effect to an international agreement or arrangement concerning the regulation of human medicines, it should be disclosed only provided that it is in the public interest to do so. A number of noble Lords have spoken with great eloquence and passion on these issues, including the noble Lords, Lord Patel, Lord Clement-Jones and Lord Freyberg, and my noble friend Lord Lansley. I have to say that I personally would draw the line at disclosing information for a commercial need as opposed to a public one.

I have a particular question about Amendment 19, which clearly states that patient information cannot be disclosed where the patient could be identified and that that information cannot be given without their consent. I remember that I was once asked to participate

[Baroness McIntosh of Pickering]
in a study; I signed the form and was delighted to do so, and never heard any more about it. I would just like to know how Amendment 19 would work in practice. At what point, and by whom, would the patient be contacted if that information was about to be disclosed and their consent sought?

I have reservations about this group. I remember the important debate that we had on the Trade Bill in this regard, and I am delighted to see that those issues are being considered in the context of this Bill as well. I have two concerns that I hope can be allayed. The first is that public need should not be deemed to collude with commercial need where it might not be in the interests of the patient. The second is about informed consent: how will the patient be consulted within the provisions of Amendment 19?

Baroness Cumberlege (Con) [V]: My Lords, this has been an interesting and well-informed debate, and I am quite reluctant to enter into it. I support government Amendment 19 and particularly Amendment 20 tabled by the noble Lord, Lord Clement-Jones. I hope I have got this right, although I am very happy to be put right if I have not. As I understand it, Amendments 19 to 25 concern consent, relating very specifically to the disclosure of information in accordance with international agreements. This is information that I think a relevant authority such as the MHRA holds in connection with human medicines.

As I listened to the noble Lord, Lord Freyberg, he raised a question in my mind about devices. We know that pharmaceuticals are much more closely regulated than devices have been, so can the Minister tell us a bit more about instances where there is a comparable agreement, and perhaps an amendment, for medical devices? I want to know whether they are on all fours with pharmaceuticals. I suspect not. Having listened to the noble Lord, Lord Freyberg, I think that there is more to hear on this.

3 pm

The Minister's Amendment 19 makes it very clear that:

"Nothing in this section authorises a disclosure of … information"

that would include patient-identifiable information without the patient's consent. I warmly welcome that, but Amendment 20 in the name of the noble Lord, Lord Clement-Jones, goes further. It seeks to ensure that such consent is informed. As the noble Lord, Lord Hunt, and others, including the noble Lord, Lord Clement-Jones, said, informed consent is very well recognised within the NHS but sadly not always adhered to. To me, Amendment 20 in the name of the noble Lord, Lord Clement-Jones, is preferable to Amendment 21, which states that

"'consent' means that an individual has given notice of their willingness for an appropriate authority to disclose patient information"

by explicitly opting in. That is not good enough.

I fully support Amendment 20, with the proviso that gaining informed consent can never be just a tick-box exercise. The information, of course, pertains to patients and their state of health, the diagnosis they have received, the treatments they have had and the outcomes from those interventions. That information, rightly, belongs to the patient. The noble Lord, Lord Hunt, mentioned care.data, and we know what a terrible debacle that was, when not enough care was given to the rights of patients over their information.

We know from the reams of evidence that we received during our review that "informed consent", albeit usually in the context of a patient/clinician consultation, was often anything but informed. However, as I understand it, this debate is not about that; it is about the information that will be passed on through international agreements. I hope I have that right.

If we are to change how the healthcare system manages, interprets and responds to informed consent, we must ensure that it does not just pay lip service. Whenever informed consent matters, we should ensure, through this Bill and elsewhere, that it really does matter and is fully protected.

I support these amendments but ask the Minister to give an assurance that, in relying on informed consent, where disclosure of information can enable a patient to be identified, the relevant authority will have evidence on four issues: first, that consent was indeed properly informed; secondly, that the patient concerned understood how their information might be used; thirdly, that any specific concerns they might have had had been addressed; and, lastly, that the patient was made fully aware that they could withdraw consent at any time. I should perhaps add to that last point that they could withdraw either via an intermediary or directly. There must be a mechanism in place to ensure that the relevant authority is made aware of this change—that the patient has withdrawn consent—and that the authority can be seen to have acted on it.

There is much in all these amendments. It has been a good debate and I look forward to the Minister's reply.

Lord Naseby (Con) [V]: It is a pleasure to follow my noble friend Lady Cumberlege, who has gone into great detail on these amendments. As far as I can see, these are mainly government amendments, plus some from other parties, and they are all broadly to be welcomed. The question I ask myself is: where are the boundaries to be set?

Very helpfully, the Minister, in his opening statement, explained in some detail the extent of information-sharing outside the UK and gave the example of the safety of medical devices. Having listened to my noble friend and the others who have contributed, I am still not quite sure about Amendments 18 and 20. I can see where they are coming from and can understand what is behind them but on this occasion I will have to listen to the Minister. These are sensitive areas and certainly we in the upper House should listen. I am also not entirely clear from the Minister's statement at the beginning what the implications of Amendment 22 are. There has already been a good deal of coverage and I will not add to it further.

Baroness Jolly (LD) [V]: These amendments relate to the use of data and information sharing. The noble Baroness, Lady Thornton, my noble friend Lord Clement-Jones and the noble Lord, Lord Patel, have put their names to some of them. The noble Lord, Lord Freyberg,

outlined clearly in the context of trade and health the power and value of data. Data is a hugely rich source for research but also a hugely valuable commodity, so we need safeguards.

Concern was raised in Committee about the level of protection in the Bill for patient information, as regulations are able to make provision about the disclosure of such information. I am grateful to the Minister for being so willing to look at this again.

The Government have responded in two main ways: with the introduction of a definition of "relevant person", thereby narrowing the definition of whom data can be shared with, and by defining what is meant by patient information. As the noble Lord, Lord Patel, explained, Amendment 24 in the name of the noble Baroness, Lady Thornton, strengthens the definition of patient information to protect information that could identify a patient, rather than just information that does.

Amendments 18, 36 and 57, led by the noble Baroness, Lady Thornton, and supported by my noble friend Lord Clement-Jones and others, would allow a relevant authority to disclose information to a person outside the UK only where required for the purpose of giving effect to an international agreement or an arrangement concerning the regulation of human medicine, provided it was within the public interest so to do. Those three amendments all pass the test put forward by the noble Baroness, Lady McIntosh of Pickering, concerning public good.

Amendment 20, from my noble friend Lord Clement-Jones, would take the Government's amendment on patient consent further by ensuring that consent given in relation to identifiable information was informed consent. The noble Baroness, Lady Cumberlege, has just raised the issue. We should not need this. Informed consent should be the default but, as it clearly is not, I support my noble friend's Amendment 20.

Similarly, Amendment 21, in the name of the noble Baroness, Lady Thornton, would ensure that patient information could be shared by an appropriate authority only if the individual to whom it related had given their explicit consent.

These amendments strengthen the Bill and therefore patient outcomes. I will listen to the Minister to see what plans the Government have to satisfy noble Lords on this group.

Baroness Thornton (Lab) [V]: My Lords, I thank all noble Lords who have taken part in this debate. I will speak to the amendments in my name, and give notice that I will test the opinion of the House on Amendment 18, along with Amendments 36 and 57, all of which are supported by the noble Lords, Lord Patel, Lord Freyberg and Lord Clement-Jones. This is unless—of course, I always live in hope—they are agreed to by the Minister.

Turning to the other amendments in my name in this group, I just want to put on record how grateful we are on our Benches for the way that the Minister and the Bill team have worked on these important issues, and how much we support the amendments that he has tabled. We do not see these amendments as in opposition; we see them as amplification and clarification.

Amendment 24 is a probing test for whether aggregate data could identify individuals through de-identification or de-anonymisation practices. The Government's amendments define patient information as data that

"identifies the individual or enables the individual to be identified (whether by itself or in combination with other information)".

This represents a welcome tightening up of the definition to include scenarios where contextual information might allow de-identified data to become identifiable. This is very important given that aggregate data can reveal patterns which allow for reidentification, especially for small patient clusters as in rare diseases and conditions. Given the rapid development of sophisticated technology, my Amendment 24 probes the test for whether anonymised aggregate data could identify individuals through this. I hope the Minister will be able to assure the House that the appropriate safeguards and checks are in place.

Amendment 21 would ensure that patient information

"can only be shared by an appropriate authority if the individual to whom it relates has given their explicit ('opt-in') consent."

We welcome the Government's requirement for consent to share patient information. However, they have not specified how this consent mechanism will work in practice. This amendment in my name would ensure that important distinction, which has been mentioned by many noble Lords across the House. Other noble Lords have also mentioned care.data, which, because of a lack of clarity about the use of data, did not work. I hope the Government will be able to assure us that explicitly informed consent will be sought and secured.

Under Amendment 18, followed by Amendments 36 and 57, data would be disclosed to persons under international agreements or arrangements only for pharmacovigilance or if "in the public interest". I hope the public interest bit answers the question from the noble Lord, Lord Lansley. I thank the noble Lords, Lord Patel, Lord Clement-Jones and Lord Freyberg, my noble friend Lord Hunt and other noble Lords for their support for this suite of amendments.

Overall, the government amendments narrow discretion and set out in more detail the purposes for the information-sharing powers. However, in our view they still potentially allow for the disclosure of patient data without consent to commercial partners for undefined, and therefore unknown, purposes to be settled as part of international agreements or trade deals. That is why the helpful read-across to the Trade Bill by the noble Lords, Lord Freyberg, Lord Clement-Jones and Lord Patel, is so important. We recognise that information-sharing and disclosure may be necessary to allow smooth functioning and support internationally on pharmacovigilance, for example, but remain concerned that NHS data—which has been described as a treasure trove, worth perhaps £9.6 billion—could be bartered as part of commercial interests in trade deals.

Amendment 18, along with Amendments 36 and 57 in my name, would allow the Secretary of State to disclose NHS data only under the terms of an international agreement or trade deal for pharmacovigilance, of if it is otherwise in the public interest. We believe "the public interest" is a legitimate test that would offer reassurance that substantive and ethical issues relating to the sharing of data would at least be considered.

[Baroness Thornton]
I hope the Minister will recognise the value of this amendment; otherwise, as I say, I would like to test the opinion of the House.

3.15 pm

Lord Bethell (Con): My Lords, we are enormously grateful to the noble Baroness, Lady Thornton, and the noble Lord, Lord Clement-Jones, for their Amendments 20 and 24 to one of my own amendments to Clause 7. These amendments seek to ensure that patient information can be shared by an appropriate authority only if the individual has given their explicit or informed consent, respectively. I completely recognise the commendable intent behind both amendments to safeguard and protect patient safety. Their intentions are benign but they are absolutely not necessary.

My lived experience for the past year has been completely aligned with the words of the noble Lords, Lord Clement-Jones and Lord Freyberg. Data is absolutely key. I have spent my time outside the Chamber working on little else: clearing the path for patient recruitment to clinical trials, so that therapies can be designed to save lives; getting data on long Covid patients from primary care to those researchers and clinicians who are trying to help them, which is an extremely complex and onerous task; getting central tracing data to local infections teams, which means transferring it between various jurisdictions; getting people to record the tests they take, which is a legal requirement but legally and technically difficult to implement; and getting test results from those who have taken them into their GP records. Most bizarrely, to me at least, I have been getting data-sharing agreements in place so that local authorities, which are crying out for the data—as their representatives here in this very Chamber cry out to me at the Dispatch Box for it—can access the dashboards with those legal agreements; or getting the data on those who may need support isolating into the hands of those charities and local authorities which are keen to support them.

Every step of the way, there has been an onerous set of legal, ethical and bureaucratic barriers. Speaking on the back of that experience, I wonder whether scientific deduction and patient safety are sometimes sidelined by other considerations. I therefore warn about measures that are driven by prejudice or secondary principles, rather than the priorities of trying to save lives and pursue science. Their unintended consequences can have a profound, stifling effect on patient safety, medical research and innovation, and on the effective running of a modern healthcare system. I can think of so many incidents where the need for data-sharing agreements, legally obtuse patient consents and all sorts of rarefied ethical reviews have caused major life-threatening obstacles and troubling issues in our response to Covid.

I know that the measures in these amendments are well intended, but I assure noble Lords that they are not necessary. For instance, Clause 7 accounts for the rare instances where it is necessary for the MHRA to share identifiable patient information internationally to support our commitment to upholding patient safety. I take this opportunity to assure noble Lords not only that this will be done only with the informed consent of the patient but that the practical implementation of some of the very measures in this Bill, such as the medical information system, will require these kinds of measures. It seems counterproductive for us to be undoing the benefits of our own information system.

Amendment 21 in the name of the noble Baroness, Lady Thornton, seeks to broaden the definition of patient information to include information that could enable identification. I reassure the noble Baroness that the MHRA absolutely follows the Information Commissioner's gold standard practices on patient data anonymisation. In order to be truly anonymised under GDPR, sufficient personal data is always stripped out so that, not only can the individual not be identified, but reasonably available means could also not enable the recipient to re-identify the individual. As such, if patient information to be shared still enables the patient to be identified, for example due to the unique nature of their condition, the amendment in my name will provide sufficient protection by requiring that patient's consent be sought before sharing their information. The MHRA keep anonymisation processes under review in line with the ICO's guidelines and continue to monitor advances in data technology.

We have heard from the noble Baroness, Lady Thornton, and the noble Lords, Lord Patel and Lord Clement-Jones, on their Amendments 18, 36 and 57, which seek to limit the purpose for which information can be shared internationally under the powers. It is important to highlight that we could only disclose information under this power where disclosure is required in order to give effect to an international agreement or arrangement concerning the regulation of human medicines, medical devices or veterinary medicines. In that regard, the clause already allows disclosure only for a particular purpose. As international co-operation in this area is important and a good, even necessary, thing, such agreements or arrangements would be in the public interest by default. The UK meeting its international obligations under these agreements and arrangements would be even more so. Furthermore, the MHRA and VMD do not share information for commercial gain—on that point I want to be absolutely categoric. Therefore, I am persuaded that these amendments are accordingly unnecessary.

We have introduced a number of amendments to these powers to clarify the types of person with whom information can be shared and, for those instances when it is necessary to share identifiable patient data internationally, introduced a lock that ensures that data can be shared only with consent. These amendments are, of course, in addition to existing data protection legislation and ICO guidance. I can assure the noble Lords that we are not complacent when it comes to the safe and appropriate use of patient data. We understand that, as technology advances, we will need to continually review the way in which we anonymise data to ensure that it remains just that.

I hope this provides noble Lords with assurance that the Bill and the additional amendments in my name provide robust safeguards to protect patient information, alongside long-standing data protection legislation already in place, and that they will not press their amendments.

Amendment 17 agreed.

Amendment 18

Moved by ***Baroness Thornton***

18: Clause 7, page 4, line 38, at end insert—

"( ) Where information is disclosed in accordance with subsection (2) such disclosure will only be permitted where—

(a) it is required as part of international cooperation for pharmacovigilance; or

(b) it is in the public interest."

Member's explanatory statement

This amendment would allow a relevant authority to disclose information to a person outside the UK where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of human medicine provided it is within the public interest to do so.

Baroness Thornton (Lab) [V]: I beg to move, and I wish to test the opinion of the House.

3.22 pm

Division conducted remotely on Amendment 18

Contents 312; Not-Contents 249.

Amendment 18 agreed.

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3.35 pm

Amendment 19

Moved by ***Lord Bethell***

19: Clause 7, page 5, line 8, at end insert—

"(4A) Nothing in this section authorises a disclosure of patient information without the consent of the individual to whom that information relates."

Member's explanatory statement

This amendment and the amendment in the Minister's name to add a definition of "patient information" to Clause 7 prevent Clause 7 authorising the disclosure of information from which patients can be identified without their consent.

The Deputy Speaker (Lord Russell of Liverpool) (CB): Does the noble Lord, Lord Clement-Jones, wish to move Amendment 20, as an amendment to Amendment 19?

Lord Clement-Jones (LD) [V]: [*Inaudible*]—very much about informed consent, but, nevertheless, I will not move the amendment.

Amendment 20 (to Amendment 19) not moved.

Amendment 21 (to Amendment 19) not moved.

Amendment 19 agreed.

Amendment 22

Moved by ***Lord Bethell***

22: Clause 7, page 5, line 14, at end insert—

"(5A) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law."

Member's explanatory statement

This amendment provides that Clause 7 does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

Amendment 22 agreed.

Amendment 23

Moved by ***Lord Bethell***

23: Clause 7, page 5, line 21, at end insert—

""patient information" means information (however recorded) which—

(a) relates to—

(i) the physical or mental health or condition of an individual,

(ii) the diagnosis of an individual's condition, or

(iii) an individual's care or treatment,

or is (to any extent) derived directly or indirectly from information relating to any of those matters, and

(b) identifies the individual or enables the individual to be identified (whether by itself or in combination with other information);"

Member's explanatory statement

See the explanatory statement for the amendment in the Minister's name adding a new subsection (4A) to Clause 7.

Amendment 24 (to Amendment 23) not moved.

Amendment 23 agreed.

Amendment 25

Moved by ***Lord Bethell***

25: Clause 7, page 5, line 24, at end insert—

""relevant person" means—

(a) the government of a country or territory outside the United Kingdom;

(b) a person who exercises functions on behalf of such a government;

(c) any other person who exercises functions or provides services relating to human medicines in a country or territory outside the United Kingdom;

(d) an international organisation that exercises functions or provides services relating to human medicines."

Member's explanatory statement

See the explanatory statement to the first amendment to Clause 7 in the Minister's name.

Amendment 25 agreed.

The Deputy Speaker (Lord Russell of Liverpool) (CB): Does the noble Lord, Lord Patel, wish to move Amendment 26?

Lord Patel (CB) [V]: No.

The Deputy Speaker (Lord Russell of Liverpool) (CB): Does the noble Baroness, Lady Thornton, wish to move Amendment 27?

Baroness Thornton (Lab) [V]: I thought these amendments were part of the group that was passed on Tuesday?

Baroness Penn (Con): The noble Baroness is correct that Amendment 27 is consequential to an amendment agreed on day 1 of Report, so she may wish to move it.

Baroness Thornton (Lab) [V]: I think Amendment 26 is similar, possibly. We may need some guidance from the clerk. Was Amendment 26 also related to the group of amendments that were agreed on Tuesday? I apologise; it is always difficult to do these things when you are not actually in the Chamber.

Baroness Penn (Con): My understanding is that Amendment 26 is also consequential to amendments passed on day 1 of Report, so we may wish to ask the

[Baroness Penn]
noble Lord, Lord Patel, whether he wishes to move his amendment, which is consequential to previous amendments agreed.

Baroness Thornton (Lab) [V]: That is what I thought

The Deputy Speaker (Lord Russell of Liverpool) (CB): I will go back to Amendment 26. Does the noble Lord, Lord Patel, wish to move Amendment 26?

Lord Patel (CB) [V]: I do not wish to move the amendment.

The Deputy Speaker (Lord Russell of Liverpool) (CB): Does the noble Baroness, Lady Thornton, wish to move that amendment?

Baroness Thornton (Lab) [V]: Yes.

Amendment 26

Moved by ***Baroness Thornton***

26: After Clause 7, insert the following new Clause—

"Requirement for draft consolidated legislation: human medicines

The Secretary of State must, within the period of three years beginning with the day on which this Act is passed, publish draft legislation consolidating the regulatory regime as it applies to human medicines."

Member's explanatory statement

This new Clause, and the other consolidation amendments in the name of Lord Patel, would require the Secretary of State to publish draft consolidated legislation within three years to streamline the existing regulatory framework. These amendments are linked to the amendment providing for a three year sunset provision in the name of Baroness Thornton.

Amendment 26 agreed.

Clause 9: Power to make regulations about veterinary medicines

Amendment 27

Moved by ***Baroness Thornton***

27: Clause 9, page 6, line 21, at end insert "for a period of three years beginning with the day on which this Act is passed."

Member's explanatory statement

This amendment provides a sunset provision for Part 2 of the Bill requiring the Government to return with primary legislation. It is linked to the sunset amendments for Parts 1 and 3 of the Bill, and the amendments in the name of Lord Patel requiring consolidated legislation.

Amendment 27 agreed.

Amendment 28

Moved by ***Baroness Jolly***

28: Clause 9, page 6, line 21, at end insert—

"( ) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (Super-affirmative procedure), in relation to regulations made by a Northern Ireland department, to section (Super-affirmative procedure: Northern Ireland), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both."

Amendment 28 agreed.

Amendments 29 to 32

Moved by ***Lord Bethell***

29: Clause 9, page 6, line 22, leave out from beginning to "promote" on line 23 and insert "In making regulations under subsection (1), the appropriate authority's overarching objective must be to"

Member's explanatory statement

This amendment provides that the appropriate authority's overarching objective in making regulations under Clause 9 must be to promote one or more of the following: the health and welfare of animals; the health and safety of the public; the protection of the environment.

30: Clause 9, page 6, line 27, leave out "they would" and insert "regulations under subsection (1) would contribute to this objective"

Member's explanatory statement

This amendment is consequential on the amendment to Clause 9(2) in the Minister's name.

31: Clause 9, page 6, line 32, leave out "an attractive or" and insert "a"

Member's explanatory statement

This amendment omits the word "attractive" from Clause 9(3)(c).

32: Clause 9, page 6, line 32, leave out "develop or supply veterinary medicines" and insert "—

(i) develop veterinary medicines, or

(ii) manufacture or supply veterinary medicines."

Member's explanatory statement

This amendment clarifies the meaning of Clause 9(3)(c).

Amendments 29 to 32 agreed.

Amendment 33

Moved by ***Lord Bethell***

33: Clause 9, page 6, line 33, at end insert—

"(3A) Where regulations under subsection (1) may have an impact on the safety of veterinary medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks."

Member's explanatory statement

This amendment provides that the appropriate authority may make regulations that may have an impact on the safety of veterinary medicines only if the authority considers that the benefits of doing so outweigh the risks.

Amendment 34, as an amendment to Amendment 33, not moved.

Amendment 33 agreed.

Clause 12: Disclosure of information in accordance with international agreements

Amendment 35

Moved by ***Lord Bethell***

35: Clause 12, page 8, line 19, after "a" insert "relevant"

Member's explanatory statement

This amendment and the other amendment to clause 12 in the Minister's name restrict the persons to whom information may be disclosed in reliance on Clause 12(2).

Amendment 35 agreed.

Amendment 36

Moved by ***Baroness Thornton***

36: Clause 12, page 8, line 21, at end insert—

"( ) Where information is disclosed in accordance with subsection (2) such disclosure will only be permitted where—

(a) it is required as part of international cooperation for pharmacovigilance; or

(b) it is in the public interest."

Member's explanatory statement

This amendment would allow a relevant authority to disclose information to a person outside the UK where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of human medicine provided it is within the public interest to do so.

Amendment 36 agreed.

Amendments 37 and 38

Moved by ***Lord Bethell***

37: Clause 12, page 8, line 39, at end insert—

"(5A) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law."

Member's explanatory statement

This amendment provides that Clause 12 does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

38: Clause 12, page 9, line 6, at end insert—

""relevant person" means—

(a) the government of a country or territory outside the United Kingdom;

(b) a person who exercises functions on behalf of such a government;

(c) any other person who exercises functions or provides services relating to veterinary medicines in a country or territory outside the United Kingdom;

(d) an international organisation that exercises functions or provides services relating to veterinary medicines."

Member's explanatory statement

See the explanatory statement to the other amendment to Clause 12 in the Minister's name.

Amendments 37 and 38 agreed.

Amendment 39

Moved by ***Lord Patel***

39: After Clause 12, insert the following new Clause—

"Requirement for draft consolidated legislation: veterinary medicines

The Secretary of State must, within the period of three years beginning with the day on which this Act is passed, publish draft legislation consolidating the regulatory regime as it applies to veterinary medicines."

Member's explanatory statement

This new Clause, and the other consolidation amendments in the name of Lord Patel, would require the Secretary of State to publish draft consolidated legislation within three years to streamline the existing regulatory framework. These amendments are linked to the amendment providing for a three year sunset provision in the name of Baroness Thornton.

Amendment 39 agreed.

Clause 14: Power to make regulations about medical devices

Amendment 40

Moved by ***Baroness Thornton***

40: Clause 14, page 9, line 32, at end insert "for a period of three years beginning with the day on which this Act is passed"

Member's explanatory statement

This amendment provides a sunset provision for Part 3 of the Bill requiring the Government to return with primary legislation. It is linked to the sunset amendments for Parts 1 and 2 of the Bill, and the amendments in the name of Lord Patel requiring consolidated legislation.

Amendment 40 agreed.

Amendment 41

Moved by ***Baroness Jolly***

41: Clause 14, page 9, line 32, at end insert—

"( ) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (Super-affirmative procedure), in relation to regulations made by a Northern Ireland department, to section (Super-affirmative procedure: Northern Ireland), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both."

Amendment 41 agreed.

3.45 pm

The Deputy Speaker (Lord Russell of Liverpool) (CB): My Lords, I should inform the House that, if Amendment 45 is agreed to, I shall not be able to call Amendment 46 by reason of pre-emption, and that the debate on the group beginning with Amendment 46 will be postponed and take place on Amendment 66.

Amendments 42 to 45

Moved by ***Lord Bethell***

42: Clause 14, page 9, line 33, leave out subsection (2) and insert—

"(2) In making regulations under subsection (1), the Secretary of State's overarching objective must be safeguarding public health."

Member's explanatory statement

This amendment provides that the Secretary of State's overarching objective in making regulations under Clause 14 must be safeguarding public health.

43: Clause 14, page 9, line 35, leave out "they would" and insert "regulations under subsection (1) would contribute to this objective"

Member's explanatory statement

This amendment is consequential on the amendment in the Minister's name substituting Clause 14(2).

44: Clause 14, page 9, line 39, leave out "an attractive or" and insert "a"

Member's explanatory statement

This amendment omits the word "attractive" from Clause 14(3)(c).

45: Clause 14, page 9, line 40, leave out "develop or supply medical devices" and insert "—

(i) carry out research relating to medical devices,

(ii) develop medical devices, or

(iii) manufacture or supply medical devices."

Member's explanatory statement

This amendment clarifies the meaning of Clause 14(3)(c).

Amendments 42 to 45 agreed.

Amendment 46 not moved.

Amendment 47

Moved by ***Lord Bethell***

47: Clause 14, page 9, line 40, at end insert—

"(4) Where regulations under subsection (1) may have an impact on the safety of medical devices, the Secretary of State may make the regulations only if the Secretary of State considers that the benefits of doing so outweigh the risks."

Member's explanatory statement

This amendment provides that the Secretary of State may make regulations that may have an impact on the safety of medical devices only if the Secretary of State considers that the benefits of doing so outweigh the risks.

Amendment 48, as an amendment to Amendment 47, not moved.

Amendment 47 agreed.

Clause 18: Information systems

Amendment 49

Moved by ***Baroness Jolly***

49: Clause 18, page 11, line 40, at end insert—

"( ) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (Super-affirmative procedure), in relation to regulations made by a Northern Ireland department, to section (Super-affirmative procedure: Northern Ireland), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both."

Amendment 49 agreed.

The Deputy Speaker (Lord Russell of Liverpool) (CB): We now come to the group beginning with Amendment 50. I remind noble Lords that Members other than the mover and the Minister may speak only once and that short questions of elucidation are discouraged. Anyone wishing to press this or anything else in this group to a Division must make that clear in debate.

Amendment 50

Moved by ***Lord Bethell***

50: After Clause 18, insert the following new Clause—

"Advisory committee

(1) The Secretary of State may by regulations establish, and make other provision about, a committee to advise the Secretary of State on such matters relating to medical devices as the regulations may specify.

(2) The regulations may (among other things) make provision about—

(a) the membership of the committee;

(b) the establishment by the committee of sub-committees;

(c) matters to which the committee may, or must, have regard;

(d) cooperation between the committee and the Commission on Human Medicines, and other bodies with expertise in relation to medical devices.

(3) The provision mentioned in subsection (2)(a) may include—

(a) provision about the number of members, their appointment, and the circumstances in which a person ceases to be a member;

(b) requirements as to the independence of members from the Secretary of State;

(c) provision about the payment of remuneration and allowances to members."

Member's explanatory statement

This new Clause would enable regulations to be made creating a statutory committee to provide advice to the Secretary of State in relation to medical devices.

Lord Bethell (Con): My Lords, in moving Amendment 50, I shall speak also to Amendments 64 and 96. We have spoken extensively about the critical importance of patient safety and the need to improve medical device safety in bold new regulations going forwards. The need for medical device scrutiny to the highest standards was expressed by noble Lords throughout Grand Committee and, of course, in the report of my noble friend Lady Cumberlege. We recognise that improved and strengthened post-market surveillance and vigilance is essential. Equally, it is critical that we take further steps to strengthen oversight and increase transparency behind regulatory decision-making. Amendment 50 would support those efforts.

This new clause provides the Government with the power to create a statutory committee for independent expert advice on matters relating to medical devices. Historically, systems for post-market surveillance for medicines and medical devices have evolved differently. However, given scientific and technological advances and the kinds of innovative products and treatments becoming available, whether classed as medicines or medical devices, there is now need for greater assurance of equally high standards of surveillance, to ensure the upmost protection of patients.

The Commission on Human Medicines, which has a statutory basis in the human medicines regulations, provides an expert independent view to the MHRA on human medicines. It is visible and is underpinned by a statutory footing in the Human Medicines Regulations 2012. There is a parallel set of experts for medical devices. The Devices Expert Advisory Committee, or DEAC, advises the MHRA on medical devices but does not have an equivalent statutory footing.

Amendment 50 would change this. Subsection (1) provides a delegated power to establish a committee to advise on matters relating to medical devices. The aim is to strengthen the vigilance system for medical devices. A statutory committee for medical devices will support structured decision-making and formal accountability, allowing for clear roles and responsibilities for independent expert advice. This will strengthen the MHRA's ability to manage safety issues which are identified in clinical use even more effectively, ensuring that timely decisions are made and appropriate action taken to protect patients.

Proposed new subsection (2) provides that regulations may include, among other things, provision about membership, matters which the committee may or must consider, and establishment of sub-committees. This subsection also allows for provision to be made regarding co-operation with other bodies with medical devices expertise and the Commission on Human Medicines, allowing for join-up and best use of our experts.

Proposed new subsection (3) lists matters that regulations under proposed new subsection (2)(a) in relation to membership may cover. This includes the number of members, their appointment, the circumstances in which they cease to be members, and requirements as to independence from the Secretary of State. Proposed new subsection 3(c) allows for provisions to be made about payment of remuneration and allowances to committee members.

The amendment also amends Clause 41, enabling regulations relating to the advisory committee to make consequential provisions. Pursuant to Clause 45, regulations are to be made by statutory instrument and subject to the affirmative procedure. We consider it appropriate that Parliament has the opportunity to scrutinise regulations made under this power, given that the placing of this committee on a statutory footing will be a key element of enhancing the safety of medical devices. These regulations will be subject to all the requirements in Clause 45: public consultation and use of the affirmative procedure; and allowing patients, and other stakeholders, to comment before regulations are made to establish the Committee.

Those regulations will set out clearly, and transparently, how the statutory committee would provide advice where the regulator identifies that there is a need for scientific, technical or clinical advice. They will set out requirements to engage patients in the advisory system; for timeframes for advice on safety concerns to be issued; and requirements to communicate publicly about new and emerging risks. Rightly, the public want more transparency and accountability in regulatory decision-making. They want clearer, greater communication and explanation relating to the performance of healthcare products in clinical use. Patients deserve clear and up-to-date information on the safety of healthcare products from credible and authoritative sources. This statutory committee will meet that need. A statutory devices advisory committee will give confidence to patients, as well as clinicians and the public, that the regulator will take account of expert views on medical devices in a fast-moving area of life sciences. It will create an equilibrium in the level of external advice informing regulatory decisions across all healthcare products.

There are two other amendments in my name in this group and I do not intend to dwell on them, as they are only minor and technical. Amendment 96 provides for consequential changes to allow the DEAC to be commenced. Amendment 64 makes a technical amendment in relation to the time limits for bringing prosecutions for an offence. Time limits already exist but, as part of the clarification of the enforcement regime in Part 3, changes were made to break the link between consumer protection legislation and medical devices, and to streamline the enforcement regime. Due to an oversight, the current time limit was removed but not then reinstated by the Bill into the medical device regulations. Without this change, the system would not function correctly. I beg to move.

Amendment 51 (to Amendment 50)
Moved by ***Baroness Wheeler***

51: After Clause 18, in subsection (1), leave out "may" and insert "must"

Member's explanatory statement

This would require the Secretary of State to make regulations to creating a statutory committee to provide advice in relation to medical devices.

Baroness Wheeler (Lab): My Lords, I thank the Minister for moving Amendment 50 enabling regulations to be made to establish the medical devices advisory committee to advise the Secretary of State and to place the existing Devices Expert Advisory Committee on a statutory footing. We welcome this proposed new clause to the information system requirements as an important step towards bringing more transparency to the devices system and ensuring that the regulator seeks independent expert advice on the safety of devices.

As will be seen from Amendments 51, 52, and 53, however—I am moving Amendment 51 on behalf of my noble friend Lady Thornton—we want the requirement on the Secretary of State to establish the MDAC as a "must do" commitment, rather than the "may" in proposed new subsections (1), (2) and (3) of the amendment in relation to: the need for the regulations; providing advice; and making key provisions, such as how independent members should be from the Secretary of State. I know that numerous debates have been held during the course of legislation going through this House about the differences between "must" and "may". However, "must" is surely the necessary language to require the Secretary of State to establish the committee and ensure its independence.

The Government's briefings on the amendment—and the Minister today—as well as referring to the committee providing independent expert advice, emphasise that this will include "the views of patients", complementing the work of the patient safety commissioner and giving patients a voice within the system of regulating medical devices. Through every stage of the Bill, noble Lords have underlined the importance of consultation with patients and end-users of medicines and medical devices. Can the Minister explain the thinking behind not including a subsection in the amendment which underlines the importance of the patient's voice and perspective? I would also be grateful if he could tell the House what he considers will be the impact on the advisory role and scope of the change to a statutory footing for the committee.

[Baroness Wheeler]

We acknowledge the need for the two technical government Amendments 64 and 96. On Amendment 64, I note the explanation from the Minister today, and in his briefing letter to Peers of 5 January, of the need to reinstate provisions in the Medical Devices Regulations 2002 extending time limits for bringing proceedings in relation to medical devices offences. Amendment 96 is a necessary consequential amendment in relation to the added clause on the MDAC under Clause 18, bringing the whole clause into force two months after the Bill is passed.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, I am glad to be able to take part in this debate, which allows the House to have a preliminary discussion about the future of medical devices regulation. I certainly welcome the establishment of an advisory committee, but I also welcome my noble friend's amendment which makes sure that the rather tentative "may" is replaced by "must". The Minister's amendment is rather open-ended. It does not specify what matters it will advise the Secretary of State on, nor does it give any indication of the likely balance of membership. This is important because, as I have said, there has been some concern over quite a few years that the regulation of medical devices is not up to the mark, nor sufficiently protective of patient safety. The report by the noble Baroness, Lady Cumberlege, has identified some weaknesses. In that regard, I declare my interest as president of GS1 UK, the bar-coding association.

We received a very helpful briefing from Professor Muireann Quigley and colleagues at the University of Birmingham, pointing to the rather confused state that medical devices regulation is in. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 came into force at the end of the EU exit transition period. These amend the Medical Devices Regulations 2002 to mirror key elements contained in EU regulations 2017/745, on medical devices, and 2017/746 on in vitro diagnostic medical devices. The aim of that was to make sure that there was good regulatory alignment between the UK and EU, as well as between different parts of the UK's own regulatory framework. This Bill, when enacted, will provide an opportunity to mandate a more streamlined legislative approach. That would benefit all stakeholders, including industry, businesses and patients.

At present, the MHRA has no involvement in the pre-market phase of medical device development and there is a question as to whether it ought to have. Birmingham University colleagues are certainly proposing a proactive regulatory role for devices that is more akin to that for medicines. This would be clinically focused and, as they say, at least as stringent as the new EU medical devices regulations. Under that proposal, manufacturers could be required to apply to the MHRA before marketing their device. The MHRA could also assess the application in a way that is proportionate to the risks. It is proposed to take account of relevant factors, such as evidence-based supply, approvals in other jurisdictions and post-marketing surveillance plans. I know that that view may not necessarily be shared by industry, which would, perhaps, be concerned about the cost and delay in achieving licensing. However, we can expect a pretty intense debate about medical device regulation in the future.

4 pm

There is also a need to reflect an industry fear that, for instance, once it becomes mandatory to use a UK process for the British market, suppliers may choose either to deprioritise Britain as a whole or else not to produce products here at all. One of the challenges is therefore to ensure that the UK remains attractive and that new sovereign regulation does not become merely duplicative and costly. Given the innovation in our own sector, this is very important indeed. The global reputation of the MHRA is clearly in our favour, as is the trend to the harmonisation of standards globally. However, we will also need to think about innovative regulation in areas such as digital healthcare, artificial intelligence and deep learning. I therefore assume and hope that the advisory committee will be very much involved in all that. That means that its membership must have a broad range of interests, including patients and users as well as industry. I hope that in winding the Minister may be able to say something about that.

The amendments in the name of my noble friend Lady Wheeler seek to create greater certainty by substituting "must" for "may". Surely that is right, and I certainly support her on that.

Lord Lansley (Con) [V]: My Lords, I am pleased to follow the noble Lord, Lord Hunt of Kings Heath, who asked some relevant and useful questions about this while welcoming the new clause and the advisory committee on medical devices as a statutory body. I join him in that and think it is a very welcome move on the Government's part. The analogy with the Commission on Human Medicines is helpful. As regards translating the Devices Expert Advisory Committee into a statutory role, in effect, in the process, as the noble Lord, Lord Hunt, suggested, there is considerable scope to think about how the Government's new and expanded roles in the regulation of medical devices can be supported by the advisory committee.

I have a number of points. The first reflects the point made by the noble Lord, Lord Hunt, which is that the MHRA has an enviable reputation as a regulatory authority for the approval of medical devices. If I recall correctly, among the European regulatory bodies something like 40% of the most important or significant medical devices were authorised by the MHRA. Other regulatory authorities in other countries will seek to supplant that. However, our reputation should enable us to establish an international position, and I hope that the advisory committee will not be confined to expertise from within the United Kingdom. There is a lot to be said for positioning the MHRA as a body providing internationally recognised authorisations for medical devices, and its scientific evaluation in that respect should be something that others look to. I therefore hope that that will assist if we have some international participation in the advisory committee structure.

Secondly, I recall, not least in the context of the vexed experience of the PIP breast implant issues back in 2010-11, that the role of notified bodies is very important.

Hitherto they have, in essence, been regulated by the European Commission, not by the UK Government, but they fall to be UK-regulated in future. There are not many of them, but there is considerable benefit in there being an advisory committee sub-committee which is focused on the work of the notified bodies. That was the weak link that probably led to the PIP breast implant problems. The regulation is all very well but we have to have bodies that we are confident are able to deliver on these things. The few notified bodies we have in this country are highly respected but we want to make sure that that is maintained even as further notified bodies are authorised.

Thirdly, I recognise that the Devices Expert Advisory Committee has leading clinicians from Scotland and Wales in its membership. However, this must be a UK advisory function, as the MHRA is. I wonder whether it would be appropriate for there to be in addition a Northern Ireland representative on the committee and for there to be perhaps some specific mechanisms to ensure that Scotland, Wales and Northern Ireland are represented in the regulations that establish the advisory committee.

I have one further point, which is that I hope that the various categories of medical devices are very carefully examined and the relevant expertise is available in relation to those. So, for example, on digital devices it is important that we have not only the clinical expertise to deal with the safety of medical devices we have at the moment but the technical expertise in the advisory committee to understand how digital devices will work in the future. That must also be the case in the special interests section related to in vitro diagnostic devices. I hope that that also will have its own special advisory committee function.

Baroness Masham of Ilton (CB) [V]: My Lords, I am pleased to follow the noble Lord, Lord Lansley. I support Amendments 51 to 53 because it is important that the new clause will read "must" instead of "may", so that the advice on medical devices will be clear and should be followed. "May" means it can be optional and makes the regulations weaker, and people might miss important aspects of care. There is no doubt that clear, correct information is the way to better patient safety. In many ways, communication within the National Health Service should be improved.

Baroness McIntosh of Pickering (Con) [V]: My Lords, I am delighted to follow the noble Baroness, Lady Masham, and earlier speakers in welcoming this group of amendments. I support government Amendments 50, 64 and 96 and welcome the placing of the advisory committee on a statutory footing, and particularly that the affirmative procedure will be used.

My question goes to the nub of Amendment 50—in which regard, if this is correct, Amendments 51 and others in this group will not be needed. Is it for the Secretary of State to decide what goes in the regulations on which presumably Parliament will be consulted under the affirmative procedure?

I can quite understand that the use of "may" appears to be discretionary, leaving open what should be included. Having got this far, it would be helpful to understand the thinking behind the use of "may" in Amendment 50, which indicates that this may be discretionary, whereas clearly it appears to be the will of the House that this is mandatory.

Baroness Jolly (LD) [V]: My Lords, we support these amendments from the Government and from the noble Baroness, Lady Thornton, which relate to the creation of a statutory committee to provide advice to the Secretary of State. Government Amendment 50 would allow the creation of such a committee in relation to medical devices, and the amendments in the name of the noble Baroness, Lady Thornton, in this group would require the Secretary of State to create the committee in Amendment 50, as the Government's amendment states only that the Government "may" create the committee, not that they must.

No Secretary of State should be above independent advice. Amendment 50 is no bad thing, and of course any advisory committee on a statutory footing should consist of patients as well as experts. I understand that there might be kickback on the amendments in the name of the noble Baroness, Lady Thornton, but a Secretary of State will rarely have expertise in medical devices, so an ad hoc independent committee to inform, advise and warn would be very valuable. A lot of thought will need to be given to working out its terms of reference. We therefore support Amendments 51 to 53. As the noble Lord, Lord Lansley, said, it will also be critical to ensure how this committee will work alongside the MHRA.

Lord Bethell (Con): My Lords, I am enormously thankful for that constructive debate. This change to the Devices Expert Advisory Committee should be welcomed. It provides for if not equivalence then equality between the medicines and medical devices regimes. It provides for transparency, which we value enormously, and it indicates our direction of travel, the step change and the commitment to patient safety that the MHRA will enshrine.

As has been noted, the committee already exists. It currently meets, and it has an impact and an effect, but these measures mean that it will be strengthened. This change is put forward not solely by the Government; it was a recommendation in the review authored by my noble friend Lady Cumberlege. It adds to the collective picture of improvements that we are making, from future regulation of devices to the medical devices information system. I reassure my noble friend Lord Lansley that we have a profound commitment to creating a regulator in the MHRA that has international influence. I say to the noble Lord, Lord Hunt, that patient representatives are already on the DEAC. As Dr June Raine made clear in her briefing to noble Lords, she and the MHRA are massively committed to the patient safety agenda and to mobilising the patient safety voice through instruments such as the DEAC but not solely through it.

It is a delegated power, but one that I hope noble Lords agree is contained. It will allow us to ensure that the structure and focus of the committee can be kept under review to make best use of its impact, and the regulations will be subject to public consultation and all the steps therein.

[Lord Bethell]

The noble Baroness, Lady Thornton, has tabled Amendments 51 to 53 to the government amendment, which would change the nature of the regulations such that they "must" rather than "may" be made. However, as I have set out, the committee already exists; it functions now. It will be strengthened by the regulations. We are committed to a more structured decision-making process that improves transparency. There is no equivocation or doubt; these regulations will be made.

The powers provided by Amendment 50 in my name will enable movement towards a more transparent, proactive, whole-life cycle approach to vigilance. Fundamentally, they will make a difference in the oversight of medical devices to the benefit of patients and patient safety.

I am grateful to noble Lords who have continued to shine a light on the importance of device safety. I hope that this additional tool in the arsenal demonstrates continued commitment and that I have provided sufficient reassurances for the noble Baroness to feel able to withdraw the amendment.

Baroness Wheeler (Lab): I thank the Minister for his response and all noble Lords and noble Baronesses who have taken part in this useful debate. The points made by my noble friend Lord Hunt and the noble Lord, Lord Lansley, about the future role of regulation were particularly pertinent, and we look forward to seeing how it develops.

I understand the Minister's response in relation to "may" or "must" and heard loudly his reassurance that there is no doubt that the committee will be established or be upgraded. That being the case, I am happy to withdraw the amendment.

Amendment 51 (to Amendment 50) withdrawn.

Amendments 52 and 53 (to Amendment 50) not moved.

Amendment 50 agreed.

Amendment 54

Moved by ***Lord Bethell***

54: Before Schedule 1, insert the following new Schedule—

"SCHEDULE A1

FURTHER PROVISION ABOUT THE COMMISSIONER FOR PATIENT SAFETY

Principles relating to core duties

1_(1) The Commissioner must prepare and publish a set of principles to govern the way in which the Commissioner will carry out the Commissioner's core duties.

(2) The Commissioner—

(a) may revise the principles, and

(b) must publish any revised version.

(3) The Commissioner must carry out a public consultation in preparing or revising the principles.

Involvement of patients

2_(1) The Commissioner must take reasonable steps to involve patients in the discharge of the Commissioner's core duties.

(2) The Commissioner must in particular take reasonable steps to—

(a) ensure that patients are aware of the Commissioner's core duties and of how they may communicate with the Commissioner, and

(b) consult patients, or persons who appear to the Commissioner to represent the interests of patients, on matters which the Commissioner proposes to consider in the discharge of the core duties.

Supplementary functions and information

3_(1) For the purposes of carrying out the core duties, the Commissioner may—

(a) make a report or recommendation to a relevant person;

(b) consult or receive information from patients or any other person the Commissioner thinks appropriate;

(c) request information from a relevant person;

(d) share information with a relevant person.

(2) A relevant person to whom a report or recommendation is made under sub-paragraph (1)(a) must provide a response to that report or recommendation within such period as the Commissioner may reasonably require.

(3) A relevant person must, so far as reasonably practicable, comply with a request by the Commissioner to provide information within such period as the Commissioner may reasonably require.

(4) Nothing in this Schedule authorises a disclosure of information which contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this Schedule).

(5) In this paragraph—

"data protection legislation" has the meaning given by section 3(9) of the Data Protection Act 2018;

"health care" means all forms of health care provided for individuals, whether relating to physical or mental health, and including ancillary care;

"relevant person" means—

(a) a person who exercises functions of a public nature, relating to medicines or medical devices, so far as those functions are exercisable in relation to England;

(b) any other person who, in the course of providing health care, provides services relating to medicines or medical devices in relation to England.

Individual cases

4_(1) The Commissioner may not exercise functions in relation to an individual case.

(2) But sub-paragraph (1) does not prevent the Commissioner considering individual cases and drawing conclusions about them for the purpose of, or in the context of, considering a general issue.

Amendments to primary legislation

5_(1) In Part 1 of the Table at the end of paragraph 3 of Schedule 1 to the Public Records Act 1958 (definition of public records), at the appropriate place insert—

"Commissioner for Patient Safety."

(2) In Part 3 of Schedule 1 to the House of Commons Disqualification Act 1975 (offices disqualifying for membership), at the appropriate place insert—

"Commissioner for Patient Safety."

(3) In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (other public bodies and offices: general), at the appropriate place insert—

"The Commissioner for Patient Safety."

(4) In section 71 of the National Health Service Act 2006 (schemes for meeting losses and liabilities etc of certain health service bodies), in subsection (2), before paragraph (h) insert—

"(ga) the Commissioner for Patient Safety,".

(5) In Part 1 of Schedule 19 to the Equality Act 2010 (authorities subject to the public sector equality duty), in the group of entries under the heading "Health, social care and social security", at the appropriate place insert—

"The Commissioner for Patient Safety."

Regulations about appointment and operation

6_(1) The Secretary of State may by regulations make such provision as the Secretary of State considers appropriate with regard to the appointment and operation of the Commissioner.

(2) Regulations under sub-paragraph (1) may (among other things) contain provision for and about—

(a) the Commissioner's terms of office;

(b) remuneration or other benefits;

(c) the provision of financial or other assistance, including staff, accommodation, equipment or other facilities, for the Commissioner;

(d) requirements to prepare business plans;

(e) requirements to prepare reports;

(f) requirements to lay documents before Parliament;

(g) requirements to provide documents to the Secretary of State or other persons specified in the regulations;

(h) the conferring of functions on other persons in relation to the Commissioner;

(i) the appointment of a board to provide advice to the Commissioner."

Member's explanatory statement

This amendment makes further provision about the Commissioner for Patient Safety established by the amendment in the Minister's name to insert a new Part before Part 1.

Amendment 54 agreed.

4.15 pm

Clause 37: Disclosure of information

Amendments 55 and 56

Moved by ***Lord Bethell***

55: Clause 37, page 22, line 1, after "a" insert "relevant"

Member's explanatory statement

This amendment and the amendment to clause 37 in the Minister's name adding a definition of "relevant person" restrict the persons to whom information may be disclosed in reliance on Clause 37(5).

56: Clause 37, page 22, line 3, at end insert—

"(5A) But subsection (5) does not authorise a disclosure of patient information without the consent of the individual to whom that information relates."

Member's explanatory statement

This amendment and the amendment in the Minister's name to add a definition of "patient information" to Clause 37 prevent Clause 37(5) authorising the disclosure of information from which patients can be identified without their consent.

Amendments 55 and 56 agreed.

Amendment 57

Moved by ***Baroness Wheeler***

57: Clause 37, page 22, line 3, at end insert—

"( ) Where information is disclosed in accordance with subsection (5) such disclosure will only be permitted where—

(a) it is required as part of international cooperation in monitoring the performance and safety of medical devices; or

(b) it is in the public interest."

Member's explanatory statement

This amendment would allow a relevant authority to disclose information to a person outside the UK where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of human medicine provided it is within the public interest to do so.

Amendment 57 agreed.

Amendments 58 to 62

Moved by ***Lord Bethell***

58: Clause 37, page 22, line 4, leave out "But"

Member's explanatory statement

This amendment is consequential on the amendment in the Minister's name adding a new subsection (5A) to Clause 37.

59: Clause 37, page 22, line 27, at end insert—

"(9A) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law."

Member's explanatory statement

This amendment provides that Clause 37 does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

60: Clause 37, page 22, leave out line 32

Member's explanatory statement

This amendment omits an unnecessary definition.

61: Clause 37, page 22, line 32, at end insert—

""patient information" means information (however recorded) which—

(a) relates to—

(i) the physical or mental health or condition of an individual,

(ii) the diagnosis of an individual's condition, or

(iii) an individual's care or treatment,

or is (to any extent) derived directly or indirectly from information relating to any of those matters, and

(b) identifies the individual or enables the individual to be identified (whether by itself or in combination with other information);"

Member's explanatory statement

See the explanatory statement for the amendment in the Minister's name adding a new subsection (5A) to Clause 37.

62: Clause 37, page 22, line 32, at end insert—

""relevant person" means—

(a) the government of a country or territory outside the United Kingdom;

(b) a person who exercises functions on behalf of such a government;

(c) any other person who exercises functions or provides services relating to medical devices in a country or territory outside the United Kingdom;

(d) an international organisation that exercises functions or provides services relating to medical devices."

Member's explanatory statement

See the explanatory statement to the first amendment to Clause 37 in the Minister's name.

Amendments 58 to 62 agreed.

The Deputy Speaker (Lord Faulkner of Worcester) (Lab): Does the noble Lord, Lord Patel, wish to move to move his Amendment 63? Lord Patel? We cannot hear the noble Lord.

Baroness Penn (Con): The noble Lord may wish to know that the amendment is consequential on an amendment passed earlier on Report, so he or a fellow signatory may wish to move it.

Amendment 63

Moved by ***Baroness Wheeler***

63: After Clause 39, insert the following new Clause—

"Requirement for draft consolidated legislation: medical devices

The Secretary of State must, within the period of three years beginning with the day on which this Act is passed, publish draft legislation consolidating the regulatory regime as it applies to medical devices."

Member's explanatory statement

This new Clause, and the other consolidation amendments in the name of Lord Patel, would require the Secretary of State to publish draft consolidated legislation within three years to streamline the existing regulatory framework. These amendments are linked to the amendment providing for a three year sunset provision in the name of Baroness Thornton.

Amendment 63 agreed.

Schedule 2: Offence of breaching provisions in the Medical Devices Regulations 2002

Amendment 64

Moved by ***Lord Bethell***

64: Schedule 2, page 39, line 39, at end insert—

"(2A) In respect of an offence under this regulation—

(a) a magistrates' court in England and Wales may try an information laid before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed;

(b) a magistrates' court in Northern Ireland may hear and determine any complaint made before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed;

(c) in Scotland, summary proceedings for the offence may be commenced before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed.

(2B) For the purposes of paragraph (2A)(a)(i), (b)(i) and (c)(i)—

(a) a certificate signed by or on behalf of the prosecutor and stating the date on which such evidence came to the prosecutor's knowledge is conclusive evidence of that fact, and

(b) a certificate stating that matter and purporting to be so signed is to be treated as so signed until the contrary is proved."

Member's explanatory statement

This amendment ensures that prosecutions for an offence under new regulation 60A of the Medical Devices Regulations 2002 can be brought before the earlier of one year from the prosecutor thinking there was sufficient evidence to justify a prosecution or three years of the commission of the offence, as is currently the case with regard to equivalent offences under section 12 of the Consumer Protection Act 1987.

Amendment 64 agreed.

Amendment 65 not moved.

The Deputy Speaker (Lord Faulkner of Worcester) (Lab): We now come to Amendment 66. I remind noble Lords that Members other than the mover and the Minister may speak only once and that short questions of elucidation are discouraged. Anyone wishing to press the amendment to a Division must make that clear in debate.

Amendment 66

Moved by ***Lord Hunt of Kings Heath***

66: After Clause 40, insert the following new Clause—

"Availability of medicines and medical devices for human use on the National Health Service

(1) The National Institute for Health and Care Excellence must have regard to the need—

(a) to address the implications of health inequalities when assessing the cost effectiveness of medicines and medical devices,

(b) to support early patient access to effective new medicines and medical devices, including by accepting a greater degree of uncertainty and risk in recommending their use,

(c) to ensure patients with rare diseases have access to medicines and medical devices that they need, and

(d) to support the use of curative therapies involving medicines and medical devices.

(2) The Secretary of State must lay a report and impact assessment before both Houses of Parliament setting out how the National Institute for Health and Care Excellence has implemented its duty under subsection (1), in particular in its manual on process and methods for developing NICE guidelines."

Member's explanatory statement

This new Clause would require the National Institute for Health and Care Excellence to ensure that its recommendations support the NHS in the ways described in subsection (1).

Lord Hunt of Kings Heath (Lab) [V]: My Lords, before I start, perhaps I may make the point to the clerks that the noble Baroness, Lady Thornton, needs to be unmuted every time the Deputy Speaker goes through the amendments so that she can move them or not. It is very frustrating; we can see it happening, and it is impossible for us to come in on this situation. That is why there is such a hiatus.

My Amendment 66 concerns NICE's current view of its methods and processes as part of the agreement on the voluntary scheme for branded medicines pricing and access, happily known as VPAS. If NICE is to maintain its global relevance, it is critical that the methods review delivers tangible changes to ensure that it can fairly and effectively assess the true value of innovative medicines.

The UK life sciences sector is at a crossroads. Without meaningful intervention from the Government, exiting the EU obviously presents significant threats to the attractiveness of the UK. We know that global boardrooms take a holistic approach when considering where to place their investment, including the attractiveness and speed of the commercial environment—we have debated these earlier in the Bill. The ability quickly to launch medicines and technologies into our market and to get medicines quickly to the patients who need them is one of the main factors that shape boardroom sentiment on future investment, alongside the quality of scientific research and the possibility of collaboration. It was the Labour Government who set up NICE to do that: to get innovative new medicines and devices to the NHS and implemented as quickly as possible.

But the UK risks missing out on a wave of breakthrough therapies, with the potential to transform outcomes, if the NICE review does not lead to meaningful change in the way it does its business. Not only do we risk losing our reputation as a leader at the cutting edge of medical science but, more importantly, patients will not be able to assess the most innovative treatments available elsewhere. So NICE's approach to appraising value must take into account the strategic benefits of the NHS remaining at the forefront of medical innovation and demonstrate that the UK Government are committed to supporting a thriving, world-leading life science sector post Brexit.

In relation to my amendment, I would like to raise issues of barriers to new innovative technologies, such as gene therapy. Gene therapy is a prime example of a medical technology that the UK should embrace, and, indeed, the Government have rightfully lauded the UK's efforts in this regard. But a procedure called the discount rate, used by NICE to adjust for future costs and health benefits when valuing treatments, discriminates against one-time therapies that offer potential long-term health benefits over many years, such as gene therapies. NICE almost always uses a 3.5% rate. It can apply a lower 1.5% rate for therapies that offer longer-term health benefits, but it has chosen to do this only on exceptionally rare occasions. I wonder whether the Minister will commit to working with NICE to review the circumstances in which the policy solution can be applied to unlock the potential of such innovations.

The VPAS was negotiated with the aim to secure a triple win for patients, government and industry. But NHS England's current bespoke commercial agreements significantly undervalue innovation, and this is something global boardrooms look at for evidence in the NICE review—that speedy access to new medicines will be improved.

Why should the Government commit to doing an impact assessment of the changes? Well, warm words and promises from Ministers are not enough; we need a clear commitment from them that they will place the emphasis on NICE to ensure meaningful action. In Committee, the Minister argued that my amendment was not necessary, and that the issues I raised were already dealt with in existing legislation and were outside the remit of the Bill. She went on to say:

"NICE, like the rest of the health system, is constantly keeping methods under review to ensure they are appropriate and support the speed of innovation in the life sciences sector,"

and she agreed about the need to get new innovations into the hands of patients quickly. In so doing, she referred to the methods and process manual produced by NICE

"in consultation with a range of stakeholders, including industry and academics."

She said:

"NICE will publish a revised manual and related impact assessment when that process is completed."—[*Official Report*, 26/10/20; col. GC 52.]

Is that sufficient?

The Ethical Medicines Industry Group has identified that medicines and medical devices often face challenges when being assessed by NICE, due the rigid focus on cost-effectiveness. Failing to consider other factors, such as the benefits of treatment in reducing health inequalities or the wider impacts on quality of life, often hinders patients' ability to access innovative life-saving treatments. The EMIG argues that introducing a health inequalities modifier would be critical to demonstrate that NICE recognises the importance of reducing the high levels of unmet medical needs in the population and to benefit the most disadvantaged and underserved patient groups. There is strong support for the introduction of this modifier among experts involved in the development of the consultation, with a document noting that there is evidence that people are willing to generate less health overall if the health is generated in disadvantaged groups, particularly for socioeconomic disadvantage.

My amendment seeks to build on expert support to ensure equitable access to innovative treatments for conditions that are not adequately treated, to drive down health inequalities and benefit the most marginalised patients. I argue that NICE must also review its appraisal system for rare disease treatments to ensure that the system in place enables patient access. Inherently, rare disease treatments serve small patient populations, and generating sufficient data to meet NICE's cost-effectiveness requirements is often challenging.

I have received a briefing from another organisation, Global Blood Therapeutics, on sickle cell disease. It argues that, in relation to the UK's most prevalent genetic disorder, SCD treatments are currently limited to managing the condition rather than addressing the underlying causes. But there is hope that a new range of therapies may change this.

On occasion, NICE has also considered treatments which may not meet its traditional cost-effectiveness thresholds but which would have a significant impact on health inequalities. But consideration of health inequalities remains rare, and I think that this needs to be revisited. If NICE is truly committed to designing an appraisal process which reduces health inequalities and provides equitable access for the most disadvantaged patients, the introduction of a health inequalities modifier, as set out in my amendment, is vital.

The UK life science sector faces a great challenge. It is a huge asset. We have to ensure that organisations such as NICE play their part in making sure that the NHS and the UK are attractive for major investment in the future. In a nutshell, that is the crunch point of my amendment. We have as well to make sure that its methodology deals with health inequalities sufficiently. I beg to move.

Baroness Finlay of Llandaff (CB) [V]: My Lords, I declare that I am vice chair of the NICE review committee. Amendment 66, moved by the noble Lord, Lord Hunt of Kings Heath, aims to ensure early access for NHS patients to medicines and medical devices. This must also involve ensuring that results of safety and efficacy from devices in real-time use—as well as in trials—are registered, published and then considered again in real time, a process that I hope will be helped and promoted by the patient safety commissioner role.

Noble Lords will remember that in Committee I tabled, along with the noble Lord, Lord Hunt of Kings Heath, an amendment to ensure provision for the development of a new rapid provisional two-year licensing procedure. The intention behind that amendment was to ensure that patients could more quickly access potentially life-saving medicines and medical devices.

I sincerely thank the Minister and his team for meeting with me on this, and for the other meetings they facilitated. I am reassured that the approval processes from the MHRA over device development are due to be revised completely over the coming year, with improved and streamlined processes, and I hope that today the Minister can confirm this, even with a timeframe, so that we can move forward quickly.

We have a unique opportunity to develop devices and roll them out to the NHS, but it is important that approval processes do not slow down or block patient access to improvements in treatment and management over a wide range of conditions, particularly rare disorders. Evidence from real-time use is crucial, and development and improvement can become a virtuous circle when that is rapidly fed back—so we become the intellectual innovation hothouse for our future prosperity, while also benefiting our patients. The UK can then be seen as a favourable place to develop, approve and supply medicines and medical devices.

Speeding up and widening approval processes, including two-year provisional licensing that I have been advocating with the Royal College of Physicians, would ensure that developing a new device from beginning to end—taking an idea from conception to supply—all in the UK is seen as an attractive prospect. Otherwise, we continue to risk new devices beginning their innovation journey in the UK, then being taken abroad part-way through the development process and marketed back to the UK. Keeping the entire process in the UK, with different models of fast-track approvals and provisional approvals, will allow better oversight of the safety and efficacy of devices during early access, with ongoing monitoring in real-time use. That would then facilitate moving into appropriately costed long-term approval processes.

We can innovate in the UK and stop intellectual capacity being outsourced. We can protect the safety of patients while getting them access to the latest treatments. It is patients who will suffer if we do not get this right, which is why the proposals in this amendment are so important.

4.30 pm

Baroness McIntosh of Pickering (Con) [V]: My Lords, I am delighted to follow the noble Baroness, Lady Finlay, and speak on this group of amendments. I can see that the noble Lord, Lord Hunt, speaks with passion and some considerable knowledge and experience of NICE. But I am concerned and would just like to understand, as we have established that patient safety absolutely has to be paramount, that patient safety could not be compromised through either of the two amendments—Amendments 46 and 66—in this group.

The noble Baroness, Lady Finlay, set out in the earlier amendment in Committee a two-year licensing procedure and, now that we have obtained an assurance that the approval processes are to be revised, I would imagine that the same procedure as set out under Amendment 66 should be considered as part of that review and revision of the processes. I would also like to further understand how a role for NICE as set out in Amendment 66 actually fits in with the Bill before us today and, in particular, the role as set out, and just agreed, of what the advisory committee should be.

My concern is absolutely that patient safety has to be paramount—first, foremost and bottom line. In my view, what is sought to be set out in these two amendments in this little group should be best done as part of an overall review of the processes to which the Government, as I understand, are already committed.

Baroness Masham of Ilton (CB) [V]: My Lords, I am grateful to my noble friend Lady Finlay of Llandaff for alerting me to the fact that government Amendment 45 pre-empted our Amendment 46. They were grouped on different days, but I am pleased that others were thinking on the same wavelength.

I am very happy to support Amendment 66 in the name of the noble Lord, Lord Hunt of King's Heath. The availability of medicines and medical devices is top of my priority list. In fact, antibiotics have saved my life on several occasions. It is important that NICE adheres to health equality: everyone who needs medicines or medical devices should be treated equally and there should be no delay. Unfortunately, with this devious coronavirus, this has not happened, but we hope for better days.

Having experienced a member of my family dying, I know that sometimes it seems worth trying anything that might help and that is in the research process. There are many really rare diseases which need orphan drugs; they can be a lifeline to the individual. I hope that NICE will consider them without delay and realise their importance and value to these small patient groups. It is so frustrating when patients in Scotland and other European countries can get medicines and medical devices, when those in England cannot; patients here have to wait—unless the public come to their rescue by crowd funding.

Many users of devices also need instruction on their use, and staff and patients need training. Personal medicine is so important and patient safety is absolutely paramount.

Lord Lansley (Con) [V]: My Lords, I am most grateful to the noble Lord, Lord Hunt of King's Heath, for his amendment and for the way he introduced it. It very helpfully allows us, at this very important moment, to take stock of how we secure the availability of medicines—although the legislation does not relate

to NICE, and I am sure it will not surprise the noble Lord, Lord Hunt, that I do not think it is appropriate for us to legislate to tell NICE how to do its work, given its independent statutory constitution. None the less, the Bill is about the availability of medicines, and it is really important for us to identify how the NICE processes can assist in ensuring that we get medicines to those who need them.

I shall say a few words about the NICE processes. First, let me address the objective, from my point of view. When I was Secretary of State, I advocated a process called "value-based pricing", which was to try to understand that not only were there quantitative factors measured in quality-adjusted life years—QALYs—which, if one were able to secure them, gave one a quantitative basis for understanding the value of a new medicine, but that in addition there were other qualitative aspects, which I described as the societal benefits and the innovation benefits. I still think that this is the right approach.

In the international context, many countries are trying to escape the potential downward spiral of reference pricing, where everybody is trying to pay less than the average. The net result, if we carry on down that path and if the American Administration pursue that path, will be that we end up with inadequate support for the industry for the development of new and innovative medicines.

What we need to do is to value innovation and support the industry for the value it delivers. However, we do not measure it precisely in those terms. When we look at our current structure in this country, we need to understand that there is an opportunity created by what is known as VPAS—the voluntary pricing and access scheme. If it is genuinely the case, and we have argued that it should be, that the industry has accepted a constraint on the overall growth of the medicines budget in the NHS, and if it is clear that, if that growth is exceeded, there will be a rebate and that rebate does indeed return to benefit patients, through the NHS or the innovative medicines fund, so promoting access to new medicines, then we will arrive at the point where both NICE and NHS England should be working together to try to secure the best value from that drugs budget. I think they should be working together to ensure that, where there is a mandate for a new medicine, it is one which is supported by, not imposed upon, NHS England. That is increasingly where we should be aiming to arrive: at a combined thought.

What goes into value-based pricing matters enormously as well. The noble Lord, Lord Hunt, referred to some of the important aspects. First, it is about societal values. For example, if we can deliver a health gain among the parts of our population where health outcomes are poorest, then we should ascribe additional value to that health gain. A modifier for health inequalities is consistent, for example, with the statutory responsibilities of the NHS to seek to address and reduce health inequalities.

Unmet medical need makes a difference. Incremental effectiveness of medicines is important, but to have a medicine available for those who thought that there was no opportunity for treatment available to them from the NHS can make an enormous difference, and I think we should ascribe additional value to that. Medicines which deliver innovative benefits—for example, which have a whole new mode of action—can lead to subsequent treatments, and we should have a method of qualitatively understanding where those innovations, even if they may not have dramatic incremental benefits, none the less give us long-term potential. We should reflect that in the price that we are prepared to pay.

Indeed, as the noble Lord, Lord Hunt, said, we should not apply a discount rate to quality-adjusted life years that is directly comparable with the discount rates that are applied to revenues over time. I think people's time preference for quality-adjusted life years is not so dramatically higher for gain now as opposed to gain in the future; there is a much greater degree of equivalence between health gain now and health gain that people will derive in future. That would certainly assist in promoting medicines that slow the progression of disease and help us to manage longer-term morbidity in our older population, which would be immensely helpful.

There is a whole range of such matters and there are many more one could talk about, but it is really important to distinguish between NICE's job in undertaking a health technology assessment, which I think should be moved from the purely quantitative to the qualitative. It should include, for example, relying not only on randomised control trial data but understanding observational data and the data we receive from the use of the innovative medicines fund to see how well medicines work and what benefits and outcomes they can deliver—sometimes in relatively small populations for rare diseases—understanding that in practice and incorporating it in its assessment.

We need to support NICE in delivering what is regarded internationally, I hope, as a gold standard of health technology assessment. We need to understand that that is separate and distinct from the business of what price the NHS should pay and on what basis the industry and we, as payers for new medicines, should agree, understanding that our objective must always be to ensure that safe, effective and high-quality medicines are available to the NHS and patients.

Baroness Jolly (LD) [V]: My Lords, these amendments relate to NHS access to medical devices, and Amendment 46 from the noble Baroness, Lady Finlay, would ensure early access for NHS patients to medical devices and allow monitoring of safety and efficacy in real-time use. This amendment is pre-empted rather by the Government's amendment, which removes the concept of attractiveness.

Amendment 66 from the noble Lord, Lord Hunt of Kings Heath, would require NICE to ensure that its recommendations support the NHS in the ways outlined in subsection (1) of the proposed new clause. This includes ensuring access to new medicines and medical devices for patients with rare diseases. Those of us who have been involved in rare diseases will be all too well aware of the problems of access to appropriate treatments for so few patients.

The interesting thing about this debate is that two of the House's big health thinkers have been speaking, and both the noble Lord, Lord Hunt of Kings Heath, and the noble Lord, Lord Lansley, have given us a really good big-picture look which takes us slightly above legislation.

[Baroness Jolly]

The noble Lord, Lord Lansley, spoke of social and innovation benefits and the need to value innovation, but with innovation does not always come success: we may have to try again. He spoke about the innovative medicines fund and the necessity for NICE and NHS England to work together. When it is put like that, it sounds very straightforward: why is that not normally happening? He talked about the importance of value-based pricing and getting the best value from the drugs budget—which, after all, is finite. He also talked about the health technology assessment, which is of course qualitative, not quantitative. I valued the contribution of this debate on the fourth group of amendments, and I will read it again with great interest.

4.45 pm

Baroness Thornton (Lab) [V]: The noble Baroness, Lady Jolly, is quite right: two of our health big thinkers have laid out the issues here. My noble friend Lord Hunt gave a wonderful introduction to Amendment 66, which covered the reasons why it is important and what it will do. The noble Lord, Lord Lansley, took us on a journey through how health inequalities can be addressed. The point, and the reason the amendment is on the Marshalled List today, is that it does not always work like that. Implementation is key. As the noble Baroness, Lady Jolly, said, requiring NICE to support NHS access to new medicines and medical devices seems kind of obvious. The challenge for the Minister here is how to use this legislation and this discussion to make what we think is obvious work better.

Baroness Penn (Con): My Lords, I know the noble Lord, Lord Hunt of Kings Heath has a long-term interest in and commitment to the work of NICE and, as such, will know that NICE's remit is set out in other legislation. I do not intend to rehearse the arguments on why we do not see that as strictly for this Bill. Instead, I hope to provide some reassurance on the issues he raises with his amendment.

The noble Lord will be aware that NICE's methods and processes for assessing the cost-effectiveness of medical technologies are internationally respected and have been developed over almost 20 years through periodic review, including extensive engagement with stakeholders, and the latest iteration of that process of periodic review of its methods is ongoing. NICE finished the first phase of its consultation on the case for change to its methods on 18 December 2020. There will be a second consultation on the case for change to its processes in the spring. The result of those will inform the final consultation on the updated methods manual in summer 2021. I hope that the noble Lord is reassured by the consultative nature of that process in considering the issues he raised.

Subsection (1)(a) of the new clause proposed in his amendment would require NICE to address the implications of health inequalities when assessing the cost effectiveness of medicines and medical devices. Subsection (1)(b) would require NICE to accept a greater degree of uncertainty and risk in recommending their use. I reassure the noble Lord that NICE is already considering both of those as part of its review, and they were both consulted on as part of the consultation on the case for change that ran from 6 November to 18 December 2020.

In that consultation, NICE noted that there may be a case for a modifier that considers health inequalities. However, further work is needed to explore how this could be defined and implemented in a health technology evaluation, and under which circumstances. This will be done in NICE's second consultation running from February to March. Such a modifier could consider the types and sources of inequality, as well as how a modifier should be applied—qualitative or quantitative. It could also consider whether such a modifier covers technologies that directly reduce inequalities—for example, by specifically targeting or providing additional benefits for a disadvantaged group; or whether indirect effects might also be considered—for example, if a technology has uniform benefits across groups, but the condition disproportionally affects a disadvantaged group. At this stage, it is not clear that there is sufficient evidence for a health inequalities modifier, but it is being explored, and will be explored further in the second stage.

I hope that level of detail on the consideration that NICE is undertaking helps to reassure the noble Lord, but of course it would not be appropriate to pre-empt that review, and we want to encourage all stakeholders to respond to it.

In addition, I remind the noble Lord that a requirement to have regard to reducing health inequalities is already imposed on NICE under Section 1C of the National Health Service Act 2006. This applies to NICE as a non-departmental public body of the Department of Health and Social Care.

Proposed new subsection 1(c) would require NICE to have regard to the need

"to ensure patients with rare diseases have access to medicines and medical devices".

The noble Baroness, Lady Wheeler, noted some concern during Grand Committee as to why NICE did not propose a rarity modifier in its methods review. A rarity modifier was considered by NICE prior to publication of the consultation document. However, stakeholders noted that rare diseases would be covered by the proposed severity modifier, which more accurately reflects society's values. Although there is of course overlap between severity and rarity, not all rare conditions are severe and some severe conditions are more common. Of course, the consultation was an opportunity for all stakeholders to express their views on this point. As noted previously, NICE is also consulting on changes, such as a more accepting attitude towards uncertainty in some situations, which should benefit medicines for rare diseases.

Where there is uncertain evidence relating to a medical technology—I appreciate this can be a challenge for rare diseases—NICE and NHSE&I have developed managed access agreements. NICE has already recommended six topics for use subject to a managed access agreement outside of cancer. NHSE&I continues to use its sophisticated commercial capabilities to negotiate deals with industry that enable patients to access the most innovative new medicines and ensure that the NHS gets good value.

Proposed new subsection 1(d) would require NICE to have regard to supporting

"the use of curative therapies involving medicines and medical devices."

The word "curative" should be used with caution, as there is no standard definition of what might be meant by it. For example, in some cases it may mean a significant amelioration in symptoms, in others that the treatment pathway is different or more tolerable.

While I appreciate that recently launched advanced therapy medicinal products hold great promise by targeting the specific cell or genetic defect, the data on long-term effectiveness is often immature at the time of marketing approval. Further, we need flexibility to respond quickly and effectively to developments in life sciences. We want to avert a situation whereby an effective therapy is not guaranteed funding because it did not meet the legal definition of a "curative therapy". However, I think that the noble Lord was more trying to get at our support for some of these innovative approaches. Again, this is being looked at in the review of NICE's methods.

NICE's working group has explored whether there is a case for changing the approach to discounting, which the noble Lord asked about, in particular the impact on technologies with long-term benefits such as one-time gene therapies. This is a complex area that needs to take into account the policy-level need to support particular types of technologies or circumstances, the limitations of the current criteria for non-reference case discounting, and the effects and any accompanying policy and affordability challenges of any change. This will be covered by the second stage of the NICE methods review. Again, while we would not want to pre-empt that review, all stakeholders are encouraged to respond to it.

Briefly, proposed new subsection (2) would require the Secretary of State to lay a report and impact assessment before both Houses of Parliament, setting out how NICE has implemented its duty under proposed new subsection (1). As I said in Grand Committee, NICE will publish its revised methods and process manual, including its impact assessment, on its website for all to access, including parliamentarians, once the process has been completed. That is the correct forum.

I will briefly address Amendment 46 in the name of the noble Baroness, Lady Finlay, which touches on similar issues—the importance of access to medical technologies, the future medical devices regulatory regime, and the critical nature of medical device safety. I pay tribute to the noble Baroness's work through her engagement with Ministers and our officials in developing government Amendment 45, which provides greater clarity on the types of activity we would intend to encourage through appropriate regulation. That includes, in respect of medical devices, carrying out research, developing medical devices, or manufacturing and supplying medical devices.

The Government support the agenda for early access to medical devices for NHS patients, as demonstrated through other mechanisms such as the rapid uptake products programme, managed by Accelerated Access Collaborative, and the medtech funding mandate, due to launch in April.

The second stated purpose of the noble Baroness's amendment—to allow monitoring of the safety and efficacy of medical devices in real-time use—is already achieved by regulations that may be made under Clause 15(1)(i) and (j), so the mechanism to deliver this is already in place. In addition, Clause 18 empowers the Secretary of State to make regulations for the establishment of a medical device information system by NHS Digital, which will support the monitoring of patient outcomes and patient safety.

The noble Baroness also asked about the timeframe for future devices regulation made under the Bill. I assure her we will consult on this issue this year.

I hope the reassurances I have provided, here and during Committee, are of comfort to noble Lords and that the noble Lord, Lord Hunt of Kings Heath, feels able to withdraw his amendment.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, I wanted to stimulate a debate on the NICE review and it certainly succeeded, because we had a very high-quality debate. I am very grateful to the Minister for what was a comprehensive and encouraging response, in a number of ways.

I will start with the noble Baroness, Lady Finlay, because she made a powerful speech and argued very convincingly for the speeding up of approval processes, alongside speeding up the introduction to the National Health Service of proven, innovative new medicines and treatments. The noble Baroness, Lady McIntosh, asked about patient safety, but my amendment and, I believe, that of the noble Baroness, Lady Finlay, would do nothing to undermine patient safety. In the first place, the Minister has already tabled an amendment to Clause 1, which we debated on the first day of Report, which gives priority to considerations of patient safety. It is clear from the explanation given for Amendment 46 from the noble Baroness, Lady Finlay, that her proposals for a preliminary licence would allow for monitoring of safety and efficacy in real time. That could be a real bonus indeed.

I thought that the noble Baroness, Lady Masham, asked the fundamental question: why are we so slow to introduce new medicines and devices? Why are we behind so many other developed countries?

The noble Lord, Lord Lansley, gave a very thoughtful contribution. He is absolutely right to argue that we need more support for innovative medicine. The tragedy is this. We have the excellent VPAS agreement whereby, essentially, industry accepts that if the cost of medicines goes above a certain agreed level it will pay a rebate back to the Government, or ideally the National Health Service. If this worked properly the resource going back would be used for innovation, but for reasons that I have never quite understood the money does not seem to go back directly in an identifiable form to the NHS. We have the bizarre situation where, locally, the NHS worries about its drug costs. When it goes above a certain level there is a rebate, but unfortunately that rebate does not seem to find its way back in a tangible, transparent form, to the NHS. We have not created out of the agreement the kind of win-win situation that surely was envisaged when the previous voluntary agreement was first developed.

[Lord Hunt of Kings Heath]

The noble Lord, Lord Lansley, mentioned one of the big issues: the need for NICE and NHS England to work together. I do not get the impression that they do work together that well, because NHS England regards most innovation as costly and therefore tries to dampen it down. I agree with the noble Lord, Lord Lansley: we need a much better partnership where we build in value for innovation and dealing with inequalities—one where NHS England would actually be on board.

The noble Baroness, Lady Jolly, and my noble friend Lady Thornton talked about this being a big-picture debate. Of course, this is not something that can be solved by an amendment to a medicines Bill, but Parliament ought to debate these important issues and, at the very least, raise some issues that the review should undertake to address.

5 pm

The noble Baroness, Lady Penn, gave us a very comprehensive response in relation to the review. I was encouraged by that. I see, from what she was saying, that many of the arguments put forward today by noble Lords will be considered. She also said that NICE has an internationally respected reputation; I agree. This is not so much about NICE's reputation or the quality of its work; it is just that, at the moment, the end product is depriving NHS patients of innovation. That is what we need to turn around.

I am very grateful to noble Lords and I beg leave to withdraw my amendment.

Amendment 66 withdrawn.

The Deputy Speaker (Lord Faulkner of Worcester) (Lab): We now come to the group consisting of Amendment 67. I remind noble Lords that Members other than the mover and the Minister may speak only once and that short questions of elucidation are discouraged. Anyone wishing to press this amendment to a Division must make that clear in the debate.

Amendment 67

Moved by ***Lord Hunt of Kings Heath***

67: After Clause 40, insert the following new Clause—

"Medicines and Medical Devices Redress Agency

The Secretary of State must, by the end of the period of 12 months beginning with the day on which this Act is passed, bring proposals before Parliament to establish a Redress Agency for those harmed by medicines and medical devices."

Lord Hunt of Kings Heath (Lab) [V]: My Lords, I want to come back to the debate on clinical negligence and the recommendation made by the noble Baroness, Lady Cumberlege, in her report for a redress agency. I declare my interest as a member of the GMC board.

We have reached a very serious position, with an exponential rise in clinical negligence costs. Twenty years ago, contingent liability was £3.9 billion; it is now £83 billion. Even allowing for inflation, I hardly think that we have become 20 times more negligent over that period. Indeed, the Minister, Nadine Dorries, told the House of Commons in a Written Answer last November:

"The continued rises in clinical negligence costs are eating into resources available for front-line care".

It is not delivering for patients and their families, either. There are huge delays in getting cases settled and huge lawyers' fees, in a quite remarkable situation where the NHS ends up paying damages in 80% of litigated clinical negligence claims. There is something wrong in the way we deal with these cases.

There have been endless reviews over the past 20 years, but precious little has happened. Seventeen years ago, an NHS redress scheme was unveiled by the then Chief Medical Officer, Sir Liam Donaldson. Legislation followed in 2006 but, 14 years later, it has yet to be implemented—and I doubt it ever will be. Since then, there has been much debate about the sustainability of Section 2(4) of the 1948 Law Reform (Personal Injuries) Act, which essentially promotes increased costs because it provides that

"there shall be disregarded, in determining the reasonableness of any expenses, the possibility of avoiding those expenses or part of them by taking advantage of facilities available under"

the NHS. In other words, the NHS tends to pay twice.

In 2017, the department and the Ministry of Justice commissioned the independent Civil Justice Council to draw up a new claims handling process for clinical negligence claims of up to £25,000, together with proposals for fixed recoverable costs for these cases. The report was published, with recommendations, in October 2019. Since then, there has been silence.

In that context, the noble Baroness, Lady Cumberlege, argued in her report *First Do No Harm* for a redress agency to be set up on an avoidable harm basis, which looks to systematic failings rather than blaming individuals. This, she thought, would encourage reporting and provide faster resolution for claimants. She argued that this

"would provide a standing structure to administer decisions using a non-adversarial process. This model is simple for patients to access as there is one point of contact. This structure enables flexibility to adapt and respond to situations as they arise."

The proposed scheme of the noble Baroness, Lady Cumberlege, is well intentioned and has popular appeal. I recognise that details need to be spelled out in relation to eligibility, qualifying criteria or conditions of entitlement for her proposed redress scheme. Of course, causality is at the heart of any consideration of patient safety remedy. Causation is at the heart of tort. The Vaccine Damage Payments Act 1979 is limited to persons disabled as a result of vaccination. Even the NHS Redress Act 2006, to which have just referred, is concerned with arrangements for redress in relation to liability in tort. The noble Baroness's approach is of course quite different from that.

The noble Baroness the Minister in Committee was not enthusiastic. In the past 48 hours we have heard the Government's response that they have,

"no current plans to establish a redress agency",

as set out in the recommendations of the noble Baroness, Lady Cumberlege. The reply went on to say:

"The government and industry have previously established redress schemes without the need for an additional agency."

Well, that is a rather disappointing dismissal and misses the point, because the noble Baroness was essentially calling for a wholesale reform of the current clinical negligence system. I urge the Minister to reconsider this matter.

Can we really go on with the exponential rise in costs to the NHS—a system in which it loses 80% of cases that reach the courts, and where huge delays take place in patients getting access to an outcome? The system is completely bust. We need a new one and I hope that the Minister will, with his colleagues, consider what action needs to be taken to improve the current situation. I beg to move.

Baroness Cumberlege (Con) [V]: My Lords, I warmly thank the noble Lord, Lord Hunt. His determination is awe-inspiring. I am so pleased that he has not left this issue mouldering on the Committee Floor but has picked it up again.

I understand what the noble Lord said about the Government not being enthusiastic. However, I have known other issues on which the Government have been less than enthusiastic. It is the way in which we put forward persuasive arguments—although setting up this agency will take a lot of work, with a lot of detail to be considered. However, other schemes have been successful. I think about the one in my area—thalidomide. That trust is still running and getting redress for people who need it. So I strongly support the amendment of the noble Lord, Lord Hunt.

In our review, we tried to achieve a very simple and accessible structure for patients through the proposed redress agency. In an update on our recommendations, the Minister in the House of Commons, Nadine Dorries, said that the Department of Health and Social Care had delivered ex-gratia payments with individual schemes without the need for a redress agency. Indeed it has.

There are four or five schemes for infected blood alone, with eligibility based on whether the patient was a haemophiliac with HIV; a haemophiliac with hepatitis C; a non-haemophiliac with HIV; or a non-haemophiliac with hepatitis C. These different schemes addressed what type of payment should be awarded according to the patient's need. What we—I am talking about my team and I—were advocating is a single point of contact for avoidably harmed patients. We felt very strongly that they had suffered enough without the necessity of finding out how to access the schemes that are relevant to them. The noble Lord, Lord Hunt, has said that something is wrong. He is right: it is wrong. This is not the way to help people who have been seriously harmed.

The problem is that, without a redress agency, each ex gratia scheme starts from scratch, which we felt was grossly inefficient. We need a standing administrative structure, funded by contributions from manufacturers and the state—both have a responsibility. At the moment, litigation is the only route, as the noble Lord, Lord Hunt, has said, for injured people to get serious compensation. We know that the process is very damaging to people. They do not like going to court, they do not like having to put forward all the information that is absolutely necessary—and sometimes not so necessary—and they do not like the fact that it is an adversarial system. We felt that the redress agency could remove the need for adversarial litigation that focuses on blaming individual doctors and nurses. The agency would be non-adversarial and would look at the systems failings that led to avoidable harm. This would help develop an open culture in healthcare and facilitate learning—we are not good at that. We know that the same mistakes happen over and again, and we felt that this was another tool to ensure that there would be much less of that.

Gathering information in one place—the agency—would make it so much easier to learn from the data that is collected and would strengthen the ability of the healthcare system to learn from the mistakes made. We have only to look at the cost of litigation of some £83 billion a year—I was very interested in what the noble Lord, Lord Hunt, said. We know that, often, the majority of those costs go to the law firms, not the individuals who have suffered so grievously. We felt that it would be much better if those huge sums of money, which are much needed by the NHS, should be used with a redress agency, which would have other advantages, as I have just outlined. A stand-alone agency, with a single entry point, would be a much better and more cost-effective way to award redress to those who suffer such avoidable harm—and many of them suffer for decades.

Baroness Bennett of Manor Castle (GP) [V]: My Lords, it is again my great pleasure to follow the noble Baroness, Lady Cumberlege, and the noble Lord, Lord Hunt of Kings Heath. I am pleased to attach my name to Amendment 67 in the name of the noble Lord.

I do not think the noble Baroness, Lady Cumberlege, will mind if I explain why I am coming in on Amendments 67 and 68 in particular. It is because I was in a meeting and asked her what her next priority would be after the broad achievement of the patient safety commissioner. She said that the redress agency was in her mind as the next priority, which is why I have chosen to make it a priority in this Bill, in which I have become considerably more involved than I was originally expecting.

Like the noble Lord, Lord Hunt, did, I have to describe the Government's response to the noble Baroness's review as very disappointing. Simply very curtly saying:

> "The Government and industry have previously established redress schemes without the need for an additional agency"

really does not engage with the arguments put by the noble Baroness in her report or reflect the strong support seen in the *British Medical Journal* editorial on 20 August, which expressed growing support for the entire review but particularly for the idea of a redress agency.

5.15 pm

It is worth setting out some of the context for this. On one level, in an ideal society a redress agency would not be necessary, or certainly not needed as urgently as it is now. Anyone suffering from illness or disability, whatever the cause, should be supported, given the resources that they need to live a full life as healthily as possible and given the chance to make a full contribution to society to the absolute top of their human potential. In such a society—with a universal

[Baroness Bennett of Manor Castle]
basic income, adequate funding for health and social care, full access to public transport and access in every building—perhaps we would not need a redress agency in the same way as we do now. There would still be an argument for compensation for avoidable suffering but not, as we are seeing in the case of children who suffer avoidable injury at birth, the need for many millions of pounds to be paid to cover the costs of support through life. However, I hardly need to add, that is not the world that we live in now.

To quote the noble Baroness's report:

"We have heard from individuals who have described how they have struggled to access the benefits that they are entitled to … Benefits assessments are not straightforward and can be daunting and hugely stressful for individuals with complex issues."

One thing that a redress agency might include in the current environment is support to help people to access the benefits that they need for their particular set of circumstances.

As the noble Baroness has said, although I shall put it more strongly than she did, families and patients do not like going to court. I would say that we all know that going to court is immensely stressful, difficult and—I hope the noble and learned Lords in your Lordships' House will forgive me for saying this—sometimes something of a lottery. The result depends on the evidence presented on the day, in the moment, and very often on the quality of the legal representation available to people.

The noble Baroness's report said that

"litigation has not proved useful to the majority of the affected individuals we have heard from."

Again, while I am not aiming to set up a dispute with the noble and learned Lords in the House, there are conditions and circumstances in which a competitive contest is not the best way to achieve a just outcome in a dispute. That is something that has been accepted broadly by society when it comes to divorce. A reparation process is not a combative process but one that seeks to take the time necessary to consider the evidence, ask for clarification and arrive at the right level of compensation and payment. That is not without stress, but there is probably considerably less. Obviously, Windrush shows us that that is not a panacea, but it is certainly better than having to go to court.

I want to make another argument from a broad social perspective. Before I make it, I need to declare my position on the All-Party Parliamentary Group on Legal Aid. We have heavily overstretched courts around the land and heavily overstretched practitioners of legal aid, a service that is increasingly unavailable in many parts of the country. We have to ask why for medical errors we are putting extra weight on the courts when there is a better alternative approach.

I have one final thought. If I cannot win the Government over with arguments about justice—about the fact, as the noble Lord, Lord Hunt, said, that the current system is "completely bust"—then surely there is an argument here for cost effectiveness. The cost of people having to go to court to get redress for medical errors, mistakes and faults is enormous. Surely the cost of a redress agency would be much less.

Lord Lansley (Con) [V]: My Lords, I am very glad to follow the noble Baroness, Lady Bennett of Manor Castle, and prior to her the movers of Amendment 67. I welcome the fact that we have this opportunity to say something about redress. Amendment 68 is to follow in the next group, and I think it important to distinguish between the need to establish a scheme of redress where the NHS or government have been responsible for something which subsequently turns out to have damaged or harmed people, and the need to establish a scheme to provide proper support to those who have been harmed. That has been done on an ex gratia basis but, if the Government sought to do so, I think it would be possible to commence the NHS Redress Act 2006 and to establish such redress schemes under a statutory footing. It is not necessary to pass legislation to make that happen.

Those are different and distinct from the process of recognising that those harmed as a result of clinical negligence or failures in treatment processes should be able to secure a remedy and redress. I say remedy advisedly because often, in my experience of talking to people who have been harmed as a result of clinical negligence—these are often cases involving harm to babies during birth—it is as important to understand what happened, to accept where responsibility lies and to understand that others will not suffer in the same way, as it is to secure redress, compensation and support, which is often support for the child throughout their life. We need to understand that that is what we are talking about, not just the question of compensation.

I am slightly surprised by Amendment 67. I wonder what we think NHS Resolution is, if not an agency within the NHS with responsibility for securing redress for those who have been harmed as a result of clinical negligence. We need to recognise the need for, and I hope the Minister will tell us that the Government have not abandoned thought of, further reform. Certainly, when we were in opposition, we argued during the passage of the NHS Redress Bill that there should be a fact-finding phase. We argued that, rather than having an adversarial process with expert witnesses and all the associated costs, we should have a phase during which a claim is brought and the facts are established on an independent basis. That could lead to arbitration procedures and a settlement, rather than court-based proceedings, and we might escape some of the burden of cost. We should remember that nearly half the total cost of compensation in the clinical negligence process through NHS Resolution is actually legal fees. If we can escape some of that through an independent fact-finding phase, an arbitration process and financial settlements which recognise the support that the NHS and taxpayers give to those who have been harmed and have enduring problems and disabilities as a result, we might escape some of the burden of cost.

As the noble Lord, Lord Hunt, said, the potential contingent liability—not on an annual basis, but in the future—has risen to £83 billion. It is an enormous sum. The amounts paid by way of premiums to NHS Resolution are a significant aspect of the cost of NHS providers. There continues to be a good argument that the Government should consider this area still in need of reform.

Baroness Jolly (LD) [V]: This amendment from the noble Lord, Lord Hunt of Kings Heath, supported by the noble Baronesses, Lady Cumberlege and Lady Bennett, would require the Secretary of State to introduce proposals for a redress agency for those harmed by medicines and medical devices. As the noble Lord, Lord Hunt of Kings Heath, said, the concept of a redress agency for those harmed in such a manner has been around for many years but has not been realised. However, in the light of the Cumberlege report, which has been a great catalyst for innovation, the Government must see that now is the time. This is a really practical and common-sense move that would provide support and relief for patients while also avoiding the need for costly litigation on both sides, saving the NHS a considerable amount of money which could be better spent.

The NHS has a duty to give proper support to those in its care who have been harmed. As the noble Lord, Lord Lansley, said, there needs to be independent fact-finding, leading to a resolution process. He cited the NHS Redress Act 2006. I ask the Minister to reflect on this debate and to speak to his right honourable friend the Secretary of State, perhaps using his charm to persuade him to think again.

One advantage of being at home for this debate, in front of your own computer in your own study, is the opportunity quickly to look online to see how easy it is to find the relevant website. It took me a couple of searches before I came up with NHS Resolution, but it was not hugely helpful or intuitive. Therefore, would the Minister also feed that back to the Secretary of State and the people who manage these schemes?

Lord Bethell (Con): My Lords, the noble Lord, Lord Hunt of Kings Heath, raises matters in Amendment 67 that he raised in Grand Committee. I completely recognise that they are of enormous concern right across the House. One could say that it is the £83 billion question. I know he is an advocate, as indeed are many noble Lords, of the conclusions of the Independent Medicines and Medical Devices Safety Review, led by my noble friend Lady Cumberlege, and I commend him and other former Health Ministers in this place.

In Committee, we had a very helpful, substantial and informative discussion on the concept and merits of a redress agency. I know that the noble Lord indicated that he would return to these matters if it seemed likely that we were unable to give an update on the way in which the department is responding to the review. I understand that he seeks further assurances and I shall attempt to give them.

As I set out in Committee, we are determined to ensure the safety of medicines and devices so that harm is less likely to happen in the first place, and, when things do go wrong, we are committed to fair redress arrangements that work for all. However, for the reasons that I set out in Committee, we do not believe it is necessary to create a new body for the purpose of providing redress for medicines and devices.

First, routes already exist if patients believe they were harmed by medicines or medical devices. They can bring a legal claim in the courts either against the manufacturer on the basis of product liability or against the actions of an NHS provider or clinician.

Secondly, the Government and manufacturers already have the ability to set up redress schemes when necessary, and in fact they have done so already, where appropriate, without ever establishing an additional agency. Setting up an overarching redress agency could become an unnecessary addition to an already complex landscape.

Thirdly, we do not believe that a redress agency in this country would necessarily make products safer or drive the right incentives for industries which are usually directed from a global level. It is a fact of life that any extra costs to firms could impact the attractiveness of the UK as a place to market and manufacture products —something that we are committed to supporting.

The noble Lord, Lord Hunt, asked what, in the absence of wholesale changes, we are doing to improve things. Since its strategy, *Delivering Fair Resolution and Learning From Harm*, was launched in 2017, NHS Resolution has successfully reduced the number of cases going to litigation. In its 2019-20 accounts, it reported that 71% of claims are now resolved without court hearings, which is extremely encouraging.

This has been accompanied by a significant increase in the use of ADR—alternative dispute resolution, referred to by my noble friend Lord Lansley—with over 1,000 mediations undertaken by 31 March 2020, with a success rate of around 80%. This is again encouraging. As a result of the strategies employed on ADR and early resolution, overall time to resolution of cases had reduced since the NAO report by an average of 26 days. The new early notification scheme for obstetric cerebral palsy has ensured that many early admissions of liability and interim payments can be made to families within months. In answer to my noble friend Lord Lansley, we keep the whole arrangement under review and assess options all the time.

5.30 pm

None of this is to say that redress reform is not important. I reassure the House that we continue to explore recommendation 4 on redress schemes for sodium valproate, mesh and HPTs, and further work is being carried out to allow a response to that recommendation. I hope my noble friend Lady Cumberlege takes some reassurance from that.

However, for the reasons set out, and as announced yesterday in the Written Ministerial Statement on the review, we currently have no plans to establish a redress agency. As the noble Lord, Lord Hunt of Kings Heath, is aware, and as the noble Baroness, Lady Bennett, might like to remember, the Government will respond to the issues raised in the amendment, in full, as part of our formal response to the independent medicines and medical devices safety review. I therefore hope the noble Lord has heard enough, so that he is reassured and able to withdraw Amendment 67.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, again, this has been an interesting debate. As was said by the noble Baroness, Lady Cumberlege, there are persuasive arguments to change the current approach to redress and clinical negligence more widely. I agree with the noble Baroness, Lady Bennett, that the Government's response was short and not really sweet.

[Lord Hunt of Kings Heath]

The noble Lord, Lord Lansley, is right to draw a distinction between schemes of redress and wider clinical negligence issues. The noble Baroness, Lady Cumberlege, has a later amendment dealing with specific recommendations on redress for the patient groups that she examined in her report. I took her argument for a redress agency to have much wider implications and considerations. The noble Lord, Lord Lansley, expressed surprise at the wording of my Amendment 67. I simply sought to bring this back, so that we could have a wider discussion, as well as deal with the issues raised around the three patient groups in the noble Baroness's report.

I have never understood why the redress Act was put on the statute book but never implemented. It is clear from talking to experts that it is regarded as flawed, but it is interesting that no Government have picked this up. Equally, we all accept that redress schemes for individual patient groups are an appropriate way forward. However, we are left with a system for clinical negligence that I simply do not believe works.

I heard what the Minister said about improvements for NHS Resolution, but the fundamental argument is that the system is getting more and more expensive—the £80 billion-plus question, as the Minister said. For patients and their relatives, it can be a daunting process, even though, as he said, more can be dealt with prior to going to court. But when the cases do go to court, NHS Resolution tends to lose them. We go back to the size of awards, where the issue, in essence, is that the NHS has to pay twice because of the way that the 1948 legislation was drafted.

At the end of the day, surely we need a thorough review of the whole issue of redress and clinical negligence. I can see that the Government do not yet accept the recommendations of the noble Baroness, Lady Cumberlege. In the end, we have to start with a clean sheet of paper to see if we can do better by patients, the NHS and all the individuals affected. Having said that, I beg leave to withdraw my amendment.

Amendment 67 withdrawn.

The Deputy Speaker (Lord Russell of Liverpool) (CB): We now come to the group consisting of Amendment 68. I remind noble Lords that Members other than the mover and the Minister may speak only once and that short questions of elucidation are discouraged. Anyone wishing to press this amendment to a Division must make that clear in debate.

Amendment 68

Moved by ***Baroness Cumberlege***

68: After Clause 40, insert the following new Clause—

"Redress schemes

The Secretary of State must, by the end of the period of three months beginning with the day on which this Act is passed, bring proposals before Parliament to establish redress schemes for those avoidably harmed by—

(a) hormone pregnancy tests,

(b) sodium valproate, and

(c) pelvic mesh."

Member's explanatory statement

This new Clause would require the Secretary of State to create redress schemes for those who have already suffered avoidable harm related to the medicines and medical devices specified in the new Clause, and would thus implement one of the recommendations made in the report of the Independent Medicines and Medical Devices Safety Review.

Baroness Cumberlege (Con) [V]: My Lords, it is interesting that these two amendments reflect each other, but I wanted them to be separate. The debate that we have had on the agency has been really interesting.

The noble Lord, Lord Hunt, has just talked about a further review of the whole system, which probably needs doing, but I am dealing all the time—through emails, letters and phone calls—with people who are suffering now. Rather than wait for a really good scheme, which I hope a redress agency would be, I feel that we should be compassionate and really understand how people are suffering today. They will suffer tomorrow. They have suffered for decades. It is time that they had some redress to help them in the very difficult and complicated lives that they lead, with huge suffering. It is not just the individual: it is the family and it is the children, especially with sodium valproate. One must think of the home. It is therefore important for society that we as a Government understand and are happy to supply some redress now.

I thank my noble friend Lord O'Shaughnessy, the noble Lord, Lord Hunt, and the noble Baroness, Lady Bennett, who have put their names to this amendment. I look forward very much to hearing what they have to say.

In the two and a half years that we spent travelling the country, listening to tragic stories from women and their families, there was absolutely no doubt in our minds that avoidable harm had been inflicted on those who openly, honestly and with great dignity told us their life stories. I have frequently mentioned what they and their families have told us, but I will spare your Lordships on this occasion because I do not need to reiterate it. Your Lordships know what we found. It is all in our report, *First Do No Harm*, if you want to dig a bit deeper. Hormone pregnancy tests, sodium valproate and surgical mesh are three interventions that have caused avoidable psychological harm in some patients. It is also clear that surgical mesh has caused significant physical harm and that sodium valproate has caused physical and neurodevelopmental harm.

Having listened to these ruined lives, we believe that the state and manufacturers have an ethical responsibility to provide discretionary payments to those who have experienced avoidable damage in these three interventions. Each of them should have its own scheme and tailored eligibility criteria. When we have, as I hope we will, a redress agency, these schemes can be subsumed into the agency.

I make it clear that these payments are not intended to cover the costs of services that are already available free of charge. I am thinking of healthcare and social security payments, and in some cases education for children. This is rather for other needs, which could include things such as travel to medical appointments—we have heard a lot about the costs of that—respite

breaks or emergency payments, when a parent has had to stop working to cover the care needed for that child or members of the family.

Patients have waited far too long for redress, some for decades, and any scheme must be set up promptly, as soon as possible. However, it should be structured so that it can be incorporated into the redress agency in future. Individuals who obtain compensation through litigation or out-of-court settlements—and we have heard of some, particularly from Johnson & Johnson and the Scottish pelvic mesh settlement—will not need recourse to these schemes. It is over and above what is already supplied by the state or is totally inadequate. So we are not setting a precedent: ex gratia payments have made by the Government to those suffering from infected blood, for example, as I mentioned in the last debate, as well as variant CJD and other areas, where treatments have caused avoidable damage.

In responding to the report's recommendations, the Patient Safety Minister, Nadine Dorries, said that our recommendation that these schemes should be established is still under consideration. I am very heartened by her words, which give me—and, much more importantly, those who are suffering—cause for hope that the Government will do the right thing.

I ask my compassionate and noble friend the Minister if he could give us more information on this. If it has not been ruled out of court, can he tell us what plans are made to ensure that these schemes become a reality, and very soon, because they are much needed? I beg to move.

Baroness Bennett of Manor Castle (GP) [V]: My Lords, I shall be brief, since I am following the powerful case put by the noble Baroness, Lady Cumberlege, for Amendment 68, to which I am pleased to attach my name, along with the noble Lords, Lord O'Shaughnessy and Lord Hunt. This is not a lesser amendment than Amendment 67 but a more limited one. As the noble Baroness said, agreeing Amendment 68 would not stop Amendment 67 from happening in future. The scheme for each individual could be rolled into a broader redress agency. I join her in welcoming the initial response to her report from the Government, which says that proposals such as that in Amendment 68 remain under consideration.

The case has been made—and I am not sure that I am allowed to do this post Brexit, but I note that in France the Government already pay into a fund for valproate damage. There are other cases around the world which reflect what already happens in other instances of medical disasters that have been acknowledged.

I commend the amendment to your Lordships' House. I do not think that we will be pressing it to a vote tonight, but I hope that the consideration that the Government continue to give will turn into action very soon.

5.45 pm

Lord O'Shaughnessy (Con) [V]: My Lords, it is a privilege to be able to support and put my name to the amendment in the name of my noble friend Lady Cumberlege. As has so often been the case in this Bill, where she leads, others follow, and I entirely endorse everything that she and the noble Baroness, Lady Bennett, have said. My reason for supporting the amendment is simple: as my noble friend made clear today, there are tens of thousands of women, men and their families who are suffering from the impact of licensed medicines and medical devices that have been wrongly used.

My noble friend's landmark review gives voice to so many people who have been ignored for too long; that is what gives it such moral power and makes the force of its arguments so irresistible. Within the final report of her review is a clear recommendation for ex gratia redress schemes to be established for those affected by the HPT, mesh and valproate scandals. To my mind, this recommendation is neither radical nor extraordinary: such schemes have been set up in the past—for the victims of thalidomide and contaminated blood. Indeed, this is a common-sense proposal, and it is urgent—because the suffering of so many continues to this day, as my noble friend pointed out.

I have spoken in the past of two women—Janet Williams and Emma Murphy—whose lives, and whose children's lives, have been changed for ever by in utero exposure to sodium valproate. They were interviewed as part of a recent Channel 4 documentary on the challenges they face in day-to-day life, the guilt they have been made to feel and their struggle to be heard. Janet and Emma's honesty and tenacity have been an inspiration to me since I met them, and I defy anyone to watch that programme and not be moved to tears.

I was also contacted recently by another lady, who has been harmed by mesh. Her name is Susan Morgan, and, with her permission, I convey her story. She described to me being on,

"a hideous journey that was thrust upon me without consent",

suffering grievous, painful and irreparable damage due to a mesh that can now never be removed. Sadly, she has lost nearly everything in dealing with the consequences of this terrible, avoidable injury, and she asks only that

"the burden of fear and worry be removed so that I can find some peace".

Therefore, I ask my noble friend the Minister: are the redress schemes proposed in the review of the noble Baroness, Lady Cumberlege, under serious consideration, as my honourable friend Nadine Dorries said in the other place earlier this week? I hope so. If so, when will they be introduced? Only a robust answer will be enough to satisfy those supporting this amendment. I close by imploring my noble friend to move quickly: these victims cannot wait any longer—their pain is real, and their need is urgent. Of course, a redress scheme will not change or right every wrong that has been done to Susan, Janet, Emma and thousands like them, but perhaps it might bring them some peace.

Baroness Jolly (LD) [V]: Amendment 68, in the name of the noble Baroness, Lady Cumberlege, requires the Secretary of State

"to create redress schemes for those who have already suffered avoidable harm"

related to hormone pregnancy tests, sodium valproate and pelvic mesh. The Minister has told us that there will be no redress agency. The noble Lord spoke passionately about suffering without redress. A significant

[Baroness Jolly]
amount will need to be paid through NHS Resolution to the women affected by these three interventions. Who will ensure that the women affected receive proper recompense? As the noble Baroness, Lady Cumberlege, has said, they have had to pay out for travel for treatment and payment for carers, and they are seriously out of pocket for what they originally thought was standard, straightforward NHS treatment.

I fear that, if there is no scheme, the NHS will have to pay more than it would through a properly managed redress scheme. This and the previous amendment are powerful signals to the Government that they must act on this issue of redress. I hope that, in summing up, the Minister will be able to share the Government's plans with us. If they have no plans, what would he suggest that these women should do? The noble Lord, Lord O'Shaughnessy, put the case very powerfully.

Lord Hunt of Kings Heath (Lab) [V]: I very much agree with the noble Baroness, Lady Jolly, that this afternoon we have given a powerful signal to the Government. Certainly, from these Benches, we very much support her amendment and her efforts to get redress for people who were grievously damaged by procedures undertaken in the National Health Service.

The noble Lord, Lord O'Shaughnessy, talked about one woman's experience of the impact of surgical mesh, and the huge pain and damage inflicted. I was very grateful to him when I had a Question on surgical mesh, which he answered, as watching it from the Gallery were a group of women from Sling the Mesh, who I had brought in. He gave a lot of time to them afterwards; perhaps it paved the way to the inquiry established under the chairmanship of the noble Baroness, Lady Cumberlege. Like him, meeting those women and talking to them about what they had suffered made me absolutely determined to do anything I could to raise the issue.

We were very fortunate that the noble Baroness, Lady Cumberlege, accepted the chairmanship of this inquiry, given the quality of her team and the extraordinary lengths to which she went to produce its very fine report. Anyone who has met the people involved and listened to the suffering that they have undertaken is left with a feeling that it is awful. Something must be done for them and I very much hope that the Minister will be sympathetic.

Lord Bethell (Con): My Lords, what a moving and heartrending set of speeches on a very important amendment, which I take extremely seriously. It raises the issue of establishing a specific redress scheme for those medicines and medical devices considered by the review: sodium valproate, the use of pelvic mesh and hormone pregnancy tests. The stories in the review, which have been told here this afternoon, are extremely moving on every single level. I cannot but pay testimony to those who have conducted the campaign and given evidence about their own personal suffering—and who, quite reasonably, look for some form of redress.

I completely understand why my noble friend Lady Cumberlege has raised this issue and why she and other noble Lords have asked for progress on her review. I also completely understand the importance that she and her team attach to this recommendation. They rightly spent considerable time drawing on a wide range of complex evidence before reaching their recommendations. The Government feel it is only right that we also give that incredibly helpful report our full consideration before responding to its recommendations. I remind noble Lords about the timeline for a response to these kinds of reviews, which we have gone over before. I think we are well within the normal response time for such reviews, Covid notwithstanding.

In order to determine whether redress schemes should be established, the Government have a duty to ensure that the final decision is fair for patients and for citizens more generally—not just the patients and citizens affected by the three treatments that my noble friend Lady Cumberlege alluded to, but all citizens and patients; you cannot favour someone over another. This requires extremely careful consideration of any proposed scheme but also the precedent that any decision sets for future policy-making. We spoke in the previous debate about the £83 billion problem. That kind of financial impact has a profound bearing on this kind of discussion.

My noble friend Lady Cumberlege asked when the Government will respond to her review. The Written Ministerial Statement of 11 January sets out the Government's interim response. I emphasise to anyone who may be confused that it is just an interim response to the report of the IMMDS review. We currently plan to respond to the report later this year; that is a commitment made by my honourable friend Nadine Dorries, the Minister in the other place. The report took over two years to compile and we therefore consider it absolutely vital for the sake of patients, especially those who have suffered greatly, to give this recommendation the full consideration it deserves.

The noble Baroness, Lady Bennett, asked why the Government have established redress schemes in the past but are unwilling to commit to the schemes proposed in this amendment. I think that one is too early to call. It is right and proper for the Government to carefully consider proposals for redress schemes on their own merits to ensure a fair outcome for patients, and citizens more generally.

The noble Lord, Lord Hunt, asked why it is taking so long to consider the recommendations. The report took over two years to compile, so we need to consider it very carefully. I do not want to use the Covid pandemic as a catch-all excuse, but the reality is that our hospitals are overwhelmed; the Department of Health has doubled in size in the last six months and even with that it is overworked and overstretched. The resources and capacity to respond to this kind of report are, I am afraid, distracted on other matters of national health crisis. However, I reassure the noble Baroness, Lady Cumberlege, and other noble Lords who have spoken that work is under way and we will set out the Government's response to this report later this year.

I could not help but be enormously moved by the testimony of the noble Lord, Lord O'Shaughnessy. In essence, he asked why the Government do not recognise that the patients highlighted in the report of the medicines and medical devices review suffered unavoidable

harm, particularly those who took hormone pregnancy tests. The Government absolutely do regard their suffering most seriously indeed and are considering the contents of the report. I am restricted in what I can see regarding hormone pregnancy tests in particular, given the live litigation, but I want to make clear the Government's position regarding a causal association between HPTs and adverse outcomes in pregnancy. The scientific evidence has been reviewed on a number of occasions, most notably by the Commission on Human Medicines expert working group on HPTs, which, as noble Lords will know, reporting its findings in November 2017. The EWG concluded that the scientific evidence did not support a causal association and that remains the Government's position.

Just as Covid-19 impacted the publication of the report, it has also had an impact on the timing of our response. I know, and recognise, that that is enormously frustrating. The Government are committed to responding and I assure the noble Baroness, Lady Cumberlege, that work is under way. Our upcoming full response will address recommendation number four. We are moved by the stories; I am totally and utterly sympathetic to the situation that the patients affected by these conditions find themselves in on a day-to-day basis. They are still living through it today. I would like to regard myself as a compassionate person, but it is not appropriate to make policy on this kind of matter through primary legislation. For that reason, I ask my noble friend to withdraw her amendment and await the Government's full response to her report.

Baroness Cumberlege (Con) [V]: My Lords, I am so grateful to noble Lords who have taken part in this debate. It has been quite short, but it is very important. As the noble Baroness, Lady Bennett, said in the previous debate on the agency, she has been involved with this Bill in a way that she did not anticipate. She has been such a stalwart, coming to my rescue on occasions, and supporting so much of what has been in the Bill from other sources. I thank her for all of that. The noble Lord, Lord O'Shaughnessy, made a powerful speech about the individuals he has met. We know Susan Morgan well; we have worked with Janet and Emma and many others who have led their own organisations. We think of patient groups as being a few people who got together—when we did not have lockdown—to have coffee and just discuss life generally. That is not the case.

One of the groups I know has 8,500 members—from all over the world, in fact. Other groups have an equal number of members, or numbers of that order. So these are important organisations. They know what it is to have real research. They come up with not just experiences; they beaver away at all our institutions, they look at what they are producing and they challenge. They are so valuable. In the way they work, when they are people who are in considerable pain—very often, they have complicated and difficult lives, having to deal with constant pain—they are thinking of others all the time. That really is so uplifting.

6 pm

I thank the noble Lord, Lord Hunt, so much for, again, a very interesting debate and for talking about the powerful signal that the Government should have got from the debate. I was very interested in his full and comprehensive points on the agency. Eventually, the two will be linked, I think, but at the moment, here and now, we should be ameliorating the terrible difficulties that these damaged people must endure.

I say this to my noble friend Lord Bethell: this Bill has actually been quite extraordinary, in a way. I congratulate him on the way in which he has dealt with it and on the number of amendments that he has put forward. I know that they often need a lot of negotiating, not only with the department but beyond it as well. I thank him for that, for listening to us, for his patience, for his consideration, for his views and for the work that he has to carry out, which we do not always see. He is also right to mention coronavirus. Many times, I have put the House of Lords on on the television and seen the noble Lord again at the Dispatch Box. It is not just about his compassion; it is about the resilience that he has had to have to carry out his duty. I thank him very much for that.

Finally, I would like to hear some dates. I have run a company. I know what it is like when you have to deliver. You have to deliver; otherwise, you go out of business. You have serious competition—you have to keep your eye on them—but you absolutely must meet deadlines. A bit of that rigour in government would be very welcome. There are tremendous tragedies that have to be dealt with, of course. There are huge concerns, especially with the virus. I understand that. I accept that having to make decisions on all sorts of very difficult issues takes a huge amount of energy and thought. However, as I said earlier, in this case, these people have been suffering for decades. It is time that they got justice. A bit of justice in terms of ameliorating the terrible suffering that they endure through some finance would be terribly important, especially for us as a Government to show that we are not only resilient but compassionate. It is time that we did that.

I thank noble Lords for this debate and beg leave to withdraw the amendment.

Amendment 68 withdrawn.

The Deputy Speaker (Baroness Barker) (LD): My Lords, we now come to the group beginning with Amendment 69. I remind noble Lords that Members other than the mover and the Minister may speak only once and that short questions of elucidation are discouraged. Anyone wishing to press this or anything else in this group to a Division must make that clear in debate.

Amendment 69

Moved by ***Baroness Wheeler***

69: After Clause 40, insert the following new Clause—

"Northern Ireland and regulatory divergence

(1) The Secretary of State must make an annual report to Parliament on areas of regulatory divergence between Northern Ireland and the rest of the United Kingdom in matters covered by this Act.

(2) Where the Secretary of State has identified areas of potential regulatory divergence between Northern Ireland and the rest of the United Kingdom, the Secretary of State must set out plans to mitigate the adverse effects of such divergence in the annual report."

Member's explanatory statement

This new Clause would require the Secretary of State to report on regulatory divergence between Northern Ireland and the rest of the UK.

Baroness Wheeler (Lab): My Lords, I am moving the amendment in the name of my noble friend Lady Thornton, which revisits the issue of regulatory divergence between Northern Ireland and the rest of the UK in matters covered by the Bill, and the need for an annual report to Parliament on this matter. The amendment also places an obligation on the Secretary of State specifically to report on plans to mitigate its adverse effects.

The Government will know that there is huge concern on this issue, strongly reflected in our Committee debates through our amendment and an amendment from the noble Lord, Lord Patel, calling for an annual report. The issue was also raised in consideration of the medicines and medical devices statutory instruments before Christmas and in the deliberations on the Northern Ireland protocol and the Trade Bill.

However, I welcome the Government's amendments in this group to Clause 44, which extend reporting obligations to apply in respect of regulations made by a Northern Ireland department and to regulations under Clause 18 on the health and social care information systems. In particular, Amendment 85 specifies a Northern Ireland department and the Northern Ireland Assembly as an appropriate legislature and relevant authority in relation to regulations made under the Act.

We also welcome the Government's acceptance of the arguments put forward by noble Lords and the Delegated Powers and Regulatory Reform Committee on the need for parliamentary scrutiny before and after delegated powers are exercised, and the introduction of a two-yearly reporting requirement in large parts of the Bill. I note that government briefings commit to the reports containing a summary of how the regulations have operated over the period under consideration, including any concerns from stakeholders and the Secretary of State's response, as well as outlining plans for further changes.

I am speaking also on Amendment 78, in the name of my noble friend Lady Thornton, supported by the noble Baroness, Lady Jolly, which in Committee we submitted for inclusion in the provisions under the previous Clause 41 on consultation but which now amends the reporting requirements in Clause 44. Our amendment specifies cohorts that must be consulted in preparation of a report to Parliament, including patients and their representatives, and other key industry stakeholders from healthcare, pharmaceuticals, veterinary and medical research organisations, and healthcare providers and regulators.

Once again, we come back to the importance of ensuring that patients and end users are part of and involved in consultation and reporting relating to existing and potential new medicines, veterinary medicines and medical devices. The stark lessons from the Cumberlege review, the Ockenden review and many other reviews that we have had are that patients' voices must be heard.

For the record, we feel that the Government's reporting requirements amendment falls short of providing the reassurances that we sought in Committee, because the relevant authority still has ultimate discretion over whom it consults. This could mean that any report could be skewed or biased by those chosen at the discretion of the Government. That is why our Amendment 78 details the key stakeholders that should be consulted.

In response to that amendment, I am sure that the Minister will come back to the often stock response to the inclusion of specific stakeholders in the Bill, namely that this would be too rigid and burdensome, and would inadvertently rule out contributions from those accidentally not listed. However, in the context of a very complex Bill and the history of often poor communications with stakeholders, I urge the Minister, if she is not happy with our list, to consider a broader amendment at Third Reading that would provide the reassurance that is clearly needed.

I come back to the key issue of regulatory divergence between Northern Ireland and the UK and reporting on this matter. Marketing, authorisation and trading processes on medicines and medical devices between Northern Ireland, the EU and the UK are complex issues, and many remain unclear. The Northern Ireland protocol and the provision for ongoing discussions to resolve key issues mean continued uncertainty for businesses, health services and patients. In this context, an annual rather than a two-yearly report to Parliament would have been more appropriate, particularly highlighting the problems arising from regulatory divergence, and the plans and progress on addressing them.

This is not the time or occasion to go into detail on the issues covered in Committee. However, in Committee the noble Lord, Lord Patel, highlighted many key matters and concerns arising from the MHRA's guidance on regulating medical devices from 1 January 2021, issued in September 2020, before Committee. I know that the MHRA has been pretty busy of late with the vital Covid-19 vaccination authorisation, but can the Minister tell us when it is envisaged that the MHRA guidance will be updated and reissued?

We have sought and been given reassurances from the Minister that the MHRA's staffing, resourcing and capacity have been substantially increased to meet its new obligations. It is a much-respected body, but, as we have said, it faces huge challenges under its new role, and we suspect that the £13 million additional funding provided to it by the Government up to the end of March 2021 will be just a pump-priming starter in the light of all that needs to be done. The Minister's reassurances over the MHRA's strategic development plans and the Government's commitment to further funding are welcome, but this is something that we will need to keep a close watch on. I beg to move.

Lord Patel (CB) [V]: My Lords, from the outset it has been clear that there was a potential for regulatory divergence in Northern Ireland from the rest of the UK for medicines and veterinary medicines, since they are referred to separately in the Bill as reserved matters in Northern Ireland. However, it has been made clear in the last quarter of 2020 that interaction with the Northern Ireland protocol makes that divergence inevitable for medical devices as well.

Guidance published by the MHRA in October, which I referred to previously, and statutory instruments laid before Parliament in the final months of 2020, set out two different systems of market authorisation and registration, among other issues, and distinguished between the Northern Ireland and Great Britain markets for medical devices and medicines alike. The Northern Ireland protocol requires that EU regulations relating to medicines, veterinary medicines and medical devices apply to Northern Ireland, while CE marks will cease to be recognised in the Great Britain market from July 2023 unless the products in question are from manufacturers based in Northern Ireland.

There are essentially two paths for manufacturers based in Northern Ireland to bring a medical device product into the Great Britain and Northern Ireland markets. The first is to go through UK-based approved bodies for their assessment and market authorisation, which will be approved for both the Great Britain and Northern Ireland markets but will not be recognised in the EU. The second is to submit an application to approved or notified bodies in the EEA to gain a CE mark and thus access to the markets of Great Britain, Northern Ireland and the EU without further needing to apply to a UK body for approvals for the Great Britain market.

By contrast, manufacturers based in Great Britain will need approval from UK-based bodies to place their products on the market in Great Britain and Northern Ireland, but will need to undertake the separate task of setting up an EU-based responsible person and apply separately for a CE mark in the EU. It appears that the recognition of a CE mark on a medicine or device coming from Northern Ireland provides easier access for Northern Ireland-based manufacturers to both the UK and EU markets. What is not clear is the extent to which this dual system between Northern Ireland and the rest of the UK will diverge in substance.

For these reasons and many others, the Government should clarify the position. The amendment would provide greater transparency on potential regulatory divergence, with a commitment to mitigate it where possible. Of course, I will not be surprised if the Minister does not accept the amendment, and neither do I think the noble Baroness will divide the House on it, but whether we agree with it or not, I hope the Minister will agree that somebody has to have some way to recognise what this divergence will do. Who will that be? Would she agree that this will be needed in due course?

6.15 pm

Lord Hunt of Kings Heath (Lab) [V]: My Lords, it is a great pleasure to follow the noble Lord, Lord Patel.

What does one say to the people of Northern Ireland? They voted to remain in the EU, their vote was ignored by the DUP, and they have been duped by the Government, who continue to deny that there is a border in the North Sea—when today we are debating ample evidence of such a border. As the noble Lord, Lord Patel, identified, the distinction the MHRA is now having to make between the EU market, the British market and the market for Northern Ireland, as well as the bureaucracy involved and the cost for British-based companies, is undeniable.

These two very modest amendments seek to ensure that Parliament gets a regular report on how this is working in relation to medicines and medical devices regulations, and that various bodies should be consulted. However, over and above that, the Minister owes the House some explanation of how we have ended up in this bizarre situation, where Northern Ireland, which wanted to be in the EU and wanted to be listened to, has ended up in this rather parallel existence, with a border down the North Sea, food shortages in its supermarkets, and in a right mess. I hope the Minister can answer that.

Baroness Jolly (LD) [V]: My Lords, the amendments in this group relate to reporting requirements and consultation. The noble Lord, Lord Hunt of Kings Heath, has just put the political case very clearly; the noble Lord, Lord Patel, looked at the technical and regulatory issues; I will look at the practical issues around health services on the island of Ireland.

Amendment 69 from the noble Baroness, Lady Thornton, would require the Secretary of State to report on regulatory divergence between Northern Ireland and the rest of the UK. Can the Minister tell us when the first report would be published, whether the Republic would be part of this consultation, and if not, why not? The noble Baroness, Lady Thornton, and I tabled this amendment to require the relevant authority to consult with patients and healthcare and industry stakeholders when preparing a report under Clause 44.

Divergence is inevitable. The situation for healthcare on the island of Ireland could become extremely complicated. In the past, patients have travelled north or south to receive treatment wherever the appropriate treatment is available. Will citizens from Northern Ireland and the Republic have to use the new GHIC, or do the Government have an agreement with the Republic so that business as usual will be the new norm—no change?

Government Amendments 75 to 77 and 79 to 85 extend the reporting requirements under Clause 44 so that they apply to regulations made by a Northern Ireland department and in respect of regulations under Clause 18. However, we cannot ignore the Republic when we talk about health in Ireland.

Baroness Penn (Con): My Lords, we now turn to the way in which reports are prepared and made on the exercise of the regulatory-making powers in the Bill.

Amendment 69 in the name of the noble Baroness, Lady Thornton, would make changes to the existing requirement to report, introduced in Grand Committee. It proposes that an additional report be made by the Secretary of State to Parliament, this time on regulatory divergence with Northern Ireland introduced as a consequence of future regulations. I understand the noble Baroness's intent. I heard the concerns raised in Grand Committee about the potential impact of regulatory divergence. The Government take that seriously. However, I will explain why this amendment is not necessary to address it.

As a reminder, the amendments made in Grand Committee provided for a reporting obligation on the operation of regulations made by the Secretary of

[Baroness Penn]

State under Clauses 1(1), 9(1) and 14(1)—one that was both forward- and backward-looking. Those reports must include any concerns raised or proposals for change made by anyone consulted by the Secretary of State in the preparation of the report, and the response to these. It will necessarily draw Parliament's attention to regulations that have been made.

Parts 1 and 2 of the Bill relating to human and veterinary medicines are matters transferred to Northern Ireland. As such, legislative consent was secured for the Bill earlier in its passage, but as amendments were made during Grand Committee, further legislative consent was sought. At Northern Ireland's request, government Amendments 75, 76, 79, 80, 81, 82 and 85 in this group replicate the existing reporting obligation for Northern Ireland. This means there will be a report laid in Parliament every two years on what new regulations have been made and any plans to make further related regulations. A separate report will be laid before Northern Ireland. Between our report and the report laid before the Northern Ireland Assembly, any areas of regulatory divergence between the UK and Northern Ireland regulatory regimes will be made clear. Therefore, it would be duplicative to require the Secretary of State to lay additional reports specifically on regulatory divergence for human and veterinary medicines and medical devices.

In addition, where there are concerns about the implementation of the protocol and its impact on patients and animals in Northern Ireland, there are formal channels in place. Officials meet regularly in the Ireland/Northern Ireland Specialised Committee. The Specialised Committee reports to the Withdrawal Agreement Joint Committee and provides advice on decisions to be taken by the Joint Committee under the protocol.

Before the end of the transition period, we raised with the EU through its specialised committee the issue of the falsified medicines directive and regulatory importation requirements for medicines moving from Great Britain to Northern Ireland after 1 January. We agreed with the EU a pragmatic one-year, time-limited approach to implementing these regulations that ensures no disruption to the flow of medicines to Northern Ireland. I say this to reassure noble Lords as to the effectiveness of those mechanisms under the protocol.

Noble Lords made a number of comments on the issue of regulatory divergence and I thought I would dwell on it briefly. The noble Lord, Lord Patel, gave a good description of future provisions regulating devices between Northern Ireland and Great Britain. He is wrong to say that the Bill lays out Northern Ireland separately because of this. It does so because medicines and veterinary medicines in Northern Ireland are the responsibility of the Northern Ireland Assembly and are therefore devolved. However, divergence may be an issue for the future, not least because the EU may change its own regulatory regime under the protocol that Northern Ireland will follow, and the UK may make changes here as well.

To reassure noble Lords, we have agreed a standstill period of two years for medicines and veterinary medicines and two and a half years for devices, during which we will continue to recognise EU regulations in these areas. This means that there is time for adequate consultation on regulations made under this Bill, for consultation on any future changes and for these mechanisms to operate properly. Divergence may be a matter for the future, but we have reporting to Parliament and public consultations on any regulations made under this Bill to address those questions.

The noble Lord, Lord Hunt, asked how we ended up here. I think that question is slightly wider than the purview of this Bill. I have quite a lot of lived experience of how we ended up here and I do not intend to recount that now.

I hope the amendments I have referred to in the name of my noble friend Lord Bethell, coupled with these other, existing arrangements, make the amendment tabled by the noble Baroness unnecessary.

Government Amendments 77, 83 and 84, also in the name of my noble friend, are made in the same light of expanding reporting obligations. In the interests of transparency and scrutiny, amendments have been made to extend the obligation to include regulations made under Clause 18—the regulation-making power in relation to the medical devices information system. We have made this change to make clear our absolute commitment to transparency, to giving Parliament continued visibility, to understanding the assessment made of any proposals or concerns raised as to how the regulations have been working, and to ensure that the regulation-making powers specifically containing provisions that may ensure or affect device safety and post-market surveillance are treated equally.

The noble Baroness, Lady Thornton, again seeks to test us on the preparation of the reports with Amendment 78, which would add a list of stakeholders to be consulted under the obligation. Again, this is unnecessary. If her concern is that the stakeholders listed may be ignored, I reassure her that the reports must summarise concerns raised, or proposals for change made, in relation to regulations enforced during the reporting period. That information will come from engagement with relevant stakeholders. Therefore, I do not think it necessary or proportionate to add a list of specific stakeholders to be consulted for each report, which will be a summary of public consultation that will already have been responded to.

I must say to the noble Baronesses, Lady Jolly and Lady Wheeler, that the Government will not return to this issue at Third Reading, so if they wish to press it, now is the moment. However, with the number of avenues already available, I hope that they are reassured that their amendment is not needed and will not wish to press it.

Baroness Wheeler (Lab): I thank the Minister for her response. I shall not go into details now, but we know that there will be significant issues of regulatory divergence, as the noble Lord, Lord Patel, my noble friend Lord Hunt and the noble Baroness, Lady Jolly, have stressed. We know that it is an issue about which we will have to be very watchful. In the circumstances we currently face, an annual report would have aided the process of working through the issues and encouraged understanding of the plans to address them and the progress being made.

On Amendment 78, the Minister is obviously not going to oblige me with a tidying-up amendment at Third Reading to underline the importance of the patient voice. I think that is a mistake; it would have been helpful. However, I beg leave to withdraw Amendment 69.

Amendment 69 withdrawn.

Clause 41: Power to make consequential etc provision

Amendments 70 and 71
Moved by ***Lord Bethell***

70: Clause 41, page 25, line 43, at end insert—

"(1) This section applies to regulations under a power in Part A1, 1, 2 or 3, apart from regulations under paragraph 9 of Schedule 1."

Member's explanatory statement

This amendment is consequential on the Minister's amendments to insert a new Part before Part 1 and a new Clause after Clause 18, and would enable regulations under powers in those provisions to make consequential and other connected provision.

71: Clause 41, page 25, line 44, leave out "Regulations under sections 1(1), 9(1), 14(1) and 18(1)" and insert "The regulations"

Member's explanatory statement

See the explanatory statement for the other amendment to Clause 41 in the Minister's name.

Amendments 70 and 71 agreed.

Clause 43: Consultation

Amendments 72 to 74
Moved by ***Lord Bethell***

72: Clause 43, page 26, line 13, after "Part" insert "A1,"

Member's explanatory statement

This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety. It requires the Secretary of State to carry out a public consultation before making regulations about the Commissioner.

73: Clause 43, page 26, line 22, leave out "1(2) and (3), 9(2) and (3) or 14(2) and (3)" and insert "1, 9 or 14"

Member's explanatory statement

This amendment would require a consultation in relation to regulations under Clause 1, 9 or 14 to include a summary of the assessment of the person making the regulations of all matters mentioned in Clause 1, 9 or 14 (as the case may be), including new subsections (3A), (3A) and (4) inserted by amendments in the Minister's name into Clauses 1, 9 and 14 respectively (overall assessment of risk-benefit analysis).

74: Clause 43, page 26, line 39, leave out from "to" to ", the" on line 40 and insert "any other regulations"

Member's explanatory statement

This amendment provides for the definition of "relevant authority" to apply in relation to regulations under new Part A1 (the Commissioner for Patient Safety) and the new Clause tabled in the Minister's name to appear after Clause 18 (advisory committee), as well as in relation to other regulations under Part 1, 2 or 3.

Amendments 72 to 74 agreed.

Clause 44: Reporting requirements

Amendments 75 to 77
Moved by ***Lord Bethell***

75: Clause 44, page 26, line 43, leave out "Secretary of State must lay before Parliament" and insert "relevant authority must lay before the appropriate legislature"

Member's explanatory statement

This amendment and the other amendments to Clause 44 in the Minister's name extend reporting obligations under Clause 44 so they apply in respect of regulations made by a Northern Ireland department and in respect of regulations under Clause 18.

76: Clause 44, page 27, line 1, leave out "Secretary of State" and insert "relevant authority"

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

77: Clause 44, page 27, line 1, leave out "and 14(1)" and insert ", 14(1) and 18(1)"

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Amendments 75 to 77 agreed.

Amendment 78 not moved.

Amendments 79 to 85
Moved by ***Lord Bethell***

79: Clause 44, page 27, line 3, leave out "Secretary of State" and insert "relevant authority"

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

80: Clause 44, page 27, line 4, leave out "Secretary of State" and insert "relevant authority"

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

81: Clause 44, page 27, line 8, leave out "Secretary of State's" and insert "relevant authority's"

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

82: Clause 44, page 27, line 9, leave out "Secretary of State" and insert "relevant authority"

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

83: Clause 44, page 27, line 10, leave out "or 14(1)" and insert ", 14(1) or 18(1)"

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

84: Clause 44, page 27, line 13, leave out "or 14(1)" and insert ", 14(1) or 18(1)"

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

85: Clause 44, page 27, line 14, at end insert—

"(5) In this section—

"appropriate legislature" means—

(a) in relation to a report of the Secretary of State, Parliament;

(b) in relation to a report of a Northern Ireland department, the Northern Ireland Assembly;

"relevant authority" means—

(a) in relation to regulations made under section 1(1) or 9(1) by the Secretary of State (whether acting alone or jointly with a Northern Ireland department), the Secretary of State;

(b) in relation to regulations made under section 1(1) or 9(1) by a Northern Ireland department (whether acting alone or jointly with the Secretary of State), the Northern Ireland department;

(c) in relation to regulations made under section 14(1) or 18(1), the Secretary of State."

Member's explanatory statement

See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Amendments 79 to 85 agreed.

Clause 45: Procedure

Amendments 86 and 87

Moved by ***Lord Bethell***

86: Clause 45, page 27, line 16, after "Part" insert "A1,"

Member's explanatory statement

This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety.

87: Clause 45, page 27, line 24, after "Part" insert "A1,"

Member's explanatory statement

This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety.

Amendments 86 and 87 agreed.

Amendments 88 to 90

Moved by ***Baroness Jolly***

88: Clause 45, page 27, line 39, column 2, leave out paragraph (b)

89: Clause 45, page 28, line 10, column 2, leave out paragraph (b)

90: Clause 45, page 28, leave out line 12

Amendments 88 to 90 agreed.

Amendment 91

Moved by ***Lord Bethell***

91: Clause 45, page 28, line 12, after "Part" insert "A1,"

Member's explanatory statement

This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety. It provides for regulations about the Commissioner to be subject to the draft affirmative procedure.

Amendment 91 agreed.

Amendments 92 and 93

Moved by ***Baroness Jolly***

92: After Clause 45, insert the following new Clause—

"Super-affirmative procedure

(1) For the purposes of section 1(1), section 9(1), section 14(1) and section 18(1), the "super-affirmative procedure" is as follows.

(2) The Secretary of State must lay before Parliament—

(a) a draft of the regulations, and

(b) a document which explains the draft regulations.

(3) Where a draft of the regulations is laid before Parliament under subsection (2), no statutory instrument containing the regulations is to be laid before Parliament until after the expiry of the 30-day period.

(4) The Secretary of State must request a committee of either House whose remit includes health, science or technology to report on the draft regulations within the 30-day period.

(5) In preparing a draft statutory instrument containing the regulations, the Secretary of State must take account of—

(a) any representations,

(b) any resolution of either House of Parliament, and

(c) any recommendations of a committee under subsection (4), made within the 30-day period with regard to the draft regulations.

(6) If, after the 30-day period, the Secretary of State wishes to make regulations in the terms of the draft or a revised draft, he or she must lay before Parliament a statement—

(a) stating whether any representations, resolutions or recommendations were made under subsection (5);

(b) giving details of any representations, resolutions or recommendations so made; and

(c) explaining any changes made in any revised draft of the regulations.

(7) The Secretary of State may make a statutory instrument containing the regulations (whether or not revised) if, after the laying of the statement required under subsection (6), a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

(8) In this section, reference to "the 30-day period" in relation to any draft regulations is to the period of 30 days beginning with the day on which the original draft regulations were laid before Parliament.

(9) For the purposes of subsection (8) no account is to be taken of any time during which Parliament is dissolved or prorogued or during which either House is adjourned for more than four days."

93: After Clause 45, insert the following new Clause—

"Super-affirmative procedure: Northern Ireland

(1) For the purposes of section 1(1), section 9(1), section 14(1) and section 18(1), the "super-affirmative resolution procedure" in the Northern Ireland Assembly is as follows.

(2) The Department must request a committee of the Assembly whose remit includes health, science or technology to report on the draft order within the 30-day period.

(3) A Northern Ireland Department must take account of—

(a) any representations,

(b) any resolution of the Assembly, and

(c) any recommendations of a committee under subsection (2), made within the 30-day period.

(4) If, after the 30-day period, the Department wishes to make an order in the terms of the draft, it must lay before the Assembly a statement—

(a) stating whether any representations were made under subsection (3)(a); and

(b) if any representations were so made, giving details of them.

(5) The Department may after the laying of such a statement lay before the Assembly for approval by affirmative resolution the draft order in its initial form, or a revised draft order together with an explanation of the changes made.

(6) In this section, reference to the "30-day period" in relation to any draft order is to the period of 30 days beginning with the day on which the original draft order was laid before the Assembly.

(7) For the purposes of subsection (6) no account is to be taken of any time during which the Assembly is dissolved or adjourned for more than four days."

Amendments 92 and 93 agreed.

Clause 47: Commencement

Amendments 94 to 96

Moved by ***Lord Bethell***

94: Clause 47, page 30, line 2, at end insert—

"(ba) section 5(4),"

Member's explanatory statement

This amendment would commence the definition of "human medicines provision" from the day on which the Bill is passed.

95: Clause 47, page 30, line 10, at end insert—

"(za) Part A1,"

Member's explanatory statement

This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety. It provides for those amendments to come into force two months after the Act is passed.

96: Clause 47, page 30, line 14, leave out "section 18" and insert "Chapter 2 of Part 3"

Member's explanatory statement

This amendment is consequential on the Minister's amendment to insert a new clause after clause 18, in Chapter 2 of Part 3, and provides for the new clause to come into force two months after the Bill is passed.

Amendments 94 to 96 agreed.

In the Title

Amendment 97

Moved by ***Lord Bethell***

97: In the Title, line 1, at beginning insert "Make provision about a Commissioner for Patient Safety in relation to human medicines and medical devices;"

Member's explanatory statement

This amendment would add a limb to the long title in relation to the new provisions tabled in the Minister's name for the purpose of establishing a Commissioner for Patient Safety.

Amendment 97 agreed.

Financial Services Bill

First Reading

The Bill was brought from the Commons, read a first time and ordered to be printed.

House adjourned at 6.28 pm.